Plaintiffs' Exhibit 444

allegiantair.com

Contract of Carriage | Allegiant Air

55-69 minutes

Effective on and after May 20, 2021

Passenger transportation by Allegiant Air, LLC. (hereafter "Carrier") is subject to the following terms and conditions, in addition to any terms and conditions printed on or in any Ticketless Travel Confirmation, specified on Carrier's Internet site with respect to electronic ticketing, or published in Carrier's schedules. By purchasing or accepting transportation, the passenger agrees to be bound thereby.

Review Allegiant's Terms and Conditions on ticketing, non-refundability, baggage and check-in.

Review Allegiant's Luggage Limitations of Liability

Review Allegiant's Notice - Overbooking of Flights

1. Definitions

Baggage means all luggage, including suitcases, garment bags, tote bags, packages, camera and electronics bags, computer and equipment cases, briefcases, typewriters, and similar articles, whether carried by the passenger in the cabin or carried in the aircraft cargo compartments. Coats and wraps, when carried by the passenger in the passenger cabin, will not be considered as baggage.

Baggage tag/Baggage Check means a document issued by Carrier solely for identification of checked baggage, a portion of which (Tag) is affixed by Carrier to a particular article of checked baggage for routing purposes and a portion of which (Check) is given to the passenger for the purpose of claiming the baggage.

Carriage means the transportation of passengers and/or baggage by air, gratuitously or for hire, and all services of Carrier incidental thereto.

Carrier means Allegiant Air, LLC.

Checked baggage means baggage of which Carrier takes sole custody and for which Carrier has attached a baggage tag(s) and/or issued a baggage check(s).

Individual with a disability means a person who:

1. has a physical or mental impairment that, on a permanent or temporary basis, substantially limits one or more major life activities;
2. has a record of such an impairment; or
3. is regarded as having such impairment, as further defined in U.S. Department of Transportation regulations at 14 C.F.R. § 382.3.

Nonstop flight means a flight scheduled to operate between the origin and destination points without intermediate stops.

One–way means travel from one point to another on Carrier's scheduled air service assigned for travel between the two points.

Passenger means any person, except members of the crew, carried or to be carried in an aircraft with the consent of Carrier.

Qualified individual with a disability means an individual with a disability who:

1. with respect to accompanying or meeting a traveler, use of ground transportation, using terminal facilities, or obtaining information about schedules, fares, or policies, takes those actions necessary to avail himself or herself of facilities or services offered by Carrier to the general public, with reasonable accommodations, as needed, provided by Carrier;
2. with respect to obtaining air transportation on Carrier, offers, or makes a good faith attempt to offer, to purchase or otherwise to validly obtain air transportation; or
3. with respect to obtaining air transportation or other services or accommodations, as provided by U.S. Department of Transportation regulations on Nondiscrimination on the Basis of Disability in Air Travel, 14 C.F.R. Part 382:

1. purchases or possesses a valid Ticketless Travel Confirmation for air transportation on Carrier and presents himself or herself at the airport for the purpose of traveling on the flight for which the Confirmation has been purchased or obtained;
2. meets reasonable, nondiscriminatory requirements of this Contract of Carriage applicable to all passengers; and
3. whose carriage will not violate the requirements of the Federal Aviation Regulations or jeopardize the safe completion of the flight or the health or safety of other persons.

Roundtrip means travel from one point to another and return to the first point.

Scheduled air service means any flight scheduled in the current edition of the Official Airline Guide (OAG), Carrier's published schedule, Carrier's Internet site, or the computer reservation system used by Carrier.

Ticketless Travel Confirmation means the electronically–recorded information in Carrier's computer reservation system that provides for the carriage of the passenger occupying a single seat and his or her baggage.

Unchecked baggage is baggage other than checked baggage.

2. Not Used

3. Application of Conditions

The terms and conditions contained in this Contract of Carriage shall govern the application of all fares, rates, and charges published by Carrier and will apply only to Carrier's routes and services. No agent, servant, or representative of Carrier has authority to change or waive any provision of this Contract of Carriage unless authorized by a corporate officer of Carrier.

4. International Travel

In the event that any passenger purchasing transportation on Carrier may be determined to be in international transportation under the Montreal Convention, Carrier's liability in the event of a passenger's death or bodily injury is limited, in most cases, to proven damages not to exceed 128,821 Special Drawing Rights per passenger, with liability up to this limit not dependent upon negligence on the part of Allegiant.

5. Electronic Surveillance of Passengers and Baggage

Passengers and their baggage are subject to inspection with an electronic detector with or without the passenger's consent or knowledge.

6. – 9. Not Used

10. Refusal to Transport

Carrier will refuse to transport, or will remove from an aircraft at any point, any passenger in the following circumstances:

A. Safety and Government Request or Regulation – Whenever such action is necessary for reasons of aviation safety or to comply with any Federal Aviation Regulation or other applicable U.S. or foreign government regulation, or to comply with any governmental request for emergency transportation in connection with the national defense, or whenever

such action is necessary or advisable by reason of weather or other conditions beyond Carrier's control (including, without limitation, acts of God, force majeure, strikes, civil commotions, embargoes, wars, hostilities, or disturbances, whether actual, threatened, or reported).

B. Search of Passenger or Property – Any passenger who refuses to permit the search of his or her person or property for explosives or a concealed, deadly, or dangerous weapon or article.

C. Proof of Identity – Any passenger who refuses on request to produce positive identification.
NOTE: Carrier shall have the right to require, but shall not be obligated to require, positive identification of persons purchasing ticketless travel and/or presenting a Ticketless Travel Confirmation for the purpose of boarding aircraft.

D. Special Medical Requirements – Carrier will refuse to transport persons requiring the following medical equipment or services, which either are not authorized or cannot be accommodated on Carrier's aircraft: medical oxygen for use onboard the aircraft, incubators, respiratory assistance devices that must receive power from the aircraft's electrical power supply, or persons who must travel on a stretcher. The user must have a sufficient power supply during the flight to power the device, including a conservative estimate of any unanticipated delays. Spare lithium batteries for POCs are prohibited from being carried in checked baggage. Devices may not be charged using on-board power outlets.

E. Qualified Individuals with a Disability – Carrier will transport qualified individuals with a disability in accordance with the conditions and requirements of U.S. Department of Transportation regulations, 14 C.F.R. Part 382, unless the carriage of such individuals may impair the safety of the flight or violate Federal Aviation Regulations. Pursuant to 14 CFR § 382.27, Carrier requires 48 hour minimum advance notice and 1 hour advance check–in for a qualified individual with a disability who wishes to receive the following services available on the carrier's flights: (1) Provision by the carrier of hazardous material packaging for a battery for a wheelchair or other assistive device, (2) Accommodations for a group of ten or more qualified individuals with a disability, who make reservations and travel as a group, (3) Provision of an on–board wheelchair on aircraft that does not have an accessible lavatory. However, pursuant to 14 C.F.R. § 382.113, Carrier will not provide certain extensive in–flight special services such as assistance in actual eating, assistance within the lavatory or at the individual's seat with elimination functions, or provision of medical services. Moreover, pursuant to 14 C.F.R. § 382.29, Carrier may require that a qualified individual with a disability be accompanied by an attendant as a condition of being provided air transportation in the following circumstances:

1. When the individual, because of a mental disability, is unable to comprehend or respond appropriately to safety instructions from Carrier's Employees, including the safety briefing required by 14 C.F.R. §§ 121.571(a)(3) & (a)(4);
2. When the individual has a mobility impairment so severe that the individual is unable to assist in his or her own evacuation of the aircraft; or
3. When the individual has both severe hearing and severe vision impairments, if the individual cannot establish some means of communication with Carrier's Employees adequate to permit transmission of the safety briefing required by 14 C.F.R. §§ 121.571(a)(3) & (a)(4)—and to enable the individual to assist in his or her own evacuation of the aircraft in the event of an emergency.

   If Carrier determines that an individual meeting the criteria of Article 10.E. (1), (2), or (3) above must travel with an attendant, contrary to the individual's self–assessment that he or she is capable of traveling independently, Carrier will not charge the individual with the disability for the transportation of the attendant while accompanying such individual. Furthermore, if, because there is not a seat available on a flight for an attendant whom Carrier has determined to be necessary, an individual with a disability having a confirmed reservation is unable to travel on the flight, such individual will be eligible for denied boarding compensation under Article 105 below. For purposes of determining whether a seat is available for an attendant, the attendant shall be deemed to have checked in at the same time as the individual with the disability.

F. Comfort and Safety – Carrier may refuse to transport or remove from the aircraft at any point any passenger in the following categories as may be necessary for the comfort or safety of such passenger or other passengers:

1. Persons whose conduct are or have been known to be disorderly, abusive, offensive, threatening, intimidating, or violent;

   NOTE: Carrier will not refuse to provide transportation to a qualified individual with a disability solely because the individual's disability results in appearance or involuntary behavior that may offend, annoy, or inconvenience crewmembers or other passengers.
2. Persons who are barefoot (other than infants);
3. Persons who are unable to occupy a seat with the seat belt fastened;
4. Persons who appear to be intoxicated or under the influence of drugs;
5. Persons who are known to have a contagious disease, if the Carrier determines the person's condition poses a direct threat as defined in 14 CFR § 382.3;
6. Persons who have an offensive odor, except where such condition is the result of a qualified disability;

7. Persons who have clothing/attire/accessories that are deemed patently offensive or obscene by other passengers and choose not to remove, change or cover the article(s).
8. Persons who wear or have on or about their persons concealed or unconcealed deadly or dangerous weapons; provided, however, that Carrier will carry passengers who meet the qualifications and conditions established in Federal Aviation Regulation, 14 C.F.R. § 108.11;
9. Manacled persons in the custody of law enforcement personnel; persons brought into the airport in manacles; persons who have resisted escorts; or escorted persons who express to Carrier's Employees an objection to being transported on the flight;
10. Persons who have misrepresented a condition which becomes evident upon arrival at the airport, and the condition renders the passenger unacceptable for carriage;
11. Infants fourteen (14) days of age or younger, unless approved for carriage in writing by an attending physician; or
12. Persons who are unwilling or unable to abide with Carrier's non–smoking rules.

Disposition of the fare of any passenger denied transportation or removed from Carrier's aircraft enroute under the provisions of Article 10 is governed by Article 90 of this Contract of Carriage.

11. – 14. Not Used

15. Ticketless Travel Confirmation – General

A. No person shall be entitled to transportation except upon presentation of a valid Ticketless Travel Confirmation or proof of identification acceptable to Carrier that transportation has been purchased through Carrier's electronic ticketing or Ticketless travel systems. Such electronic ticketing documentation shall entitle the person to transportation only between the points of origin and destination.

B. A Ticketless Travel Confirmation is valid for 365 calendar days from the date of issue, except as noted below:

1. Ticketless Travel Confirmations issued with fare restrictions, i.e., nonrefundable fares, are valid only on the flight and date shown on the Ticketless Travel Confirmation. If a Customer purchases transportation with fare restrictions but chooses not to travel on the flight and date for which the Ticketless Travel Confirmation is issued, the fare paid may, within 365 calendar days from the date of purchase, be applied toward the purchase of another Ticketless Travel Confirmation; however, the new Confirmation may be subject to a change fee and be more expensive or subject to different terms, conditions, or restrictions. No cash refund or credit card adjustments will be made for Ticketless Travel

Confirmations with fare restrictions.

C. Ticketless Travel Confirmations are not transferable unless specified thereon, but Carrier is not liable to the owner of a Confirmation for honoring or refunding such Confirmation when presented by another person.

16. – 19. Not Used

20. Reservations

A. A reservation on a given flight is valid when the availability and allocation of space is confirmed by a Reservations Sales Agent of Carrier or upon issuance of a Ticketless Travel Confirmation number, and the passenger's name is entered into Carrier's reservations system.

B. Airport check–in time limits: Carrier may cancel the reservation of any passenger who fails to check–in at least 45 minutes and arrive at the boarding gate at least 30 minutes before the scheduled departure time of the flight for which the reservation was made.

C. Carrier will refuse to carry any person when such refusal is necessary to comply with an applicable governmental regulation.

D. When a roundtrip or multi–segment reservation has been made and the passenger fails to claim his or her reservation for the first portion of the trip, Carrier reserves the right to cancel the return or continuing portions of the passenger's reservation for purposes of reservation inventory management. Carrier does not prohibit or penalize what is commonly known as "back–to–back" or "hidden–city" ticketing.

21. Groups Policies

A. Groups of ten (10) or more will need to be booked on multiple reservations.

22. – 24. Not Used

25. Ground Transportation

Carrier does not assume responsibility for the ground transportation of any passenger or his or her baggage between any airport used by Carrier and any other location. Ground transportation is at the passenger's risk and expense. An exception to this article is if, for reasons outside Carrier’s control, the Carrier is unable to land at the airport of the scheduled destination and is diverted to another airport as described in article 85.G.

26. – 29. Not Used

30. Application of Fares – General

A. Transportation is subject to the fares and charges in effect on the date on which such Ticketless Travel Confirmation was issued. If a Ticketless Travel Confirmation has been issued before an increase in the fare becomes effective, it shall be honored for transportation between the points, and at the class of service, for which it was purchased. The only exception for a post-purchase price increase would apply if the full amount of the itinerary has not yet been paid. This includes, but is not limited to, an increase in the price of seats, an increase in the price for the carriage of passenger baggage, an increase in an applicable fuel surcharge, or an increase in a government-imposed tax or fee. Fares may fluctuate and are subject to change without notice. No refunds or airline system credits will be provided after a reservation has been made through Customer Care. However, customer can make changes to reservations online at www.allegiantair.com.

B. Fares are published in Carrier's reservations system and may be obtained from an Allegiant Air Reservations Sales Agent by telephone at (702) 505-8888 on Carrier's Internet site at www.allegiantair.com, or through an authorized travel agent. Some travel agencies, however, may impose an additional charge for this service.

C. All published fares and charges are stated in U.S. currency.

D. No stopovers are permitted on published fares, except upon combination of local fares.

31. – 34. Not Used

35. Carriage of Children

A. Children Under Two (2) Years of Age – One child under two (2) years of age, not occupying a seat, will be carried without charge when accompanied by a fare–paying passenger fifteen (15) years of age or older. Carrier cannot guarantee that an unoccupied seat will be available for any child traveling without charge and without a confirmed reservation. Proof of age, such as a birth certificate, is required. Safety seats for children without a confirmed reservation may have to be transported as checked baggage if unoccupied seats are not available.

B. Children under two (2) years of age traveling on a confirmed reservation, with or without the use of a safety seat, will be charged the applicable fare.

C. Unaccompanied Minor Children

1. Carrier does not accept reservations for carriage of fare-paying Unaccompanied Minors or unescorted children under the age of fifteen (15) years.
2. Children fourteen (14) years and younger must be accompanied by an adult fifteen (15) years or older.
3. Special supervision for any travelers is not offered.

D. Responsibilities of Carrier – Carrier assumes no responsibilities for travelers fifteen (15) to seventeen (17) years old beyond those applicable to adult passengers.

E. In the case of a flight for which Carrier has issued a weather advisory, Carrier will refuse carriage to any passenger under the age of 18 if not traveling with a passenger age 18 or older. Carrier will provide passengers refused carriage under this provision transportation on Carrier's next flight to passenger's destination that is not subject to a weather advisory and on which space is available, or a refund of the unused portion of passenger's fare in accordance with Article 90 below. A "weather advisory" is issued by Carrier and notified to passengers when weather conditions may prevent the flight from landing at the planned destination because airport conditions or visibility fall below FAA or Carrier safety requirements, meaning Carrier may be unable to operate the flight or may have to land at an alternate airport.

36. Not Used

37. – 41. Not Used

42. Internet Fares

Special promotional fares may be available via the Internet on Carrier's website (Internet address: www.allegiantair.com). Seat availability, fares, and fare restrictions are published in the website presentation.

43. Stopovers

A. Carrier's local fares for a flight or flights between a passenger's point of origin and destination shall apply only to published nonstop flights, except as provided in Article 85.A. below.

B. A stopover shall occur when a passenger arriving at an intermediate or connection point on his or her itinerary fails to depart from such intermediate point on the published connecting flight to the passenger's next intermediate or destination. In the event of a single stopover, the passenger's fare shall be the sum of the appropriate local fares between the point of origin and stopover and the appropriate local fare between the point of stopover and destination. In the event of multiple stopovers, the passenger's fare shall be the sum of:

1. the appropriate local fare between the point of origin and first stopover; plus
2. the appropriate local fare(s) between each stopover point and the next subsequent stopover point, if any; plus
3. the appropriate local fare(s) between the point of last stopover and destination.

44. Not Used

45. Acceptance of Baggage – General

A. Inspection – All baggage tendered to Carrier for transportation is subject to inspection by Carrier.

B. Acceptance – Carrier will accept as baggage such personal property as is necessary or appropriate for the wear, use, comfort, or convenience of the passenger, as the personal property of the fare–paying passenger and not intended for sale to other persons, subject to the following conditions:

1. Carrier will refuse to accept baggage for transportation on any flight other than the flight on which the passenger is transported;
2. Carrier will refuse to accept any baggage for transportation if it or its contents cannot withstand ordinary handling, or if its weight, size, or character renders it unsuitable for transportation on the particular aircraft on which it is to be carried, unless the passenger releases Carrier from liability;
3. Each piece of baggage tendered to Carrier for carriage must have affixed thereto a current identification tag or label with the passenger' s name, address, and telephone number (if available);
4. With the exception of wheelchairs, other mobility aids, and assistive devices used by an individual with a disability, Carrier will not accept as baggage any item having outside measurements (i.e., the sum of the greatest outside length plus the greatest outside height plus the greatest outside width) that exceed eighty (80) inches, or that weigh more than forty (40) pounds, except as provided in Article 65 below;
5. Carrier will refuse to accept baggage that, because of its nature, contents, or characteristics (such as sharp objects, paint, corrosives, or other prohibited hazardous materials), might cause injury to passengers or Carrier's Employees, damage to aircraft or other equipment, or damage to other baggage; and
6. Carrier will not accept baggage that cannot safely be carried in the baggage compartment of the aircraft.

46. Carry–on Baggage

A. Carrier will determine whether or not any baggage of a passenger, because of its weight, size, contents, or character, may be carried in the passenger cabin of the aircraft. Each item of carry–on baggage may have external dimensions no larger than nine inches by fourteen inches by twenty-two inches (9 in. x 14 in. x 22 in.). All carry–on baggage must be stowed underneath a seat or in an overhead compartment. Hard–sided items (i.e.,

those with inflexible surfaces) may be placed only on the floor of the overhead compartment (i.e., not on top of other items in the compartment) or underneath a seat. Carry–on baggage is the sole responsibility of the passenger. Claims for damaged, lost, forgotten, or stolen carry–on baggage will not be accepted by Carrier. Allegiant Air will charge a fee for a carry-on bag as well as for items intended to carry–on board the aircraft, but which exceed the specified dimensions, and/or require the services of gate checking at the aircraft door.

B. In accordance with FAA/TSA Security Directives, passengers are restricted to one (1) item of carry–on baggage that does not exceed external dimensions of nine inches by fourteen inches by twenty-two inches (9 in. x 14 in. x 22 in.) (e.g., roll–aboard bag, garment bag, tote bag) plus one smaller personal–type item (e.g., purse, briefcase, laptop computer, small backpack), not to exceed external dimensions of seven inches by fifteen inches by sixteen inches (7 in. x15 in. x16 in.), provided that such items are capable of being carried onboard the aircraft by one person without assistance and are capable of being stowed in an overhead compartment or completely underneath a seat. If requested, qualified individuals with a disability will be provided assistance by Carrier's Representatives in loading, stowing, and retrieving carry–on items, including authorized assistive devices. Carrier reserves the right to further restrict the size and number of carry–on items.

C. In addition to the carry-on baggage allowance provided herein, items such as reading material, food for en route consumption, a diaper bag, a small camera, and a coat, jacket, wrap, or similar outer garment, may be carried onboard the aircraft.

D. Mobility and other assistive devices authorized for carriage in the aircraft cabin upon which a qualified individual with a disability is dependent may be carried in addition to the two (2) item cabin baggage allowance.

E. Unless unoccupied seats are available on a flight, Carrier requires a reservation and purchase of transportation at the appropriate fare to ensure that a safety seat or infant seat may be used during flight. Only federally–approved and labeled safety seats or infant seats are permitted for use aboard Carrier's aircraft. Federal regulations prohibit the use of child booster seats and harness–type or vest–type restraining devices, except for the AmSafe Aviation CARES.

F. The following conditions apply to acceptance for carriage in the aircraft passenger cabin of bass violas, cellos, guitars, and other musical instruments, and electronic, computer, and audio/video equipment and parts thereof, whose size prevents such instruments or equipment from being handled as normal carry–on baggage:

1. the instrument or equipment must be contained in a case;

2. a reservation must be made for the instrument or equipment at the applicable fare;

3. the instrument or equipment must be secured in the first window seat aft of a floor–to–ceiling bulkhead. Such seats are limited in availability.

G. Carrier will refuse to transport items of carry–on baggage that may be harmful or dangerous to a passenger, the flight crew, or the aircraft.

47. Live Animals – Pets

A. General Rules and Conditions

The passenger assumes full responsibility for the conduct of his or her accompanying pet. In the event Allegiant incurs any loss, damage, delay, expense or legal liability of any kind in connection with the transport of such animal, ***the passenger accepts full responsibility for same and will reimburse Allegiant for the full amount of such loss, damage, delay, expense or legal liability incurred by Allegiant***.

Transportation of animals in the aircraft cabin must meet the following conditions:

- Allegiant will transport live animals only in the passenger cabin on flights within the contiguous 48 United States.
- All animals must be at least eight (8) weeks of age.
- Allegiant will not transport animals as checked baggage. Pets that can be carried on board include domestic dogs and cats only, and the pet must be transported in a hard-sided or soft-sided, leak-proof carrier that can fit under a seat.
- Pets must remain in the carrier at all times in the airport gate area and while aboard the aircraft. If a passenger does not comply, the animal may be denied boarding for future flights.
- All pet carriers may not exceed external dimensions of nine inches by sixteen inches by nineteen inches (9 in. X 16 in. x 19 in.).
- An Allegiant representative at the departure airport will determine if there is adequate room in the carrier for any pet. In the event of a disagreement, the Allegiant representative’s decision will control.
- Animals cannot be ill or in distress.
- There is a non-refundable fifty dollar ($50.00) fee for each one-way flight for a pet carrier.
- Customers with animals in a carrier may not occupy a bulkhead row, an exit row, or the rows in front of or behind an exit row.
- Pets or pet carriers may NOT be placed in or strapped into a passenger seat and must be placed under the seat directly in front of the passenger bringing the pet. All animals are

required to be harmless, non-disruptive and odorless.

- Passengers with a pet carrier may bring one personal item, not to exceed exterior dimensions of 7 in. x 15 in. x 16 in. (17.8 cm x 38.1 cm x 40.6 cm), which may be stored in the overhead bin space free of charge.
- Passengers who choose to bring a carry-on bag along with a pet carrier, will be charged accordingly for the carry-on bag and must ensure that the carry-on bag does not exceed exterior dimensions of 9 in. x 14 in. x 22 in. (22.9 cm x 35.6 cm x 55.9 cm).
- Allegiant assumes no responsibility for the health or well-being of pets before, during or after a flight.

48. Service Animals

48.1. General Rules and Conditions

The passenger assumes full responsibility for the conduct of his or her accompanying service animal(s). In the event Allegiant incurs any loss, damage, delay, expense or legal liability of any kind in connection with the transport of such animal, ***the passenger accepts full responsibility for same and will reimburse Allegiant for the full amount of such loss, damage, delay, expense or legal liability incurred by Allegiant***.

48.2 Service Animals

A service animal is a dog, regardless of breed or type, that is individually trained to do work or perform task for the benefit of a qualified individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability. To assist Allegiant in verifying the training of the animal and determining whether the service animal poses a direct threat to the health or safety of others, Allegiant requires the following form to be fully completed and emailed or mailed to Allegiant at least 48 hours prior to scheduled departure. If travel is purchased within 48 hours of scheduled departure, the passenger must present the fully completed form to an Allegiant representative at least 30 minutes prior to departure.

U.S. Department of Transportation Service Animal Air Transportation Form

48.4 Animal Transport and Miscellaneous

1. Allegiant only permits domestic dogs that are being used as service animal(s) by individuals with disabilities to accompany such individuals in the aircraft cabin at no charge.
2. Allegiant permits a service animal to accompany a qualified individual with a disability at either a bulkhead seat or a seat other than a bulkhead seat, as the individual prefers, unless the animal obstructs an aisle or other area that must remain unobstructed in order

to facilitate an emergency evacuation. All seating accommodation requests must be made at least 24 hours prior to scheduled departure. If a seat request is made within 24 hours of scheduled departure, Allegiant will make a reasonable effort to accommodate the request without displacing another passenger.

3. Passengers are limited to two (2) fully trained service animals if required to perform work or tasks directly related to the passenger's disability. All such animal(s) must remain under the control of the passenger at all times and be leashed, harnessed or tethered to the passenger at all times.

4. All animals are required to fit within the foot space of the disabled passenger and are prohibited from encroaching on the foot space of another passenger. If the animal encroaches on another passenger's foot space, the disabled passenger may be required to purchase a second seat to accommodate the animal. Animals are prohibited from occupying a seat and from sitting on or eating off of tray tables. Allegiant reserves the right to deny the transport of any animal that is improperly cleaned and/or has a foul odor, that appears to be ill or in physical distress, or that in the judgment of an Allegiant representative at the departure airport poses a direct threat to the health or safety of others.

5. Service animals in-training and Law Enforcement/Search and Rescue dogs may be considered for by Allegiant for transport on a case-by-case basis. Allegiant requires at least 72 hours prior notification and submission of any supporting documentation requested by Allegiant.

6. All animals are expected to be trained to behave in a public setting. Per the Code of Federal Regulations, Title 14, Part 382 (administered by the U.S. Department of Transportation), Allegiant reserves the right to deny transport to any animal displaying disruptive behavior, such as, but limited to:

1. Growling, snarling, biting, attempting to bite or acting in an aggressive manner
2. Running around or jumping on other passengers
3. Relieving itself in the airport terminal or in the aircraft cabin
4. Barking excessively (other than alerting passenger as trained)

If a passenger or a fully trained service animal does not meet the requirements of this Article 48, Allegiant reserves the right to deny boarding and/or transport of the animal.

49. – 54. Not Used

55. Checking of Baggage

A. Carrier will accept baggage for checking from a fare–paying passenger when tendered to

Carrier no earlier than two (2) hours in advance of flight departure time at Carrier' s airport ticket counter or curb–side check–in station, or at an earlier time on the day of commencement of travel as may be authorized by Carrier's Employees at the departure airport. Carrier will not check baggage tendered:

1. to a point beyond the destination indicated on the passenger's Ticketless Travel Confirmation;
2. to an intermediate stop or connection point;
3. for a flight to be operated on a later date.

56. – 59. Not Used

60. Checked Baggage Allowance

Upon presentation of a bag to be checked by a fare–paying passenger of a valid Ticketless Travel Confirmation, a checked baggage fee will apply.

Each piece of sporting equipment will be considered a checked bag with all applicable fees applied per person, per bag, per segment. All Baggage Fees are non-refundable except as provided in Article 65 below. Each bag must weigh 40 lbs or less and the outside measurements of each bag must not exceed eighty (80) inches. Applicable fees will be applied for those bags exceeding the weight and size limits. The total number of bags allowed may not exceed 5 per passenger.

- Firearms – Carrier will not accept assembled firearms and ammunition for transportation except as follows:

1. All passengers must declare their firearm at time of check-in.
2. Passengers must be 18 years of age to check a firearm.
3. Firearms and ammunition cannot be carried on board the aircraft but are accepted in checked baggage only.
4. Firearms must be unloaded and encased in a locked, hard-sided container acceptable to Allegiant for withstanding normal checked baggage handling without sustaining damage to the firearm. Only the individual checking the baggage should retain the key or combination.

1. Firearm parts, including magazines, clips, bolts and firing pins, are prohibited in carry-on baggage, but may be transported in checked baggage.
2. Replica firearms, including firearm replicas that are toys, may be transported in checked baggage only.
3. Rifle scopes are permitted in carry-on and checked baggage.

5. There is no limit to the number of firearms or corresponding accessories a passenger can carry in the locked hard-sided container.

1. Carrier will accept no more than a total gross weight of eleven (11) pounds of ammunition per passenger
2. Oversize / overweight restrictions still apply.
3. Ammunition must be in the manufacturer's original container or equivalent fiber, wood, or metal container specifically designed to carry ammunition, including removed handgun magazine. This carrier must provide sufficient cartridge separation.

- If a mobility aid or assistive device, upon which a passenger who is a qualified individual with a disability is dependent, cannot be carried in the passenger cabin due to space limitations, such aid or device will be checked and carried in addition to the 2 piece maximum without charge.

61. – 64. Not Used

65. Excess Baggage Charges

A. Application – Excess baggage charges specified in this Article will be applicable from the point at which the baggage is accepted to the point to which the baggage is checked.

B. Charges:

1. Baggage in excess of the five (5) bag maximum specified in Article 60 above will incur a charge of fifty dollars ($50.00) per piece per segment.
2. Baggage in excess of eighty (80) inches but not more than one hundred fifteen (115) inches (sum of outside length plus outside height plus outside width) will incur an oversize charge of seventy–five dollars ($75.00) per item in addition to the assessed Baggage Fee.
3. Baggage weighing between forty–one (41) and seventy (70) pounds will be accepted as checked baggage for an excess weight charge of fifty dollars ($50.00) per item in addition to the assessed Baggage Fee. Baggage weighing between seventy–one (71) and ninety-nine (99) pounds will be accepted as checked baggage for an excess weight charge of seventy–five dollars ($75.00) per item in addition to the assessed Baggage Fee.

C. No baggage more than 99 lbs. will be accepted.

66. – 74. Not Used

75. Baggage – Limitation of Liability

A. The liability, if any, of Carrier for loss of, damage to, or delay in the delivery of checked or unchecked baggage and/or its contents, with the exception of wheelchairs, mobility aids,

and assistive devices used by an individual with a disability, is limited to the proven amount of damage or loss, but in no event shall be greater than three-thousand, eight-hundred dollars ($3,800) Domestic or 1,288 Special Drawing Rights International per fare-paying passenger. Carrier will compensate the passenger for reasonable, actual and documented damages incurred as a result of the loss of, damage to, or delayed delivery of such baggage up to the limit of liability or declared valuation, whichever is higher, provided the passenger has exercised reasonable effort to minimize the amount of damage. Actual value for reimbursement of lost or damaged property shall be determined by the documented original purchase price less depreciation for prior usage.

B. Carrier will be liable for such personal property only for the period in which it is in the custody of Carrier. While every reasonable effort will be made to return items inadvertently left behind by passengers onboard an aircraft, Carrier assumes no custody or responsibility for property carried onboard an aircraft by a passenger.

C. Carrier's liability with respect to damage to wheelchairs, other mobility aids, and assistive devices upon which an individual with a disability is dependent shall be the documented cost of repair. If a wheelchair, mobility aid, or assistive device is lost or irreparably damaged, the criteria for calculating the compensation for a lost, damaged, or destroyed wheelchair or other assistive device shall be the original purchase price of the device without depreciation. Carrier will also compensate the passenger for other reasonable expenses incurred as a result of the loss of, damage to, or delayed delivery of the wheelchair, mobility aid, or assistive device.

D. Carrier assumes no responsibility and will not be liable for money, jewelry, cameras, photographic, video and electronic equipment (including computers), silverware, natural fur products, precious gems and metals, medication, negotiable papers, securities, business documents, samples, items intended for sale, paintings and other works of art, antiques, collectors' items, photographs, artifacts, antiques, heirlooms, manuscripts, furs, keys, spirits, irreplaceable books or publications, and similar valuables, except for claims arising from international flights covered by the Montreal Convention. Carrier discourages the foregoing items being placed in checked baggage.

76. Fragile and Perishable Items as Baggage

Carrier may, but is not obligated to, conditionally accept previously damaged, improperly packed, fragile, or perishable items for carriage as checked baggage subject to the passenger's assumption of risk for damage to or destruction of such items. Fragile or perishable items will not be accepted as checked baggage unless they are properly packed in an original factory–sealed carton or case designed for shipping such items and if the item does not pose a risk of damage to other checked baggage.

77. – 79. Not Used

80. Claims

A. In the case of loss of, damage to, or delay in delivery of baggage, no claim will be entertained by Carrier unless preliminary written notice of such claim is presented to Carrier at the airport, within four (4) hours after arrival of the flight on which the loss, damage, or delay is alleged to have occurred or within twenty-four (24) hours for missing contents. The preliminary notice may thereafter be amended in writing; however, such amended claim must be presented to Carrier no later than twenty–one (21) days after the occurrence of the event giving rise to the claim.

B. Failure to provide notice within the foregoing time limits will not bar a claim if the claimant establishes to the satisfaction of Carrier that he or she was unable, through no fault or omission of the claimant, to provide notice within the specified time limits.

C. To the maximum extent permitted by law, no legal action on any claim described above may be maintained against Carrier unless commenced within one (1) year of Carrier's written denial of a claim, in whole or in part.

81. Class Action Waiver

Any person who purchases air transportation and/or any ground accommodation or service from Carrier agrees, on behalf of such purchaser and anyone on whose behalf he or she makes such a purchase, that any lawsuit brought against Carrier, any of its affiliated entities, or any of its agents, directors, employees or officials related to this Contract of Carriage, any air transportation and/or ground accommodation or service purchased from Carrier, or any use of or dealings with Carrier’s website shall be brought only in an individual capacity, and shall not be brought in or asserted as part of a class action proceeding. Purchaser warrants that all persons described in the foregoing sentence are bound thereby and by all other provisions of this Contract of Carriage.

82. Smoking

Smoking aboard Carrier's aircraft is prohibited by federal law.

83. Health Risks

An inherent risk of air travel is the possibility that one or more passengers on a flight may have a communicable disease, and that one or more other passengers may contract the disease. This could include Covid-19 or other serious disease. Despite the efforts of Carrier, public health authorities and others to minimize the spread of disease, Carrier can offer no assurance that a passenger will not contract a viral or other disease while aboard

an aircraft operated by Carrier or while using airport facilities utilized by Carrier. Accordingly, you hereby agree on behalf of yourself and anyone on whose behalf you make a purchase from Carrier, that neither Carrier nor any of its agents, directors, employees, officials or affiliated entities shall have any liability whatsoever in respect of disease, however contracted.

84. Photos & Videos Onboard

The use of small cameras or mobile devised for photography and video is permitted onboard provided you keep the purpose of your photography and video to capturing personal events. Photographing or recording other customers or airline personnel without their express consent is prohibited. Airline personnel reserve the right to prohibit photos and videos onboard the aircraft if it becomes a disturbance to them or other passengers.

85. Failure to Operate as Scheduled

A. This article covers:

1. Canceled Flights (both voluntarily changed by the carrier and for reasons beyond the carrier's control)
2. Late or Irregular Operations (both voluntarily changed by the carrier and for reasons beyond the carrier's control)
3. Schedule Changes

B. Cancel/Delay reasons beyond the carrier's control include, but are not limited to, acts of God, governmental actions, fire, weather, mechanical difficulties, Air Traffic Control, strikes or labor disputes, or inability to obtain fuel for the flight in question.

C. Carrier shall use its best efforts to notify all affected passengers promptly of planned schedule changes and service withdrawals.

D. If Carrier delays, cancels, or fails to operate any flight according to Carrier's published schedule, provided in the case of delay that the delay is significant, Carrier will, at the request of a passenger confirmed on an affected flight:

1. transport the passenger on another of Allegiant's flights on which space is available at no additional charge; or
2. refund the unused portion of the passenger's fare in accordance with Article 90 below; or
3. in the case of a schedule change made voluntarily by Carrier, and provided the schedule change is significant, refund the unused portion of the passenger's fare in accordance with Article 90 below.

E. Carrier shall not be liable for any consequential damages or incidental costs incurred by

the passengers such as, but not limited to, loss of wages/income/salaries/emotional distress that arise from the failure or delay in operating any flight.

F. Carrier will attempt to transport passengers and their baggage promptly and as scheduled. Flight schedules, however, are subject to change without notice, and the times shown in or on Carrier's published schedules and advertising are not guaranteed. At times, without prior notice to passengers, Carrier may need to substitute other aircraft, airlines or means of transportation and may change, add, or omit intermediate or connecting stops. Carrier cannot guarantee that passengers will make connections to other flights of its own or those of other airlines. In the event of flight schedule changes, Carrier will attempt to notify affected passengers as soon as possible at the airport or en route.

G. If a flight is unable to land at the destination airport and is diverted to another airport, the carriage by air shall, unless the aircraft continues to the original destination, be deemed to be completed when the aircraft arrives at the diversion airport. Carrier may, however, arrange or designate alternative transportation, whether by Carrier's own service or by other means of transportation specified by Carrier (which may include ground transportation) to transport passengers to the original destination without additional cost. Exceptions may include situations where alternative transportation is prevented by safety concerns. When alternative transportation to the original destination is provided by or at the direction of Carrier, any arrangements made by one or more passengers on their own will not be paid for or reimbursed by Carrier and are at the passengers' own risk.

86. – 89. Not Used

90. Refunds

A. Nonrefundable fares – Nonrefundable fares are not eligible for refunds, except as provided in Articles 85.A above and 90.B.through 90.D. below.

B. Flight terminations or involuntary cancellations – If a passenger's scheduled transportation is canceled, or terminated before the passenger has reached his or her final destination as a result of a flight cancellation or omission of a scheduled stop, Carrier will, at the passenger's option, transport the passenger on another of Carrier's flights on which space is available at no additional charge, or refund the fare for the unused transportation, or provide a credit voucher for such amount toward the purchase of future travel.

C. Denied boarding – If Carrier denies boarding or removes a passenger from an aircraft under conditions described in Article 10 (except Articles 10.B, 10.C, and 10.F) or Article 35.F above, Carrier will refund the fare paid for the unused portion thereof. If Carrier denies boarding or removes a passenger under any of the circumstances enumerated in Article 10.B, 10.C or 10.F, fares paid for any unused travel segment shall be forfeited and

non-refundable.

D. Eligible fare refunds and credits will be made by Carrier as follows:

1. when no portion of the transportation has been provided, the refund or credit will be issued in an amount equal to the fare paid (subject to Article 90.C above) less applicable change fees;

2. when a portion of the transportation has been provided, the refund or credit will be made in an amount equal to the difference, if any, between the total fare paid and the fare applicable to the transportation provided, (subject to Article 90.C above) less applicable change fees; or

3. if a customer cancels an entire air transportation itinerary within 24 hours after booking the itinerary and the scheduled time of departure of the initial flight in the itinerary was at least one week (168 hours) away at the time of booking, a full refund will be issued; provided, this does not apply when the air transportation was purchased as part of a package consisting of air and ground elements. Such cancellation may be accomplished online via the customer's "My Allegiant" account or by contacting the Allegiant Reservation Center by telephone.

E. Carrier shall make eligible refunds according to the original form of payment. Refunds for fares purchased with a debit or credit card shall be processed for crediting back to the same card account no later than seven (7) days from the date the refund request is received by Carrier. All credit refunds will be issued in the currency used at purchase (USD). Refunds for fares purchased with cash or by check will be issued by check no later than twenty (20) days after the refund request is received by Carrier; provided that, with regard to fares purchased by check, in cases where Carrier has reasonable cause to suspect fraud, Carrier may delay making an otherwise eligible refund until such time as the check by which the fare was purchased has cleared the financial institution on which it was drawn and Carrier has received payment from such institution. Refunds for fares purchased with instalment payments offered through a third party company, must be requested to Allegiant for the cancelation of the itinerary but the third party company will manage the settlement of the credit line and the final refund to the Customer.

91. – 104. Not Used

105. Denied Boarding Compensation

A. The following definitions, as prescribed in 14 C.F.R. § 250.1, pertain solely to the denied boarding compensation provisions of this Article:

- Airport means the airport at which the direct or connecting flight, on which the passenger holds confirmed reserved space, is planned to arrive or some other airport serving the

same metropolitan area, provided that the transportation to the other airport is accepted (i.e., used) by the passenger.

- Comparable air transportation means transportation provided to passengers at no extra cost by a direct air carrier holding a certificate of public convenience and necessity or commuter authority issued by the U.S. Department of Transportation, or by a foreign air carrier holding a foreign air carrier permit issued by the U.S. Department of Transportation authorizing the scheduled air transportation of persons.
- Confirmed reserved space means space on a specific date and on a specific flight of Carrier which has been requested by a passenger and which Carrier or its authorized agent has verified, by appropriate notation on the ticket or Ticketless Travel Confirmation, or in any other manner provided by this Contract of Carriage, as being reserved for the accommodation of the passenger.
- Stopover means a deliberate interruption of a journey by the passenger, scheduled to exceed four (4) hours, at a point between the place of departure and the place of final destination.
- The sum of the values of the passenger's remaining flight coupons means the sum of the applicable one–way fares, including any surcharges, airport or passenger facility charges, and air transportation taxes, less any applicable discounts.

B. Request for Volunteers – In the event of an unintentional overbooked flight, Carrier shall request volunteers for denied boarding. A volunteer is a person who responds to Carrier's request for volunteers and who willingly accepts Carrier's offer of compensation, in any amount, in exchange for relinquishing his or her confirmed reserved space. Any other passenger denied boarding is considered to have been denied boarding involuntarily, even if that passenger accepts denied boarding compensation. If an insufficient number of volunteers come forward, Carrier may deny boarding to other passengers. However, Carrier will not deny boarding to any passenger involuntarily who was earlier asked to volunteer without having been informed about the possibility of being denied boarding involuntarily and the amount of compensation specified in Article 105.E. below.

C. Conditions for Payment of Compensation to Passengers Involuntarily Denied Boarding due to an Oversell – Subject to the exception in Article 105.D. below, Carrier will tender to a passenger the amount of compensation specified in Article 105.E. below, when:

1. the passenger holds a ticket for confirmed reserved space and presents himself or herself for carriage at the appropriate time and place, having complied fully with Carrier's requirements as to ticketing, reconfirmation, check-in, and acceptability for transportation in accordance with this Contract of Carriage; and
2. other than for reasons set forth in Article 10 above, or when resulting from substitution for

operational or safety reasons of an aircraft having a lesser seating capacity than the aircraft originally scheduled, Carrier is unable to accommodate the passenger on the flight for which the passenger holds confirmed reserved space, and such flight departs without the passenger.

D. Exception – The passenger will not be eligible for compensation if Carrier offers comparable air transportation, or other transportation used by the passenger at no extra cost, that, at the time such arrangements are made, is planned to arrive at the airport of the passenger's next stopover or, if none, at the airport of the passenger's final destination not later than one (1) hour after the planned arrival time of the passenger's original flight or flights.

E. Amount of Compensation Payable to Passengers Involuntarily Denied Boarding Due to an Oversell:

1. Domestic Transportation Passengers traveling between points within the United States (including the territories and possessions) who are denied boarding involuntarily from an oversold flight are entitled to: (1) No compensation if the carrier offers alternate transportation that is planned to arrive at the passenger’s destination or first stopover not later than one hour after the planned arrival time of the passenger’s original flight; (2) 200% of the fare to the passenger’s destination or first stopover, with a maximum of $775, if the carrier offers alternate transportation that is planned to arrive at the passenger’s destination or first stopover more than one hour but less than two hours after the planned arrival time of the passenger’s original flight; and (3) 400% of the fare to the passenger’s destination or first stopover, with a maximum of $1,550, if the carrier does not offer alternate transportation that is planned to arrive at the airport of the passenger’s destination or first stopover less than two hours after the planned arrival time of the passenger’s original flight.

0 to 1 hour arrival delay.	No compensation.
1 to 2 hour arrival delay.	200% of one-way fare (but no more than $775).
Over 2 hours arrival delay.	400% of one-way fare (but no more than $1,550).

2. Except as provided below, the airline must give each passenger who qualifies for involuntary denied boarding compensation a payment by cash or check for the amount specified above, on the day and at the place the involuntary denied boarding occurs. If the airline arranges alternate transportation for the passenger’s convenience that departs before the payment can be made, the payment shall be sent to the passenger within 24 hours. The air carrier may offer free or discounted transportation in place of the cash payment. In that event, the carrier must disclose all material restrictions on the use of the free or discounted transportation before the passenger decides whether to accept the

transportation in lieu of a cash or check payment. The passenger may insist on the cash/check payment or refuse all compensation and bring private legal action.

3. Acceptance of the compensation may relieve Allegiant Air from any further liability to the passenger caused by its failure to honor the confirmed reservation. However, the passenger may decline the payment and seek to recover damages in a court of law or in some other manner.

106. – 115. Not Used

116. Ticketless Travel Acceptability

Carrier will accept only its own electronic Ticketless Travel Confirmation, and then only if all transportation written thereon uses the services of Carrier. Any tickets issued in conjunction with travel on another carrier will not be accepted.

117. – 123. Not Used

124. Check Acceptance

Allegiant accepts most major credit and debit cards. Allegiant does not accept cash, check, or money orders in-flight or at any airport location.

125. - 126. Not Used

127. Right to Change Contract

Carrier reserves the right, to the extent not prohibited by federal law, to change, delete, or add to any of the terms of this Contract of Carriage without prior notice. All changes must be in writing and approved by a corporate officer of Carrier.

Plaintiffs' Exhibit 445

DELTA DOMESTIC GENERAL RULES TARIFF
[Last Modified April 13, 2021]

RULE 1: General Provisions

A. Contract of Carriage

When you buy a ticket from or travel on Delta, you enter into a contract with us, and you agree to be bound by its terms. The terms of your contract are set forth in:

- your Ticket;
- these Conditions of Carriage; and
- our published fare rules and regulations, which may govern the calculation of the fare and other charges that apply to your itinerary.

This document is Delta's Domestic Conditions of Carriage. It applies only to travel entirely within the United States of America and states the terms upon which Delta offers to transport passengers.

Any reference to “Delta” in this contract refers to Delta Air Lines, the Delta Shuttle, and the Delta Connection carriers. Some flights marketed by Delta may be operated by the other carriers. If any Carrier other than Delta is operating a flight, we will identify that Carrier in our schedules and in written or oral communications with you during the booking process. The terms of transportation applicable to Delta specified in these Conditions of Carriage apply to flights operated by the Delta Connection and Delta Shuttle carriers, and to codeshare flights marketed by Delta.

Delta may act as an agent to issue tickets, check baggage and book reservations for transportation via other Carriers which have interline agreements with Delta. For interline flights operated by other Carriers, the conditions of carriage of the operating Carrier will apply. Other Carriers may have different terms and conditions applicable to their flights, and these may be obtained directly from the other Carriers.

B. Amendments to Conditions of Carriage

Delta may amend these Conditions of Carriage at any time, except as provided by law. Your travel is governed by the rules that were in effect on the date you purchased your ticket; provided, however, that Delta reserves the right to apply rules currently in effect on the date of your travel where reasonably necessary for operational reasons and where the change in rule does not have a material negative impact upon you. No Delta employee or ticketing agent has the authority to modify any provision of the Conditions of Carriage unless authorized in writing by a Delta corporate officer.

RULE 2: SCHEDULES AND OPERATIONS

Delta will exercise reasonable efforts to transport you and your baggage from your origin to your destination with reasonable dispatch, but published schedules, flight times, aircraft types, seat assignments, and similar details reflected in the ticket or Delta’s published schedules are not guaranteed and form no part of this contract. Delta may substitute alternate Carriers or aircraft, change its schedules, delay or cancel flights, change seat assignments, and alter or omit stopping places shown on the ticket as required by its operations in Delta’s sole discretion. Delta’s sole liability in the event of such changes is set forth in Rule 22. Delta is not responsible or liable for making connections, failing to operate any flight according to schedule, changing the schedule or any flight, changing seat assignments or aircraft types, or revising the routings by which Delta carries the passenger from the ticketed origin to destination.

RULE 3: DEFINITIONS

Animals, in addition to the usual connotation, include reptiles, birds, and fish.

Applicable Full Fare means the one-way fares, whether specifically published or derived by construction, for the class of service designated in the Carrier's official general schedule for the aircraft, or cabin of the aircraft used by the passenger.

Carrier means any air carrier shown as a participant in this tariff.

Co-Terminal - Two or more relatively adjacent airports which for the purpose of these fares will be considered the same point.

Days - Full calendar days, including weekend days and legal holidays (but not including the date that any notice is sent).

Dependent – The spouse and children of U.S. Military Personnel or U.S. embassy personnel stationed overseas who are dependent upon such personnel for financial support.

Dot Hazardous Materials Regulations means the hazardous materials regulations issued by the Materials Transportation Bureau of the Department of Transportation in Title 49 of the Code of Federal Regulations, Parts 171 through 177 (49 CFR 171-177).

Fare Component - The fare paid for the portion of the itinerary between the origin and destination/Stopover point.

Government Transport Request (GTR) - Form used for ticket payment and travel authorization for passengers traveling on official business for the federal government by the U.S.

Group means the minimum number of passengers specified in conjunction with the fare as provided for in the applicable fare rules. Less than the minimum number of passengers may not travel at group fares, even upon payment of the minimum number of fares, unless specifically permitted in a given fare rule.

Immediate Family means spouse, domestic partner, children, step-children, grandchildren, parents, step-parents, grandparents, brothers, step-brothers, sisters, step-sisters, daughters-in-law, sons-in-law, fathers-in-law, mothers-in-law, aunts, uncles, nieces, nephews, brother-in-law and sisters-in-law.

Interlining means utilizing the services of more than one Carrier in connection with a particular fare.

Military Agencies means departments of the Army, Navy and Air Force; the Marine Corps; the Coast Guard; the respective academies of the Army, Navy, Air Force and Coast Guard; and the National Guard. The Reserve Officer Training Corps is not included.

Military Passenger means military personnel of the U.S. Military Agencies who are on active duty status or who have been discharged from active military service within seven Days of the date of travel.

Person with a Disability means any person who has a physical or mental impairment that, on a permanent or temporary basis, substantially limits one or more major life activities, has a record of

such an impairment, or is regarded as having such an impairment. This term shall be further defined as required by applicable law, including 14 C.F.R. 382.3.

Personal Attendant means the travel companion of a Person with a Disability that is attending to the personal needs of the passenger with a disability.

Qualifying Alternative Transportation means comparable air transportation, or other transportation used by the passenger, at no extra cost to the passenger, that at the time such arrangements are made is scheduled to arrive at the passenger's next Stopover, or, if none, final destination within two hours after the planned arrival time of the passenger's original flight or flights.

Reroute means to issue a new ticket, or honor an existing ticket, covering transportation to the original destination, but via a different routing than that designated on the ticket.

Round Trip means any trip, the ultimate destination of which is the point of origin, and which is legal routing and comprised of an outbound and return segment. Reservations for all segments of a trip for tickets issued at round-trip fares must be confirmed in the same (a single) passenger name record (PNR)

Routing means the Carrier(s) and/or the cities and/or class of service and/or type of aircraft (jet or propeller) via which transportation is provided between two points.

Safety Assistant means a person required by Delta to travel with a Person with a Disability, pursuant to Rule 6(C): to attend to the Person with a Disability's in-flight medical needs; to assist the Person with a Disability's communication with crewmembers; or to assist the Person with a Disability's evacuation from the aircraft in the event of an emergency.

Self-reliant means that a person does not require services related to a disability beyond that normally provided by the Carrier or beyond that which applicable law requires the Carrier to provide.

Standby Passenger - Passenger who will be enplaned on a flight subject to the availability of space at departure time and only after all passengers having reservations for such flight, have been enplaned on such flight. Not all flights will be available for standby. All specific standby rules are governed by Rule 15.

Stopover means a deliberate interruption of a journey by the passenger, agreed to in advance by the Carrier, at a point between the place of departure and the place of destination. Unless otherwise noted, a stopover will occur when a passenger arrives at a point and fails to depart from such point on:

a) The first flight on which space is available, or

b) The flight that will provide for the passenger's earliest arrival at an intermediate or junction point(s) or destination point, via the Carrier and class of service as shown on the passenger's ticket, provided however, that in no event will a stopover occur when the passenger departs from the intermediate/junction point on a flight shown in the Carrier's official general schedule as departing within four hours after arrival at such point.

United States of America- The area comprising the 50 states; the District of Columbia; Puerto Rico; the U.S. Virgin Islands; American Samoa; Kanton; Guam; Midway and Wake Islands.

U.S. Armed Forces/U.S. Military Agencies - Department of the Army, Navy, Air Force, Marine Corps, and Coast Guard of the United States of America, the respective academies of the Army, Navy, Air Force, and Coast Guard, and does not include the National Guard Bureau or the Reserve Officer Training Corps, or members of the reserves not holding a valid duty armed forces of the United States green identification card.

U.S. Military Personnel - Unless otherwise indicated, refers only to active duty military personnel, and means Military personnel of the United States Military Agencies holding a valid active duty U.S. Armed Forces green identification card, on active duty status and traveling on authorized furlough, leave, or pass, but expressly excluding Military Personnel on temporary duty orders traveling to or from their temporary duty station.

RULE 4: PERSONAL DATA

The passenger recognizes that personal data has been given to Carrier for the purposes of making a reservation for carriage, obtaining ancillary services, facilitating immigration and entry requirements, and making available such data to government agencies. For these purposes, the passenger authorizes Carrier to retain such data and to transmit it to its own offices, other Carriers, or the providers of such services, in whatever country they may be located. All passenger information shall be handled in accordance with Delta's Privacy Policy (https://www.delta.com/content/www/en_US/privacy-and-security.html).

RULE 5: INTER-AIRPORT TRANSPORTATION

When a metropolitan area is served by more than one airport and the passenger requires connecting service with arrival at one airport and departure from another airport, transportation between those airports must be arranged by and at the expense of the passenger. Baggage must be claimed and rechecked by the passenger.

RULE 6: CARRIAGE OF PERSONS WITH DISABILITIES

A) Acceptance for Carriage

Delta will make every effort to accommodate a Person with a Disability and will not refuse to transport a person solely based on the person's disability, except as permitted or required by law.

B) Acceptance of Declaration of Self-Reliance

Unless Delta determines a Safety Assistant is essential for safety, pursuant to Rule 6(C), Delta will accept the determination made by or on behalf of a Person with a Disability as to self-reliance. Once advised that the person is "self-reliant", Delta shall not refuse such passenger transportation on the basis that the Person with a Disability is not accompanied by a Personal Attendant or based on the assumption that the passenger may require extraordinary assistance from airline employees in meeting the passenger's needs.

C) Accompanying Safety Assistant Required for Certain Passengers

Delta may require that a Safety Assistant accompany a Person with a Disability as a condition of providing transportation if Delta determines that such an assistant is essential for safety, such as in, but not limited to, the following circumstances:

1) A passenger is unable to comprehend or respond appropriately to safety related instructions due to a mental disability;
2) A passenger is unable to physically assist in the passenger's own evacuation from the aircraft due to a severe mobility impairment; or
3) A passenger is unable to establish a means of communication with Delta personnel sufficient to receive the safety briefing due to having both severe hearing and vision impairments.

D) Medical Clearance

Delta will not require a medical clearance for a Person with a Disability as a condition of travel, except as permitted by law. Delta may require a medical certificate when, in good faith and using its reasonable discretion, Delta determines there is reasonable doubt that a passenger can complete the flight safely without requiring extraordinary medical assistance.

E) Seating Restrictions and Assignments

When a person identifies the nature of his or her disability, Delta will, to the extent possible, accommodate the passenger with a seat assignment that suits the passenger's needs, including seating the passenger together with any Safety Assistant or Personal Attendant traveling with the passenger. Persons with a disability will not be prohibited from occupying seats in designated emergency exit rows, except to the extent required by law.

F) Acceptance of Aids

In addition to the regular baggage allowance, Delta will accept, without charge, as priority checked baggage, mobility aids, including but not limited to:

1) an electric wheelchair, a scooter or a manually operated rigid-frame wheelchair;
2) a manually operated, folding wheelchair;
3) a walker, a cane, crutches or braces;
4) any device that assists the person to communicate; and
5) any prosthesis or medical device.

Where space permits, Delta will, without charge, permit the passenger to store a manually operated, folding wheelchair and other small mobility aids in the passenger cabin during the flight. The assembling and disassembling of mobility aids will be provided by Delta, without charge. Wheelchairs and mobility aids will be the last items to be stowed in the aircraft hold and the first items to be removed.

G) Manually Operated Wheelchair Access

To the extent permitted by space and facilities, Delta will permit a passenger using a manually operated wheelchair to remain in the wheelchair:

1) until the passenger reaches the boarding gate;
2) while the passenger is moving between the terminal and the aircraft door; and
3) while the passenger is moving between the terminal and the aircraft.

H) Service Animals

Delta will accept for transportation, without charge, a service Animal required to assist a Person with a Disability. Service Animals are defined as only dogs, regardless of breed, specifically trained to assist a Person with a Disability. To the extent possible, Delta will assign a seat to the person that provides sufficient space for the person and the service Animal. Delta will permit the service Animal to accompany the person onboard the aircraft and to remain on the floor at the person's seat. The service Animal will not be permitted to occupy a passenger seat. To the extent permitted or required by law, Delta reserves the right to deny transportation to any service animal when reasonably necessary, in Delta's sole discretion, for the comfort or safety of passengers or crewmembers or for the prevention of damage to the property of Delta or its passengers or employees.

I) Services to be Provided to Persons with Disabilities

Upon request, Delta will provide the following services to a Person with a Disability:

1) assistance with registration at the check-in counter;
2) assistance in proceeding to the boarding area;
3) assistance in boarding and deplaning;
4) assistance in stowing and retrieving carry-on baggage and retrieving checked baggage;
5) assistance in moving to and from an aircraft lavatory;
6) assistance in proceeding to the general public area or, in some cases, to a representative of another Carrier;
7) transfer between the person's own mobility aid and a mobility aid provided by Delta;
8) transfer between a mobility aid and the passenger's seat;
9) limited assistance with meals, such as opening packages, identifying items, and cutting large food portions;
10) inquiring periodically during a flight about a passenger's needs; and
11) briefing individual passengers with disabilities and any attendant on emergency procedures and the layout of the cabin.

J) Advance Notice for Special Services

To the extent permitted by law, Delta may require advance notice for certain special services desired by a Person with a Disability. Services applicable under this rule include but are not limited to:

1) transportation of an electric wheelchair on an aircraft of less than 60;
2) provision of hazardous materials packaging for batteries or other assistive device that are required to have such packaging;
3) accommodation for a Group of 10 or more passengers with disabilities traveling as a Group;
4) provision of an onboard wheelchair on an aircraft of 60 seats or more;
5) transportation of a Service Animal in the cabin (unless the ticket is purchased less than 48 hours prior to departure);
6) transportation of a Service Animal on a Segment scheduled to take 8 or more hours; or
7) accommodation of a passenger with both severe vision and hearing impairments.

Such requests should be made by the passenger at the time of reservation and as far in advance as possible. If a passenger requests a special service at least 48 hours prior to departure, Delta will, to the extent possible, provide the service. If a passenger requests a service less than 48 hours prior to departure, Delta will make a reasonable effort to provide the service.

K) Boarding and Deplaning

Where a Person with a Disability requests assistance in boarding or seating or in stowing carry-on baggage, Delta will allow the passenger to board the aircraft in advance of other passengers where time permits.

L) Communication and Confirmation of Information

Delta will use reasonable efforts ensure that announcements to passengers concerning stops, delays, schedule changes, connections, on-board services, and claiming baggage are communicated to any person with a disability in a manner sufficient for the person to understand the communication.

M) Inquire Periodically

When passengers in wheelchairs that are not independently mobile are waiting to board an aircraft, Delta will inquire periodically about their needs and shall attend to those needs where the services required are usually provided by Delta.

RULE 7: REFUSAL TO TRANSPORT

Delta may refuse to transport any passenger, and may remove any passenger from its aircraft at any time, for any of the following reasons:

A) Government Request or Force Majeure
Whenever necessary to comply with any law, regulation or government directive or request; or when advisable in Delta's sole discretion due to weather or other conditions beyond Delta's control including Acts of God, strikes, civil unrest, embargoes, war, and other similar matters of force majeure.

B) Search of Passenger or Property

When a passenger refuses to permit search of his person or property for explosives, weapons, dangerous materials, or other prohibited items.

C) Proof of Identity
When a passenger refuses to produce positive identification on request;

D) Failure to Comply with Delta's Rules or Contract of Carriage

When a passenger fails or refuses to comply with any of Delta's rules or regulations, or any term of the Contract of Carriage.

E) Passenger's Conduct or Condition

Delta will not refuse to provide transportation to a Person with a Disability, as defined in 14 C.F.R. § 382.5 and 382.31, based upon the passenger's disability, except as allowed or required by law. Delta will not refuse to provide transportation based upon race, color, national origin, religion, sex, or ancestry. Subject to those qualifications, Delta may refuse to transport any passenger, or may remove any passenger from its aircraft, when refusal to transport or removal of the passenger is reasonably necessary in Delta's sole discretion for the passenger's comfort or safety, for the comfort or safety of other passengers or Delta employees, or for the prevention of damage to the property of Delta or its passengers or employees. By way of example, and without limitation, Delta may refuse to transport or may remove passengers from its aircraft in any of the following situations:

1) When the passenger's conduct is disorderly, abusive or violent, or the passenger appears to be intoxicated or under the influence of drugs;
2) When the passenger is barefoot;
3) When the passenger interferes with the flight crew's activities, or fails to obey the instruction of any member of the flight crew;
4) When the passenger has a contagious disease that may be transmissible to other passengers during the normal course of the flight;
5) When the passenger is unable to sit in a seat with the seatbelt fastened;
6) When the passenger's behavior may be hazardous or creates a risk of harm to himself/herself, the crew, or other passengers or to the Carrier's aircraft and/or property, or the property of other passengers;
7) When the passenger is seriously ill, unless the passenger provides a physician's written permission to fly; or
8) When the passenger's conduct, attire, hygiene or odor creates an unreasonable risk of offense or annoyance to other passengers.

G) Recourse of Passenger

Passengers shall not engage in any conduct that would authorize Delta to refuse transport under this Rule. The sole recourse of any passenger refused carriage or removed for any reason specified in this Rule shall be recovery of the refund value of the unused portion of his or her ticket as provided in Rule 22.

RULE 8: ACCEPTANCE OF CHILDREN

A) Accompanied Children

(1) General Rule

Except as set forth in this Rule, children under the age of 15 will not be accepted for transportation unless they are accompanied on the same flight in the same cabin by a parent, legal guardian, or other passenger at least 18 years of age. Delta may require documentation verifying the child's age at check-in. A valid passport, birth certificate or other government-issued identification are all acceptable.

(2) Accompanied Children Less Than 2 Years Old.

One child less than 2 years old not occupying a seat may travel with an adult fare-paying passenger at least 18 years old or parent/legal guardian at no additional charge. Additional infants, and infants occupying a seat, must pay the applicable adult fare. A maximum of 2 infants is permitted for each adult. Delta recommends that any child occupying a seat be placed in an approved safety seat. Infants who will reach their second birthday during a journey must occupy a seat and pay the applicable adult fare for the entire journey.

(3) Accompanied Children 2 Years and Older

The fare for children ages 2 years and older will be the Applicable Adult Fare.

B) Unaccompanied Children Under the age of 15.

Children under the age of 15 may travel unaccompanied on Delta only under the following conditions:

(1) Children under the age of 5

No child under the age of 5 will be accepted for unaccompanied travel.

(2) Children aged 5 through 14

Children ages 5 through 7 may travel unaccompanied on non-stop flights only and may not connect to other airlines. Children ages 8 through 14 may travel unaccompanied on Delta's non-stop or connecting flights, but may not connect to other airlines with the exception of Delta Connection, KLM and Air France.

C) Unaccompanied Minor Service

(1) When Unaccompanied Minor Service is Required

Except as otherwise provided in this Rule, Unaccompanied Minor Service is required for all passengers under the age of 15 that Delta accepts for transportation.

(2) Unaccompanied Minor Service Defined

Unaccompanied Minor Service means that Delta will provide supervision for the child from the time of boarding until the child is met at the stop over point or destination. Delta will assume no financial or guardianship responsibilities for unaccompanied children beyond those applicable to an adult passenger. Delta has the right, but is not obligated to require identification of the responsible party meeting the child at a transfer point or final destination. An unaccompanied minor must be confirmed to destination and may not be confirmed on the last connecting flight of the evening (with the exception of markets where there is only one connection and it is the last flight of the day, or for flights to or from Alaska or Hawaii), nor may an unaccompanied minor travel on a flight expected to terminate short of, or bypass, the child's destination. Delta may temporarily suspend unaccompanied minor travel and/or rebook the child on an alternate flight if there is a possibility that weather, irregular operations, or other conditions may cause a flight to be diverted. Delta requires that a parent or responsible adult accompany the child until boarding, and this adult must provide the name, telephone number, and address of the party meeting the child at the transfer point or final destination. Delta reserves the right to refuse to release an unaccompanied child to anyone other than the pre-designated party. Delta representatives cannot administer medicine to children flying alone. An unaccompanied minor may not travel on any domestic flight greater than 2 hours in length which departs between 9 PM and 5 AM ("red-eye flight"). This restriction does not apply for red-eye flights to/from Hawaii and Alaska, however, an unaccompanied minor on a red-eye flight from Hawaii or Alaska may not connect to a domestic red-eye flight or to the last flight of the day unless it is the only flight option for the day.

D) Unaccompanied Children Ages 15-17

Although not required, a parent or guardian may request Unaccompanied Minor Service for unaccompanied minors ages 15-17. The applicable unaccompanied minor service charge will apply.

E) Unaccompanied Minor Service Charge

In addition to the applicable fare, unaccompanied minors for whom Unaccompanied Minor Service is required or has been requested must pay an unaccompanied minor service charge in the amounts set forth below. Delta reserves the right to refuse to transport any unaccompanied minor for whom Unaccompanied Minor Services are required or requested but for whom the applicable unaccompanied minor service fee has not been paid. If 2 or more unaccompanied minors who are members of the same Immediate Family and ticketed together are traveling together, only one service charge will be assessed.

The unaccompanied minor service charge will be specified at: https://www.delta.com/content/www/en_US/traveling-with-us/special-travel-needs/children.html and is incorporated by reference.

RULE 9: SPECIALLY TRAINED SERVICE DOGS

Delta accepts for transportation, without charge, dogs trained: (1) to lead the blind, when the dog accompanies a passenger with impaired vision dependent upon such dog; (2) to assist the deaf, when the dog accompanies a passenger with impaired hearing dependent upon such dog; (3) to assist the physically and psychiatrically impaired passengers dependent upon such dog, or (4) in explosive detection or search and rescue, only when such dogs are accompanied by U.S. military and U.S. government handlers. In the cases of (1) and (2) above, Delta will also accept such dogs when accompanied by the dog's trainer and is en-route to the domicile of the owner for completion of training. In all cases, the service dog will be permitted to accompany such passenger into the cabin but will not be permitted to occupy a seat.

RULE 10: SMOKE FREE SERVICE

Delta prohibits smoking and the use of all smokeless tobacco products (including e-cigarettes) on all flights.

RULE 11: PASSENGER MEDICAL OXYGEN

On flights operated by Delta or Delta Connection, only portable oxygen concentrators (POCs) approved by the FAA are accepted for inflight medical oxygen. A 48-hour notice is required. Please see https://www.delta.com/content/www/en_US/traveling-with-us/special-travel-needs/disabilities.html to obtain information regarding the required medical certificate from a licensed physician and medical screening prior to flight. Medical screening service is provided by Delta at no cost to the passenger. If the passenger makes any voluntary change to his/her itinerary after completion of the medical screening, re-screening may be required. Passengers using POCs on a Delta flight must be seated in a row other than an emergency exit or bulkhead.

RULE 12: TICKETS

A) You must present a valid ticket for transportation, which entitles you to transportation only between points of origin and destination via the ticketed routing.

B) Tickets are not transferable. The purchaser of the ticket and the passenger are responsible for ensuring that the ticket accurately states the passenger's name. Presentation of a ticket for transportation by someone other than the passenger named on the ticket renders the ticket void.

C) Tickets are valid for travel only when used in accordance with all terms and conditions of sale.

D) Where a ticket is invalidated as the result of the passenger's non-compliance with any term or condition of sale, Delta may:

   A) Cancel any remaining portion of the passenger's itinerary or bookings,

   B) Confiscate any unused portion of the ticket,

   C) Refuse to board the passenger or check the passenger's baggage, and/or

   D) Assess the passenger for the reasonable remaining value of the ticket, which shall be no less than the difference between the fare actually paid and the lowest fare applicable to the passenger's actual itinerary.

E) Ticket Expiration

A ticket is valid for one year from the date of issue, and all travel must be completed within the validity period. If exchanged, whether travel has commenced or not, the ticket must be reissued and all travel completed within one year from the original date of issue. However, certain fares may have different periods of validity, in which case the specific rules associated with the fare will apply. If the passenger is prevented from using the ticket, or a portion of the ticket, before the one-year expiration date due to lack of space or flight cancellation, the ticket will remain valid until space can be provided.

F) An electronic ticket (E-Ticket/ET) is the record of agreement maintained and processed within the Carrier's electronic reservation system. A written receipt is provided to the purchaser of the electronic ticket which contains a reference for retrieving the record within the Carrier's reservation system and summary of the ticket information. The Carrier may mandate the issuance of an electronic ticket (ET) regardless of market, Carrier, form of payment, and customer type (including SkyMiles and participating Carrier frequent flyer members).

G) External Reissue Charge

Delta will collect a nonrefundable fee of USD $50.00 for reissue by Delta of tickets originally issued in the United States or Canada by any ticketing source other than Delta, however, the charge does not apply to same day confirmed transactions, IROP or schedule change situations, SkyMiles upgrade reissues, tickets reissued on delta.com, or tickets issued at military or government fares. This fee applies to all changes to tickets issued at the request of the passenger.

H) Capacity Limitations

Delta will limit the number of passengers carried on any one flight in any fare class or cabin, and such fares and fare classes will not necessarily be available on all flights or in all markets. The number of seats which Delta makes available on a given flight is determined by Delta's best judgment of the anticipated t otal passenger load on each flight.

RULE 13: CONFIRMATION OF RESERVATIONS

No reservation on Delta is valid until the availability and allocation of the reserved space is confirmed by Delta or its agent and entered in Delta's electronic reservations system.

Unless an earlier ticketing deadline is imposed by the applicable fare rule or other agreement between Delta and the passenger, Delta must receive payment and the reservation must be ticketed at least 30 minutes prior to the scheduled flight departure time. Failure to comply with this ticketing deadline or an earlier ticketing deadline imposed by the applicable fare rule or other agreement with the passenger will result in cancellation of the reservation without notice. A list of airports imposing an earlier ticketing deadline is set forth at delta.com and incorporated herein by reference.

RULE 14: CANCELLATION OF RESERVATIONS

A) Delta Will Cancel reservations of any passenger whenever such action is necessary to comply with any governmental regulation, or to comply with any governmental request for emergency transportation in connection with the national defense, or whenever such action is necessary or advisable by reason of weather or other conditions beyond its control.

B) The Transportation Security Agency's (TSA) Secure Flight Program requires that Delta collect

the following additional information from passengers when making a reservation to fly within, into or out of the United States and reservations for point-to-point international flights operated by U.S.- based airlines:

1) Full Name (required), as it appears on government-issued I.D. approved for use when traveling
2) Date of Birth (required)
3) Gender (required)
4) Redress Number (optional)

Delta may cancel your reservation if the reservation does not include the required Secure Flight Passenger Data (full name, date of birth and gender) at least 72 hours prior to your scheduled departure. This cancellation policy applies to all Delta tickets, including tickets for our codeshare partners' flights.

C) Failure To Appear

If you fail to appear for any flight in your itinerary without giving Delta notice in advance of the departure of the flight, Delta may cancel your reservation for all remaining flights in your itinerary.

D) Airport Check-In Time Limits

1) Reservations Subject to Cancellation for Failure to Meet Check-in and Boarding Deadlines

Your reservation may be cancelled if you do not comply with all applicable check-in procedures by the check-in deadline for your flight, or if you not at the gate and ready for boarding by the applicable boarding deadline. The check-in and boarding deadlines in effect on the date of travel will apply and are posted on delta.com.

2) Passenger Responsibility to Allow Sufficient Time

You must arrive at the airport with sufficient time to comply with all check-in procedures, complete security screening, comply with all other government requirements and departure processing, and arrive at the gate by the applicable boarding deadline. Delta will not delay flights for passengers who are not at the gate and ready to board on time, and is not liable for any loss or expense due to the passenger's failure to comply with this provision.

RULE 15: VOLUNTARY STANDBY TRAVEL

Tickets may not be used for voluntary standby travel on any flight other than the ticketed flight unless expressly permitted by the fare rules of the ticket. When voluntary standby travel on another flight is permitted, the following provisions apply:

1) Voluntary standby travel is subject to the availability of seats at departure time in the same cabin as originally ticketed and does not guarantee transportation on the requested flight(s) including the origin, downline, or connecting flights. Request for voluntary standby travel may be made up to 24 hours prior to original ticketed departure time. Notwithstanding anything set forth herein, Same Day Paid Standby travel is not permitted for Basic Economy fares.

2) Voluntary standby travel is limited to passengers with a confirmed ticketed reservation for a later flight on the same day of travel. Delta will not permit changes to the origin, destination, or co-terminals, or to the routing for fares that are flight-specific or require specific routing.

3) Delta reserves the right to charge a nonrefundable same day standby fee when a passenger requests to standby for an alternate flight for which the passenger does not hold a confirmed reservation. The fee, if any, may be assessed based on each Segment from the passenger's origin to destination or next point of stop over. These fees will be charged if the passenger flies any portion of the Segment, therefore, passengers that are removed at intermediate points on through flights and/or voluntarily deplaned at a destination other than the destination for which the fee was intended will not be eligible for a partial or whole refund. Refer to delta.com for current standby fees.

4) Delta is not liable to pay compensation, including but not limited to, denied boarding compensation and amenities, for a failure to provide transportation and/or accommodate the passenger's request for voluntary standby travel.

5) Delta reserves the right to discontinue accepting and placing passengers on the airport standby list.

6) Eligibility for same day standby is at Delta's discretion and may be restricted based on operational considerations or limited to selected flights, specified booking classes, payment by credit card only. Eligibility may also be restricted by the fare rules governing the passenger's ticket.

7) Delta may choose to accommodate passengers from the airport standby list in any specified order and may take into account ticket value, frequent flyer status, check-in time, and other factors.

8) Delta reserves the right to limit the number of passengers on the airport standby list, only accept the passenger's standby request at an airport location, and limit the minimum and maximum time frames that airport standby listing is allowed.

RULE 16: FARES

A) Fares Applicable Only For Ticketed Itinerary

Fares apply for travel only between the points for which they are published. Tickets may not be issued at fare(s) published to and/or from a more distant point(s) than the points being traveled, even when issuance of such tickets may produce a lower fare.

B) Erroneous Fares

Delta will exercise reasonable efforts to ensure that all fares it publishes are accurate and available for sale, but Delta, as a policy, does not file nor intend to file tickets priced at a zero fare or that are erroneous or reasonably apparent as erroneous. If an erroneous fare is inadvertently published for sale and a ticket is issued at the erroneous fare before it has been corrected, Delta reserves the right to cancel the ticket purchase and refund all amounts paid by the purchaser or, at the purchaser's option, to reissue the ticket for the correct fare.
In this event, Delta will also reimburse any reasonable, actual, and verifiable out-of-pocket expenses incurred by the purchaser in reliance upon the ticket purchase. The purchaser must provide receipts or other evidence of such actual costs incurred in support of any reimbursement request.

C) Circumvention of Published Fares

Delta prohibits ticketing practices intended to circumvent the published fare that Delta intends to offer for your true itinerary. These practices include:

1) Back to Back Ticketing - The purchase or usage of two or more tickets issued at round trip fares, or the combination of two or more round trip fares end to end on the same ticket for the purpose of circumventing minimum stay requirements.

2) Throwaway Ticketing - The purchase or usage of round trip fares for one way travel.

3) Hidden City/Point Beyond Ticketing - The purchase or usage of a fare from a point before the passenger's actual origin or to a point beyond the passenger's actual destination.

D) When the fare between any 2 points is not specifically published via the desired routing, the fare will be constructed by combining two or more separate fares, via the desired routing from the passenger's point of origin to point of destination, which produce the lowest fare for the class of service used; provided, however, that combined fare will not exceed the lowest fare determined in accordance with this rule and the applicable fare rules. Delta's direct sales channels will offer customers the lowest applicable published fare for itineraries between points in the United States on Delta, Delta Connection, Delta Shuttle and Delta Codeshare flights for the flights, dates and class of service requested to which our representatives have access. Please note that Delta will quote lowest published fare that we offer for the specific airports and type of itinerary that you request. We do not search for or quote fares for other itineraries, including by combining one-way or other fares. Fares not accessible directly from Delta may include, but are not limited to, unpublished fares, consolidator fares, negotiated fares, tour or package fares, and discounts available only via Internet web sites.

E) Duplicate, Fictitious and impossible/illogical bookings

Delta prohibits duplicate, impossible, or fictitious bookings, including but not limited to multiple conflicting itineraries for the same passenger on the same day or bookings with connections that depart before the arrival of the inbound flight. Delta reserves the right to cancel any such booking which has not been ticketed, and to cancel and refund any such booking which is ticketed at a refundable fare.

RULE 17: BAGGAGE

A. Checked and Carry-On Baggage Policies and Restrictions

Ticketed passengers may check baggage and carry baggage on board Delta aircraft, subject to this rule. Delta's baggage policies and baggage fees are available at www.delta.com/bags and are incorporated by reference as if set forth in this contract of carriage. These policies restrict the quantity, size and weight of baggage, and govern the carriage of hazardous and dangerous goods, and special items (such as sporting equipment, medical equipment and mobility aids, musical instruments, and fragile and perishable items).

B. Baggage Liability

1. General Limitation of Liability for Loss of, Damage to, or Delay in Delivery of Baggage

Delta's liability for loss, damage, or delay in the delivery of a passenger's checked baggage, carry-on baggage, or other personal property tendered to Delta in connection with air transportation on Delta shall be limited to proven damage or loss. Actual value for reimbursement of lost or damaged property shall be determined by the documented original purchase price less any applicable depreciation for prior usage. Under no circumstances shall the liability for loss, damage, or delay in the delivery of baggage exceed

$3,800 per fare-paying passenger. These limitations shall also apply to baggage or personal property if and to the extent accepted by Delta for temporary storage at a city or airport ticket office or elsewhere before or after the passenger's trip.

2. Preexisting Damage/ Ordinary Wear and Tear

Delta is not liable for preexisting damage (including minor cuts, scratches, and broken zippers as a result of over packing) or for wear and tear resulting from ordinary handling of baggage.

3. Special Items

a) Wheelchairs and Personal Assistive Devices

The maximum liability limitations set forth above shall not apply to claims for loss, damage, or delay in the delivery of wheelchairs or other assistive devices. Delta will accept these items as checked baggage regardless of packaging, but will not be responsible for repair or replacement of such items due to damage existing at the time of acceptance (which will be noted by Delta on a release form at the time of acceptance).

b) No Liability for Loss or Damage to Fragile, Perishable, or Precious Items Not Identified to Delta at the Time of Check-In

Delta is not liable for any loss or damage to precious items, nor for deterioration or spoilage resulting from delay in delivery of any perishable items, nor for damage to or damage caused by, fragile articles that are unsuitably packed, if such items are included in the passenger's checked baggage without Delta's knowledge. The passenger must identify such items to Delta at the time of check-in.

c) Fragile or Perishable Items Accepted Pursuant to Limited Liability Release

Delta is not liable for loss, damage, or delay in the delivery of a passenger's baggage or other property accepted by Delta pursuant to the execution of a Limited Liability Release form executed by the passenger for the purpose of inducing Delta to carry the item, except as expressly provided by the Limited Liability Release.

4. Loss Due To Government or Airport Action

Delta is not liable for loss, damage, or delay of a passenger's checked baggage, carry-on baggage, wheelchair or assistive device, or any personal item that may result from a security search of such items conducted by an agent of any local, state, or federal agency in charge of airport security screening, or from confiscation by an agent of any local, state, or federal agency.

5. Time Limitations for Baggage Claims

Delta is not liable for any loss, damage, or delay in the delivery of baggage arising out of or in connection with transportation of, or failure to transport any baggage unless notice of a claim is presented to a Delta office within 24 hours after the alleged occurrence of the events causing the claim, and unless the action is commenced within one year after such alleged occurrence. Any notification received within 24 hours that informs Delta of the nature of the claim will suffice, and Delta may deny any claim not presented within 24 hours of the alleged occurrence. Written notification of loss must be received by Delta's system baggage within 21 Days after the alleged occurrence, and Delta may deny any claim for failure to provide written notice within 21 Days.

6. Carriage By Multiple Carriers

When the transportation includes Delta and one or more Carriers with a limitation of liability exceeding $3,800 for each fare-paying passenger and responsibility for loss, damage, or delay in delivery of baggage cannot be determined, the liability limit of $3,800 for each fare-paying passenger will be applied to all Carriers. Whenever responsibility for loss, damage, or delay in delivery of baggage cannot be determined and when transportation is via Delta and one or more Carriers which exclude certain items in checked baggage from their liability, Delta will not be liable for the excluded items.

C. Governing Rules for Domestic Codeshare Flights

When the passenger's travel involves domestic flights operated by a Delta domestic codeshare partner other than a Delta Connection carrier, the baggage rules of the marketing carrier on the first Segment of a round trip, or the marketing carrier on the first Segment of each one way trip will govern when determining baggage acceptance policies and applicable baggage fees. Notwithstanding the foregoing, the baggage liability provisions set forth above shall govern the liability of Delta and/or any Delta Connection carrier with respect to any transportation subject to this contract of carriage.

RULE 18: ELECTRONIC SURVEILLANCE

Passengers and their baggage are subject to inspection with an electronic detector with or without the passenger's consent or knowledge.

RULE 19: FLIGHT DELAYS/CANCELLATIONS

A. Delta's Liability in the Event of Schedule Changes, Delays and Flight Cancellations

If there is a flight cancellation, diversion, delay of greater than 120 minutes, or that will cause a passenger to miss connections, Delta will (at passenger's request) cancel the remaining ticket and refund the unused portion of the ticket and unused ancillary fees in the original form of payment in accordance with Rule 22. If the passenger does not request cancellation and refund of the remaining portion of the ticket, Delta will transport the passenger to the destination on Delta's next flight on which seats are available in the class of service originally purchased. At Delta's sole discretion and if acceptable to the passenger, Delta may arrange for the passenger to travel on another Carrier or via ground transportation. If acceptable to the passenger, Delta may provide transportation in a lower class of service, in which case the passenger may be entitled to a partial refund. If space on the next available flight is available only in a higher class of service than purchased, Delta will transport the passenger on the flight, although Delta reserves the right to upgrade other passengers on the flight according to its upgrade priority policy to make space in the class of service originally purchased. Delta will not be liable under any circumstances for any special, incidental or consequential damages arising from the foregoing.

B. Delta's Liability for Additional Amenities in the Event of Schedule Changes, Delays and Flight Cancellations

Except as provided above, Delta shall have no liability if the flight cancellation, diversion or delay was due to force majeure. As used in this rule, "force majeure" means actual, threatened or reported:

(1) Weather conditions or acts of God;
(2) Riots, civil unrest, embargoes, war, hostilities, or unsettled international conditions;
(3) Strikes, work stoppages, slowdowns, lockout, or any other labor-related dispute;
(4) Government regulation, demand, directive or requirement;
(5) Shortages of labor, fuel, or facilities; or
(6) Any other condition beyond Delta's control or any fact not reasonably foreseen by Delta.

However, when a passenger's travel is interrupted for more than 4 hours after the scheduled departure time as a result of flight cancellation or delay on the date of travel other than from force majeure, Delta will provide the passenger with the following additional amenities during the delay:

(a) Hotels

If overnight accommodations are available at Delta contracted facilities, Delta will provide the passenger with a voucher for one night's lodging when the delay is during the period of 10:00 pm to 6:00 am. Delta will provide free public ground transportation to the hotel if the hotel does not offer such service. If accommodations are not available, Delta will provide the passenger with a voucher that may be applied to future travel on Delta equal in value to the contracted hotel rate, up to $100 USD.

(b) Ground Transportation

In lieu of lodging or other amenities, Delta will furnish ground transportation to the destination airport if a passenger's flight is diverted to an alternative airport and if the destination on the ticket and the diverted airport destination are within the following city groups:

San Francisco, CA (SFO)/ Oakland, CA (OAK)/ San Jose, CA (SJC)
Los Angeles, CA (LAX)/ Long Beach, CA (LGB)/ Ontario, CA (ONT)/ Santa Ana, CA (SNA)
Denver, CO (DEN)/ Colorado Springs (COS)
O'Hare – Chicago, IL (ORD)/ Midway – Chicago, IL (MDW)
Dallas-Ft. Worth, TX (DFW)/ Dallas, TX Love Field (DAL)
Bush Intercontinental – Houston, TX (IAH)/ Hobby – Houston, TX (HOU)
Fort Lauderdale, FL (FLL)/ Miami, FL (MIA)/ West Palm Beach, FL (PBI)
Baltimore, MD (BWI)/ National – Washington, DC (DCA)/ Dulles – Washington, DC (IAD)
Newark, NJ (EWR)/ LaGuardia – New York, NY (LGA)/ John F. Kennedy – New York, NY (JFK)
Orlando, FL (MCO)/ Tampa, FL (TPA)/ Daytona Beach, FL (DAB)/ Melbourne, FL (MLB)/Sarasota Bradenton, FL (SRQ)

(c) Additional Amenities

Delta will provide such additional or alternative amenities as are necessary to maintain the safety and/or welfare of customers with special needs such as unaccompanied children and customers with disabilities. Such amenities will be furnished consistent with special needs and/or circumstances.

C. Extended Tarmac Delays – Codeshare Services

In the event of extended tarmac delays on flights operated by a Delta codeshare partner, the contingency plan for lengthy tarmac delays of the operating Carrier will apply.

RULE 20: DENIED BOARDING COMPENSATION

A) Overbooking of Flights
Because passengers with confirmed reservations on a flight sometimes fail to show, Delta reserves the right to sell more tickets for travel on each flight than there are seats available on the aircraft. In some cases, this may result in a flight in which Delta cannot accommodate one or more passengers with confirmed reservations (an "oversold flight"). Delta may deny boarding to passengers with confirmed reservations on an oversold flight as set forth in this rule. The rights of passengers who are denied boarding shall be governed by this rule.

B) Request For Volunteers

Before denying boarding to any passenger holding a confirmed reservation on an oversold flight, Delta will ask other passengers on the flight to voluntarily give up their seat in exchange for compensation in an amount and form to be determined by Delta in its sole discretion. If a sufficient number of volunteers agree to give up their seats in response to Delta's offer, then no passenger with a confirmed reservation will be involuntarily denied boarding due to the oversale of the flight. If there are more volunteers than required, selection of the volunteer(s) to receive compensation will be determined in Delta's sole discretion.

C) Involuntary Denied Boarding

If an insufficient number of passengers volunteer to give up their seats in response to Delta's offer, Delta may involuntarily deny boarding to one or more passengers on the oversold flight according to the following boarding priority rules:

1) Passengers Holding Tickets for Travel in Premium Cabin, SkyMiles members identified with a Diamond Medallion ("DM"), Platinum Medallion ("PM"), or Gold Medallion ("GM") elite-status designation, and passengers holding tickets purchased under a DL corporate travel agreement.

   Passengers holding tickets for confirmed space in the First or Business class cabin, SkyMiles members identified with a DM, PM, or GM elite-status designation, and passengers holding tickets purchased under a DL corporate travel agreement will be accommodated before other passengers holding tickets and/or boarding passes for confirmed space in the Coach cabin.

2) Passengers With Boarding Passes

   Subject to the terms set forth in Rule 20(c)(1) and (4), passengers holding boarding passes who check in and present themselves at the departure gate in compliance with Rule 13 will be accommodated before passengers traveling in the same cabin who have not been issued boarding passes or who fail to comply with applicable check-in requirements. Subject to the availability of seats on the aircraft, boarding passes may be obtained by passengers who hold tickets for confirmed reserved space in the following manner:

   a) for passengers traveling on electronic tickets, through the Online Check-in feature on Delta.com within 24 hours of scheduled departure

   b) for passengers traveling on electronic tickets, through a Delta airport kiosk within four hours of scheduled departure

   c) from a Delta airport ticket counter and/or the check-in desk located in the departure area.

3) Passengers Without Boarding Passes

   Passengers with confirmed reservations who have not been issued a boarding pass and present themselves at the departure gate in compliance with Rule 13 will be accommodated according to the following priority rules:

   a) Passengers who have been rebooked to the present flight as a result of an irregular operation (e.g., delay, cancellation) of a previously booked flight.

   b) SkyMiles members identified with a Silver Medallion ("FO") elite-status designation.

   c) Passengers with a SkyTeam Elite or Elite Plus status.

d) Passengers without any elite-status designation.

Within each of the foregoing groups, passengers are prioritized first by class of service and then by time of check-in.

4) Special Needs Passengers

Because of the special needs of passengers with disabilities, unaccompanied minors, and aged or infirm passengers, and active members of the U.S. Armed Forces on travel orders, Delta reserves the right to accommodate such passengers without regard to the boarding priorities established by this provision.

D) Transportation For Passengers Denied Boarding

Delta will provide transportation to passengers who volunteer to relinquish their seats or who are denied boarding involuntarily due to the oversale of a flight as follows:

1) Next Available Flight

Delta will transport the passenger on its next flight on which space is available to the passenger's next Stopover, or if none, to the passenger's destination, at no additional cost to the passenger.

2) Transportation on Other Airlines

At Delta's sole discretion, Delta may instead arrange for transportation on any other Carrier or combination of Carriers to the passenger's next Stopover, or if none, to the passenger's destination, at no additional cost to the passenger.

3) Overnight Stay Required

If the transportation provided to a passenger pursuant to this section requires that the passenger stay overnight before continuing his/her travel, Delta will provide hotel accommodations to the passenger at no additional cost. If hotel accommodations are unavailable, Delta will compensate the passenger with a credit voucher valid for future purchases from Delta in an amount commensurate in value with the local average contracted hotel rate up to $100 USD, to be determined by Delta.

E) Compensation For Involuntary Denied Boarding

When a passenger with a confirmed reservation is involuntarily denied boarding on an oversold flight pursuant to this rule, Delta's sole liability to the passenger shall be to provide alternative transportation as provided in paragraph D, above, and to pay denied boarding compensation, if applicable, pursuant to the terms and conditions of this rule.

1) Conditions For Payment of Involuntary Denied Boarding Compensation

The passenger shall not be entitled to any compensation for involuntary denied boarding if:

a) Passenger's Failure to Comply with Contract of Carriage

The passenger has not complied fully with Delta's contract of carriage or tariff provisions regarding ticketing, reconfirmation, check-in, or acceptability for transportation

b) Substitution of Equipment

The flight for which the passenger holds confirmed space is unable to accommodate that passenger because of substitution of equipment of lesser capacity when required by operational or safety reasons; or, on an aircraft with a designed passenger capacity of 60 or fewer seats, the flight for which the passenger holds confirmed reserved space is unable to accommodate that passenger due to weight/balance restrictions when required by operational or safety reasons.

c) Carriage in Alternative Cabin
Delta offers to accommodate the passenger in a section of the aircraft other than that specified on his/her ticket at no extra charge; provided however that if a passenger is seated in a section for which a lower fare applies, the passenger will be entitled to a refund of the difference in fare.

d) Alternative Transportation
Delta arranges comparable air transportation, or other transportation used by the passenger, at no extra cost to the passenger, that at the time such arrangements are made is scheduled to arrive at the passenger's next Stopover, or, if none, final destination within one hour after the planned arrival time of the passenger's original flight or flights.

F) Amount of Involuntary Denied Boarding Compensation
If all conditions for compensation are met, then Delta shall pay compensation to passengers involuntarily denied boarding in an amount to be calculated as follows:

1) When Delta arranges Qualifying Alternative Transportation
If Delta arranges Qualifying Alternative Transportation, then Delta will pay denied boarding compensation in an amount equal to 200% of the fare (including any surcharges and air transportation taxes) to the passenger's next Stopover, or if none, to his/her final destination, but no more than $775.00.

2) Where Delta cannot arrange Qualifying Alternative Transportation
If Delta cannot arrange Qualifying Alternative Transportation, then Delta will pay denied boarding compensation in an amount equal to 400% of the fare (including any surcharges and air transportation taxes) to the passenger's next Stopover, or if none, to his/her final destination, but no more than $1550.00.

G) Time of Payment for Involuntary Denied Boarding Compensation
If all conditions for compensation are met, Delta will pay any involuntary denied boarding compensation on the day and at the place where the denial of boarding occurred, in cash or immediately negotiable check; provided, however, that if the alternative transportation arranged for the passenger's convenience departs before the payment can be made to the passenger, then payment will be made by mail or other means within 24 hours after the denied boarding occurs.

RULE 21: REROUTING

A General Provisions

1. Fare Applicable To Rerouting Or Change In Destination
a. Unless otherwise specified in the fare rule, a passenger may change the routing, destination, Carrier(s), class of service, or dates of travel specified on an unused ticket in accordance with paragraph 2) below, provided that, after transportation has commenced, a one-way ticket will not be converted into any other type of ticket (such as a round-trip, circle-trip or open-jaw trip ticket).

b. Except as otherwise provided in Rule 19, the fares and charges applicable, when a rerouting or change in ultimate destination is made at passenger's request prior to arrival at the ultimate destination named on the original ticket, shall be the applicable fare and charges for the entire revised itinerary in effect on the date that the rerouting or change in ultimate destination is entered on the passenger's new ticket.

c. Rule 12(E) applies for validity of voluntarily exchanged/reissued tickets.

2. Fare Applicable To Upgrading Class Of Service While In Flight
When a passenger moves from one class of service to another while in flight, an additional collection will be made in an amount equal to the difference between:

1. The one-way fare applicable to the class of service used from passenger's point of origin on such flight to the last scheduled stop prior to the passenger's change in class of service, plus the one-way fare in the new class of service from such stop to the passenger's destination on such flight, and

2. The fare paid for transportation from the passenger's origin to destination on such flight.

When the amount described in 1) above is less than the amount described in 2) above, no additional collection will be made. The acceptance of such passenger in the class of service to which he/she is moving for travel beyond the next scheduled stopping point in the flight is subject to availability. Discounts will not apply.

B. Ticket reissue procedures

-Unless otherwise specified in a fare rule, the following procedures will apply to Delta ticket reissues.

For nonrefundable fares:
- If the price of the new ticket is lower than the ticket being reissued, the difference in ticket price will be provided to the passenger in the form of a non-refundable Delta travel voucher at the time of reissue.
- If the price of the new ticket is equal to or higher than the ticket being reissued any difference in fare will be collected at the time of reissue.

For refundable fares:
- If the price of the new ticket is lower than the ticket being reissued, any difference In fare will be refunded to the original form of payment at the time of reissue.
- If the price of the new ticket is higher than the ticket being reissued, the difference in fare will be collected at the time of reissue.

-Flights must be rebooked and the ticket reissued at the time of the change.

1. Unused tickets
When making changes to an unused ticket, Delta will cancel the itinerary and start over, issuing a new ticket using current fares subject to all applicable fare rules. The value of the original ticket may be applied toward the purchase of the new ticket. If the unused fare is refundable, the value of the original ticket may be applied toward the purchase of the new ticket.
2. Partially Used Tickets
   a. When making changes to partially used tickets, Delta will apply one of the following procedures resulting in the lowest fare:

i. Reprice the itinerary, attempting to keep fares of the fully flown fare components and replacing the unflown fare components using current fares. No changes are permitted to the fare break points of the fully flown fare components. Delta will validate all fare rules at the time of reissue. The new ticket may be a lower or equal or higher price than the previous ticket.

-OR-

ii. Issue a new ticket using current fares and validating all fare rules at the time of reissue. If the original fare is nonrefundable, the Carrier will apply the remaining value for the unflown Segments of the partially used ticket, if any toward the purchase of a new ticket. For refundable fares, Delta will apply the remaining value from the partially used ticket, if any, toward the purchase of a new ticket.

C. Same Day Confirmed

Unless otherwise specified in the fare rules, a passenger holding a nonrefundable ticket may change to another flight to the same destination operated by Delta or a Delta Connection carrier on the same day, subject to the policies set forth at https://www.delta.com/content/www/en_US/traveling-with-us/ticket-changes-refunds/sameday-travel-changes.html and incorporated herein.

RULE 22: REFUNDS

A. Involuntary Refunds

If a refund is required because of Delta's failure to operate on schedule or refusal to transport (except as a result of passenger's failure to comply with the contract of carriage), the following refund will be made directly to you:

1) If no portion of the ticket has been used, the refund will be an amount equal to the fare paid.

2) If a portion of the ticket has been used and termination (interruption) occurs:

a) At A Fare Breakpoint - The refund will be an amount equal to the fare paid for the unused transportation from the point of termination (interruption) to the destination or next Stopover point named on the ticket, or to a point at which transportation is to be resumed. No refund will apply when alternate transportation is provided by Delta and accepted by the passenger.

b) Within A Fare Component - The refund will be an amount equal to the percentage of unflown mileage to fare component total mileage by prorating the fare paid for the fare component, from the point of termination/interruption to the destination, or next Stopover point named on the ticket, or to the point at which transportation is to be resumed. No refund will apply when alternate transportation is provided by Delta and accepted by the passenger.

B. Voluntary Refunds

1. Nonrefundable Tickets

Most tickets issued by Delta are nonrefundable. Delta will not refund any portion of a fare that is nonrefundable, and Delta will not refund any taxes, fees or charges collected upon nonrefundable tickets. Delta may permit a portion of the fare paid for an unused nonrefundable ticket to be applied toward the

purchase of future travel on Delta, or to upgrade or downgrade those tickets after purchase, as set forth in the applicable fare rule. Delta may charge an administrative service charge for processing any permitted changes to nonrefundable tickets, which will be deducted from any credit toward the purchase of future travel on Delta, or collected at the time the change is processed, as applicable.

In the event of death of the passenger prior to the date of travel, tickets issued at nonrefundable fares will be refunded to the deceased passengers' estate upon request.

2. Fully Refundable Tickets

If your ticket was purchased at a fare that is fully refundable, Delta will issue a refund of any unused refundable portion of your ticket at your request. You must surrender any unused portion of the ticket at the time of the refund request. No refund will be issued on any ticket unless Delta receives a request for the refund and any unused coupons are surrendered to Delta within one year of the original issue date of the ticket. The amount of the refund will be calculated as follows:

1. If no portion of the ticket has been used, Delta will refund the total fare and all taxes, fees or charges paid.

2. If a portion of the ticket has been used, Delta will refund an amount equal to (a) the total fare and all taxes, fees or charges paid, minus (b) the fare and taxes, fees or charges for the used portion of the ticket.

C. Time Limit for Refund Requests

No refund will be issued on any ticket unless Delta receives a request for the refund and any unused coupons are surrendered to Delta within one year of the original issue date of the ticket.

D. Form of Refund

Delta will issue refunds on eligible tickets as follows:

1. Tickets paid for by credit card will be refunded to the credit card account used to purchase the ticket, typically within seven business days of Delta's initial receipt of refund request.

2. Tickets paid for by cash, if cash is accepted by Delta, will be refunded by check issued to the person named as a passenger on the ticket, typically within 20 business days of Delta's receipt of initial refund request.

3. Tickets charged under a universal air travel plan will be refunded to the subscriber against whose account the ticket was charged.

4. Tickets issued against governmental transportation requests shall be issued as required by applicable government regulation.

5. Tickets paid with any other form of payment will be issued back to the original form of payment.

D. Overcharges

No claims for overcharge shall be valid and DL shall have no liability if claim is more than forty five (45) days after the date of issue of the ticket.

RULE 23: CURRENCY; DECLINED OR DISPUTED FORMS OF PAYMENT

Except as otherwise provided, all fares and charges between points in the United States are stated in dollars and cents of the lawful currency of the United States. Except as set forth in this contract of carriage, a

passenger is liable for the entire ticket price and fees for an issued ticket, notwithstanding any dispute, chargeback or declined form of payment. Delta reserves the right to collect all such amounts at any time, including after transportation has been provided.

RULE 24: GOVERNING LAW; ENTIRE AGREEMENT; LIMITATION OF LIABILITY

Any and all matters arising out of or relating to this Contract of Carriage and/or the subject matter hereof shall be governed by and enforced in accordance with the laws of the United States of America and, to the extent not preempted by Federal law, the laws of the State of Georgia without regard to conflict of law principles, regardless of the legal theory upon which such matter is asserted. This Contract of Carriage, including the Ticket and Fare Rules, represents the entire agreement between the parties relating to transportation by Carrier, and shall supersede all prior representations, understandings or agreements pertaining thereto, either oral or written. No other covenants, warranties, undertakings or understandings may be implied, in law or in equity.

Delta shall not be liable for any punitive, consequential or special damages arising out of or in connection with carriage or other services performed by Delta, whether or not Delta had knowledge that such damage might be incurred. Delta shall not be liable for any damage arising out of its compliance with any laws, government regulations, orders, rules, requirements or security directives or as a result of a passenger's failure to comply with such laws, government regulations, orders, rules, requirements or security directives or as a result of Passenger's reliance on advice provided by Delta regarding such laws, regulations, orders, rules, requirements or security directives.

Election or failure by Delta to enforce any provision of the contract of carriage shall not constitute a waiver of its rights and remedies with regard to such provision or any other provision.

Plaintiffs' Exhibit 446

Contract of Carriage

Effective Date: 04/13/2021

For a summary of changes, click here.

LIST OF EFFECTIVE PAGES

REVISION NUMBER	77	REVISION DATE	04/13/21

Chapter/Page	Revision/Date
00.00 Pg. 1	Rev36 04/13/11
00.00 Pg. 2	Rev36 04/13/11
00.00 Pg. 3	Rev77 04/13/21
Pg. 1	Rev77 04/13/21
Pg. 2	Rev77 04/13/21
Pg. 3	Rev77 04/13/21
Pg. 4	Rev77 04/13/21
Pg. 5	Rev77 04/13/21
Pg. 6	Rev77 04/13/21
Pg. 7	Rev77 04/13/21
Pg. 8	Rev77 04/13/21
Pg. 9	Rev77 04/13/21
Pg. 10	Rev77 04/13/21
Pg. 11	Rev77 04/13/21
Pg. 12	Rev77 04/13/21
Pg. 13	Rev77 04/13/21
Pg. 14	Rev77 04/13/21
Pg. 15	Rev77 04/13/21
Pg. 16	Rev77 04/13/21
Pg. 17	Rev77 04/13/21
Pg. 18	Rev77 04/13/21
Pg. 19	Rev77 04/13/21
Pg. 20	Rev77 04/13/21
Pg. 21	Rev77 04/13/21
Pg. 22	Rev77 04/13/21
Pg. 23	Rev77 04/13/21
Pg. 24	Rev77 04/13/21

FRONTIER

Table Of Contents

1. Introduction

The following terms and conditions as well as such additional terms and conditions presented on Frontier Airlines' website, fare rules, published schedules or printed on or in any ticket or ticket-less travel authorization apply to all tickets issued for travel on flights operated by or for Frontier Airlines, Inc. (“Frontier”), as well as that transportation, regardless of whether such ticket was sold by Frontier or its authorized agents or whether such ticket is used (“Contract of Carriage”).

This document is available for public inspection at all Frontier locations. Copies may be obtained by visiting the Frontier's web site at www.FlyFrontier.com or by writing to: Frontier Airlines, Inc., Customer Relations, 4545 Airport Way, Denver, CO 80239.

2. Definitions

A. **Codeshare** -- A marketing and business arrangement in which two airlines “share” the same flight (which might include connecting legs). One airline places its designator code and flight number on a flight operated by the other airline, and markets and sells tickets for that shared flight as part of its published schedule.

B. **Code** -- The U.S. Internal Revenue Code of 1986, as amended.

C. **DOT** -- U.S. Department of Transportation.

D. **FAA** -- U.S. Federal Aviation Administration.

E. **Fare Rules** -- The rules and requirements associated with a ticket.

F. **IATA** -- International Air Transport Association.

G. **No-Show Cancellation** -- The automatic cancellation of a passenger’s ticket upon such passenger failing to either (i) check-in for such passenger’s flight, or (ii) board such passenger’s flight, in either instance within the required times. The automatic cancellation will apply to all subsequent flights, including return flights, on the itinerary. Presentation of a ticket by someone other than the named passenger renders the ticket void and the ticket will then be treated as a No-Show Cancellation for all purposes of this Contract of Carriage. (See section 20.)

H. **Qualified Individual with a Disability** -- An individual with a disability who: (i) has a physical or mental impairment that, on a permanent or temporary basis, substantially limits one or more major life activities; (ii) has a record of such an impairment; or, (iii) is regarded as having such an impairment, as further defined in 14 CFR 382.5.

I. **Standby Passenger** -- A passenger boarded subject to availability of seat space at departure time and only after all passengers having confirmed reservations for the flight have been boarded.

J. **Stopover** -- An intentional interruption in a passenger’s trip in excess of 4 hours at a point between the place of departure and the final destination.

K. **STRETCH Seat** - A seat located in the front rows and exit rows of certain Frontier aircraft that have additional legroom. These seats are made available to passengers for a fee.

L. **Ticket** -The record of agreement, including electronic tickets, for passenger air transportation provided by the airline under certain terms and conditions to the passenger as described on the ticket, in the fare rules, and in this Contract of Carriage.

M. **TSA** -- U.S. Transportation Security Administration.

3. Refusal to Transport and Special Conditions

A. Frontier may refuse to provide transportation to any person and may require that a passenger leave an aircraft or be removed from an aircraft for the following reasons, in which case Frontier will provide a refund of the amount paid for their ticket, which will be the limit of Frontier's liability.

1) Government Request -- To comply with a government requisition of space or request for emergency transportation (e.g., in connection with national defense or natural disaster (actual, threatened, or reported)).

2) No Seat for Safety Assistant - If a passenger requires a safety assistant (see section 3. B.6) and there is not a seat available on the applicable flight and, thus, both the passenger and the safety assistant are denied transportation. For purposes of determining whether a seat is available for a safety assistant, the safety assistant is deemed to have checked in at the same time as the individual with the disability.

B. Frontier may refuse to provide transportation to any person and may require that a passenger leave an aircraft or be removed from an aircraft for the following reasons, in which case no refund will be due and Frontier will have no further liability.

1) Government Direction - To comply with a direction of a government official acting in their official capacity to remove or not provide transportation to a specific individual.

2) Identification -- The passenger refuses to produce a government-issued identification as required by Frontier's representatives or as required by law.

3) Passports/Visas -- The passenger intending to travel across any international border fails to possess and present all valid documents (passports, visas, certificates, etc.) required by the laws of the countries from, over, or into which the passenger will fly, which will in all cases be the passenger's exclusive responsibility.

4) Failure to Check In or Appear - The passenger fails to check-in for their flight within the required times or appear for boarding of that flight within the required times. (The ticket will be deemed to be a No-Show Cancellation (see Section 2.G) and canceled. All subsequent flights, including return flights, on the itinerary will also be treated as No-Show Cancellations (see Section 20)).

5) Special Medical Requirements -- The passenger will be refused transport if the passenger requires medical equipment be used in flight or services (i) not provided by Frontier, (ii) that may not be used in flight, or (iii) does not have sufficient supplies therefor. The foregoing includes any medical equipment that would require use of power from the aircraft, medical equipment for which the passenger does not have sufficient batteries for the duration of the flight plus unexpected delays. Passengers must be able to sit in a single seat with the seat in the full and upright position, which precludes passengers that must lie flat or that must be transported on a stretcher. Frontier does not provide medical oxygen.

EXCEPTION: A respiratory device (e.g., ventilator, respirator, CPAP machine or Portable Oxygen Concentrator) is considered an assistive device and is permitted as carry-on or checked baggage at no charge provided that all batteries must be transported in carry-on baggage and must be packaged in a manner that protects them from physical damage and short circuits, and provided that if the device is to be used in flight: (i) the passenger must carry enough fully-charged batteries to power the device throughout the entire journey including all ground time (between connections), the duration of the flight and for unexpected delays, (ii) the device must be approved by the FAA with stickers indicating such, and (iii) prior to traveling, the passenger must complete the Portable Oxygen Concentrator Medical Authorization (form 30881) available on Frontier's website or obtain a medical statement from the passenger's physician addressing the points on the POC Medical Authorization form.

NOTE: Passengers are referred to 14 CFR Part 121, SFAR No. 106 for regulations regarding and a list of Portable Oxygen Concentrators that are approved for use on aircraft.

6) Qualified Individual with a Disability -- If transportation is refused because the passenger fails to comply with the following: Qualified individuals with a disability will be transported in accordance with the conditions and requirements of 14 C.F.R. § 382 unless the carriage of such individuals may impair the safety of the flight or violate Federal Aviation Regulations. Pursuant to 14 C.F.R. § 382.113, Frontier does not provide certain extensive in flight special services such as assistance in actual eating, assistance within the lavatory or at the individual's seat with elimination functions, or provision of medical services. Moreover, pursuant to 14 C.F.R. § 382.29, a qualified individual with a disability may be required to be accompanied by a safety assistant as a condition of being provided air transportation in any of the following circumstances: (i) when the individual, because of a mental disability, is unable to comprehend or respond appropriately to safety instructions from employees, including the required safety briefing, (ii) when the individual has a mobility impairment so severe that the individual is unable to assist in the passenger's own evacuation of the aircraft, (iii) when the individual has both severe hearing and severe vision impairments, if the individual cannot establish some means of communication with employees adequate to permit transmission of the required safety briefing, (iv) on the day of departure, if it is determined that an individual meeting the criteria of (i), (ii) or (iii) must travel with a safety assistant, contrary to the individual's self-assessment that the passenger is capable of traveling independently, the safety assistant will not be charged to accompany the individual with a disability.

7) Prisoners - If transportation is refused because of a failure to comply with the following: Frontier accepts up to two "low risk" prisoners with hand restraints per flight. If the flight is 4 hours or less, at least one armed or unarmed law enforcement officer must accompany the prisoners. If the flight is more than 4 hours, at least two armed or unarmed law enforcement officers must accompany the prisoners. At no time may any prisoner be left unattended. No prisoners are accepted on codeshare itineraries.

8) Resistant Prisoners - Any prisoner who has resisted or is reasonably believed to be capable of resisting the prisoner's escort.

9) Proper Attire - Any passenger who is barefoot and over 3 years of age, unless required to be barefoot for medical reasons, or who is not otherwise fully clothed in clothing that is not lewd or obscene, threatening, intimidating, or would be objectionable to reasonable persons.

10) Malodorous Condition - Any passenger who has a severe or offensive body odor that is not due to a disability.

11) Intoxication - Any passenger who appears to be intoxicated or under the influence of drugs.

12) Communicable Disease or Infection - A passenger who has a communicable disease or infection (that is known or reasonably believed to pose a direct threat to the health or safety of others in the course of flight) may be denied boarding by Frontier. If such a passenger presents a medical certificate dated within 10 days of the date of the flight for which it is being presented that includes specific conditions under which the individual can travel and not pose a direct threat to the health and safety of other persons, transportation will be provided to such individual unless it is not reasonable or feasible to implement the conditions set forth in the medical certificate as necessary to prevent the transmission of the disease or infection to other persons in the normal course of flight. Unacceptable measures include, but are not limited to: a required separation between the passenger and other persons, use of medical equipment not permitted to be used on the aircraft, or a requirement that any other passenger wear protective gear.

a) 2019 Novel Coronavirus (COVID-19) – Frontier may screen passengers during the check-in and boarding process, and may deny boarding to passengers who Frontier reasonably believes do not meet Frontier's COVID-19 screening measures. Screening will include, but is not be limited to: completion of a health acknowledgment, required wearing of facial coverings, and submission to a temperature check. Notwithstanding Section 11 above, a passenger who presents a medical certificate dated within 10 days of the date of the flight for which it is being presented may be denied boarding if, on the planned date of travel, the passenger fails to meet Frontier's COVID-19 screening measures.

13) Refusal or Inability to Sit - Any passenger who is unwilling or unable to sit in an upright position during takeoff and landing with the seat belt fastened.

14) Failure to Follow Instructions - Any passenger who refuses to obey instructions from an employee or crewmember.

15) Use of Ticket Issued to Other Person - Any passenger who attempts to use a ticket not issued to that person. (This ticket will be deemed to be a No-Show Cancellation (see Section 2.G) and canceled. All subsequent flights, including return flights, on the itinerary will also be treated as No-Show Cancellations (see Section 20)).

16) Interference - Any passenger who interferes with any member of the flight crew in pursuit of their duties or attempts to do so.

17) Smoking - Any passenger who smokes or attempts to smoke on an aircraft.

18) Weapon - Any passenger who, except as permitted by law (see 49 C.F.R. § 1544.219), wears or has on or about their persons concealed or unconcealed, deadly or dangerous weapons.

19) Purchase in Violation of Contract of Carriage - Any passenger that purchases a ticket in violation of this Contract of Carriage or any fare rule. In addition, Frontier may (i) invalidate the tickets or any other that may have been purchased in the same manner, (ii) cancel any remaining portion of the passenger's itinerary, or (iii) confiscate any unused portions of the ticket.

20) General Refusal - Any person whom Frontier has informed is not permitted to purchase transportation from Frontier.

C. Refusal to Sell Transportation - Frontier may refuse to sell transportation to any person, including the following, and may inform such persons that they are not permitted to purchase transportation from Frontier:

1) Refusal to Comply - A person who refuses to comply with instruction given by employees or representatives prohibiting the solicitation of items for sale or purchase, including airline tickets, passes, or travel award certificates.

2) Prior Conduct - A person who has disrupted airline operations, mistreated employees, or has not complied with Frontier's policies or otherwise violates this Contract of Carriage.

3) Misconduct - A person who has committed a fraudulent act against Frontier.

D. Customer of Size - If, in Frontier's sole judgment, a passenger is unable to sit in an aircraft seat without lifting either or both armrests and occupying all or a portion of the adjacent seats, or encroaching into the aisle or adjacent seats, the passenger will be required to purchase a ticket for an additional seat (or more, if required to accommodate the passenger) at the price then applicable. If sufficient, contiguous seats are not available, the passenger will be given the option to switch to flights on which such seats are available (for which applicable fees will apply) or be given a refund.

E. Allergies (Peanut, Pet, or Chemical) - Items are not removed from the aircraft to accommodate a passenger's allergy to a particular food, substance, or chemical. A variety of snacks are served on board many flights, including products that may contain peanuts or other nuts. A “peanut-free” or “chemical-free” environment cannot be provided to passengers onboard the aircraft. Passengers are advised to consult a healthcare professional regarding the risks of onboard exposure to any allergen.

F. Pregnancy - Passengers who are pregnant are urged to consult with their doctor on whether it is safe to travel by air, including with due consideration to the possibility of turbulence, cabin pressurization, significantly increased risk of deep vein thrombosis associated with pregnancy, and lack of ready access to medical care. This is particularly important for women in their ninth month of pregnancy, who are urged to obtain an examination from their physician shortly before flying to confirm air travel will be safe. Women with a history of complications or premature delivery should not fly if pregnant. By traveling with Frontier, pregnant women acknowledge and accept these risks.Different policies for passengers who are pregnant may apply on any leg of a codeshare flight that is operated by the codeshare airline.

G. Electronic Surveillance of Passengers and Baggage - Passengers and their baggage are subject to inspection, including via electronic means, with or without the passenger's consent or knowledge.

H. Diversion While in Flight or Return to Gate- In the event that Frontier is required to divert an aircraft while in flight or return to gate because a passenger requires medical attention or due to the passenger's conduct, the passenger may be required to reimburse Frontier for the costs that Frontier incurs, including the cost to accommodate other passengers. The amount due will be as determined by Frontier.

4. International Transportation

A. Compliance with Regulations - Passengers shall comply with all laws, regulations, orders, demands, or travel requirements of countries to be flown from, into, or over. Frontier is not liable for any aid or information given by any agent or employee to any passenger in connection with obtaining necessary documents or complying therewith (including as may be provided in this Contract of Carriage) or the consequences to any passenger resulting from the passenger’s failure to obtain such documents or to comply with such laws, regulations, orders, demands, requirements, or instructions.

B. Compliance with Foreign Country Regulations regarding Importation of Goods - Passengers shall comply with all laws, regulations, orders, demands, or travel requirements of countries to be flown from, into, or over. Frontier is not liable for the consequences to any passenger resulting from the passenger’s failure to comply with such laws, regulations, orders, demands, requirements, or instructions.

C. Customs Inspection - If required, a passenger must attend the inspection of the passenger’s baggage, checked or unchecked, by customs or other government officials. Frontier accepts no responsibility to the passenger if they fail to observe this condition.

D. Government Regulation - No liability shall attach to Frontier if, based on what it understands to be applicable law, government regulation, demand, order, or requirement, it refuses to carry passenger. If, however, it is ultimately determined that Frontier was incorrect, the limit of its liability will be to refund the amount paid for the ticket on which transportation was refused.

E. International Operations - Frontier is required to make an attempt to obtain emergency contact information from a passenger traveling into or out of a foreign country. If a passenger refuses to provide emergency contact information, Frontier will document the attempt and may require the passenger to sign the document.

F. Indemnification - A passenger shall indemnify Frontier for any loss, damage, or expense suffered or incurred by Frontier by reason of the passenger's failure to possess any required travel documents or other failure to comply with the provisions of this section, including the applicable fare if Frontier is required to transport the passenger home from a country. Frontier is not liable to the passenger for loss or expense due to the passenger's failure to comply with this provision.

G. Baggage Limitation - Passengers shall comply with all laws, regulations, orders, demands, or travel requirements regarding baggage size and weight limitations of countries to be flown from, into, or over. Frontier is not liable for the consequences to any passenger resulting from the passenger's failure to comply with such laws, regulations, orders, demands, requirements, or instructions.

5. Child Passengers

A. Accompanied Children -- Children from 7 days through 14 years of age may travel with another passenger who is at least 15 years old.

B. Unaccompanied Children

1) Frontier does not allow children under the age of 15 years old to travel unaccompanied; they must be accompanied by a passenger who is at least 15 years old. Passengers who are 15 years old or older may travel on Frontier without an adult companion. A birth certificate, official school ID, or other form of ID may be requested for age verification purposes if the child's age appears questionable.

NOTE: Passengers under age 18 traveling without both parents may need additional documentation to travel across international borders, depending on the country's requirements.

C. Infant and Child Fares (except as otherwise provided in a specific fare rule) are as follows:

1) Infants under 2 years of age are accepted, without charge, when the infant does not occupy a separate seat and is accompanied by a fare-paying passenger at least 15 years old. A birth certificate may be requested for age verification purposes if the infant's age appears questionable.

NOTE: Due to supplemental equipment considerations, the number of infants accepted per flight may be limited based on aircraft type.

2) One adult may accompany up to two infants under the age of 2.

a) When an adult passenger is traveling with two infants under 2 years of age, a seat must be purchased for at least one infant. The fare is the same as an adult fare.

3) Children 7 days - 14 years of age occupying a seat are charged the same fare as an adult passenger.

NOTE: Passengers under age 2 traveling as lap children (not purchasing a seat) are subject to international taxes. These taxes must be paid prior to boarding the originating departure flight.

D. Child Restraint Systems - Frontier accepts infant and child restraint systems (car seat or harness) approved for air travel that fit in the applicable aircraft seat with the arm rest down that meet the following requirements:

1) Approved seats manufactured to U.S. standards between January 1, 1981, and February 25, 1985, must bear the label: "This child restraint system conforms to all applicable Federal motor vehicle safety standards."

2) Seats manufactured to U.S. standards on or after February 26, 1985, must bear two labels: (i) "This child restraint system conforms to all applicable Federal motor vehicle safety standards" and (ii) "THIS RESTRAINT IS CERTIFIED FOR USE IN MOTOR VEHICLES AND AIRCRAFT" in red lettering.

3) Seats not meeting the above criteria must bear a label or markings showing: (i) the seat was approved by a foreign government, (ii) the seat was manufactured under the standards of the United Nations, (iii) the seat or child restraint device furnished by the certificate holder was approved by the FAA through Type Certificate or Supplemental Type Certificate, or (iv) the seat or child restraint device was approved by the FAA in accordance with 14 C.F.R § 21.8(d), or FAA Technical Standard Order C-100b, or a later version.

   NOTE 1: A child under the age of 2 must be held in the passenger's lap or be seated in an approved car seat for taxi, takeoff, and landing.

   NOTE 2: Frontier encourages all adults traveling with infants under 2 years of age to secure the infant in an approved car seat or harness in the infant's own purchased seat.

4) Child Harness - The FAA-approved AMSafe Aviation C.A.R.E.S. child harness device may be used on-board the aircraft. It is designed for children weighing between 22 and 44 pounds (between 10 and 20 kilograms) and must bear the label "FAA Approved in accordance with 14 CFR 21.305(d) approved for aircraft use only."

5) Car Seats - A car seat may be used by a child between the ages of 7 days and 2 years if seat space is available after boarding, even if a seat has not been purchased for the child. A car seat may be used by any child when a separate seat has been purchased. To use a car seat onboard the aircraft:

   a) It must bear manufacturer labels identifying approval for aircraft use, as described in subsection (1) and (2) above.

   b) It must have a solid seat and solid back.

   c) It must have restraint straps installed to hold the child in the car seat.

   d) The child may not exceed the weight limitation of the car seat.

   e) It may not be placed in the emergency exit rows, in the seats immediately in front of or behind the exit rows, or in any seat that has an airbag seatbelt installed.

   f) Window seats are the preferred location for a car seat, so it does not impede a passenger's movement or egress into the aisle. Other seat assignments are permitted provided the car seat is not obstructing the egress of any passenger.

   g) It must be secured by a seat belt at all times.

6) Booster Seats - Booster seats may be carried onboard aircraft but must be stowed in an overhead compartment or underneath the seat for takeoff and landing. Once the aircraft has reached cruising altitude, the passenger may use the seat during the flight. The booster seat must be stowed when the aircraft begins its descent.

6. Service Animals

A. General - The following categories of service animals are allowed in the cabin without charge:

1) Trained service dogs that assist passengers with disabilities. Passengers traveling with a service dog must complete and submit the Department of Transportation Service Animal Air Transportation Form, attesting to the dog's health, behavior, and training. For reservations booked more than 48 hours prior to travel, passengers must submit the completed form no later than 48 hours prior to travel. For reservations booked less than 48 hours prior to travel, passengers must submit the completed form in person to a Customer Service Agent upon arrival at the airport. Only dogs will be accepted as trained service animals. The animal must be at least 4 months old. The passenger is required to keep the animal under control at all times, with the animal on a leash or harness while in the boarding area and onboard the aircraft. Psychiatric support animals are recognized as trained service animals. Comfort animals, companionship animals, or any other non-task-trained animals are not recognized as service animals. Service animals in training will not be accepted.

2) Service Animals trained in explosive detection, contraband search, or search and rescue on active duty and traveling for that purpose will be accepted for travel. The passenger must present credible documentation the animal is traveling for that purpose.

B. Seating - The passenger may sit anywhere, except in an emergency exit row, provided the animal does not obstruct an aisle or egress of passengers in an emergency evacuation. The animal must fit under the seat or on the passenger's lap. If the passenger is seated in row 1, the animal will not be allowed on the passenger's lap. The animal may not occupy a seat. An animal that cannot or does not comply with the foregoing will not be accepted.

C. International - Restrictions for travel with an animal to international destinations vary by country. Frontier recommends contacting the appropriate embassy or consulate before purchasing a ticket for travel with a service animal or emotional support animal. Different policies may apply on any leg of a codeshare flight that is operated by the codeshare airline.

D. Oxygen - No oxygen will be administered to a service animal in the event of an emergency.

7. Smoking

A. Smoking is prohibited on all flights.

B. Federal law prohibits tampering with, disabling, or destroying any smoke detector installed in an aircraft lavatory.

C. The use of electronic smoking devices is prohibited at all times on all aircraft.

8. Tickets

A. A passenger is entitled to transportation only upon presentation of a valid electronic ticket (e-ticket). The ticket entitles the passenger to transportation between the point of origin and the destination.

NOTE: Paper tickets are not issued on Frontier ticket stock. Only electronic tickets are issued for travel on Frontier. However, paper tickets from other airlines may be accepted for travel at Frontier's discretion.

B. Tickets are honored only in the order in which they are issued.

C. The following practices are prohibited:

1) Back to Back Ticketing -- The purchase or use of portions of tickets from two or more tickets issued as round-trip fares or other scheme for circumventing minimum stay requirements.

2) Throwaway Ticketing -- The purchase or use of round-trip tickets for one-way travel.

3) Hidden City/Point Beyond Ticketing -- The purchase or use of a ticket from a point before the passenger's actual origin or to a point beyond the passenger's actual destination.

D. A ticket which has not been properly issued or paid for, or which has been altered, mutilated, or improperly issued by an unauthorized party is not valid for travel or refund.

E. The purchaser of a ticket and the passenger intending to use it are responsible for ensuring that the ticket accurately states the name of the passenger.

F. A ticket may only be used by the person named on the ticket. Frontier is not liable to the purchaser of a ticket if the ticket is used by someone other than the person named on the ticket.

G. Presentation of a ticket by someone other than the named passenger renders the ticket void. The ticket is subject to confiscation, and the ticket will then be treated as a No-Show Cancellation for all purposes of this Contract of Carriage. (See section 20.)

H. An additional processing fee may apply to each ticket purchased or changed via Frontier's reservation center.

9. Ticket Validity and Itinerary Changes

A. Period of Validity

1) Tickets issued by Frontier are valid for transportation only on the flights and dates shown on the ticket and have no value and are not valid for transportation thereafter. If a passenger cancels a ticket before the scheduled flight departure time, the value of the ticket less a service fee will be retained for 90 days from the date of cancellation of the ticket in the form of an electronic credit. The credit has no cash or refund value and may only be applied to a single subsequent ticket on a Frontier flight for the same passenger as the original ticket. In the case of a No-Show Cancellation, see section 20.

2) Except as required by law or as provided in this Contract of Carriage, Frontier shall have no obligation of any kind to reschedule any passengers who cancels a ticket before the scheduled flight departure time or to provide them with any refund or other credit for unused tickets.

3) Except as required by law or as provided in this Contract of Carriage, in the case of a No-Show Cancellation, Frontier shall have no obligation of any kind to reschedule any such passengers on any other flight, and the rules respecting No-Show Cancellations shall apply (see section 20.).

B. Except for tickets purchased for travel within 7 days (168 hours) of purchase, all tickets may be canceled within twenty-four (24) hours of the purchase and a full refund will be given. After that time, except for tickets that are purchased as refundable, all tickets are non-refundable.

10. Check-in Times

A. Airport Check-In - It is the passenger's responsibility to arrive at the airport, taking into consideration travel time both to and within the applicable airport, including processing through the security check point with enough time to complete check-in and security screening processes.

B. Passengers can check in beginning 2 hours before departure at Frontier's airport check-in counters or 24 hours before departure at www.FlyFrontier.com or on the Frontier mobile app, if the reservation is eligible for online or mobile app check-in.

C. Check-In Times

1) For domestic flights (originating and to a destination within the United States), the passenger must be checked in with a printed boarding pass or a Frontier mobile app boarding pass in-hand at least 45 minutes prior to scheduled departure whether or not checking bags.

2) For international flights, the passenger must be checked in with a printed boarding pass or a Frontier mobile app boarding pass in-hand at least 60 minutes prior to scheduled departure.

D. Time Limit for Checking Bags - Baggage to be checked must be presented at the airport within the minimum check-in time. Passengers who present baggage after the minimum check-in time may be refused transport. At some airports, the counter may close at the check-in cut-off time, in such cases, passenger and baggage check-in are not permitted after the check-in deadline. In the event that baggage is accepted after the minimum check-in time, the passenger will be liable for any costs and fees for the bag to be delivered in the event that it is not carried on the same flight.

E. Availability for Boarding - Tickets and seat assignments are subject to cancellation for passengers who fail to make themselves available for boarding at the departure gate at least 20 minutes prior to scheduled departure.

F. Failure to Check In or Appear - If a passenger fails to check in or board the flight within the required time, the ticket will be deemed to be a No-Show Cancellation (see Section 2.G) and canceled. All subsequent flights, including return flights, on the itinerary will also be treated as No-Show Cancellations (see Section 20).

G. Misconnected Passengers - The ticket of any passenger who does not meet the minimum check-in time due to the late arrival of an inbound connecting flight operating by Frontier will be accommodated on the next available flight operated by Frontier to the same destination. Frontier will not provide transportation on another airline or reimburse the cost of transportation purchased from another airline. The ticket of any passenger who does not meet the minimum check-in time due to the late arrival of an inbound connecting flight operated by any other airline will be canceled and no refund or accommodation on another flight will be due unless available and purchased at the applicable price by the passenger.

11. Fares

A. Fares apply for transportation only between the airports for which they are published.

B. When a passenger requires connecting service with arrival at one airport and departure from another airport, transportation between those airports must be arranged by and at the expense of the passenger.

C. Fares are subject to change without notice until a ticket is issued.

12. Checked Baggage

A. Fees applicable to checked baggage:

1) Baggage fees apply to each checked bag.

2) Active U.S. military personnel, with Common Access Card (CAC), may check two bags at no charge for all types of tickets. Overweight and oversize charges for the first two free bags are also waived. This policy is for active U.S. military personnel only and does not extend to family members or traveling companions.

B. Baggage Allowance Exceptions - The following may be checked or carried on at no charge and do not count toward the passenger's baggage allowance.

1) Medical Assistive Devices - Canes, crutches, braces, wheelchairs, etc. for the use of the passenger. There is no limit to the number of mobility aids a passenger may check. Medical assistive devices must be packed separately, in protective packaging, for baggage fees to be waived.

2) Wheelchairs - In compliance with federal law, wheelchairs or other types of mobility devices for the passenger are accepted as checked baggage in addition to the passenger's baggage allowance at no additional charge. Certain Frontier aircraft can accommodate up to two wheelchairs up to 40 inches (101 cm) high, 50 inches (127 cm) long, 13 inches (33 cm) wide, and weighing no more than 70 pounds (31 kilograms) in the cabin of the aircraft on a first-come, first-served basis. Wheelchairs carried in the cabin of the aircraft will be brought to the front of the aircraft after all other passengers have deplaned.

3) Essential Infant or Child Items - Child restraint devices, car seats, strollers, diaper bags, and other essential baby items when the infant is traveling. These items must be packed separately, in protective packaging, for baggage fees to be waived.

C. Acceptable Baggage - Frontier will accept for transportation as baggage such personal property necessary or appropriate for the wear, use, comfort, or convenience of the passenger for the purpose of the trip, subject to the following:

1) Checked baggage may not exceed 62 inches (157 cm) in linear dimension (height plus length plus width), nor more than 180 inches (457 cm) in any of those dimensions, or weigh more than 50 pounds (22.6 kilograms). Additional fees apply to items that exceed those size and weight limitations. Baggage weighing 100 or more pounds (45 kilograms) is not accepted.

NOTE 1: For baggage checked to or from Canada, no baggage weighing more than 70 pounds (31.75 kilograms) will be accepted.

2) The TSA website maintains a list of items that passengers are not permitted to check in baggage. See www.tsa.gov for a complete list. Baggage containing any items on that list will not be accepted.

3) An item for transportation not suitably packaged to withstand ordinary handling and turbulence, or of a size, weight, or character that renders it unsuitable for transportation will not be accepted.

4) The passenger is responsible for ensuring that all items packed in checked baggage are properly packaged and padded to resist handling and turbulence. (Refer to section 17.)

5) All baggage is subject to inspection by Frontier. Frontier is not, however, obligated to perform an inspection. Frontier will refuse to transport or will remove baggage if the passenger refuses to submit the baggage for inspection.

6) Frontier will not accept baggage or other personal property for storage.

7) Frontier will check baggage only when the passenger presents a valid ticket for transportation on the applicable flight.

8) The passenger's name, address, and telephone number must appear on the baggage.

9) Frontier has the right to refuse to transport baggage on any flight other than the one carrying the passenger.

10) Baggage will not be checked:

a) To a point that is not reflected on the passenger's ticket.

b) Other than the passenger's destination on the applicable flight, but if the flight is a connecting flight, to the final destination, but if that connecting flight is scheduled to depart from an airport different from the one at which the passenger is scheduled to arrive then only to the destination of the first leg.

11) Live animals are not accepted as checked baggage.

12) Agricultural items, perishable items, or products that do not conform with customs or agricultural government law at the flight's destination will not be accepted.

13) Frontier will not accept for carriage any restricted/hazardous materials as defined in the DOT Hazardous Materials Regulations (49 C.F.R. §§ 171-177) and IATA Dangerous Goods Regulations. Examples of such goods are (i) liquor products over 140 proof, (ii) gasoline-powered tools, (iii) compressed gases, (iv) corrosives (such as acids and wet batteries), (v) explosives (such as dynamite and fireworks), (vi) flammables (such as matches and lighter fuels), (vii) poisons, and (viii) magnetic and radioactive materials. Electronic smoking devices (commonly referred to as e-cigarettes or personal vaporizers) pose a safety risk and are not permitted in checked baggage. These items are permitted in carry-on baggage. Spare lithium batteries are not allowed in checked baggage.

14) Perishable items must be packaged properly such that they cannot leak through their packaging. (Refer to section 17.)

D. Codeshare Flights – The baggage policy of the airline on which a passenger originally booked the codeshare flight will apply to the entire itinerary.

13. Carry-On Baggage

A. Passengers are permitted up to two carry-on items:

1) One free personal item not larger than 8" x 14" x 18" (20 cm x 35 cm x 45 cm) that must fit within the personal item portion of the bag sizer.

2) One carry-on item not larger than 10"H x 16"W x 24"L (25 cm x 40 cm x 114 cm) and weighing not more than 35 pounds (15 kilograms) that may be placed in the overhead compartment or under the seat. A fee for the carry-on item may apply based on the ticket type purchased. Active U.S. military personnel, with Common Access Card (CAC), may take a carry-on item free of charge for all types of tickets.

3) Items that exceed these dimensions or are in excess of the allowance will be gate checked to which a fee will apply.

B. The TSA website maintains a list of items that passengers are not permitted to carry onboard an aircraft. See www.tsa.gov for a complete list. Carry-on items containing any items on that list will not be accepted.

C. The passenger is responsible for all items brought on board the aircraft. Items must be stored under a seat or in the overhead compartment.

D. Use of Portable Electronic Devices (PEDs)

1) Small authorized PEDs are devices under 2 pounds and are of a size that can easily be placed in a seat pocket along with the other materials that are normally found in the seat pocket (Passenger Safety Information Card, Menu or airsickness bag). They include devices like tablets, readers, and mobile phones and may be used during all phases of flight when in airplane mode including taxi, takeoff, and landing. However, if using them during taxi, takeoff, and landing, you must secure these devices by holding them, putting them in your pocket or holster, or placing them in a seatback pocket.

2) Large authorized PEDs are devices 2 pounds or more such as full-size laptops. They must be turned off and stowed during taxi, takeoff, and landing. You may stow them under the seat in front of you or in an overhead compartment. These devices may be used above 10,000 feet when authorized by a Flight Attendant announcement.

3) On all flights operating outside U.S. airspace, PEDs cannot be used during taxi, takeoff, and landing, but may be used in airplane mode above 10,000 feet when authorized by a Flight Attendant announcement.

E. Sound Emitting Devices - Portable electronic devices that emit sound (e.g., music or video players or games) may be used only with headphones and provided the sound, even via the headphones, cannot be heard by others.

F. Codeshare Flights – The baggage policy of the airline on which a passenger originally booked the codeshare flight will apply to the entire itinerary.

14. Cabin-Seat Baggage

A. Cargo stowed inside the main cabin of the aircraft and occupying a passenger seat is referred to as “Cabin-Seat Baggage.” Cabin-Seat Baggage may be transported on flights operated by Frontier subject to the following conditions:

1) The full fare for the ticket for the applicable seat is paid. There is no carry-on baggage allowance or baggage allowance for that ticket. If the Cabin-Seat Baggage must be accommodated into a STRETCH seat due to its size or at the passenger's request, the STRETCH seat fee applies.

2) The Cabin-Seat Baggage must be packaged or covered in a manner to avoid possible injury to passengers and crew.

3) The Cabin-Seat Baggage must be carried aboard the aircraft by the passenger.

4) The Cabin-Seat Baggage may not weigh more than 100 pounds (45 kilograms).

5) The Cabin-Seat Baggage cannot exceed size dimensions of 57" height x 17.84" width x 9.3" depth (144.78 cm x 45.31 cm x 23.62 cm).

6) The Cabin-Seat Baggage must fit in the seat without blocking aircraft signage or extending into the aisle and be secured with a seatbelt or other approved method.

7) Certain seats may not accommodate Cabin-Seat Baggage. Frontier will assign seats as appropriate.

8) Except as provided herein, Frontier is not responsible for damage to Cabin-Seat Baggage.

9) Cabin-Seat Baggage does not count toward the passenger's baggage allowance.

15. Conditions and Charges for Special Items

The following items are accepted as checked or carry-on baggage, subject to the conditions specified and payment of applicable fees.

NOTE: Refer to the Sports Equipment and Special/Fragile Items chart hosted at www.FlyFrontier.com for other items which have specific packaging or other requirements which need to be met in order to be transported by air. All items listed on the Sports Equipment and Special/Fragile Items chart are subject to baggage fees. Baggage fees for excess, oversize, and overweight are cumulative and all may be assessed on one item.

A. Firearms -- Firearms are accepted as checked baggage on flights within the United States, but not international flights. Carriage of any firearm is subject to the following conditions:

1) In accordance with federal law, a passenger who presents baggage that contains a firearm must (i) ensure the firearm is unloaded, (ii) pack the firearm in a lockable, hard-sided container, (iii) declare the firearm unloaded at the time of check-in, and (iv) sign a "Firearms Unloaded" declaration.

2) If the firearm is in a locked, hard-sided container INSIDE a piece of checked baggage, the declaration must be placed inside the checked baggage and proximate to, but not inside of, that container.

3) If the firearm is in a locked, hard-sided container, but NOT INSIDE a piece of checked baggage, the declaration must be placed inside the container.

4) After screening, the passenger must lock the firearm container and retain the key or combination.

5) The passenger must make arrangements for and assume full responsibility for complying with any applicable laws, customs and government regulations, or restrictions of the state or territory to which the firearm is being transported.

B. Ammunition - Ammunition for firearms (whether or not the firearm is also being carried) is accepted as checked baggage on flights within the United States, but not international flights, subject to the following conditions:

1) The ammunition must be securely packed in the original manufacturer's packaging, fiber (such as cardboard), wood, or metal boxes or other sturdy and durable packaging providing sufficient cartridge separation.

2) Each passenger is allowed up to 11 pounds (4.9 kilograms) of ammunition.

3) Loaded ammunition clips and magazines must also be securely boxed.

4) Ammunition may be packed with the firearm.

C. Live Animals -- Frontier accepts live animals only in the cabin of the aircraft, not as checked baggage. The transportation of live animals is subject to fees for carriage and the terms and conditions below.

EXCEPTION: See separate rules with respect to service animals referred to in *6. Service Animals*.

1) Only the following animals are permitted:

a) Domestic Flights -- Domesticated dogs, cats, rabbits, guinea pigs, hamsters, or small household birds.

b) International Flights -- Domesticated dogs and cats.

2) The passengers carrying the animal are responsible for making arrangements and assuming full responsibility for complying with any applicable laws, customs and other governmental regulations, requirements or restrictions of the country, state or territory to which the animal is being transported.

3) The passengers carrying the animal are responsible for paying any import/export fees, duties, or taxes that may apply as well as any fines for failing to comply with applicable law.

4) International - Restrictions for travel with an animal to international destinations vary by country. Frontier recommends contacting the appropriate embassy or consulate before purchasing a ticket for travel.

5) The passengers carrying the animal are responsible for making advance reservations because no more than ten pet containers will be accepted per flight.

6) No passenger may carry more than one pet container.

7) The animal must remain in a pet container at all times and may not be fed while onboard the aircraft.

8) The pet container must be large enough for the pet to stand, turn around, and lie down in a natural position and fit underneath the seat in front of the passenger.

9) The animal may not disrupt other passengers and the passenger must be able to quiet the animal without removing it from the container.

10) The container counts toward the carry-on baggage allowance.

11) No oxygen will be administered to an animal in the event of an emergency.

D. Human Remains:

1) Crematory remains (human or animal) may be transported as carry-on or checked baggage subject to the following conditions:

a) The container must be made of a material such as wood or plastic that can be successfully screened by the TSA. If the container cannot be screened, it will not be allowed.

b) If the container is checked, it must be sufficiently packaged in a well-insulated and sturdy container.

c) If the container is carried onboard the flight, it counts toward the passenger's carry-on allowance and it must meet carry-on baggage dimensions.

2) Human remains in caskets are not accepted.

E. Dry Ice (frozen carbon dioxide) -- Dry ice may be carried under the following conditions:

1) A maximum of 5.5 pounds (2.5 kilograms) of dry ice per passenger is accepted in checked or carry-on baggage.

2) The cooler or package must permit the release of carbon dioxide gas. Styrofoam containers are not accepted.

F. Bicycle - Bicycles may be carried under the following conditions:

1) The handlebars must be fixed sideways, and the pedals removed or wrapped in plastic foam or similar material and the entire bicycle is encased in a hard-sided case.

2) Bicycles may only be carried as checked baggage.

3) A fee applies for each bicycle checked as baggage.

4) Bicycles are excluded from baggage liability unless packaged in a hard-sided case.

G. Special Items - The following items may exceed carry-on baggage dimensions but may be taken as a carry-on item (and count toward the carry-on bag allowance) as long as they fit in the overhead bin: fishing rods, tennis rackets, wedding attire, poster tubes, and musical instruments. If any such items are comprised of more than one piece, they must be packaged together to be considered one item. The carry-on bag fee applies.

H. Codeshare Flights – The baggage policy of the airline on which a passenger originally booked the codeshare flight will apply to the entire itinerary.

16. Limitations of Liability

A. Consequential Damages – Unless it is specifically stated otherwise in this Contract of Carriage, or as required by any applicable law, Frontier is not liable for any indirect, special, or consequential damages arising out of or resulting from transportation provided, delay in transportation, or any failure to provide transportation.

B. International Transportation – With respect to international transportation, as defined in the following referenced conventions, as applicable, Frontier's liability will be limited as specified in, as and if applicable, (i) the Convention for the Unification of Certain Rules Relating to International Carriage by Air signed at Warsaw, October 12, 1929, as amended ("Warsaw Convention"), but subject to the Agreement entered into by Frontier pursuant to 14 C.F.R. Part 203 or (ii) the Convention for the Unification of Certain Rules for International Carriage by Air, signed at Montreal, May 28, 1999 ("Montreal Convention").

17. Claim Limits and Procedures

A. Limitations of Liability

1) Domestic Flights – With respect to domestic flights (i.e., those flights originating and ending within the United States) without any scheduled stops outside of the United States, or international flights to which neither the Warsaw Convention or the Montreal Convention apply, Frontier's limit of liability, if any, for the loss, damage or delay in the carriage of checked baggage shall be limited to $3,800 for all bags checked under a single ticketed passenger's name. Frontier will not be liable for:

i) The following items included in checked baggage, with or without the knowledge of Frontier:

- alcohol
- antiques
- art, paintings
- art supplies
- artifacts
- bags made from lightweight material not designed for shipping
- blueprints
- books
- business documents
- CDs
- cell phones
- Cigars, cigarettes, electronic cigarettes, vape pens
- collectibles
- computer equipment (including hardware, software and all accessories)
- dentures
- drugs prohibited by federal or state law
- DVDs
- eyeglasses
- files
- food/perishables
- fragile articles or other similar valuable items and commercial effects
- hand and power tools
- heirlooms
- irreplaceable items
- jewelry
- keys
- machinery and its parts
- manuscripts
- medication
- money
- natural fur products
- negotiable papers/ instruments
- optics
- orthodontics
- orthotics
- photographic/video/ electronic equipment and accessories
- precious metals or stones
- publications
- samples
- securities
- silverware
- sound reproduction equipment
- sunglasses
- surgical supports
- toys

ii) Articles strapped, taped, or tied to other pieces of baggage, which may become separated as a result of normal handling during transportation

iii) Damage to the following items when not packed in a hard-sided case or other packing that is suitable for the item:

- Prosthetic devices
- Medical equipment

- Musical instruments
- Recreational or sporting equipment
- Baby items including car seats and strollers

iv) Damage to handles, straps, wheels, and zippers arising from normal wear and tear caused by ordinary handling of baggage

v) Damage arising from ordinary wear and tear, such as cuts, scratches, scuffs, stains, dents, punctures, marks, and dirt

vi) Damage resulting from over-packing or misuse

vii) Damage arising from liquids on or in baggage; including weather (e.g., rain, snow)

2) International Flights/Montreal Convention – With respect to international flights to which the Montreal Convention applies, Frontier's limit of liability, if any, for the loss, damage or delay in the carriage of baggage (whether checked or carry-on) shall be limited to 1,288 Special Drawing Rights per ticketed passenger. The conversion rate, available at www.imf.org, in effect on the date of loss will be used for determining maximum liability amount.

3) International Flights/Warsaw Convention – With respect to international flights to which the Warsaw Convention applies, Frontier's limit of liability, if any, for the loss, damage or delay of (i) checked baggage shall be limited to 17 Special Drawing Rights per pound, or actual value, whichever is less, (ii) carry-on baggage shall be limited to 332 Special Drawing Rights or actual value, whichever is less. The conversion rate, available at www.imf.org, in effect on the date of loss will be used for determining maximum liability amount. Absent evidence to the contrary, bags will be presumed to weigh 20 pounds.

4) Frontier does not accept declarations of higher value or accept fees based on such declarations.

5) Subject to the above specified limits of liability, Frontier will compensate a passenger whose baggage has been lost, damaged or delayed for reasonable, documented direct damages up to the specified limit of liability, provided the passenger has made reasonable effort to minimize the amount of damage and provided documentation of the loss. The compensation due for lost or damaged property will be determined by the lesser of the documented original purchase price less applicable depreciation or the cost to make repairs.

6) Frontier's liability for wheelchairs, mobility aids, and assistive devices used by a passenger with a disability if lost or damaged by Frontier shall be up to the original purchase price of the device without regard to the above limitations of liability.

7) Passengers who incur incidental expenses as a result of delayed baggage delivery will be reimbursed per established DOT guidelines, subject to the above limitations of liability (as applicable). Any amounts paid to the passenger for incidental expenses will be deducted from the total loss amount prior to check issuance.

8) Frontier will not be liable for loss or damage to carry-on baggage unless such damage is caused by Frontier's or its agent's negligence, which does not include damage resulting from turbulence, shifting of items during flight, or ordinary handling, including placing the baggage in overhead compartments or under seats.

9) Frontier's employees and agents are not liable to passengers.

B. Time Limit to Make Claims and Procedures

1) With respect to domestic flights and those international flights to which the Montreal Convention does not apply, any claim based on damage, delay, or loss of baggage must be reported to Frontier within 4 hours of the arrival of the flight on which the loss or damage is claimed to have occurred. Claims for pilferage may be made up to 24 hours after flight arrival. Any documentation required to support the claim must be submitted within 30 days from the date the requesting passenger receives the claim form packet from Frontier; Frontier will not be liable if the completed claims are not submitted, with documentation, within that time period.
2) With respect to international flights to which the Montreal Convention applies, in the case of baggage damage, the person entitled to delivery must submit in writing to Frontier as soon as possible after discovery of the damage, and at the latest in writing 7 days from receipt of checked baggage and in the case of delay or loss, complaints must be made at the latest within 21 days from the date on which the baggage has been placed at the passenger's disposal or should have been placed at the passenger's disposal in the case of loss. All claims must be made in writing and must be accompanied by supporting documentation. Any subsequent request for documentation from Frontier must be provided to Frontier within 21 days of the request.

18. Failure to Operate on Schedule or Failure to Carry

A. Liability Limited - Frontier will use reasonable efforts to transport passengers and baggage to the purchased destination, but published schedules, flight times, aircraft types, seat assignments, and similar details set forth in the ticket or Frontier's published schedules are not guaranteed and form no part of this Contract of Carriage. Frontier may substitute alternate aircraft, change schedules, delay or cancel flights, change seat assignments, and alter or omit stopping places shown on the ticket as required by its operations in Frontier's sole discretion. Frontier's obligations for failure to operate any flight, failure to operate a flight according to its schedule, or for changing the schedule or type of equipment used on any flight, with or without notice to the passenger, are set forth below.

B. Force Majeure - In the occurrence of a force majeure event, Frontier may cancel, divert, or delay any flight without liability except to provide a refund for the unused portion of the ticket.

C. Delay, Misconnection, or Cancellation - In the event (i) a passenger's flight is canceled, (ii) a passenger is denied boarding because an aircraft with lesser capacity is substituted, (iii) a passenger misses a connecting Frontier flight due to a delay or cancellation of a Frontier flight (but not flights of other carriers), (iv) a passenger is delivered to a different destination because of the omission of a scheduled stop to which the passenger held a ticket, to the extent possible, Frontier will provide transportation on its own flights at no additional charge to the passenger's original destination or equivalent destination as provided herein. Frontier will have no obligation to provide transportation on another carrier. If Frontier cannot provide the foregoing transportation, Frontier shall, if requested, provide a refund for the unused portion of the passenger's ticket in lieu of the transportation under the foregoing. The foregoing shall be the limit of Frontier's liability for the matters covered by this provision.

D. For purposes of involuntary reroute, the following groups of cities are considered to be the same point. If Frontier is able to provide transportation to one of the specified alternative cities, Frontier has met its obligation for transport to the final destination.

- Chicago-O'Hare (ORD) /Milwaukee (MKE)
- Ft. Lauderdale (FLL) /West Palm Beach (PBI) / Miami (MIA)
- Los Angeles (LAX) /Orange County (SNA)
- Madison (MSN)/Milwaukee (MKE)

- New York La Guardia (LGA) /Trenton (TTN) /Philadelphia (PHL)
- Orange County (SNA) /San Diego (SAN)
- Orlando (MCO) /St. Augustine (UST)
- Orlando (MCO) /Tampa (TPA)
- Washington Dulles (IAD) /Washington National (DCA)

E. Schedule Change Prior to Day of Travel -- When a passenger's itinerary is changed because of a modification in Frontier's schedule, arrangements will be made to:

1) Transport the passenger over its own route system to the destination; or

2) In the event Frontier determines that the schedule modification is significant, Frontier shall, if requested, provide passengers a refund of the cost of the unused portion of the ticket.

F. Extended Onboard Ground Delays -- In accordance with FAA regulations, Frontier maintains and complies with a separate Contingency Plan for Lengthy Tarmac Delays. Frontier's Contingency Plan for Lengthy Tarmac Delays may be found on Frontier's website at https://az832049.vo.msecnd.net/media/1567/f9-contingency-plan-for-extended-tarmac-delays-2015.pdf. Frontier's Contingency Plan for Lengthy Tarmac Delays is subject to change without notice and is not part of this Contract of Carriage.

19. Denied Boarding Compensation

When a seat cannot be provided due to an inadequate number of seats for the number of passengers holding confirmed reservations (overbooking), the actions described in this section will be taken.

A. Voluntary -- Passengers on a flight with an overbooking will be encouraged to voluntarily relinquish their seats in exchange for alternate travel and for compensation in the form of an Electronic Travel Certificate for future transportation within 90 days on Frontier. The request and selection of volunteers will be in a manner determined solely by Frontier.

B. Involuntary -- If insufficient passengers volunteer, passengers who cannot be accommodated on the flight will be denied boarding and Frontier will provide transportation on Frontier's flights to the same destination. After a passenger's boarding pass is collected or scanned and accepted by the gate agent, and the passenger has boarded, a passenger may be removed from a flight only for safety or security reasons or in accordance with Section 3 of this Contract of Carriage.

C. Amount of Compensation -- Frontier will compensate a passenger for involuntary-denied boarding based on the new arrival time after the originally scheduled arrival time as follows:

Domestic	International	Compensation
New arrival time within :59	New arrival time within :59	No Compensation
New arrival time within 1 - 1:59	New arrival time within 1 - 3:59	200% (2x) of the one-way fare, not to exceed $775
New arrival time 2 hours or more	New arrival time 4 hours or more	400% (4x) of the one-way fare, not to exceed $1550

NOTE 1: Frontier will not provide compensation for denied boarding when an aircraft of lesser capacity is substituted due to operational or safety reasons.

NOTE 2: No compensation will be due if boarding is denied for reasons other than overbooking (e.g., pursuant to applicable law or other provisions of this Contract of Carriage).

D. Onward Transportation for Passengers Denied Boarding

1) A passenger denied boarding, voluntarily or involuntarily, pursuant to this section, will be transported on Frontier's next available flight on which space is available and at no additional charge.

2) If a passenger who has been denied boarding, voluntarily or involuntarily, pursuant to this section, wishes to modify the travel date, if space is available, a ticket will be provided for travel within 72 hours at no additional charge.

E. Electronic Travel Certificates - Frontier may offer passengers denied boarding involuntarily an Electronic Travel Voucher good for transportation on Frontier in lieu of cash compensation otherwise due under this section. Passengers may decline such offer in favor of the applicable cash compensation. The Electronic Travel Certificate has no refund value, will expire 90 days from date of issuance, is not transferable and may only be used to purchase tickets for the passenger to whom it is issued. Only one Electronic Travel Certificate may be used per ticket at the time of purchase. Electronic Travel Certificates may not be applied to ancillary fees and charges (e.g., seat fees, baggage fees) applied to group travel, or combined with other offers. If a ticket purchased with an Electronic Travel Certificate costs less than the amount of the certificate, no residual value remains. Changes to a ticket purchased with an Electronic Travel Certificate may result in a change fee and any additional fare difference based on the rules of the issued ticket.

F. Time of Offer and Payment of Compensation

1) The offer of compensation for overbooking will be made by Frontier on the day and at the place where the failure to provide confirmed space occurred. If accepted, compensation will be given to the passenger. If the alternative transportation arranged for the passenger's convenience departs before the payment can be made, payment will be made by mail or other means within 24 hours after the denied boarding occurs.

2) Acceptance of any Denied Boarding Compensation constitutes full compensation for damages incurred by the passenger as a result of Frontier's failure to provide the passenger with a confirmed seat.

20. Refunds; No-Show Cancellations and Service Charges

A. The provisions of this Section (20.A) shall apply with respect to refunds for tickets under this Contract of Carriage:

1) All refunds will be subject to government laws, rules, regulations, or orders of the country in which the ticket was originally purchased and of the country in which the refund is being made.

2) The first portion of any amount refunded will be the full amount of taxes and fees imposed on the ticket purchase.

3) If applicable, cancellation fees or service charges will be assessed in a separate transaction and netted against the refunded amount.

4) No Use - If no portion of the ticket has been used, the refund amount will be equal to the fare, plus any ancillary purchases (checked or carry-on bag, seat assignments, etc.) and all charges, taxes, and fees paid for the ticket issued to the passenger.

5) Partial use - If a portion of the ticket has been used:

a) One-way ticket: If travel was terminated at an intermediate or stopover point, the refund amount will be equal to the amount of the fare and all ancillary purchases (checked or carry-on bag, seat assignments, etc.) paid from the point of termination to the destination or to the point at which transportation is to resume and will be the lowest one-way fare for the class of service paid for minus any discount, plus all charges, taxes, and fees proportionately attributable, which shall be reasonably determined by Frontier.

b) Round-trip ticket purchased: the refund amount will be equal to the amount of the fare and ancillary purchases (checked or carry-on bag, seat assignments, etc.) paid on the unused portion of the ticket, plus all charges, taxes, and fees proportionately attributable, which shall be reasonably determined by Frontier.

B. In addition to the provisions of Section 20.A, in situations other than No-Show Cancellations, the provisions of this Section (20.B) shall apply with respect to refunds for tickets under this Contract of Carriage:

1) For refundable tickets that are canceled prior to flight departure, passengers should fill out an online request, available at www.FlyFrontier.com.

2) For tickets that are canceled up to 24 hours after the time of purchase (excluding tickets purchased within seven days before travel, which will be held as a credit, subject to a cancellation fee), passengers should cancel their tickets online at www.FlyFrontier.com.

3) Payment - A refund will be provided only to the original purchaser's form of payment. However, if, at the time of the application for refund, evidence is submitted that a company purchased the ticket on behalf of its employee or a travel agency has made a refund to its client, the refund will be made directly to the employee's company or the travel agency. The Table below illustrates other rules respecting payment:

Payment Type	Refunded To
Universal Air Travel Plan	The subscriber against whose account the ticket was charged
Transportation Request issued by a government agency other than a U.S. government agency	The government agency that issued the transportation request
U.S. Government Transportation Request	The U.S. government agency that issued the U.S. Government Transportation Request with a check payable to the “Treasurer of the United States”
Credit Card	The account of the person to whom the credit card was issued
Travel Voucher	The original voucher will be reinstated if the cancellation is within 90 days of the voucher issue date

4) Identity - Frontier does not assume responsibility to confirm that the person using or presenting a ticket for refund is the true owner of the ticket.

C. In situations involving a No-Show Cancellation, in addition to the provisions of Section 20.A, the provisions of this Section (20.C) shall apply with respect to refunds for tickets under this Contract of Carriage.

1) Automatic Refund; No Additional Submission Required – In the case of a No-Show Cancellation, the refund described in Section 20.A shall be automatically refunded to the purchaser.

2) Automatic Imposition of a No-Show Cancellation Service Charge.

a) Refund – The refund described in Section 20.A shall be given, but will be netted against the No-Show Cancellation Service Charge in a separate transaction.

b) Imposition of a No-Show Cancellation Service Charge – A No-Show Cancellation Service Charge will apply with respect to the ticket (or the segment for which the No-Show Cancellation applies) in the amount of the fare plus all ancillary purchases plus all charges, taxes and fees attributable to the fare and ancillary purchases.

c) The payment of the No-Show Cancellation Service Charge shall not entitle the purchaser (and, if different, the passenger or other party to whom a refund would otherwise be due) to transportation.

D. To the extent required by applicable law, including Code § 6415(a) and the regulations promulgated thereunder, the purchaser (and, if different, the passenger or other party to whom a refund would otherwise be due) hereby consents to Frontier recovering any allowance of a credit or refund of any overpayment of governmental fees or tax imposed, including pursuant to Code § 4261, including in each case which overpayment arises directly or indirectly as a result of a No-Show Cancellation as contemplated in this Contract of Carriage.

21. Currency and Mode of Payment and Fees

A. Fares, fees, charges, and taxes charged or collected by Frontier are due in United States dollars, except for bookings made through available Canadian online travel sites, which are due in Canadian dollars. Any purchases made in connection with such bookings would also be due in Canadian dollars.

B. All amounts due to Frontier must be paid with a credit card. Frontier does not accept cash for any transactions, including those on Frontier's aircraft.

C. Frontier does not accept personal checks, traveler's checks, certified (cashier's) checks, or money orders.

D. A service charge will apply to any improper chargeback on a credit card and may be charged to the same credit card via which the chargeback is made.

22. Miscellaneous

A. Subordination to Law - In all cases, this Contract of Carriage will be subordinate to any applicable law.

B. Metric References - Conversion of British units to metric units are approximate and for reference only. The British unit will apply.

C. Change Without Notice - Except as may be required by applicable laws, government regulations, orders, and requirements, Frontier reserves the right to amend this Contract of Carriage without notice, provided that no such change shall apply to carriage that has commenced.

D. No Waiver/Modification of Terms - No employee or agent of Frontier has the authority to waive, modify, or alter any provisions of the Contract of Carriage unless authorized by a corporate officer of Frontier. Accommodations provided beyond what is required by the Contract of Carriage do not alter the Contract of Carriage. Frontier's employees and agents, including third party travel agents and online travel sites, are only authorized to sell tickets for air transportation on Frontier subject to the Contract of Carriage.

E. Changes in Rules, Fares, and Charges - Unless otherwise provided within specific fare rules, transportation is subject to the rules, fares, and charges in effect on the date a ticket is issued, determined by the validation stamped or imprinted on the ticket, or valid electronic ticket.

F. Taxes and Charges - When the ticket is issued for the effective date, all government, airport, vendor, or other charges that apply to passenger travel into foreign countries are the responsibility of the passenger to whom the ticket was originally issued and are in addition to the published fare and charges.

G. Fares/Charges - Specific fares and charges information is available through Frontier reservations offices and at www.FlyFrontier.com.

H. No Class Action - Any case brought pursuant to this Contract of Carriage, Frontier's Tarmac Delay Plan, or Frontier's Customer Service Plan may be brought in a party's individual capacity and not as a plaintiff or class member in any purported class or representative proceeding.

I. Time Limit for Action - No legal action may be brought by a passenger against Frontier unless commenced within 6 months from the date of the alleged incident.

J. Choice of Law - This Contract of Carriage will be governed by and construed in accordance with the laws of the United States of America and the State of Colorado without regard to conflict of law principles or law. All right to trial by jury in any action, proceeding or counterclaim arising out of or in connection with this Contract of Carriage is irrevocably waived.

K. Codeshare Flights – Except for baggage policies (see section 12. , section 13. , and section 15.), the policies, rules, and procedures of the operating airline will apply on any codeshare flight.

FRONTIER

REVISION FILING INSTRUCTIONS / HIGHLIGHTS

«FirstName» «LastName»
«Dist_Loc»

Contract of Carriage

REVISION NUMBER: __77_

REVISION DATE: 04/13/21

Instructions for paper manuals:

For an online version of Contract of Carriage, click here.

1. Insert the attached revision as instructed below.
   - Pages to be removed are listed in the left-hand column. A horizontal line in this column means no pages are to be removed.
   - Pages to be inserted are listed in the middle column. A horizontal line in this column means no pages are to be inserted.
   - A description of the revision is found in the right-hand column.
2. Fill in the Revision Date, Date Posted, and Posted By fields on the **Record of Revisions** page.
3. Direct questions regarding this revision to: **Tech Pubs at 720-374-4341.**

REMOVE PAGES	INSERT PAGES	REVISION HIGHLIGHTS	Page 1 of 1
		Changes made per PCR 21-210	
00.00 Pg. 3	00.00 Pg. 3	**List of Effective Pages** – Updated	
Pgs. 1-24	Pgs. 1-24	**Updated:** Table of Contents 3. Refusal to Transport and Special Conditions 17. Claim Limits and Procedures 19. Denied Boarding Compensation	

JetBlue Airways Contract of Carriage

Last Revised: 2021-05-19

Domestic transportation and international transportation by JetBlue Airways Corporation ("Carrier" or "JetBlue") is subject to the terms and conditions contained in this Contract of Carriage and, where applicable, also subject to treaties, government regulations, and tariffs on file with the U.S. Department of Transportation, as well as any terms, conditions, and/or restrictions applicable to your booking channel. If your itinerary involves travel on a flight operated by a JetBlue Codeshare Partner (as defined below), please see Section 35. If your itinerary involves travel on a flight operated by a JetBlue interline partner, please see Section 36. By making a reservation or accepting transportation on Carrier, each Passenger (as defined below) agrees to be bound by all of the following terms and conditions.

1. Definitions

Assistive Device refers to any piece of equipment that assists an Individual with a Disability to cope with the effects of his or her disability, and may include medical devices and medications.

Battery-Powered Mobility Aid refers to an assistive device used by individuals with mobility impairments such as a wheelchair, scooter or a Segway when it is used as a mobility device by a person with a mobility-related disability.

Blue Basic Fare, Blue Fare, Blue Plus Fare, Blue Extra Fare, and Mint refer to fare options offered for purchase. Details regarding fare options are available at www.jetblue.com/fares.

Carriage refers to the transportation of passengers and/or baggage by air, together with any related services of Carrier in connection with such transportation.

Carrier means JetBlue Airways Corporation.

Codeshare Partner means another airline operating a flight on which Carrier has placed its airline designator code, "B6."

Confirmed Reservation means a space on a specific date and on a specific flight and in a specific class of service of Carrier which has been requested by a Passenger, including a Passenger with a "Zero Fare Ticket," and which Carrier or its agent has verified, by appropriate notation on the ticket or in any other manner provided therefore by Carrier, as being reserved for the accommodation of the Passenger.

Controllable Irregularity as used in Section 37, means a delay, cancellation or diversion that is not caused by a Force Majeure Event. For the sake of clarity, if in a chain of multiple events, the original irregularity is due to a Force Majeure Event, the cause of the subsequent event(s) reasonably related to the original irregularity shall be deemed an Uncontrollable Irregularity.

Convention means, whichever of the following applies:

- Convention for the Unification of Certain Rules Relating to International Carriage By Air, signed at Warsaw, October 12, 1929 ("Warsaw Convention").
- Warsaw Convention, as Amended at the Hague, 1955 ("Hague Protocol").
- Warsaw Convention, as Amended at the Hague, 1955 and by Protocol No. 4 of Montreal, 1975 ("Montreal Protocol No. 4").
- Convention for the Unification of Certain Rules for International Carriage By Air done at Montreal 1999 ("Montreal Convention").

Credit shall mean a credit in a specified dollar amount valid for one (1) year from the date of issuance. A Credit must be used (travel booked and flown) within one (1) year from date of issuance. Credits are non-transferable unless otherwise stated herein.

Departure Delay, as used in Sections 37 and 38, means a delay prior to pushback from the Gate.

Force Majeure Event means an event(s) outside of JetBlue's reasonable control which includes, but is not limited to, weather conditions; acts of government or airport authorities (e.g., Air Traffic Control Delays, runway closures, airport construction); acts of God; U.S. military or airlift emergency or substantially expanded U.S. military airlift requirements, as determined by the U.S. government; grounding of a substantial number of aircraft as a result of activation of the U.S. Civil Reserve Air Fleet; strikes or labor unrest; civil commotions, embargoes, wars or other hostilities, whether actual, threatened or reported; government regulation, demand or requirement; damage to aircraft caused

by a third-party; emergency situation requiring care, protection or response to protect person or property or any event that is not reasonably foreseen, predicted or anticipated by JetBlue.

Gate means either where a plane loads or deplanes Passengers into a terminal building via a jetbridge or, in the case of a hardstand, via a people mover, bus, or air stairs.

Ground Delay, as used in Section 37, means a delay involving a flight that, in the case of departures, has boarded and pushed back from the Gate but that is not in the air and, in the case of arrivals, has landed but has not yet arrived at a Gate. In the case of compensation issued pursuant to the Customer Bill of Rights under Section 37, this does not include flights that were diverted or forced to make an unscheduled stop.

Individual with a Disability is an individual or Passenger who:

a. has a physical or mental impairment that, on a permanent or temporary

b. basis, substantially limits one or more major life activities,

c. has a record of such an impairment, or is regarded as having such an impairment, as further defined in U.S. Department of Transportation regulations in 14 CFR Part 382.3 or Regulation (EC) No. 1107/2006, as applicable.

Interline Transportation means carriage on more than one carrier where carriers agree to accept each other's tickets and baggage.

Mint refers to Carrier's premium service fare option. Details regarding Mint service are available at http://www.jetblue.com/flying-on-jetblue/mint/.

Non-Revenue Passenger is a Passenger who is traveling on a JetBlue travel certificate, an employee pass, a travel pass issued to JetBlue employees for transfer to family and friends (known as a "Buddy Pass"), a JetBlue frequent flyer program award (known as a "TrueBlue Award" or "True Pass"), VIP pass, Travel Card, other airline employees traveling free of charge or at a reduced rate.

Passenger is any person, except members of the crew working the flight, who enters into a contract of transportation or other agreement (or for whom a contract of transportation or other agreement is entered into) with Carrier by which the person is to be transported in an aircraft with the consent of Carrier. A person who is identified, at any time and in any way, as a knowing participant in the commission of a War Risk Occurrence shall not be considered to be a "Passenger" for the purposes of this Contract of Carriage.

Qualified Individual with a Disability means a Passenger or individual with a disability who:

a. with respect to accompanying or meeting a traveler, use of ground transportation, use of terminal facilities or obtaining information about schedules, fares or policies, takes those actions necessary to avail himself or herself of facilities or services offered by Carrier to the general public, with reasonable accommodations, as needed, provided by Carrier;

b. with respect to obtaining a reservation for air transportation on Carrier, offers or makes a good faith attempt to offer to purchase or otherwise to validly obtain a reservation;

c. with respect to obtaining air transportation on other services or accommodations required by U.S. Department of Transportation regulations in 14 CFR Part 382:

1. purchases or possesses a valid reservation for air transportation on Carrier and presents himself or herself at the airport for the purpose of traveling on the flight for which the ticket has been purchased or obtained;

2. meets reasonable, nondiscriminatory Contract of Carriage requirements applicable to all Passengers; and

3. whose carriage will not violate the requirements of Federal Aviation Regulations or, in the reasonable expectation of Carrier personnel, jeopardize the safe completion of the flight or the health or safety of other persons.

Service Animal refers to a dog, regardless of breed or type, that is individually trained to do work or perform tasks for the benefit of a Qualified Individual with a Disability, including a physical, sensory, psychiatric, intellectual, or other mental disability.

Stopover refers to a deliberate interruption of a journey by a Passenger, scheduled to exceed four (4) hours, at a point between the place of departure and the final destination.

Tariffs mean the international passenger rules tariffs publicly filed with the U.S. Department of Transportation.

Uncontrollable Irregularity, as used in Section 37, means a delay, cancellation or diversion that is caused by a Force Majeure Event. For the sake of clarity, if in a chain of multiple events, the original irregularity is due to a Force Majeure Event, the cause of the subsequent event(s) reasonably related to the original irregularity shall be deemed an Uncontrollable Irregularity.

Zero Fare Ticket means a ticket acquired without a substantial monetary payment such as by using frequent flier miles or vouchers, or a consolidator ticket obtained after a monetary payment that does not show a fare amount on the ticket. A Zero Fare Ticket does not include free or reduced rate air transportation provided to employees and guests.

2. Nature of Contract

This Contract of Carriage applies to and governs Carrier's routes only. No agent, servant or representative of Carrier has authority to change or waive any provision of this Contract of Carriage, unless authorized in writing by a corporate officer of Carrier. Unless otherwise prohibited by law, this Contract constitutes the entire agreement between Carrier and Passenger or the party on behalf of whom this contract was entered.

3. Reservations

a. All reservations on Carrier are confirmed and delivered electronically.

b. No person shall be entitled to transportation without a valid, Confirmed Reservation. No reservation shall be considered a Confirmed Reservation if purchase is not completed at least thirty (30) minutes prior to scheduled departure and until payment in full has been received. No reservation paid by credit card shall be considered a Confirmed Reservation if the transaction is not accepted by Carrier for any reason, whether or not Passenger is notified that the reservation has been cancelled.

c. Name changes are only permitted in the case of refundable fares. All other reservations are non-transferable and non-assignable. Non-refundable fares may only be used by the Passenger named on the reservation at the time the reservation is made.

d. Carrier reserves the right to refuse carriage to any person who has acquired a reservation in violation of applicable law or Carrier’s rules and regulations, or without legal capacity to contract.

e. Seat assignments are not guaranteed and are subject to change without notice. Passenger may not occupy a seat other than the seat(s) to which Passenger is assigned except when so authorized or instructed by crewmembers on duty.

4. Changes, Cancellations, and Refunds

a. Non-Refundable Fares

1. Changes

a. Non-refundable fares purchased before February 25, 2021, with the exception of Blue Basic Fares, may be changed prior to the scheduled departure time subject to availability, for up to a Two Hundred Dollar ($200) or One Hundred and Fifty Pound (£150) change fee and any applicable fare difference.

b. Non-refundable fares purchased on or after February 25, 2021, with the exception of Blue Basic Fares, may be changed prior to the scheduled departure time without penalty, subject to availability and any applicable fare difference. Blue Basic Fares may be changed prior to the scheduled departure time for up to a Two Hundred Dollar ($200) or One Hundred and Fifty Pound (£150) change fee, subject to availability and any applicable fare difference.

2. Cancellations:

a. Non-refundable fares purchased before February 25, 2021, with the exception of Blue Basic Fares, may be cancelled prior to the scheduled departure time for a Credit for future air-only travel on Carrier. Refunds are not allowed. Credit is subject to up to a Two Hundred Dollar ($200) or One Hundred and Fifty Pound (£150) service fee.

b. Non-refundable fares purchased on or after February 25, 2021 may be cancelled prior to the scheduled departure time for a Credit for future air-only travel on Carrier. Refunds are not

allowed. Credit is issued without penalty, except Blue Basic Fares, for which Credit is subject to up to a Two Hundred Dollar ($200) or One Hundred and Fifty Pound (£150) service fee.

c. Credit may be used to book a new air-only reservation on Carrier in the name of the Passenger or in the name of any other person designated by the Passenger. Failure to cancel prior to scheduled departure will result in the cancellation of all remaining segments associated with the reservation and forfeiture of fare and any fees for ancillary products or services purchased. In the event of cancellation of a non-refundable fare, taxes and fees will be included in the Credit where permitted by applicable law. Taxes and fees will not be refunded except when required by applicable law and, where permitted, only upon written request by Passenger.

3. Standby Travel:

In the case of reservations for non-refundable fares purchased before February 25, 2021, with the exception of Blue Basic Fares, for travel that does not involve (i) a change in departure city or arrival city, or (ii) a change between a JetBlue-operated flight and a JetBlue flight that contains a segment operated by a Codeshare Partner or interline partner, Passengers may change their reservation to standby travel for the flight immediately preceding their original departure with payment of the additional service fee applicable to the fare option purchased. Passengers may not change their reservation to standby travel for the flight immediately preceding their original departure if such a change would result in changing the date of travel, a change in the departure city or arrival city, or a change between a JetBlue-operated flight and a JetBlue flight that contains a segment operated by a JetBlue Codeshare Partner or interline partner. For non-refundable fares purchased on or after February 25, 2021, all fare options are eligible for standby travel as described above.

4. Following receipt of payment from a Passenger, JetBlue will allow a reservation to be held at the quoted fare for twenty-four (24) hours, if the reservation is made at least one week prior to the flight's departure.

If such reservation is canceled within twenty-four (24) hours of booking, Passenger will receive a full refund without assessment of a cancellation fee

2. Federal Government Fares:

    1. Changes: Fully refundable Federal Government Fares may be changed at any time subject to availability and any applicable fare difference.

    2. Cancellations: Fully refundable Federal Government Fares may be cancelled at any time and Passenger will receive a full refund. Fare refunds will be made by Carrier to the original form of payment.

    3. Refunds: Refunds shall be made by Carrier to the original form of payment, except that when a portion of the trip has been made, the refund will be made in an amount equal to the applicable one-way fare (less any applicable discount) for the portion of the trip cancelled or not operated as scheduled by Carrier.

3. Refundable Fares:

    1. Changes:

    The fare paid for a Passenger who purchases a fully refundable ticket may be changed at any time prior to scheduled departure, subject to availability and any applicable fare difference. If the reservation is not changed prior to scheduled departure, all money associated with the fare will be a Credit valid for future travel on JetBlue.

    2. Cancellations:

    Reservations for refundable fares may be cancelled at any time prior to scheduled departure and Passenger will receive a full refund. Failure to cancel prior to scheduled departure will result in the cancellation of all remaining segments associated with the reservation and all money associated with the fare will be a Credit valid for future travel on JetBlue.

    3. Refunds:

    For Passengers who are eligible to receive a refund under this Section, refunds shall be made by Carrier to the original form of payment, except that when a portion of the trip has been made, the refund will

be made in an amount equal to the applicable one-way fare (less any applicable discount) for the portion of the trip cancelled or not operated as scheduled by Carrier.

4. Combined Fares

   Where one leg of a fare is ticketed as a refundable fare and another leg of a fare is ticketed as a non-refundable fare, the applicable refund and cancellation policies for refundable fares will apply only to the refundable portion and the applicable refund and cancellation policies for the non-refundable fare will apply to the non-refundable portion.

5. Failure of a Passenger to adhere to the following time requirements may result in the cancellation of the Passenger's reservation, seat assignments and forfeiture of payment:

   1. For domestic travel:

      a. Passengers traveling without checked baggage must have obtained a boarding pass thirty (30) minutes prior to scheduled departure;

      b. Passengers traveling with checked baggage must have obtained a boarding pass and have dropped off their baggage forty (40) minutes prior to scheduled departure; and

      c. All Passengers must be onboard the aircraft fifteen (15) minutes prior to scheduled or posted aircraft departure time.

   2. For international travel:

      a. Passengers traveling with or without checked baggage must have obtained a boarding pass and have dropped off their baggage sixty (60) minutes prior to scheduled departure; and

      b. All Passengers must be onboard the aircraft fifteen (15) minutes prior to scheduled or posted aircraft departure time.

6. Carrier will refuse to honor any reservation when such action is reasonably deemed to be necessary to comply with applicable governmental regulations or requests.

7. Except in the case of Federal Government Fares, when a round trip or multi-segment reservation has been made and the Passenger fails to honor his or her reservation for the first portion of the trip, Carrier will cancel, without notification, the return portion or the continuing portion of the Passenger's reservation and Passenger forfeits any remaining fare.
8. If part of your itinerary involves travel on an interline partner, please see Section 36 for information regarding changes, cancellations and refunds.

5. Group Reservations

Reservations for eight (8) or nine (9) Passengers traveling on the same itinerary must be made by calling 1-800-JETBLUE. Reservations for ten (10) or more Passengers traveling on the same itinerary must be made through Carrier's Group Desk. Refundable fares are not available for group reservations. If a group reservation is canceled within twenty-four (24) hours of booking and such reservation is made one week or more prior to the flight's departure, payment will be refunded in full without assessment of a cancellation fee. Such refund will include any deposit that a party or individual is required to make at the time of booking. Such group reservations are subject to all applicable group policies and procedures established by Carrier.

6. Fares

a. Transportation on Carrier is subject to the fares, taxes and charges in effect on the date on which the Confirmed Reservation was made. If the reservation has been confirmed and e-ticket issued before an increase in the fare becomes effective, the reservation shall be honored for transportation as purchased. If the fare decreases after a Confirmed Reservation has been made and e-ticket issued, Carrier will not refund, credit or make any adjustment to the original fare.
b. Fares apply only between the points named and via the routing as shown in Carrier's current schedule and are not applicable to or from intermediate points.
c. Carrier has non-refundable fares and refundable fares. Refundable fares may not be available on all flights. Refundable fares are not available for group reservations (as further explained in Section 5). Refundable Federal

Government Fares are available only to travelers who utilize a SmartPay government issued credit card or GTRs. Federal Government Fares are not available to the general public.

d. No Stopovers are permitted on published fares, except upon combination of local fares.

e. Carrier does not offer special fares for infants, children, senior citizens, military personnel or any other category of passenger, except Federal Government employees.

f. Carrier reserves the right to collect additional taxes, fees or charges imposed by a governmental entity after the reservation has been made and paid for, but before transportation commences.

7. Unaccompanied Minors

a. Carrier will not allow any child under the age of five (5) years to travel on any flight unless accompanied by a Passenger fourteen (14) years of age or older.

b. Subject to an additional fee, unaccompanied children between the ages of five (5) and under fourteen (14) years will be accepted by Carrier, provided the child has a Confirmed Reservation, and the flight on which he/she travels is a non-stop flight. Unaccompanied children will not be accepted on flights with intermediate stops or on connecting flights. The parent or adult guardian/custodian must provide Carrier with the completed Unaccompanied Minor Form, evidencing that the child will be met by another parent or adult guardian/custodian upon deplaning at his/her destination. The person meeting the child at his/her destination will be required to present positive identification and sign a release on the Form. The terms and conditions of the Form are hereby incorporated by reference.

c. Passengers fourteen (14) years of age or older are considered adults for purposes of this Section.

d. Carrier reserves the right to limit the number of unaccompanied minors on any flight in the interest of safety, and such determination is made solely at the discretion of Carrier. Should Carrier refuse carriage to any unaccompanied

minor on this basis, no recovery is available under Section 27 or 37, but Carrier will endeavor to accommodate the unaccompanied minor on the next available flight.

e. Carrier will assign seating to unaccompanied minors entirely at its discretion. If any additional fees were collected by Carrier for the purpose of a particular seat assignment for the unaccompanied minor, an appropriate refund will be issued.

f. If any part of the itinerary involves travel on a Codeshare Partner, please see Section 35 and if any part of the itinerary involves travel on an interline partner, please see Section 36 for differences regarding additional requirements that may apply.

8. Infants and Small Children; Child Restraint Systems

a. Carrier encourages all adults traveling with children under the age of two (2) years to secure the child in an approved car seat or child restraint system in the child's own, purchased seat. A paying adult Passenger may carry, free of charge, on his or her lap, one child over three (3) days and under two (2) years of age. For Passengers departing from international destinations with lap infants, Carrier will collect APHIS (Department of Agriculture) and INS (Customs and Border Protection) taxes at the airport for the lap infant. Carrier reserves the right to request proof of age (e.g. passport, birth certificate or immunization record) before accepting an infant for travel as a lap child. Infants between three (3) and fourteen (14) days old must have written approval from their attending physician to travel. Carrier does not reserve a seat for such children unless a separate reservation is purchased at the regular, applicable fare.

b. If a separate reservation has been made for the child over three (3) days and under two (2) years of age, the child may travel in a separate seat, provided that the child must be securely placed in an FAA-approved child restraint system that conforms to the following guidelines:

1. Car seats manufactured on or after February 26, 1985 must bear two labels, (1) "THIS RESTRAINT IS CERTIFIED FOR USE IN MOTOR VEHICLES AND AIRCRAFT", in red lettering; and (2) "THIS CHILD

RESTRAINT SYSTEM CONFORMS TO ALL APPLICABLE FEDERAL MOTOR VEHICLE SAFETY STANDARDS," this second statement need not be in red lettering.

2. Car seats manufactured between 1981 and 1985 must state "THIS CHILD RESTRAINT SYSTEM CONFORMS TO ALL APPLICABLE FEDERAL MOTOR VEHICLE SAFETY STANDARDS."
3. FAA approved CARES Child Restraint System must state "FAA APPROVED IN ACCORDANCE WITH 14 CFR PART 21.305(D) APPROVED FOR AIRCRAFT USE ONLY."
4. Booster type seats, vest and harness type child restraint systems, lap held child restraints or seats manufactured before 1981 are not acceptable for use.
5. Child restraint systems may not be used in an emergency exit row, aisle seat or middle seat if the window seat is occupied.
6. It is the responsibility of the child's parent or accompanying adult to ensure that the restraint device functions correctly, that the child is adequately secured by the device, that the child's weight does not exceed applicable limitations and that the device has been properly secured to the aircraft seat.
7. Children may not be placed in booster seats, restraint vests, restraint harnesses and other devices not meeting the FAA requirements set forth above.

9. Inspection of Passengers and Baggage

Baggage tendered for transportation either as checked baggage or as carry-on baggage is subject to inspection for security and safety reasons. Passengers and their baggage are subject to inspection with or without the Passenger's consent or knowledge.

10. Carry-on Baggage

a. All carry-on baggage must be stowed in an overhead bin or placed completely under the passenger seat directly in front of the Passenger. Carry-on baggage is the sole responsibility of the Passenger. Claims for lost, forgotten, or stolen carry-on baggage will not be accepted by Carrier, except as otherwise required by applicable law.

b. For reservations purchased before February 25, 2021, provided there is space for its stowage at the time the Passenger boards, each Passenger is restricted to one (1) carry-on item that must be placed in the overhead bin. On all aircraft, carry-on items must not exceed external dimensions of twenty-two inches by fourteen inches by nine inches (22” x 14” x 9”), except for musical instruments as set forth in Section 10F. In addition to the one (1) carry-on item, Passenger may carry a small personal item such as a purse, briefcase, laptop computer case, small backpack, or a small camera. The personal item must fit completely under the seat in front of the Passenger. On any given flight, Carrier reserves the right to further restrict the number of carry-on items as circumstances may require. For Blue Basic Fares purchased on or after February 25, 2021 for travel on or after July 20, 2021, except for itineraries including travel on Carrier to or from the United Kingdom, Passengers are restricted to one (1) personal item, as described above, and a Passenger traveling on a Blue Basic Fare that brings any carry-on item, as described above, to the gate will incur the applicable excess baggage charges as described in Section 13 and the item will be handled as checked baggage.

c. Mobility and other Assistive Devices upon which a Qualified Individual with a Disability is dependent may be carried in addition to the carry-on baggage allowance.

d. Pets

   1. No animals are allowed to be transported on Carrier as checked baggage; however, Carrier will permit small dogs and cats to be transported by Passengers in-cabin (no other animals are allowed). Pets will not be permitted in Mint. Passengers are responsible for complying with any applicable laws and/or governmental regulations of the destination to and from which the animal is being transported,

including furnishing valid health and rabies vaccination certificates when required. The charge to the Passenger for transporting a pet in-cabin is One Hundred and Twenty-Five Dollars ($125) per pet, each way. A Passenger may not transport more than one pet per flight. Payment must be made at the time the Passenger makes his or her reservation.

2. All in-cabin pets must be transported in an approved kennel, with only one pet per kennel.

3. In certain cases, search and rescue dogs may be permitted to travel on Carrier. A fee may apply.

4. maximum of four pets may travel in-cabin on any flight.

5. Refer to Section 34 for restrictions relating to travel to and from international destinations.

6. If part of your itinerary involves travel on a Codeshare Partner, please see Section 35 for differences regarding acceptance of pets.

7. If part of your itinerary involves travel on an interline partner, please see Section 36 for differences regarding acceptance of pets.

e. Service Animals

1. Carrier will accept Service Animals for use by Qualified Individuals with a Disability to accompany a Passenger on a flight at no charge. Only two Service Animals will be accepted per traveling Qualified Individual with a Disability and Service Animals must be harnessed, leashed, or otherwise tethered. Upon request, Carrier, or airport personnel, as applicable, will escort a Passenger with a Service Animal to an animal relief area at the airport.

2. Carrier requires that a Passenger traveling with a Service Animal provide 48 hours' advance notice prior to travel and the submission at the time of notice the applicable form attesting to the animal's training and good behavior, and certifying the animal's good health.

3. Carrier will permit a Service Animal to accompany a Passenger who is a Qualified Individual with a Disability in any seat in which the Passenger sits, as long as the Service Animal fits within the Passenger's foot space

without obstructing an aisle or other area that must remain unobstructed in order to facilitate emergency evacuation. Service Animals may not occupy a seat.

4. For travel to/from international destinations or to/from Puerto Rico or the U.S. Virgin Islands, certain additional health requirements may apply. Refer to Section 34 for restrictions relating to travel to and from international destinations.

5. A trained Service Animal being delivered to its owner's domicile by a trainer will be permitted to travel at no charge.

6. Animals in training will not be transported.

7. Passenger assumes full responsibility for the conduct of his or her accompanying Service Animal. In the event Carrier incurs any loss, damage, delay, expense or legal liability of any kind in connection with the transport of such animal, Passenger accepts full liability for and shall reimburse Carrier for all such sums incurred.

8. Carrier reserves the right to refuse transport of a Service Animal if the animal is too large to permit safe transport, exhibits aggressive behavior, demonstrates behavior that is inappropriate for a public setting or is otherwise determined by Carrier to pose a safety or security threat.

f. Musical Instruments

1. Small musical instruments (such as violins and guitars) of an appropriate size and weight are permitted for stowage in the overhead bin or under a Passenger seat on a first-come, first-served basis if there is space for such stowage at the time the Passenger boards, and will count as the Passenger’s carry-on item.

2. Large musical instruments (such as basses and cellos) of a size that prevents the instrument from being handled as normal carry-on baggage, and electronic equipment of a size that prevents it from being handled as normal carry-on baggage, will be accepted in the aircraft cabin subject to the following:

a. the instrument or equipment must be contained in a case and the weight of the instrument, including the case or covering, cannot exceed one hundred and sixty five (165) pounds;

b. the Passenger carrying the instrument or equipment in the aircraft cabin has purchased the additional seat(s) to accommodate the instrument or equipment ; and

c. the instrument or equipment can be stowed in accordance with FAA requirements for carriage of carry-on baggage or cargo.

g. Carrier will refuse baggage articles or items that, for whatever reason, might create a risk of harm to the aircraft, its crew or its Passengers.

h. If part of your itinerary involves travel on a Codeshare Partner, please see Section 35. If part of your itinerary involves travel on an interline partner, please see Section 36.

11. Checked Baggage General

Subject to the restrictions set forth below, Carrier will check the baggage of a fare-paying Passenger for the flight on which the Passenger is traveling. Passenger may not check baggage for transportation on any flight other than the flight on which the Passenger is traveling. Carrier will not check baggage to a destination other than the final destination on the Passenger's reservation. Acceptance of baggage by Carrier is subject to the following terms and conditions:

a. Each piece of baggage must have a current identification tag or label on the outside containing the Passenger's name, address and telephone number;

b. Carrier will refuse to accept property as baggage which, because of its nature or characteristics, might cause damage to other baggage; and

c. Carrier will not accept as baggage any article which cannot be carried in the baggage compartment of the aircraft.

Passengers may check baggage up to four (4) hours prior to their scheduled departure, provided that the Passengers remain in the airport facility. See Section 34 for additional restrictions that apply to international destinations.

If part of your itinerary involves travel on a Codeshare Partner, please see Section 35. If part of your itinerary involves travel on an interline partner, please see Section 36.

12. Baggage Allowance

Carrier will allow Passengers with Confirmed Reservations the following included checked baggage allowance (see Section 34 for additional terms and restrictions that may apply to international travel):

a. For Blue Plus Fares one (1) piece of baggage and Mint two (2) pieces of baggage, of which the sum of the greatest outside length, plus the greatest outside width, plus the greatest outside height does not exceed sixty-two (62) inches for any individual piece or sporting equipment as described in Section 13B and weighing less than 51 pounds. In the case of oversize and overweight baggage or items, excess baggage charges described in Section 13 may apply, except for travel to and from international destinations which is governed by Section 34.

b. One infant stroller and one infant car seat may be checked in addition to the included baggage allowance at no charge to any Passenger.

c. Mobility and Assistive Devices which cannot be carried in the cabin due to space limitations will be checked and carried in addition to the included baggage allowance, without charge, provided the Passenger is dependent upon such items.

d. One musical instrument packed in a hard-sided container may be transported as the Passenger's checked baggage in accordance with the included baggage allowance if meeting the size and weight restrictions contained in Section 12A. In the case of large or additional musical instruments, excess baggage charges described in Section 13 may apply.

e. If part of your itinerary involves travel on a Codeshare Partner, please see Section 35. If part of your itinerary involves travel on an interline partner, please see Section 36.

13. Excess Baggage Charges

a. The following excess baggage fees apply (see Section 34 for additional terms and restrictions that may apply to international travel and for the excess baggage fees that apply to itineraries including travel on Carrier to or from the United Kingdom):

1. For Blue Basic Fares, Blue Fares, and Blue Extra Fares, one (1) piece of baggage that meets the weight and size limitations set forth in Section 12 is subject to a charge of Thirty Five Dollars ($35).

2. For all Fares except Mint, a second piece of checked baggage that meets the weight and size limitations set forth in Section 12 is subject to a charge of Forty Five Dollars ($45).

3. For all Fares, including Mint, baggage in excess of two pieces that meets the weight and size limitations set forth in Section 12 is subject to a charge of One Hundred and Fifty Dollars ($150) per piece, except as further limited to certain international destinations as described in Section 34.

4. Baggage in excess of sixty-two (62) inches but less than eighty (80) inches (sum of outside length plus outside height plus outside width) is subject to an oversize charge of One Hundred and Fifty Dollars ($150) per piece, with the exception of a standard hard-sided golf bag of up to eighty (80) inches which will not be subject to oversize fees. Baggage in excess of eighty (80) inches will not be accepted as checked baggage.

5. Baggage weighing between fifty-one (51) pounds and ninety-nine (99) pounds is subject to an excess weight charge of One Hundred and Fifty Dollars ($150) per piece. Baggage weighing one hundred (100) pounds or more will not be accepted as checked baggage.

6. An item of baggage that exceeds the included baggage allowance described in Section 12, is oversized, and/or overweight will be subject to a combined fee.

7. For Blue Basic Fares purchased on or after February 25, 2021 for travel on or after July 20, 2021, any carry-on item that is checked at the gate will be subject to a gate check fee in the amount of the applicable baggage fee under this Section and an additional amount of up to Thirty Dollars ($30).

8. Notwithstanding the foregoing restrictions, military Passengers may check one duffel bag, B-4 bag, or sea bag which exceeds the sixty-two (62) inches in dimensions in lieu of one (1) included bag. In addition, hanging garment bags with outside dimensions up to ninety (90) inches will be accepted as part of the included baggage allowance, if the bags are flexible.

b. Passengers may check the following items of sporting equipment properly packed in an appropriate hard-sided container, with each listed category counting as one bag for purposes of the included baggage allowance explained in Section 12:

1. one (1) golf bag containing not more than fourteen (14) golf clubs, three (3) golf balls and one (1) pair of golf shoes;

2. fishing equipment containing not more than two (2) fishing rods, one (1) reel, one (1) landing net, one (1) pair of fishing boots and one (1) fishing tackle box;

3. one (1) pair of snow skis or one snowboard packed in a suitable container, with one (1) pair of ski boots;

4. one (1) pair of water skis, one (1) tow rope and one (1) life preserver belt or vest, packed in a suitable container;

5. one (1) sporting gun case holding no more than two (2) rifles, two (2) shotguns, or four (4) pistols, each unloaded, subject to restrictions on firearms set forth in Section 14 and Section 34 for travel to and from international destinations;

6. one (1) bowling ball bag, designed for this purpose, one (1) bowling ball, and one (1) pair of bowling shoes; or

7. two (2) hockey or lacrosse sticks, taped together.

Sporting equipment items checked in excess of the one (1) bag allowance will be subject to standard excess baggage charges. Refer to Section 34 for restrictions relating to travel to and from international destinations.

c. The following items are excluded from the baggage weight and size limitations set forth above, except that items weighing one hundred (100) pounds or more, unless otherwise noted, will not be accepted as checked baggage. These items shall be acceptable for carriage upon a Passenger's compliance with all special packing requirements and payment of applicable fees:

   1. single seat, non-motorized bicycles will be accepted as baggage if packaged in a hard-sided, padded bicycle case. Pedals and handlebars must be removed and stored so as to not create a risk of damage to other baggage;

   2. surfboards, with a single surfboard packed in each surfboard case and properly packed to prevent damage to the board and other baggage; or

   3. windsurfing and kitesurfing boards, when properly packed to prevent damage to the board, sail, boom, related equipment and to other baggage.

   4. Musical instruments, when packed in a hard-sided container, where the weight of the musical instrument (including the container) does not exceed one hundred and sixty-five (165) pounds and the sum of the greatest outside length, plus the greatest outside width, plus the greatest outside height of the container does not exceed one hundred and fifty (150) inches.

d. Refer to Section 34 for additional terms and restrictions that may apply to travel to and from certain international destinations.

e. If part of your itinerary involves travel on a Codeshare Partner, please see Section 35. If part of your itinerary involves travel on an interline partner, please see Section 36.

14. Firearms

a. Carrier will refuse to accept for transportation any firearms and ammunition other than sporting firearms that are not loaded and that are suitably encased. Rifles and shotguns must be packed in either a lockable crush-proof container specifically designed for the firearm, or in its own lockable hard sided case. Handguns must be packed inside a lockable hard sided gun case or in its own lockable hard sided case. Carrier will not accept for transportation any firearms in cases or luggage that cannot be locked.

b. All firearms require a Firearms Unloaded Declaration Tag to be read and signed by the Passenger. The Passenger is solely responsible for clearing the weapon of any live charges.

c. Passengers may check up to eleven (11) pounds of ammunition as checked baggage only. Ammunition must be housed separately from a locked firearm. The ammunition must be packaged in the manufacturer's original container or other fiber, wood or metal box that provides for adequate cartridge separation and is specifically designed to carry ammunition. Under no circumstances may a Passenger carry ammunition on board an aircraft.

d. Passengers under the age of eighteen (18) will not be allowed to check any type of firearm as checked baggage.

e. When checking a weapon, Passengers must declare to a representative of Carrier that a weapon is being checked. If a security checkpoint is located prior to the check-in counter of Carrier, the Passenger must declare the existence of a weapon to security personnel.

f. Firearms are not permitted to be carried or checked as baggage for travel to or from international destinations without prior government approval and supporting documents as governed by Section 34. If appropriate prior government approval and supporting documents are received, Sections 14A through 14F shall apply to carriage of firearms and ammunition to all international destinations.

g. If part of your itinerary involves travel on a Codeshare Partner, please see Section 35. If part of your itinerary involves travel on an interline partner, please see Section 36.

15. Dangerous Goods

Federal law prohibits hazardous materials from being included in either checked or carry-on baggage. Items such as explosives, compressed gases, oxidizers, corrosives, flammable liquids and solids, loaded firearms, radioactive materials and poisons are considered hazardous. Some common examples of prohibited items include paints, mace/tear gas, lighter fluid, oxygen bottles and fireworks. Other common items that may be carried, in limited quantities, within baggage include hairspray, perfume, and certain medicines that the Passenger must use during flight. Dry ice will be accepted within carry-on or checked baggage if the dry ice is contained in a package that (a) allows the release of carbon dioxide, (b) is plainly marked with the words “dry ice” or “carbon dioxide solid” together with the net weight of the dry ice and the name of the contents being cooled, and (c) the package contains less than five and a half (5.5) pounds of dry ice. Self-heating meals will be accepted within carry-on or checked baggage; however activation and use of self-heating meals will be prohibited onboard the aircraft.

16. Wheelchairs and Wheelchair Batteries

Carrier will accept wheelchairs, whether manually operated or battery operated, as checked baggage on the same flight as the Passenger who uses the device, unless the Passenger requests stowage of his or her manual wheelchair within the cabin (subject to the specific aircraft configuration or other applicable limitations).

In addition to manual wheelchairs, Carrier will accept for in-cabin stowage other mobility aids such as crutches, braces, canes, and walkers, provided approved stowage is available and complies with federal regulations. Other Assistive Devices, including prescription medicine, syringes, or auto-injectors to administer medicine and other medical equipment discussed in Section 17 may be stowed and used within the cabin.

If a manual wheelchair, mobility device or other Assistive Device cannot be stowed in-cabin, Carrier will transport them in the baggage compartment.

Carrier will accept additional wheelchair batteries and battery-powered wheelchairs with the battery attached if the battery is labeled by the manufacturer as non-spillable. Batteries lacking non-spillable manufacturer labeling and spillable batteries that cannot remain in an upright position must be placed in special shipping boxes. Due to the

advance notice requirement that may apply to obtaining these boxes, Passengers should advise Carrier at least forty-eight (48) hours before scheduled departure of the need for an appropriate battery box. Carrier will accept lithium batteries for in-cabin stowage with terminals taped or enclosed in a case. For stowage in the baggage compartment, only lithium batteries whose terminals are completely enclosed in a case are permitted, all others must be removed from the device and stowed in the cabin. Damaged or leaking batteries will not be transported.

Carrier will accept from Passengers written directions on disassembly and reassembly of wheelchairs, other mobility aids, and Assistive Devices. As described in Section 12C and Section 18, respectively, excess baggage charges and limits on liability for loss or damage to any items described in this paragraph do not apply where such charges or limits are prohibited by law or regulation.

If part of your itinerary involves travel on a Codeshare Partner, please see Section 35. If part of your itinerary involves travel on an interline partner, please see Section 36.

17. Medical Equipment and Supplies

Carrier will allow a Qualified Individual with a Disability to use in the passenger cabin a personal ventilator, respirator, continuous positive airway pressure machine (CPAP), bilevel positive airway pressure machine (BiPap) or an FAA-approved portable oxygen concentrator (POC). These medical devices must meet FAA requirements, display a manufacturer's label that it meets such requirements, and can only be stowed and used consistent with FAA, TSA and PHMSA regulations. Passengers must bring an adequate supply of non-spillable batteries, plainly marked as such, to last for 150% of the expected travel time. Carrier may deny boarding if a Passenger does not comply with the foregoing requirements.

18. Baggage - Limitation of Liability

Carrier will accept as checked baggage such personal property as is necessary or appropriate for the wear, use, comfort, or convenience of the Passenger for the purpose of the trip, subject to the following conditions:

a. International Transportation: Please see Section 23.

b. Domestic Transportation: Carrier's liability for loss of, damage to or delay in the delivery of checked or unchecked baggage or its contents is limited to proven damage or loss. Under no circumstances will Carrier's liability exceed Three Thousand Eight Hundred Dollars ($3,800), unless Passenger is traveling with wheelchairs, mobility aids and/or Assistive Devices or Passenger has purchased excess coverage. Qualified Individuals with a Disability traveling with wheelchairs or Assistive Devices, or mobility aids will have no limit on liability for repair or replacement of such wheelchairs, Assistive Devices, or mobility aids. To obtain excess coverage, Passenger must declare excess valuation at the time of check-in and pay an additional charge of One Dollar ($1.00) for each One Hundred Dollars ($100), or fraction thereof, of excess valuation. Maximum liability is not to exceed Five Thousand Dollars ($5,000), including the Three Thousand Eight Hundred Dollar ($3,800) standard liability per Passenger. Excess coverage is not available on items described in Sections 18F, 19 or 20. Passengers must make a reasonable effort to minimize the amount of damage or loss. Actual value for reimbursement of lost or damaged property shall be determined by the documented original purchase price less any applicable depreciation for prior usage or damage.

c. Carrier will be liable for personal property only for the period in which it is in the custody of Carrier. Carrier will assume no liability or responsibility for property carried onboard an aircraft by a Passenger and retained in the custody of the Passenger, except as otherwise required by applicable law.

d. Carrier's liability for loss, delay or damage to baggage is limited, unless a higher value is declared in advance and additional charges are paid. When excess value is declared, baggage will be checked and excess valuation charges collected only to point of Stopover or to destination.

e. Baggage checked at the Gate or on board the aircraft will be subject to the same restrictions and liability limits as baggage checked at the ticket counter.

f. Carrier will not accept for carriage medicines, money, checks, securities, jewelry (including watches), wigs, cameras, video, audio and other electronic equipment (including computers, software or music devices), CDs, DVDs, automotive parts, boat parts, silverware, optical equipment (including contact lenses), dental and orthodontic devices or equipment, keys, negotiable papers, securities, business documents, samples, items intended for sale, paintings, antiques, artifacts, manuscripts, animal antlers, furs, irreplaceable books,

writing instruments, heirlooms, collector's items or publications and similar valuables contained in checked or unchecked baggage. Excess valuation may not be declared on any such items. Passengers are encouraged to carry such valuable items personally. In the case of domestic transportation, Carrier reserves the right to require the Passenger to sign a limited liability release before accepting any such items for transportation. In the case of domestic transportation, if any valuable items of the type described in this paragraph are lost, damaged or delayed, Passenger will not be entitled to any reimbursement or compensation from Carrier, whether or not a limited liability release has been signed by Passenger.

g. Carrier shall not be liable for loss or damage to items including but not limited to baggage wheels, pockets, pull handles, handles, zippers, hanger hooks, external locks, pull straps or security straps resulting from fair wear and tear or the ordinary handling of baggage. Further, Carrier shall not be liable for loss, damage or delay caused by manufacturer's defect, by overpacked baggage or as a result of the inherent defect or quality of the baggage.

h. Under no circumstances shall Carrier be liable to any Passenger for any type of special, incidental or consequential damages related to the damage, loss or delay of checked baggage.

i. If part of your itinerary involves travel on a Codeshare Partner, please see Section 35. If part of your itinerary involves travel on an interline partner, please see Section 36.

19. Fragile and Perishable Items as Baggage

Carrier, in its discretion, may refuse to accept any fragile or perishable goods.

For domestic transportation, Carrier assumes no liability for fragile or perishable goods. Excess valuation may not be declared on such items. If Carrier does accept such goods for transportation, in the case of domestic transportation, it reserves the right to require the Passenger to sign a limited release with respect to such goods. In the case of domestic transportation, Carrier shall not be responsible for loss, damage or delay of such fragile items whether or not such a limited release has been signed by the Passenger.

Fragile items include, without limitation, items such as bicycles, blueprints, cameras, ceramics, china, crystal, dolls, figurines, flash equipment, flowers, glass or glass containers, lenses, maps, mirrors, models, musical instruments or equipment, paintings, perfumes, makeup, liquids, bottles, plants, sculptures, strollers, trophies, vases and wines.

Perishable items include, without limitation, items such as: fruits, vegetables, meats, fish, poultry, bakery products and other forms of food, flowers and floral displays and plants. Such items may also be subject to applicable agriculture rules of the destination jurisdiction. Dry ice shipments are limited by dangerous goods regulations and are discussed separately in Section 15.

20. Improperly Packaged and Damaged Items; Late Items

Carrier reserves the right to refuse to transport items that are improperly packaged or that are damaged at the time the item is checked, or that are presented to be checked as baggage less than forty (40) minutes before scheduled domestic flight departure and sixty (60) minutes before scheduled international flight departure. Refer to Section 34 for restrictions relating to travel to and from international destinations. If such items are accepted, Carrier is not liable for any loss or damage resulting from the inherent defect or quality of the item. As a condition of accepting such items, Carrier may require the Passenger to sign a limited liability release form. Carrier shall not be responsible for loss, damage or delay of such items whether or not such a limited release has been signed by the Passenger.

21. Smoking and Vaping

Smoking or vaping aboard the aircraft is prohibited in accordance with federal law.

22. Notice of Claims

a. For domestic transportation, initial notice of any claim for loss, damage, or delay in delivery of baggage must be given at any Passenger service counter or any office of Carrier within four (4) hours after arrival of the flight on which the loss, damage or delay is alleged to have occurred. Confirming written notice of any baggage related claim, and initial written notice of any other type of claim against Carrier, with appropriate details of the claim, must be given to Carrier not more than twenty-one (21) days after occurrence of the event giving rise to the claim. Failure to give notice within these time limits will not bar the claim if the claimant establishes to the satisfaction of Carrier that he/she was unable to give such notice. For domestic transportation, legal action on any claim described above must be brought within one (1) year of Carrier's written denial, in whole or in part, of the claim.

b. For international transportation, please see Section 23.

c. With respect to any claim for compensation of any nature, Passenger must submit their claim directly to Carrier and allow 28 days, or any shorter time as prescribed by local law, for Carrier to respond. Carrier will not accept or process any claims submitted by a third party on behalf of any Passenger unless this period has elapsed without a response to Passenger. Notwithstanding this limitation, Carrier will permit a Passenger to make a claim on behalf of other Passengers on the same reservation, Passengers lacking capacity to submit their own claims, and claims on behalf of minor Passengers. Carrier may require and evaluate proof that any party other than Passenger is authorized to submit a claim on their behalf. Passenger may consult with legal or other third party advisors before submitting a claim directly. Claims may be submitted online at https://www.jetblue.com/customer-assurance/cancellations-delays.

23. Advice to International Passengers on Carrier Liability

a. Application of Montreal or Warsaw Convention: For the purposes of international carriage governed by the Montreal Convention or the Warsaw Convention, whichever may apply, the liability rules set out in the applicable

Convention as implemented by this Section are fully incorporated by reference in this Contract of Carriage and shall supersede any other provisions of this contract which may be inconsistent with those rules.

b. Death or Injury of Passengers:

1. The Carrier shall be liable under Article 17 of the Montreal Convention or Warsaw Convention, whichever may apply, for recoverable compensatory damages sustained in the case of death or bodily injury of a Passenger, as provided in the following paragraphs:

   a. The Carrier shall not be able to exclude or limit its liability for damages not exceeding 128,821 Special Drawing Rights for each Passenger.

   b. The Carrier shall not be liable for damages to the extent that they exceed 128,821 Special Drawing Rights for each Passenger if the Carrier proves that: (i) such damage was not due to the negligence or other wrongful act or omission of the Carrier or its servants or agents; or (ii) such damage was solely due to the negligence or other wrongful act or omission of a third party.

   c. The Carrier reserves all other defenses and limitations available under the Montreal Convention or Warsaw Convention, whichever may apply, to such claims including, but not limited to, the exoneration defense of Article 20 of the Montreal Convention and Article 21 of the Warsaw Convention, except that the Carrier shall not invoke Articles 20 and 22(1) of the Warsaw Convention in a manner inconsistent with paragraphs (a) and (b) hereof.

   d. With respect to third parties, the Carrier reserves all rights of recourse against any other person, including, without limitation, rights of contribution and indemnity.

   e. The Carrier agrees that, subject to applicable law, recoverable compensatory damages for such claims may be determined by reference to the laws of the country of the domicile or country of permanent residence of the Passenger.

2. In cases of bodily injury or death, the Carrier shall make an advance payment where the Carrier determines it is necessary to meet the immediate economic needs of, and hardship suffered by, a Passenger as provided in the following paragraphs:

   a. Unless a dispute arises over the identity of the person to whom an advance payment shall be made, the Carrier shall, without delay, make the advance payment to the Passenger in an amount or amounts determined by the Carrier in its sole discretion. In the event of death of a Passenger, the amount of the advance payment shall not be less than 16,000 Special Drawing Rights, which shall be paid to a representative of the Passenger's next of kin eligible to receive such advance payment as determined by the Carrier in its sole discretion.

   b. The Carrier shall make the advance payment as an advance against the Carrier's liability under the Montreal Convention or the Warsaw Convention, whichever may apply. An advance payment shall not constitute recognition of liability. An advance payment shall be offset against, or deducted from the payment of, any settlement or judgment with respect to any claim for compensation on behalf of the Passenger.

   c. The Carrier, in making an advance payment, does not waive any rights, defenses, or limitations available under the Montreal Convention or the Warsaw Convention, whichever may apply, to any claim, nor shall acceptance of an advance payment constitute a release of any claim, whatsoever, by any person.

   d. The Carrier, in making an advance payment, preserves its right to seek contribution or indemnity from any other person for such payment, which shall not be deemed to be a voluntary contribution or contractual payment on the part of the Carrier.

   e. The Carrier may recover an advance payment from any person where it is proven that the Carrier is not liable for any damage sustained by the Passenger, or where it is proven that the person was not entitled to receive the payment, or where and to the extent that it is proven that the person who received the advance payment caused, or contributed to, the damage.

c. Delay of Passengers: The Carrier shall be liable for damage occasioned by delay in the carriage of Passengers by air, as provided in the following paragraphs:

1. The Carrier shall not be liable if it proves that it and its servants and agents took all measures that could reasonably be required to avoid the damage, or that it was impossible for it or them to take such measures.

2. Airport, Air Traffic Control, security, and other facilities or personnel, whether public or private, not under the control and direction of the Carrier are not servants or agents of the Carrier, and the Carrier is not liable to the extent the delay is caused by these kinds of facilities or personnel.

3. Damages occasioned by delay are subject to the terms, limitations and defenses set forth in the Montreal Convention and the Warsaw Convention, whichever may apply. They include foreseeable compensatory damages sustained by a Passenger and do not include mental injury damages.

4. The Carrier reserves all defenses and limitations available under the Montreal Convention or the Warsaw Convention, whichever may apply to claims for damage occasioned by delay, including, but not limited to, the exoneration defense of Article 20 of the Montreal Convention and Article 21 of the Warsaw Convention. Under the Montreal Convention, the liability of the Carrier for damage caused by delay is limited to 5,346 Special Drawing Rights per Passenger. The limits of liability shall not apply in cases described in Article 22(5) of the Montreal Convention or Article 25 of the Warsaw Convention, whichever may apply.

d. Destruction, Loss, or Delay of Baggage: The Carrier is liable for damages sustained in the case of destruction or loss of, damage to, or delay of checked and unchecked Baggage, as provided in the following paragraphs:

1. Except as provided below, the liability of the Carrier is limited to 1,288 Special Drawing Rights for each passenger in the case of destruction, loss, damage, or delay of Baggage, whether checked or unchecked, under the Montreal Convention or the Warsaw Convention, whichever may apply. Unless the Passenger proves otherwise:

i. All Baggage checked by a Passenger shall be considered to be the property of that Passenger;

ii. A particular piece of Baggage, checked or unchecked, shall not be considered to be the property of more than one Passenger;

iii. Unchecked Baggage, including personal items, shall be considered to be the property of the Passenger in possession of the Baggage at the time of embarkation

2. If a Passenger makes, at the time checked Baggage is handed to the Carrier, a special declaration of interest and has paid a supplementary sum, if applicable, the Carrier will be liable for destruction, loss, damage, or delay of such checked Baggage in an amount not exceeding the declared amount, unless the Carrier proves that the declared amount is greater than the Passenger's actual interest in delivery at destination. The declared amount, and the Carrier's liability, shall not exceed the total amount of declaration permissible under the Carrier's regulations, inclusive of the limitation of paragraph D(1) hereof. In the case of transportation under the Warsaw Convention, no supplementary sum shall apply unless the declared amount exceeds 19 Special Drawing Rights per kilogram of the total recorded weight of the checked Baggage at the time the Baggage is handed to the Carrier. Nevertheless, the Carrier may impose charges for pieces of Baggage in excess of any free allowance the Carrier may provide.

3. In the case of unchecked Baggage, the Carrier is liable only to the extent the damage resulted from its fault, or that of its servants or agents.

4. The Carrier is not liable for destruction, loss, damage, or delay of baggage not in the charge of the Carrier, including Baggage undergoing security inspections or measures not under the control and direction of the carrier.

5. The Carrier reserves all defenses and limitations available under the Montreal Convention and the Warsaw Convention, whichever may apply, to such claims including, but not limited to, the defense of Article 20 of the Warsaw Convention and Article 19 of the Montreal Convention, and the exoneration defense of Article 21 of the Warsaw Convention and Article 20 of the Montreal Convention, except that the

Carrier shall not invoke Article 22(2) and (3) of the Warsaw Convention in a manner inconsistent with paragraph D(1) hereof. The limits of liability shall not apply in cases described in Article 25 of the Warsaw Convention or Article 22(5) of the Montreal Convention, whichever may apply.

e. Time Limitations on Claims and Actions: Under the Montreal Convention and the Warsaw Convention, whichever may apply, an action for damages must be brought within two years, and a complaint must be made to the Carrier no later than seven (7) calendar days in the case of damage to baggage, and twenty one (21) calendar days in the case of delay thereof.

f. ADVICE TO INTERNATIONAL PASSENGERS ON CARRIER LIABILITY:

1. Passengers on a journey involving an ultimate destination or a stop in a country other than the country of departure are advised that international treaties known as the Montreal Convention, or its predecessor, the Warsaw Convention, including its amendments, may apply to the entire journey, including any portion thereof within a country. For such passengers, the treaty, including special contracts of carriage embodied in applicable tariffs, governs and may limit the liability of the Carrier in respect of death or injury to passengers, and for destruction or loss of, or damage to, baggage, and for delay of passengers and baggage.

2. Limits of Liability in connection with services provided in the European Union (EU): The applicable limits of liability for your journey on a flight ticketed by this carrier are:

a. There are no financial limits for death or bodily injury and the air carrier may make an advance payment to meet immediate economic needs of the person entitled to claim compensation;

b. In the case of destruction, loss of, or damage or delay to baggage, 1,288 Special Drawing Rights per passenger in most cases. You may benefit from a higher limit of liability for loss of, damage or delay to baggage by making at check-in a special declaration of the value of your baggage and paying any supplementary fee that may apply. Alternatively, if the value of your baggage exceeds the applicable limit of liability, you should fully insure it before you travel;

c. In the case of delay to your journey, 5,346 Special Drawing Rights per passenger.

If your journey involves carriage by other carriers please contact them for information on their limits of liability.

24. Refusal to Transport

Passengers will be refused transportation on Carrier for reasons including, but not limited to, the following:

a. Passengers whose transportation on Carrier must be denied in order to comply with any government regulation, or to comply with any governmental request for emergency transportation in connection with the national defense.

b. Passengers whose transportation on Carrier is reasonably deemed by Carrier to be inadvisable or inappropriate due to special circumstances or concerns beyond the control of Carrier, including, without limitation, a Force Majeure Event.

c. Passengers who refuse to permit a search of his or her person or property for explosives or for concealed, deadly or dangerous weapons or other prohibited articles, or who refuse on request to produce positive identification.

d. Passengers requiring medical oxygen for use on board the aircraft, incubators or hook-ups for a respirator to the aircraft electrical power supply, or persons who must travel on a stretcher. However, JetBlue will not deny boarding to a Qualified Individual with a Disability who travels with a Portable Oxygen Concentrator (POC) unless such individual must use the POC during the flight with a hook-up to the aircraft electrical power supply.

e. A Qualified Individual with a Disability pursuant to 14 CFR Part 382 whose carriage may impair the safety of the flight or violate Federal Aviation Regulations. Carrier may require that a Qualified Individual with a Disability be accompanied by an assistant as a condition of being provided air transportation under the following circumstances:

1. person who, because of a mental disability, is unable to comprehend or respond accordingly to safety instructions from Carrier personnel, including the safety briefing required by 14 CFR Parts 121.571(a)(3) and (a)(4); or the safety regulations of a foreign carrier's government, as applicable;

2. person with a mobility impairment so severe that the person is unable to physically assist in his or her own evacuation of the aircraft;

3. person who has both severe hearing and severe vision impairments, if the person cannot establish some means of communication with Carrier personnel that is adequate to both permit transmission of the safety briefing required by 14 CFR Part 121.571(a)(3) or (a)(4) or the safety regulations of a foreign carrier's government, as applicable, and to enable the Passenger to assist in his or her own evacuation of the aircraft in the event of an emergency;

4. If Carrier determines that a person meeting the criteria of paragraph E(1), (2) or (3) of this Section must travel with an assistant, contrary to the individual's self-assessment that he or she is capable of traveling independently, Carrier will not charge for the transportation of the assistant while accompanying a Qualified Individual with a Disability requiring an assistant at Carrier's discretion:

    i. If, because there is not a seat available on a flight for an assistant whom Carrier has determined to be necessary, a Qualified Individual with a Disability with a Confirmed Reservation is unable to travel on the flight, the Qualified Individual with a Disability will be eligible for denied boarding compensation under Section 27;

    ii. For purposes of determining whether a seat is available for an assistant, the assistant shall be deemed to have checked in at the same time as the Qualified Individual with a Disability; and

    iii. Carrier is not required to find or provide a safety assistant.

f. Comfort and Safety: In the following categories where refusal or removal may be necessary for the comfort or safety of the Passenger(s) or other Passengers:

1. Persons whose conduct is or has been known to be disorderly, abusive, offensive, threatening, intimidating violent, or whose clothing is lewd, obscene, or patently offensive;
2. Persons who are barefoot and over five (5) years old;
3. Persons who are unable to sit in the seat in the full upright position with the seat belt fastened;
4. Persons who appear to be intoxicated or under the influence of drugs;
5. Persons with a communicable disease or infection whose condition poses a direct threat to the health or safety of others. However, Carrier will permit a Passenger who meets the foregoing criteria to travel if he/she provides a medical certificate to Carrier dated within ten (10) days of the scheduled date of travel from the Passenger's physician stating that the Passenger is capable of completing the flight safely without requiring extraordinary medical assistance;
6. Persons who refuse to comply with instructions given by Carrier station management, supervisory personnel or uniformed flight crew;
7. Persons who have an offensive odor, except where such condition is the result of a qualified disability;
8. Persons who wear or have on or about their persons concealed or unconcealed deadly or dangerous weapons; provided, however, that Carrier will carry Passengers who meet the qualifications and conditions established in 14 CFR Part 108.11;
9. Manacled persons in the custody of law enforcement personnel; persons brought to the airport in manacles; persons who have resisted escorts; or escorted persons who express to Carrier personnel objection to the flight;
10. Persons who have misrepresented a condition which becomes evident upon arrival at the airport, and the condition is unacceptable for passage;
11. Pregnant Passengers expecting to deliver within seven (7) days, unless such Passenger provides a doctor’s certificate dated no more than seventy-two (72) hours prior to departure stating that the doctor has examined and found the Passenger to be physically fit for air travel

to and from the destination requested on the date of the flight and that the estimated date of delivery is after the date of the last flight in the Passenger's itinerary. In the case of codeshare travel, codeshare partner may have more restrictive terms. In the case of Interline Transportation, the interline partner may have more restrictive terms;

12. Passengers between the age of three (3) and fourteen (14) days, unless attending physician approves travel;

13. Passengers who are unwilling or unable to abide by Carrier's no-smoking rules; and

14. Carrier will not refuse to provide transportation to a Qualified Individual with a Disability solely because the person's disability results in appearance or involuntary behavior that may offend, annoy or inconvenience crewmembers or other Passengers. Carrier will not provide certain extensive inflight special services including, but not limited to, assistance in actual eating, assistance within the restroom or assistance at the Passenger's seat with elimination functions, or provision of medical services. In the case of codeshare travel, codeshare partner may have more restrictive terms. In the case of Interline Transportation, the interline partner may have more restrictive terms.

15. Any Passenger who cannot be transported safely for any reason.

g. The tickets of any Passenger refused passage or removed enroute under the provisions of this Section 24 will be refunded in accordance with Section 26. Such a refund shall be the sole recourse of any Passenger refused passage or removed enroute. UNDER NO CIRCUMSTANCES WILL CARRIER BE LIABLE TO ANY PASSENGER OR REFUSED PASSENGER FOR ANY TYPE OF INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

25. Failure to Operate as Scheduled

a. Whenever Carrier cancels or otherwise fails to operate any scheduled flight, Carrier will, at the request of the Passenger, either (i) transport the Passenger on another of Carrier's flights on which space is available in the same class of service at no additional charge, or (ii) provide Passenger with a full refund

in accordance with Section 26. Except as may be provided in Section 37, Carrier shall have no other liability or responsibility to any Passenger as a result of a failure to operate any flight. UNDER NO CIRCUMSTANCES SHALL CARRIER BE LIABLE TO ANY PASSENGER FOR ANY TYPE OF SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.

b. Carrier will endeavor to carry Passengers and their baggage with reasonable dispatch, but times shown in schedules or elsewhere are not guaranteed and form no part of this Contract of Carriage. Carrier may, without notice, substitute alternate carriers or aircraft and, if necessary, may alter or omit intermediate stops shown on the reservation. All schedules are subject to change without notice. Carrier is not responsible and assumes no liability for failure to make connections on its own flights or the flights of any other airline. UNDER NO CIRCUMSTANCES SHALL CARRIER BE LIABLE TO ANY PASSENGER FOR ANY TYPE OF SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.

c. Except as provided above, Carrier shall have no liability for damages for any delay, flight cancellation, or default in performing hereunder if such delay, cancellation or default is caused by conditions beyond its control due to force majeure. As used in this section, “force majeure” means actual, threatened or reported:

1. Weather conditions or acts of God;
2. Riots, civil unrest, protests, embargoes, pandemic declaration or public health emergency, war, hostilities, or unsettled international conditions;
3. Strikes, work stoppages, slowdowns, lockout, or any other labor-related dispute;
4. Wars, embargos, or other hostilities;
5. Government regulation, demand, directive or requirement;
6. Shortages of labor, fuel, or facilities; or
7. Any other condition or cause beyond Carrier’s control or any fact not reasonably foreseen by Carrier.

26. Relief for Failure to Transport / Failure to Operate

If Carrier cancels a flight or fails to operate a flight as scheduled, the Passenger may be entitled to relief under the provisions of Section 37. If Carrier denies boarding to a Passenger with a valid reservation, the Passenger will be entitled, at his or her option, to either (i) transportation at no extra charge on another of Carrier's flights to the same destination, subject to space availability, or (ii) a refund of the applicable fare paid by Passenger. When a portion of the trip has been made, the refund will be made in an amount equal to the applicable one-way fare (less any applicable discount) for the portion of the trip cancelled or not operated as scheduled by Carrier.

27. Denied Boarding Compensation

a. If a Passenger holding a Confirmed Reservation presents him or herself for carriage at the appropriate time and place, having complied fully with Carrier's requirements as to reservations and check-in, and if the flight for which the Passenger holds a Confirmed Reservation is oversold and, due to oversales, JetBlue is unable to accommodate the Passenger and departs without him or her, the Passenger shall be entitled to the denied boarding compensation described in Section 27B immediately below, unless (i) the Passenger responds to Carrier's request for volunteers and who willingly accepts Carriers' offer of compensation, in any amount; or (ii) one of the exceptions to eligibility for denied boarding compensation in Section 27D below applies. For the sake of clarity, a Passenger who responds to Carrier's request for volunteers and who willingly accepts Carrier's offer of compensation shall not be considered to be involuntarily denied boarding and shall not be entitled to denied boarding compensation.

b. Passenger who is denied boarding involuntarily, subject to the exceptions in Section 27D below, shall be entitled to One Thousand Five Hundred and Fifty Dollars ($1,550).

c. Acceptance of denied boarding compensation relieves Carrier from any further liability caused by its failure to honor the Passenger's original Confirmed Reservation.

d. Passengers denied boarding involuntarily are not entitled to denied boarding compensation if:

1. The Passenger does not fully comply with this Contract of Carriage regarding ticketing, reconfirmation, check-in, acceptability for transportation;

2. The flight originates in the United Kingdom or a European Community state;

3. The flight for which the Passenger holds a Confirmed Reservation is unable to accommodate that Passenger because of substitution of equipment of lesser capacity when required by operational or safety reasons;

4. The Passenger is offered accommodations or is seated in a section of the aircraft other than that specified on the ticket at no extra charge, except that a Passenger seated in a section for which a lower fare is charged shall be entitled to an appropriate refund;

5. Carrier arranges alternate transportation, or other transportation used by the Passenger at no extra cost to the Passenger, that at the time such arrangements are made is planned to arrive at the airport of the Passenger's next Stopover or, if none, at the airport of the final destination not later than one (1) hour after the planned arrival time of the Passenger's original flight; or

6. The Passenger voluntarily relinquishes his or her Confirmed Reservation in exchange for compensation offered by Carrier.

e. In determining which Passengers holding Confirmed Reservations shall be denied boarding involuntarily, Carrier shall deny boarding to such Passengers in the order of when Passengers checked in, commencing with those Passengers who checked in last.

f. Before denied boarding occurs, Carrier will give a written explanatory statement to Passengers who are denied boarding.

28. Reservations on Other Carriers

Carrier will only accept reservations made on, or tickets issued by, other carriers, in accordance with federal law when a carrier has ceased operations following bankruptcy.

29. Right to Change Contract of Carriage

Carrier reserves the right, to the extent not prohibited by applicable law, to change, delete, or add to any of the terms of this Contract of Carriage without prior notice. All changes must be in writing and must be available for public inspection at each of Carrier's ticket offices. To the extent there is a conflict between the Contract of Carriage and your itinerary, ServiceNow, or other publications, the Contract of Carriage governs. Previous versions of the Contract of Carriage may be obtained by contacting JetBlue at 1-800-JETBLUE (**deaf or hard of hearing customers** TTY/TDD line available by dialing 711) or by contacting us through http://www.jetblue.com/help/contactus/.

30. Ground Transportation

Ground transportation is exclusively the responsibility of Passenger.

31. Check Acceptance

Carrier will not accept checks as payment for purchase, except in the case of Group Reservations as defined in Section 5. For Group Reservations, personal checks made payable to Carrier for the exact amount of purchase must include imprinted name, mailing address and telephone number. A valid driver's license with picture (or valid passport) as personal identification is required. Carrier reserves the right to require that checks be approved by a third-party check approval system.

A service charge of Fifteen Dollars ($15) will be assessed to a Passenger on all returned checks. This service charge is in addition to any applicable bank charges assessed against Carrier or the Passenger.

32. Government Laws and Regulations

All transportation is sold and all carriage is performed subject to compliance with all applicable government laws and regulations, including those of the Federal Aviation Administration and U.S. Department of Transportation, Transportation Security Administration, and all applicable Conventions, special contracts, treaties, and tariffs, many of which are not specified herein but are nevertheless binding on Carrier and all Passengers.

Carrier shall not be liable for any damage arising out of its compliance with any laws, government regulations, orders, rules, requirements or security directives or as a result of Passenger's failure to comply with such laws, government regulations, orders, rules, requirements or security directives or as a result of Passenger's reliance on advice provided by JetBlue regarding such laws, regulations, orders, rules, requirements or security directives.

Immigration and Customs Regulations: It is the Passenger's responsibility to obtain and have possession of all required travel documents. Carrier assumes no responsibility for compliance by Passengers with immigration and customs laws and regulations of each country from, through, or to which a flight is operated. Carrier shall not be responsible for any information or assistance given to a Passenger by any agent in connection with obtaining such necessary documents or complying with such laws and regulations, or any consequence to any Passenger resulting from his or her failure to obtain such documents and comply with such laws and regulations.

33. U.S. Territory Travel

For all travel to and from U.S. territories, the following rules apply:

a. Satellite TV and other inflight connectivity services, where available, may be inoperative on the transoceanic portions of the flight. Carrier is not liable, in contract or otherwise, to the Passenger for any such unavailability of satellite TV or other inflight connectivity.

b. Passengers remain responsible for any and all documentation requirements and proof of citizenship. Carrier shall not be responsible for a Passenger's failure to present or provide documentation required under the applicable laws of the territories to or from which a Passenger travels or through which Passenger may transit.

34. International Travel

For international travel on a Carrier-operated flight the following rules apply:

a. Baggage:

1. For travel to and from the Dominican Republic or Haiti, Carrier will not accept more than two (2) pieces of checked baggage and will not accept oversized (over sixty-two (62) inches in overall dimensions) or overweight (over fifty (50) pounds) baggage. A first and second piece of checked baggage may be subject to excess baggage charges as set forth in Section 13.

2. For travel to and from Ecuador, Guyana, Peru or Trinidad and Tobago, Carrier will not accept more than two (2) pieces of checked baggage and will not accept oversized (over sixty-two (62) inches in overall dimensions) baggage or baggage weighing over seventy (70) pounds. A first and second piece of checked baggage or overweight baggage (between 51 and 70 pounds) may be subject to excess baggage charges as set forth in Section 13.

3. For travel to and from Cuba, Carrier will not accept more than five (5) pieces of checked baggage. A first, second, third, fourth and fifth piece of checked baggage, oversized baggage (between sixty-two (62) and eighty (80) inches in overall dimensions), or overweight baggage (between 51 and 99 pounds) may be subject to excess baggage charges as set forth in Section 13. Checked baggage in excess of three (3) pieces will not be accepted during any Carrier baggage embargo period.

4. For travel to and from the United Kingdom, the following excess baggage fees apply in the prevailing local currency:

a. For Blue Basic Fares, Blue Fares, and Blue Extra Fares, one (1) piece of baggage that meets the weight and size limitations set forth in Section 12 is subject to a charge of Sixty Five Dollars ($65) or Fifty Five Pounds (£55).

b. For all Fares except Mint, a second piece of checked baggage that meets the weight and size limitations set forth in Section 12 is subject to a charge of One Hundred and Five Dollars ($105) or Eighty Five Pounds (£85).

c. For all Fares, including Mint, baggage in excess of two pieces that meets the weight and size limitations set forth in Section 12 is subject to a charge of Two Hundred Dollars ($200) or One Hundred and Fifty Pounds (£150) per piece.

d. Baggage in excess of sixty-two (62) inches but less than eighty (80) inches (sum of outside length plus outside height plus outside width) is subject to an oversize charge of One Hundred and Fifty Dollars ($150) or One Hundred and Twenty Pounds (£120) per piece, with the exception of a standard hard-sided golf bag of up to eighty (80) inches which will not be subject to oversize fees. Baggage in excess of eighty (80) inches will not be accepted as checked baggage.

e. Baggage weighing between fifty-one (51) pounds and ninety-nine (99) pounds is subject to an excess weight charge of One Hundred and Fifty Dollars ($150) or One Hundred and Twenty Pounds (£120) per piece. Baggage weighing one hundred (100) pounds or more will not be accepted as checked baggage.

f. An item of baggage that exceeds the included baggage allowance described in Section 12, is oversized, and/or overweight will be subject to a combined fee.

5. For travel to and from all international destinations except the Dominican Republic, Ecuador, Guyana, Haiti, Peru or Trinidad and Tobago, Carrier will accept excess, overweight and/or oversized baggage on an aircraft

weight (load factor) basis. If accepted by Carrier, excess, overweight and/or oversized baggage may be subject to excess baggage charges as set forth in Section 13.

6. With respect to sporting equipment, for travel to and from the Dominican Republic, Haiti, Peru or Trinidad and Tobago, bicycles, hockey sticks, lacrosse sticks, skis, snowboards and water skis will not be accepted. For travel to and from Bermuda; Cuba; Santo Domingo, Dominican Republic; Santiago, Dominican Republic; Haiti, Peru or Trinidad and Tobago, surfboards, kitesurfing boards and windsurfing boards will not be accepted.

7. No boxes will be permitted as checked baggage except for travel to and from Cuba, as set forth within this section. If such items are accepted, Carrier may require the Passenger to sign a limited liability release form. Carrier shall not be responsible for loss, damage or delay of such items whether or not such a limited release has been signed by the Passenger.

8. For travel to and from Cuba, factory sealed boxes may be accepted subject to the excess baggage charges as set forth within this section and in Section 13. No boxes will be accepted during any Carrier baggage embargo period.

9. Carrier reserves the right to refuse to transport items that are presented to be checked as baggage less than sixty (60) minutes before scheduled flight departure.

b. Pets and Service Animals: Passengers are responsible for complying with any applicable laws and/or governmental regulations of the destination to and from which the animal is being transported, including furnishing valid health and rabies vaccination certificates, when required. Due to the strict requirements mandated by the local governments of Barbados and Trinidad and Tobago the transport of live animals and pets is not permitted by Carrier for travel to those countries. For travel to and from the United Kingdom, pets will not be permitted by Carrier, and Service Animals will be permitted by Carrier as required by applicable laws.

c. Firearms: Firearms are not permitted to be carried or checked as baggage without prior government approval and supporting documentation.

d. Satellite TV and inflight connectivity services: On all flights to and from international destinations, satellite TV and other inflight connectivity services, where available, may be inoperative on the transoceanic portions of the flight. Carrier is not liable, in contract or otherwise, to the Passenger for any such unavailability of such services.

e. Transit Without Visa: Carrier will not permit transit without visa.

f. Documentation: Passengers are responsible for any and all documentation requirements and proof of citizenship. Carrier shall not be responsible for a Passenger's failure to present or provide documentation required under the applicable laws of the territories to or from which a Passenger travels or through which Passenger may transit. Subject to applicable law and regulations, Passenger agrees to pay the applicable fare in the event Carrier, on government order, is required to return Passenger to their point of origin or elsewhere due to Passenger's inadmissibility into or deportation from a country, whether of transit or of destination. The fare applicable will be the fare in effect when the ticket is issued, and any difference between this fare and any unused fare paid by Passenger will be collected from or refunded to Passenger as applicable. The fare collected for carriage to the point of refusal or deportation will not be refunded by the Carrier, unless such refund is compelled by local law.

   With respect to travel to Cuba, Passengers are responsible for determining their applicable license category and Carrier shall not be responsible for a Passenger's failure to comply with such licensing requirements.

g. Conflict With Local Law: Except where otherwise mandated by applicable international law or treaty, should the enforcement of any provision of this Contract of Carriage conflict with the domestic law or regulation of a non-U.S. state, the invalidation or non-enforcement of that provision to comply with such local law does not otherwise invalidate the enforceability of any contractual terms not implicated thereby.

35. Codeshare Flights

a. Operated by Codeshare Partner: Carrier has entered into codeshare arrangements with certain Codeshare Partners enabling Carrier to provide air transportation services to Passengers on flights operated by Codeshare

Partners. Transportation provided by Carrier under a codeshare arrangement is designated by a flight number that includes Carrier's two-letter airline designator code, "B6." However, the flight is operated by a Codeshare Partner.

Those Passengers purchasing tickets for a Carrier flight (any ticket for a flight with designator code "B6" in the flight number on Passenger's itinerary), are subject to the Contract of Carriage with Carrier, regardless of the airline operating the flight. Carrier accepts responsibility for the entirety of that journey under Carrier's designator code pursuant to this Contract of Carriage.

Each Codeshare Partner promulgates rules with respect to the operation of its own flights, and some may differ from Carrier's rules for flights operated by Carrier. For example, a Codeshare Partner may have rules governing check-in requirements, carriage of animals, baggage, baggage liability, carriage of musical instruments, smoking, unaccompanied minors and/or denied boarding compensation that differ from Carrier's rules for flights Carrier operates. Additionally, when a Codeshare Partner operates a flight on which Carrier's designator code "B6" appears on the Passenger's itinerary, the Codeshare Partner's contingency plan for lengthy tarmac delays applies. The conditions of carriage of Carrier's Codeshare Partners are available at the following links and are incorporated herein by reference. Passengers traveling on a flight operated by a Codeshare Partner should review the applicable conditions of carriage to ensure familiarity and compliance with all rules and terms.

Carrier does not allow unaccompanied minors on flights with intermediate stops or on connecting flights, therefore, if travel involves transfer to or from a Codeshare Partner, unaccompanied minors will not be allowed. However, an unaccompanied minor may be allowed to travel on a Codeshare Partner's non-stop itinerary. The Codeshare Partner's rules governing unaccompanied minors will apply and you may need to contact the Codeshare Partner directly.

1. American Airlines:

   https://www.aa.com/i18n/customer-service/support/conditions-of-carriage.jsp

2. Cape Air:

   https://www.capeair.com/flying_with_us/carriage_05.pdf

3. Emirates:

http://www.emirates.com/english/plan_book/essential_information/rules_and_notices/rules_notices.aspx

4. Hawaiian Airlines:

   https://www.hawaiianairlines.com/legal/domestic-contract-of-carriage

5. Icelandair:

   http://www.icelandair.us/information/about-icelandair/privacy-terms/

6. JetSuite:

   https://www.jetsuitex.com/ContractofCarriage.pdf

7. Seabourne:

   http://www.seaborneairlines.com/fly-with-us/contract-of-carriage/

8. Silver Airways:

   http://www.silverairways.com/docs/site/legaldocs/contract-of-carriage

9. South African Airways:

   http://www.flysaa.com/Journeys/conditions_of_Contract.action

b. Operated by Carrier: Carrier also enters into certain codeshare relationships where another airline places its code on certain Carrier-operated flights. If you have purchased a ticket on a flight operated by Carrier but your ticket includes another airline's designator code in the flight number, your condition of carriage is with that airline, not Carrier. For example, the following airlines may place their code on certain Carrier-operated flights, and the conditions of carriage applicable to transportation on such flights are available at the following links.

1. Aer Lingus:

   http://www.aerlingus.com/i18n/en/htmlPopups/conds_of_carriage.html

2. American Airlines:

   https://www.aa.com/i18n/customer-service/support/conditions-of-carriage.jsp

3. Azul – Linhas Aereas Brasileiras:

   http://www.voeazul.com.br/en/flights-international/contract-of-carriage

4. El Al:

http://www.elal.co.il/elal/english/terms_conditions/termsandconditions070108.html

5. Emirates:

   http://www.emirates.com/english/plan_book/essential_information/rules_and_notices/rules_notices.aspx

6. Etihad:

   http://www.etihad.com/en/legal/conditions-of-carriage/

7. Hawaiian Airlines:

   https://www.hawaiianairlines.com/legal/domestic-contract-of-carriage

8. Icelandair:

   http://www.icelandair.us/information/about-icelandair/privacy-terms/

9. Japan Airlines:

   http://www.jal.co.jp/en/carriage/index_c001.html

10. Qatar:

    https://www.qatarairways.com/en-us/legal/conditions-of-carriage.html

11. Royal Air Maroc:

    http://www.royalairmaroc.com/us-en/Travel-Info/General-terms-and-conditions

12. Singapore Airlines:

    http://www.singaporeair.com/jsp/cms/en_UK/global_footer/conditions-carriage.jsp

13. South African Airways:

    http://www.flysaa.com/Journeys/conditions_of_Contract.action

14. TAP Portugal:

    https://www.flytap.com/en-pt/transport-conditions

15. Turkish Airlines:

    https://www.turkishairlines.com/en-us/legal-notice/general-conditions-of-carriage/index.html

36. Interline Transportation

When Carrier undertakes to issue a ticket, check baggage, or make any other arrangements for transportation over the lines of any other airline on an interline basis (whether or not such transportation is part of a through service), Carrier will act only as agent for such other airline in these limited capacities, and will assume no responsibility for the acts or omissions of such other airline, including but not limited to, providing flight status information, delays and other acts or omissions that arise from their flight operations.

Transportation on any interline partner is governed by that airline's contract or conditions of carriage. CARRIER SHALL NOT BE LIABLE FOR ANY DEATH OR INJURY TO A PASSENGER OCCURRING ON A FLIGHT THAT IS NOT OPERATED BY CARRIER. In the case of transportation on a Carrier-operated flight as part of an interline itinerary, transportation is governed by Carrier's Contract of Carriage, except in the following areas where the interline partner's rules may apply:

1. Baggage acceptance, policies and fees including, but not limited to, size, weight and quantity as well as acceptance of certain items, including musical instruments;
2. Carriage of unaccompanied minors and/or young adults;
3. Carriage of pets in the cabin of the aircraft;
4. Policies for carriage of pregnant passengers; and
5. Changes, cancellations and refunds.

With respect to baggage in particular, as required by the U.S. Department of Transportation, baggage service charges for your entire itinerary are determined by the marketing carrier for the first segment of your itinerary. Your originating marketing carrier is defined as the airline whose flight number is assigned to the first segment of your itinerary. If this airline is not Carrier, different charges may apply. Baggage service charges are those in effect on the date of ticketing.

In the case of transportation on a Cape Air flight, due to the size of Cape Air's aircraft and operational limitations, certain terms and conditions differ from those of Carrier, including:

1. Policies and procedures for carriage of Assistive Devices for Qualified Individuals with a Disability (e.g. wheelchairs); and

2. Policies and procedures for Qualified Individuals with a Disability. For example, Passengers must be able to climb three (3) stairs to board a Cape Air-operated flight with or without an assistant.

Carrier does not allow unaccompanied minors on flights with intermediate stops or on connecting flights, therefore, if travel involves transfer to or from an interline partner's flight, unaccompanied minors will not be allowed. However, an unaccompanied minor may be allowed to travel on an interline partner's non-stop itinerary. The interline partner's rules governing unaccompanied minors will apply and you may need to contact the interline partner directly.

For more information, please see the interline partner's contract or conditions of carriage.

1. Aer Lingus:

   http://www.aerlingus.com/i18n/en/htmlPopups/conds_of_carriage.html

2. Aeroflot:

   http://www.aeroflot.com/cms/en/before_and_after_fly/pact

3. Air China:

   http://www.airchina.com.cn/www/en/html/index/general_conditions_o/general_passenger/1006/

4. Air India:

   http://www.airindia.in/Images/pdf/Conditions_Carriage.pdf

5. Air Italy:

   https://www.airitaly.com/en-en/legalinfo/index.aspx

6. Air Serbia:

   https://www.airserbia.com/en/conditions-of-carriage

7. All Nippon Airways:

   http://www.ana.co.jp/wws/us/e/asw_common/siteinfo/conditions-of-carriage/

8. Asiana Airlines:

   https://flyasiana.com/C/US/EN/contents/terms-of-transportation-and-notification

9. Avianca:

http://www.avianca.com/en-mx/contract-of-carriage.aspx

10. Azul – Linhas Aereas Brasileiras:

    http://www.voeazul.com.br/en/flights-international/contract-of-carriage

11. British Airways:

    http://www.britishairways.com/travel/genconcarr/public/en_us

12. Brussels Airlines:

    http://www.brusselsairlines.com/en-be/misc/conditions.aspx

13. Cape Air:

    https://www.capeair.com/flying_with_us/carriage_05.pdf

14. Cathay Pacific:

    http://www.cathaypacific.com/content/dam/cx/legal-and-privacy/general-conditions-of-carriage-for-passengers-baggage-en.pdf

15. China Airlines:

    https://www.china-airlines.com/nl/en/terms-and-conditions/transportation-clauses

16. China Eastern:

    https://ca.ceair.com/newCMS/ca/en/content/en_Footer/AboutUS/201903/t20190328_4431.html

17. China Southern:

    https://global.csair.com/US/GB/booking-policy/international-carriage-conditions

18. Condor Air:

    https://www.condor.com/us/help-contact/gtbc.jsp

19. Egyptair:

    http://www.egyptair.com/en/Pages/Conditions-of-Carriage.aspx

20. El Al:

    http://www.elal.co.il/elal/english/terms_conditions/termsandconditions070108.html

21. Emirates:

http://www.emirates.com/english/plan_book/essential_information/rules_and_notices/rules_notices.aspx

22. Etihad Airways:

    http://www.etihad.com/en/legal/conditions-of-carriage/

23. EVA Air:

    http://www.evaair.com/en-us/conditions-of-carriage/

24. FlyDubai:

    https://www.flydubai.com/en/information/policies/conditions-of-carriage

25. Hainan Airlines:

    https://www.hainanairlines.com/HUPortal/dyn/portal/DisplayPage?COUNTRY_SITE=US=CBHZCBHZ=US=GCIC

26. Hawaiian Airlines:

    https://www.hawaiianairlines.com/legal/domestic-contract-of-carriage

27. Iberia:

    http://www.iberia.com/us/bills/conditions/

28. Icelandair:

    http://www.icelandair.us/information/about-icelandair/privacy-terms/

29. Interjet:

    https://www.interjet.com/en-us/legal-information/regulations-and-policies/contract-of-carriage

30. Japan Airlines:

    http://www.jal.co.jp/en/carriage/index_c001.html

31. JSX:

    https://www.jetsuitex.com/ContractofCarriage.pdf

32. Korean Air:

    https://www.koreanair.com/global/en/footers/terms-of-carriage.html

33. LATAM Airlines:

https://www.latam.com/en_un/transparency/airport-transport-agreement-conditions/

34. LIAT:

http://www.liat.com/UserFiles/File/Conditions%20of%20Carriage%20FINAL.pdf

35. LOT Polish Airlines:

http://www.lot.com/us/en/web/newlot/conditions-of-carriage

36. Lufthansa:

https://www.lufthansa.com/xx/en/business-terms-and-conditions-1

37. Porter Airlines:

https://www.flyporter.com/travel/Conditions-Of-Carriage?culture=en-CA

38. Qatar Airways:

http://www.qatarairways.com/us/en/conditions-of-carriage.page

39. Royal Air Maroc:

http://www.royalairmaroc.com/us-en/Travel-Info/General-terms-and-conditions

40. SATA:

https://www.azoresairlines.pt/en/information/customer-commitment/general-conditions-of-carriage

41. Saudi Arabian Airlines:

https://www.saudia.com/help/useful-links/legal-and-terms-and-conditions/general-conditions-of-carriage

42. Seaborne:

http://www.seaborneairlines.com/fly-with-us/contract-of-carriage/

43. Silver Airways:

http://www.silverairways.com/docs/site/legaldocs/contract-of-carriage

44. Singapore Airlines:

http://www.singaporeair.com/jsp/cms/en_UK/global_footer/conditions-carriage.jsp

45. South African Airways:

    http://www.flysaa.com/Journeys/conditions_of_Contract.action

46. TAP Portugal:

    https://www.flytap.com/en-pt/transport-conditions

47. Turkish Airlines:

    https://www.turkishairlines.com/en-pt/legal-notice/general-conditions-of-carriage/index.html

48. Ukraine International Airlines:

    https://www.flyuia.com/us/en/information/rules-and-regulations/carriage-agreement

37. JetBlue Airways Passenger Bill of Rights and Tarmac Contingency Plan

a. GENERAL

1. JetBlue has coordinated relevant portions of its Tarmac Contingency Plan with airport authorities at all U.S. large, medium, small, and no hub airports JetBlue serves, including U.S. large, medium, small, and no hub diversion airports. JetBlue has sufficient resources to implement this Plan.

2. For purposes of this Section 37, a “Passenger” means a Passenger, as defined in Section 1 and, except in the cases where a Non-Revenue Passenger may be entitled to compensation, shall exclude Non-Revenue Passengers except Passengers using TrueBlue Award Flights. Capitalized terms shall have the meanings as set forth in this paragraph and Section 1. All refunds of one-way or roundtrip travel under subsections C, D, E, or F, of this Section 37, shall exclude taxes and fees paid at the time of purchase. To the extent a Passenger is entitled to a refund but did not purchase travel through a Carrier booking channel (1-800-JETBLUE, jetblue.com or at the airport or a city ticket office), the Passenger will be responsible for contacting Carrier to obtain compensation under this Section 37, except subsection H.

All refunds will be to the original form of payment. To the extent a Passenger booked travel using a TrueBlue Award, compensation under this Section 37 will be provided in the form of TrueBlue Points, except in the case of involuntary denied boarding.

3. Passengers on JetBlue itineraries originating in the United Kingdom or in a European Community state are not eligible for the compensation or relief described in this Section 37, except to the extent that the provision of any component of such compensation or relief is otherwise independently compelled by applicable local law or regulation and/or claimed consistent therewith.

b. INFORMATION

JetBlue will notify Passengers of the following: known delays of thirty (30) minutes or more, cancellations, and diversions. Notification will be given in any of the following forms: via jetblue.com, via telephone (upon request), on flight information display systems, via airport announcement, via onboard announcement, via email or via text message.

c. CANCELLATIONS

A Passenger whose flight is cancelled by JetBlue will receive, at the Passenger's option, a full refund or reaccommodation on the next available JetBlue flight in the same class of service at no additional charge or fare, except when a portion of the trip has been made. Any refund will be made in an amount equal to the applicable one-way fare for the portion of the trip cancelled or not operated as scheduled by JetBlue. In the case of a cancellation due to a Controllable Irregularity, where alternate transportation with a scheduled departure within one hour is unavailable, Passengers will receive the following compensation:

1. Flights cancelled within four (4) hours of scheduled departure, Passengers are entitled to a Fifty Dollar ($50) Credit valid for future travel on JetBlue.

2. Flights cancelled after scheduled departure, Passengers are entitled to a One Hundred Dollar ($100) Credit valid for future travel on JetBlue.

d. DEPARTURE DELAY

In the case of a Departure Delay that is caused by a Controllable Irregularity, Passengers will receive the following compensation:

1. Flight delayed between 3 hours and 3 hours, 59 minutes after scheduled departure time, Passengers are entitled to a Fifty Dollar ($50) Credit valid for future travel on JetBlue.
2. Flight delayed between 4 hours and 4 hours, 59 minutes after scheduled departure time, Passengers are entitled to a One Hundred Dollar ($100) Credit valid for future travel on JetBlue.
3. Flight delayed between 5 hours and 5 hours, 59 minutes after scheduled departure time, Passengers are entitled to a One Hundred and Fifty Dollar ($150) Credit valid for future travel on JetBlue.
4. Flight delayed for 6 or more hours after scheduled departure time, Passengers are entitled to a Two Hundred Dollar ($200) Credit valid for future travel on JetBlue.

e. GROUND DELAYS ON ARRIVAL

In the case of a Ground Delay on arrival caused by a Controllable or Uncontrollable Irregularity, except those necessitated by a security event, Passengers will receive the following compensation:

1. Ground Delay between 1 hour and 1 hour, 59 minutes after scheduled arrival time, Passengers are entitled to a Fifty Dollar ($50) Credit valid for future travel on JetBlue.
2. Ground Delay between 2 hours and 2 hours, 59 minutes after scheduled arrival time, Passengers are entitled to a One Hundred and Twenty-Five Dollar ($125) Credit valid for future travel on JetBlue.
3. Ground Delay for 3 hours or more after scheduled arrival time, Passengers are entitled to a Two Hundred Dollar ($200) Credit valid for future travel on JetBlue.

f. GROUND DELAYS ON DEPARTURE

In the case of a Ground Delay on departure, caused by a Controllable or Uncontrollable Irregularity, except those necessitated by a security event, Passengers will receive the following compensation:

1. Ground Delay between 3 hours and 4 hours, 59 minutes after scheduled departure time, Passengers are entitled to a One Hundred Dollar ($100) Credit valid for future travel on JetBlue.

2. Ground Delay for 5 hours and 5 hours, 59 minutes after scheduled departure time, Passengers are entitled to a One Hundred and Seventy-Five Dollar ($175) Credit valid for future travel on JetBlue.

3. Ground Delay for 6 hours or more after scheduled departure time, Passengers are entitled to a Two Hundred and Fifty Dollar ($250) Credit valid for future travel on JetBlue.

g. GROUND DELAYS, GENERAL

At all U.S. large, medium, small, and no hub airports JetBlue serves, including U.S. large, medium, small, and no hub diversion airports, JetBlue will provide Passengers experiencing a Ground Delay with food and drink (potable water) no later than two (2) hours after the aircraft leaves the Gate unless the Pilot-in-Command determines there is a safety or security-related reason for not doing so. JetBlue will provide Passengers with, access to operable restrooms and, as necessary, medical treatment. In addition to the relief under subsections E and F of this Section, JetBlue will not permit the aircraft to remain on a tarmac for more than three (3) hours for domestic flights or for more than four (4) hours for international flights, unless the Pilot-in-Command determines there is a safety-related or security-related reason for remaining on the tarmac or Air Traffic Control advises the Pilot-in-Command that returning to the Gate or another disembarkation point elsewhere in order to deplane would significantly disrupt airport operations.

For Passengers traveling on a Carrier flight operated by a Codeshare Partner, please see Section 35, as the operating carrier's contingency plan (i.e. the Codeshare Partner's contingency plan) for a Ground Delay will apply.

h. OVERBOOKINGS

Passengers, including those holding Zero Fare Tickets, who are involuntarily denied boarding as a result of an overbooking shall receive denied boarding compensation in accordance with Section 27. For the sake of clarity, a Passenger who responds to Carrier's request for volunteers and who

willingly accepts Carrier's offer of compensation shall not be considered to be involuntarily denied boarding and shall not be entitled to denied boarding compensation under this Section 37 or Section 27.

38. Passenger Service Plan

a. Carrier sets forth its Passenger Service Plan below. Policies and procedures addressing the following areas are set forth in the documents hyperlinked. The hyperlinked documents are directional in nature, do not expressly form a term of this Contract of Carriage, and are subject to change from time-to-time.

1. Carriers fare rules are set forth in Section 6 of this Contract of Carriage. Additional rules may be set forth in close proximity to a particular fare. Passengers calling 1-800-JETBLUE or visiting our Carrier ticket offices or ticket counters will be offered the lowest available fare, exclusive of Internet only fares or special fares that may be offered for limited duration through particular booking channels, when specific dates and times are provided. In the event the lowest available fare is not quoted, Carrier's liability is limited to the difference between the fare quoted and the lowest available fare for which the Passenger was eligible at that time.

2. Carrier will notify Passengers of known delays of thirty (30) minutes or more, cancellations and diversions.

3. Subject to the terms of this Contract of Carriage including but not limited to Sections 20 (Improperly Packaged and Damaged Items; Late Items), 25 (Failure to Operate as Scheduled), 26 (Relief for Failure to Transport / Failure to Operate) and 32 (Government Laws and Regulations), and applicable law, Carrier will endeavor to deliver baggage on time, including making every reasonable effort to return mishandled bags within twenty-four (24) hours, reimbursing Passengers for reasonable expenses that occur because of any delay on domestic flights or as required on international flights and reimbursing Passengers for any fees associated with transportation of a lost bag.

4. Carrier is an instant purchase airline. Carrier does not hold reservations without payment.

5. Carrier's rules regarding fare refunds are set forth in Section 4 of this Contract of Carriage. Subject to such rules, Carrier strives to provide credit card refunds promptly and cash or check refunds within twenty (20) days of receipt of all necessary information. This includes refunds of fees for optional services on flights from which the Passenger was bumped due to an oversales situation. Some fares are nonrefundable.

6. Carrier will accommodate Passengers with disabilities and other special needs, including during Ground Delays consistent with its obligations under 14 CFR Part 382 or Regulation (EC) No. 1107/2006, as applicable.

7. Carrier will meet Passengers' essential needs during Ground Delays consistent with its obligations under 14 CFR Part 259.4.

8. Carrier will treat "bumped" Passengers with fairness and consistency in the case of oversales consistent with its obligations under 14 CFR Part 250 and Section 27 (Denied Boarding Compensation) of this Contract of Carriage.

9. Carrier discloses a Passenger's travel itinerary as follows:

   i. at the time a Passenger pays for a fare on-line; and

   ii. in a Passenger's e-ticket receipt email.

10. Carrier discloses the TrueBlue Frequent Flyer Rules as follows:

    i. via http://www.jetblue.com/tb/terms.asp; and

    ii. at the time a TrueBlue Member logs into the TrueBlue program on jetblue.com; and

    iii. at the time a TrueBlue Member signs up via jetblue.com to become a member of TrueBlue or, in the case of Passengers who sign up via the JetBlue co-branded credit card, at the time a Passenger activates his or her TrueBlue Account.

11. Carrier discloses the aircraft configuration as follows:

    i. via http://help.jetblue.com/SRVS/CGI-BIN/webisapi.dll/,/?St=183,E=0000000000024436663,K=3792,Sxi=11,Case=obj(383379); and

ii. by searching “aircraft configuration” under the “help tool” on jetblue.com

12. If a Passenger’s travel is disrupted due to a Controllable Irregularity and the Passenger experiences a Departure Delay of six (6) of more hours, Carrier may, upon request from the Passenger, provide the following amenities: meal vouchers and/or a hotel voucher.

13. Carrier will notify Passengers in a timely manner of changes to their travel itinerary.

14. Carrier will ensure responsiveness to consumer problems as required under 14 CFR Part 259.7.

39. Personal Information

Carrier may use personal information collected from and about Passenger to perform the activities contemplated in this Contract of Carriage, including, but not limited to, Carriage, transfers to Codeshare Partners and other carriers, and transfers to government entities, as well as further described in Carrier's privacy policy available at https://www.jetblue.com/legal/privacy. Such personal information may be transmitted to the United States and other countries.

40. Governing Law/Section Headings/Waiver

United States federal law shall govern any matter relating to or arising under this Contract of Carriage. To the extent any such matter is not preempted by federal law, the laws of the State of New York shall apply, without regard to conflict of laws principles Each Passenger waives the right to a jury trial. The section headings used in this Contract of Carriage are intended for convenience only and in no way define, limit or describe the scope or substance of any of the provisions of this document. If Carrier fails to enforce any of the sections of this Contract of Carriage or fails to exercise any election, such failure will not be considered to be a waiver of those provisions, rights or elections or in any way affect the validity of the Contract of Carriage.

Each Passenger agrees, on behalf of themself and anyone on whose behalf they are purchasing, that any lawsuit brought against Carrier or any of its affiliated entities, agents, directors, employees, and/or officers related to this Contract of Carriage, their ticket, and/or their use of or dealings with Carrier's website will be brought only in an individual capacity and may not be brought, alleged or asserted as part of a class action proceeding.

41. Controlling Language

English is the controlling language of this Contract of Carriage. To the extent there is any conflict between the English translation and another language translation, English controls.

[End of Document]

spirit®

CONTRACT OF CARRIAGE

INCLUDES GUEST SERVICE PLAN & TARMAC DELAY PLAN

UPDATED AS OF JUNE 24, 2021

TABLE OF CONTENTS

1. DEFINITIONS

A. **Assistive Device** means any piece of equipment that assists a guest with a disability to hear, see, communicate, maneuver, or perform other functions of daily life, and may include medical devices and medications.

B. **Guest with Disabilities** means any individual who has a physical or mental impairment that, on a permanent or temporary basis, substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment.

C. **Denied Boarding** is used in Spirit's Contract of Carriage to refer to a situation in which more guests hold confirmed reservations than there are seats available (oversold flight) for a specific flight on a specific date. In such situation, guests may be voluntarily or involuntarily denied boarding in accordance with section 9 herein.

D. **DOT** means U.S. Department of Transportation.

E. **FAA** means U.S. Federal Aviation Administration.

F. **IATA** means International Air Transport Association.

G. **Montreal Convention** means the Convention for the Unification of Certain Rules for International Carriage by Air, executed in Montreal, on May 28, 1999, including any amendments thereto.

H. **Reservation Credit(s)** (future travel/flight credit or credit shell – these terms are all interchangeable) are non-transferable and may only be used by a guest on the original reservation. Your Reservation Credit will detail any applicable terms and conditions.

I. **Spirit Airlines Guest Service Plan** outlines Spirit's policies and addresses circumstances that may have an impact on our Guests' travel plans, purchase decisions or overall expectations.

J. **Stopover** means a voluntary interruption in the guest's journey at an intermediate city that isn't the destination for longer than the time allowed for a layover.

K. **TSA** means U.S. Transportation Security Administration.

L. **Warsaw Convention** means the Convention for the Unification of Certain Rules Relating to International Carriage by Air, executed in Warsaw, on October 12, 1929, including any amendments thereto.

2. RESERVATIONS

2.1 *Confirmed Reservations*

2.1.1. Guests who have purchased a reservation through the following methods hold a confirmed reservation:

a. Direct bookings made with Spirit Airlines via Spirit's website (www.spirit.com) or by contacting the Spirit Airlines Reservations Center at 855-728-3555.

b. Travel agency or internet travel site bookings (purchased other than at Spirit's website (www.spirit.com).

2.1.2. Confirmed Reservation Validity

No one shall be entitled to transportation without a confirmed reservation. Subject to any applicable limitations or restrictions set forth herein, guests with confirmed reservations will be entitled to transportation between airports of origin and destination. Confirmed reservations are valid for the dates and flights indicated in the reservation.

No reservation paid by credit card shall be considered a confirmed reservation if the transaction is not accepted by the carrier for any reason, whether or not the guest is notified that the reservation has been cancelled. Original credit card used may be requested at check-in in order to confirm the reservation.

2.2 *Refusal to Sell Transportation*

2.2.1. Spirit may refuse to sell transportation to any person, including the following, and may inform such persons that they are not permitted to purchase transportation from Spirit:

a. Prior Misconduct – A person who has disrupted airline operations (at Spirit or other airlines), mistreated employees (of Spirit or others), or has not complied with Spirit's policies or has otherwise violated this Contract of Carriage.

b. Misconduct – A person who has committed a fraudulent act against Spirit.

2.3 *Check-In*

2.3.1. Guests are required to have a boarding pass in-hand by the check-in time limit outlined in section 2.4.1.a. Check-in begins at least two (2) hours prior to departure at the Spirit airport ticket counter or 24 hours prior to flight departure on Spirit's website (www.spirit.com) if eligible for online check-in. A Boarding Pass service charge will be applied to guests who choose to have their boarding pass printed by an agent at domestic airports except West Palm Beach, FL.

2.3.2. It is the guest's responsibility to arrive at the airport with enough time to complete check-in and security screening processes, taking into consideration travel time both to and within the applicable airport, as well as processing through the security check point.

a. For domestic flights, Spirit recommends that guests arrive at the airport at least two (2) hours prior to (original) scheduled departure.

b. For international flights, Spirit recommends that guests arrive at the airport at least three (3) hours prior to (original) scheduled departure.

2.3.3. Guests wanting to check baggage may do so at the ticket counter once airport check-in begins. Baggage will not be accepted more than four (4) hours before scheduled departure time. Baggage must be checked at the ticket counter at least 45 minutes prior to the (original) scheduled departure time for all domestic flights, and 60 minutes for all international flights including U.S.V.I. flights. Guests who present baggage after this time limit may be refused transportation. In the event that baggage is accepted after this time limit, the guest will be liable for any applicable delivery costs if the bag is not carried on the same flight as the guest.

2.4 Cancellation of Reservations

2.4.1. All reservations and seat assignments are subject to cancellation without notice if:

a. The guest does not have a boarding pass in-hand at least 45 minutes prior to the (original) scheduled departure time for all domestic flights, and 60 minutes prior to the (original) scheduled departure time for all international flights including U.S.V.I. flights.

b. The guest fails to make themself available for boarding at the gate at least 15 minutes prior to (original) scheduled departure time for domestic flights; or 30 minutes prior to the (original) scheduled departure time for international flights even if the guest has already checked in for the flight at a location designated for check-in.

In the event of a delay, guests are recommended to remain in the gate area for updates and possible early departures. Spirit shall not be liable to any guest who misses a flight, which departed earlier than the estimated departure time posted for the delay.

c. The guest fails to travel on any flight segment of a booked itinerary and fails to modify/cancel their reservation prior to the time limit outlined in section 3.3. In such instances, all subsequent flight segments on the itinerary will be cancelled.

d. Such action is necessary to comply with any governmental regulation or direction, or to comply with any governmental request for emergency transportation in connection with the national defense.

e. The guest has been informed that he/she is not permitted to purchase transportation from Spirit.

2.4.2. If Spirit refuses to transport the guest for any of the reasons stated above, the guest would not be eligible for denied boarding compensation.

3. FARES

3.1 *General*

Fares are subject to change until purchased. All domestic and international fares are per guest for each way of travel and include the base fare plus any applicable taxes, fees and surcharges; however, certain foreign countries may charge additional taxes and fees that are collected directly by the local government or local airport authority upon arrival or departure. Additional Spirit optional services may apply.

Spirit offers a range of fares and on certain discount fares, availability may be limited, and restrictions may apply. Subject to certain exceptions and/or restrictions set forth hereinafter, all reservations are non-refundable. All Spirit reservations are non-transferable.

3.2 *Currency/Method of Payment*

3.2.1. All fares and charges are listed in United States dollars (USD).

3.2.2. Spirit does NOT accept cash, traveler's checks, certified (cashier's) checks, and money orders at certain domestic and international airports. At such airports, Spirit will accept credit/debit cards only. For further information, please visit www.spirit.com at https://customersupport.spirit.com/hc/en-us/articles/217154817-Can-I-pay-with-cash-.

NOTE: Cash conversion kiosks (operated and independently managed by companies not affiliated with Spirit Airlines) may be available at some airport locations. In no event shall Spirit Airlines be liable for any direct, indirect, incidental or consequential damage arising out of the use of such cash conversion machines.

3.3 *Guest Initiated Modifications*

3.3.1. Changes to an itinerary must be made at least 45 minutes prior to the (original) scheduled departure time for all domestic flights, and 60 minutes prior to the (original) scheduled departure time for all International flights including U.S.V.I. flights (See section 2.4.1.a.). Online changes must be made at least one hour prior to the (original) scheduled departure.

Itinerary changes are subject to a per guest service charge, plus any difference in airfare for the alternate requested date(s) or flight(s), and any difference in government taxes and fees. With the exception of optional service charges for carry-on bags and/or first and second checked bags, any difference in carrier's optional service charges may also apply.

3.3.2. Cancellations to an itinerary must be made at least 45 minutes prior to the (original) scheduled departure time for all domestic flights, and 60 minutes prior to the (original) scheduled departure time for all International flights including U.S.V.I. flights (See section 2.4.1.a.). Online changes must be made at least one hour prior to the (original) scheduled departure.

Itinerary changes are subject to a per guest service charge. A credit for future travel on Spirit may be issued if any remaining value exists. Certain carrier charges may be excluded from the value of the credit. All credits for future travel must be booked within 60 days of issuance for travel on any flight dates available in the system and have no cash value. A credit for future travel is non-transferable. Taxes and fees will not be refunded except when required by applicable law and when requested. Failure to cancel prior to the time limit specified above will result in forfeiture of fare.

3.3.3. All Spirit fares and optional services are purchased as non-refundable; however, a refund will be allowed if a reservation is canceled within 24 hours of initial booking, provided the reservation was made seven (7) days (168 hours) or more prior to the flight's scheduled departure.

3.3.4. Optional services may be purchased separately during the booking process by calling Reservations, on spirit.com or at the airports. Click here for optional services.

3.4 *Routing*

A fare applies only to the following:

3.4.1. Transportation between airports via the intermediate cities, if any, specified by Spirit in reference to that fare.

3.4.2. Reservations may not be issued or accepted for transportation that will either originate or terminate at an airport other than the airport for which the fares are published.

3.5 *Children's Fare*

Spirit Airlines does not offer children fares.

4. ACCEPTANCE/REFUSAL OF GUESTS

4.1 *Identification*

A guest who refuses or fails to produce identification upon request may be denied service.

4.2 *Travel Requirements and Documentation*

The guest shall comply with all laws, regulations, orders, demands, or travel requirements (including but not limited to passports, visas, and health/immunization requirements) of countries to be flown from, into, or over, and with all rules, regulations, and instructions of Spirit.

4.2.1 Spirit shall not be liable for:

a. any aid or information given by any agent or employee of Spirit to any guest in connection with obtaining necessary documents or complying with such laws, regulations, orders, demands, requirements, or instructions, whether given orally, in writing, or otherwise;

b. the consequences to any guest resulting from his/her failure to obtain such documents or to comply with such laws, regulations, orders, demands, requirements, or instructions;

c. any expenses incurred due to the guest's failure to comply with this provision.

4.2.2 Spirit reserves, in its sole discretion, the right to refuse carriage to any guest who has not, in the judgment of Spirit, complied with applicable laws and regulations and Spirit policies.

4.2.3 The guest agrees to pay the applicable fare whenever Spirit, on government order, is required to return a guest to his or her point of origin or elsewhere due to the guest's inadmissibility into or deportation from a country, whether of transit or of destination.

4.2.4 Spirit reserves the right to hold, photocopy, or otherwise make an image reproduction of a travel document presented by any guest and accepted by Spirit as a condition of boarding.

4.3 *Conduct/Condition*

4.3.1. A guest shall not be permitted to board the aircraft or may be required to leave an aircraft if that guest:

a. is disorderly, abusive, violent, or their conduct creates an unreasonable risk of offense or annoyance to other guests;

b. appears to be intoxicated or under the influence of drugs;

c. interferes or attempts to interfere with any member of the flight crew in the pursuit of his/her duties, or fails to obey lawful instructions of flight crew members;

d. is or is perceived by the flight crew to pose a security threat or risk of harm or damage to the airline, its aircraft or property, and/or other guests, or their property;

e. has a contagious disease that is transmissible during the normal course of a flight, e.g., chicken pox;

f. is unable or unwilling to sit in a seat with a seat belt fastened during the normal course of a flight;

g. is barefoot or inadequately clothed, or whose clothing is lewd, obscene, or offensive in nature; or

h. has an offensive odor unless caused by a qualified disability.

4.3.2. If a guest is not permitted to board and/or required to leave an aircraft for safety and/or regulatory reasons under paragraph 4.3 and its sub sections, the guest will not be eligible for a refund.

4.3.3. Diversion of Aircraft - If Spirit is required to divert an aircraft to land at a location other than its intended destination, return an aircraft to a gate during taxi prior to takeoff or if a flight is delayed due to a passenger's disruptive or disorderly conduct, Spirit will be entitled to reimbursement from the passenger for the additional costs that Spirit incurs for such incidents including, but not limited to, costs to accommodate other passengers, excess crew and ground handling costs, fuel and fees. The amount due will be as determined by Spirit.

4.4 *Refusal to Transport*

Spirit may refuse to transport, or remove from any flight, any guest for the following reasons:

4.4.1. Compliance with any government regulation or with government request for emergency transportation in connection with national defense or national disasters (actual, threatened, or reported).

4.4.2. Whenever necessary or advisable by reason of weather or other conditions beyond its control (including, without limitation, acts of God, labor disturbances, strikes, civil commotions, embargoes, wars, hostilities, or disturbances) actual, threatened, or reported.

4.4.3. Refusal by a guest to permit a search of person or property for explosives, or for deadly or dangerous weapons, articles, or substances.

4.4.4. Spirit may refuse to transport any guest who is traveling across any international boundary if:

4.4.4.1. the travel documents of such guest are not in order;

4.4.4.2. for any reason, such guest's embarkation from, transit through or entry into any country from, thru, or to which such guest desires transportation would be unlawful; or

4.4.4.3. such guest fails or refuses to comply with the rules and regulations of Spirit.

4.4.5. All guests are required to wear an appropriate face covering while at the airport, on the jet bridge, and onboard the aircraft.

All face coverings must:

- Snugly cover the nose and mouth and be secure under the chin, and
- Have at least two layers of fabric (e.g., disposable non-medical face mask, multi-layered cloth face covering)

The following items are not considered appropriate face coverings:

- Open-chin triangle bandanas
- Face coverings containing valves or mesh material
- Face shields

4.4.5.1. Exceptions:

The following guests may be exempt from the face covering requirements:

- Children under the age of two; and
- Guests who cannot wear or safely wear an appropriate face mask due to a disability recognized by the Americans with Disabilities Act (ADA) who meet certain criteria. Additional information regarding this exemption can be found at our COVID-19 FAQ page under "I have an upcoming flight and cannot wear a face mask due to a disability."

NOTE: This exemption is narrowly interpreted and will be vetted through a strict approval process. Spirit will not allow a guest onboard who simply does not want to wear a mask because they find mask-wearing difficult.

4.5 Prisoners

Spirit Airlines will not transport prisoners in the custody of law enforcement under any circumstances with or without restraints.

4.6 Guests with Disabilities

All guests with disabilities will be provided transportation except when refused transportation per the FAA Regulations regarding safety. Guests with disabilities need not give advance notice. A 48-hour advance notice is only required for the services, equipment, and accommodations stated in the DOT's 14 CFR part 382.27 (c) regarding nondiscrimination on the basis of a disability in air travel.

4.6.1. Attendants

Guests with disabilities are not required to travel with an attendant unless it is determined by the carrier that an attendant is essential for safety as stated in the DOT's 14 C.F.R. part 382.29 regarding nondiscrimination on the basis of a disability in air travel. Spirit personnel are not obligated to provide special assistance for personal needs (e.g., assistance in actual eating, assistance within the restroom, provision of medical services).

NOTE: Attendants must be at least 15 years of age at the time of travel.

4.6.2. Medical Certificates

If there is reasonable doubt that a guest can complete their flight safely, without requiring extraordinary medical assistance during flight, a medical certificate may be required in order for the guest to travel. A medical certificate is a written statement from a doctor asserting that an individual is capable of completing a flight safely, without requiring extraordinary medical assistance during flight. Medical certificate must be dated within 10 days of the guest's departure flight.

4.7 Communicable Disease

If a guest has a disease that is potentially transmissible during flight, a medical certificate is required and must state that the guest's condition would not be communicable to other guests during the normal course of the flight. If it is potentially transmissible during the flight, but this can be prevented if certain conditions or precautions are implemented, the certificate would have to describe those conditions or precautions. In such instances, Spirit will put forth reasonable effort to carry out these measures, however, if Spirit is unable to do so, the guest will not be permitted to travel. A medical certificate in the situation of a communicable disease must be dated within 10 days of the flight for which the guest intends to travel (not 10 days prior to the guest's initial departure flight).

4.8 Respiratory Assistive Devices/Portable Oxygen Concentrators (POC)

Certain respiratory assistive devices (including portable oxygen concentrators, respirators, and ventilators) which are approved by the FAA for use in flight may be used on board Spirit Airlines aircraft. Guests using such permitted devices must do so strictly in accordance with applicable regulations, including the carriage of sufficient batteries. Spirit Airlines personnel are not trained to assist with or operate such devices.

Guests are encouraged to review any applicable requirements by referring to Spirit's website (www.spirit.com) or by contacting Spirit Airlines Reservations at 855-728-3555. It is also recommended that the guest call Spirit Airlines Reservations at least 48 hours before scheduled departure, to have it documented that the guest will be traveling with and using a respiratory assistive device onboard. To use a POC on board, guests must have an FAA approved POC. For more information, please review Portable Oxygen Concentrators within the Special Items Chart in 7.5.

4.9 Pregnancy

Guests who are pregnant are urged to consult with their physician on whether it is safe to travel by air, including with due consideration the possibility of turbulence, cabin pressurization, significantly increased risk of deep vein thrombosis associated with pregnancy, and lack of ready access to medical care. This is particularly important for women in their ninth month of pregnancy, who are urged to obtain an examination from her physician shortly before flying to confirm that flying by air will be safe. Women with a history of complications or premature delivery should not fly at all. By travelling with Spirit, pregnant women acknowledge and accept these risks.

4.10 Guests of Size

Additional Seat Purchase – The purchase of more than one seat for use by a single guest is required to accommodate a guest of size who encroaches on an adjacent seat area and/or is unable to sit in a single seat with the armrests lowered.

4.10.1. The guest of size can either purchase a seat assignment in a Big Front Seat or purchase another reservation for an additional seat on the aircraft. Please see section 4.11.2 for information related to seatbelt extensions and inflatable seatbelts.

4.10.2. If there are no available seats on the aircraft, the guest will be booked on Spirit's next available flight or the reservation will be refunded.

4.11 *Seats*

4.11.1 It is the guest's responsibility to notify Spirit of a unique seating need. In accordance with the Contract of Carriage, Spirit may refuse to transport individuals who are unable or unwilling to comply with Spirit's seating requirements.

4.11.2 Inflatable Seatbelts

Inflatable seatbelts are located on Spirit's Airbus A319, A320, and A321 aircraft, which includes some Big Front Seats (For additional information related to inflatable seatbelt locations, click here.). Any guest who occupies a seat that is equipped with an inflatable seatbelt must have their seatbelt securely fastened (buckled low and tight) around the guest's lap. Additionally, any guest traveling with a lap child or service animal that will sit in the guest's lap shall not be permitted to occupy a seat equipped with an inflatable seatbelt. Car seats may not be accommodated in any seat equipped with an inflatable seatbelt.

If a crew member determines that the guest cannot be safely accommodated as indicated above, he/she will attempt to reseat the guest and, if the original seat was purchased, the guest will be entitled to a refund for the optional service charge paid for such seat.

NOTE: Seatbelt extensions may not be used in any seat equipped with an inflatable seatbelt.

5. ACCEPTANCE OF CHILDREN

5.1 *Accompanied Children*

Accompanied children are accepted for transportation on both domestic and international flights as follows:

5.1.1. Children under 15 years of age are accepted when accompanied on the same flight by another guest who is at least 15 years of age.

5.1.2. For travel to/from an international destination, all children, regardless of age, are required to have a valid passport and all foreign government documentation required for entry into and departure from the foreign country. These documents must be provided to Spirit at time of check in. It is the guest's responsibility to verify foreign government documentation and entry requirements.

5.2 *Unaccompanied Children*

Unaccompanied children are accepted for transportation only on domestic flights as follows:

5.2.1. For travel wholly within the United States and its territories, children at least 5 years of age through 14 years of age are accepted for unaccompanied travel on Spirit flights that do not involve a scheduled change of aircraft (i.e., connecting flights). Unaccompanied children will not be accepted for travel on connecting flights or for travel on international flights.

5.2.2. Children less than 5 years of age will not be accepted for unaccompanied travel.

5.2.3. Spirit does not accept unaccompanied children for travel to/from international destinations.

5.2.4. Young adults aged 15 or older are permitted to travel alone domestically and internationally. For international travel, they are required to have a valid passport and any other documents required by the country they are traveling to.

5.2.5. A service charge will apply for each unaccompanied child per way of travel, which includes Federal Excise Tax required to be collected and remitted to the U.S. government.

5.2.6. All travel by unaccompanied children must be on flights on which the child holds a confirmed reservation.

5.2.7. Gate Passes and Handling Procedures for Unaccompanied Minors

5.2.7.1. All unaccompanied children must check in at the airport ticket counter with his/her parent or other responsible adult. Online check-in is not available for unaccompanied children.

Be sure to arrive to the airport early in order to complete the required documentation and to see the child safely through security screening (when permitted by airport) and identify the child to the gate agent for the boarding process.

5.2.7.2. The adult must remain at the airport until 15 minutes after the flight takes off.

5.2.7.3. Spirit must be provided the name and phone number of the parent or other responsible adult who will meet the child upon deplaning. The Guest Service Agent documents the information on an Unaccompanied Minor form, and places a copy of this information into a pouch. The pouch is then placed around the child's neck to identify to the Flight Attendants that the child is traveling alone as an unaccompanied minor.

If the minor(s) is not met upon arrival by the individual responsible for meeting the minor(s), Spirit shall take whatever action deemed necessary by Spirit to ensure the minor(s) safe custody, including the return of the minor(s) to the airport of departure. The responsible adult who accompanied the minor(s) to the departure airport shall be responsible to reimburse Spirit for any and all expenses incurred by such actions.

5.2.7.4. The person dropping off the child must obtain a gate pass at the airport ticket counter (where permitted), then escort the child to the gate. The person picking up the child must obtain a gate pass at the airport ticket counter (where permitted) to proceed to the gate for the arrival of the flight. Spirit Airlines requires a photo Identification

from the person(s) designated to meet the minor at the destination and will not release the child to anyone else.

Gate passes are only provided for an escort of an Unaccompanied Minor and for people who require assistance. Gate passes are not issued to anyone who requests a gate pass; there must be a valid reason. TSA requirements/security restrictions may vary based on the airport; thus, gate passes will be issued dependent on the current airport security/TSA guidelines.

5.3 *Infants*

5.3.1. Spirit encourages all adults traveling with children under the age of two (2) to purchase a seat for the child and secure the child in an FAA approved car seat. A paying adult guest may carry on his or her lap one infant over seven (7) days and under two (2) years of age (24 months). Once a child reaches their second birthday, they are no longer permitted to travel as a lap child. Spirit reserves the right to request documented proof of age for any traveler 2 years of age or younger. Please be prepared to provide documentation (birth certificate, passport, etc.) upon request.

5.3.2. If space is available after boarding, or if a separate reservation has been purchased for an infant over seven (7) days and under two (2) years of age, the infant may travel in a separate seat, provided that the infant must be securely placed in an FAA approved child restraint system (car seat) which meets the guidelines in section 5.4.

5.3.3. An infant, age seven (7) days or less or an infant requiring an incubator or other life-support systems shall not be accepted for travel on Spirit.

5.4 *Car Seats*

One (1) car seat and one (1) stroller (i.e., collapsible stroller, compact folding stroller, or folding wagon) will be accepted per child as checked baggage at no charge. These items are not considered part of the guest's baggage allowance. Car seats may be carried on board the aircraft if a seat has been purchased for the child; one (1) child per car seat. To be accepted for use on board, car seats must be FAA approved and conform to the following guidelines:

5.4.1. Child Seats manufactured before 2/26/1985 must bear the label "This child restraint system conforms to all applicable federal motor vehicle safety standards."

5.4.2. Child Seats manufactured after 2/25/1985 must bear the following two labels:

1) "This child restraint system conforms to all applicable federal motor vehicle safety standards" and,

2) "This restraint is certified for use in motor vehicles and aircraft."

5.4.3. Child Seats bearing the approval of a foreign government or seats manufactured under the standards of the United Nations are also acceptable.

NOTE: Car seats may not occupy a seat in an exit row, the row in front of or behind an exit row, or any seat equipped with an inflatable seat belt.

Some FAA approved car seats may not always fit in certain Spirit Airlines aircraft seats (see minimum seating dimensions below). Depending on the type of aircraft, Spirit Airlines will either try to re-seat the guest or re-accommodate them. If the car seat is not able to be safely accommodated on the aircraft (e.g., car seat too large for the aircraft seat) and the guest has purchased an extra seat which cannot be utilized, a refund will be issued without penalty.

Spirit Airlines minimum seating dimensions can be found by visiting Spirit's website at https://customersupport.spirit.com/hc/en-us/articles/202096526-Can-I-bring-my-child-s-car-seat-and-or-stroller-onboard-.

NOTE: Car seats that exceed these dimensions may not fit or be safely accommodated on Spirit Airlines seats.

5.4.4. CARES Child Aviation Restraint Systems are acceptable for use on board as an alternative to a car seat. A CARES device is a child safety harness that has been approved by the FAA to be used for aviation use only.

6. ACCEPTANCE OF ANIMALS

6.1 *General*

The guest assumes full responsibility for the conduct of his or her accompanying pet or service animal. In the event Spirit incurs any loss, damage, delay, expense or legal liability of any kind in connection with the transport of such animal, the guest accepts full liability for any sums incurred.

6.2 *Pet Animals in Cabin*

Transportation of pet animals in cabin must meet the following conditions:

On domestic flights (between two points within the United States or between the United States and its territories), for an extra charge, Spirit will only accept domesticated dogs, cats and in some cities rabbits and small household birds (including parrots, finches, canaries and parakeets). Birds that are not considered household birds and will not be accepted are farm poultry, waterfowl, game birds, birds of prey, or flightless birds. Guests traveling to/from U.S territories are responsible for checking with the local government for specific laws or regulations regarding the acceptance of pets, including furnishing valid health and rabies vaccination certificates. Rabbits and birds are not accepted to and from cities in Puerto Rico and the U.S.V.I. For additional information please contact Spirit Guest Service at 855-728-3555.

Spirit Airlines does NOT accept pets in cabin for travel on international flights except in the case of service animals when permitted by the international destination and provided the guest complies with the requirements in section 6.3, including any specific requirement(s) of the international destination.

Spirit will accept pets for transportation in the guest cabin under the following conditions:

1) The animal is harmless, not offensive, odorless, and requires no attention during transit.

2) The container must be inspected and approved by Spirit and able to fit underneath the seat in front of the guest traveling with the animal. (Maximum container size is 18" x 14" x 9" (45.72 cm x 35.56 cm x 22.86 cm) in overall dimensions (L x W x H). The combined weight of the pet and carrier may not exceed 40 pounds (18.14 kg). The pet must be able to stand and turn around in the container.

3) Only one (1) pet container, per guest with a confirmed reservation is permitted. A maximum of two (2) similar pets (e.g., two dogs, two cats) may travel in one (1) container provided the animals are small enough to be accommodated in one (1) pet carrier. The pet(s) may NOT be removed from the container during transit.

4) A maximum of six (6) pet containers are allowed per aircraft cabin.

5) In the event the animal becomes offensive or causes a disturbance during transit, the pet will be removed at the first en route stop.

6) Spirit assumes no responsibility for the impaired health or death of the animal.

7) There is a service charge for each pet carrier.

8) Unaccompanied Minors are not permitted to travel with pets.

9) A pet carrier containing a pet counts towards the guest's carryon baggage allowance.

6.3 Service Animals

Spirit accepts for transportation, without charge, service dogs if they meet the requirements detailed in this section. No other type of animal will be accepted.

A service animal is defined as a dog, regardless of breed or type, that is individually trained to do work or perform tasks for the benefit of a qualified individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability.

Spirit reserves the right to ask if an animal is needed to provide assistance for a disability. Our team members are trained to ask certain questions to determine if an animal is a service animal.

NOTE: More than two (2) service animals per guest will not be accepted.

6.3.1. Service Animal Accommodation

The service dog must be accommodated in accordance with FAA safety regulations.

The service dog must be able to fit on your lap if the dog is smaller than a two-year-old child, or fit within your foot space without blocking the egress of any other guest. If the dog is in a pet carrier, the pet carrier requirements in section 6.2 must be met.

Spirit will make every reasonable effort to accommodate the guest in the event that the assistance of up to two (2) service dogs is required. If the dogs cannot be accommodated together at a single passenger seat or if a dog is too large to be safely accommodated, the guest may purchase an additional reservation(s), so that the dog(s) can be accommodated in accordance with FAA safety regulations, or the guest may be accommodated on a later flight where more seats are available.

6.3.2. Service Animal Air Transportation Form and Advance Notice

Effective February 15, 2021, to travel with a service dog, you must submit the U.S. Department of Transportation (DOT) Service Animal Air Transportation Form attesting to the dog's health, training, and behavior at least 48 hours before your flight. Spirit's Guest Care Department will notify you upon document approval.

The form may be completed at the airport if you purchased your reservation within 48 hours of departure. Be sure to arrive early.

Instructions:

1. Download the Service Animal Air Transportation Form at www.spirit.com/serviceanimals.
2. Read and complete the form.

   NOTE: Two (2) forms are required if traveling with two (2) service dogs.
3. Submit the form(s) at http://www.spirit.com/submitserviceanimaldocat least 48 hours before the flight.

   NOTE: Guest Care will notify you upon document approval.
4. Keep the form with you for the entire duration of your trip.

NOTE: The form must be submitted for each reservation as they are not kept on file.

6.3.3. International Travel

For international travel, depending on the international destination, specific documentation regarding the service dog may be required. Guests are responsible for checking with the destination country for rules of acceptance of service animals as certain countries have restrictions and/or quarantine guidelines. For additional information please contact Spirit Guest Care at 855-728-3555.

6.3.4. Animal Behavior

The service dog must remain under the control of its handler. If at any time the dog shows signs that it will cause a disruption in the cabin, it has not been trained to function as a service animal in a public setting, or any signs of aggression, it will not be allowed to travel.

6.3.5. Emotional Support Animals and Service Animals in Training

Spirit accepts emotional support animals and service animals in training for transportation as a pet in cabin for an extra charge. The animals must meet all the applicable pet in cabin conditions detailed in section 6.2.

6.3.6. Search and Rescue Animals

Animals trained to detect explosives or trained for search and rescue on official duty status may be transported. Spirit Airlines reserves the right to request documentation.

6.4 Animals Checked as Baggage

Spirit Airlines does NOT accept animals as cargo or as checked baggage.

7. BAGGAGE

7.1 General

7.1.1. All baggage charges are non-refundable and may be paid in advance or at the airport. Certain countries may require taxes be collected on baggage charges. In such instances in addition to any other applicable charges set forth herein, such taxes will be collected by Spirit and paid to the taxing authority or as required under local regulations. In the event of a modification of an itinerary, the guest may have to pay any applicable increase in baggage charges. See section 3.3 for further information.

7.1.2. Baggage charges are applicable per item, per way of travel, with the exception of stopovers and reservations purchased with multiple individual flight segments rather than as a valid connecting flight within the Spirit reservation system. In such instances, baggage charges are applicable per item, per individual flight segment. It is the guest's responsibility to claim their checked item(s) at each point of stopover. The item(s) must then be re-checked at the ticket counter prior to boarding the next flight segment on the reservation. Spirit is not liable for baggage which is not transferred due to the purchase of a non-valid connection.

7.2 Carry-On Baggage

7.2.1. One (1) carry-on bag is permitted in the aircraft cabin for a charge.

7.2.2. Spirit Airlines guests may bring one (1) carry-on bag plus one (1) personal item (such as a purse, laptop computer, backpack, or duty free item) on board providing they meet the size limitations listed in sections 7.2.3 and 7.2.4.

7.2.3. Carry-on baggage must fit into an overhead bin or under-seat space and not be more than 22 inches by 18 inches by 10 inches (56 cm x 46 cm x 25 cm) including handles and wheels. Pieces exceeding these dimensions must become checked baggage.

7.2.4. Personal items may not exceed the dimensions of 18 inches by 14 inches by 8 inches (45 cm x 35 cm x 20 cm) including handles and wheels. Any item that

exceeds these dimensions is no longer considered a personal item and a carry-on or checked bag charge will apply.

7.2.5. The following items do not count towards a guest's carry-on allowance. Although these articles are exempt from carry-on limitations, they must be properly stowed for ground movement, takeoff and landing.

These exempt articles include, but are not necessarily limited to the following:

a) Assist pet carrier when traveling with assist/service animal

b) Camera

c) Crutches/Canes/Braces or other prosthetic device upon which the guest is dependent

d) Guest assistive devices & service animals

e) Food for consumption on board the flight

f) Infant bag, when traveling with the infant

g) Infant/Child Car Seats, when the child is carried in the seat

h) One Duty Free box or bag containing Duty Free items

i) Outer garments (coats/hats/wraps)

j) Reading material for the flight

k) One collapsible stroller, compact folding stroller, or folding wagon, when the child is carried in the device

l) Umbrella

7.2.6. Spirit may require that a carry-on be checked as baggage if the item cannot be safely stowed or if it doesn't comply with Spirit's baggage policies set forth herein. Excess items will be charged according to checked baggage charges.

7.2.7. Seat Baggage

An item of baggage may occupy a seat, subject to applicable regulations, provided the guest accompanies the property, the item meets specified dimensions, the item can be properly secured by the seatbelt, reservations are made in advance, and the applicable fare is paid. Items accepted as seat baggage cannot block placards or signs.

Animals are NOT accepted as seat baggage.

7.3 Checked Baggage

7.3.1. Charges apply for all checked baggage. Spirit Airlines allows up to five checked bags/items per paying guest (restrictions may apply to certain destinations and during specific times of the year).

7.3.2. Checked Baggage Size and Weight Restrictions:

7.3.2.1. Any checked baggage that exceeds the standard size and weight limit including handles and wheels is subject to excess baggage charges in addition to the standard checked baggage charge (a standard checked

bag is defined as a bag not exceeding 62 linear inches in overall dimensions (Length + Width + Height) and 40 pounds in weight).

7.3.2.2. Spirit Airlines will not accept baggage that weighs more than 100 pounds with the exception of mobility aid devices and musical instruments (For more information on musical instruments see the Special Items chart in section 7.5).

7.3.2.3. With the exception of certain items, Spirit Airlines will not accept baggage that measures more than 80 linear inches in overall dimensions (Length + Width + Height).

7.3.2.4. From December 1st to January 10th, the following restrictions apply to guests flying to and from international destinations (except Lima, Peru see section 7.3.2.5, and Colombia and Ecuador see section 7.3.2.6). Guests may check one (1) item and may purchase additional checked items on a first-come first-serve basis based on inventory. Overweight baggage is subject to overweight baggage charges. Oversized items up to 80 linear inches in overall dimensions (203 cm) are permitted and are subject to oversized baggage charges.

7.3.2.5. When traveling to and from Lima, Peru, guests may check one (1) item and may purchase additional checked items on a first-come first-serve basis based on inventory. Overweight baggage is subject to overweight baggage charges. With the exception of Bicycles, Ski Equipment, Surfboards, and Javelin/Vaulting Pole Equipment as stated in section 7.5, items measuring more than 80 linear inches in overall dimensions will not be accepted. From December 1st to January 10th, any item (including those listed above) will not be accepted if the item(s) exceeds 80 linear inches.

7.3.2.6. When traveling to and from Colombia and Ecuador, guests may check one (1) item and may purchase additional checked items on a first-come first-serve basis based on inventory. Checked items are subject to overweight and oversized charges.

7.3.3. Spirit will check baggage for a guest with a valid reservation subject to the following conditions:

7.3.3.1 Baggage must be checked at the airport in advance of flight departures as described in section 2.3.3.

7.3.3.2 Name identification is required on the outside of all baggage. Spirit recommends placing identification, including phone number, on the inside as well.

7.3.4 Baggage will only be checked to:

7.3.4.1 To the guest's final destination or to the guest's next airport of stopover.

7.3.4.2 Spirit will refuse to transport or will remove at any airport, baggage that a guest refuses to submit for inspection. Spirit may refuse to transport a guest's baggage on any flight other than the flight carrying the guest.

7.3.5 Delayed, Damaged and Lost Baggage

In the event your baggage does not arrive at your destination with you, please file a report to immediately initiate a search for the mishandled piece(s). If a bag/item is delayed, lost, damaged or pilfered, a Spirit Airlines representative must be notified and a report must be filed within four (4) hours of arrival of the flight on which the guest traveled (unless applicable law or treaty provides for a longer period of time).

For international travel, in the case of baggage damage, the guest entitled to delivery must notify Spirit as soon as possible after discovery of the damage, and no later than seven (7) days from receipt of checked baggage. In the case of delay or loss, Spirit must be notified no later than twenty-one (21) days from the date on which the baggage should have been placed at the guest's disposal.

For your convenience, most U.S. domestic locations offer a virtual Baggage Service Office. Information about filing a report via the virtual Baggage Service Office can be found in the baggage claim area at each of these locations. In international and Caribbean locations, including Puerto Rico and the U.S.V.I, guests will file a report with a Guest Service Agent at the airport.

Reasonable efforts will be made to deliver delayed baggage within 24 hours of flight arrival. Once your belongings are located, they will be returned to you as quickly as possible. Baggage delayed due to guest's late check-in, change in destination after check-in or a guest traveling standby, will be delivered at the guest's expense.

7.3.6 Delayed Baggage - Reimbursable Expenses

Spirit Airlines allows reasonable interim expenses for guests whose bags have been delayed. Interim expenses incurred are limited to reasonable personal items, such as clothing and toiletries purchased as a result of the delay. All original receipts must be provided for reimbursement; copies will not be accepted. Spirit Airlines reserves the right to request that items purchased as a result of a delayed bag be returned prior to the issuance of compensation. Items purchased are intended to replace items in a delayed bag. Any reimbursement is considered an advance and will be deducted from a final settlement in the unlikely event the bag is deemed lost.

7.3.7 Delayed Baggage – In Excess of Five (5) Days

If your baggage has not been located and returned within five (5) days, a claim should be filed with Central Baggage. To file a claim, you will need to complete the online claim form. The online claim form is a different form from the delayed baggage report that is filed at the airport. Additional information and details that you provide on this form will assist Central Baggage with advanced

tracing and help improve the likelihood of success in locating your baggage. For further details on filing a claim, see section 7.3.9.

7.3.8 Damaged Baggage

If your bag is damaged a report must be completed within the required time limit set forth in section 7.3.5.

Once a report is completed, a claim should be filed with Central Baggage. To file a claim, you will need to complete the online claim form. For further details on filing a claim, see section 7.3.9.

7.3.9 Filing A Baggage Claim

All claims for compensation (e.g., delay, loss, damage and pilferage) are filed at www.spirit.com/bagclaim and must include a completed online claim form inclusive of all the required documents.

Verifiable proof of purchase (receipts) is required for all claimed items with a declared value of $50.00 and higher. For interim expenses, verifiable proof of purchase of reasonably priced items is required for all items.

NOTE: Spirit Airlines reserves the right to request original documents of interim purchases to be mailed.

Actual value for reimbursement of all mishandled baggage is determined by the original purchase price, less reasonable depreciation for prior usage (not applicable to assistive devices).

The claim and all the required documents must be received within thirty (30) days of the date of arrival unless applicable law or treaty provides for a longer period of time.

7.4 Fragile and Perishable Items

Fragile/Perishable items are only accepted if a Spirit employee is made aware of such item, and a release is signed that indemnifies Spirit against liability for damage to, loss or spoilage of, or delay in delivery resulting in damage to, loss or spoilage of such items. Failure to alert Spirit of fragile/perishable items in baggage may result in denial of loss or damage claims.

The following are some examples of items that are fragile or perishable, or otherwise unsuitable as checked baggage, and are subject to the conditions of acceptance set forth above: bicycles, blueprints, cameras, ceramics, china, crystal, dolls, figurines, flash equipment, flowers, glass or glass containers, lenses, maps, mirrors, models, paintings, perfumes, liquids, bottles, musical instruments and equipment, kites, surfboards, seafood, plants, sculptures, strollers, trophies, vases, folding wagons and wines.

Perishable items include, without limitation, items such as fruit, vegetables, meats, fish, poultry, bakery products and other forms of food, flowers and floral displays and plants and similar articles requiring maintenance at specific temperatures such as medicine must meet local agricultural guidelines.

Spirit will refuse to accept property for transportation that is not suitably packaged to withstand ordinary handling, the size, weight or character of which makes it unsuitable for transportation, or that cannot be accommodated without harming or annoying guests. Fragile and perishable items will be accepted if the tube, container or case is designed for shipping such items, and it is packed in leak-proof containers or in airline approved protective material.

NOTE: Plastic bags or foam containers are not acceptable for frozen food or other items that may leak during transit.

7.5 *Conditions for Acceptance of Special Items*

The following items may be accepted as carry-on and/or checked baggage with restrictions. Standard baggage charges apply to ALL checked items and carry-on items (that exceed personal item dimensions), except where a special charge is indicated below. Size and weight charges may also apply, unless the overweight or oversized charge is specifically waived as stated below. To be accepted as carry-on baggage, the item must be within the size limits listed in section 7.2. Checked baggage may require a limited liability release tag, which can be obtained at the Spirit Airline's airport ticket counter.

For safety and security reasons, all items must be securely packed inside a bag or case/container. Unsecured items may not be attached to a bag. Items that are packed separately will be considered two separate items and are subject to separate service charges.

SPIRIT DOES NOT PROVIDE SHIPPING BOXES.

NOTE: The following list is NOT all inclusive.

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Alcohol	A maximum of 5 Liters or 1.3 gallons of liquor products containing more than 24% and no more than 70% alcohol by volume are allowed to be carried per guest in checked baggage. Containers must be unopened and packaged so as not to break or leak. One duty free box or bag containing duty free items is permitted in addition to the standard carry-on baggage allowance. * Liquor products over 70% alcohol by volume (over 140 proof) will NOT be accepted.	Yes – with exceptions*	Yes – with exceptions*	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Antlers	Dimension (L + W + H) must not exceed 120 linear inches. Head/skull must be completely clean and free of residue. Points must be covered and protected.	No	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Archery Equipment	Archery equipment must be packed in a case or in a container of sufficient strength to protect the bows and quiver with arrows from accidental damage.	No	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Artistic Items	Items include but are not limited to: oversized pictures, drawings, statues, models, souvenirs, art objects, curios and similar articles.	Yes	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Balls/ Balloons	Items include but are not limited to: Footballs, soccer balls, basketballs, volleyballs. Items may need to be slightly deflated for safe transport. Helium balloons may be transported if completely deflated.	Yes	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Baseball Equipment	* While baseball equipment will be accepted, baseball bats will not be accepted as carry-on baggage.	Yes – with exceptions*	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Bicycles	Bicycles are included as part of the guest's standard baggage allowance and will be accepted for a special charge per direction. Oversize limits and charges are waived for bicycles. Overweight charges are waived for bicycles. Bicycle equipment may consist of (1) non-motorized touring or racing bicycle with a single seat. Bicycles should be prepared for transportation by the guest. Bicycle must be placed in a cardboard or hard cased bike container. Bicycle tires must be deflated. Bicycles not enclosed will NOT be accepted. * Spirit reserves the right to refuse transportation of these items due to safety and/or operational limitations.	No	Yes – with exceptions*	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Body boards, Boogie boards, Kiteboards, and Wakeboards,	One item includes one board with any keels or fins removed and placed in checked baggage to prevent damage. One item will count as a checked bag provided it does not exceed 62 linear inches. Overweight charges are applicable. Items that exceed 62 linear inches will be classified as surfing equipment and will have a special charge per direction. See Surfing Equipment for more details.	No	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Bowling Equipment	* To be stowed onboard, bowling bags must fit under the seat in front of you, and contain only one (1) bowling ball. Bowling balls may not be stowed in the overhead bins.	Yes – with exceptions*	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Boxes and Plastic Containers	Boxes may be opened and inspected upon check-in. Boxes must meet the same restrictions contained in our baggage acceptance policy. Boxes must have the strength to hold the contents. Spirit is not responsible for packaging/re-packaging any boxes. * Boxes may be transported as checked baggage to all locations except when embargos are in place. Boxes containing or having contained hazardous material are NOT accepted.	Yes	Yes – with exceptions*	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Camping Gear	Items include but are not limited to: Backpacks, sleeping bags, and knapsacks * Any dangerous goods such as flares, camping stove fuel, etc. are NOT accepted.	Yes – with exceptions*	Yes – with exceptions*	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Ceramics/ Chinaware/ Glass	Items include but are not limited to: Pots, statues, bowls, dishes, glasses or other containers made of clay hardened by heat, earthenware, crockery, and containers or ornaments made of porcelain or baked clay, and items made of or containing glass and similar articles. * To be accepted as checked baggage, these items must be packed properly.	Yes	Yes – with exceptions*	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Dry Ice	Spirit accepts solid dry ice in quantities not exceeding 5.5 lbs. in carry-on or checked baggage. The following conditions apply: • The dry ice must be used as a refrigerant for the contents of the container. • The container must be ventilated to allow for the venting of carbon dioxide gas. • Additionally, as checked baggage, the package must: o Be clearly marked “DRY ICE” or “CARBON DIOXIDE SOLID” o Be marked with the net weight of the dry ice or an indication that the net weight of the dry ice is 5.5 pounds (2.5 kg.) or less.	Yes	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Electric Chainsaws	Electric chainsaws must be packaged in original container or hard sided container for safe transport. Spirit does NOT permit other types of powered chain saws, such as fuel or gas powered, on any flight due to the DOT’s requirements for transporting hazardous materials.	No	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Electric Skateboards & Hover Boards	Electric skateboards and hover boards are NOT allowed for transport.	No	No	N/A

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Electronic Cigarettes (e-cigarettes)	* E-cigarettes and other battery-powered smoking devices are NOT allowed to be used onboard any Spirit Airlines aircraft. Some countries (e.g. Dominican Republic) prohibit the carriage of these devices in carry-on baggage, checked baggage, and/or on one's person, in which case Spirit will enforce such prohibition(s).	Yes – with exceptions*	No	N/A

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Electronics	Items include but are not limited to: All video and audio devices, televisions, radios, computers, stereo equipment, VCR players, VCR recorders and their accessories, typewriters, hair dryers, sewing machines, specialized equipment, and similar articles.	Yes	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Firearms & Ammunitions	**Firearms** Firearms are accepted provided that all of the following provisions are met: 1. The guest checking the firearm is at least 18 years of age. 2. The guest is not traveling to an international destination. 3. The guest declares the firearm to be unloaded and signs a Firearms Declaration tag. NOTE: A guest checking multiple firearms must complete a Firearms Declaration tag for each firearm checked. 4. The firearm is in a hard-sided container which is locked, and only the guest retains the key or combination. 5. A signed Firearms Declaration tag(s) must be placed as follows: • If the hard-sided locked container is inside another piece of luggage, the tag shall be placed inside the luggage next to the locked container. • If the firearm is a rifle or shotgun, the tag shall be placed inside the locked hard-sided rifle or shotgun case. • If the firearm is contained in a locked hard-sided suitcase, the tag shall be placed inside the suitcase next to the firearm.	No	Yes	No

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
	Ammunitions Small arms ammunition (up to 19.1 mm for rifle and pistol cartridges, any size shotgun shells) for personal use is accepted provided that all of the following provisions are met: 1. The guest is not traveling on an international flight, and is not under the age of eighteen. 2. Amount of ammunition must not exceed eleven pounds (11 lb.) per guest. 3. Ammunition must be securely packed in boxes or other packaging specifically designed to carry small amounts of ammunition. Ammunition clips and magazines must also be securely boxed. 4. Firearms and properly packaged ammunition may be carried in the same hard-sided container. Or, the ammunition may be carried in a separate piece of checked baggage.			

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Fishing Equipment	Fishing rods/poles must be secured in a case or container. Guests may pack reels or fragile tackle that do not pose a security threat in their carry-on baggage. * Tackle Equipment such as sharp fishing may be considered dangerous, such as large fish hooks, should be sheathed, securely wrapped, and will be accepted as checked baggage only.	Yes – with exceptions*	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Golf Equipment	Golf bags containing golf clubs are exempt from oversize charges; however, overweight charges are applicable. Golf equipment should be enclosed with a cover to prevent loss of contents. Hard sided carriers are recommended. *Golf Clubs will not be accepted as carry-on baggage.	Yes – with exceptions*	Yes	Yes (soft-sided golf bags only)

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Hockey Equipment	One item of hockey equipment includes two (2) hockey sticks (taped together) and one bag containing only hockey equipment. Bags containing hockey sticks are exempt from oversize charges; however, overweight charges are applicable. *Hockey sticks will not be accepted as carry-on baggage.	Yes – with exceptions*	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Household Articles	Lamps, lamp shades, furniture and items of similar nature are acceptable if properly packaged.	Yes	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Ice	Spirit does not accept any form of loose or cubed ice for transport to be packed in coolers, lunch bags, etc. * Frozen water in bottles or ice packs can be used as a refrigerant.	Yes – with exceptions*	Yes – with exceptions*	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Incubators	Incubators are NOT allowed for transport.	No	No	N/A

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Javelin/ Vaulting Pole Equipment	Vaulting poles and javelins are exempt from size limits; however, oversize charges apply if the item is greater than 62 linear inches. Overweight charges are applicable. * Spirit reserves the right to refuse transportation of these items due to safety and/or operational limitations.	No	Yes – with exceptions*	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Kayak, Boat, Canoes	Kayaks, Boats, and Canoes are NOT allowed for transport.	No	No	N/A

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Lacrosse Equipment	One item of lacrosse equipment includes two (2) lacrosse sticks (taped together) and one bag containing only lacrosse equipment. Bags containing lacrosse sticks are exempt from oversize charges; however, overweight charges are applicable. * Lacrosse sticks will not be accepted as carry-on baggage.	Yes – with exceptions*	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Lithium Ion Batteries for Mobility Assistive Devices	* A maximum of one spare battery not exceeding 300 watt hours (Wh), **or** two spares batteries not exceeding 160 Wh each may be carried in carry-on baggage. Spare batteries are NOT accepted as checked baggage. Rechargeable lithium ion batteries without a protective housing must be removed from the mobility assistive device and battery terminals protected from short circuit. The battery is limited in size to no more than 300 Wh, and may be carried in carry-on baggage only. The guest must advise Spirit of the battery location. Rechargeable lithium ion batteries with a protective housing may remain installed and be checked with the mobility assistive device only if it is securely attached to the device, and the terminals protected from short circuit. The battery cables may remain connected only if the device is protected from accidental activation. Lithium ion batteries with a protective housing are not limited in Wh when checked with the assistive device.	Yes – with exceptions*	Yes – with exceptions*	N/A

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Lithium Ion Batteries for Portable Electronic Devices	* Each installed or spare lithium battery must not exceed 100 Watt-hours (Wh). Additionally, each installed or spare lithium battery must be of a type proven to meet the requirements of each test in the UN Manual of Tests and Criteria, Part III, Sub-section 38.3. **Spare Batteries** Spare lithium batteries are accepted in carry-on baggage ONLY. In carry-on baggage, a reasonable number of individually protected lithium ion batteries each not exceeding 100 Wh, may be carried per person. Each spare lithium battery must be individually protected so as to prevent short circuits (e.g., by placement in original retail packaging, by otherwise insulating terminals by taping over exposed terminals, or placing each battery in a separate plastic bag or protective pouch).	**Installed and Spares** Yes – with exceptions*	**Installed** Yes - with exceptions* **Spares** No	No

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Lithium Metal Batteries for Portable Electronic Devices	* The lithium content for lithium metal (non-rechargeable) batteries may not exceed 2 grams per battery. Additionally, each installed or spare lithium battery must be of a type proven to meet the requirements of each test in the UN Manual of Tests and Criteria, Part III, Sub-section 38.3. **Spare Batteries** Spare lithium batteries are accepted in carry-on baggage ONLY. Spare batteries must be protected from damage and short circuit.	**Installed and Spares** Yes – with exceptions*	**Installed** Yes - with exceptions* **Spares** No	No

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Martial Arts	Items include but are not limited to: Billy clubs, blackjacks, brass knuckles, kubaton, martial arts weapons, night sticks, nunchaku, stun guns, shocking devices and throwing stars.	No	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Medical Portable Electronic Devices (M-PED)	Medical Portable Electronic Devices (e.g., External Defibrillator Life Vests) may be transported at no charge when carried by itself or with other assistive devices, medications and/or medical supplies. These devices do not count towards the guest's baggage allowance. * Please see Medical Certificates for further information regarding when Medical Certificates may be required. For battery requirements see Lithium Ion Batteries for Portable Electronic Devices or Lithium Metal Batteries for Portable Electronic Devices as applicable.	Yes – with exceptions*	Yes – with exceptions*	N/A

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Musical Instruments	Musical Instruments are included as part of the guest's standard baggage. Musical instruments are considered a fragile item. Fragile items will be accepted as checked	Yes – with exceptions*	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
	baggage if they are appropriately packaged in a container/case designed for shipping such items. Music instruments that exceed 150 linear inches or 165 lbs. will not be accepted. * Small musical instruments (e.g. violins, flutes, guitars, etc.) are permitted as carry-on baggage as long as the instrument can be safely stowed in the overhead bin or under the guest's seat. Stowage in the overhead bins is available on a first-come, first-serve basis.			

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Musical Instruments as Seat Baggage (Cargo in the Cabin)	Spirit Airlines allows the carriage of musical instruments in the cabin as seat baggage (cargo in the cabin) if the instrument is too large to be stowed safely in a suitable baggage compartment in the aircraft cabin or under a passenger seat. The guest must purchase an additional seat and the cost is the applicable fare for the portions of the flight that the extra seat is requested plus sales tax. No additional fees will be charged. The instrument must be appropriately packaged in a container/case in a manner to avoid possible injury to guests and guest compartment occupants. The instrument may not impose any load on seats or the floor structure that exceeds the load limitation for those components. The item must be properly secured by the aircraft's seatbelt or other tie down having enough strength to eliminate the possibility of shifting under all normally anticipated flight and ground conditions. The instrument cannot block any guest's view of the "SEAT BELT" sign, "NO SMOKING" sign or required "EXIT" sign. The instrument cannot occupy an emergency exit seat or impede access to the cabin aisle. The instrument may occupy a middle seat provided the adjacent window seat remains unoccupied.	Yes	N/A	N/A

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Nebulizers, Respirators and Ventilators	These devices may be transported at no charge when carried by itself or with other assistive devices, medications and/or medical supplies. These devices do not count towards the guest's baggage allowance. Such devices with labels showing that they meet FAA safety requirements can be used during flight.	Yes	Yes	No

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Non-Spillable Wet Batteries for Portable Electronic Devices	* For a non-spillable battery, each battery must not exceed a voltage greater than 12 volts and a watt-hour rating of not more than 100 Wh. No more than two individually protected spare batteries may be carried. To be accepted as checked baggage, the battery terminals must be protected from damage and short circuit and be	**Installed and Spares** Yes – with exceptions*	**Installed and Spares** Yes – with exceptions*	No

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
	contained within strong packaging. The packaging must be marked “non-spillable”.			

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Oxygen	Contained oxygen and other gasses, e.g., in cylinders, canisters are NOT permitted for carriage on Spirit Airlines. Spirit does NOT offer oxygen onboard its aircraft.	No	No	N/A

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Paintball Equipment	Paintball guns are not considered a firearm and may be transported in unlocked, soft or hard-sided baggage. Compressed gas cylinders are NOT permitted for carriage on Spirit Airlines.	No	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Parachute Equipment	* Sporting parachutes are acceptable provided the parachute and its accessories do not include any items that are prohibited from being carried, e.g., compressed gas cylinders, flares or other hazardous materials.	Yes – with exceptions*	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Photographic Equipment	Items include but are not limited to: All cameras, VCR recorders/ players, photoflash equipment, photometers, spectroscopes, photo tubes, and/or other similar devices using sensitive tubes or plates and film (still or movie), exposed or unexposed, as well as all related attachments or accessories. * Chemicals used for film development are NOT accepted for transport.	Yes – with exceptions*	Yes – with exceptions*	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Portable Dialysis Machines	Portable dialysis machines may be transported at no charge when carried by itself or with other assistive devices, medications and/or medical supplies. These devices do not count towards the guest’s baggage allowance. * These devices are NOT permitted for use on Spirit’s aircraft.	Yes – with exceptions*	Yes	No

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Portable Oxygen Concentrators	Portable Oxygen Concentrators (POC) are battery-powered concentrators that provide the user with a pulse flow of concentrated oxygen, without storing Oxygen. These items may be transported at no charge when carried by itself or with other assistive devices, medications and/or medical	Yes	Yes	No

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
	supplies. These devices do not count towards the guest's baggage allowance. To be used onboard, a POC must be on the FAA approved list or it must bear a permanent label on the exterior of the device containing the following certification statement in red lettering: "*The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board aircraft.*" The labeling requirement does not apply to Portable Oxygen Concentrators on the FAA approved list. The FAA approved list is as follows: • Airsep Focus • AirSep FreeStyle • AirSep FreeStyle 5 • AirSep LifeStyle • Delphi RS-00400 • DeVilbiss Healthcare iGo • Inogen One • Inogen One G2 • Inogen One G3 • Inova Labs LifeChoice • Inova Labs LifeChoice Activox • International Biophysics LifeChoice • Invacare Solo2 • Invacare XP02 • Oxlife Independence Oxygen Concentrator • Oxus Inc. RS-00400 • Precision Medical EasyPulse • Respironics EverGo • Respironics Simply Go • SeQual Eclipse • SeQual eQuinox Oxygen System (model 4000) • SeQual Oxywell Oxygen System (model 4000) • SeQual SAROS • VBox Trooper Oxygen Concentrator			

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Precision Instruments	Items include but are not limited to: Microscopes, oscilloscopes, meters, counters, polygraphs, electrographs, medical equipment and similar articles. * A limited liability release form is not required for medical equipment.	Yes	Yes	Yes – with exceptions*

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Ski (Water or Snow) and Snowboard Equipment	One item of equipment will count as a checked bag. One item of ski equipment is considered:	No	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
	• One pair of skis, with one pair of ski poles, and one pair of ski boots; or • One snowboard and one pair snowboard boots. Bags containing skis or snowboards are exempt from oversize limits; however, oversize charges apply if the bag is greater than 62 linear inches. Overweight charges are applicable. Note: If boots are packed separately from ski/snowboard equipment, they must be in a ski/snowboard boot bag to be considered part of the one piece of checked baggage.			

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Scuba Diving Equipment	Compressed gas cylinders (scuba tanks), full or empty, will NOT be accepted for transport. * Sharp objects, such as unloaded spear guns, knives and tools, must be packed in checked baggage only, and must be sheathed or securely wrapped.	Yes – with exceptions*	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Skateboards	Non-motorized/Non-battery operated skateboards will be accepted. *To be accepted as carry-on baggage, the skateboard must be within Spirit's carry-on size and must be stowed with the wheels up, preferably under the seat. If placed in the overhead bin, the skateboard must be wheels up and stowed in a way to prevent rolling out of the bin when it is reopened.	Yes – with exceptions*	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Smart Bags / Battery-powered Baggage	Battery-powered baggage and smart bags (e.g., baggage with built in batteries) are NOT allowed for transport.	No	No	N/A

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Surfing Equipment	Surfboards are included as part of the guest's standard baggage allowance and will be accepted for a special charge per direction. One bag containing up to two surfboards will be accepted. Oversize limits and charges are waived for surfing equipment. Overweight charges are waived for surfing equipment. Additional items packed inside a surfboard case are not considered part of the surfboard equipment and additional charges will apply. * Spirit reserves the right to refuse transportation of these items due to safety and/or operational limitations.	No	Yes – with exceptions*	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Tennis Equipment		Yes	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Tools/Power Tools	Items include but are not limited to: Axes, hatchets, cattle prods, crowbars, hammers, drills, table saws, screwdrivers, wrenches, and pliers.	No	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Wheelchairs	In addition to the standard baggage allowance and at no charge, Spirit Airlines will accept wheelchairs and other mobility assistive devices (manual and electric/battery operated) as checked baggage on the same flight as the guest who uses the device, unless the guest requests stowage of his or her manual folding and collapsible wheelchair within the aircraft cabin. At the time of check-in, electric-powered wheelchairs must have cables disconnected and terminals protected against electrical shortages. Spirit strongly recommends that guests requiring this service check-in at least 90 minutes before departure. Guests must check-in at the departure gate at least 45 minutes prior to the (original) scheduled flight departure time. The battery must be disconnected and terminals protected against electrical shorting and must be contained in a leak proof box fastened securely to the wheelchair. It may be necessary to remove the battery if the wheelchair cannot be loaded, stowed, and unloaded in an upright manner. * Once one guest's manual folding and collapsible wheelchair has been accepted for accommodation in the passenger cabin, Spirit Airlines will accept one (1) additional manual folding and collapsible wheelchair as long as no other guests are displaced.	Yes – with exceptions*	Yes	No

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Windsurfing Equipment	Windsurfing equipment is NOT accepted for transport.	No	No	N/A

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Wood Carvings	* Guests transporting wood carvings to/from Jamaica are required to place the item(s) in checked baggage per Jamaican government regulations.	Yes – with exceptions*	Yes	Yes

Item	Description	Carry-on?	Checked?	Requires Limited Liability Release
Urns, Human/Animal Remains & Organs	Spirit will NOT accept human or animal remains and/or organs, with the exception of cremated human or animal remains being transported as follows: ***Domestic Travel** To be transported as carry-on baggage, the crematory container must undergo successful X-ray screening by TSA. If a container is made of a material that prevents screeners from clearly seeing what is inside, the container will not be allowed through the checkpoint. Per TSA guidance, out of respect to the deceased and their family and friends, under no circumstances will a TSA officer open the container even if the guest requests this be done. NOTE: Documentation from the funeral home is not sufficient to carry a crematory container through security and onto a plane without screening. To be transported as checked baggage, the crematory container must be successfully screened during the checked baggage screening process. The TSA will screen the container for explosive materials/devices using a variety of techniques; if cleared, it will be permitted as checked baggage only. The TSA recommends that guests transport remains in temporary or permanent containers constructed of light-weight materials such as plastic or wood that can be successfully x-rayed. **International Travel** Countries have different regulations and documentation requirements for receiving cremated remains. It is the guest's responsibility to obtain importation permission from the embassy (or appropriate government office) of the country to which they are traveling. Although the guest can contact the embassy or appropriate government office to complete the necessary legal paperwork, Spirit recommends that they acquire the services of a funeral director to assist with the necessary arrangements.	Yes – with exceptions*	Yes – with exceptions*	No

7.6 *Restricted Articles*

The following list is classified as hazardous and may not be carried in baggage. The list is not all-inclusive and Spirit may reject any substance it deems to be a threat to safety.

7.6.1. Liquor products over 140 proof.

7.6.2. Gasoline-powered tools.

7.6.3. Compressed gases.

7.6.4. Corrosives (such as acids and wet batteries).

7.6.5. Explosives (such as dynamite, but also including fireworks).

7.6.6. Flammables (such as matches and lighter fuels).

7.6.7. Poisons.

7.6.8. Magnetic and radioactive materials and all other items by government regulations.

7.6.9. Additional prohibited or restricted hazardous or dangerous goods and materials can be found in the following resources in effect at the time of travel:

a) DOT hazardous materials regulations (49CFR 171-177)

b) IATA Dangerous Goods Regulations

c) TSA Permitted and Prohibited Items

7.7 *Limitations of Liability*

Except to the extent inconsistent with applicable laws, Spirit Airlines will not accept liability for the following:

a. Cosmetic and/or superficial damage caused to baggage as a result of normal wear and tear during the course of any of the operations of carriage. Normal wear and tear includes but is not limited to, minor cuts, scratches, scuffs, dents, and soiling that do not impact the functionality of such baggage.

b. Loss, damage, or delay as the result of actions taken by the TSA, Customs, or other governmental agencies

c. Loss or damage to unchecked baggage (baggage that is in the custody of the guest and includes carry-on baggage) unless such damage is caused by our negligence, which excludes damage resulting from turbulence or shifting of items during flight.

d. Damage caused by a passenger's property, whether such damage is to the passenger's own property or to other's property.

e. Claims of missing or damaged articles if a passenger's checked baggage is not damaged, delayed, or lost.

f. Claims of damage of the inside contents of a hard-sided case if the outside of the case is not damaged.

g. Claims of damage to or missing articles from car seats, strollers, and folding wagons when carried as checked baggage.

7.7.1. Domestic Baggage – Limitation of Liability

7.7.1.1. Spirit assumes no responsibility or liability for the following items in or as checked or carry-on baggage:

- Antiques,
- Artifacts,
- Art supplies,

- Backpacks or knapsacks not designed for travel (e.g., made from plastic, vinyl, or other easily torn material, with aluminum frames or other easily bent material, with protruding straps or buckles.)
- Blueprints, maps, historical documents
- Books,
- Business documents,
- CD/DVDs
- Business equipment and business samples
- China, glass, ceramics, pottery, and other related items.
- Collectibles,
- Commercial items,
- Computer hardware and software, including laptops, and accessories,
- Cosmetics,
- Drugs prohibited by federal and/or state law,
- E-cigarettes and other battery-powered smoking devices,
- Electronic equipment and accessories including cell phones, e-readers, electronic games, and other related items.
- Eyeglasses, binoculars, sunglasses, (prescription or non-prescription), contact lenses, and all other eyewear and eye/vision devices.
- Furs and fur products,
- Fragile items (see section 7.4)
- Garment bags not designed for travel
- Heirlooms,
- Human organs,
- Irreplaceable items,
- Jewelry,
- Keys,
- Liquids, including alcohol/liquor
- Machinery (including parts),
- Manuscripts,
- Medication
- Medical equipment (not used as assistive devices pursuant to 14 CFR 382.3);
- Money, gift cards negotiable papers, and securities,
- Musical instruments,
- Orthodontics,
- Perfumes,
- Perishable items, (see section 7.4)
- Photos and personal documents
- Photographic, cinematographic, audio, video, equipment and accessories, cameras and related items.
- Precious metals and stones,
- Publications,
- Samples,
- Silverware,
- Tobacco products,

- Tools, battery powered hand tools, toolboxes and containers,
- Watches and timepieces.
- Works of art, such as paintings and sculptures, or
- Similar valuable, fragile, or perishable items or items not packaged in accordance with other rules described in this contract.

7.7.1.2. For travel wholly between U.S. points, liability for loss, delay or damage to checked baggage is limited to $3,800 per guest holding a confirmed reservation.

7.7.2 International Baggage– Limitation of Liability

7.7.2.1. Spirit will NOT accept any agricultural items, perishable items or any product that does not conform to the Customs and/or Agricultural government entities of any foreign country that the guest is entering into or leaving from on a Spirit flight.

7.7.2.2. Limitations on the number, size and weight of checked baggage apply.

7.7.2.3. For travel to/from international destinations, the limitations of liability, as applicable under the Warsaw Convention or the Montreal Convention, will apply.

a) For international travel (including domestic portions of international itineraries) to which the Warsaw Convention applies:

Liability for loss, delay or damage to checked baggage is limited to approximately $9.07 per pound for checked baggage and $400 per guest for unchecked baggage.

Liability is for a maximum of 40 lbs/18.1 kgs ($362.80) per checked bag, unless the guest pays an additional checked baggage charge, and the precise weight of the baggage is noted on the guest's baggage claim check.

b) For international travel (including domestic portions of international itineraries) to which the Montreal Convention applies:

Liability for loss, delay or damage to checked baggage is limited to 1,288 Special Drawing Rights (“SDR”).

For international travel, the weight of each piece of checked baggage is presumed to be the applicable standard baggage allowance set forth above. This weight will establish the carrier's maximum liability, unless excess weight is clearly noted on the Guest's claim check, and additional charges are paid. If the weight of the baggage is not recorded on the Baggage Check, then it is presumed that the weight of the baggage falls within the standard baggage allowance set forth above.

7.7.3. Spirit does NOT accept declarations of higher value.

7.8 *Portable Electronic Devices*

7.8.1 Use of Portable Electronic Devices Onboard the Aircraft

- Small authorized PEDs are devices under two (2) pounds and are of a size that can easily be placed in a seat pocket along with the other materials that are normally found in the seat pocket (Passenger Safety Information Card, Menu and/or airsickness bag). They include devices like tablets, readers and mobile phones and may be used during all phases of flight including taxi, take-off and landing. However, if using them during taxi, take-off and landing, you must secure these devices by holding them, putting them in your pocket or holster, or placing them in a seatback pocket.

- Large authorized PEDs are devices two (2) pounds or more such as full-size laptops. They must be turned off and stowed during taxi, takeoff and landing. You can stow them by having them under the seat in front of you or in an overhead compartment. These devices may be used about 10,000 feet when authorized by a Flight Attendant announcement.

- On all flights operating outside U.S. airspace, portable electronic devices cannot be used during taxi, takeoff and landing, but may be used above 10,000 feet when authorized by a Flight Attendant announcement.

- Headsets or earphones (buds) are required for any audible portable device and any cords or accessories must not impede emergency egress.

- Devices must have their cellular network service disabled, commonly known as “Airplane Mode”, from the time the aircraft door is closed for departure from the gate until the aircraft is taxiing to the gate upon arrival when authorized by a Flight Attendant announcement.

- Cell phone use is still limited and calls cannot be made during times when cellular network is to be disabled.

- Items which may not be operated at any time inside the aircraft include: TV receivers, remote controlled toys, e-cigarettes, radio transmitters and personal air purifiers.

- Due to safety concerns, guests must comply with all crewmembers instructions regarding the use of portable electronic devices.

- The DOT, with the FAA and Pipeline and Hazardous materials Safety Administration (PHMSA) has issued an emergency order banning all Samsung Galaxy Note7 smartphone devices for air transportation. Samsung Galaxy Note7 devices may not be transported on anyone’s person, in carry-on baggage, or in checked baggage on all flights to, from, or within the United States.

8. SCHEDULE CHANGES, DELAYED FLIGHTS AND CANCELED FLIGHTS

8.1 *Spirit Airlines Responsibility for Schedules and Operations*

Times shown in a timetable or elsewhere are not guaranteed and form no part of the terms of transportation. Spirit may, without notice, substitute alternate carriers or aircraft, and may alter or omit stopping places shown on the reservation. Schedules are subject to change without notice. Spirit is not responsible or liable for making connections (on its own flights or flights of any other carrier), or for failing to operate any flight according to schedule, or for changing the schedule of any flight.

8.2 *Rebooking*

When a guest holding a confirmed reservation on a Spirit flight which is delayed because of a schedule irregularity (including but not limited to, a missed connection, flight cancellation, omission of a scheduled stop, substitution of equipment, or schedule change), Spirit may rebook the guest on Spirit's first flight on which seats are available to the guest's original destination without additional charge. Our staff will focus on rebooking as many guests as possible on alternate flights, either direct to the destination or via connections through other airports to best accommodate the guest's needs. Guests may also have the option to obtain a refund consistent with section 10.2.3.

A change may be made to an itinerary without a charge and/or fare difference when the itinerary was affected by a cancelled flight, an eligible schedule change or a delayed flight (greater than two hours from the original departure time) provided:

- The same departure and arrival airports are booked and;
- The itinerary is rebooked within Spirit's authorized date ranges (currently within 7 days of the departure date).

With limited exceptions, Spirit will not reimburse guests for flights that they book on other carriers.

8.3 *Amenities/Services for Guests*

Spirit will not assume expenses incurred as a result of a flight delay, cancellation, or schedule change. Spirit may provide limited amenities and services, which may be required by certain guests in order to maintain their safety, health and welfare. Amenities provided by Spirit are provided as a courtesy to the guest and are not to be considered an obligation of Spirit.

In the case of a cancellation or misconnection, if rebooking options are available the following day, and the cancellation was due to our failure, we may offer overnight hotel accommodations for non-local guests. However, if the cancellation or misconnection is caused by severe weather, Air Traffic Control decisions or other issues outside of Spirit's control, we cannot offer such accommodations. We will, nevertheless, make reasonable efforts to provide information enabling guests to secure accommodations on their own. No lodging will be provided to a guest on any Spirit flight which is delayed or canceled in the originating city on the guest's reservation.

9. DENIED BOARDING

When Spirit is unable to provide a previously confirmed seat due to an oversell condition, Spirit will take voluntary and/or involuntary denied boarding guests in accordance with regulations of the DOT as specified below:

9.1 *Voluntary*

If a flight is oversold (more guests hold confirmed reservations than there are seats available), no one may be denied boarding against his or her will until airline personnel first ask for volunteers who will give up their reservations willingly in exchange for payment of Spirit's choosing.

9.2 *Involuntary*

If a flight is oversold and there are not enough volunteers, other guests may be denied boarding involuntarily in accordance with the following:

9.2.1. With the exception of Unaccompanied Minors and Guests with Disabilities, the last guest(s) to check in may be denied boarding in the event of an oversell, weight and balance or reduction of aircraft capacity due to inoperable seats when required for operational or safety reasons.

9.2.2. If guests are to be denied boarding involuntarily (after volunteers are solicited), they will be selected based on their time of check-in, in other words the last guest to check in on the flight will be the first guest removed from the flight. Spirit reserves the right to modify the manner of priority per 14 C.F.R. Section 250.3.

9.3 *Exceptions to Payment of Compensation for Denied Boarding*

No denied boarding compensation will be made if:

9.3.1. The denied boarding is a result of a substitution of an aircraft with lesser capacity. Guests will be denied boarding based on the following criteria:

- Time of booking if the flight is outside of 3 hours prior to the (original) scheduled departure time, or
- Time of check-in if the flight is within airport control of 3 hours prior to the (original) scheduled departure time.

9.3.2. The guest is accommodated on a flight scheduled to arrive within one (1) hour of the original arrival time.

9.3.3. The guest has not fully complied with the airline's reservation or check-in time limits or the guest is not acceptable for transportation under the airline's usual rules and practices.

9.4 *Denied Boarding Regulations*

9.4.1 Compensation for Denied Boarding

If you have been denied a reserved seat on Spirit Airlines, you are probably entitled to monetary compensation. In the case of an oversold flight, Spirit will

provide information explains the airline's obligation and the guest's rights in the case of an oversold flight, in accordance with regulations of the *DOT.*

9.4.2 Volunteers and Boarding Priorities

If a flight is oversold (more guests hold confirmed reservations than there are seats available), no one may be denied boarding against his or her will until airline personnel first ask for volunteers who will give up their reservation willingly, in exchange for compensation of the airline's choosing. If there are not enough volunteers, other guests may be denied boarding involuntarily in accordance with the following boarding priority of Spirit Airlines.

9.4.3 Compensation of Involuntary Denied Boarding

If you are denied boarding involuntarily, you are entitled to a payment of ''denied boarding compensation'' from the airline unless:

1) you have not fully complied with the airline's ticketing, check-in and reconfirmation requirements, or you are not accepted for transportation under the airline's usual rules and practices; or

2) you are denied boarding because the flight is canceled; or

3) you are denied boarding because a smaller capacity aircraft was substituted for safety or operational reasons; or

4) you are offered accommodations in a section of the aircraft other than specified in your ticket, at no extra charge (a guest seated in a section for which a lower fare is charged must be given an appropriate refund); or

5) Spirit is able to place you on another flight or flights that are planned to reach your next stopover or final destination within one hour of the planned arrival time of your original flight.

9.4.4 Amount of Denied Boarding Compensation

Domestic Transportation

Guests traveling between points within the United States (including the territories and possessions) that are denied boarding involuntarily from an oversold flight are entitled to:

1) no compensation if the carrier offers alternate transportation that is planned to arrive at the guest's destination or first stopover not later than one hour after the planned arrival time of the guest's original flight;

2) at least the lower amount of 200% of the fare to the guest's destination or first stopover or $775, if the carrier offers alternate transportation that is planned to arrive at the guest's destination or first stopover more than one hour but less than two hours after the planned arrival time of the guest's original flight; or

3) at least the lower amount of 400% of the fare to the guest's destination or first stopover or $1,550, if the carrier does not offer alternate transportation that is planned to arrive at the airport of the guest's destination or first stopover less than two hours after the planned arrival time of the guest's original flight.

Length of Arrival Delay to Final Destination Due To Over Sale	Amount of Compensation
0 to 1 hour arrival delay	No compensation
1 to 2 hour arrival delay	At least the lower amount of 200% of fare to destination or $775
Over 2 hour arrival delay	At least the lower amount of 400% of fare to destination or $1,550

International Transportation

Guests traveling from the United States to a foreign point who are denied boarding involuntarily from an oversold flight originating at a U.S. airport are entitled to:

1) no compensation if the carrier offers alternate transportation that is planned to arrive at the guest's destination or first stopover not later than one hour after the planned arrival time of the guest's original flight;

2) at least the lower amount of 200% of the fare to the guest's destination or first stopover or $775, if the carrier offers alternate transportation that is planned to arrive at the guest's destination or first stopover more than one hour but less than four hours after the planned arrival time of the guest's original flight; or

3) at least the lower amount of 400% of the fare to the guest's destination or first stopover or $1,550, if the carrier does not offer alternate transportation that is planned to arrive at the airport of the guest's destination or first stopover less than four hours after the planned arrival time of the guest's original flight.

Length of Arrival Delay to Final Destination Due To Over Sale	Amount of Compensation
0 to 1 hour arrival delay	No compensation
1 to 4 hour arrival delay	At least the lower amount of 200% of fare to destination or $775
Over 4 hour arrival delay	At least the lower amount of 400% of fare to destination or $1,550

9.4.5 Alternate Transportation

''Alternate transportation'' is air transportation with a confirmed reservation at no additional charge (by any scheduled airline licensed by DOT), or other transportation accepted and used by the guest in the case of denied boarding.

9.4.6 Method of Payment

Except as provided below, the airline must give each guest who qualifies for involuntary denied boarding compensation a payment by cash or check for the

amount specified above, on the day and at the place the involuntary denied boarding occurs.

If the airline arranges alternate transportation for the guest's convenience that departs before the payment can be made, the payment shall be sent to the guest within 24 hours.

The air carrier may offer free or discounted transportation in place of the Involuntary Denied Boarding Compensation payment. In that event, the carrier must disclose all material restrictions on the use of the free or discounted transportation before the guest decides whether to accept the transportation in lieu of Involuntary Denied Boarding Compensation. The guest may insist on the Involuntary Denied Boarding Compensation or refuse all compensation.

9.4.7 Guest's Options

Acceptance of the compensation may relieve Spirit Airlines from any further liability to the guest caused by its failure to honor the confirmed reservation. However, the guest may decline the payment and seek to recover damages in a court of law or in some other manner.

10. REFUNDS

10.1 *Voluntary*

Refunds will be made in accordance with applicable fare rules. No refunds will be made for non-refundable reservations.

10.2 *Involuntary*

In the event that Spirit is unable to provide a previously confirmed seat and is unable to reroute the guest via Spirit, Spirit will refund as indicated below:

10.2.1. If no portion of the reservation has been used, the refund will be equal to the fare paid by the guest.

10.2.2. If a portion of the reservation has been used, the refund will be equal to the amount of the unused portion.

10.2.3. Guests involved in a Spirit Airlines cancellation or delay in excess of two (2) hours will have three (3) options available to them: 1) re-accommodation, 2) a credit for future travel, or 3) a refund.

10.2.4. Refunds will only be issued to the form of payment used to complete the original purchase.*Foreign Currency Refunds*

10.3.1 Spirit will pay the refund in the form that was used in purchasing the original reservation; however, cash refunds will be issued in the form of a check. Spirit will observe any refund restriction that may be published in the applicable rules governing the original transportation document.

10.3.2 All refunds will be subject to government laws, rules, regulations, or orders of the country in which the reservation was originally purchased and of the country in which the refund is being made.

10.4 *Refund Contacts*

Guests entitled to refunds may apply for a refund by contacting Spirit Guest Care at 855-728-3555 or the request may be made in writing via our web site at www.spirit.com, or by writing to Corporate Guest Relations, Attention: Refunds, 2800 Executive Way, Miramar, FL 33025.

11. NON-REVENUE GUESTS

Non-revenue guests refers to direct Spirit team members, their eligible dependents, buddy pass holders, and other airline employees who will be enplaned on a flight subject to availability of space at departure time (standby), free of charge or at a reduced rate, with the exception of any applicable booking fees, international taxes and imputed income. Certain optional service charges may also be applicable. Team members are encouraged to review Spirit's Travel Policy prior to travel.

Every effort will be made to seat non-revenue guests, but only after all revenue guests have been assigned seats. Non-revenue guests are not entitled to service recovery compensation, denied boarding compensation, or amenities related to trip interruptions.

Liability limits shall be the same for non-revenue guests as revenue guests. Please refer to section 12 or, in the case of baggage, to subsection 7.7 herein for additional information.

12. DISCLAIMER OF CONSEQUENTIAL DAMAGES, MODIFICATIONS, AND LIMITATIONS OF LIABILITY

12.1 *Disclaimer of Consequential Damages*

Purchase of a reservation does not guarantee transportation. Spirit shall in no event be liable for direct, indirect, special or consequential damages resulting from the performance or delay in performance of, or failure to perform, transportation of guests and other services whether or not Spirit has knowledge that such damages might be incurred.

12.2 *Disclaimer of Modifications*

12.2.1 Spirit Airlines Contract of Carriage is subject to change without notice.

12.2.2 Spirit shall not be liable for false, misleading or inaccurate information provided by travel agencies and third party websites.

12.2.3 Information provided outside of this contract, including via links provided herein, are not considered part of Spirit's Contract of Carriage.

12.3 *Limitations of Liability*

Spirit's liability for any accident, injury, or death is governed by applicable laws.

12.3.1 If the guest's journey involves an ultimate destination or stop in a country other than the country of departure, the Warsaw Convention or the Montreal Convention may be applicable.

The convention governs, and in most cases limits, the liability of carriers in respect of death, personal injury to guests, and for destruction or loss of, or damage to, baggage, and for delay of guests and baggage, as follows:

- The financial limits for any damages, including recoverable compensatory damages sustained in the case of death or bodily injury of a passenger, shall not exceed 128,821 Special Drawing Rights (SDR) for each passenger.
- In the case of destruction, loss of, or damage or delay to baggage, 1,288 Special Drawing Rights (SDR).
- In the case of delay to a guest's journey, 5,346 Special Drawing Rights (SDR) per guest.

12.4 *Waiver/Modification of Terms of Contract of Carriage*

No employee of Spirit has the authority to modify, waive or alter any term of this Contract of Carriage unless authorized by an officer of Spirit Airlines.

13. CHOICE OF LAW AND VENUE

13.1 This Contract of Carriage will be governed by and construed in accordance with the laws of the United States of America and the State of Florida without regard to conflict of law principles or law.

All right to trial by jury in any action, proceeding or counterclaim arising out of or in connection with this Contract of Carriage is irrevocably waived.

13.2 No Class Action – Any case brought pursuant to this Contract of Carriage, Spirit's Tarmac Delay Plan, or Spirit's Guest Service Plan must be brought in a party's individual capacity and not as a plaintiff or class member in any purported class or representative proceeding.

13.3 Time Limit – No legal action may be brought by a passenger against Spirit or its directors, officers, employees or agents unless commenced within six (6) months from the date of the alleged incident.

14. SPIRIT AIRLINES TARMAC DELAY PLAN

Spirit Airlines Contingency Plan for Lengthy Tarmac Delays includes the following:

14.1 For domestic flights, Spirit Airlines will not permit an aircraft to remain on the tarmac for more than three (3) hours before allowing guests to deplane for arrival flights, or before the pilot begins maneuvering the aircraft to a suitable disembarkation point (in areas controlled by Spirit), or before the request for permission to return to a suitable disembarkation point is made to the Federal Aviation Administration, control tower,

airport authority , or other relevant authority directing the aircraft's operations on the tarmac (in areas not controlled by Spirit) for departure flights, unless:

a) The pilot-in-command determines that deplaning passengers at a suitable disembarkation point would jeopardize passenger safety or security, or there is a safety-related or security-related reason (e.g., weather, a directive from an appropriate government agency, etc.) why the aircraft cannot leave its position on the tarmac to deplane guests; or

b) Air Traffic Control advises the pilot-in-command that returning to the gate or another disembarkation point elsewhere in order to deplane guests would significantly disrupt airport operations.

14.2 For international flights operated by Spirit Airlines that depart from or arrive at a U.S. airport, Spirit Airlines will not permit an aircraft to remain on the tarmac at a U.S. airport for more than four (4) hours before allowing guests to deplane for arrival flights, or before the pilot begins maneuvering the aircraft to a suitable disembarkation point (in areas controlled by Spirit), or before the request for permission to return to a suitable disembarkation point is made to the Federal Aviation Administration, control tower, airport authority, or other relevant authority directing the aircraft's operations on the tarmac (in areas not controlled by Spirit) for departure flights, unless:

a) The pilot-in-command determines that deplaning passengers at a suitable disembarkation point would jeopardize passenger safety or security, or there is a safety-related or security-related reason (e.g., weather, a directive from an appropriate government agency, etc.) why the aircraft cannot leave its position on the tarmac to deplane guests; or

b) Air Traffic Control advises the pilot-in-command that returning to the gate or another disembarkation point elsewhere in order to deplane guests would significantly disrupt airport operations.

14.3 For all flights covered by this plan, Spirit Airlines shall do the following:

a) Provide adequate food and potable water no later than two (2) hours after guests no longer have the opportunity to deplane (in case of a departure) or the aircraft touches down (in case of an arrival) if the aircraft remains on the tarmac, unless the pilot-in-command determines that safety or security considerations preclude such service;

b) Ensure operable lavatory facilities, comfortable cabin temperatures, as well as adequate medical attention if needed, while the aircraft remains on the tarmac;

c) Ensure that the guests on the delayed flight will receive notifications regarding the status of the delay when the tarmac delay exceeds 30 minutes for the flight;

d) Ensure that the guests on the delayed flight will receive timely notification each time the opportunity to deplane actually exists at all suitable disembarkation points for all departing flights and diversions.

14.4 Spirit Airlines has sufficient resources to implement the plan; and

14.5 Spirit Airlines' plan has been coordinated with the following:

a) Airport authorities (including terminal facility operators where applicable) at each U.S. large hub airport, medium hub airport, small hub airport and non-hub airport that the carrier serves, as well as its regular U.S. diversion airports, and will share facilities and make gates available at the airport in the event of an emergency;

b) U.S. Customs and Border Protection (CBP) at each large U.S. hub airport, medium hub airport, small hub airport and non-hub airport that is regularly used for that carrier's international flights, including diversion airports; and

c) The TSA at each U.S. large hub airport, medium hub airport, small hub airport and non-hub airport that the carrier serves, including diversion airports.

15. Spirit Airlines Guest Service Plan

Content of Guest Service Plan

1. Offer the lowest fare available.
2. Notify guests of known delays, cancellations and diversions.
3. Deliver baggage on time.
4. Allow reservations to be held or cancelled without penalty for a defined amount of time.
5. Provide prompt reservation refunds.
6. Properly accommodate guests with disabilities and other special needs, including during tarmac delays.
7. Meet guests' essential needs during lengthy tarmac delays.
8. Handle "bumped" guests with fairness and consistency in the case of oversales.
9. Disclose travel itinerary, cancellations, Frequent Flyer Rules, aircraft seating configurations and lavatory availability.
10. Notifying guests in a timely manner of changes in their travel itineraries.
11. Ensure responsiveness to guest complaints.
12. Identify the services to mitigate guest inconveniences resulting from cancellations and misconnects.

1. Offer the Lowest Available Fare

Lower fares may be available at the airport. Certain fares such, as Internet promotions, are not accessible to the Reservations Agent and may only be purchased at our web site, www.spirit.com.

Recommendations:

If you have time to plan and are flexible with your travel dates, booking travel and purchasing your reservations in advance may result in a lower fare, especially during peak travel seasons and holidays.

2. Notify Guests of Known Delays, Cancellations and Diversions

We will give our guests, whether at the airport, onboard an aircraft, or elsewhere with computer or telephone access, the best available information regarding delays and cancellations in a timely manner.

Because we know that timely and accurate communication regarding travel interruptions is important, we make every reasonable effort to provide guests and employees with the most accurate, up-to-date flight information as quickly and frequently as possible.

Recommendations:

Prior to your trip, you can visit our Flight Information page on Spirit's website (www.spirit.com) for flight and travel information. When making your reservations, providing Spirit with your contact information (phone numbers and/or e-mail address) can help us reach you in the event that a delay or cancellation becomes apparent before you leave for the airport or while you are in transit. Simply enter the information when making a reservation online at Spirit's website (www.spirit.com) or give it to your Spirit Reservations Agent.

If a flight is delayed or cancelled, Spirit works automatically to re-accommodate guests in advance when possible. If you miss your connection due to a delayed flight, or if your flight is cancelled, a new boarding pass for your revised itinerary may be obtained at the airport.

3. Deliver Baggage On Time

We strive to ensure that all checked baggage arrives at your final destination on time; however, representatives will be available during posted hours for guests who require assistance with mishandled baggage.

In the event your baggage does not arrive at your destination with you, please file a delayed baggage report to immediately initiate a search for the missing piece(s). Once your belongings are located, they will be returned to you as quickly as possible. Retain your baggage claim receipts for tracing and settlement, if necessary.

If your baggage cannot be located within five (5) days, you will need to complete the online claim form (see Spirit's Contract of Carriage (section 7.3.7) so that Central Baggage can assist with advanced tracing.

The online claim form can be found online at: www.spirit.com/bagclaim.

For further information pertaining to delayed, lost and damaged baggage, see Spirit's Contract of Carriage section 7.3.5. For further information pertaining to limitations of liability, see Spirit's Contract of Carriage section 7.7.

Recommendations:

We recommend you attach a baggage identification tag to each of your bags that clearly displays your name, address and telephone number. In addition, we suggest you place this same information and a copy of your itinerary inside the bags.

Be sure to carry necessities such as medication, keys and passports, as well as cameras, electronics, iPods, laptop computers, jewelry, cash and personal documents with you on the aircraft.

Always use baggage designed to withstand the stress of airport baggage handling systems and avoid over-packing.

4. Allow Reservations to be Held or Cancelled Without Payment

Spirit does not hold reservations without payment.

Refunds are allowed for reservations made seven (7) days (168 hours) or more prior to your departure, provided that you make the refund request within 24 hours of your initial reservation.

5. Provide Prompt Ticket Refunds

For guests due a refund, who purchased their reservations (including any charges associated with the fare) with a credit card, Spirit will process the credit within seven (7) business days. Due to various billing cycles, a credit card statement may not reflect a refund immediately.

For guests due a refund, who purchased their reservation (including any charges associated with the fare) with cash, Spirit will issue a refund check within 20 business days of Spirit receiving your refund request.

6. Properly Accommodate Guests with Disabilities and Other Special Needs, including during Tarmac Delays

We will provide our guests who have special needs, including guests with disabilities and unaccompanied minors, with the level of attention, respect and care they require. For further information pertaining to minors traveling unaccompanied, see Spirit's Contract of Carriage section 5.2.

Spirit's policies and procedures are in accordance with 14 CFR Part 382, Nondiscrimination on the Basis of Disability in Air Travel, which implements the Air Carrier Access Act. A copy of 14 CFR Part 382 may be obtained from the DOT by any of the following means:

1. Calling from within the United States, by telephone via the Toll-Free Hotline for Air Travelers with Disabilities at 1-800-778-4838 (voice) or 1-800-455-9880 (TTY)

2. Calling the Aviation Consumer Protection Division at 202-366-2220 (voice) or 202-366-0511 (TTY)

3. Writing to the Air Consumer Protection Division, C-75, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building, Room W96-432, Washington, DC 20590

4. Visiting the Aviation Consumer Protection Divisions' website at https://www.transportation.gov/airconsumer.

Recommendations:

When making your reservations, be sure to notify Spirit of any special needs you may have. This will alert our employees to your circumstances so they can better prepare to assist you when you arrive at the airport. To assist Spirit in providing you with prompt assistance,

please notify a Spirit team member of any special needs you may have upon your arrival to the airport.

7. Meet Guests' Essential Needs during Lengthy On-Board Delays

Spirit is committed to operating a reliable schedule for every guest. Weather, Air Traffic Control and other issues can cause delays and cancellations. Our commitment is to make our guests who experience long on-aircraft delays as comfortable as possible. Spirit has a contingency plan to meet guest's essential needs during lengthy tarmac delays. For more information on our commitment to you, please see Spirit's Contract of Carriage section 14.

When an on-aircraft delay occurs, we will manage the situation aggressively to minimize delays of greater than two (2) hours and make every reasonable effort to prevent those with longer durations. In the event of a lengthy delay, to provide food, water, restroom facilities and access to medical treatment for Guests onboard an airplane. For delays more than three (3) hours domestically or more than four (4) hours internationally, Guests will be allowed to deplane, subject to the Captain's and Air Traffic Control's concurrence.

Recommendations:

While Spirit offers food onboard for purchase, guests are always welcome to bring food onboard any of our flights. If you are traveling with children, be sure to pack extra snacks and beverages (subject to TSA rules), as well as diapers and changing essentials.

8. Handling Denied Boarding Guests with Fairness and Consistency in the Case of Oversales

When guests are denied boarding due to an overbooked flight, they will be compensated and treated fairly and consistently. Removing paying guests is the last resort. First, volunteers will be solicited. If there are no volunteers, then the last guest to check-in may need to be removed; however, Spirit reserves the right to determine the manner of priority per 14 C.F.R. Section 250.3. See Spirit's Contract of Carriage section 9 for more information about denied boarding options and compensation.

Recommendations:

Guests can check Spirit's website (www.spirit.com) under HELP for specific airport information and recommended check-in times prior to leaving for the airport. Please arrive at the airport in plenty of time to check your bags. Please review Spirit's Contract of Carriage sections 2.3 and 2.4 for further details related to check-in time limits.

9. Disclose Travel Itinerary, Cancellation Policies, Frequent Flyer Rules, Aircraft Seating Configurations and Lavatory Availability

We will make every attempt to provide our guests with accurate, up-to-date information about their travel itineraries, our aircraft seating configurations (including lavatory availability), frequent flyer rules, and cancellation policies.

Reservations Agents can relay cancellation and refund policies to guests upon request at the time of booking. These policies can also be found in section 3.3 of Spirit's Contract of Carriage

For the Terms and Conditions of the Free Spirit Program, please see https://content.spirit.com/Shared/en-us/Documents/FS_Terms_and_Conditions.pdf

For Spirit's aircraft configuration information on (including lavatory availability), please see: https://customersupport.spirit.com/hc/en-us/articles/202098616-Do-I-have-to-purchase-a-seat-assignment-

For aircraft disinfection requirements, visit the Aviation Consumer Protection Division website at (https:/www.transportation.gov/airconsumer) or send a letter to the mailing address below:

Aviation Consumer Protection Division, C-75
U.S. Department of Transportation
1200 Jersey Ave., S.E.
Washington, D.C. 20590

If you've purchased a reservation to Jamaica or Panama, please view the link below to view the Insecticide Notice visit: https://www.transportation.gov/airconsumer/spray

10. Notifying Consumers in a Timely Manner of Changes in Their Travel Itineraries

When a change occurs to your scheduled flight, we will make every effort to communicate the schedule change via telephone or e-mail in advance of the date of travel, if known. Otherwise, the information will be provided upon airport check-in and at the gate.

Recommendations:

When making your reservations, providing Spirit with your contact information (phone numbers and/or e-mail address) may help us reach you in the event that a delay or cancellation becomes apparent before you leave for the airport or while you are in transit. Enter the information when making a reservation online at Spirit's website (www.spirit.com), or give it to your Spirit Reservations Agent.

11. Ensure Responsiveness to Guest Complaints

When our guests have complaints, we will respond with the required information in a professional, courteous manner that reflects the high value we place on each guest.

1. You may contact Spirit with your complaints, compliments or questions at: https://customersupport.spirit.com/hc/en-us/articles/202097936-Do-you-have-a-question-comment-or-complaint-

2. In Writing:

   Spirit Guest Relations
   2800 Executive Way
   Miramar, FL 33025

You will receive an initial acknowledgement of your communications within 30 days and a substantive reply within 60 days. Guest Relations can assist you with post-travel concerns as well. Please have your flight number and date(s) of travel handy when you contact us.

12. Identify the Services to Mitigate Guest Inconveniences Resulting from Cancellations and Misconnections

When our guests are inconvenienced either from a cancellation or a delayed flight within our control, we will provide amenities and services to minimize the impact to the guest. Spirit will make every effort to assist our guests and minimize their inconvenience resulting from cancellations or misconnections. See Spirit's Contract of Carriage section 8 for further information related to flight cancellations and misconnections.

In the case of a cancellation or misconnection, our staff will focus on rebooking guests on alternate flights, either direct to the destination or via connections through other airports to best accommodate the guest's needs.

If rebooking options are available the following day, we may offer overnight hotel accommodations for non-local guests. However, if the cancellation or misconnection is because of severe weather, Air Traffic Control decisions or other issues outside of Spirit's control, we cannot offer such accommodations, though we will make reasonable efforts to provide information enabling guests to secure accommodations on their own.

Recommendations:

Please carry necessity items like medication with you. Also, when traveling with children, please pack extra snacks and beverages as well as diapers and changing essentials in preparation for an unplanned event.

Contains Nonbinding Recommendations

Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)

Guidance for Industry and Food and Drug Administration Staff

May 2020

This document supersedes "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)" issued April 2020.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, and the FDA webpage titled "Search for FDA Guidance Documents," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 20018 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-SurgicalMasks@fda.hhs.gov

Contains Nonbinding Recommendations

Table of Contents

Contains Nonbinding Recommendations

Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for healthcare personnel (HCP)[1] for the duration of the COVID-19 public health emergency.

This policy is intended to remain in effect only for the duration of the public health emergency

[1] As used in the three EUAs for filtering facepiece respirators in effect at the time of this guidance, healthcare personnel (HCP) refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These healthcare personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," *available at* https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2," and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[2] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[3]

FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for use by the general public, and of filtering facepiece respirators (including N95 respirators) for use by HCP in healthcare settings.

This document supersedes the guidance, "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)," issued April 2020. The April 2020 version revised the original guidance, "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency," issued March 25, 2020, to include face shields and to provide FDA's recommendations regarding alternatives when FDA-cleared or NIOSH-approved N95 respirators are not available. This version includes additional updates regarding alternatives when FDA-cleared or NIOSH-approved N95 respirators are not available and removes FDA's prior recommendations regarding emergency use

[2] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.
[3] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

authorizations (EUAs) for decontamination of face masks and filtering facepiece respirators.[4]

III. Scope

There are many products marketed in the United States as "face masks" that offer a range of protection against potential health hazards. Face masks[5] and respirators are regulated by FDA when they meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Generally, face masks fall within this definition when they are intended for a medical purpose, including for use by HCP.[6] Face masks that are not intended for a medical purpose are not medical devices, as described in further detail below. FDA-regulated face masks and respirators are listed in Table 1:

Table 1

Classification Regulation	Device Type	Product Code[7]
21 CFR 878.4040	Mask, Surgical	FXX
	Pediatric/Child Facemask	OXZ
	Accessory, Surgical Apparel (Face Shield)[8]	LYU
	Surgical mask with antimicrobial/antiviral agent	OUK
	Respirator, Surgical	MSH
	N95 Respirator with Antimicrobial/Antiviral Agent	ONT
21 CFR 880.6260	N95 Respirator with Antimicrobial/Antiviral Agent for Use by the General Public in Public Health Medical Emergencies	ORW
21 CFR 880.6260	Respirator, N95, for Use by the General Public in Public Health Medical Emergencies	NZJ

[4] Concurrently with issuance of this revised guidance, the FDA is issuing the guidance, "Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."

[5] FDA also considers face mask and surgical mask accessories that are intended to help hold the mask to the face (e.g., surgical mask strap holders, tension release bands) to fall within the scope of this guidance. Respirator accessories are not included in the scope of this guidance.

[6] As used in this guidance "intended for a medical purpose" means that the device is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease and, therefore, meets the definition of "device" set forth in section 201(h) of the FD&C Act.

[7] For more information see the Product Classification Database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

[8] The scope of this guidance is limited to face shields and their accessories that are intended to help to hold the face shield to the face under product code LYU, "Accessory, Surgical Apparel." Face shields and their accessories that are intended to help to hold the face shield to the face are class I devices and are exempt from premarket notification requirements under 510(k) of the FD&C Act. *See* 21 CFR 878.4040. Face shields combined with devices other than a face mask (e.g., a gown, hood or toga) are not within the scope of this guidance. *See* "Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency" *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.

This policy does **NOT** apply to other types of masks including but not limited to those in Table 2.

Table 2

Classification Regulation	Device Type	Product Code
21 CFR 868.5450	Humidifier, Respiratory Mask	OBN
	Humidifier, Respiratory Gas	BTT
21 CFR 868.5550	Mask, Anesthetic, Gas	BSJ
21 CFR 868.5580	Mask, Oxygen	BYG
21 CFR 868.5600	Mask, Oxygen, Low Concentration, Venturi	BYG
21 CFR 868.5570	Mask, Oxygen, Non-Rebreathing	KGB
21 CFR 868.5905	Resuscitator, Manual, Non Self-Inflating	NHK
	Mask, Ventilator, Non-Continuous, Reprocessed	NMC
21 CFR 868.5560	Strap, Head, Gas Mask	BTK

FDA recognizes that, when personal protective equipment (PPE), such as FDA-cleared surgical masks or respirators, are unavailable, individuals, including HCP, might improvise. FDA does not intend to object to individuals' distribution and use of improvised PPE when FDA-cleared or authorized surgical masks or respirators are not available.

IV. Definitions

For the purposes of this guidance, the following definitions are used.

Face Mask – A mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. Face masks are for use by the general public and HCP only as source control in accordance with CDC recommendations.[9,10]

Face Shield - A face shield is a device used to protect the user's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials. Generally, a face shield is situated at the crown of the head and is constructed with plastic to cover the user's eyes and face.

Surgical Mask – A mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests.[11]

Filtering Facepiece Respirator – A filtering facepiece respirator (FFR) is a device that is a disposable half-face-piece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates.

[9] Source control refers to the use of a facemask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19.

[10] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.

[11] CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles.

N95 Respirator – A disposable half-mask filtering facepiece respirator (FFR) that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Such an N95 FFR used in a healthcare setting is regulated by FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act or is a class II cleared device.

NIOSH Approved N95 Respirator – An N95 respirator, approved by NIOSH that meets filtration efficiency level per 42 CFR 84.181.

Surgical N95 Respirator – A disposable FFR used in a healthcare setting that is worn by HCP during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.181. A surgical N95 respirator is regulated by FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act or is a class II cleared device.

V. Policy

A. Overview

FDA is taking steps to expand the availability of face masks and respirators and believes the policy set forth in this guidance may help address the urgent public health concerns caused by shortages of such products by taking a risk-based approach and clarifying the policies that FDA intends to apply to masks and respirators, including these products' associated indications and claims.

B. Face Masks, Face Shields, and N95 Respirators Not Intended for a Medical Purpose

Face masks, face shields, and N95 respirators are devices when they meet the definition of a device set forth in section 201(h) of the FD&C Act. Under section 201(h) of the FD&C Act, these products are devices when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.

Other face masks, face shields, and FFRs are marketed to the general public for general, non-medical purposes, such as use in construction and other industrial applications. Because they are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, FDA device marketing authorization is **not** required, and all the other requirements of the FD&C Act do **not** apply to manufacturers, importers, and distributors of these products.

Face masks, face shields, and respirators are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19). Face masks, face shields, and respirators are not devices when they are intended for a non-medical

purpose, such as for use in construction. When evaluating whether these products are intended for a medical purpose, among other considerations, FDA will consider whether:

1) they are labeled or otherwise intended for use by a HCP;
2) they are labeled or otherwise for use in a health care facility or environment; and
3) they include any drugs, biologics, or anti-microbial/anti-viral agents.

C. Face Masks Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection

In general, FDA recommends that HCP follow current Centers for Disease Control and Prevention (CDC) guidance regarding personal protective equipment (PPE) that should be used during the COVID-19 outbreak.[12] Health care employers must also comply with standards of the Occupational Safety and Health Administration (OSHA) that require PPE to protect workers and that apply to infectious disease hazards.[13] Face masks are to be used for source control only, and are not personal protective equipment, meaning they are not a substitute for FFRs or for surgical face masks.[14]

In the April 2, 2020 publication of this guidance, FDA provided flexibility regarding distribution and use of face masks without compliance with certain regulatory requirements, including submission of a 510(k) under certain circumstances. FDA's policy was based on the evolving public health emergency and the increased need for devices for source control. In addition to this policy and in response to the shortage of face masks, on April 18, 2020 FDA issued an EUA for certain face masks[15] that FDA determined met the criteria for issuance under Section 564 of the Act. This EUA has succeeded in increasing the availability of face masks for HCP and the general public for use as source control when FDA-cleared face masks are not available.

Wherever possible, HCP and the general public should continue to use FDA-cleared face masks as source control or, when those are not available, face masks authorized under the EUA. However, to help foster the availability of equipment that might offer some benefit to HCP and the general public during the COVID-19 outbreak, FDA is continuing its April 2, 2020 policy regarding face masks, recognizing there is some overlap with the EUA. Thus, for the duration of the public health emergency FDA does not intend to object to the distribution and use of face masks, with or without a face shield (not including respirators), that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face mask does not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, Reports of Corrections and Removals in 21 CFR Part 806, and Unique

[12] https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html.
[13] *See* 29 CFR 1910 subpart I.
[14] See FDA's EUA for face masks (non-surgical) available at https://www.fda.gov/media/137121/download and FAQs on the Emergency Use Authorization for Face Masks (Non-Surgical) available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-emergency-use-authorization-face-masks-non-surgical.
[15] https://www.fda.gov/media/137121/download.

Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA currently believes such devices would not create such an undue risk where:

- The product includes labeling that accurately describes the product as a face mask (as opposed to a surgical mask or FFR) and includes a list of the body contacting materials (which does not include any drugs or biologics);

- The product includes labeling that makes recommendations that would reduce sufficiently the risk of use, for example, recommendations against: use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high intensity heat source or flammable gas; and

- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses and does not include particulate filtration claims.

D. Face Shields Intended for a Medical Purpose

In general, FDA recommends that HCP follow current Centers for Disease Control and Prevention (CDC) guidance regarding PPE that should be used during the COVID-19 outbreak.[16] Health care employers must also comply with standards of the Occupational Safety and Health Administration (OSHA) that require PPE to protect workers and that apply to infectious disease hazards.[17] To help foster the availability of equipment that might offer some benefit to HCP and the general public during the COVID-19 outbreak, for the duration of the public health emergency, FDA does not intend to object to the distribution and use of face shields that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face shield does not create an undue risk in light of the public health emergency: Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR Part 820, Reports of Corrections and Removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA currently believes such devices would not create such an undue risk where:

- The product includes labeling that accurately describes the product as a face shield and includes a list of the body contacting materials (which does not include any drugs, or biologics);

- The face shield does not contain any materials that will cause flammability, or the product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);

[16] https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html.
[17] *See* 29 CFR 1910 subpart I.

- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses, or for radiation protection.

E. Surgical Masks Intended to Provide Liquid Barrier Protection

Surgical masks are class II devices that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are tested for flammability and biocompatibility. For the duration of the declared public health emergency, FDA does not intend to object to the distribution and use of surgical masks without compliance with the following regulatory requirements where the surgical mask does not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, Reports of Corrections and Removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA currently believes such devices would not create such an undue risk where:

- The product meets fluid resistance testing (liquid barrier performance) consistent with standard ASTM F1862[18] Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);

- The product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);

- The product includes labeling that accurately describes the product as a surgical mask and includes a list of the body contacting materials (which does not include any drugs or biologics); and

- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses and does not include particulate filtration claims.

[18] For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

F. Alternatives When FDA-Cleared or NIOSH-Approved N95 Respirators are Not Available

CDC published on its website Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies,[19] which, as part of a set of crisis management recommendations, identifies alternatives to FDA-cleared or NIOSH-approved N95 respirators approved under standards used in other countries, some of which were evaluated under methods that are similar to NIOSH-approved N95 respirators.

In the April 2, 2020 publication of this guidance, FDA provided flexibility regarding distribution and use of respirators identified in the CDC recommendations without compliance with certain regulatory requirements, including submission of a 510(k) under certain circumstances. FDA's policy was based on the evolving public health emergency and the increasing need for respiratory protection devices for HCP, which was rapidly outpacing the supply of FDA-cleared or NIOSH-approved respirators. The guidance also recommended that importers take appropriate steps to verify the authenticity of products they import.

In addition to this policy and in response to the shortage of respirators, FDA issued emergency use authorizations (EUAs) for certain respirators that FDA determined met the criteria for issuance under Section 564 of the Act.[20] These EUAs have succeeded in increasing the availability of respirators for HCP when FDA-cleared or NIOSH-approved respirators are not available.

Since the April 2, 2020 publication of this guidance, FDA has become aware of concerns regarding the performance of certain respirators based on testing conducted by the CDC.[21] This indicates that greater FDA oversight of respirators that are not FDA-cleared or authorized under an EUA is important to protect the public health. As a result of these changed circumstances, FDA is discontinuing its previous policy from April 2, 2020 under which FDA did not intend to object to the distribution and use of certain respirators that were not FDA-cleared or authorized under an EUA and did not meet other regulatory requirements.

FDA currently believes that FDA-cleared or NIOSH-approved N95 respirators should be used when they are available, but when they are not, FDA recommends using FDA-authorized respirators before any other alternatives. This is consistent with the CDC's approach for optimizing the supply of N95 respirators. FDA does not recommend using a product as a respirator unless it has been FDA-cleared, NIOSH-approved, or authorized by FDA for emergency use as a respirator. Such a product could instead be used as a face mask by the general public and HCP as source control when certain criteria are met under the EUA for face masks.[22] In that case, the product should be labeled accordingly and not used as a respirator.[23]

---

[19] https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html.

[20] See FDA's webpage regarding emergency use authorizations, available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe.

[21] https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html.

[22] https://www.fda.gov/media/137121/download.

[23] Source control refers to the use of a facemask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19. See also https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.

In addition, FDA notes that HCP should ensure that respirators adequately fit. Hospitals and end users should be aware that it may be difficult to achieve an adequate fit when wearing respirators with ear loops instead of head straps. When proper fit is not achieved for a respirator, it should not be used as a respiratory protective device.

VI. EUAs for Face Masks Intended for a Medical Purpose, Surgical Masks and N95 Respirators

Wherever possible, health care facilities should continue to use FDA-cleared surgical masks and NIOSH-approved and/or FDA-cleared N95 respirators, or better. In response to the COVID-19 pandemic, FDA has also issued EUAs that authorize certain FFRs, including NIOSH-approved FFRs,[24] imported non-NIOSH-approved disposable FFRs from certain jurisdictions excluding China,[25] and non-NIOSH-approved disposable FFRs manufactured in China,[26] for use in healthcare settings by HCP. These EUAs are intended to help increase availability of these devices to front-line personnel during the public health emergency. FDA has also issued an EUA for face masks[27] for use by the general public and HCP as source control.

For devices that do not fall within the scope of these EUAs, FDA is interested in interacting with manufacturers on additional device-specific EUAs. This may include manufacturers of masks and respirators that are not currently legally marketed in the US as well as manufacturers who have not previously manufactured masks or respirators with capabilities to increase supply of these devices.

FDA would find it helpful if such manufacturers (whether foreign or domestic) send FDA the following information to CDRH-COVID19-SurgicalMasks@fda.hhs.gov; FDA believes this information will be valuable in assessing whether the device would be able to meet the EUA requirements. FDA believes that companies may already have available information to help support an EUA request such as the information outlined below. FDA will expeditiously review this information, and other required information,[28] to determine whether the device can be authorized under an EUA.

1) For current face mask and respirator manufacturers whose product(s) are not currently marketed in the US, FDA recommends providing the following information:
    a. General information such as your contact information, name and place of business, email address, and contact information for a U.S. agent (if any) in addition to general information about the device such as the proprietary or brand name, model number, and marketing authorization in your country (or region).
    b. A copy of the product labeling.
    c. Whether the device currently has marketing authorization in another regulatory jurisdiction (including certification number, if available).

[24] https://www.fda.gov/media/135763/download.
[25] https://www.fda.gov/media/136403/download.
[26] https://www.fda.gov/media/136664/download.
[27] https://www.fda.gov/media/137121/download.
[28] See Section 564 of the FD&C Act.

d. Whether the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes* or an equivalent quality system and the manufacturer or importer has documentation of such.
e. Description of testing conducted on the device, including any standards met, such as liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate. For surgical N95 respirators, FDA recommends including fluid resistance testing (liquid barrier performance).

2) For face mask manufacturers who have not previously been engaged in medical device manufacturing but with capabilities to increase supply of these devices:

FDA welcomes the opportunity to work with manufacturers not previously engaged in medical device manufacturing with the interest and capability to manufacture face masks and respirators. This may include US manufacturers in other manufacturing sectors. These manufacturers should send an email to the address above and describe their proposed approach. FDA intends to work collaboratively with these manufacturers through its EUA process.

For any face mask or FFR (including N95 respirators) issued an EUA, FDA will include appropriate conditions of authorization in accordance with section 564 of the FD&C Act. Although this is a case-by-case determination, based on current information and experience, we will likely include the following conditions:

- Appropriate conditions designed to ensure that HCP administering the device are informed—
  - that FDA has authorized the emergency use of the device;
  - of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
  - of the alternatives to the device that are available, and of their benefits and risks.

- Appropriate conditions designed to ensure that individuals to whom the device is administered are informed—
  - that FDA has authorized the emergency use of the device;
  - of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
  - of the option to accept or refuse administration of the device, of the consequence, if any, of refusing administration of the device, and of the alternatives to the device that are available and of their benefits and risks.

- Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the device. FDA intends to include conditions that are consistent with those promulgated under 21 CFR Part 803.

- For manufacturers of the device, appropriate conditions concerning recordkeeping and reporting, including records access by FDA, with respect to emergency use of the device.

U.S. FOOD & DRUG ADMINISTRATION

Plaintiff's Exhibit 450

April 24, 2020

To: Manufacturers of Face Masks;
Health Care Personnel;
Hospital Purchasing Departments and Distributors; and
Any Other Stakeholders.

On April 18, 2020, in response to concerns relating to insufficient supply and availability of face masks,[1,2] the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) authorizing the use of face masks for use by members of the general public, including health care personnel (HCP)[3] in healthcare settings as personal protective equipment (PPE), to cover their noses and mouths, in accordance with Centers for Disease Control and Prevention (CDC) recommendations, to prevent the spread of the virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States

[1] A face mask is a device, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. It includes cloth face coverings as a subset. It may be for single or multiple uses, and if for multiple uses it may be laundered or cleaned. There are many products marketed in the United States as "face masks" that offer a range of protection against potential health hazards. Face masks are regulated by FDA when they meet the definition of a "device" under section 201(h) of the Act. Generally, face masks fall within this definition when they are intended for a medical purpose. Face masks are regulated under 21 CFR 878.4040 as Class I 510(k)-exempt devices (non-surgical masks).

[2] Surgical masks are not covered within the scope of this authorization. Surgical masks are masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are regulated under 21 CFR 878.4040 as class II devices requiring premarket notification. Additionally, these masks meet certain fluid barrier protection standards and Class I or Class II flammability tests. More information on the distinction is provided in FDA guidance, titled "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency" available at https://www.fda.gov/media/136449/download.

[3] HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

citizens living abroad, and that involves the virus that causes COVID-19.[4] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[5]

On April 24, 2020 in response to questions and concerns that have been received by FDA since issuance of the April 18, 2020 letter of authorization and having concluded that revising the April 18, 2020 EUA is appropriate to protect the public health or safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the April 18, 2020 letter in its entirety with amendments[6] incorporated. Specifically, FDA is clarifying through this re-issued letter that facemasks, including cloth face coverings, are authorized to be used by HCP only as source control[7,8] in accordance with CDC recommendations under this EUA.[9] As stated in the April 18 letter, face masks are authorized for use by the general public to cover their noses and mouths, in accordance with CDC recommendations.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of face masks for use in accordance with CDC recommendations, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

For the most current CDC recommendations on the use of face masks by the general public during COVID-19, please visit CDC's webpage: Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission For the most recent recommendations on use of face masks by HCPs in a healthcare setting, see: Strategies to Optimize the Supply of PPE and Equipment.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of face masks in accordance with CDC recommendations as source control as described in the Scope of Authorization (Section II) to

---

[4] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020)

[5] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

[6] The amendments to the April 18, 2020 letter clarify that the eligible facemasks are to be used for source control only, and are not personal protective equipment, meaning they are not a substitute for filtering face piece respirators or for surgical face masks. This reissued EUA does not change any aspects of the April 18, 2020 letter with respect to the use of face masks by the general public.

[7] Source control refers to the use of a facemask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19.

[8] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

[9] In addition, health care employers should refer to standards of the Occupational Safety and Health Administration (OSHA) that apply to PPE to protect workers and infectious disease hazards. *See* 29 CFR 1910 subpart I.

help prevent spread of the virus during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized face masks may be effective as source control to help prevent the spread of SARS-CoV-2 by infected individuals who may or may not have symptoms of COVID-19 during the COVID-19 pandemic, and that the known and potential benefits of face masks, when used in accordance with the scope of this authorization (Section II), outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of face masks for source control by the general public and for HCPs to help prevent the spread of the virus due to face mask shortages during the COVID-19 pandemic.[10,11]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of face masks, including cloth face coverings, as source control for use by members of the general public, as well as HCP in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of the SARS-CoV-2 during the COVID-19 pandemic. The facemasks are not intended to be used by HCPs as PPE, meaning they are neither substitutable for respiratory protective devices such as filtering face piece respirators, nor for surgical face masks. This use is consistent with face masks regulated as Class I 510(k)-exempt face masks under 21 CFR 878.4040.

Authorized Face Masks

Face masks are authorized under this EUA when they are intended for use as source control, by members of the general public as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic. Authorized face masks must meet the following requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);

[10] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[11] Providing authorization for the introduction into interstate commerce of face masks by manufacturers that do not customarily engage in the manufacture of medical devices helps meet the needs of the healthcare system. In addition, increased availability of face masks helps meet the needs for source control for the general population, reserving FDA-cleared surgical masks and FDA-cleared or -authorized N95 and N95 equivalent Face Filtering Respirators for use by HCP. Providing HCP who are on the forefront of the COVID-19 response with sufficient PPE is necessary in order to help prevent HCP exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic.

2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection;
3. The product labeling includes recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high;
4. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction;
5. The product is not labeled as a respiratory protective device, and therefore should not be used for particulate filtration; and
6. The product is not labeled for use in high risk aerosol generating procedures.[12]

Manufacturers of face masks that are used as described above and meet the above requirements (i.e., are within this section (the Scope of Authorization, Section II)) do not need to take any action, other than complying with the Conditions of Authorization (Section IV) to be authorized under this EUA. FDA's posting and public announcement of this EUA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization, serves as face mask manufacturers' notification of authorization.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of face masks as described within this section (the Scope of Authorization, Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that face masks may be effective as described within this section (the Scope of Authorization, Section II) of this letter, pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I of this letter, and concludes that face masks (as described in this section, the Scope of Authorization, Section II), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of face masks must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), face masks, as source control, are authorized for use by members of the general public, as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic.

[12] Examples of aerosol generating procedures in healthcare settings may be found at https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html

III. Waiver of Certain FDA Requirements

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under sections 520(f)(1). FDA grants that waiver, including the quality system requirements under 21 CFR Part 820 and labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements in 21 CFR Part 830 and 21 CFR 801.20, except that face masks must include the labeling elements specified in the Conditions of Authorization (Section IV).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions to this authorization:

Manufacturers and Distributors of Authorized Products[13]

A. Manufacturers and Distributors will make face masks available with labeling that includes a description of the product as a face mask, including a list of the body contacting materials (which does not include any drugs or biologics).

B. Manufacturers and Distributors of authorized products shall not label the product: 1) as a surgical mask, to provide liquid barrier protection; 2) for use in a clinical setting where the infection risk level through inhalation exposure is high; 3) for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses; 4) as a respiratory protective device; or 5) for high risk aerosol-generating procedures.

C. Manufacturers must make the required labeling available to each end user or end user facility (each hospital) in hard copy or in an alternative format (e.g., electronic labeling on the manufacturer's website). Instructions on how to access the labeling if provided in an alternative format must be available to each end user or end user facility.

D. Manufacturers and Distributors will include instructions for recommended cleaning and/or disinfection materials and processes, if applicable, for their authorized product(s). Manufacturers must provide these instructions, if applicable, to each end user or end user facility (e.g., each hospital) in hard copy or in an alternative format (e.g., electronic instructions). Instructions on how to access the labeling if provided in an alternative format must be available to each end user or end user facility.

[13] The requirements under 21 CFR Part 806 (Reports of Corrections and Removals) and 21 CFR Part 807 (Registration and Listing) do not apply to products authorized under an EUA. As such, compliance with these regulations are not required under this EUA.

E. Manufacturers will have a process in place for reporting adverse events of which they become aware to FDA under 21 CFR Part 803. Adverse events of which the manufacturer becomes aware will be reported to FDA. See FDA's webpage "Medical Device Reporting (MDR): How to Report Medical Device Problems"[14] for reporting requirements and procedures.[15]

F. Manufacturers and distributors will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

G. Through a process of inventory control, manufacturers and distributors will maintain records of the entities to which they distribute the face masks and the numbers of each such product they distribute.

H. Manufacturers and distributors are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

Conditions Related to Advertising and Promotion

I. All printed matter, including advertising and promotional materials, relating to the use of the authorized face mask shall be consistent with the labeling elements listed in Section II of this EUA, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

J. No printed matter, including advertising or promotional materials, relating to the use of the authorized face mask may represent or suggest that such product is safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.

K. All advertising and promotional descriptive printed matter relating to the use of the product shall clearly and conspicuously state that

- The product has not been FDA cleared or approved
- The product has been authorized by FDA under an EUA for use as source control by the general public as well as by HCP in healthcare settings as to help prevent the spread of infection or illness during the COVID-19 pandemic.
- This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices,

[14] FDA guidance, titled "Medical Device Reporting (MDR): How to Report Medical Device Problems" is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

[15] Also refer to FDA guidance, titled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic" available at https://www.fda.gov/media/72498/download.

during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/S/

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

delegated herein prior to the effective date of this delegation.

Robert McGowan,

Chief of Staff, CDC.

[FR Doc. 2020–06471 Filed 3–26–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Ryan White HIV/AIDS Treatment Extension Act of 2009: Update to the List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed To Include Coronavirus Disease 2019 (COVID–19), the Disease Caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS–CoV–2)

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), of the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is adding coronavirus disease 2019 (COVID–19), the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2), to the *List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May be Exposed.* The list and companion guidelines are published by NIOSH pursuant to the Ryan White HIV/AIDS Treatment Extension Act of 2009. NIOSH encourages medical facilities to review the agency's guidelines describing the manner in which medical facilities should make determinations on whether an emergency response employee was exposed to COVID–19, the disease caused by SARS–CoV–2.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Office of the Director, NIOSH; 1090 Tusculum Avenue, MS:C–48, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Statutory Authority

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 (Pub. L. 101–381) was reauthorized in 1996, 2000, 2006, and 2009. The most recent reauthorization, the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111–87), amended the Public Health Service Act (PHS Act, 42 U.S.C. 201–300ii) and, pursuant to Section 2695, requires the HHS Secretary to establish the following: A list of potentially life-threatening infectious diseases, including emerging infectious diseases, to which emergency response employees (ERE) may be exposed while responding to emergencies; guidelines describing circumstances in which EREs may be exposed to these diseases, taking into account the conditions under which emergency response is provided; and guidelines describing the manner in which medical facilities should make determinations about exposures to EREs.

In a **Federal Register** notice published on July 14, 2010, the HHS Secretary delegated this responsibility to the CDC Director.[1] The CDC Director further assigned the responsibility to the NIOSH Director and formally re-delegated the authority to develop the list and guidelines to NIOSH on August 27, 2018.[2]

Addition of COVID–19, the Disease Caused by the Virus SARS–COV–2, to the List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed

The list of potentially life-threatening infectious diseases maintained by NIOSH is available in a **Federal Register** notice published on November 2, 2011 (76 FR 67736), available on the NIOSH website at *https://www.cdc.gov/niosh/topics/ryanwhite/default.html.* With this notice the NIOSH *List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed* is updated by the addition of the following:

C. Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means

■ COVID–19 (the disease caused by the virus SARS–CoV–2)

COVID–19, the disease caused by the virus SARS–CoV–2, is being added to the existing list. COVID–19, the disease caused by the virus SARS–CoV–2, is a potentially life-threatening emerging infectious disease that is thought to be spread primarily by respiratory droplets generated by an infectious person through events such as coughing or sneezing (*https://www.cdc.gov/coronavirus/2019-ncov/index.html*).

EREs may be exposed to COVID–19, the disease caused by the virus SARS-CoV–2, by a victim of an emergency who may be infected with SARS–CoV–2 while attending to, treating, assisting, or transporting the victim to a medical facility. Medical facilities should review the NIOSH guidelines describing the manner in which medical facilities should make determinations about exposures to life-threatening infectious diseases, including COVID–19, available on the NIOSH website at *https://www.cdc.gov/niosh/topics/ryanwhite/default.html.*

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2020–06458 Filed 3–26–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Emergency Use Authorization Declaration

ACTION: Notice of Emergency Use Authorization Declaration.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV). The virus is now named SARS–CoV–2, which causes the illness COVID–19. On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination was effective February 4, 2020, and this declaration is effective March 24, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human

[1] 75 FR 40842.

[2] 83 FR 50379 (October 4, 2018).

Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 of the FD&C Act, 21 U.S.C. 360bbb–3, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met. The Office of the Assistant Secretary for Preparedness and Response, HHS, requested that the FDA, HHS, issue an EUA for certain medical devices to allow the Department to take response measures based on information currently available about the virus that causes COVID–19. The determination of a public health emergency, and the declaration that circumstances exist justifying emergency use of certain medical devices by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for these devices for emergency use under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV). The virus is now named SARS–CoV–2, which causes the illness COVID–19.

III. Declaration of the Secretary of Health and Human Services

On March 24, 2020, on the basis of my determination of a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the novel (new) coronavirus, SARS–CoV–2, I declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Dated: March 24, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–06541 Filed 3–25–20; 4:15 pm]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel NIAAA Review Subcommittee Member Conflict Review Panel.

Date: April 7, 2020.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Suite 2118, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Philippe Marmillot, Ph.D., National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 301–443–2861 *marmillotp@mail.nih.gov*.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group Epidemiology, Prevention and Behavior Research Review Subcommittee.

Date: June 8, 2020.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Conference Room B, Bethesda, MD 20817.

Contact Person: Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch Office of Extramural Activities National Institute on Alcohol Abuse and Alcoholism, 6700b Rockledge Drive, Room 2120, MSC 6902 Bethesda, MD 20892, 301–443–4032, *anna.ghambaryan@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research

receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Stephanie Choi (see **FOR FURTHER INFORMATION CONTACT**) no later than April 3, 2020.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session for a specific breakout session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments (and requests to participate in the focused sessions). Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 10, 2020. All requests to make oral presentations must be received by the close of registration on April 3, 2020, midnight Eastern Time. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than April 24, 2020, midnight Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Persons attending FDA's workshops are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Please register online by April 3, 2020, midnight Eastern Time to attend the workshop remotely. Please note that remote attendees will not be able to speak or make presentations during the public comment session or during any other session of the workshop. To join the main sessions of the workshop via the webcast, please go to *https://collaboration.fda.gov/gdrsipw2020/.* Webcast information for the four breakout sessions will be provided separately via email upon successful registration.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov* or at *https://www.fda.gov/gdufaregscience.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/gdufaregscience.*

Dated: March 4, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04866 Filed 3–9–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Emergency Use Declaration

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined, pursuant to his authority under section 564 of the FD&C Act, that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV). The virus is now named SARS–CoV–2, which causes the illness COVID–19.

On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID–19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination was effective February 4, 2020, and this declaration is effective March 2, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA), authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security, pursuant to section 319F–2 of the Public Health Service (PHS) Act,[1] sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.[2]

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances

[1] 42 U.S.C. 247d–6b.

[2] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Public Law 113–5, the Secretary may make determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency in accordance with section 319 of the PHS Act, 42 U.S.C. 247d to support a determination or declaration made under section 564 of the FD&C Act.

exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of such an authorization under section 564 of the FD&C Act are met.

The Centers for Disease Control and Prevention (CDC), HHS, requested that the FDA, HHS, issue an EUA for personal respiratory protective devices to allow the Department to take preparedness measures, based on information currently available about the virus that causes COVID–19. The determination of a public health emergency, and the declaration that circumstances exist justifying emergency use of personal respiratory protective devices by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for respiratory protective devices for emergency use under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV). The virus is now named SARS–CoV–2, which causes the illness COVID–19.

III. Declaration of the Secretary of Health and Human Services

On March 2, 2020, on the basis of my determination of a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the novel (new) coronavirus, I declared that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID–19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Alex M. Azar II,

Secretary.

[FR Doc. 2020–04823 Filed 3–9–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Investigator Initiated Extended Clinical Trial (R01 Clinical Trial Required).

Date: March 24, 2020.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53A, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Julio C. Aliberti, Ph.D., Scientific Review Officer, Immunology Review Branch, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53A, Rockville, MD 20892–9823, 301–761–7322, *julio.aliberti@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 4, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–04780 Filed 3–9–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed).

Date: April 6–8, 2020.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Bethesda, MD 20892–9834, (240) 669–5026, *haririmf@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 4, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–04782 Filed 3–9–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant

Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Charles Viviano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2680, Silver Spring, MD 20993–0002, 240–402–2975.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this draft guidance to propose select updates to the FDA guidance document ''Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' The existing guidance on devices used for the treatment of BPH remains in effect, in its current form, until this draft guidance is finalized. FDA intends to incorporate this draft guidance into one final guidance document after obtaining and considering public comment on these select updates. The sections of the existing BPH guidance that are not affected by this select update will not be substantively changed and will remain in effect.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1724 and the full title to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
807, subpart E	Premarket Notification	0910–0120
812	Investigational Device Exemption	0910–0078
814, subparts A through E	Premarket Approval Applications	0910–0231
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo Classification Process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15089 Filed 7–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance and reissuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA has issued, and in some cases reissued, the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance and reissuance, are listed in this document, and are available on FDA's website at the links indicated.

DATES: These Authorizations are applicable on their date of issuance.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. The Authorizations

Having concluded that the criteria for the issuance and, in some cases reissuance, of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID–19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, are available on the internet from the FDA web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The lists that follow include Authorizations issued, in some cases reissued, from April 11, 2020, through May 15, 2020, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. FDA is

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

hereby announcing the following Authorizations for in vitro diagnostics: [3]

- Ortho-Clinical Diagnostics, Inc.'s VITROS Immunodiagnostic Products Anti-SARS–CoV–2 Total Reagent Pack, issued April 14, 2020;
- Chembio Diagnostic System, Inc.'s DPP COVID–19 IgM/IgG System, issued April 14, 2020;
- Mount Sinai Laboratory's COVID–19 [enzyme-linked immunosorbent assay] ELISA IgG Antibody Test, issued April 15, 2020;
- Maccura Biotechnology (USA) LLC's SARS–CoV–2 Fluorescent PCR Kit, issued April 15, 2020;
- GenoSensor, LLC's GS COVID–19 RT–PCR KIT, issued April 16, 2020;
- KorvaLabs Inc.'s Curative-Korva SARS–CoV–2 Assay, issued April 16, 2020;
- Fosun Pharma USA Inc.'s Fosun COVID–19 RT–PCR Detection Kit, issued April 17, 2020;
- OSANG Healthcare's GeneFinder COVID–19 Plus RealAmp Kit, issued April 18, 2020;
- Trax Management Services Inc.'s PhoenixDx 2019–CoV, issued April 20, 2020;
- Laboratory Corporation of America's COVID–19 RT–PCR Test, reissued April 20, 2020 (original issuance March 16, 2020);
- Seegene, Inc.'s Allplex 2019–nCoV Assay, issued April 21, 2020;
- altona Diagnostics GmbH's RealStar SARS–CoV–2 RT–PCR Kits U.S., issued April 22, 2020;
- SD Biosensor, Inc.'s STANDARD M nCoV Real-Time Detection Kit, issued April 23, 2020;
- Autobio Diagnostics Co. Ltd.'s Anti-SARS–CoV–2 Rapid Test, issued April 24, 2020;
- Ortho-Clinical Diagnostics, Inc.'s VITROS Immunodiagnostic Products Anti-SARS–CoV–2 IgG Reagent Pack, issued April 24, 2020;
- DiaSorin Inc.'s LIAISON SARS–CoV–2 S1/S2 IgG, issued April 24, 2020;
- Abbott Laboratories Inc.'s SARS–CoV–2 IgG assay, issued April 26, 2020;
- SEASUN BIOMATERIALS's U–TOP COVID–19 Detection Kit, issued April 27, 2020;
- Bio-Rad Laboratories, Inc's Platelia SARS–CoV–2 Total Ab assay, issued April 29, 2020;
- Rheonix, Inc.'s Rheonix COVID–19 MDx Assay, issued April 29, 2020;
- LabGenomics Co., Ltd.'s LabGun COVID–19 RT–PCR Kit, issued April 29, 2020;
- Wadsworth Center, New York State Department of Health's New York SARS–CoV Microsphere Immunoassay for Antibody Detection, issued April 30, 2020;
- BioFire Diagnostics, LLC's BioFire Respiratory Panel 2.1 (RP2.1), issued May 1, 2020;
- Bio-Rad Laboratories, Inc.'s Bio-Rad SARS–CoV–2 ddPCR Test, issued May 1, 2020;
- Roche Diagnostics's Elecsys Anti-SARS–CoV–2, issued May 2, 2020;
- Sansure BioTech Inc.'s Novel Coronavirus (2019–nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing), issued May 4, 2020;
- EUROIMUN US Inc.'s Anti-SARS–CoV–2 ELISA (IgG), issued May 4, 2020;
- Fast Track Diagnostics Luxembourg S.á.r.l's. (a Siemens Healthineers Company) FTD SARS–CoV–2, issued May 5, 2020;
- BioMérieux SA's SARS–COV–2 R–GENE, issued May 6, 2020;
- Sherlock BioSciences, Inc.'s Sherlock CRISPR SARS–CoV–2 Kit, issued May 6, 2020;
- OPTI Medical Systems, Inc.'s OPTI SARS–CoV–2 RT PCR Test, issued May 6, 2020;
- Zymo Research Corp.'s Quick SARS–Cov–2rRT–PCR Kit, issued May 7, 2020;
- Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics-Rutgers University's Rutgers Clinical Genomics Laboratory TaqPath SARS–CoV–2 Assay, reissued May 7, 2020 (original issuance April 10, 2020);
- Gnomegen LLC's Gnomegen COVID–19–RT–qPCR Detection Kit, issued May 8, 2020;
- Quidel Corporation's Sofia 2 SARS Antigen FIA, issued May 8, 2020;
- Abbott Molecular Inc.'s Alinity m SARS–CoV–2 assay, issued May 11, 2020;
- 1drop Inc.'s 1copy COVID–19 qPR Multi Kit, issued May 11, 2020;
- Applied DNA Sciences, Inc.'s Linea COVID–19 Assay Kit, issued May 13, 2020;
- GeneMatrix, Inc.'s NeoPlex COVID–19 Detection Kit, issued May 14, 2020;
- Hologic, Inc., Aptima SARS–CoV–2 assay, issued May 14, 2020;
- Assurance Scientific Laboratories' Assurance SARS–CoV–2 Panel, issued May 15, 2020;
- Fulgent Therapeutics, LLC's Fulgent COVID–19 by RT–PCR Test, issued May 15, 2020; and
- Certain SARS–CoV–2 Antibody Tests (lateral flow or ELISA tests) that are for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. 263a, to perform moderate or high complexity tests, issued on April 28, 2020 (a current list of tests included under this EUA is available at *https://www.fda.gov/media/137471/download*).

FDA is hereby announcing the following Authorizations for personal respiratory protective devices: [4]

- Certain Non-[National Institute of Industrial and Occupational Safety]NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China, reissued May 7, 2020, (original issuance April 3, 2020). A current list of respirators included under this EUA is available at *https://www.fda.gov/media/136663/download*).

FDA is hereby announcing the following Authorizations for other medical devices:

- B. Braun Medical, Inc.'s B. Braun Space and Outlook Pumps, issued April 11, 2020; [5]
- Advanced Sterilization Products, Inc.'s ASP STERRAD Sterilization Systems, issued April 11, 2020; [6]

[3] As set forth in the EUAs for these devices, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the devices may be effective in diagnosing COVID–19, and that the known and potential benefits of the devices, when used for diagnosing COVID–19, outweigh the known and potential risks of such devices; and (3) there is no adequate, approved, and available alternative to the emergency use of the devices.

[4] As set forth in the EUAs, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is either reasonable to believe that the authorized respirators may be effective in preventing healthcare personnel (HCP) exposure to pathogenic biological airborne particulates during Filtering Facepiece Respirator (FFR) shortages, and that the known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages during COVID–19, outweigh the known and potential risks of such products, and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[5] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the B. Braun Space and Outlook Pumps may be effective for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat COVID–19 patients of all ages and for the ground medical transport use of the Infusomat Space Volumetric Infusion Pump System, and that the known and potential benefits of the B. Braun Space and Outlook Pumps for these uses, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[6] As set forth in this EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to

Continued

- Certain Face Shields, reissued April 13, 2020 (original issuance April 9, 2020); [7]
- Synapse Biomedical, Inc.'s TransAeris Diaphragm Pacing System, issued April 13, 2020; [8]
- Stryker Instruments' STERIZONE VP4 Sterilizer, issued April 14, 2020; [9]
- Lungpacer Medical USA, Inc.'s Lungpacer DPTS, issued April 14, 2020 (see footnote 8);
- ExThera Medical Corporation's Seraph 100 Microbind Affinity Blood Filter, issued April 17, 2020; [10]
- Certain Face Masks, issued April 18, 2020, and reissued April 24, 2020; [11]
- Sterilucent, Inc.'s Sterilucent Sterilizer System, issued April 20, 2020; [12]
- Philips Medizin Systeme Boeblingen GmbH's IntelliVue Patient Monitors, issued April 21, 2020; [13]
- ALung Technologies, Inc.'s Hemolung RAS, issued April 22, 2020; [14]
- Baxter Healthcare Corp.'s oXiris Set device, issued April 23, 2020; [15]
- VitalConnect, Inc.'s VitalPatch, issued April 26, 2020; [16]
- Fresenius Medical Care's multiFiltrate PRO System and multiBic/multiPlus Solutions to provide continuous renal replacement therapy, issued May 1, 2020; [17]
- Liberate Medical, LLC's VentFree, issued May 1, 2020; [18]

FDA, it is reasonable to believe that the ASP STERRAD Sterilization Systems may be effective at preventing exposure to pathogenic airborne particulates when there are insufficient supplies of N95 respirators during the COVID–19 pandemic by decontaminating, for a maximum of two decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS–CoV–2 or other pathogenic microorganisms, and that the known and potential benefits of the Sterilization Systems, when used to decontaminate compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic airborne particulates during N95 respirator shortages during the COVID–19 pandemic, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[7] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized face shields may be effective at preventing HCP exposure to fluid biological airborne particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer, and that the known and potential benefits of face shields, when used to prevent HCP exposure to such particulates during face shield shortages during COVID–19 outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[8] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective for emergency use to treat patients by assisting in weaning patients off ventilators in healthcare settings during the COVID–19 pandemic, and that the known and potential benefits of the such product, for such use, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative.

[9] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the STERIZONE VP4 N95 Respirator Decontamination Cycle may be effective at preventing exposure to pathogenic airborne particulates by decontaminating, for a maximum of two decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS–CoV–2 or other pathogenic microorganisms, and that the known and potential benefits of this device, when used as described, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the STERIZONE VP4 N95 Respirator Decontamination Cycle for decontaminating compatible N95 respirators for single-user reuse by HCPs during FFR shortages during the COVID–19 pandemic.

[10] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Seraph 100 Microbind Affinity Blood Filter device may be effective in treating patients 18 years of age or older with confirmed COVID–19 admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure, and that the known and potential benefits of the Seraph 100 Microbind Affinity Blood Filter device, when used to treat such patients, outweigh the known and potential risks of the device; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[11] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized face masks may be effective as source control to help prevent the spread of SARS–CoV–2 by infected individuals who may or may not have symptoms of COVID–19 during the COVID–19 pandemic, and that the known and potential benefits of face masks, when used in accordance with the scope of this authorization, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[12] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Sterilucent Sterilization System may be effective at decontaminating compatible N95 respirators for single-user reuse by HCPs to prevent exposure to pathogenic biological airborne particulates, and that the known and potential benefits of this device, when used as described, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[13] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the IntelliVue Patient Monitors may be effective in preventing COVID–19 exposure in healthcare providers, through use of remote patient monitoring, and that the known and potential benefits of such products, for such use, outweigh the known and potential risks of the IntelliVue Patient Monitors; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[14] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Hemolung RAS may be effective in treating lung failure when used as described in the Scope of Authorization, and that the known and potential benefits of the Hemolung RAS for treating these patients, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[15] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the oXiris Set device may be effective in treating patients 18 years of age or older with confirmed COVID–19 admitted to the ICU with confirmed or imminent respiratory failure in need of blood purification, including use in continuous renal replacement therapy, and that the known and potential benefits of the oXiris Set device, when used to treat such patients, outweigh the known and potential risks of the oXiris Set device; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[16] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in remotely monitoring and detecting QT interval changes of an ECG in patients who are undergoing treatment in a hospital setting for COVID–19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (*e.g.,* hydroxychloroquine or chloroquine, especially when used in combination with azithromycin), the known and potential benefits of product for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[17] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness and multiple organ failure, including acute kidney injury, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that your multiFiltrate PRO System and multiBic/multiPlus Solutions may be effective in delivering CRRT in an acute care environment, and that the known and potential benefits of the multiFiltrate PRO System and multiBic/multiPlus Solutions, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[18] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes

- Certain Protective Barrier Enclosures, issued May 1, 2020; [19]
- PhsiolGuard Corp. Ltd.'s PhysiolGuard ECG–QT Analysis System, issued May 5, 2020 (refer to footnote 15);
- Duke University Health System's Duke Decontamination System, issued May 7, 2020; [20]
- Comunale's Patient Isolation Transport Unit, issued May 8, 2020; [21]
- Ascom (US) Inc.'s teleCARE IP Nurse Call System, issued May 11, 2020; [22]
- Eko Devices, Inc.'s Eko ELEFT, issued May 11, 2020; [23]
- Certain Infusion Pumps and Infusion Pump Accessories, issued May 13, 2020; [24]
- G Medical Innovations Ltd.'s VSMS Patch, issued May 14, 2020; [25] and
- Everlywell Inc.'s Everlywell COVID–19 Test Home Collection Kit, issued May 15, 2020.[26]

Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15137 Filed 7–13–20; 8:45 am]

BILLING CODE 4164–01–P

COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that VentFree may be effective for emergency use by HCP in healthcare settings to treat adult patients by reducing disuse atrophy of the abdominal wall muscles, which may reduce the number of days of ventilator support in patients who require mechanical ventilation during the COVID–19 pandemic, and that the known and potential benefits of the such products, for such use, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[19] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized protective barrier enclosures may be effective at preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE when caring for or performing medical procedures on patients who are known or suspected to have COVID–19 in healthcare settings and that the known and potential benefits of protective barrier enclosures, for such use, outweigh the known and potential risks of such product; and, (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[20] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Duke Decontamination System may be effective at decontaminating compatible N95 respirators for reuse by HCPs to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[21] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the PITU may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, and that the known and potential benefits of such products, when used by HCP for temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID–19 requiring airborne or droplet isolation precautions in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, outweigh the known and potential risks of the PITU; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[22] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the use of the teleCARE IP Nurse Call System in healthcare environments may be effective for preventing COVID–19 exposure in healthcare providers by enabling remote communication between patients and healthcare providers, and, for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare provider. FDA concluded that the known and potential benefits of the teleCARE IP Nurse Call System, for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[23] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the ELEFT may be effective for use by HCP to provide an assessment of LVEF for use as a diagnostic aid to screen for potential cardiac complications associated with COVID–19 or underlying cardiac conditions that may affect clinical management of COVID–19, in adult patients having or suspected of having COVID–19 and that the known and potential benefits of ELEFT, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[24] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that authorized infusion pumps and infusion pump accessories may be effective for use by HCPs to treat conditions caused by COVID–19 with the controlled infusion of medications, TPN, and/or other fluids, and that the known and potential benefits of such products, for such use outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[25] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the VSMS Patchmay be effective in remotely monitoring QT interval prolongation on an ECG in patients who are undergoing treatment in a hospital setting for COVID–19 with drugs that can prolong QT intervals and may cause life-threatening arrhythmias (*e.g.,* hydroxychloroquine or chloroquine, especially when used in combination with azithromycin), the known and potential benefits of the VSMS Patch, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[26] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the home-collected human specimen, and that the known and potential benefits of the product when used for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1313]

Electronic Submissions; Data Standards; Support for Standard for the Exchange of Nonclinical Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) Center for Biologics Evaluation and Research (CBER) is announcing support for the current version of Clinical Data Interchange Standards Consortium (CDISC) Standard for the Exchange of Nonclinical Data (SEND) and an update to the FDA Data Standards Catalog for the submission of nonclinical data in new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs). This update does not apply to noncommercial INDs for a product that is not intended for commercial distribution (research and investigator-sponsored INDs); INDs and BLAs for devices that are regulated by CBER as biological products under the Public Health Services (PHS) Act; and submissions for blood and blood components, including Source Plasma.

Additional Draft Q&As on Biosimilar Development and the BPCI Act.'' The Q&A format is intended to inform prospective applicants and facilitate the development of proposed biosimilars and proposed interchangeable biosimilars, as well as to describe FDA's interpretation of certain statutory requirements added by the BPCI Act.

The BPCI Act created an abbreviated licensure pathway in section 351(k) of the PHS Act (42 U.S.C. 262(k)) for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product (see sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)). FDA believes that guidance for industry that provides answers to commonly asked questions regarding FDA's interpretation of the BPCI Act will enhance transparency and facilitate the development and approval of biosimilar and interchangeable products.

FDA has been using the format of Q&A guidance to describe the Agency's thinking on and update certain information and recommendations relevant to the development of biosimilar and interchangeable products. This draft guidance document contains only Q&As that are in draft form. After FDA has considered any comments on the Q&As contained in this draft guidance received during the relevant comment period and, as appropriate, incorporated suggested changes to the Q&A, individual Q&As will be finalized and moved to the final guidance document ''Questions and Answers on Biosimilar Development and the BPCI Act,'' which is updated as appropriate. The final guidance contains Q&As that have been through the public comment process and reflects FDA's current thinking on the topics described. A Q&A may be withdrawn and removed from the Q&A guidance documents if, for instance, the issue addressed in the Q&A has been addressed in another FDA guidance document. No such changes to currently issued draft or final guidance documents are being made in connection with the issuance of this draft guidance.

FDA has maintained the original numbering of the Q&As used in the December 2018 final guidance ''Questions and Answers on Biosimilar Development and the BPCI Act'' and the December 2018 draft guidance ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2).'' This draft guidance document provides new Q&As. It does not replace the draft guidance document entitled ''New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2),'' issued December 12, 2018.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The Q&As in this draft guidance, when finalized, will appear in the final guidance, and the final guidance will represent the current thinking of FDA on the Q&As posed in the ''Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for submission of an investigational new drug application have been approved under OMB control number 0910–0014. The collections of information in 21 CFR 314.50 for submission of a new drug application have been approved under OMB control number 0910–0001. The collections of information in section 351(a) of the PHS Act and 21 CFR part 601 for submission of a biologics license application (BLA) have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the PHS Act and 21 CFR part 601 for submission of a BLA have been approved under OMB control number 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: November 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25606 Filed 11–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance and reissuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA has issued, and in some cases reissued, the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance and reissuance, are listed in this document, and are available on FDA's website at the links indicated.

DATES: These Authorizations are applicable on their date of issuance/reissuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION**

section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under section 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. The Authorizations

Having concluded that the criteria for the issuance and, in some cases reissuance, of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID–19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, are available on the internet from the FDA web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The lists that follow include Authorizations issued, in some cases reissued, from May 16, 2020, through September 14, 2020, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. FDA is hereby announcing the following Authorizations for molecular diagnostic

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

and antigen tests for COVID–19, excluding multianalyte tests: [3]

- Color Genomics, Inc.'s Color SARS–CoV–2 LAMP Diagnostic Assay, issued May 18, 2020, and reissued July 24, 2020;
- Quidel Corp.'s Lyra Direct SARS–CoV–2 Assay, issued May 18, 2020;
- P23 Labs, LLC's P23 Labs TaqPath SARSd–CoV–2 Assay, issued May 21, 2020, and reissued July 10, 2020;
- SEASUN BIOMATERIALS, Inc.'s AQ–TOP COVID–19 Rapid Detection Kit, issued May 21, 2020;
- SolGent Co., Ltd.'s DiaPlexQ Novel Coronavirus (2019–nCoV) Detection Kit, issued May 21, 2020;
- BioCore Co., Ltd.'s BioCore 2019–nCoV Real Time PCR Kit, issued May 21, 2020;
- Exact Sciences Laboratories' SARSd–CoV–2 (N gene detection) Test, issued May 22, 2020, and reissued August 3, 2020;
- dba SpectronRx's Hymon SARSd–CoV–2 Test Kit, issued May 22, 2020;
- PrivaPath Diagnostics, Inc.'s LetsGetChecked Coronavirus (COVID–19) Test, issued May 28, 2020, and reissued August 14, 2020;
- Gravity Diagnostics, LLC's Gravity Diagnostics COVID–19 Assay, issued June 1, 2020;
- Phosphorus Diagnostics LLC's Phosphorus COVID–19 RT–qPCR Test, issued June 4, 2020;
- Genetron Health (Beijing) Co., Ltd.'s Genetron SARSd–CoV–2 RNA Test, issued June 5, 2020;
- Euroimmun US Inc.'s EURORealTime SARSd–CoV–2, issued June 8, 2020;
- ChromaCode Inc.'s HDPCR SARSd–CoV–2 Assay, issued June 9, 2020;
- Illumina, Inc.'s Illumina COVIDSeq Test, issued June 9, 2020;
- Tide Laboratories, LLC's DTPM COVID–19 RT–PCR Test, issued June 10, 2020;
- TBG Biotechnology Corp.'s ExProbe SARSd–CoV–2 Testing Kit, issued June 10, 2020;
- Cue Health, Inc.'s Cue COVID–19 Test, issued June 10, 2020;
- RTA Laboratories Biological Products Pharmaceutical and Machinery Industry's Diagnovital SARSd–CoV–2 Real-Time PCR Kit, issued June 12, 2020;
- Kaiser Permanente Mid-Atlantic States's KPMAS COVID–19 Test, issued June 13, 2020, and reissued September 9, 2020;
- Applied BioCode, Inc.'s BioCode SARSd–CoV–2 Assay, issued June 15, 2020;
- The Ohio State University Wexner Medical Center's OSUWMC COVID–19 RT–PCR test, issued June 17, 2020;
- Omnipathology Solutions Medical Corp.'s Omni COVID–19 Assay by RT–PCR, issued June 17, 2020;
- Jiangsu Bioperfectus Technologies Co., Ltd.'s COVID–19 Coronavirus Real Time PCR Kit, issued June 18, 2020;
- 3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.'s TRUPCR SARSd–CoV–2 Kit, issued June 18, 2020;
- HealthQuest Esoterics's HealthQuest Esoterics TaqPath SARSd–CoV–2 Assay, issued June 23, 2020;
- University of Alabama at Birmingham Fungal Reference Lab's FRL SARS CoV–2 Test, issued June 23, 2020;
- Gencurix, Inc.'s GenePro SARSd–CoV–2 Test, issued June 23, 2020;
- University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory's MD Anderson High-throughput SARSd–CoV–2 RT–PCR Assay, issued June 24, 2020;
- Diagnostic Solutions Laboratory, LLC's DSL COVID–19 Assay, issued June 25, 2020;
- PreciGenome LLC's FastPlex Triplex SARSd–CoV–2 detection kit (RT–Digital PCR), issued June 25, 2020;
- PlexBio Co., Ltd.'s IntelliPlex SARSd–CoV–2 Detection Kit, issued June 25, 2020;
- Inform Diagnostics, Inc.'s Inform Diagnostics SARSd–CoV–2 RT–PCR Assay, issued June 26, 2020;
- Acupath Laboratories, Inc.'s Acupath COVID–19 Real-Time (RT–PCR) Assay, issued June 29, 2020;
- LifeHope Labs' LifeHope 2019–nCoV Real-Time RT–PCR Diagnostic Panel, issued June 29, 2020;
- Psomagen, Inc.'s Psoma COVID–19 RT Test, issued June 30, 2020;
- TNS Co., Ltd.'s (Bio TNS) COVID–19 RT–PCR Peptide Nucleic Acid (PNA) kit, issued June 30, 2020;
- The Kroger Co.'s Kroger Health COVID–19 Test Home Collection Kit, issued June 30, 2020;
- CENTOGENE US, LLC's CentoFast–SARSd–CoV–2 RT–PCR Assay, issued July 1, 2020;
- Becton, Dickinson and Co.'s BD Veritor System for Rapid Detection of SARSd–CoV–2, issued July 2, 2020;
- Laboratorio Clinico Toledo's Laboratorio Clinico Toledo SARSd–CoV–2 Assay, issued July 6, 2020;
- Gene By Gene's Gene By Gene SARSd–CoV–2 Detection Test, issued July 7, 2020;
- Access Bio, Inc.'s CareStart COVID–19 MDx RT–PCR, issued July 7, 2020;
- Enzo Life Sciences, Inc.'s AMPIPROBE SARSd–CoV–2 Test System, issued July 7, 2020;
- Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard's CRSP SARSd–CoV–2 Real-time Reverse Transcriptase (RT)–PCR Diagnostic Assay, issued July 8, 2020;
- BioSewoom, Inc.'s Real-Q 2019–nCoV Detection Kit, issued July 9, 2020;
- UCSF Health Clinical Laboratories, UCSF Clinical Labs at China Basin's SARSd–CoV–2 RNA DETECTR Assay, issued July 9, 2020;
- Boston Medical Center's BMC–CReM COVID–19 Test, issued July 10, 2020;
- KogeneBiotech Co., Ltd.'s PowerChek 2019–nCoV Real-time PCR Kit, issued July 13, 2020;
- Trax Management Services Inc.'s PhoenixDx SARSd–CoV–2 Multiplex, issued July 13, 2020;
- Compass Laboratory Services, LLC's Compass Laboratory Services SARSd–CoV2 Assay, issued July 13, 2020;
- Quest Diagnostics Infectious Disease, Inc.'s Quest Diagnostics PF SARSd–CoV–2 Assay, issued July 15, 2020, and reissued August 21, 2020;
- Quest Diagnostics Infectious Disease, Inc.'s Quest Diagnostics RC SARSd–CoV–2 Assay, issued July 15, 2020, and reissued August 21, 2020;
- Quest Diagnostics Infectious Disease, Inc.'s Quest Diagnostics HA SARSd–CoV–2 Assay, issued July 15, 2020, and reissued August 21, 2020;
- Boston Heart Diagnostics' Boston Heart COVID–19 RT–PCR Test, issued July 16, 2020;
- Access Genetics, LLC's OraRisk COVID–19 RT–PCR, issued July 17, 2020;
- DiaCarta, Inc.'s QuantiVirus SARSd–CoV–2 Multiplex Test Kit, issued July 21, 2020;
- Helix OpCo LLC's (dba Helix's) Helix COVID–19 Test, issued July 23, 2020;
- Jiangsu CoWin Biotech Co., Ltd.'s Novel Coronavirus (SARSd–CoV–2) Fast Nucleic Acid Detection Kit (PCR-Fluorescence Probing), issued July 24, 2020;
- LabCorp's COVID–19 RT–PCR Test, reissued July 24, 2020 (original issuance March 16, 2020);
- Eli Lilly and Co.'s Lilly SARSd–CoV–2 Assay, issued July 27, 2020;

[3] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing COVID–19, and that the known and potential benefits of the products, when used for diagnosing COVID–19, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

- Sandia National Laboratories' SNL–NM 2019 nCoV Real-Time RT–PCR Diagnostic Assay, issued July 27, 2020;
- Clinical Reference Laboratory, Inc.'s CRL Rapid Response, issued July 30, 2020;
- University of California San Diego Health's UCSD RC SARSd–CoV–2 Assay, issued July 31, 2020;
- Xiamen Zeesan Biotech Co., Ltd.'s SARSd–CoV–2 Test Kit (Real-time PCR), issued July 31, 2020;
- ISPM Labs, LLC dba Capstone Healthcare's Genus SARSd–CoV–2 Assay, issued August 3, 2020;
- Poplar Healthcare's Poplar SARSd–CoV–2 TMA Pooling assay, issued August 3, 2020;
- Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute's Cleveland Clinic SARSd–CoV–2 Assay, issued August 3, 2020;
- Ethos Laboratories' Ethos Laboratories SARSd–CoV–2 MALDI–TOF Assay, issued August 3, 2020;
- Wren Laboratories LLC's Wren Laboratories COVID–19 PCR Test, issued August 3, 2020;
- Vela Operations Singapore Pte Ltd.'s ViroKey SARSd–CoV–2 RT–PCR Test, issued August 5, 2020;
- Helix OpCo LLC's (dba Helix) Helix COVID–19 NGS Test, issued August 6, 2020;
- George Washington University Public Health Laboratory's GWU SARSd–CoV–2 RT–PCR Test, issued August 7, 2020;
- Quest Diagnostics Infectious Disease, Inc.'s SARSd–CoV–2 RNA, Qualitative Real-Time RT–PCR, reissued August 7, 2020 (original issuance March 17, 2020);
- Alpha Genomix Laboratories' Alpha Genomix TaqPath SARSd–CoV–2 Combo Assay, issued August 10, 2020;
- Solaris Diagnostics' Solaris Multiplex SARSd–CoV–2 Assay, issued August 10, 2020;
- Biomeme, Inc.'s Biomeme SARSd–CoV–2 Real-Time RT–PCR Test, issued August 11, 2020;
- LumiraDx UK Ltd.'s LumiraDx SARS–CoV–2 RNA STAR, issued August 11, 2020;
- Pro-Lab Diagnostics' Pro-AmpRT SARSd–CoV–2 Test, issued August 13, 2020;
- Yale School of Public Health, Department of Epidemiology of Microbial Diseases' SalivaDirect, issued August 15, 2020, and reissued August 28, 2020;
- ZhuHai Sinochips Bioscience Co., Ltd.'s COVID–19 Nucleic Acid RT–PCR Test Kit, issued August 17, 2020;
- LumiraDx UK Ltd.'s LumiraDx SARSd–CoV–2 Ag Test, issued August 18, 2020;
- Assurance Scientific Laboratories' Assurance SARSd–CoV–2 Panel, reissued August 19, 2020 (original issuance May 15, 2020);
- Guardant Health, Inc.'s Guardant-19, issued August 21, 2020;
- DxTerity Diagnostics, Inc.'s DxTerity SARSd–CoV–2 RT–PCR Test, issued August 21, 2020;
- Texas Department of State Health Services, Laboratory Services Section's Texas Department of State Health Services SARSd–CoV–2 Assay, issued August 21, 2020;
- Fluidigm Corp.'s Advanta Dx SARSd–CoV–2 RT–PCR Assay, issued August 25, 2020;
- QDx Pathology Services' QDX SARSd–CoV–2 Assay, issued August 25, 2020;
- Cuur Diagnostics' Cuur Diagnostics SARSd–CoV–2 Molecular Assay, issued August 26, 2020;
- Abbott Diagnostics Scarborough, Inc.'s BinaxNOW COVID–19 Ag Card, issued August 26, 2020;
- Patients Choice Laboratories, LLC's PCL SARSd–CoV–2 Real-Time RT–PCR Assay, issued August 28, 2020;
- DxTerity Diagnostics, Inc.'s DxTerity SARSd–CoV–2 RT PCR CE Test, issued August 28, 2020;
- T2 Biosystems, Inc.'s T2SARSd–CoV–2 Panel, issued August 31, 2020;
- MiraDx's MiraDx SARSd–CoV–2 RT–PCR assay, issued August 31, 2020;
- Mammoth Biosciences, Inc.'s SARSd–CoV–2 DETECTR Reagent Kit, issued August 31, 2020;
- BayCare Laboratories, LLC's BayCare SARSd–CoV–2 RT PCR Assay, issued August 31, 2020;
- Detectachem Inc.'s MobileDetect Bio BCC19 (MD-Bio BCC19) Test Kit, issued September 1, 2020;
- OPTOLANE Technologies, Inc.'s Kaira 2019–nCoV Detection Kit, issued September 1, 2020;
- Bioeksen R&D Technologies Ltd.'s Bio-Speedy Direct RT–qPCR SARSd–CoV–2, issued September 2, 2020;
- BillionToOne, Inc.'s qSanger-COVID–19 Assay, issued September 4, 2020;
- Verily Life Sciences' Verily COVID–19 RT–PCR Test, issued September 8, 2020; and
- Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.'s Wantai SARSd–CoV–2 RT–PCR Kit, issued September 9, 2020.

FDA is hereby announcing the following Authorizations for serology tests: [4]

- Healgen Scientific LLC's COVID–19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma), issued May 29, 2020;
- Siemens Healthcare Diagnostics Inc.'s Atellica IM SARSd–CoV–2 Total (COV2T), issued May 29, 2020;
- Siemens Healthcare Diagnostics Inc.'s ADVIA Centaur SARSd–CoV–2 Total (COV2T), issued May 29, 2020;
- Hangzhou Biotest Biotech Co., Ltd.'s RightSign COVID–19 IgG/IgM Rapid Test Cassette, issued June 4, 2020;
- Vibrant America Clinical Labs' Vibrant COVID–19 Ab Assay, issued June 4, 2020;
- Siemens Healthcare Diagnostics Inc.'s Dimension Vista SARSd–CoV–2 Total antibody assay (COV2T), issued June 8, 2020;
- Siemens Healthcare Diagnostics Inc.'s Dimension EXL SARSd–CoV–2 Total antibody assay (CV2T), issued June 8, 2020;
- InBios International, Inc.'s SCoV–2 Detect IgG ELISA [enzyme-linked immunosorbent assay], issued June 10, 2020;
- Cellex Inc.'s qSARSd–CoV–2 IgG/IgM Rapid Test, reissued June 12, 2020 (original issuance April 1, 2020);
- Emory Medical Laboratories' SARSd–CoV–2 RBD IgG test, issued June 15, 2020;
- Biohit Healthcare (Hefei) Co. Ltd.'s Biohit SARSd–CoV–2 IgM/IgG Antibody Test Kit, issued June 18, 2020;
- Hangzhou Laihe Biotech Co., Ltd.'s LYHER Novel Coronavirus (2019–nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold), issued June 19, 2020;
- Babson Diagnostics, Inc.'s Babson Diagnostics aC19G1, issued June 23, 2020;
- Beckman Coulter, Inc.'s Access SARSd–CoV–2 IgG, issued June 26, 2020;
- InBios International, Inc.'s SCoV–2 Detect IgM ELISA, issued June 30, 2020;
- Assure Tech.'s (Hangzhou Co., Ltd.) Assure COVID–19 IgG/IgM Rapid Test Device, issued July 6, 2020;
- Diazyme Laboratories, Inc.'s Diazyme DZ-Lite SARSd–CoV–2 IgG CLIA Kit, issued July 8, 2020;
- Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.'s WANTAI SARSd–CoV–2 Ab Rapid Test, July 10, 2020;

[4] As set forth in the EUAs for these products, FDA has concluded that: (1) SARSd–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing recent or prior infection with SARSd–CoV–2 by identifying individuals with an adaptive immune response to the virus that causes COVID–19, and that the known and potential benefits of the products when used for such use, outweigh the known and potential risks of the products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

- Salofa Oy's Sienna-Clarity COVIBLOCK COVID–19 IgG/IgM Rapid Test Cassette, issued July 13, 2020;
- Luminex Corp.'s xMAP SARSd–CoV–2 Multi-Antigen IgG Assay, issued July 16, 2020;
- Megna Health, Inc.'s Rapid COVID–19 IgM/IgG Combo Test Kit, issued July 17, 2020;
- Access Bio, Inc.'s CareStart COVID–19 IgM/IgG, issued July 24, 2020;
- Xiamen Biotime Biotechnology Co., Ltd.'s BIOTIME SARSd–CoV–2 IgG/IgM Rapid Qualitative Test, issued July 24, 2020;
- Siemens Healthcare Diagnostics Inc.'s ADVIA Centaur SARSd–CoV–2 IgG (COV2G), issued July 31, 2020;
- Siemens Healthcare Diagnostics Inc.'s Atellica IM SARSd–CoV–2 IgG (COV2G), issued July 31, 2020;
- Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.'s WANTAI SARSd–CoV–2 Ab ELISA, issued August 5, 2020;
- bioMérieux SA's VIDAS SARSd–CoV–2 IgM, issued August 6, 2020;
- bioMérieux SA's VIDAS SARSd–CoV–2 IgG, issued August 6, 2020;
- Diazyme Laboratories, Inc.'s Diazyme DZ-Lite SARSd–CoV–2 IgM CLIA Kit, issued August 17, 2020;
- BioCheck, Inc.'s BioCheck SARSd–CoV–2 IgG and IgM Combo Test, issued August 17, 2020;
- Biocan Diagnostics Inc.'s Tell Me Fast Novel Coronavirus (COVID–19) IgG/IgM Antibody Test, issued August 25, 2020;
- TBG Biotechnology Corp.'s TBG SARSd–CoV–2 IgG/IgM Rapid Test Kit, issued August 31, 2020;
- University of Arizona Genetics Core for Clinical Services' COVID–19 ELISA pan-Ig Antibody Test, issued August 31, 2020;
- Sugentech, Inc.'s SGTi-flex COVID–19 IgG, issued September 3, 2020;
- BioCheck, Inc.'s BioCheck SARS–CoV–2 IgG Antibody Test Kit, issued September 9, 2020;
- BioCheck, Inc.'s BioCheck SARS–CoV–2 IgM Antibody Test Kit, issued September 9, 2020; and
- Shenzhen New Industries Biomedical Engineering Co., Ltd.'s MAGLUMI 2019–nCoV IgM/IgG, issued September 14, 2020.

FDA is hereby announcing the following Authorizations for multianalyte in vitro diagnostics: [5]

- Centers for Disease Control and Prevention's Influenza SARS–CoV–2 (Flu SC2) Multiplex Assay, issued July 2, 2020;
- Roche Molecular Systems, Inc.'s cobas SARS–CoV–2 & Influenza A/B, issued September 3, 2020; and
- Roche Molecular Systems, Inc.'s cobas SARS–CoV–2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System, issued September 14, 2020.

FDA is hereby announcing the following Authorizations for personal respiratory protective devices: [6]

- Certain Non-National Institute of Industrial and Occupational Safety (NIOSH)-Approved Disposable Filtering Facepiece Respirators Manufactured in China, reissued June 6, 2020 (original issuance April 3, 2020). A current list of respirator models authorized by this EUA is available at *https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixa;* and
- Certain Imported, Non-NIOSH Approved Disposable Filtering Facepiece Respirators, reissued June 6, 2020 (original issuance March 24, 2020). A current list of respirator models authorized by this EUA is available at *https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#exhibit1.*

FDA is hereby announcing the following Authorizations for other medical devices:

- Baxter Healthcare Corp.'s Prismaflex ST Set, issued May 20, 2020; [7]
- STERIS Corp.'s AMSCO Medium Steam Sterilizers + the STERIS STEAM Decon Cycle, issued May 21, 2020; [8]
- Certain Gowns and Other Apparel, issued May 22, 2020; [9]
- CLEW Medical Ltd.'s CLEWICU System, issued May 26, 2020; [10]
- Abiomed, Inc.'s Impella RP System, issued May 29, 2020; [11]

[5] As set forth in the EUAs, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus, and/or influenza B virus nucleic acids and that the known and potential benefits of the products when used for such a use, outweigh the known and potential risks of the products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[6] As set forth in the EUAs, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized respirators may be effective in preventing healthcare personnel (HCP) exposure to pathogenic biological airborne particulates during Filtering Facepiece Respirator (FFR) shortages, and that the known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages during COVID–19, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

[7] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Prismaflex ST Set may be effective to treat patients in an acute care environment during the COVID–19 pandemic, and that the known and potential benefits of the Prismaflex ST Set, when used for such use, outweigh the known and potential risks of the Prismaflex ST Set; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[8] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers may be effective at decontaminating compatible N95 respirators for single-user reuse by HCPs to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates for a maximum of 10 decontamination cycles per respirator, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[9] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized gowns and other apparel worn by HCPs may be effective at preventing the transfer of microorganisms, bodily fluids, and particulate material in low or minimal risk situations by providing minimal-to-low barrier protection to HCP and patients to prevent the spread of COVID–19, and that the known and potential benefits of gowns and other apparel for such use, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of these products.

[10] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CLEWICU System may be effective in treating COVID–19, when used by HCP in the intensive care unit (ICU) as a diagnostic aid to assist with the early identification of adult patients who are likely to be diagnosed with respiratory failure or hemodynamic instability which are common complications associated with COVID–19, and that the known and potential benefits of the CLEWICU System, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[11] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Impella RP may be effective in providing temporary right

- Roche Diagnostics' Elecsys IL–6, issued on June 2, 2020; [12]
- Battelle Memorial Institute's Battelle CCDS Critical Care Decontamination System (''Batelle Decontamination System''), reissued June 6, 2020 [13] (original issuance March 29, 2020);
- STERIS Corp.'s STERIS Sterilization System, reissued June 6, 2020 [14] (original issuance April 9, 2020);
- Stryker Instruments' STERIZONE VP4 N95 Respirator Decontamination Cycle, reissued June 6, 2020 [15] (original issuance on April 14, 2020);
- Advanced Sterilization Products, Inc.'s (ASP) STERRAD 100S, NX, and 100NX Sterilization Systems (''ASP STERRAD Sterilization Systems''), reissued June 6, 2020 [16] (original issuance April 11, 2020);
- Stryker Sustainability Solutions' (SSS) SSS VHP N95 Respirator Decontamination System, issued May 27, 2020, reissued June 6, 2020; [17]
- Sterilucent, Inc.'s Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (''Sterilucent Sterilization System''), reissued June 6, 2020 [18] (original issuance April 20, 2020);
- Duke University Health System's Duke Decontamination System for Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor (''Duke Decontamination System''), reissued June 6, 2020 [19] (original issuance May 7, 2020);
- Technical Safety Services LLC's 20–CS Decontamination System, issued June 13, 2020; [20]
- Oceanetics, Inc.'s Negative-pressure Respiratory System with Advanced Ventilation Return (''NRSAVR–100''), issued June 13, 2020; [21]
- US Army and MHS's COVID–19 Airway Management Isolation Chamber (CAMIC), issued May 19, 2020 and reissued to US Army Medical Research Development Command June 22, 2020; [22]

ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m2, for the treatment of acute right heart failure or decompensation caused by complications related COVID–19, including pulmonary embolism, and that the known and potential benefits of the Impella RP, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[12] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in treating COVID–19, by assisting in identifying severe inflammatory response in patients with confirmed COVID–19 illness to aid in determining the risk of intubation with mechanical ventilation, and that the known and potential benefits of this product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[13] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Battelle Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCPs to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[14] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the STERIS Sterilization Systems may be effective at decontaminating compatible N95 respirators for single-user reuse by HCPs to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[15] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the STERIZONE VP4 N95 Respirator Decontamination Cycle may be effective at preventing exposure to pathogenic biological airborne particulates by decontaminating, for a maximum of 2 decontamination cycles per respirator, comparable N95 respirators that are contaminated with SARS–CoV–2 or other pathogenic microorganisms, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[16] As set forth in this EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the ASP STERRAD Sterilization Systems may be effective at decontaminating, for a maximum of 2 decontamination cycles per respirator, compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of the ASP STERRAD Sterilization Systems, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[17] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the SSS VHP N95 Respirator Decontamination may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[18] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Sterilucent Sterilization System may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates, and that the known and potential benefits of this device, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[19] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Duke Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[20] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the 20–CS Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCPs to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[21] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the NRSAVR–100 may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, at the time of definitive airway management, or when performing medical procedures, or during transport of patients with suspected or confirmed diagnosis of COVID–19 and that the known and potential benefits of the NRSAVR–100 for such use outweigh its known and potential risks; and (3) there is no adequate, approved available alternative to the emergency use of this product.

[22] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

Continued

- electroCore, Inc.'s gammaCore Sapphire CV, issued July 10, 2020; [23]
- Michigan State University Animal Care Program's MSU Decontamination System, issued July 24, 2020; [24]
- IkonX, Inc.'s Airway Dome, issued July 24, 2020; [25]
- Abiomed, Inc.'s Impella Left Ventricular (LV) Support Systems, issued August 3, 2020; [26]
- Disposable, single-use surgical masks, issued August 5, 2020.[27] A current list of surgical masks authorized by this EUA is available here: *https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixasurgicalmasks;*
- Baxter Healthcare Corp.'s Prismaflex HF20 Set, issued August 10, 2020; [28]
- NovaSterilis, Inc.'s Nova2200 using the NovaClean decontamination process for decontaminating compatible N95 respirators, issued August 20, 2020; [29] and
- Color Genomics, Inc.'s Color COVID–19 Self-Swab Collection Kit, issued August 31, 2020.[30]

Dated: November 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–25603 Filed 11–19–20; 8:45 am]

BILLING CODE 4164–01–P

(2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CAMIC may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE when transporting or performing medical procedures on patients who are known or suspected to have COVID–19, and that the known and potential benefits of the CAMIC for such use outweigh its known and potential risks; and (3) there is no adequate, approved available alternative to the emergency use of the product.

[23] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the gammaCore Sapphire CV may be effective for acute emergency use at home or in a healthcare setting to treat adult patients with known or suspected COVID–19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their HCP, by using non-invasive Vagus Nerve Stimulation (nVNS) on either side of the patients neck, and that the known and potential benefits of this product for such use outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[24] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the MSU Decontamination System may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[25] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Airway Dome may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, at the time of definitive airway management, when performing airway-related medical procedures or during certain transport of patients with suspected or confirmed diagnosis of COVID–19 and that the known and potential benefits of the Airway Dome for such use outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[26] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Impella LV Support Systems may be effective when used by HCP in the hospital setting for providing temporary LV unloading and support to treat critical care patients with confirmed COVID–19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V–A ECMO support or late cardiac decompensation from myocarditis while on V–V ECMO support, and that the known and potential benefits of the Impella LV Support System, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[27] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized surgical masks may be effective for use in healthcare settings by HCPs as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID–19 pandemic, and that the known and potential benefits of the authorized surgical masks, when used consistent with the scope of the authorization, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[28] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness and multiple organ failure, including acute kidney injury, to humans infected by this virus; (2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Prismaflex HF20 Set (cartridge, including hemodialyzer plus tubing set) may be effective at providing continuous renal replacement therapy (CRRT) to treat low weight patients who have low blood volume and who have acute renal failure, fluid overload, or both, and who cannot tolerate a larger extracorporeal circuit volume in an acute care environment during the COVID–19 emergency and that the known and potential benefits of the Prismaflex HF20 Set, when used for such use, outweigh the known and potential risks of the Prismaflex HF20 Set; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[29] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Nova2200 may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[30] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that this product may be effective in diagnosing COVID–19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the self-collected human specimen, and that the known and potential benefits of this product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2107]

Cross Labeling Oncology Drugs in Combination Drug Regimens; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Cross Labeling Oncology Drugs in Combination Drug Regimens.'' This guidance describes FDA's current recommendations on including relevant information in labeling for oncology drugs approved for use in combination drug regimens.

DATES: Submit either electronic or written comments on the draft guidance by January 19, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Plaintiff's Exhibit 455

phe.gov

Renewal of Determination That A Public Health Emergency Exists

1 minute

As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective July 20, 2021, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, and that I renewed on April 15, 2021, that a public health emergency exists and has existed since January 27, 2020, nationwide.

July 19, 2021 _____ Date		/s/ _____ Xavier Becerra

Plaintiff's Exhibit 456

fda.gov

FAQs on the Emergency Use Authorization for Face Masks (Non-Surgical)

4-5 minutes

April 26, 2020

Q: Why did the FDA re-issue the Emergency Use Authorization (EUA) for face masks?

A: The FDA received questions about the original face mask EUA posted on April 18, 2020. On April 24, 2020, the FDA updated and re-issued the EUA to clarify that face masks, including cloth face coverings, that are authorized by the EUA are only authorized for use by the general public and health care personnel as source control.

These face masks are not authorized to be personal protective equipment, meaning they are not a substitute for filtering face piece respirators or for surgical face masks.

Q: What does wearing a face mask for source control mean?

A: Source control means preventing the transmission of infection through a person's respiratory secretions which are produced when speaking, coughing, or sneezing. Face masks, including cloth face coverings, help with source control by covering the wearer's mouth and nose. COVID-19 may be spread through respiratory secretions by individuals who may or may not have symptoms of COVID-19.

For more information on source control, see the CDC's Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings.

Cloth face coverings made from common, easily accessible materials are an additional, voluntary public health approach to help slow the spread of COVID-19. The CDC has a list of FAQs about Cloth Face Coverings for use by the general public.

Q: During the COVID-19 public health emergency, when should health care personnel wear face masks?

A: Face masks are not personal protective equipment. Health care facilities should not purchase or offer these masks as substitutes for surgical masks or filtering facepiece respirators. Face masks, including cloth facial coverings, when used as source control, may help in preventing or slowing the spread of COVID-19. Face masks are authorized under this EUA to be worn for source control only, including in the healthcare setting.

Personal protective equipment (i.e., surgical masks and filtering facepiece respirators) are critical supplies that must continue to be reserved for health care personnel and other medical first responders, as recommended in the CDC's Strategies for Optimizing the Supply of Facemasks.

Face masks should NOT be used in place of surgical masks or filtering facepiece respirators to provide protections such as:

- Liquid barrier protection
- Antimicrobial or antiviral protection, prevention, or reduction
- Respiratory protection
- Particulate filtration
- Protection in high-risk aerosol generating procedures

Q: What type of face mask should someone who is suspected or confirmed with COVID-19 wear?

A: In What to Do if You Are Sick, the CDC recommends wearing a cloth face covering to control the spread of the virus to others. The CDC also provides recommendations to prevent transmission from infected individuals.

Q: How should health care facilities prioritize the use of masks?

A: The CDC provides strategies for optimizing the supply of face masks when there is limited supply. The FDA also provides information about conservation strategies for face masks.

Plaintiff's Exhibit 457

Particulate Respirator N95

User Instructions
8210*Plus*/8210*Plus*MX/ 8210/8210MX/07048/8110S

⚠ WARNING

This respirator helps protect against certain particles. **Misuse may result in sickness or death.** For correct use, consult supervisor and these *User Instructions*, or call 3M in U.S.A., 1-800-247-3941. In Canada, call Technical Service at 1-800-267-4414. In Mexico, call 01-800-712-0646.

IMPORTANT

Before use, wearer must read and understand these *User Instructions*. Keep these instructions for reference.

Use For

Particles such as those from grinding, sanding, sweeping, sawing, bagging, or processing minerals, coal, iron ore, flour, metal, wood, pollen, and certain other substances. Liquid or non-oil based particles from sprays that do not also emit oil aerosols or vapors. Follow all applicable local regulations. For additional information on 3M use recommendations for this class of respirator please consult the 3M Respirator Selection Guide found on the Personal Safety web site at www.3M.com/respiratorselector or call 1-800-243-4630 in U.S.A. In Canada, call 1-800 267-4414.

Do Not Use For

Do not use for gases and vapors, oil aerosols, asbestos, or sandblasting; particulate concentrations that exceed either 10 times the occupational exposure limit or applicable government regulations, whichever is lower. In the United States, do not use when the U.S. Occupational Safety and Health Administration (OSHA) substance specific standards, such as those for arsenic, cadmium, lead in the construction industry, or 4,4'-methylene dianiline (MDA), specify other types of respiratory protection. This respirator does not supply oxygen.

Biological Particles

This respirator can help reduce inhalation exposures to certain airborne biological particles (e.g. mold, *Bacillus anthracis*, *Mycobacterium tuberculosis*, etc.) but cannot eliminate the risk of contracting infection, illness or disease. OSHA and other government agencies have not established safe exposure limits for these contaminants.

Use Instructions

1. Failure to follow all instructions and limitations on the use of this respirator and/or failure to wear this respirator during all times of exposure can reduce respirator effectiveness and **may result in sickness or death.**
2. In the U.S., before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the requirements of OSHA 29 CFR 1910.134, such as training, fit testing, medical evaluation, and applicable OSHA substance specific standards. In Canada, CSA standard Z94.4 requirements must be met and/or requirements of the applicable jurisdiction, as appropriate. Follow all applicable local regulations.
3. The particles which can be dangerous to your health include those so small that you cannot see them.
4. Leave the contaminated area immediately and contact supervisor if dizziness, irritation, or other distress occurs.
5. Store the respirator away from contaminated areas when not in use.
6. Inspect respirator before each use to ensure that it is in good operating condition. Examine all the respirator parts for signs of damage including the two headbands, attachment points, nose foam, and noseclip. The respirator should be disposed of immediately upon observation of damaged or missing parts. Filtering facepieces are to be inspected prior to each use to assure there are no holes in the breathing zone other than the punctures around staples and no damage has occurred. Enlarged holes resulting from ripped or torn filter material around staple punctures are considered damage. Immediately replace respirator if damaged. Staple perforations do not affect NIOSH approval (For 8110S only).
7. Conduct a user seal check before each use as specified in the Fitting Instructions section. **If you cannot achieve a proper seal, do not use the respirator.**
8. Dispose of used product in accordance with applicable regulations.

Use Limitations

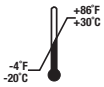
1. This respirator does not supply oxygen. Do not use in atmospheres containing less than 19.5% oxygen.
2. Do not use when concentrations of contaminants are immediately dangerous to life and health, are unknown or when concentrations exceed 10 times the permissible exposure limit (PEL) or according to specific OSHA standards or applicable government regulations, whichever is lower.
3. Do not alter, wash, abuse or misuse this respirator.
4. Do not use with beards or other facial hair or other conditions that prevent a good seal between the face and the sealing surface of the respirator.
5. Respirators can help protect your lungs against certain airborne contaminants. They will not prevent entry through other routes such as the skin, which would require additional personal protective equipment (PPE).
6. This respirator is designed for occupational/professional use by adults who are properly trained in its use and limitations. This respirator is not designed to be used by children.

7. Individuals with a compromised respiratory system, such as asthma or emphysema, should consult a physician and must complete a medical evaluation prior to use.
8. When stored in accordance with temperature and humidity conditions specified below, the product may be used until the "use by" date specified on the packaging.

Storage Conditions and Shelf Life

Before use, store respirators in the original packaging away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals. When stored in accordance with temperature and humidity conditions specified below, the product may be used until the "use by" date specified on packaging. Always inspect product and conduct a user seal check before use as specified in the *User Instructions*. **If you cannot achieve a proper seal, do not use the respirator.**

End of Shelf Life
Use respirators before the "use by" date specified on packaging



Storage Temperature Range
-20°C (-4°F) to +30°C (+86°F).

Storage Maximum Relative Humidity
<80% RH

Time Use Limitation

If respirator becomes damaged, soiled or breathing becomes difficult, leave the contaminated area immediately and replace the respirator.

Fitting Instructions

Must be followed each time respirator is worn.

1. Prestretch top and bottom straps before placing respirator on the face (8210/8210MX only) (Fig. 1).
2. Cup the respirator in your hand, with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand (Fig. 2).
3. Position the respirator under your chin with the nosepiece up. Pull the top strap over your head resting it high at the top back of your head. Pull the bottom strap over your head and position it around the neck below the ears (Fig. 3).
4. Place your fingertips from both hands at the top of the metal nosepiece. Using two hands, mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece (Fig. 4).
   ⚠ Pinching the nosepiece using one hand may result in improper fit and less effective respirator performance. Use two hands.
5. Perform a User Seal Check prior to each wearing. To check the respirator-to-face seal, place both hands completely over the respirator and exhale sharply. Be careful not to disturb the position of the respirator. If air leaks around nose, readjust the nosepiece as described in step 4. If air leaks at the respirator edges, work the straps back along the sides of your head (Fig. 5). **If you CANNOT achieve a proper seal, DO NOT enter the contaminated area. See your supervisor.**

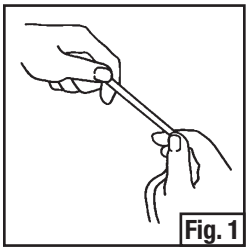


Fig. 1

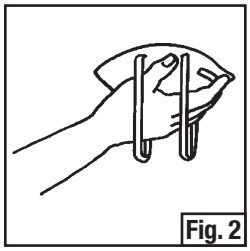


Fig. 2

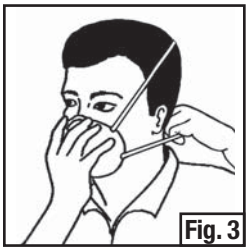


Fig. 3

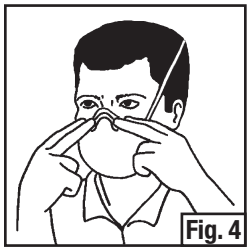


Fig. 4

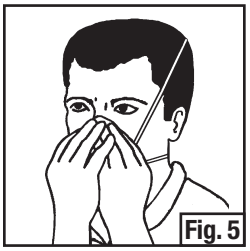


Fig. 5

Removal Instructions

See step 3 of *Fitting Instructions* and cup respirator in hand to maintain position on face. Pull bottom strap over head. Still holding respirator in position, pull top strap over head and remove respirator.

This respirator contains no components made from natural rubber latex.

Plaintiff's Exhibit 458

Personal Protective Equipment EUAs

Personal Protective Equipment (PPE) (/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control) refers to protective clothing, helmets, gloves, face shields, goggles, respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.

To help address concerns about availability during the COVID-19 pandemic, the FDA has issued Emergency Use Authorizations (EUAs) for certain PPE products including face shields, other barriers, and respiratory protective devices such as respirators. Additionally, the FDA has issued recommendations and policies about PPE which can be found here: Recent Final Medical Device Guidance Documents (/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/recent-final-medical-device-guidance-documents).

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA, including an Interactive Review Template For Non-IVD Products (/media/137965/download). Additionally, the FDA has posted a Surgical Masks EUA Template for Addition to Appendix A (/media/140896/download) of the Surgical Mask Umbrella EUA.

Table of Personal Protective Equipment (PPE) EUAs

- Umbrella EUA for Surgical Masks
- N95 and Other Respirators EUAs
- Face Shields and Other Barrier EUAs

FDA Revokes Emergency Use Authorizations for Non-NIOSH-Approved Disposable Respirators and Decontamination Systems as Access to FDA-authorized and NIOSH-approved N95s Increases Nationwide

On June 30, 2021, the FDA announced the revocation (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations) of the following EUAs:

- Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-niosh-approved-disposable-filtering-facepiece-respirators#imported) (effective July 6, 2021)
- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-niosh-approved-disposable-filtering-facepiece-respirators#china) (effective July 6, 2021)
- Decontamination and Bioburden Reduction System EUAs for Personal Protective Equipment (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#decontamination) (effective June 30, 2021)

> As of the effective date of the revocations, these devices will no longer be authorized for use by health care personnel in health care settings. For additional information, please see Update: FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities (/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-or-decontaminated-disposable-respirators).
>
> Historical information regarding these EUAs can be found on Historical Information about Device Emergency Use Authorizations (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations).

Umbrella EUA for Surgical Masks

On August 5, 2020, the FDA issued an umbrella EUA for certain disposable, single-use surgical masks in response to concerns relating to insufficient supply and availability of such masks. This EUA authorized the emergency use of surgical masks that met certain performance requirements for use in healthcare settings by health care personnel (HCP) as PPE, to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic. Surgical masks that have been confirmed by FDA to meet the criteria under the EUA are included below in Appendix A as authorized surgical masks.

- EUA Letter of Authorization - Umbrella EUA for Surgical Masks (/media/140894/download)
- Fact Sheet for Healthcare Personnel (/media/140895/download)
- Appendix A: Authorized Surgical Masks
- Surgical Masks Removed from Appendix A

The Surgical Masks EUA Template for Addition to Appendix A (/media/140896/download) can be used to provide the information requested in the EUA to the FDA.

Appendix A: Authorized Surgical Masks

The table below includes a list of surgical masks authorized by this Umbrella EUA for emergency use during the COVID-19 public health emergency.

All authorized surgical masks in the table below (Appendix A) are assigned the QMF product code.

Search:

Show 100 entries

Date of Addition	Manufacturer	Authorized Product Name (including model numbers)

Date of Addition	Manufacturer	Authorized Product Name (including model numbers)
07/16/2021	INTAI Technology CORP	9W001200 (50 pieces/box) 9W001201 (30 boxes/carton)
07/12/2021	SurgiMac Manufacturing Inc.	Surgical Mask (Model – MAC-6501)
07/02/2021	Sesa LLC	Sesa Health Surgical Mask (Model Number - SH.PPE.SM.2L3)
07/02/2021	LM Surgical Mask	3-ply level 3 Earloop - LM0787 3-ply level 3 Head Straps - LM1019
07/01/2021	Connecticut Mask Company, LLC	CMC Surgical Mask 10 (Model - CMC 10; ASTM Level 1) CMC Surgical Mask 30 (Model - CMC30; ASTM Level 3)
06/30/2021	Thrace Polyfilms S.A.	Surgical Masks Model PLF.IIR
05/26/2021	Linghe International co. Ltd.	Linghe Disposable, Single-Use Surgical Mask (Model Number: Best02)
05/21/2021	Medtecs USA Corporation	Medtecs Medical Mask (Model FM-140G)
05/21/2021	Filtra-Systems Company, LLC	Filtra Systems Surgical Face Mask (Model number – 0605202)
05/12/2021	Lumensource, LLC	Lumensource Surgical Mask Model # PKM-S201B
05/07/2021	Altor Safety	3 Ply Surgical Mask (Model # 62212) 4 Ply Surgical Mask (Model #62232)
05/07/2021	Health Pro Supplies Limited	Medical Surgical Mask HP2723 (Large) Medical Surgical Mask HP9503
04/29/2021	Phoenix Quality MFG, LLC	PQM LibertyAir Surgical MaskModel - S-9501-EUA
04/29/2021	Honeywell International Inc.	Procedure Mask with Earloops (PM345 C)
04/29/2021	Honeywell International Inc.	Procedure Mask with Earloops (PM345 D)
04/29/2021	Honeywell International Inc.	Procedure Mask with Earloops (PM345 E)
04/28/2021	Devshree International Pvt. Ltd.	Hoplon Brand Disposable Single Use Surgical Masks Level 1 per ASTM F2100 H3SS
04/21/2021	GRAFICA VENETA S.p.A.	MASK MEDICA GV 2 GV2-GVII-202007
04/19/2021	BLUETRACK, Inc.	Healthcare Pro Surgical Masks S-3050-WH

Date of Addition	Manufacturer	Authorized Product Name (including model numbers)
04/16/2021	Manohar Filaments Private Limited	3 Ply Surgical Mask MF-SM3-EH
04/06/2021	Keeo Life Private Limited	3PLY Surgical Mask KF-SM3-EL 4PLY Surgical Mask KF-SM4-EL
03/30/2021	PZero Innovations, Inc.	PZero Surgical Mask Model Number: FM20PZ00
03/29/2021	Protektair, Inc	Protektair-3 Surgical Mask Model #: PSM-3000
03/19/2021	Cleveland Veteran Business Solutions	CVBS Surgical Mask - Model Number: SM1
02/12/2021	SIO International Wisconsin, Inc	Sharp MQ-3050 Surgical mask; Foxconn MQ-3050 Surgical mask
01/29/2021	131co Inc.	ARX Surgical Mask (Model number ARX1001)
01/22/2021	Honeywell International Inc.	Procedure Mask with Earloops Model #: 559250M D
01/19/2021	KNH Enterprise Co., Ltd.	KNH Surgical Face Mask Model Numbers: 902E1 (Ear Loop Level 1 – inner loop) 902E1-1 (Ear Loop Level 1 – outer loop) 902E2 (Ear Loop Level 2 – inner loop) 902E2-1 (Ear Loop Level 2 – outer loop) 902D1-M (3D Level 1 – size M) 902D1-L (3D Level 1 – size L) 902D2-M (3D Level 2 – size M) 902D2-L (3D Level 2 – size L) 902Z1 (Z-Folded Level 1) 902Z1 (Z-Folded Level 2)
12/19/2020	Honeywell International Inc.	Procedure Mask with Earloops Model #: 559250M B and 559250M C
12/16/2020	Honeywell International Inc.	Procedure Mask with Earloops Model #: 559250M
12/10/2020	Danameco Medical Joint Stock Corporation	D-Care Surgical Face Mask 3 ply (white), TAMMY Surgical Face Mask 3 ply (white) Model/AMIS Numbers: KTY60WK050, KTY75WK050, KTY74WK050
12/10/2020	MOCACARE Corporation	MOCACARE Procedure Mask (Level 1) Model #: BC1003
12/09/2020	Nomad Goods	Nomad Surgical Mask N-MASK-3

Date of Addition	Manufacturer	Authorized Product Name (including model numbers)
11/20/2020	Rymco Medical	Surgical Mask (Tie-On) Model #: IMABEU Surgical Mask (Earloop) Model #: IMSBEU
11/06/2020	EcoGuard Inc.	Surgical Mask - Disposable Single-Use 4-Ply Earloop Model #: EcoGuard A ECO03 Surgical Mask - Disposable Single-Use 4-Ply Tie-on Model #: EcoGuard A ECO04
11/03/2020	Fischer Manufacturing, LLC	Heartland Health Surgical Mask
10/15/2020	Brandix Apparel Solutions Limited	Disposable Surgical Mask BRNDX-DSM-001-LARGE
10/08/2020	WPT Corporation	WPT ASTM F2100-19 Level 3 Earloop Surgical Face Mask (Model # SMS2020)
10/05/2020	Hanesbrands, Inc.	Hanes Surgical Mask 01, Small and Large
08/18/2020	Venus Group, Inc.	Venus Medical Grade Disposable Surgical Mask
08/08/2020	Outdoor Research	Outdoor Research Surgical Mask model #OR2159

Showing 1 to 41 of 41 entries

Previous 1 Next

Surgical Masks Removed from Appendix A

These surgical mask models had been on the list of authorized surgical masks in Appendix A but no longer meet the EUA's (/media/140894/download) scope of authorization and thus are no longer authorized and have accordingly been removed from Appendix A.

Search:

Show 100 entries

Date No Longer Authorized	Manufacturer	Surgical Mask Model(s) No Longer Authorized
07/23/2021	Altor Safety	3 Ply Surgical Mask (Model #62222)
06/15/2021	Premium-PPE Amerishield	Premium PPE Amerishield Disposable Surgical Mask Model #: PPE-M-AS-SUR-lvl2-S

Date No Longer Authorized	Manufacturer	Surgical Mask Model(s) No Longer Authorized
03/19/2021	Homtex, Inc.	Sovereign America Surgical Mask Model #: 2000SM1, Blue color
02/02/2021	EcoGuard Inc.	Surgical Mask - Disposable Single-Use 3-Ply Earloop Model #: EcoGuard B ECO01 Surgical Mask - Disposable Single-Use 3-Ply Tie-on Model #: EcoGuard B ECO02
01/21/2021	Premier Guard USA LLC	Premier Guard USA Surgical Face Mask 20-1002-SFM3

Showing 1 to 5 of 5 entries

Previous 1 Next

N95 and Other Respirators EUAs (including EUAs for NIOSH-Approved N95s and imported respirators)

The table below includes information about respirators authorized for emergency use by healthcare personnel during the COVID-19 public health emergency.

Search:

Show 100 entries

Date EUA Issued	PPE (Letter of Authorization)	Other Documents
03/28/2020	NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency (/media/135763/download)	• EUA Clarification Letter on Respirators (/media/136023/download)

Showing 1 to 1 of 1 entries

Previous 1 Next

Face Shields and Other Barrier EUAs

On May 1, 2020, the FDA issued an umbrella EUA for emergency use of protective barrier enclosures by HCP when caring for or performing medical procedures on patients who are known

Plaintiff's Exhibit 459

fda.gov

Revoked EUAs for Non-NIOSH-Approved Disposable FFRs

7-9 minutes

Revoked EUAs for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators

On this page:

Umbrella EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs) Manufactured in China (Revoked effective July 6, 2021)

On April 3, 2020, the FDA issued an umbrella EUA for certain filtering face-piece respirators (FFRs) that are manufactured in China and are not approved by the National Institute for Occupational Safety and Health (NIOSH). Respirator models that were authorized by this EUA were listed in Appendix A and were authorized for emergency use by healthcare personnel in healthcare settings in accordance with CDC recommendations. Summaries of FDA's reissuances of this EUA follow.

As part of the federal government's quality assessment of these respirators, the FDA, working with CDC's NIOSH, conducted additional assessments and found that NIOSH's data indicated that some of the respirators authorized under the April 3, 2020 EUA did not meet the expected performance standards. In response, the FDA revised and reissued the EUA on May 7, 2020, including revising the third eligibility criterion such that all respirators that were previously authorized only under that criterion were no longer within the scope of authorization and were accordingly removed from Appendix A unless the respirator model was authorized under one of the remaining eligibility criterion in the May 7th letter.

Additionally, the FDA, in collaboration with CDC's NIOSH, increased surveillance and sampling of all respirators imported from China. All respirator shipments from China that came into the U.S. were subject to random sampling and testing by CDC's NIOSH to determine whether the respirator meets the expected particulate filtration standards.

On June 6, 2020, the FDA further revised the Scope of Authorization of this EUA, including, among other changes, further revision to the eligibility criteria to provide additional specificity regarding the jurisdictions eligible for review and to remove decontaminated respirators from the scope of authorized products such that authorized respirator models listed in Appendix A are not authorized if they are decontaminated.

On October 15, 2020, the FDA reissued the EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators manufactured in China to authorize for emergency use only those respirators listed in the EUA's Appendix A as of the date of this reissuance. As of October 15, 2020, this EUA no longer included the three eligibility criteria that were included in the previous June 6, 2020 authorization letter, meaning the FDA no longer reviewed requests to add new respirator models to Appendix A based on those criteria as of October 15, 2020.

On June 30, 2021, the FDA announced the revocation of EUA (effective July 6, 2021).

- Revoked EUA Letter of Authorization - Umbrella EUA: Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China
- Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA FAQs
- Appendix A (Last Updated February 18, 2021; All models revoked effective July 6, 2021)
- Respirator Models Previously Removed from Appendix A (Last Updated October 15, 2020; All models revoked effective July 6, 2021)

Appendix A (Last Updated February 18, 2021; All models revoked effective July 6, 2021)

The table below includes a list of non-NIOSH-approved respirator models manufactured in China that were authorized at the time this Umbrella EUA was revoked.

These respirators were authorized for use by healthcare personnel in healthcare settings in accordance with the CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators.

Respirator Models Previously Removed from Appendix A (Last Updated October 15, 2020; All models revoked effective July 6, 2021)

These respirator models had been on the list of authorized respirators in Appendix A but no longer met the EUA eligibility criteria and thus were no longer authorized. Results from NIOSH's testing are provided at: https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html

---

Umbrella EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs) (Revoked effective July 6, 2021)

On March 24, 2020, the FDA issued an umbrella EUA for certain imported disposable filtering facepiece respirators (FFRs) that are not approved by the National Institute for Occupational Safety and Health (NIOSH) and that met eligibility criteria as described in the EUA. Under this EUA, respirators, listed in Exhibit 1, were authorized for use in healthcare settings by healthcare personnel (HCP) when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak.

On March 28, 2020, FDA revised this EUA to authorize the use of certain authorized respirators that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system.

On June 6, 2020, FDA again revised the EUA to exclude decontaminated respirators with exhalation valves from the scope of authorization, as well as to add additional specificity regarding which jurisdictions were included in the second criterion for eligibility.

On March 24, 2021, the FDA revised this EUA to authorize for emergency use only those respirators listed in the EUA's Exhibit 1 as of the date of this reissuance. The FDA no longer reviewed requests to add new respirator models to Exhibit 1 of this EUA after March 24, 2021.

On June 30, 2021, the FDA announced the revocation of EUA (effective July 6, 2021).

- Revoked EUA Letter of Authorization - Umbrella EUA Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators
- Exhibit 1 (Last Updated March 8, 2021; All models revoked effective July 6, 2021)

Exhibit 1 (Last Updated March 8, 2021; All models revoked effective July 6, 2021)

The table below includes a list of non-NIOSH-approved disposable FFRs that were authorized under this Umbrella EUA for emergency use in healthcare settings by HCP when used in accordance with CDC recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators.

Revoked EUAs for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators

FDA Revokes Emergency Use Authorizations for Non-NIOSH-Approved Disposable Respirators and Decontamination Systems as Access to FDA-authorized and NIOSH-approved N95s Increases Nationwide

On June 30, 2021, the FDA announced the revocation (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations) of the following EUAs:

- Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-niosh-approved-disposable-filtering-facepiece-respirators#imported) (effective July 6, 2021)
- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-niosh-approved-disposable-filtering-facepiece-respirators#china) (effective July 6, 2021)
- Decontamination and Bioburden Reduction System EUAs for Personal Protective Equipment (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#decontamination) (effective June 30, 2021)

As of the effective date of the revocations, these devices will no longer be authorized for use by health care personnel in health care settings. For additional information, please see Update: FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities (/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-or-decontaminated-disposable-respirators).

Historical information regarding these EUAs can be found on Historical Information about Device Emergency Use Authorizations (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations).

Top ()

On this page:

Umbrella EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs) Manufactured in China (Revoked effective July 6, 2021)

On April 3, 2020, the FDA issued an umbrella EUA for certain filtering face-piece respirators (FFRs) that are manufactured in China and are not approved by the National Institute for Occupational Safety and Health (NIOSH). Respirator models that were authorized by this EUA were listed in Appendix A and were authorized for emergency use by healthcare personnel in healthcare settings in accordance with CDC recommendations. Summaries of FDA's reissuances of this EUA follow.

As part of the federal government's quality assessment of these respirators, the FDA, working with CDC's NIOSH, conducted additional assessments and found that NIOSH's data indicated that some of the respirators authorized under the April 3, 2020 EUA did not meet the expected performance standards. In response, the FDA revised and reissued the EUA on May 7, 2020, including revising the third eligibility criterion such that all respirators that were previously authorized only under that criterion were no longer within the scope of authorization and were accordingly removed from Appendix A unless the respirator model was authorized under one of the remaining eligibility criterion in the May 7th letter. Additionally, the FDA, in collaboration with CDC's NIOSH, increased surveillance and sampling of all respirators imported from China. All respirator shipments from China that came into the U.S. were subject to random sampling and testing by CDC's NIOSH to determine whether the respirator meets the expected particulate filtration standards.

On June 6, 2020, the FDA further revised the Scope of Authorization of this EUA, including, among other changes, further revision to the eligibility criteria to provide additional specificity regarding the jurisdictions eligible for review and to remove decontaminated respirators from the scope of authorized products such that authorized

Top ()

respirator models listed in Appendix A are not authorized if they are decontaminated.

On October 15, 2020, the FDA reissued the EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators manufactured in China to authorize for emergency use only those respirators listed in the EUA's Appendix A as of the date of this reissuance. As of October 15, 2020, this EUA no longer included the three eligibility criteria that were included in the previous June 6, 2020 authorization letter, meaning the FDA no longer reviewed requests to add new respirator models to Appendix A based on those criteria as of October 15, 2020.

On June 30, 2021, the FDA announced the revocation (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations) of EUA (effective July 6, 2021).

- Revoked EUA Letter of Authorization - Umbrella EUA: Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (/media/136664/download)
- Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA FAQs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic)
- Appendix A (Last Updated February 18, 2021; All models revoked effective July 6, 2021)
- Respirator Models Previously Removed from Appendix A (Last Updated October 15, 2020; All models revoked effective July 6, 2021)

Appendix A (Last Updated February 18, 2021; All models revoked effective July 6, 2021)

The table below includes a list of non-NIOSH-approved respirator models manufactured in China that were authorized at the time this Umbrella EUA (/media/136664/download) was revoked.

These respirators were authorized for use by healthcare personnel in healthcare settings in accordance with the CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html).

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
3M	9001, 9002, 9501, 9501+, 9501V+, 9502, 9502+, 9502V+, 9505+, 9541, 9541V, 9542, 9542V, 9552, 9552V	• 9001: IFU (https://multimedia.3m.com/mws/media/1827635O/3m-particulate-respirator-9001-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9002: IFU (https://multimedia.3m.com/mws/media/1827636O/3m-particulate-respirator-9002-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9501: IFU (https://multimedia.3m.com/mws/media/1827633O/3m-particulate-respirator-9501-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9501+: IFU (https://multimedia.3m.com/mws/media/1827631O/3m-particulate-respirator-9501-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9501V+: IFU (https://multimedia.3m.com/mws/media/1827630O/3m-particulate-respirator-9501v-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9502: IFU (https://multimedia.3m.com/mws/media/1826785O/3m-particulate-respirator-9502-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9502+: IFU (https://multimedia.3m.com/mws/media/1828869O/3m-particulate-respirator-9502-user-instructions-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9502V+: IFU (https://multimedia.3m.com/mws/media/1826783O/3m-particulate-respirator-n95-9502v-ui-for-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9505+: IFU (https://multimedia.3m.com/mws/media/1827632O/3m-particulate-respirator-9505-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
		• 9541: IFU (https://multimedia.3m.com/mws/media/1827634O/3m-particulate-respirator-9541-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9541V: IFU (https://multimedia.3m.com/mws/media/1827629O/3m-particulate-respirator-9541v-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9542: IFU (https://multimedia.3m.com/mws/media/1826786O/3m-particulate-respirator-9542-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9542V: IFU (https://multimedia.3m.com/mws/media/1826789O/3m-particulate-respirator-9542v-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9552: IFU (https://multimedia.3m.com/mws/media/1825857O/3m-95-5-2-particulate-respirator-n95-user-instruction-eua-website.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9552V: IFU (https://multimedia.3m.com/mws/media/1826807O/3m-particulate-respirator-9552v-ui-eua.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Allmed Medical Products Co., Ltd	LP220002	• IFU (http://www.allmed-china.com/index.php?m=content&c=index&a=show&catid=20&id=33) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
AnDum Protective Equipment Technology (Changzhou) Co.,Ltd.	AD-1001	• IFU (http://www.an-dum.com/index.php?m=content&c=index&a=show&catid=184&id=158) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Anhui Hanxiutang Biotechnology Co., Ltd.	HXT-01	• IFU (http://www.ahhxt.cn/en/Products/Product_categories_1/16.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
ANHUI JIABAO PROTECTIVE EQUIPMENTS CO.,LTD	JB-RP001	• IFU (http://en.jiabaofhyp.com/display/432588.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Anhui Jinrui Auto Parts Co., Ltd.	JR-01	• IFU (http://www.jinruikeji.com/cn/jksy/index_138.aspx) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Anhui Zhongke Duling Commercial Appliance Co. Ltd	M-9501	
Anshun Health and Medical Technology Co., Ltd.	AKF6002	• IFU (http://www.runbomask.com/AKF6002-FFP2-NR/AKF6002FFP2NR-1.shtml) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
AOK Tooling Ltd. (aka Shenzhonghai Medical)	20130040, 20130045A, 20180021, 20130038, 20190019, 910, 20190029	• 20130040: IFU (http://www.toolingexpress.com/images/20130040-InstructionsforUse.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 20130045A: IFU (http://www.toolingexpress.com/images/20130045-InstructionsforUse.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 20180021: IFU (http://www.toolingexpress.com/images/20180021-InstructionsforUse.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 20130038: IFU (http://www.toolingexpress.com/images/20130038-InstructionsforUse.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 20190019: IFU (http://www.toolingexpress.com/images/20190019-InstructionsforUse.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 910: IFU (http://www.toolingexpress.com/images/910-Instruction.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 20190029: IFU (http://www.toolingexpress.com/images/20190029-Instruction.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Baoding Yinhong Yuhe Medical Device Manufacturing Co., Ltd.	YH/KN95-1	
Bei Bei Safety Co Ltd.	B702, B702V, B704, B704V	• IFU (https://www.beibeisafety.com/upload/download/20051521254900000002.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Beifa Anhui Manufacturing Co., Ltd.	BF-A-01	• IFU (http://www.beifa.com/en/productsd.php?tid=1227&pid=6417) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Beijing Topnew Import & Export Co., Ltd.	ZY95	• IFU (http://ie.topnew.cn/english/productf.aspx?from=groupmessage&isappinstalled=0) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
BG PRECISION CO. LTD	KN95-N	• IFU (http://www.bgprecision.cn/news-16-1.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
BYD Precision Manufacture Co. Ltd.	DG3101, DN1102	• DG3101: IFU (https://www.byd.care/pages/kn95) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • DN1102: IFU (https://www.byd.care/pages/kn95-respirator) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Careable Biotechnology Co., Ltd.	CARE002, CARE003	• IFU (https://www.careablemask.com/aboutus/37115.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Carte Medical Equipment (Suzhou) Co., Ltd	K8201	• IFU (http://www.carteholding.com/page.asp?id=854) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Changsha Changjiu Medical Technology Co. Ltd.	KN95-05, KN95-08	• IFU (http://www.hncjmed.com/articles/2286/2020-7/65216.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Changshu Dayi Health Protection Articles Co., Ltd	DY-3	• IFU (http://en.dayimedical.cn/use.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Chengde Technology Co.	KN95	• IFU (https://yizhantongimage.oss-accelerate.aliyuncs.com/UploadFiles/2021012221072772737.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Chongqing China Nano Technology Co., Ltd.	ZN6005	• IFU (http://www.zhongnakeji.com/product/namixianweixincailiao/61.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Chongqing Zisun (Zaisheng) Technology Corp., Ltd.	ZS-ZD-FJ-1, ZS-ZD-WJ-1	• IFU (https://en.cqzskj.com/news/news_show/?id=5579&cid=1306The) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Creative Concepts Manufacturing Ltd. aka Huizhou RD Plastic Co., Ltd	02676	• IFU (https://www.mediconceptsgroup.com/kn95/manual/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Deli Group Co., LTD.	ET30000	
DONGGUAN AOXING AUDIO VISUAL EQUIPMENT CO.,LTD	AX-KF95	• IFU (https://www.aoxing.net/en/ProductDetail/3778814.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Dongguan Arun Industrial Co., LTD	KN95 N9	• IFU (http://www.all-round.com.cn/ProductView.Asp?ID=27) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Dongguan City Outdoorsy Co., Ltd.	OD-001	• IFU (http://www.outdoorsy360.com/product/pro1/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Dongguan Pan American Electronics Co., Ltd.	KN95-01, KN95-02, N1001	• KN95-01: IFU (http://panamericanelectronics.com/uploads/soft/200618/Instruction%20for%20Use%20for%20KN95-01.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • KN95-02: IFU (http://panamericanelectronics.com/uploads/soft/200618/Instruction%20for%20Use%20for%20KN95-02.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • N1001: IFU (http://panamericanelectronics.com/uploads/soft/200618/Instruction%20for%20Use%20for%20N1001.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Dongguan Rysam Medical Equipment Manufacturing Co.	Particle Filtering half mask RSN95B, Particle Filtering half mask RSN99V	• IFU (https://www.rysam.cn/eua) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Dongguan Sengtor Plastics Products Co., Ltd.	KN95	• IFU (https://www.sengtor.com/instructions-for-use) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Donghua Siecom Communication Technology Co.,Ltd	ZGKNM-01	• IFU (https://www.siecom.cn/?app=survival&act=details&id=89) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
ESound Medical Device Co., Ltd.	20182140615 Folded	• IFU (http://www.e-soundmed.com/h-pd-130.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
FOSHAN FLOCON MEDICAL EQUIPMENTS CO., LTD	M1	
Foshan Nanhai Chuanzhishang Clothing Co., LTD	CZ-S02	
Fujian Dahong Industrial Development Co. Ltd.	PGT-0095	
Fujian Leephick Pharmaceutical Industry Co. Ltd.	KPM-3	• IFU (https://www.leephick.com/product/ffp2_filtering_half_mask_headband_/133.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Fujian Yifa Healthcare Products Co., Ltd.	Y195	• IFU (https://en.newyifagroup.com/article/90.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Fujian Yongtai Sanlian Garment Co., Ltd.	N95 Particulate Respirator (Xier)	
Fuzhou Chunlan Medical Equipment Co., Ltd.	CL-P1	• IFU (http://www.fjchunlan.com/en/pd.jsp?id=14) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong GangRong Medical Technology Co., Ltd	GR200	• IFU (http://www.gdgrmt.com/blog-single4.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
GUANGDONG GOLDEN LEAVES TECHNOLOGY DEVELOPMENT CO., LTD.	8862 KN95	• IFU (http://www.cnjymedical.com/detail?id=8862) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
GUANGDONG JINGCOS CO., LTD	95J1	
Guangdong KINGFA SCI. & TECH. Co. Ltd.	KF-A F01, KF-A F10(SC)	• IFU (http://www.kingfa.com/en/respirator3/642.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong Languan Medical Biotechnology Co., Ltd.	LGKN95	• IFU (http://www.blueguan.com.cn/cn/produ/Product_Instruction/index.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong Nuokang Medical Technology Co., Ltd.	KN95 Non-Surgical Disposable Particulate FFR	• IFU (https://www.nuokang.net/respirator?product_id=9) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong Seyouse Technology and Culture CO,.LTD	SS-001	
Guangdong Tengrui Pharmaceutical Technology Co., Ltd.	LSH-201	• IFU (http://www.tengruipharm.com/views/167/cid/49.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong Willing Technology Corporation	WL-01	• IFU (http://www.willingchina.com/e/proDetail.php?id=24135&cateid=37413) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Guangdong Winsun Personal Care Products Co., Ltd.	YS0003	• IFU (https://gdwinsun.en.made-in-china.com/product/qOQEPhjWEUVw/China-Protective-Ys0003-Filter-in-Stock-Face-Mask-with-FFP2-Approved.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong Yidao Medical	YD-002	• IFU (http://www.superyidao.com/en/product/product-44-633.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangdong Zhizhen Biological Medicine Co., Ltd.	KN95 Three-Dimensional Protective Face Mask	• IFU (http://www.zhizhenmedic.com/instruction.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangxi MC Medical equipment Co., Ltd	MC010501	• IFU (http://www.mcmedical.net/en/h-pd-3.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
GUANGZHOU BIOFIL AIR PURIFICATION MATERIALS CO.,LTD	MY3D2	• IFU (http:/www.baifeier.com.cn/en/article-28481-41890.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangzhou Bofeite Safety Protective Supplies Co., Ltd.	HT9510V, HT9510	
Guangzhou Carrot Mall Network Technologies Co., Ltd.	IRYS-01	• IFU (http://www.ivrou.com/images/Intended_Use_and%20Other_Instructions_of_IVROU.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangzhou Harley Commodity Company Limited	L-103V KN95	• IFU (http://www.kn95.net/english/cpzx/gykz/188.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Guangzhou Nan Qi Xing Non-Woven Co., Ltd.	KN-1 Respirator	• IFU (https://www.gznqx.com/china-kn95-china-masks-customized-nanqixing) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guangzhou Powecom Labor Insurance Supplies Co., LTD	KN95	• IFU (http://www.powecom.com/eng_product.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Guanyang Yunhan Textile Co., Ltd.	YH-9500	• IFU (http://www.yohansupplies.com/en/?p=page&sortid=263&typeid=302&pid=3698&showlist=2) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Haishi Hainuo Lexiang Medical Technology (Qingdao) Co., Ltd.	LX1001	
HANGZHOU FILTECH INTELLIGENT CO., LTD.	Filtech Face Mask Model F860, F862, F890V, F891V, F890, F861	• F860: IFU (http://www.filtech.cn/filtechmask/FFP2/F860.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • F862: IFU (http://www.filtech.cn/filtechmask/FFP2/F862.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • F890V: IFU (http://www.filtech.cn/filtechmask/FFP3/F890V.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • F891V: IFU (http://www.filtech.cn/filtechmask/FFP3/F891V.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hangzhou Gang Yu Health Products Co., Ltd.	GY2020001	• IFU (http://www.gywsyp.com/index.php/product/detail/53.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Hangzhou San Qiang Safety Protection Products Co., Ltd.	9420 (FFP2), 9420V (FFP2), 9480 (FFP2), 9450B, 9480V (FFP2), 9980V (FFP3), 9920V (FFP3)	• 9420 (FFP2), 9420V (FFP2), 9480 (FFP2), 9480V (FFP2): IFU (http://www.qqq-ppe.com/public/upload/certification/20200708/914f310e94bb5508cc1e8396d83aeb55.jpg) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • 9980V (FFP3), 9920V (FFP3): IFU (http://www.qqq-ppe.com/public/upload/certification/20200708/9f0bcbe3a824a8b44d64978dd83d32ea.jpg) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hebei Pengyuan Optoelectronics Co., Ltd.	SUPERNOVA-P2	• IFU (https://www.china-supernova.com/sale-13193847-face-mask-instructions-for-model-supernova-p2.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Henan Aklly Filter Engineering Co., Ltd.	KZ888E	• IFU (http://www.hnsaklly.com/eng/news/4_119) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Henan Bingzun Industrial Co.,Ltd.	8410	• IFU (http://m.zunyue188.com/kz222/vip_doc/17753275.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Henan Yadu Industrial Co., Ltd	Flat Fold	• IFU (http://www.yadu-medical.com/new/new-43-284.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Heyuan COE Communication Technology Co., Ltd.	CHMM-NB	• IFU (//www.hycoe.com/showpro.asp?ID=65) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hubei Huaqiang High-Tech Co., Ltd.	Flat Fold (Earloop) Non-Sterile	• IFU (http://www.huaqiang.world/23341.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Hui Zhou Tian Chang Industrial Co., Ltd.	N002-AW	• IFU (https://carewe.store/pages/instruction-for-use-n002-aw-ffp2) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Huizhou Green Communication Equipment Manufacturing Co., Ltd	G95200 Particle Filtering Half Mask	• IFU (http://www.green-cem.com/en/productsDetail.php?id=13) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Huizhou Huinuo Technology Co., Ltd	9501A	• IFU (http://www.hvn-china.com/en/pro/kn95/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Huizhou Yibaidu Medical Device Technology Co., Ltd.	YBD-2	
Hunan Boltpower Guokang Medical Equipment Co., Ltd.	GK-002A	• IFU (http://www.djjgkyl.com/product/11.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hunan Changyuan Technology Co., Ltd.	CY005 Filtering Half Mask	• IFU (https://dcmask.com/ffp2-face-mask/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hunan EEXI Technology & Service Co., Ltd.	YX152, YX153	• YX152: IFU (https://www.hunaneexi.com/productinfo/450184.html?templateId=1133605) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • YX153: IFU (https://www.hunaneexi.com/productinfo/5440.html?templateId=1133605) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Hunan Hengchang Pharmaceutical Co., LTD.	N9501-L (non-sterile type)	• IFU (http://www.hcyy.com/sustainableQualityShow.php?cid=36&id=36&wid=341) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hunan Jianyuan Medical Science and Technology Co. Ltd.	JY009A	• IFU (http://en.jyylkj.com/product/58.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Hunan Kangweining Medical Devices Co., Ltd.	YH-I (non-sterile) and YH-II (sterile)	• IFU (http://www.kwnmc.com/Mask/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiande Chaomei Daily Chemicals Co.	F-Y3-A	• IFU (http://www.cmmask.net/products/details/yyfhkz-135.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiangmen Nostop Electric Co., Ltd	JW-017	• IFU (http://www.nostop.cn/InformationofourEUAlistedrespirator.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
JIANGSU CHANGMEI MEDTECH CO.,LTD	DFM-01	• IFU (http://www.czmed.com/index.php?option=com_k2&view=itemlist&layout=category&task=category&id=229&Itemid=744&lang=en) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
JiangSu EverSmart Nano Technology Co., Ltd.	HZ-KN95	• IFU (http://www.eversmartnano.com/article-detail/bLARp49B) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
JIANGSU HOMCAN MEDICAL TECHNOLOGY CO. LTD	HC-NP95A	• IFU (https://www.homcan.cn/FFP2-instructions) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Jiangsu Jiaao Medical Technology Co., Ltd.	JA95-1 Filtering half mask	• IFU (http://www.jiaaomed.cn/pd.jsp?id=7) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiangsu Kangershun Protective Equipment Co., Ltd.	KES-002	• IFU (https://fdamaster.com/kes-002-user-instruction/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiangsu Sanfo Outdoor Products Co., Ltd	CX9501-P	• IFU (http://www.cx365mask.com/h-col-108.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiangsu Yimao Filter Media Co., Ltd	9570K, 9560K	• 9560K • 9570K: IFU (https://www.eimoeco.com/pd42376175.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jiaxing Yinuo Busway Co., Ltd.	YJ-P2	
Jingzhou Strong Sciences & Technology Development Co.,ltd	ST-A9502, A9507	• ST-A9502: IFU (http://www.jzstrong.com/enshop/bencandy.php?fid=3&id=197) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • A9507: IFU (http://www.jzstrong.com/enshop/bencandy.php?fid=3&id=198) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jinhua Ai Kou Protective Equipment Co.,	AK003	• IFU (http://www.aaikou.com/aaikou/products/18974771.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jinhua Jiadaifu Medical Supplies Co., Ltd.	Disposable Non-Medical Face Mask (KN95)	• IFU (http://www.jiadf.com/a.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Jinwells (Tianjin) Science and Technology Co., Ltd.	JWS-1, JWS-2	• JWS-1: IFU (http://www.jinwells.com/default.aspx?pageid=14&pageType=detail&id=59) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • JWS-2: IFU (http://www.jinwells.com/default.aspx?pageid=14&pageType=detail&id=60) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Jinyi (Tianjin) Medical Technology Co., Ltd.	JY9501	• IFU (http://www.jinyimedical.com/aspcms/news/2020-8-21/185.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Lanshan Shendun Technology Co., Ltd.	SD-KN95	• IFU (http://en.lamdownmask.com/article/1013/1005) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Liaoning Dalian Jieying Energy Saving Environmental Protection Technology Development Co., Ltd.	JY-FH-F, JY-FH	• JY-FH-F: IFU (https://www.jieyingtechnology.com/Content/show/catid/109/id/17/lang/en.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) • JY-FH: IFU (https://www.jieyingtechnology.com/Content/show/catid/88/id/14/lang/en.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
Lu'an Bi Hai Protective Equipment Co., Ltd.	BH2020	
Meizhuangchen Health Technology (Shenzhen) Co., Ltd.	ENKN95-001	

Top ()

Manufacturer	Respirator Model(s)	Instructions for Use
Naton Medical Protective Mask (Zhuozhou) Co., Ltd	FS9501-L, FS9501-M, FS9501-S; FS9901-L, FS9901-M, FS9901-S	• IFU (http://www.natonmask.com/index.php?m=content&c=index&a=lists&catid=25) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
ORICH Medical Equipment (Tianjin) Co., Ltd.	N95 Folded Form (Non-sterile)	• IFU (https://www.orichmed.com/particulate-respirator-583.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Showing 1 to 100 of 167 entries

Previous 1 2 Next

Respirator Models Previously Removed from Appendix A (Last Updated October 15, 2020; All models revoked effective July 6, 2021)

These respirator models had been on the list of authorized respirators in Appendix A but no longer met the EUA (/media/136664/download) eligibility criteria and thus were no longer authorized. Results from NIOSH's testing are provided at: https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html (https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html)

Search:

Show 100 entries

Date No longer Authorized	Manufacturer	Respirator Model(s) No Longer Authorized
10/15/2020	HeiQ Materials AG	HVB-FFP2-01
06/06/2020	Fujian Kang Chen Daily Necessities Co, Ltd.	K0450, 57793

Top ()

Date No longer Authorized	Manufacturer	Respirator Model(s) No Longer Authorized
05/07/2020	AAB (China) Co., Ltd	KN95
05/07/2020	Anshun Health and Medical Technology Co., LTD	AKF2002
05/07/2020	Bei (Dong Shan) Protective Supplies Co., LTD	B707
05/07/2020	Changsha JNEYL Medical Equipment Co., Ltd	JN-9501
05/07/2020	Changzhou Wedream Medical Device Co., Ltd	KN95
05/07/2020	Chongqing China Nano Technology Co., Ltd	ZN8005
05/07/2020	Chongqing Zaisheng Technology Co., Ltd.	ZS-A950
05/07/2020	Chuzhou Qiao Dong Industrial Co., Ltd	Langie KN95 FFP2
05/07/2020	Creative Concepts Manufacturing Ltd	02669, KN95
05/07/2020	CTT CO. Ltd.	KN95
05/07/2020	Daddybaby Co. Ltd.	KN95 FFP2
05/07/2020	DongGuan HuaGang Communication Technology Co., Ltd	KN95-A; KN95-B
05/07/2020	Dongguan Leihuo Medical Device Co., LTD	CPFM-100, CPFM-101, LH-KN95
05/07/2020	Dongguan Xianda Medical Equipment Co., Ltd	KN95
05/07/2020	Foshan Nanhai Weijian Sanbang Protective Equipment Technology Co., Ltd	KN95 Model 9051A
05/07/2020	Fujian Pageone Garment Co., Ltd	KN95

Top ()

Date No longer Authorized	Manufacturer	Respirator Model(s) No Longer Authorized
05/07/2020	Guangdong Fei Fan MStar Technology Ltd	KN95
05/07/2020	Guangdong Kaper Protection Technology Co., Ltd	KP-K02 (N95)
05/07/2020	Guangzhou Aiyinmei Co., LTD	A&F KN95
05/07/2020	Guangzhou Sunjoy Auto Supplies Co., LTD	Earhook folding type K1-K100, Headband folding type K1-K100
05/07/2020	Guangzhou Yihere Medical Technology Development Co., Ltd	YH-MFK-B95, YH-MFK-Z95
05/07/2020	Guizhou Bocai Medical Device Co., Ltd.	Bocai KN95
05/07/2020	Henan Fengzhihuang Industrial Co., Ltd	HF/KN95-3
05/07/2020	Henan Youmaisi Health Technology Co. LTD	YMS-AN95
05/07/2020	Huizhou Huinuo Technology Co., LTD	HV-N White 9501B
05/07/2020	Huizhou Jiahe Cubic Technology Co., LTD	KN95
05/07/2020	Huizhou Lexuslance Technology Co. Ltd.	LK 003
05/07/2020	Improve Medical (Hunan) Co., Ltd.	PPDS Disposable Protective Respirator Strap Headband, PPDS Disposable Protective Respirator Ear Hook
05/07/2020	Jiangsu Weichuangli New Materials Co., Ltd.	WCL-0075
05/07/2020	Jiangxi Hornet Industrial Co. Ltd.	S-KN95
05/07/2020	Jiangxi Yifengyuan Biological Engineering Co., Ltd.	N95, KN95

Top ()

Date No longer Authorized	Manufacturer	Respirator Model(s) No Longer Authorized
05/07/2020	Jinan Vhold Co., LTD	VH-95
05/07/2020	Juntech (Jiaxing) Healthcare Materials Co. Ltd	KN95
05/07/2020	Panzhihua Gangcheng Group Yasheng Industrial Co., Ltd.	KN95
05/07/2020	Qingdao Orphila Medical Technology Co. LTD.	OM-KN95-FFP2
05/07/2020	Qingyuan Leite Technology Development Co.	GV-0095A, GVHKN95
05/07/2020	Shandong Daddy's Choice Health Science and Technology Co., Ltd	Purism KN95
05/07/2020	Shandong Huishoutang Pharmaceutical Co	KN95
05/07/2020	Shandong Shengquan New Material Co., Ltd	SNN70370B (Willow leaf form valveless)
05/07/2020	Shauguan Taijie Protection Technology Co. Ltd.	KN95
05/07/2020	Shenzhen Horb Technology Corp., Ltd	1.7.02.02.0001
05/07/2020	Shenzhen Missadola Technology Co., Ltd, dba 1AK Medical Supplies	2626-1 KN95
05/07/2020	Sunright Medical Technology (GuangDong) Co., LTD	KN95-C3
05/07/2020	Tianjin Benmo Medical Equipment Co., Ltd.	KN95
05/07/2020	Winner Medical Co. Ltd.	WN-N95FG
05/07/2020	Yiwu Henghao household products Co., Ltd	HH-KN95-001

Top ()

Date No longer Authorized	Manufacturer	Respirator Model(s) No Longer Authorized
05/07/2020	Yiwu Yifan Knitting Co. Ltd	KN95
05/07/2020	Zhangzhou Easepal Industrial Corp.	MASK-104
05/07/2020	Zhejiang Baiyi Intelligent Garment Co LTD	KN95
05/07/2020	Zhejiang Shengtai Baby Products Co Ltd	KN95
05/07/2020	Zhengzhou QBS New Material Co., LTD	KN95
05/07/2020	Zhengzhou Wanshenshan Healthcare PPE Co., Ltd.	KN95

Showing 1 to 54 of 54 entries

Previous 1 Next

Umbrella EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs) (Revoked effective July 6, 2021)

On March 24, 2020, the FDA issued an umbrella EUA for certain imported disposable filtering facepiece respirators (FFRs) that are not approved by the National Institute for Occupational Safety and Health (NIOSH) and that met eligibility criteria as described in the EUA. Under this EUA, respirators, listed in Exhibit 1, were authorized for use in healthcare settings by healthcare personnel (HCP) when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak.

On March 28, 2020, FDA revised this EUA to authorize the use of certain authorized respirators that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system.

Top ()

On June 6, 2020, FDA again revised the EUA to exclude decontaminated respirators with exhalation valves from the scope of authorization, as well as to add additional specificity regarding which jurisdictions were included in the second criterion for eligibility.

On March 24, 2021, the FDA revised this EUA to authorize for emergency use only those respirators listed in the EUA's Exhibit 1 as of the date of this reissuance. The FDA no longer reviewed requests to add new respirator models to Exhibit 1 of this EUA after March 24, 2021.

On June 30, 2021, the FDA announced the revocation (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations) of EUA (effective July 6, 2021).

- Revoked EUA Letter of Authorization - Umbrella EUA Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (/media/136403/download)
- Exhibit 1 (Last Updated March 8, 2021; All models revoked effective July 6, 2021)

Exhibit 1 (Last Updated March 8, 2021; All models revoked effective July 6, 2021)

The table below includes a list of non-NIOSH-approved disposable FFRs that were authorized under this Umbrella EUA (/media/136403/download) for emergency use in healthcare settings by HCP when used in accordance with CDC recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html).

Search:

Show 100 entries

Manufacturer	Respirator Model(s)	Country of Manufacture	Instructions for Use
3M	8205	Japan	
3M	8822	South Korea	

Top ()

Manufacturer	Respirator Model(s)	Country of Manufacture	Instructions for Use
3M	9320+	UK, Singapore, Turkey	
3M	9322+	UK, Singapore, Turkey	
Advanced Medical Devices Pty Limited	Nano-Tech P2 Particulate Respirator - T4	Australia	• IFU (https://amdmed.com.au/instruction-to-use/) (http://www.fda.gov/about-fda/website-policies/wel
Allix Co., Ltd.	AM 200	South Korea	
Alumitek Ingenieria S de RL de CV	MXN95R1	Mexico	• IFU (https://en.safetyproductsmfg.com/respirador-n (http://www.fda.gov/about-fda/website-policies/wel
Ap Mascarillas S.A. de C.V.	AP M10, AP Z6	Mexico	
Best Pacific Vietnam Company Limited	MASK-VN-22	Vietnam	• IFU (http://vn.doctorcross.com/labeling_VN22) (/about-fda/website-policies/website-disclaimer)
BioSerenity	1016-07003-US	France	

Top ()

Manufacturer	Respirator Model(s)	Country of Manufacture	Instructions for Use
Brands Unlimited S.A. de C.V.	Medimask MM-001, MM-002, MM-003 A, MM-003 B, MM-003 C, MM-003 D, MM-003 E, MM-003 F, MM-003 G, MM-003 H, MM-003 I, MM-003 J, MM-003 K, MM-003 L, MM-004 A, MM-004 B, MM-004 C, MM-004 D, MM-004 E, MM-004 F, MM-004 G, MM-004 H, MM-004 I, MM-004 J, MM-004 K, and MM-004 L	Mexico	
BTL Industries	FLAT-FIT Healthcare Respirator	Bulgaria	• IFU (https://btl-misc.s3.eu-west-1.amazonaws.com/misc/BTL_Respirator_LF_User-Manual_ENESUS100 (http://www.fda.gov/about-fda/website-policies/wel
Care Essentials Pty Ltd	MSK-001, MSK-001S, MSK-002, MSK-002S	Australia	• IFU (https://www.careessentials.com.au/product-inf instructions/) (http://www.fda.gov/about-fda/we /website-disclaimer)
Dromex	Model 1020	South Africa	
Evolve Group Pty Ltd	IPKIS P2 Respirator	Australia	

Top ()

Manufacturer	Respirator Model(s)	Country of Manufacture	Instructions for Use
Galia Textil S.A. DE C.V	GTN95	Mexico	
GCE Lighting / Savoy International	MRP-FFP2-AM-20	France	• IFU (https://www.savoy-international.com/wp-conte /manual-FFP2-savoy-international.pdf) (http://wv fda/website-policies/website-disclaimer)
Grupo 10X SA DE CV d.b.a Sanitek Pro	Sanitek Pro N95	Mexico	• IFU (https://sanitekpro.com/n95-respirator/) (htt /about-fda/website-policies/website-disclaimer)
Hwa Yui Co., Ltd	HY20	South Korea	• IFU (https://www.hwayui.co.kr/2021/02/03/instructi masks/) (http://www.fda.gov/about-fda/website- disclaimer)
Hygiene Austria LP GmbH	HA PP02	Austria	
Keeo Life Private Limited	KF-SG-N95-HL, KF-SG-N95-EL	India	
Lanaco Limited	WAIRE P2	New Zealand	• IFU (https://lanaco.co.nz/wp-content/uploads/2020 Respirator-v2.1-Insert-Card-User-Instructions-1.pdf) (http://www.fda.gov/about-fda/website-policies/wel
Layfield Canada Ltd.	1970EU	Canada	• IFU (https://layfieldmedical.com/wp-content/upload /layfield_1970eu_respirator_m00006013_user_instru (http://www.fda.gov/about-fda/website-policies,
Macopharma	F2001N	France	• IFU (https://www.macopharma.com/wp-content/upl /NOTEURO60-01.2021.pdf) (http://www.fda.gov/ policies/website-disclaimer)
Manohar Filaments Private Limited	MF-SG-N95-HH, MF-SG-N95-EH	India	• MF-SG-N95-HH: IFU (http://www.mfpl.care/N95-IFU- (http://www.fda.gov/about-fda/website-policies/wel • MF-SG-N95-EH: IFU (http://www.mfpl.care/N95-IFU-E (http://www.fda.gov/about-fda/website-policies/wel

Top ()

Manufacturer	Respirator Model(s)	Country of Manufacture	Instructions for Use
Mkteks Mensucat Tekstil Sanayi VE Ticaret Limited Sirketi	WV NR 101	Turkey	
MUSK Medikal Tekstil Plastik Sanayi Ve Ticaret Limited Sirketi	MUSK001	Turkey	
MY ARLET	ARLET 5000 FFP2 NR, ARLET 6000 FFP3 NR	Turkey	• IFU (http://myarlet.com/pdf/ffp3.pdf) (http://ww fda/website-policies/website-disclaimer)
Novita, 9 Koi Marketing Pte Ltd	R5, R7	Singapore	• IFU (https://novita.com.sg/web/respirator/r5r7userg (http://www.fda.gov/about-fda/website-policies/wel
NTI Vina Co. Ltd.	SG9010V	Vietnam	• IFU (http://enwglobal.com/en/bbs /content.php?co_id=instruction_to_use) (http://w fda/website-policies/website-disclaimer)
Plastcor Do Brasil LTDA	ECHO PFF2 CA 38.811	Brazil	• IFU (http://plastcors.com/instructionsforuse.pdf) (http://www.fda.gov/about-fda/website-policies/wel
Productos Químicos y Farmacéuticos R&M S.A de C.V.	PLB 95	Mexico	
Rang Company	MB100	South Korea	
Rose Personal Protective Equipment Industry and Trade Anonym Company	IRYS-08	Turkey	• IFU (http://ivrou.com /pdf/Intended%20Use%20and%20Other%20Instructi revised.pdf) (http://www.fda.gov/about-fda/webs /website-disclaimer)

Top ()

Manufacturer	Respirator Model(s)	Country of Manufacture	Instructions for Use
Softmed Manufacturing Pty Ltd	SM-RC201, SM-RF202	Australia	• SM-RC201: Labeling (https://softmedusa.com/instru /LA-009_USA_Medical_P2_CUP_SM-RC201-20_Head (http://www.fda.gov/about-fda/website-policies/wel (https://softmedusa.com/instructions /IFU_1_00_Insert_USA_Cup_Respirator_V1.pdf) (I /about-fda/website-policies/website-disclaimer) • SM-RF202: IFU (https://softmedusa.com/instruction /IFU_2_00_Insert_USA_95_Folded_Respirator_V1.pdf (http://www.fda.gov/about-fda/website-policies/wel
Sonata Calcetin S.A. de C.V.	CB01	Mexico	

Top ()

Manufacturer	Respirator Model(s)	Country of Manufacture	Instructions for Use
Tenamyd Pharmaceutical Corporation	Tenamyd FM-N95 Model YCKTC13, Tenafa® N-95 Model YCTFA04, Tenami® N-95 Model YCTM102, YCTFM02, YCTFA07, YCTMI08, YCTFM01, YCTFA06, YCTMI07	Vietnam	• YCKTC13: IFU (https://tenamydpharma.com/san-pha n95-(model-ycktc13)) (http://www.fda.gov/about policies/website-disclaimer) • YCTFA04: IFU (https://tenamydpharma.com/san-pha n95-(model-yctfa04)) (http://www.fda.gov/about policies/website-disclaimer) • YCTFM02: IFU (https://tenamydpharma.com/san-ph n95-2011-(model-yctfm02)) (http://www.fda.gov/ policies/website-disclaimer) • YCTFA07: IFU (https://tenamydpharma.com/san-pha n95-2011-(model-yctfa07)) (http://www.fda.gov/ policies/website-disclaimer) • YCTMI08: IFU (https://tenamydpharma.com/san-pha n95-2011-(model-yctmi08)) (http://www.fda.gov/ policies/website-disclaimer) • YCTFM01: IFU (https://tenamydpharma.com/san-ph n95-duck-beak-(model-yctfm01)) (http://www.fda fda/website-policies/website-disclaimer) • YCTFA06: IFU (https://tenamydpharma.com/san-pha beak-(model-yctfa06)) (http://www.fda.gov/abou policies/website-disclaimer) • YCTMI07: IFU (https://tenamydpharma.com/san-pha beak-(model-yctmi07)) (http://www.fda.gov/abou policies/website-disclaimer) • YCTMI02: IFU (https://tenamydpharma.com/san-pha n95-(model-yctm102)) (http://www.fda.gov/abou policies/website-disclaimer)
TRN MODA TEKSTIL SAN VE TIC LTD STI	O2BLS-NRFM002, O2BLS-NRFM003	Turkey	

Showing 1 to 38 of 38 entries

Previous 1 Next

Top()

Emergency Use Authorization of Medical Products and Related Authorities

Guidance for Industry and Other Stakeholders

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of the Chief Scientist
Office of Counterterrorism and Emerging Threats

January 2017

Procedural
OMB Control No. 0910-0595
Expiration Date 08/31/2022
See additional PRA statement in section IX of this guidance.

Contains Nonbinding Recommendations

Emergency Use Authorization of Medical Products and Related Authorities[1]

Guidance for Industry and Other Stakeholders

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance explains FDA's general recommendations and procedures applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[2] as amended or added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA)[3]. The provisions in PAHPRA, described in section II of this guidance, include key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents, including emerging infectious disease threats such as pandemic influenza. PAHPRA clarifies and enhances FDA's authority to support emergency preparedness and response and foster the

[1] This guidance was prepared by the Office of Counterterrorism and Emerging Threats (OCET) in cooperation with the Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), and Center for Drug Evaluation and Research (CDER).

[2] 21 U.S.C. 360bbb-3, 360bbb-3a, and 360bbb-3b. Section 564 was first added to the FD&C Act by the Project BioShield Act of 2004 (Public Law 108-276). Hereafter in this document, statutory references (e.g., "section __") are to the FD&C Act, except where otherwise indicated.

[3] Public Law 113-5. Section 3088 of the 21st Century Cures Act, signed into law by the President on December 13, 2016, amends sections 564, 564A, and 564B of the FD&C Act to add new authorities to: (1) authorize emergency use of unapproved animal drugs, (2) make applicable other emergency use authorities (e.g., to issue emergency dispensing orders, waive compliance with current good manufacturing practices (CGMPs), make available Centers for Disease Control and Prevention (CDC) emergency use instructions, and extend expiration dates) to approved animal drugs, and (3) allow unapproved animal drugs to be held for emergency use. While much of what is described in this guidance will apply to these new authorities, this guidance does not by its terms reference them; FDA asks anyone interested in utilizing these authorities to contact FDA directly to discuss how to proceed. FDA plans to review these new authorities and address any new procedural issues raised as we develop more experience with these new authorities.

development and availability of medical products for use in these emergencies. These medical products, also referred to as "medical countermeasures" or "MCMs," include drugs[4] (e.g., antivirals and antidotes), biological products (e.g., vaccines, blood products, and biological therapeutics), and devices (e.g., *in vitro* diagnostics and personal protective equipment). This guidance finalizes the draft guidance, *Emergency Use Authorization of Medical Products and Related Authorities (April 2016)* and replaces the following two guidance documents, *Emergency Use Authorization of Medical Products* (July 2007) and *Emergency Use Authorization Questions and Answers* (April 2009).

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. SCOPE OF GUIDANCE

This document is intended to inform all stakeholders[5] involved in emergency response activities and FDA staff of FDA's general recommendations and procedures for:

(1) Issuance of Emergency Use Authorizations (EUAs) under section 564;

(2) Implementation of the emergency use authorities set forth in section 564A; and

(3) Reliance on the governmental pre-positioning authority set forth in section 564B."

[4] Throughout this guidance references to "drugs" and "drug products" include both drugs approved under the FD&C Act and biological products licensed under the Public Health Service (PHS) Act, but not biological products that also meet the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)).

[5] For purposes of this guidance, "stakeholders" include industry and government sponsors and other government stakeholders/entities involved in emergency response activities (including Federal, State, local, tribal, or territorial government stakeholders/entities). The term "government stakeholders" refers to the public health and/or emergency response agencies or their agents/delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundaries (e.g., city, county, tribal, territorial, State, or Federal), or functional range or sphere of authority (e.g., law enforcement, public health, military health) to prescribe, administer, deliver, distribute, hold, or dispense a medical product during an emergency situation.

Section 564, as amended by PAHPRA, permits the Commissioner[6] to authorize the emergency use of an unapproved medical product or an unapproved use of an approved[7] medical product for certain emergency circumstances (discussed in section III.A of this guidance) after the HHS Secretary has made a declaration of emergency or threat justifying authorization of emergency use. The Commissioner may issue an EUA to allow an MCM to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a CBRN agent when there are no adequate, approved, and available alternatives. Section III of this guidance addresses EUAs.

Section 564A, as added by PAHPRA, establishes streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved MCMs *without* FDA issuing an EUA, which can be a resource-intensive process. These authorities, and the definition of eligible products to which they apply, are discussed in section IV of this guidance. These authorities, which apply only to eligible FDA-approved medical products intended for use during a CBRN emergency, include provisions that:

- Empower FDA to extend the expiration date of an eligible FDA-approved MCM stockpiled for use in a CBRN emergency and to establish appropriate conditions relating to such extensions, such as appropriate storage, sampling, and labeling;

- Permit FDA to waive otherwise-applicable current good manufacturing practice (CGMP) requirements[8] (e.g., storage or handling) to accommodate emergency response needs;

- Allow emergency dispensing of MCMs during an actual CBRN emergency event without requiring an individual prescription for each recipient[9] of the MCM or all of the information otherwise required or by responders who may not otherwise be

---

[6] As provided in section 1003 and existing delegations of authority (found in the FDA Staff Manual Guide 1410.10), the Secretary of Health and Human Services (HHS Secretary or Secretary of HHS) has delegated most of the authorities under sections 564, 564A, and 564B to the Commissioner of FDA (Commissioner). Thus, this guidance refers to either FDA or the Commissioner rather than the HHS Secretary, except where the HHS Secretary has traditionally exercised the authority or has delegated it to another official (e.g., the authority to issue emergency use instructions pursuant to section 564A(e) was delegated to the Director of the CDC).

[7] Unless otherwise specified, the terms "approved product" and "FDA-approved product" refer to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the FD&C Act or section 351 of the PHS Act, as applicable. For purposes of this document, an "unapproved" product refers to a product that is not approved, licensed, or cleared for commercial distribution under section 505, 510(k), or 515 of the FD&C Act or section 351 of the PHS Act; an "unapproved use of an approved product" refers to a product that is approved, licensed, or cleared under such a provision but for which the specific use is not an approved, licensed, or cleared use of the product. See section 564(a)(2).

[8] As applied to medical devices, these are referred to as "Quality System Regulation" requirements. See 21 CFR 820.

[9] For purposes of this guidance, the term "recipient(s)" refers to individual(s) to whom an MCM product is administered or on whom the product is used.

licensed to dispense, if permitted by state law in the state where such dispensing occurs or if in accordance with an order issued by FDA; and

- Permit the Centers for Disease Control and Prevention (CDC) to create and issue "emergency use instructions" (EUI) concerning the FDA-approved conditions of use for eligible products.[10]

In addition, PAHPRA amended section 505-1(k) to authorize FDA to waive Risk Evaluation and Mitigation Strategy (REMS) requirements for CBRN emergencies.

Finally, section 564B, also added by PAHPRA, permits government stakeholders to pre-position (e.g., stockpile, forward-deploy) MCMs in anticipation of FDA approval or clearance, authorization of an investigational use, or the issuance of an EUA, to enable these stakeholders to prepare for potential rapid deployment during an actual CBRN emergency. This authority is discussed in section V of this guidance.

III. EMERGENCY USE AUTHORIZATIONS

The EUA authority under section 564 allows FDA to facilitate availability and unapproved uses of MCMs needed to prepare for and respond to CBRN emergencies. The EUA authority is separate and distinct from use of a medical product under an investigational application (i.e., Investigational New Drug Application (IND) or Investigational Device Exemption (IDE)), section 561 expanded access authorities,[11] and section 564A emergency use authorities discussed in section IV of this guidance.

[10] U.S. Department of Health and Human Services, Delegation of Authority of section 564A(e) of the Federal Food, Drug, and Cosmetic Act, December 16, 2013, see http://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/UCM510446.pdf.

[11] For general information on expanded access mechanisms, see http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm.

Before an EUA declaration terminates, the Secretary of HHS must provide advance notice that is sufficient to allow for the disposition of an unapproved product, and of any labeling or other information provided related to an unapproved use of an approved product (section 564(b)(3)).[19]

B. EUA MEDICAL PRODUCTS

1. Criteria for Issuance

During the effective period of the HHS Secretary's EUA declaration, FDA may authorize the introduction of a medical product into interstate commerce when the product is intended for use during an actual or potential emergency. EUA candidate products include medical products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the FD&C Act or section 351 of the PHS Act.

After the requisite determination and declaration have been issued, and after feasible and appropriate consultations, FDA may issue an EUA only if FDA concludes that the following four statutory criteria for issuance have been met. If the product does not meet the statutory criteria for issuance or is not otherwise an appropriate candidate, an alternative regulatory mechanism (i.e., access under an IND or IDE, which can include expanded access protocols[20]) may be an appropriate means to provide patients access to an unapproved use of a product in a CBRN emergency.

a. Serious or Life-Threatening Disease or Condition

For FDA to issue an EUA, the CBRN agent(s) referred to in the HHS Secretary's EUA declaration must be capable of causing a serious or life-threatening disease or condition.

b. Evidence of Effectiveness

Medical products that may be considered for an EUA are those that "may be effective" to prevent, diagnose, or treat serious or life-threatening diseases or conditions that can be caused by a CBRN agent(s) identified in the HHS Secretary's declaration of emergency or threat of emergency under section 564(b). Potential EUA products also include those that may be effective to mitigate a disease or condition caused by an FDA-regulated product (including a product authorized for emergency use under section 564 or an approved product) used to diagnose, treat, or prevent a disease or condition caused by a CBRN agent.

---

[19] The Secretary of HHS publishes in the Federal Register notice of each EUA declaration justifying issuance of an EUA, with an explanation of the basis of the declaration under section 564(b)(1), as well as any advance notice of termination of such a declaration.

[20] For general information on expanded access mechanisms, see http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm.

The "may be effective" standard for EUAs provides for a lower level of evidence than the "effectiveness" standard that FDA uses for product approvals.[21] FDA intends to assess the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis, as explained below. If, based on the totality of the scientific evidence available, it is reasonable to believe that the product may be effective for the specified use, FDA may authorize its emergency use, provided that other statutory criteria for issuing an EUA also are met.

c. Risk-Benefit Analysis

A product may be considered for an EUA if the Commissioner determines that the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product. In making this assessment, FDA must take into consideration the material threat posed by the CBRN agent(s) identified in the HHS Secretary's declaration of emergency or threat of emergency if applicable (section 564(c)).

In determining whether the known and potential benefits of the product outweigh the known and potential risks, FDA intends to look at the totality of the scientific evidence to make an overall risk-benefit determination. Such evidence, which could arise from a variety of sources, may include (but is not limited to): results of domestic and foreign clinical trials, *in vivo* efficacy data from animal models, and *in vitro* data, available for FDA consideration. FDA will also assess the quality and quantity of the available evidence, given the current state of scientific knowledge. The types of evidence that FDA may consider and that should be submitted to support a request for an EUA are discussed more fully in section III.D.2 of this guidance.

d. No Alternatives

For FDA to issue an EUA, there must be no adequate, approved, and available alternative to the candidate product for diagnosing, preventing, or treating the disease or condition. A potential alternative product may be considered "unavailable" if there are insufficient supplies of the approved alternative to fully meet the emergency need. A potential alternative product may be considered "inadequate" if, for example, there are contraindicating data for special circumstances or populations (e.g., children, immunocompromised individuals, or individuals with a drug allergy), if a dosage form of an approved product is inappropriate for use in a special population (e.g., a tablet for individuals who cannot swallow pills), or if the agent is or may be resistant to approved and available alternative products.

[21] Regulations regarding treatment INDs and IDEs also use the terminology "may be effective." A request for a treatment IND for a drug or biologic intended to treat an immediately life-threatening disease may be granted when, among other things, there is evidence that the drug may be effective for its intended use in its intended population (21 CFR 312.320(a)(3)(ii)). For devices, a treatment IDE may be withdrawn if FDA determines that the available scientific evidence fails to provide a reasonable basis for concluding that the device "may be effective for its intended population" (21 CFR 812. 36(d)(2)(iv)(A)). It should be noted that FDA's decisions on requests for EUAs and treatment INDs and IDEs involve product-specific and circumstance-dependent determinations of risks and benefits. FDA also notes that the amount, type, and quality of evidence available to support an EUA may not always be the same as that required for expanded access, IDEs, or humanitarian device exemptions under the FD&C Act and FDA regulations.

- Dosing information (if applicable), including any specific instructions for special populations; and

- Contact information for reporting adverse events and additional information about the product.

Health care professionals or authorized dispensers will likely have very limited time to review Fact Sheets during an emergency and, therefore, FDA anticipates that Fact Sheets typically will be brief (i.e., a few pages). FDA makes available on its website Fact Sheets for products for which an EUA is issued.[41]

FDA further recommends that Fact Sheets target the health care professional or authorized dispenser who has the most basic level of training, recognizing that individuals responding to an emergency may have different levels of training, could come from a variety of backgrounds, and may have different types of experience or speak different languages. FDA recommends that Fact Sheets accompany the EUA product in an accessible form (e.g., printable as a hard copy) when the product is distributed to the health care professional or authorized dispenser if practicable. To the extent consistent with other conditions of authorization, information on the EUA product also may be disseminated to health care professionals or authorized dispensers through mass media (including print, broadcast, radio, satellite, Internet, or other electronic means of dissemination), videos/DVDs, or direct communication from public health agencies.

For unapproved drug products, which do not have FDA-approved labeling for any indication, FDA recommends that, in addition to the brief summary information found in a Fact Sheet, the sponsor also develop more detailed information similar to what health care professionals are accustomed to finding in FDA-approved package inserts. For medical devices regulated, such as *in vitro* diagnostics, in addition to the brief summary information found in a Fact Sheet, FDA recommends the sponsor also develop separate Instructions for Use.[42]

With respect to an EUA that authorizes a change in labeling of an approved product, but for which the manufacturer chooses not to make such labeling change, the EUA may not authorize the product's distributor or any other person to alter or obscure the manufacturer's labeling (section 564(e)(2)(B)).[43] In such a situation, however, FDA must, to the extent practicable given the applicable circumstances, authorize a person acting pursuant to such EUA to provide, in

[41]For examples of Health Care Professional Fact Sheets, see FDA's website at: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm#current.

[42] For examples of Instructions for Use, see FDA's website at: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm#current.

[43] We note that this prohibition does not apply to changes in expiration dating permitted pursuant to section 564A(b). See section IV.B of this guidance.

addition to the manufacturer's labeling, appropriate information with respect to the product, such as that provided in the brief Fact Sheet described above.[44]

b. Information for Recipients

Although informed consent as generally required under FDA regulations[45] is not required for administration or use of an EUA product, section 564 does provide EUA conditions to ensure that recipients are informed about the MCM they receive under an EUA. For an unapproved product (section 564(e)(1)(A)(ii)) and for an unapproved use of an approved product (section 564(e)(2)(A)), the statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstances:

- That FDA has authorized emergency use of the product;
- Of the significant known and potential benefits and risks associated with the emergency use of the product, and of the extent to which such benefits and risks are unknown;
- That they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product;[46] and
- Of any available alternatives to the product and of the risks and benefits of available alternatives.

Therefore, FDA recommends that a request for an EUA include a "Fact Sheet" for recipients that includes essential information about the product. In addition to the above information, the Agency recommends that the content of the Fact Sheets for recipients include the following information:

- Product name and explanation of the intended use of the product;
- A description of the disease/condition;

[44] Additional information provided under section 564(e)(2)(B)(ii) as a condition of authorization is not considered "labeling" for purposes of section 502 of the FD&C Act while the EUA for the product is effective.

[45] See 21 CFR part 50.

[46] The President may under certain circumstances waive the option for members of the armed forces to accept or refuse administration of an EUA product (10 U.S.C. 1107a). In addition, the option to accept or refuse may not be practicable with regard to certain diagnostics because, for example, when a sample is taken from an individual it may be unknown, even to the health care professional, which diagnostic test will be used to test the sample. For this reason, Fact Sheets for both health care professionals and recipients may not accompany an EUA diagnostic product, but instead be publicly posted for reference when receiving test results.

- A description of items to discuss with a health care provider and adverse event information, including contact information for how to get more information and for reporting adverse reactions; and

- Dosing information (if applicable), including specific instructions for home use or preparation (if applicable).

FDA recommends that recipients be given as much appropriate information as possible given the nature of the emergency and the conditions of the authorization.[47] Ordinarily, FDA expects that some written form of information will be given to recipients with the MCM, similar to the Fact Sheet for health care professionals or authorized dispensers. FDA recognizes that these Fact Sheets, like those for health care professionals or authorized dispensers, will generally be brief. To ensure that individuals of varying educational levels comprehend the information provided, FDA recommends that all written information be stated in the simplest language possible using techniques to improve health literacy.[48] In addition, translations to other languages may be appropriate if practicable.[49] FDA recognizes that some flexibility may be needed for health care providers or authorized dispensers to make minor, nonsubstantive changes to the fact sheets for recipients such as adding local contact information, using specific letterhead or minor format changes.

FDA acknowledges that exigent circumstances may dictate the use of other appropriate dissemination methods. Therefore, FDA expects that information would be disseminated in the most effective and expeditious way possible to reach the recipient before administration or use of an EUA product.[50] If, however, taking the time needed to provide such information would diminish or negate the effectiveness of the product for the recipient, FDA may include as a condition of authorization that the information be provided to the recipient as soon as practicable after dispensing. Other methods of dissemination may include internet posting, mass media, videos/DVDs, or direct communication from health care professionals and public health agencies.

2. Monitoring and Reporting of Adverse Events

For an unapproved product (section 564(e)(1)(A)(iii)), EUA conditions for monitoring and reporting of adverse events are required to the extent practicable given the circumstances of the emergency; such conditions may be established for an EUA for an unapproved use of an approved product (section 564(e)(2)(A)), at the discretion of FDA.

---

[47] For examples of Patient/Recipient Fact Sheets, see FDA's website at: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm#current.

[48] See, e.g., http://www.health.gov/communication/literacy/quickguide/healthinfo.htm.

[49] When the translation of a fact sheet to a foreign language is determined to be appropriate and necessary, the party producing the translation is responsible for the accuracy and completeness of the translation; FDA does not intend to review translations to ensure their accuracy.

[50] As noted above, however, this may not be practicable or appropriate for certain diagnostic tests.

Conditions may be placed to enable the collection and analysis of information on the safety and effectiveness of the EUA product during the period when the authorization is in effect and for a reasonable time following such period. FDA expects that the primary focus of adverse event-related conditions will be capturing serious adverse events and applying appropriate mechanism(s) for the collection of follow-up clinical information. Some reporting may be directed to predefined mechanisms to capture adverse event data (e.g., FDA's Safety Information and Adverse Event Reporting System (MedWatch) or Vaccine Adverse Event Reporting System (VAERS)). FDA will work with product sponsors in some circumstances to develop proposals for more active data collection and follow-up mechanisms to capture adverse event information under the EUA. FDA encourages EUA sponsors to provide proposals for data collection and follow-up during pre-EUA interactions.

3. Records

To the extent practicable given the circumstances of the emergency, FDA must establish conditions for a manufacturer of an unapproved product to maintain records and to grant FDA access to records concerning the EUA product.[51] FDA anticipates that such conditions may relate to, for example, the number of doses, devices, or other unit(s) (including lot identification) that have been shipped or sold under an EUA; or the name and addresses of the facilities to and from which the EUA product was shipped. FDA may also impose comparable recordkeeping requirements on any person (e.g., an authorized distributor or dispenser) other than a manufacturer who carries out any activity for an unapproved EUA product (section 564(e)(1)(B)(iv)).

FDA may also impose recordkeeping and records access requirements on any person (including a manufacturer) engaged in an activity for which an EUA is issued for an unapproved use of an approved product (section 564(e)(2)(A)). In addition to the examples noted above for unapproved EUA products, examples may include conditions relating to actual use of the product and disposition of any unused product, and monitoring of patients who have been administered the product under an EUA.

4. Additional Conditions of Authorization

FDA, on a case-by-case basis and to the extent feasible given the circumstances of the emergency, may establish additional conditions that FDA finds to be necessary or appropriate to protect the public health (section 564(e)) [52], such as the following:

- *Distribution and administration*— conditions may be placed on which entities may distribute and who may administer the product, and how distribution and administration are to be performed. In addition, conditions may be placed on the

[51] Section 564(e)(1)(A)(iv).

[52] Section 564(e)(1)(B) (for unapproved products) and 564(e)(2)(A) (for unapproved uses of approved products).

1. Revision and Revocation

FDA will periodically review the circumstances and appropriateness of an EUA, including circumstances that might warrant revocation of the EUA. The review will include regular assessment based on additional information provided by the sponsor of the progress made with respect to the approval, licensure, or clearance of the unapproved product, or of the unapproved use of an approved product, for which an EUA was issued.

FDA may revise or revoke an EUA if the circumstances justifying its issuance (under section 564(b)(1)) no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety.[58] Such circumstances may include significant adverse inspectional findings (e.g., when an inspection of the manufacturing site and processes has raised significant questions regarding the purity, potency, or safety of the EUA product that materially affect the risk/benefit assessment upon which the EUA was based); reports of adverse events (number or severity) linked to, or suspected of being caused by, the EUA product; product failure; product ineffectiveness (such as newly emerging data that may contribute to revision of the FDA's initial conclusion that the product "may be effective" against a particular CBRN agent); a request from the sponsor to revoke the EUA; a material change in the risk/benefit assessment based on evolving understanding of the disease or condition and/or availability of authorized MCMs; or as provided in section 564(b)(2), a change in the approval status of the product may make an EUA unnecessary.

2. Product Disposition and Continued Use

Upon revocation of an EUA or its termination as a result of the termination of the HHS EUA declaration supporting it, an unapproved product or its labeling, and product information for an unapproved use of an approved product, must be disposed of pursuant to section 564(b)(2)(B) and (b)(3).[59] Notwithstanding any such revocation or termination, under section 564(f)(2) an authorization shall continue to be effective to provide for continued use in any patient who began treatment before revocation or termination (to the extent found necessary by the patient's attending physician). Any study or future use of an EUA product beyond the term of a declaration is subject to investigational product regulations (e.g., IND regulations).

H. PUBLICATION

FDA will promptly publish in the Federal Register a notice of each EUA, including an explanation of the reasons for issuance, a description of the intended use, and any contraindications of the EUA product. The Agency also will promptly publish in the Federal Register each termination or revocation of an EUA and an explanation of the reasons for the decision. Although FDA is not required to publish notice of an EUA revision(s) in the Federal

[58] Section 564(g)(2).

[59] Section 564(b)(2)(B) provides that FDA shall consult with the manufacturer of the product with respect to the appropriate disposition.

Register, FDA plans to post any revisions to EUAs on FDA's website at http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm.[60]

I. OPTION TO CARRY OUT AUTHORIZED ACTIVITIES

If a manufacturer is the sole source of an unapproved product authorized for emergency use, that manufacturer must inform FDA, within a reasonable time after the authorization, if the manufacturer does not intend to make its product available for use under the EUA (section 564(l)). The Commissioner does not have the authority under section 564 to require a person to carry out any activity for which an EUA is issued. Section 564(l), however, does not limit FDA's authority to impose conditions on persons who carry out any activity for which an EUA is issued.

IV. EMERGENCY USE OF ELIGIBLE FDA-APPROVED MCMs WITHOUT AN EUA

Section 564A allows FDA to facilitate certain emergency activities involving FDA-approved MCMs without an EUA. This authority is independent of the EUA authority under section 564. In the past, to address concerns about potential FD&C Act violations related to the activities discussed in this section involving MCMs, FDA has either: (1) exercised its enforcement discretion with respect to the activity; or (2) issued an EUA to ensure that use of such MCMs remains covered under any otherwise applicable protections under the PREP Act [61] (discussed in section VII of this guidance). MCMs used under this authority qualify for applicable PREP Act protection.[62]

In some cases, FDA and CDC may coordinate activities under section 564A authorities including the issuance of an emergency dispensing order, waiver of cGMPs, waiver of REMS, extension of expiration dating, and/or issuance of EUI for specific MCMs.[63]

---

[60] In publicly releasing information on an EUA, FDA will take necessary steps to protect nonpublic information and information otherwise protected by law, as appropriate.

[61] *See* 42 U.S.C. 247d-6d.

[62] *See* 42 U.S.C. 247d-6d(i)(1)(C), (i)(7)(B)(iii).

[63] See, e.g., Emergency Dispensing Information tables for doxycycline and ciprofloxacin at: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm495126.htm#doxy http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm495126.htm#cipro.

duties.[76] Under the legal principles of implied conflict preemption, courts have found state law preempted where it is impossible to comply with both federal and state law, or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[77] Consistent with this case law, section 4(a) of Executive Order 13132 states that "[a]gencies shall construe... a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."[78]

FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564. Similarly, an order or waiver issued under section 564A and pre-positioning under section 564B preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements related to the activity authorized under sections 564A or 564B.

To the extent state or local law may impose requirements different from or in addition to those imposed by the EUA for a particular medical product within the scope of the declared emergency or threat of emergency (e.g., requirements on prescribing, dispensing, administering, or labeling of the medical product), such law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," and "conflicts with the exercise of Federal authority under [§ 564]." The same rationale applies to an order or waiver issued under section 564A and pre-positioning of an MCM under section 564B.

Affected state laws may include, but are not limited to, laws governing the administration of investigational medical products, such as informed consent laws and laws requiring Institutional Review Board approval, and laws governing the prescribing or dispensing of medical products, such as laws limiting who may prescribe or dispense medical products and under what circumstances.

Moreover, the PREP Act, which expressly provides immunity from tort liability associated with certain MCM activities, preempts state laws that are different from, or in conflict with, any requirement applicable to a covered countermeasure under the PREP

---

[76] Medtronic v. Lohr, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in the judgment); id. at 510 (O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992) (plurality opinion); id. at 548-49 (Scalia, J., joined by Thomas, J., concurring in judgment in part and dissenting in part). Under the same reasoning, state regulations and local ordinances would also be preempted.

[77] See Arizona v. United States, 132 S. Ct. 2492, 2501, 2505, 2507 (2012); Crosby v. National Foreign Trade Council, 530 U.S. 363, 373 (2000); Geier v. American Honda Motor Company, Inc., 529 U.S. 861, 873 (2000); Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

[78] Exec. Order No. 13132, 64 FR 43255 (August 4, 1999).

Plaintiff's Exhibit 461

fda.gov

Face Masks, Including Surgical Masks, and Respirators for COVID-19

18-22 minutes

This page provides information on FDA-regulated face masks (including cloth face coverings), surgical masks, and respirators (filtering facepiece respirators, such as N95 respirators) intended for a medical purpose to assist in preventing the spread of infectious materials during the COVID-19 pandemic.

This page does not cover:

- Powered respirators, such as powered air purifying respirators (PAPRs)
- Face shields
- Non-health care use of face masks and respirators intended to limit industrial or general exposure to non-infectious particles, such as during construction or other industrial use.

The information provided may be useful to manufacturers and importers of face masks, surgical masks, and respirators, as well as health care facilities and health care personnel.

To help expand the availability of face masks (including cloth face coverings), surgical masks, and respirators, the FDA is providing certain regulatory flexibility for the duration of the COVID-19 public health emergency, as described in the Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised), and has issued emergency use authorizations (EUAs) for face masks, surgical masks, and respirators that meet certain criteria. The FDA regularly updates its communications about face masks, surgical masks, and respirators, including the answers to frequently asked questions on this page.

On this page:

- Manufacturing and importing face masks, surgical masks, and respirators during the COVID-19 pandemic
- Purchasing face masks, surgical masks, and respirators during the COVID-19 pandemic
- Reporting shortages of or problems with face masks, surgical masks, or respirators

---

The Basics on Face Masks, Surgical Masks, and Respirators

Q: Is there a difference between a face mask, a surgical mask, and a respirator?

A: Face masks, surgical masks, and respirators all cover a wearer's nose and mouth, but they differ in several aspects.

- **Face masks:** A mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. Face masks that are not intended for a medical purpose are not considered medical devices. Face masks may be used by the general public and health care personnel as source control in accordance with CDC recommendations on Interim Infection Prevention and Control.
- **Surgical masks:** A mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks intended for medical purposes are considered medical devices. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests. Surgical masks are also tested for biocompatibility and are considered personal protective equipment (PPE). While surgical masks may be effective in blocking splashes and large-particle droplets, they do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the mask and your face. Surgical masks are not respiratory protective devices (unlike respirators).
- **Respirators, known as filtering facepiece respirators (FFRs),** including N95s and surgical N95s, filter at least 95 percent of airborne particles. They are PPE that tightly fit the face and provide certain filtration efficiency levels to help reduce wearer exposure to pathogenic airborne particles in a health care setting. They provide a higher level of protection against viruses and bacteria when properly fit-tested.

  This CDC infographic (PDF - 227KB) explains the differences between surgical masks and N95 respirators.

Q: Which face masks and surgical masks are medical devices regulated by the FDA?

A: The FDA regulates face masks, including cloth face coverings, and surgical masks as

medical devices when they are marketed for medical purposes. Medical purposes include uses related to COVID-19, such as face masks to help stop the spread of disease, surgical masks, and surgical masks with antimicrobial/antiviral agents. Face masks marketed to the general public for general non-medical purposes, such as for use in construction and other industrial applications, are not medical devices.

Using Face Masks, Surgical Masks, and Respirators

Q: Do face masks provide protection from coronavirus?

A: Masks may help prevent people who have COVID-19 from spreading the virus to others. The CDC has guidance for wearing masks. Wearing a face mask may limit exposure to respiratory droplets and large particles and may help prevent people who have COVID-19 from spreading the virus.

Q: Are face masks, surgical masks, and respirators safe to wear?

A: If worn properly, face masks, surgical masks, or respirators may reduce the chance of spreading a COVID-19 infection between you and those around you. The CDC provides information on Using PPE and Considerations for Wearing Masks.

FDA-cleared surgical masks and respirators have been used by health care personnel for years and have been worn in health care facilities during extended procedures without harm to the wearer. Health care personnel with medical conditions should discuss concerns they may have with wearing respirators with their own health care providers. Health care personnel should follow the manufacturer's instructions and their facility's policies for use of all PPE.

Q: What does wearing a face mask for 'source control' mean?

A: Source control refers to use of cloth face coverings or face masks to cover a person's mouth and nose when they are talking, sneezing, or coughing to reduce the likelihood of transmission of infection by preventing the spread of respiratory secretions. COVID-19 may be spread by individuals who may or may not have symptoms of COVID-19.

The use of cloth face coverings made from common, easily accessible materials are an additional public health approach to help slow the spread of COVID-19. The CDC has guidance for wearing masks.

Face masks intended for a medical purpose, such as prevention of infectious disease transmission, are subject to FDA regulation. The FDA has issued an emergency use authorization (EUA) as well as guidance on regulatory flexibility for such products. For more information, see "I'm interested in manufacturing face masks or surgical masks for the

COVID-19 pandemic. What do I need to do?"

For more information on source control, see the CDC's Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic.

Q: During the COVID-19 public health emergency, when should health care personnel wear face masks or respirators?

A: During the COVID-19 public health emergency, the CDC recommends health care personnel wear face masks at all times while they are in the health care facility, including in breakrooms or common areas where they might encounter co-workers or visitors.

When available, surgical masks (a specific type of face mask) are preferred over cloth face coverings for health care personnel as surgical masks offer both source control and protection for the wearer against exposure to splashes and sprays of infectious material from others.

- Cloth face coverings should NOT be worn instead of a respirator or surgical mask if more than source control is needed.
- Wear an N95 or equivalent or higher-level respirator, instead of a face mask, for:
- Aerosol generating procedures (refer to "Which procedures are considered aerosol generating procedures in healthcare settings?" on the CDC's Clinical Questions about COVID-19: Questions and Answers page).
- Surgical procedures that might pose a higher risk for transmission if the patient has COVID-19 (for example, that generate potentially infectious aerosols or involve anatomic regions where viral loads might be higher, such as the nose and throat, oropharynx, or respiratory tract). Refer to "During the COVID-19 pandemic, are there special considerations for surgical and other procedural care settings, including performance of aerosol-generating procedures (AGPs)?" on the CDC's Clinical Questions about COVID-19: Questions and Answers page.
- Health care personnel should consult their institutional policies for further guidance on what type of face mask or respirator to use.

The CDC provides information on infection control measures for COVID-19 on its Clinical Questions about COVID-19: Questions and Answers page

Shortages of Face Masks, Surgical Masks, and Respirators During the COVID-19 Pandemic

Q: Can we use expired face masks or surgical masks? Do they offer the

protection needed?

A: Face masks and surgical masks are designed to serve as protective barriers and may still offer some protection even if they are used beyond the manufacturer's designated shelf life or expiration date. If there is no date available on the face mask label or packaging, facilities should contact the manufacturer. The user should inspect all masks prior to use and, if there are concerns such as degraded materials (such as elastic) or visible tears, the product should be discarded. For additional information please refer to the CDC's Strategies for Optimizing the Supply of Facemasks.

Q: How do I know what the manufacturer-designated shelf life is?

A: The manufacturer-designated shelf life or expiration date may be found on the product labeling or packaging, or you can contact the manufacturer directly.

Emergency Use Authorizations for Face Masks, Surgical Masks, and Respirators

Q: Why does the FDA issue Emergency Use Authorizations (EUAs)?

A: EUAs authorize the use of medical devices that are not FDA-cleared or approved. The EUA authority allows the FDA to help strengthen the nation's public health protections against emerging infectious disease threats by facilitating the availability and use of medical devices needed during public health emergencies.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may authorize the emergency use of an unapproved or uncleared medical product or an unapproved / uncleared use of an approved/cleared medical product for certain emergency circumstances after the HHS Secretary has made a declaration of emergency or threat justifying emergency use. The FDA Commissioner may issue an EUA to authorize a medical product for use in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, or available alternatives. The Emergency Use Authorizations (EUAs) for diagnostic, non-diagnostic, and therapeutic medical devices that the FDA has issued related to COVID-19 may be revised, terminated, or revoked as needed.

For details on the Emergency Use Authorizations for these devices, see:

- Personal Protective Equipment EUAs
- Face Mask EUA (PDF - 98KB)

If you need help with the EUA process for face masks, surgical masks, or respirators, contact CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov.

To identify FDA-cleared surgical masks and respirators, search the 510(k) Premarket Notification database.

Q: What is a pre-EUA?

A: To help prepare for potential and current emergencies, the FDA works with medical device developers to prepare pre-EUA packages when appropriate. A pre-EUA package contains data and information about the safety, quality, and effectiveness of the product, its intended use, and information about the emergency or potential emergency situation. The pre-EUA process allows the FDA's scientific and technical subject matter experts to begin a review of information and consideration of the EUA statutory criteria, assist in the development of conditions of authorization, fact sheets, and other documentation that would be needed for an EUA, and also helps to facilitate completion of EUA requests during a current emergency declaration.

If you need help with the pre-EUA process for face masks, surgical masks, or respirators, contact CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov.

For additional information, refer to Emergency Use Authorization of Medical Products and Related Authorities.

Q: What is an Umbrella EUA?

A: Many EUAs apply only to a specific medical device. Generally, an *umbrella* EUA authorizes many devices that meet specific criteria for that device type, helping to facilitate access to those devices by streamlining the process associated with EUAs (for example, EUA request submission and FDA authorization) for any medical devices that meet the requirements within the EUA.

Q: What type of mask does the umbrella EUA for surgical masks authorize?

A: The FDA issued an umbrella EUA in response to insufficient availability of disposable, single-use surgical masks. This EUA established performance criteria for the surgical mask to be authorized for use in health care settings by health care personnel as PPE.

Performance criteria that must be met include liquid barrier performance, particulate filtration efficiency, air flow resistance, and use of biocompatible, non-cytotoxic, non-irritating, and non-sensitizing materials. Surgical masks that have been confirmed by the FDA to meet the criteria are listed in Appendix A of the EUA as authorized surgical masks.

To be added to Appendix A, test reports must be submitted to the FDA demonstrating that the surgical mask meets the performance criteria. Requests can be submitted to the FDA with the subject line "Surgical Masks EUA" to CDRH-nondiagnosticEUA-templates@fda.hhs.gov. The Surgical Masks EUA Template for Addition to Appendix A

(DOCX - 56KB) can be used to provide the required information.

Manufacturers, importers, and distributors must also comply with the conditions of authorization found in Section IV of the EUA Letter of Authorization (PDF - 101KB).

The following surgical masks are not covered in the scope of this EUA:

- Surgical masks that are FDA-cleared
- Surgical masks that are manufactured in China
- Surgical masks that include drugs, biologics, nanoparticles, or antimicrobial/antiviral agents

Q. What type of respirators does the umbrella EUA for NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency authorize?

A: Respirators authorized by this EUA (PDF - 176KB) include:

- Non-powered air-purifying particulate FFRs and reusable respirators such as elastomeric half and full facepiece respirators, approved by NIOSH.
- Other powered air purifying respirators (PAPRs) approved by NIOSH.
- FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf life, are not damaged, and have been held in accordance with manufacturers' storage conditions in strategic stockpiles (referred to as expired FFRs).

Q. If I am producing surgical masks or respirators under an EUA during COVID-19, what do I need to do to continue after the emergency is over?

A: For manufacturers of medical products and uses that are not approved, cleared, or licensed to continue legally marketing their devices after the public health emergency is over, manufacturers may submit marketing applications under the traditional premarket pathways.

Device manufacturers are encouraged to pursue marketing applications through the appropriate regulatory pathway (such as 510(k), De Novo request, PMA) during the emergency so that devices can remain on the market once the EUA is no longer in effect. For more information, see the MOU 225-18-006 and FAQs on Emergency Use Authorizations (EUAs) for Medical Devices During the COVID-19 Pandemic.

Manufacturing and Importing Face Masks, Surgical Masks, and Respirators During the COVID-19 Pandemic

Q: I'm interested in manufacturing face masks or surgical masks for the

COVID-19 pandemic. What do I need to do?

A: Face masks intended for a medical purpose, such as prevention of infectious disease transmission, are subject to FDA regulation. The FDA has issued guidance on regulatory flexibility for such products, as well as several EUAs.

The guidance provides an enforcement discretion policy for face masks intended for a medical purpose for COVID-19, such as for use as source control. The FDA does not intend to enforce certain regulatory requirements, including 510(k) premarket notification, Quality System Regulations (QSR), establishment registration and device listing, reporting under 21 CFR Part 806, and unique device identification (UDI).

These face masks, intended for use by health care personnel and the general public as source control to help stop the spread, may be authorized under the umbrella EUA for face masks (PDF - 92KB) without submitting documentation to the FDA if the face mask meets the EUA eligibility requirements. A face mask authorized under this EUA must comply with the Conditions of Authorization (Section IV) of the EUA.

For a surgical mask to be added to the Surgical Mask EUA Appendix A, test reports must be submitted to the FDA demonstrating that the surgical mask meets the performance criteria for liquid barrier protection. Requests can be submitted to the FDA with the subject line "Surgical Masks EUA" to CDRH-nondiagnosticEUA-templates@fda.hhs.gov. The Surgical Masks EUA Template for Addition to Appendix A (PDF - 176KB) can be used to provide the required information.

Manufacturers, importers, and distributors of surgical masks must also comply with the conditions of authorization found in Section IV of the EUA Letter of Authorization (PDF - 101KB).

The following surgical masks are not covered in the scope of this EUA:

- Surgical masks that are FDA-cleared
- Surgical masks that are manufactured in China
- Surgical masks that include drugs, biologics, nanoparticles, or antimicrobial/antiviral agents.

Purchasing Face Masks, Surgical Masks, and Respirators During the COVID-19 Pandemic

Reporting Shortages of or Problems with Face Masks, Surgical Masks, or Respirators

Plaintiff's Exhibit 462

fda.gov

Certain Respirators from China May Not Provide Adequate Protection

13-16 minutes

Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection - Letter to Health Care Providers

The U.S. Food and Drug Administration (FDA) is concerned that certain filtering facepiece respirators (respirators) from China may not provide consistent and adequate respiratory protection to health care personnel exposed to COVID-19 based on additional filtration performance testing conducted by the National Institute for Occupational Safety and Health (NIOSH) - National Personal Protective Technology Laboratory (NPPTL) of the Centers for Disease Control and Prevention (CDC) (referred to below as the NIOSH testing). Based on the FDA's increased understanding of the performance and design of these respirators, the FDA has decided that these respirators should not be decontaminated for reuse by health care personnel. As such, the FDA has revised and reissued the May 7, 2020, EUA.

On May 7, 2020, the FDA reissued the April 3, 2020 EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China to revise the third eligibility criterion – the criterion for authorization of respirators based on review of test reports from recognized independent test laboratories submitted to the FDA by the manufacturer or importer – and accordingly removed from Appendix A the respirators that had been authorized under that criterion but were no longer authorized based on this revision.[1] The FDA took this public health action primarily because a number of these respirators failed to demonstrate a minimum particulate filtration efficiency of 95 percent in testing conducted at NIOSH.

On June 6, 2020, the FDA further revised this criterion such that respirators that are authorized under this criterion and that do not meet performance expectations are no

longer authorized. Respirators that have a failing grade as indicated by NIOSH testing may be re-labeled as face masks and authorized as face masks for use as source control if certain criteria are met under the Face Mask umbrella EUA. For other information, please see the FDA's enforcement policy on face masks, as described in the Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) Guidance.

Non-NIOSH-approved disposable filtering facepiece respirators that meet the other eligibility criteria in the reissued Emergency Use Authorization remain authorized by the FDA for use during the COVID-19 pandemic and continue to be listed in Appendix A.

Considerations

Health care facilities with these respirators in inventory should review the considerations listed below. The information is specific to respirators that are designed to achieve a very close facial fit and to filter airborne particles. These considerations are not applicable to surgical masks or face masks that are loose-fitting and create a physical barrier between the health care personnel's mouth and nose and potential contaminants in the immediate environment.

- Respirators that no longer appear in Appendix A of the EUA may not reliably provide a minimum percent particulate filtration efficiency of 95 percent. Refer to the NIOSH assessment webpage to determine whether non-NIOSH-approved disposable filtering facepiece respirators manufactured in China have been tested and to review the testing results.
- A complete list of Respirator Models No Longer Authorized is available on our website.
- NIOSH regularly updates its list of testing results.
- Respirators that have been tested by NIOSH and failed to demonstrate a Minimum Particulate Filtration Efficiency of 95 percent may be considered for use as face masks for source control if they do not have exhalation valves, to help slow the spread of infection when a person speaks, coughs, or sneezes. Health care facilities should be aware that this use of face masks is different from personal protective equipment for health care personnel.
- Health care facilities with these respirators that failed the NIOSH testing may wish to consider a number of factors in deciding to use these products as face masks, including current need, inventory, facility practices, and acceptable uses.

- At this time and based on the available information, the FDA believes that any respirators listed in Appendix A may not be reliably decontaminated in any decontamination system authorized for use during the COVID-19 pandemic.
- If you have respirators that were removed from Appendix A based on the May 7, 2020, update to the third criterion and you want NIOSH to test their filtration efficiency, you can request NIOSH testing by submitting the International Respirator Assessment Request.

Additional Information

Health care facilities may find the following information useful when considering the purchase or use of respirators:

- Products labeled as "respirators" must meet the applicable FDA requirements or receive an Emergency Use Authorization to be imported and distributed in the United States. However, products labeled as "face masks" are subject to different requirements from products labeled as "respirators." "Face masks" do not need to be on Appendix A to the reissued EUA, or on Exhibit 1 to the June 6, 2020, EUA for imported respirators, to be imported and distributed in the United States. But face masks are not considered PPE. For more information, please see the Face Mask umbrella EUA which authorizes face masks that meet certain criteria, as well as the Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised).
- Consistent with CDC's recommendations, HCP should use an FDA-cleared or NIOSH-approved respirator before another authorized, imported respirator, when available. The FDA authorized the emergency use of all NIOSH-approved air purifying respirators for use in healthcare settings during the COVID-19 public health emergency. The CDC provides a list of NIOSH-Approved Particulate Filtering Facepiece Respirators and powered air purifying respirators.
- If FDA-cleared or NIOSH-approved respirators are not available, consider using respirators covered under one of the other FDA Emergency Use Authorizations for respirators. Based on the totality of scientific evidence and other information available to FDA, it is reasonable to believe these authorized respirators may be effective at preventing exposure to certain particulates to prevent the spread of COVID-19. These respirators are listed in Exhibit 1 of the June 6, 2020, Imported, Non-NIOSH Approved Disposable Filtering Facepiece Respirators Emergency Use Authorization for respirators manufactured in other countries, or Appendix A of the Emergency Use

Authorization for Non-NIOSH Approved Disposable Filtering Facepiece Respirators manufactured in China. The lists in Appendix A and in Exhibit 1 are updated on a rolling basis as new information becomes available for FDA to review.

- Consider asking questions of the seller and conducting a physical assessment of the product and fit testing, to make the most informed benefit-risk decision about respirator use.
- Continue to ensure that "fit testing" of respirators is conducted with health care personnel so that a very close facial fit is achieved. Many respirators manufactured in China have an ear loop design. According to the CDC, limited assessment of ear loop designs indicate there may pose difficulty achieving a proper fit. Follow your health care facility's guidelines for conducting fit testing.
- If a used respirator that is FDA-cleared or NIOSH-approved is available and a new respirator covered under one of the FDA Emergency Use Authorizations for respirators is not available, you may consider decontaminating and reusing the used respirator with a decontamination system that has an FDA Emergency Use Authorization, if the used respirator is compatible with the decontamination system.
- If your facility is using respirators that have been removed from Appendix A, these respirators are no longer authorized by FDA for single use or for reuse by an FDA authorized decontamination system.
- Additionally, as of June 6, 2020, any KN95 respirator, or any respirators with exhalation valves, should not be decontaminated and are no longer authorized to be decontaminated by any authorized decontamination systems.
- If you have concerns about respirators or questions about the packaging, labeling, or quality of the respirators, consider replacing, discarding, or returning the respirators to the distributor.

See Frequently Asked Questions (FAQs) about Non-NIOSH-Approved Filtering Facepiece Respirators for more information.

FDA Actions

The FDA continues to actively monitor and take action to mitigate any potential shortages in the supply chain, including the medical device supply chain. This includes taking action to help assure health care personnel on the front lines have the necessary supplies of personal protective equipment to meet the demand.

Additionally, on June 6, 2020, the FDA reissued the Emergency Use Authorization (EUA) for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China by revising the Scope of Authorization to revise that authorized respirators listed in Appendix A will no longer be authorized if decontaminated. The FDA also reauthorized the EUAs for multiple decontamination systems so that these decontamination systems are no longer authorized to decontaminate respirators manufactured in China nor are they authorized to decontaminate respirators with exhalation valves, where applicable. For more information on the FDA's revised EUAs on respirators and decontamination systems, please see the FDA's press release.

The FDA continues to collaborate with the CDC to increase the availability and ensure the integrity of respirators during the COVID-19 public health emergency.

The FDA will continue to keep health care providers and the public informed if new or additional information becomes available.

If additional information becomes available that indicates respirators are not eligible to be authorized, they will be removed from Appendix A and this removal will be publicly communicated on the Respirator Models No Longer Authorized-COVID19 document.

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with respirators.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program.
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations.
- Health care providers employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.
- Fraudulent COVID-19 products pose a serious risk to public health. We encourage any concerns about potential counterfeit or fraudulent product be sent to FDA-COVID-19-Fraudulent-Products@fda.hhs.gov. If possible, please include a description of the product along with a picture of the product's labeling.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (DICE).

Additional Resources:

- Personal Protective Equipment Emergency Use Authorizations
- The FDA's Video "What is an Emergency Use Authorization?"
- NIOSH's Healthcare Respiratory Protection Resources Fit Testing
- The Occupational Safety and Health Administration's (OSHA) video about Respiratory Protection Fit Testing
- The CDC's Counterfeit Respirators/Misrepresentation of NIOSH-Approval and Factors to Consider When Planning to Purchase Respirators from Another Country provides information about recognizing counterfeit respirators, recommended best practices for proper respirator use, and to assist buyers in making procurement decisions.

---

[1] However, respirators previously authorized by meeting the original third eligibility criterion (i.e., review of independent test lab reports) for which manufacturers have requested FDA sample collection and NIOSH testing and have demonstrated greater than or equal to 95 percent filtration efficiency per a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059), https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf, within 45 days of EUA reissuance on May 7, 2020, are eligible for authorization under the revised third criterion and are listed on Appendix A.

Plaintiff's Exhibit 463

FDA -- Surgical Masks EUA
Template for Addition to Appendix A

This template includes the data/information requirements needed by FDA to support addition of a surgical mask to the list of authorized surgical masks in Appendix A under the Surgical Masks EUA (the "Surgical Masks EUA" or "EUA"), as set forth in the EUA. ***As explained in the EUA, once completed, please send this interactive review template with the subject line "Surgical Masks Eligible for EUA" to CDRH-nondiagnosticEUA-templates@fda.hhs.gov.***

GENERAL INFORMATION ABOUT THIS TEMPLATE

- In order to be added to Appendix A, consistent with the criteria and requirements in Section II of the EUA, text highlighted in yellow [text] must be provided to FDA as applicable to each model number.

- This is a template for addition to Appendix A of the Surgical Mask EUA and is not a guidance document. It contains no new information.

- Any trade secret or confidential commercial information provided within the template and during the interactive review process will remain confidential.

- Please remember that if your product is added to this specific EUA, the authorization would only be for the use specified in the EUA and subject to the conditions in the EUA. This device must not be introduced into interstate commerce for uses outside the authorized use without obtaining marketing clearance, approval, IDE, or another EUA by the FDA.

- The Surgical Mask EUA is only in effect until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) or the EUA is revoked under Section 564(g) of the Act.

- ***The EUA is not a pathway to permanent marketing of your product.*** For information on premarket submissions, refer to FDA's website on "How to Study and Market Your Device" at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device. For information on FDA's enforcement policy for surgical masks, see FDA guidance *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)*. For guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to FDA guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device*.

Template for Addition to Appendix A of the Surgical Mask EUA

A. Required Information from Section II of the EUA:

1) Applicant

Applicant information:
- Applicant Company Name:
- Applicant Address:
- Applicant Contact Person:
- Applicant Contact Phone#:
- Applicant Contact Email:

Correspondent information (if different from the Applicant):
- Correspondent Company Name:
- Correspondent Address:
- Correspondent Contact Person:
- Correspondent Contact Phone#:
- Correspondent Contact Email:

2) Device proprietary or brand name, model number:

Proprietary Name - [product trade name]
Established Name - [generic name]
Model number - [model number]

3) Product Labeling

[Provide a copy of the product labeling, including the instructions for use.]

As stated in the EUA, the product labeling must:

- Describe the product as a disposable, single-use surgical mask. The labeling must include a list of the body contacting materials (which does not include any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents);
- State that the product is not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators;
- State that surgical masks are not intended to provide protection against pathogenic biological airborne particulates and are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure;
- Not include statements that would misrepresent the product or create an undue risk in light of the public health emergency. For example, the labeling must not include any express or implied claims for: (1) reuse, (2) antimicrobial or

antiviral protection or related uses, (3) infection prevention, infection reduction, or related uses, or (4) viral filtration efficiency.

4) Device Marketing Estimate

[Provide an estimate of the number of surgical masks you are planning to market and distribute during the public health emergency.]

5) Evidence Demonstrating The Surgical Mask Meets The Criteria

[Provide a summary of the evidence demonstrating that the surgical mask meets the criteria required in the EUA, including test reports.]

As set forth in the EUA, a surgical mask is authorized if it has been designed, evaluated, and validated consistent with the following performance criteria and is not excluded from the scope of authorization. The following surgical masks are excluded from the scope and are not authorized under this EUA: (1) surgical masks that are FDA-cleared; (2) surgical masks that are manufactured in China; and (3) surgical masks that include drugs, biologics, nanoparticles, or antimicrobial/antiviral agents.

a. Fluid Resistance Requirements

[Provide test reports to demonstrate that the model meets fluid resistance requirements (liquid barrier performance) consistent with ASTM F1862: *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity).*]

b. Flammability Testing

[Provide test reports to demonstrate that the textiles used in the surgical mask meet flammability performance consistent with the definition of either a Class 1 or Class 2 textile in 16 CFR Part 1610]

c. Particle Filtration Testing

[Provide test reports to demonstrate that the model meets particulate filtration efficiency requirements consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks.*]

d. Air Flow Resistance (i.e., Breathability) Assessment

[Provide evidence, including test reports, to demonstrate that the model meets air flow resistance (i.e., breathability) requirements with an acceptance criterion of <6 mm H_2O/cm^2 for differential pressure (delta P) testing consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks* for those masks composed of 4 or more layers.]

e. Biocompatibility Assessment

[Provide evidence, including test reports, indicating how the model has materials of manufacture that are either (1) non-cytotoxic, non-irritating and non-sensitizing consistent with the recommendations in FDA's guidance, "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*'" or (2) conform to the following biocompatibility standards:

- ISO 10993-1: *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- ISO 10993-5: *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10: *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.*]

6) Authorized Distributors and/or Authorized Importers

[Please provide a list of authorized distributors and/or authorized importers, including contact information (name, address, contact person, phone number, and email).]

B. FDA Summary of Documentation and Review [for FDA Internal Use Only]

FDA reviewers will include a brief summary of the documentation provided and their conclusion of whether the product meets the criteria identified in Section II.

FDA reviewers should clearly distinguish their comments and edits in the document from the information provided by the sponsor.

C. Review Log [for FDA Internal Use Only]

Use the table below to document interactions between FDA or the sponsor.

Date	**Type of Interaction** (phone/ email/ formal submission-DCC)	**Brief Description** (e.g., questions asked/ feedback from FDA received / any word documents included)
[X]	[X]	[X]

D. Next Steps

Once FDA review is completed, if the eligible product has been confirmed to meet the criteria of the EUA, then you will receive an email notification with that information and your product will be added to Appendix A of the Surgical Mask EUA. If the product is

not eligible for addition to or fails to meet the criteria of the EUA, then you will receive an email notification with that information. Please note that, as set forth in FDA's guidance Emergency Use Authorization of Medical Products and Related Authorities, FDA intends to prioritize its review of EUA requests during a declared emergency based on various factors, including the extent to which the product would serve a significant unmet medical need.

E. Finalizing Review [for FDA Internal Use Only]

Once FDA review is completed, FDA reviewers should finalize the documentation, sign and date this template, and document concurrence from the OHT management.

Plaintiff's Exhibit 464

sgs.com

FDA Issues New Emergency Use Authorization for Surgical Masks

8-10 minutes

Aug. 20, 2020

SAFEGUARDS | Personal Protective EquipmentNO. 123/20

On August 5, 2020, the US Food and Drug Administration (FDA) issued an umbrella emergency use authorization (EUA) for certain disposable, single-use surgical masks in response to concerns relating to insufficient supply and availability of such masks.

This EUA authorizes the emergency use of surgical masks that meet certain performance requirements for use in healthcare settings by health care personnel as personal protective equipment to provide a physical barrier to fluids and particulate materials to prevent healthcare personnel (HCP) exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.

FDA's Emergency Use Authorizations

During a public health emergency, the FDA can use EUA to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives.

Before the FDA can issue an EUA, the Secretary of Health and Human Services must make a declaration of emergency or threat justifying authorization of emergency use for a

product.

When the emergency is over, the EUA declaration is terminated, and all EUAs issued based on that declaration will no longer remain in effect.

Typically, EUAs will established certain requirements intended to mitigate undue risk of unapproved or unapproved use of medical devices. Meeting applicable requirements outlined in an EUA are essential.

To help address concerns about availability during the COVID-19 pandemic, the FDA has issued EUAs for certain PPE products including face shields, other barriers, and respiratory protective devices such as respirators.

To aid in the industry understanding, the FDA has released an FAQ on EUAs for medical devices during the COVID-19 pandemic.

Requirements of FDA's Surgical Masks EUA

As with other EUAs, to limit undue risk of the authorized surgical masks the EUA includes labeling and performance requirements, among other requirements.

Key labeling requirements include:

- Describe the product as a disposable, single-use surgical mask. The labeling must include a list of the body contacting materials (which does not include any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents)
- State that the product is not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators
- State that surgical masks are not intended to provide protection against pathogenic biological airborne particulates and are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure; and
- Not include statements that would misrepresent the product or create an undue risk in light of the public health emergency. For example, the labeling must not include any express or implied claims for: (1) reuse, (2) antimicrobial or antiviral protection or related uses, (3) infection prevention, infection reduction, or related uses, or (4) viral filtration efficiency

In addition to above labeling, authorized products must be accompanied with a fact sheet when being made available to HCP:

- Fact Sheet for Healthcare Personnel: Emergency Use of Authorized Disposable, Single Use Surgical Masks During the COVID-19 Pandemic

Specific performance criteria for authorized surgical masks include:

- Fluid resistance requirements (liquid barrier performance) consistent with ASTM F1862: *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*
- Flammability performance consistent with the definition of either a Class 1 or Class 2 textile in 16 CFR Part 1610
- Particulate filtration efficiency requirements consistent with *ASTM F2100: Standard Specification for Performance of Materials Used in Medical Face Masks*
- Air flow resistance (i.e. breathability) requirements with an acceptance criterion of <6 mm H2O/cm2 for differential pressure (delta P) testing consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks* for those masks composed of 4 or more layers
- The materials of manufacture are either:
- Non-cytotoxic, non-irritating and non-sensitizing consistent with the recommendations in the FDA's guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'"10 or
- Conform to the following biocompatibility standards:
- ISO 10993-1: *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- ISO 10993-5: *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10: *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*

The FDA has provided a template that can be used for submittal to FDA. Referred as "Template A", it includes the data/information requirements needed by FDA to support addition of a surgical mask to the list of authorized surgical masks in Appendix A under the Surgical Masks EUA, as set forth in the EUA. Once completed, templates can be submitted along with test reports to the above criteria for review via e-mail with the subject line "Surgical Masks Eligible for EUA" to CDRH-nondiagnosticEUA-templates@fda.hhs.gov

Surgical masks that have been confirmed by the FDA to meet the criteria under the EUA are included in "Appendix A: Authorized Surgical Masks" which can be found on the FDA website.

Note, the following surgical masks are excluded from the scope and are not authorized under this EUA:

- Surgical masks that are FDA-cleared
- Surgical masks that are manufactured in China, and

- Surgical masks that include drugs, biologics, nanoparticles, or antimicrobial/antiviral agents

SGS is committed to providing information about development in regulations for consumer products as complimentary services. Through a global network of laboratories, SGS provides a wide range of services including physical/mechanical testing, analytical testing and consultancy work for technical and non-technical parameters applicable to a comprehensive range of consumer products. Please do not hesitate to contact us for further information.

NEXT STEP:

Additionally, the FDA has issued recommendations and policies about PPE which can be found here: Recent Final Medical Device Guidance Documents.

SGS can assist with testing to the methods specified in this surgical mask EUA, as well as other FDA guidances and regulations.

For enquiries, please contact:

Matthew McGarrity
Hardlines Technical Manager
t: 9738978889

Stay on top of regulatory changes within your industry: subscribe to SafeGuardS!

Read more articles for the Consumer Goods and Retail industry

FACT SHEET FOR HEALTHCARE PERSONNEL

Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic
August 5, 2020

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of authorized disposable, single-use surgical masks (hereafter referred to as "authorized surgical masks") during the COVID-19 pandemic.

Certain surgical masks are authorized for emergency use by healthcare personnel (HCP) in healthcare settings as personal protective equipment (PPE) to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic. This Fact Sheet is specific to surgical masks that were authorized by the United States Food and Drug Administration (FDA) under an emergency use authorization (EUA).

Healthcare personnel should adhere to Standard and Transmission-based Precautions when caring for patients with SARS-CoV-2 infection per CDC guidelines.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the Centers for Disease Control and Prevention (CDC) webpage for the most up to date information.

What do I need to know about the emergency use of authorized surgical masks?

- Authorized surgical masks meet the fluid barrier, flammability, and particulate filtration efficiency performance requirements set forth in the EUA and do not pose significant risks concerning breathability and biocompatibility.
- Authorized surgical masks may be effective in blocking respiratory droplets and large particles.
- Authorized surgical masks do not include drugs, biologics, nanoparticles or antimicrobial/antiviral agents and are not FDA-cleared.
- HCP should review the authorized surgical mask labeling prior to use and follow the instructions for use.

Use appropriate PPE when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

When is it not appropriate to use an authorized surgical mask?

- Authorized surgical masks are not intended to replace the need for FDA-cleared surgical masks.
- Surgical masks may not provide the user a reliable level of protection from inhaling smaller airborne particles and are not personal respiratory protective devices. They are not intended to replace the need for FDA-cleared or authorized respirators.
- Because of the loose fit between the surface of the surgical mask and the user's face, surgical masks used by HCP are not considered respiratory protection against pathogenic biological airborne particulates.
- Surgical masks are not recommended for use in aerosol generating procedures and any clinical

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

FACT SHEET FOR HEALTHCARE PERSONNEL

Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic
August 5, 2020

Coronavirus Disease 2019 (COVID-19)

conditions where there is significant risk of infection through inhalation exposure. Under those conditions, a filtering facepiece respirator (such as an N95 respirator) with a tight fit should be used to provide a more reliable level of respiratory protection.

What are the known and potential benefits and risks of authorized surgical masks?

Potential benefits of authorized surgical masks:

- Decreases risk of transmitting the SARS-CoV-2 virus to the wearer, other HCP, or patients
- Helps prevent HCP exposure to the spread of infection or illness

Potential risks of authorized surgical masks:

- Inadequate barrier protection leading to spread of infection or illness
- Loose-fitting contributing to inadequate respiratory protection against pathogenic biological airborne particulates
- Adverse reaction to device materials
- Flammable in the presence of high intensity heat sources or flammable gas
- Difficulty breathing

What is an EUA?

The FDA has made surgical masks available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

This product has been authorized by FDA under an EUA for use by HCP as PPE in healthcare settings to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic. An authorized surgical mask made available under an EUA has not undergone the same type of review as an FDA-approved or cleared device. This product has not been FDA-cleared or approved. However, in the absence of an FDA-approved or cleared alternative and based on the totality of scientific evidence, it is reasonable to believe the authorized surgical mask may be effective for the authorized use. This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, unless the authorization is terminated or revoked sooner.

An FDA approved or cleared device should be used instead of the authorized surgical mask under EUA, when available.

Where can I go for updates and more information?

CDC webpages:
General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

U.S. FOOD & DRUG ADMINISTRATION

Plaintiff's Exhibit 466

August 5, 2020

To: Manufacturers of Surgical Masks;
Health Care Personnel;
Hospital Purchasing Departments;
Authorized Distributors and Authorized Importers; and
Any Other Stakeholders

The U.S. Food and Drug Administration (FDA) is issuing this Emergency Use Authorization (EUA) in response to concerns relating to the insufficient supply and availability of disposable, single-use surgical masks[1,2] (hereafter also referred to as "surgical masks") for use in healthcare settings by health care personnel (HCP)[3] as personal protective equipment (PPE)[4] to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[5]

---

[1] A surgical mask is a mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks are generally regulated by FDA as Class II devices under 21 CFR 878.4040 – Surgical apparel.

[2] FDA-cleared surgical face masks, non-surgical face masks, surgical masks with antimicrobial/antiviral agent, and all particulate filtering facepiece respirators are not within the scope of this authorization.

[3] For the purposes of this EUA, HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

[4] Surgical masks may be effective in blocking splashes and large particle droplets. While surgical masks are not protective against smaller airborne particulates as described in Section II, they are considered PPE because they are intended to be used to protect HCP from infectious disease hazards. Surgical masks are different from non-surgical face masks, which are only used as source control by the general public and are not considered PPE.

[5] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[6]

As discussed further below, I have concluded that a surgical mask meeting the criteria set forth in Section II meets the criteria for issuance of an EUA under Section 564(c) of the Act.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of surgical masks that meet the criteria set forth in Section II pursuant to the Conditions of Authorization (Section IV) of this letter (referred to in this letter as "authorized surgical masks"). Authorized surgical masks will be added to this letter of authorization in Appendix A, as described in the Scope of Authorization (Section II).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of authorized surgical masks as described in the Scope of Authorization (Section II) of this letter for use in healthcare settings by HCP as PPE during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized surgical masks may be effective for use in healthcare settings by HCPs as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic, and that the known and potential benefits of the authorized surgical masks, when used consistent with the scope of this authorization (Section II), outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of these authorized surgical masks for use in healthcare settings by HCP to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.[7,8]

---

[6] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

[7] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[8] There are not sufficient quantities of surgical masks to meet the needs of the U.S. healthcare system. These articles of PPE are an integral part of patient care during the COVID-19 pandemic. Providing authorization for the introduction into interstate commerce of surgical masks by manufacturers, including those that do not customarily engage in the manufacture of medical devices, helps meet the needs of the healthcare system. Providing HCP who

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized surgical masks, for use in healthcare settings by HCP as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.

Surgical masks are not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators. Surgical masks may be effective in blocking splashes and large-particle droplets; however, because of the loose fit between the surface of the surgical mask and the user's face, leakage can occur around the edge of the mask when the user inhales. Therefore, a surgical mask may not provide the user with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection. For this reason, surgical masks are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure. In such clinical conditions, a filtering facepiece respirator (such as an N95 respirator) with a tight fit is recommended to provide a more reliable level of respiratory protection against pathogenic biologic airborne particulates.

Authorized Surgical Masks

Surgical masks that have been designed, evaluated, and validated consistent with the following performance criteria and that are not excluded, are authorized for the above-described intended use. The following surgical masks are excluded from the scope and are not authorized under this EUA: (1) surgical masks that are FDA-cleared; (2) surgical masks that are manufactured in China; and (3) surgical masks that include drugs, biologics, nanoparticles, or antimicrobial/antiviral agents. A surgical mask that is not excluded is authorized if it meets the following performance criteria:

- Fluid resistance requirements (liquid barrier performance) consistent with ASTM F1862: *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);* [9]
- Flammability performance consistent with the definition of either a Class 1 or Class 2 textile in 16 CFR Part 1610;

---

are on the forefront of the COVID-19 response with sufficient PPE is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

[9] For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

- Particulate filtration efficiency requirements consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks*;
- Air flow resistance (i.e., breathability) requirements with an acceptance criterion of <6 mm H_2O/cm^2 for differential pressure (delta P) testing consistent with ASTM F2100: *Standard Specification for Performance of Materials Used in Medical Face Masks* for those masks composed of 4 or more layers; and
- The materials of manufacture are either (1) non-cytotoxic, non-irritating and non-sensitizing consistent with the recommendations in FDA's guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'"[10] or (2) conform to the following biocompatibility standards:
    - ISO 10993-1: *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
    - ISO 10993-5: *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
    - ISO 10993-10: *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.*

To be added to Appendix A as an authorized surgical mask under this EUA, the surgical mask must not be excluded and manufacturers must provide test reports that demonstrate that the surgical mask meets the performance criteria above. Manufacturers may request the inclusion of any surgical mask model in Appendix A by submitting a request to FDA with the subject line "Surgical Masks EUA" to CDRH-nondiagnosticEUA-templates@fda.hhs.gov and include the following information, which will allow FDA to confirm that the surgical mask meets the criteria and provide other relevant information:

- Manufacturer contact information, name and address of business, email address, contact information for a U.S. agent (if any), in addition to general information about the device such as the proprietary or brand name, model number (if any);

- A copy of the product labeling;

- An estimate of the number of surgical masks you are planning to market and distribute during the public health emergency;

- A summary of the evidence demonstrating that the surgical mask meets the above criteria, including test reports; and

- A list of authorized distributor(s) and/or authorized importer(s),[11] including contact information (name, address, contact person, phone number, and email).

---

[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and.

[11] "Authorized Distributor(s)" and "Authorized Importer(s)" are identified by the manufacturer in an EUA submission as an entity allowed to import and/or distribute the device. If the entity distributing the device is also the entity importing the device, the manufacturer should so indicate on the list provided to FDA.

The labeling of the authorized surgical masks must:

- Describe the product as a disposable, single-use surgical mask. The labeling must include a list of the body contacting materials (which does not include any drugs, biologics, nanoparticles, or antimicrobial/antiviral agents);

- State that the product is not intended to replace the need for FDA-cleared surgical masks or FDA-cleared or authorized respirators;

- State that surgical masks are not intended to provide protection against pathogenic biological airborne particulates and are not recommended for use in aerosol generating procedures and any clinical conditions where there is significant risk of infection through inhalation exposure; and

- Not include statements that would misrepresent the product or create an undue risk in light of the public health emergency. For example, the labeling must not include any express or implied claims for: (1) reuse, (2) antimicrobial or antiviral protection or related uses, (3) infection prevention, infection reduction, or related uses, or (4) viral filtration efficiency.

Authorized products must be accompanied by the above required labeling, and in addition, the authorized products must be accompanied by the following information pertaining to the emergency use, which are authorized to be made available to HCPs:

- Fact Sheet for Healthcare Personnel: Emergency Use of Authorized Disposable, Single-Use Surgical Masks During the COVID-19 Pandemic

The manufacturer's labeling (which must meet the labeling requirements specified above) and the fact sheet, are referred to as "authorized labeling."

FDA may remove an authorized surgical mask from Appendix A of this EUA if FDA has reason to believe that the product no longer meets the Scope of Authorization (Section II) or any of the Conditions of Authorization (Section IV). FDA will provide the manufacturer 24 hours advance notice of such removal and may work with the manufacturer to resolve the issue(s) that led to removal of the device(s) from Appendix A. Products that are removed from Appendix A will appear on a list maintained on FDA's website.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized surgical masks as described within this section (the Scope of Authorization, Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that authorized surgical masks may be effective as described within this section (the Scope of Authorization, Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that authorized surgical masks (as described in the Scope of Authorization, Section II), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of authorized surgical masks must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), surgical masks that are determined to meet the criteria set forth in this section (Section II) are authorized under the terms and conditions of this EUA.

III. Waiver of Certain FDA Requirements

I am waiving applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized surgical masks that are used in accordance with this EUA.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions to this authorization:

Manufacturers of Authorized Products

A. Manufacturers will make authorized products available with the authorized labeling (including the labeling requirements described in Section II). Manufacturers must make available all labeling in English, to each end user facility (e.g., each hospital) that receives the authorized products, and may include the authorized labeling with each individual authorized product.

B. Manufacturers must comply with 21 CFR Part 803, and must have a process in place for reporting adverse events of which they become aware to FDA consistent with 21 CFR Part 803. See FDA's webpage "Medical Device Reporting (MDR): How to Report Medical Device Problems"[12] for additional information concerning reporting requirements under 21 CFR Part 803 and procedures.

C. Manufacturers will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[12] FDA guidance, titled "Medical Device Reporting (MDR): How to Report Medical Device Problems" is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

D. Through a process of inventory control, manufacturers will maintain records of the entities to which they distribute the surgical masks and the numbers of each such product they distribute.

E. Manufacturers will notify FDA of any authorized distributor(s) and/or authorized importers of the authorized surgical masks, including the name, address, and phone number of any authorized distributor(s) and authorized importer(s), and provide authorized distributor(s) and authorized importer(s) with a copy of this EUA and any updates.

F. Manufacturers are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

G. Manufacturers of authorized surgical masks will submit, upon FDA's request, new lots of the authorized surgical masks for testing by FDA or by another entity designated by FDA. The manufacturers must not distribute any lot or shipment that fails testing, meaning the lot or shipment containing a lot that did not perform as expected based on the performance criteria in the Scope of Authorization (Section II). FDA will make the manufacturer aware of the testing results.

Authorized Distributors and Authorized Importers

H. Authorized Distributors and Authorized Importers must ensure that authorized surgical masks comply with condition A of this EUA.

I. Through a process of inventory control, Authorized Distributors and Authorized Importers will maintain records of the entities to which they distribute the surgical masks and how many of each authorized product model they distribute or import, as applicable.

J. Authorized Distributors and Authorized Importers will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

K. Authorized Distributors and Authorized Importers of authorized surgical masks will submit, upon FDA's request, lots or shipments of the authorized surgical masks for testing by FDA or by another entity designated by FDA. Authorized Distributors and Authorized Importers must not distribute any lot or shipment that fails testing, meaning the lot or shipment containing a lot that did not perform as expected based on the performance criteria in the Scope of Authorization (Section II). FDA will make the Authorized Distributor or Authorized Importer aware of the testing results.

Conditions Related to Advertising and Promotion

L. All descriptive printed matter, including advertising and promotional materials, relating to the use of the authorized surgical mask shall be consistent with the labeling requirements listed in Section II and this section (Conditions of Authorization) of this EUA, and the applicable requirements set forth in the Act and FDA regulations.

M. No descriptive printed matter, including advertising or promotional materials, relating to the use of the authorized surgical mask may represent or suggest that such product is safe or effective for the prevention or treatment of COVID-19.

N. All descriptive printed matter, including advertising and promotional materials, relating to the use of the product shall clearly and conspicuously state that:

- The product has not been FDA cleared or approved.
- The product has been authorized by FDA under an EUA for use in healthcare settings by HCP as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.
- This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

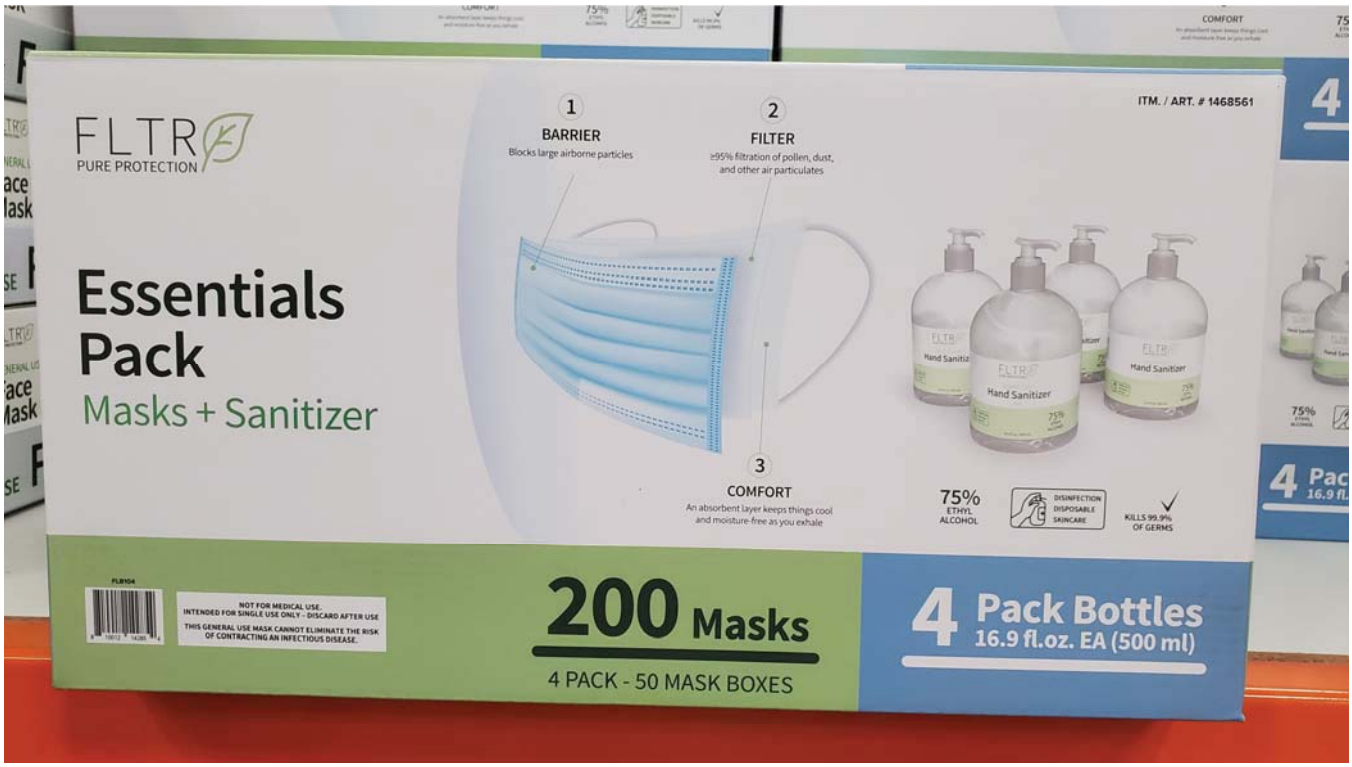
This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

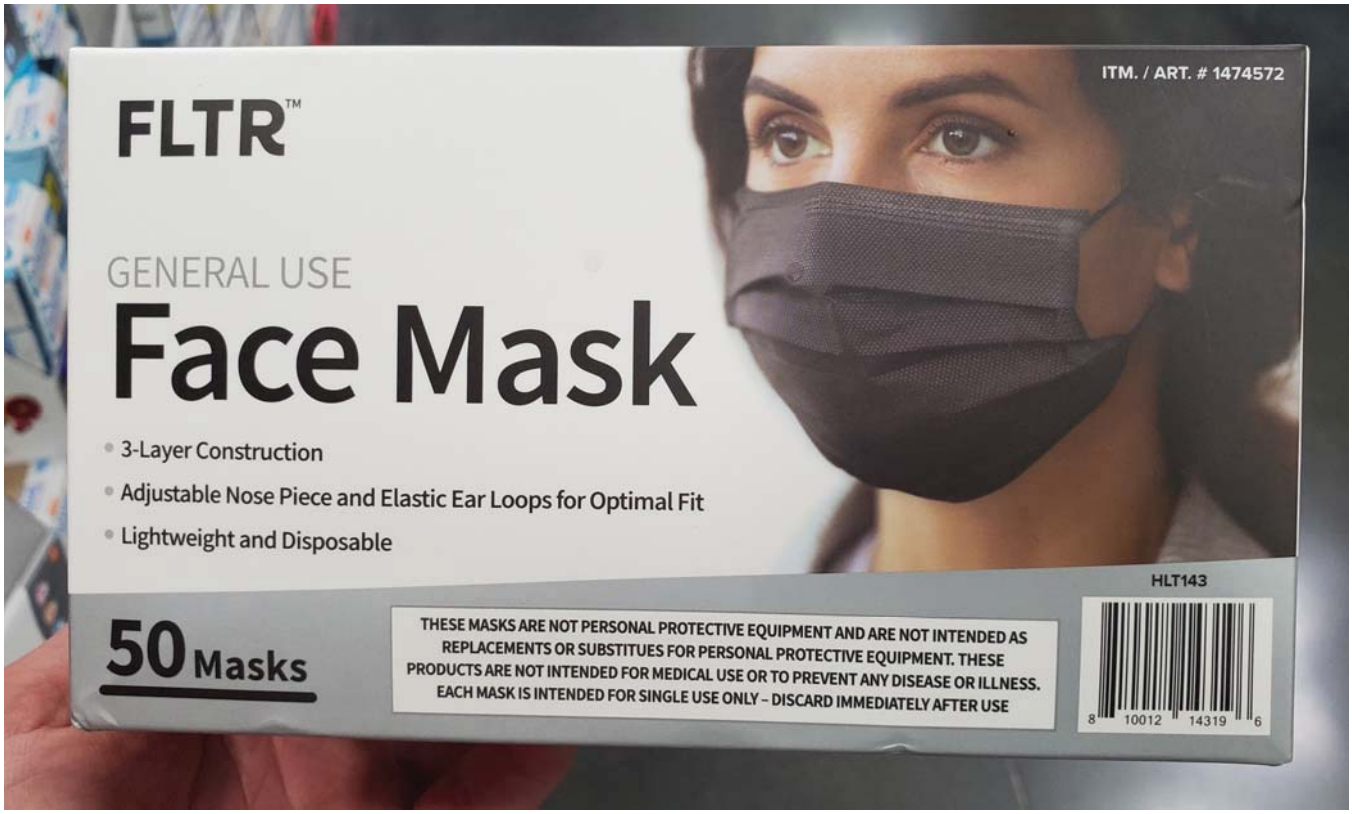
_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Plaintiff's Exhibit 467



Plaintiff's Exhibit 468



Plaintiff's Exhibit 469

Understanding the Difference

	Surgical Mask	N95 Respirator
		
Testing and Approval	Cleared by the U.S. Food and Drug Administration (**FDA**)	Evaluated, tested, and approved by **NIOSH** as per the requirements in 42 CFR Part 84
Intended Use and Purpose	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (**only non-oil aerosols**).
Face Seal Fit	Loose-fitting	Tight-fitting
Fit Testing Requirement	No	Yes
User Seal Check Requirement	No	Yes. Required each time the respirator is donned (put on)
Filtration	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles
Leakage	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales
Use Limitations	Disposable. Discard after each patient encounter.	Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Plaintiff's Exhibit 470

Laws regulating masks 29CFR 1910.134

From: JEFFREY PENCE (jmpmgdir@sbcglobal.net)

To: lucas.wall@yahoo.com

Date: Sunday, July 11, 2021, 2:12 PM EDT

Hello Lucas,

My name is Jeff Pence and I came across your lawsuit against the government about wearing masks on a plane. I Think I have information that also may help you.
Title 29 CFR 1910.134 regulates respirators and when they can be worn. In the Cliff's note version it basically states you can not where one if you are going to be in an environment where the O2 level falls below 19.5%, the working O2 level on a plane is 15.9%. This is why the airlines are having problems with people on a plane, they are oxygen deprived (hypoxia) which can lead to deadly consequences.

I can explain this for you if you want more information and go into appendix c and how all this works. The reason I know a lot about this is I was an insulator for 30 + years and had blood clots in my lungs (side effect of wearing a respirator or mask).

Here are the laws by osha standards for wearing a mask

https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134

In osha's training manual "Major Requirements of OSHA's Respiratory Protection Standard 29 CFR 1910.134" on page 2 of the manual is a flow chart which states "Are Respirators: necessary to protect the health of the employee; or required by the employer? Yes. Must establish and implement a written respirator program with worksite-specific procedures.

https://www.osha.gov/sites/default/files/training-library_major_requirements.pdf

In appendix c, Part A Section 2. of the osha laws, is the questionnaire that must be filled out by the physician. These are the questions that would exempt you from wearing a mask. If you look at question 12, it asks how long will you be wearing the mask and what kind of physical activity will you be doing. The reason these questions are asked because if you are doing physical labor you have to make sure that the oxygen level does not fall below 19.5% which can happen during physical labor. This is why you can not jog or run for long periods of time wearing a mask. These schools do not understand this because they are making the kids run laps while wearing a mask and some schools kids are wearing masks while playing soccer. This can and will KILL someone.

https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppC

These links here provide osha's interpretations of the law

https://www.osha.gov/laws-regs/standardinterpretations/2017-12-20

https://www.osha.gov/laws-regs/standardinterpretations/2009-07-14-0

https://www.osha.gov/laws-regs/standardinterpretations/1999-10-01

This is a link to a case where someone died who would have been exempt from wearing a mask if they followed osha's laws

Inspection Detail | Occupational Safety and Health Administration

Inspection Detail | Occupational Safety and Health Administration

Inspection Detail

Here are the directions of a 3m n95 mask and it states 1. May result in sickness or death. 2. Follow osha guidelines.

https://multimedia.3m.com/mws/media/92131O/3m-8000-series-n95-particulate-respirator-user-instructions.pdf

This is just the overview of what I have.

Sincerely

Jeffrey Pence
jmpmgdir@sbcglobal.net
cell 708-710-6966
Home 815-478-3439

Plaintiff's Exhibit 471

By Standard Number / 1910.134 - Respiratory Protection.

- **Part Number:** 1910
- **Part Number Title:** Occupational Safety and Health Standards
- **Subpart:** 1910 Subpart I
- **Subpart Title:** Personal Protective Equipment
- **Standard Number:** 1910.134
- **Title:** Respiratory Protection.
- **Appendix:** A; B-1; B-2; C; D
- **GPO Source:** e-CFR

Department of Labor
OSHA

1910.134(a)

Permissible practice.

1910.134(a)(1)

In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to this section.

1910.134(a)(2)

A respirator shall be provided to each employee when such equipment is necessary to protect the health of such employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protection program, which shall include the requirements outlined in paragraph (c) of this section. The program shall cover each employee required by this section to use a respirator.

1910.134(b)

Definitions. The following definitions are important terms used in the respiratory protection standard in this section.

Air-purifying respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

Assigned protection factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section.

Atmosphere-supplying respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

Canister or cartridge means a container with a filter, sorbent, or catalyst, or combination of these items, which removes specific contaminants from the air passed through the container.

Demand respirator means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a

negative pressure is created inside the facepiece by inhalation.

Emergency situation means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of an airborne contaminant.

Employee exposure means exposure to a concentration of an airborne contaminant that would occur if the employee were not using respiratory protection.

End-of-service-life indicator (ESLI) means a system that warns the respirator user of the approach of the end of adequate respiratory protection, for example, that the sorbent is approaching saturation or is no longer effective.

Escape-only respirator means a respirator intended to be used only for emergency exit.

Filter or air purifying element means a component used in respirators to remove solid or liquid aerosols from the inspired air.

Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium.

Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual. (See also Qualitative fit test QLFT and Quantitative fit test QNFT.)

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

High efficiency particulate air (HEPA) filter means a filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter. The equivalent NIOSH 42 CFR 84 particulate filters are the N100, R100, and P100 filters.

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Immediately dangerous to life or health (IDLH) means an atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual's ability to escape from a dangerous atmosphere.

Interior structural firefighting means the physical activity of fire suppression, rescue or both, inside of buildings or enclosed structures which are involved in a fire situation beyond the incipient stage. (See 29 CFR 1910.155)

Loose-fitting facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The MUC can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the required OSHA permissible exposure limit, short-term exposure limit, or ceiling limit. When no OSHA exposure limit is available for a hazardous substance, an employer must determine an MUC on the basis of relevant available information and informed professional judgment.

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Oxygen deficient atmosphere means an atmosphere with an oxygen content below 19.5% by volume.

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all of the health care services required by paragraph (e) of this section.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Respiratory inlet covering means that portion of a respirator that forms the protective barrier between the user's respiratory tract and an air-purifying device or breathing air source, or both. It may be a facepiece, helmet, hood, suit, or a mouthpiece respirator with nose clamp.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Service life means the period of time that a respirator, filter or sorbent, or other respiratory equipment provides adequate protection to the wearer.

Supplied-air respirator (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

This section means this respiratory protection standard.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

User seal check means an action conducted by the respirator user to determine if the respirator is properly seated to the face.

1910.134(c)

Respiratory protection program. This paragraph requires the employer to develop and implement a written respiratory protection program with required worksite-specific procedures and elements for required respirator use. The program must be administered by a suitably trained program administrator. In addition, certain program elements may be required for voluntary use to prevent potential hazards associated with the use of the respirator. The Small Entity Compliance Guide contains criteria for the selection of a program administrator and a sample program that

meets the requirements of this paragraph. Copies of the Small Entity Compliance Guide will be available on or about April 8, 1998 from the Occupational Safety and Health Administration's Office of Publications, Room N 3101, 200 Constitution Avenue, NW, Washington, DC, 20210 (202-219-4667).

1910.134(c)(1)

In any workplace where respirators are necessary to protect the health of the employee or whenever respirators are required by the employer, the employer shall establish and implement a written respiratory protection program with worksite-specific procedures. The program shall be updated as necessary to reflect those changes in workplace conditions that affect respirator use. The employer shall include in the program the following provisions of this section, as applicable:

1910.134(c)(1)(i)

Procedures for selecting respirators for use in the workplace;

1910.134(c)(1)(ii)

Medical evaluations of employees required to use respirators;

1910.134(c)(1)(iii)

Fit testing procedures for tight-fitting respirators;

1910.134(c)(1)(iv)

Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;

1910.134(c)(1)(v)

Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators;

1910.134(c)(1)(vi)

Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators;

1910.134(c)(1)(vii)

Training of employees in the respiratory hazards to which they are potentially exposed during routine and emergency situations;

1910.134(c)(1)(viii)

Training of employees in the proper use of respirators, including putting on and removing them, any limitations on their use, and their maintenance; and

1910.134(c)(1)(ix)

Procedures for regularly evaluating the effectiveness of the program.

1910.134(c)(2)

Where respirator use is not required:

1910.134(c)(2)(i)

An employer may provide respirators at the request of employees or permit employees to use their own respirators, if the employer determines that such respirator use will not in itself create a hazard. If the employer determines that any voluntary respirator use is permissible, the employer shall provide the respirator users with the information contained in Appendix D to this section ("Information for Employees Using Respirators When Not Required Under the Standard"); and

1910.134(c)(2)(ii)

In addition, the employer must establish and implement those elements of a written respiratory protection program necessary to ensure that any employee using a respirator voluntarily is medically able to use that respirator, and that the respirator is cleaned, stored, and maintained so that its use does not present a health hazard to the user. Exception: Employers are not required to include in a written respiratory protection program those employees whose only use of respirators involves the voluntary use of filtering facepieces (dust masks).

1910.134(c)(3)

The employer shall designate a program administrator who is qualified by appropriate training or experience that is commensurate with the complexity of the program to administer or oversee the respiratory protection program and conduct the required evaluations of program effectiveness.

1910.134(c)(4)

The employer shall provide respirators, training, and medical evaluations at no cost to the employee.

1910.134(d)

Selection of respirators. This paragraph requires the employer to evaluate respiratory hazard(s) in the workplace, identify relevant workplace and user factors, and base respirator selection on these factors. The paragraph also specifies appropriately protective respirators for use in IDLH atmospheres, and limits the selection and use of air-purifying respirators.

1910.134(d)(1)

General requirements.

1910.134(d)(1)(i)

The employer shall select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is exposed and workplace and user factors that affect respirator performance and reliability.

1910.134(d)(1)(ii)

The employer shall select a NIOSH-certified respirator. The respirator shall be used in compliance with the conditions of its certification.

1910.134(d)(1)(iii)

The employer shall identify and evaluate the respiratory hazard(s) in the workplace; this evaluation shall include a reasonable estimate of employee exposures to respiratory hazard(s) and an identification of the contaminant's chemical state and physical form. Where the employer cannot identify or reasonably estimate the employee exposure, the employer shall consider the atmosphere to be IDLH.

1910.134(d)(1)(iv)

The employer shall select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

1910.134(d)(2)

Respirators for IDLH atmospheres.

1910.134(d)(2)(i)
The employer shall provide the following respirators for employee use in IDLH atmospheres:

1910.134(d)(2)(i)(A)
A full facepiece pressure demand SCBA certified by NIOSH for a minimum service life of thirty minutes, or

1910.134(d)(2)(i)(B)
A combination full facepiece pressure demand supplied-air respirator (SAR) with auxiliary self-contained air supply.

1910.134(d)(2)(ii)
Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

1910.134(d)(2)(iii)
All oxygen-deficient atmospheres shall be considered IDLH. Exception: If the employer demonstrates that, under all foreseeable conditions, the oxygen concentration can be maintained within the ranges specified in Table II of this section (i.e., for the altitudes set out in the table), then any atmosphere-supplying respirator may be used.

1910.134(d)(3)
Respirators for atmospheres that are not IDLH.

1910.134(d)(3)(i)
The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements, under routine and reasonably foreseeable emergency situations.

1910.134(d)(3)(i)(A)
Assigned Protection Factors (APFs) Employers must use the assigned protection factors listed in Table 1 to select a respirator that meets or exceeds the required level of employee protection. When using a combination respirator (e.g., airline respirators with an air-purifying filter), employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.

Table 1. -- Assigned Protection Factors[5]

Type of respirator[1], [2]	Quarter mask	Half mask	Full facepiece	Helmet/ hood	Loose-fitting facepiece
1. Air-Purifying Respirator	5	[3]10	50	.....	.....
2. Powered Air-Purifying Respirator (PAPR)	.....	50	1,000	[4]25/1,000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator					
• Demand mode	.....	10	50	.....	.....
• Continuous flow mode	.....	50	1,000	[4]25/1,000	25
• Pressure-demand or other positive-pressure mode	.....	50	1,000	.....	.....
4. Self-Contained Breathing Apparatus (SCBA)					
• Demand mode	.....	10	50	50	.....
• Pressure-demand or other positive-pressure mode (e.g., open/closed circuit)	.....	.....	10,000	10,000	.....

Notes:
[1]Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for

use at lower concentrations of that substance, or when required respirator use is independent of concentration.
[2]The assigned protection factors in Table 1 are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.
[3]This APF category includes filtering facepieces, and half masks with elastomeric facepieces.
[4]The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.
[5]These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR 1910 subpart Z, employers must refer to the appropriate substance-specific standards in that subpart. Escape respirators for other IDLH atmospheres are specified by 29 CFR 1910.134 (d)(2)(ii).

1910.134(d)(3)(i)(B)
Maximum Use Concentration (MUC)

1910.134(d)(3)(i)(B)(1)
The employer must select a respirator for employee use that maintains the employee's exposure to the hazardous substance, when measured outside the respirator, at or below the MUC.

1910.134(d)(3)(i)(B)(2)
Employers must not apply MUCs to conditions that are immediately dangerous to life or health (IDLH); instead, they must use respirators listed for IDLH conditions in paragraph (d)(2) of this standard.

1910.134(d)(3)(i)(B)(3)
When the calculated MUC exceeds the IDLH level for a hazardous substance, or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.

1910.134(d)(3)(ii)
The respirator selected shall be appropriate for the chemical state and physical form of the contaminant.

1910.134(d)(3)(iii)
For protection against gases and vapors, the employer shall provide:

1910.134(d)(3)(iii)(A)
An atmosphere-supplying respirator, or

1910.134(d)(3)(iii)(B)
An air-purifying respirator, provided that:

1910.134(d)(3)(iii)(B)(1)
The respirator is equipped with an end-of-service-life indicator (ESLI) certified by NIOSH for the contaminant; or

1910.134(d)(3)(iii)(B)(2)
If there is no ESLI appropriate for conditions in the employer's workplace, the employer implements a change schedule for canisters and cartridges that is based on objective information or data that will ensure that canisters and cartridges are changed before the end of their service life. The employer shall describe in the respirator program the information and data relied upon and the basis for the canister and cartridge change schedule and the basis for reliance on the data.

1910.134(d)(3)(iv)

For protection against particulates, the employer shall provide:

1910.134(d)(3)(iv)(A)

An atmosphere-supplying respirator; or

1910.134(d)(3)(iv)(B)

An air-purifying respirator equipped with a filter certified by NIOSH under 30 CFR part 11 as a high efficiency particulate air (HEPA) filter, or an air-purifying respirator equipped with a filter certified for particulates by NIOSH under 42 CFR part 84; or

1910.134(d)(3)(iv)(C)

For contaminants consisting primarily of particles with mass median aerodynamic diameters (MMAD) of at least 2 micrometers, an air-purifying respirator equipped with any filter certified for particulates by NIOSH.

TABLE I. -- ASSIGNED PROTECTION FACTORS

[RESERVED]

TABLE II

Altitude (ft.)	Oxygen deficient Atmospheres (% 0_2) for which the employer atmosphere-may rely on supplying respirators
Less than 3,001	16.0-19.5
3,001-4,000	16.4-19.5
4,001-5,000	17.1-19.5
5,001-6,000	17.8-19.5
6,001-7,000	18.5-19.5
7,001-8,000[1]	19.3-19.5.

[1]Above 8,000 feet the exception does not apply. Oxygen-enriched breathing air must be supplied above 14,000 feet.

1910.134(e)

Medical evaluation. Using a respirator may place a physiological burden on employees that varies with the type of respirator worn, the job and workplace conditions in which the respirator is used, and the medical status of the employee. Accordingly, this paragraph specifies the minimum requirements for medical evaluation that employers must implement to determine the employee's ability to use a respirator.

1910.134(e)(1)

General. The employer shall provide a medical evaluation to determine the employee's ability to use a respirator, before the employee is fit tested or required to use the respirator in the workplace. The employer may discontinue an employee's medical evaluations when the employee is no longer required to use a respirator.

1910.134(e)(2)

Medical evaluation procedures.

1910.134(e)(2)(i)
The employer shall identify a physician or other licensed health care professional (PLHCP) to perform medical evaluations using a medical questionnaire or an initial medical examination that obtains the same information as the medical questionnaire.

1910.134(e)(2)(ii)
The medical evaluation shall obtain the information requested by the questionnaire in Sections 1 and 2, Part A of Appendix C of this section.

1910.134(e)(3)
Follow-up medical examination.

1910.134(e)(3)(i)
The employer shall ensure that a follow-up medical examination is provided for an employee who gives a positive response to any question among questions 1 through 8 in Section 2, Part A of Appendix C or whose initial medical examination demonstrates the need for a follow-up medical examination.

1910.134(e)(3)(ii)
The follow-up medical examination shall include any medical tests, consultations, or diagnostic procedures that the PLHCP deems necessary to make a final determination.

1910.134(e)(4)
Administration of the medical questionnaire and examinations.

1910.134(e)(4)(i)
The medical questionnaire and examinations shall be administered confidentially during the employee's normal working hours or at a time and place convenient to the employee. The medical questionnaire shall be administered in a manner that ensures that the employee understands its content.

1910.134(e)(4)(ii)
The employer shall provide the employee with an opportunity to discuss the questionnaire and examination results with the PLHCP.

1910.134(e)(5)
Supplemental information for the PLHCP.

1910.134(e)(5)(i)
The following information must be provided to the PLHCP before the PLHCP makes a recommendation concerning an employee's ability to use a respirator:

1910.134(e)(5)(i)(A)
(A) The type and weight of the respirator to be used by the employee;

1910.134(e)(5)(i)(B)
The duration and frequency of respirator use (including use for rescue and escape);

1910.134(e)(5)(i)(C)
The expected physical work effort;

1910.134(e)(5)(i)(D)

Additional protective clothing and equipment to be worn; and

1910.134(e)(5)(i)(E)
Temperature and humidity extremes that may be encountered.

1910.134(e)(5)(ii)
Any supplemental information provided previously to the PLHCP regarding an employee need not be provided for a subsequent medical evaluation if the information and the PLHCP remain the same.

1910.134(e)(5)(iii)
The employer shall provide the PLHCP with a copy of the written respiratory protection program and a copy of this section.

Note to Paragraph (e)(5)(iii): When the employer replaces a PLHCP, the employer must ensure that the new PLHCP obtains this information, either by providing the documents directly to the PLHCP or having the documents transferred from the former PLHCP to the new PLHCP. However, OSHA does not expect employers to have employees medically reevaluated solely because a new PLHCP has been selected.

1910.134(e)(6)
Medical determination. In determining the employee's ability to use a respirator, the employer shall:

1910.134(e)(6)(i)
Obtain a written recommendation regarding the employee's ability to use the respirator from the PLHCP. The recommendation shall provide only the following information:

1910.134(e)(6)(i)(A)
Any limitations on respirator use related to the medical condition of the employee, or relating to the workplace conditions in which the respirator will be used, including whether or not the employee is medically able to use the respirator;

1910.134(e)(6)(i)(B)
The need, if any, for follow-up medical evaluations; and

1910.134(e)(6)(i)(C)
A statement that the PLHCP has provided the employee with a copy of the PLHCP's written recommendation.

1910.134(e)(6)(ii)
If the respirator is a negative pressure respirator and the PLHCP finds a medical condition that may place the employee's health at increased risk if the respirator is used, the employer shall provide a PAPR if the PLHCP's medical evaluation finds that the employee can use such a respirator; if a subsequent medical evaluation finds that the employee is medically able to use a negative pressure respirator, then the employer is no longer required to provide a PAPR.

1910.134(e)(7)
Additional medical evaluations. At a minimum, the employer shall provide additional medical evaluations that comply with the requirements of this section if:

1910.134(e)(7)(i)
An employee reports medical signs or symptoms that are related to ability to use a respirator;

1910.134(e)(7)(ii)

A PLHCP, supervisor, or the respirator program administrator informs the employer that an employee needs to be reevaluated;

1910.134(e)(7)(iii)
Information from the respiratory protection program, including observations made during fit testing and program evaluation, indicates a need for employee reevaluation; or

1910.134(e)(7)(iv)
A change occurs in workplace conditions (e.g., physical work effort, protective clothing, temperature) that may result in a substantial increase in the physiological burden placed on an employee.

1910.134(f)
Fit testing. This paragraph requires that, before an employee may be required to use any respirator with a negative or positive pressure tight-fitting facepiece, the employee must be fit tested with the same make, model, style, and size of respirator that will be used. This paragraph specifies the kinds of fit tests allowed, the procedures for conducting them, and how the results of the fit tests must be used.

1910.134(f)(1)
The employer shall ensure that employees using a tight-fitting facepiece respirator pass an appropriate qualitative fit test (QLFT) or quantitative fit test (QNFT) as stated in this paragraph.

1910.134(f)(2)
The employer shall ensure that an employee using a tight-fitting facepiece respirator is fit tested prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or make) is used, and at least annually thereafter.

1910.134(f)(3)
The employer shall conduct an additional fit test whenever the employee reports, or the employer, PLHCP, supervisor, or program administrator makes visual observations of, changes in the employee's physical condition that could affect respirator fit. Such conditions include, but are not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight.

1910.134(f)(4)
If after passing a QLFT or QNFT, the employee subsequently notifies the employer, program administrator, supervisor, or PLHCP that the fit of the respirator is unacceptable, the employee shall be given a reasonable opportunity to select a different respirator facepiece and to be retested.

1910.134(f)(5)
The fit test shall be administered using an OSHA-accepted QLFT or QNFT protocol. The OSHA-accepted QLFT and QNFT protocols and procedures are contained in Appendix A of this section.

1910.134(f)(6)
QLFT may only be used to fit test negative pressure air-purifying respirators that must achieve a fit factor of 100 or less.

1910.134(f)(7)
If the fit factor, as determined through an OSHA-accepted QNFT protocol, is equal to or greater than 100 for tight-fitting half facepieces, or equal to or greater than 500 for tight-fitting full facepieces, the QNFT has been passed with that respirator.

1910.134(f)(8)

Fit testing of tight-fitting atmosphere-supplying respirators and tight-fitting powered air-purifying respirators shall be accomplished by performing quantitative or qualitative fit testing in the negative pressure mode, regardless of the mode of operation (negative or positive pressure) that is used for respiratory protection.

1910.134(f)(8)(i)
Qualitative fit testing of these respirators shall be accomplished by temporarily converting the respirator user's actual facepiece into a negative pressure respirator with appropriate filters, or by using an identical negative pressure air-purifying respirator facepiece with the same sealing surfaces as a surrogate for the atmosphere-supplying or powered air-purifying respirator facepiece.

1910.134(f)(8)(ii)
Quantitative fit testing of these respirators shall be accomplished by modifying the facepiece to allow sampling inside the facepiece in the breathing zone of the user, midway between the nose and mouth. This requirement shall be accomplished by installing a permanent sampling probe onto a surrogate facepiece, or by using a sampling adapter designed to temporarily provide a means of sampling air from inside the facepiece.

1910.134(f)(8)(iii)
Any modifications to the respirator facepiece for fit testing shall be completely removed, and the facepiece restored to NIOSH-approved configuration, before that facepiece can be used in the workplace.

1910.134(g)
Use of respirators. This paragraph requires employers to establish and implement procedures for the proper use of respirators. These requirements include prohibiting conditions that may result in facepiece seal leakage, preventing employees from removing respirators in hazardous environments, taking actions to ensure continued effective respirator operation throughout the work shift, and establishing procedures for the use of respirators in IDLH atmospheres or in interior structural firefighting situations.

1910.134(g)(1)
Facepiece seal protection.

1910.134(g)(1)(i)
The employer shall not permit respirators with tight-fitting facepieces to be worn by employees who have:

1910.134(g)(1)(i)(A)
Facial hair that comes between the sealing surface of the facepiece and the face or that interferes with valve function; or

1910.134(g)(1)(i)(B)
Any condition that interferes with the face-to-facepiece seal or valve function.

1910.134(g)(1)(ii)
If an employee wears corrective glasses or goggles or other personal protective equipment, the employer shall ensure that such equipment is worn in a manner that does not interfere with the seal of the facepiece to the face of the user.

1910.134(g)(1)(iii)
For all tight-fitting respirators, the employer shall ensure that employees perform a user seal check each time they put on the respirator using the procedures in Appendix B-1 or procedures recommended by the respirator manufacturer that the employer demonstrates are as effective as those in Appendix B-1 of this section.

1910.134(g)(2)

Continuing respirator effectiveness.

1910.134(g)(2)(i)
Appropriate surveillance shall be maintained of work area conditions and degree of employee exposure or stress. When there is a change in work area conditions or degree of employee exposure or stress that may affect respirator effectiveness, the employer shall reevaluate the continued effectiveness of the respirator.

1910.134(g)(2)(ii)
The employer shall ensure that employees leave the respirator use area:

1910.134(g)(2)(ii)(A)
To wash their faces and respirator facepieces as necessary to prevent eye or skin irritation associated with respirator use; or

1910.134(g)(2)(ii)(B)
If they detect vapor or gas breakthrough, changes in breathing resistance, or leakage of the facepiece; or

1910.134(g)(2)(ii)(C)
To replace the respirator or the filter, cartridge, or canister elements.

1910.134(g)(2)(iii)
If the employee detects vapor or gas breakthrough, changes in breathing resistance, or leakage of the facepiece, the employer must replace or repair the respirator before allowing the employee to return to the work area.

1910.134(g)(3)
Procedures for IDLH atmospheres. For all IDLH atmospheres, the employer shall ensure that:

1910.134(g)(3)(i)
One employee or, when needed, more than one employee is located outside the IDLH atmosphere;

1910.134(g)(3)(ii)
Visual, voice, or signal line communication is maintained between the employee(s) in the IDLH atmosphere and the employee(s) located outside the IDLH atmosphere;

1910.134(g)(3)(iii)
The employee(s) located outside the IDLH atmosphere are trained and equipped to provide effective emergency rescue;

1910.134(g)(3)(iv)
The employer or designee is notified before the employee(s) located outside the IDLH atmosphere enter the IDLH atmosphere to provide emergency rescue;

1910.134(g)(3)(v)
The employer or designee authorized to do so by the employer, once notified, provides necessary assistance appropriate to the situation;

1910.134(g)(3)(vi)
Employee(s) located outside the IDLH atmospheres are equipped with:

1910.134(g)(3)(vi)(A)
Pressure demand or other positive pressure SCBAs, or a pressure demand or other positive pressure supplied-air

respirator with auxiliary SCBA; and either

1910.134(g)(3)(vi)(B)
Appropriate retrieval equipment for removing the employee(s) who enter(s) these hazardous atmospheres where retrieval equipment would contribute to the rescue of the employee(s) and would not increase the overall risk resulting from entry; or

1910.134(g)(3)(vi)(C)
Equivalent means for rescue where retrieval equipment is not required under paragraph (g)(3)(vi)(B).

1910.134(g)(4)
Procedures for interior structural firefighting. In addition to the requirements set forth under paragraph (g)(3), in interior structural fires, the employer shall ensure that:

1910.134(g)(4)(i)
At least two employees enter the IDLH atmosphere and remain in visual or voice contact with one another at all times;

1910.134(g)(4)(ii)
At least two employees are located outside the IDLH atmosphere; and

1910.134(g)(4)(iii)
All employees engaged in interior structural firefighting use SCBAs.

Note 1 to paragraph (g): One of the two individuals located outside the IDLH atmosphere may be assigned to an additional role, such as incident commander in charge of the emergency or safety officer, so long as this individual is able to perform assistance or rescue activities without jeopardizing the safety or health of any firefighter working at the incident.

Note 2 to paragraph (g): Nothing in this section is meant to preclude firefighters from performing emergency rescue activities before an entire team has assembled.

1910.134(h)
Maintenance and care of respirators. This paragraph requires the employer to provide for the cleaning and disinfecting, storage, inspection, and repair of respirators used by employees.

1910.134(h)(1)
Cleaning and disinfecting. The employer shall provide each respirator user with a respirator that is clean, sanitary, and in good working order. The employer shall ensure that respirators are cleaned and disinfected using the procedures in Appendix B-2 of this section, or procedures recommended by the respirator manufacturer, provided that such procedures are of equivalent effectiveness. The respirators shall be cleaned and disinfected at the following intervals:

1910.134(h)(1)(i)
Respirators issued for the exclusive use of an employee shall be cleaned and disinfected as often as necessary to be maintained in a sanitary condition;

1910.134(h)(1)(ii)
Respirators issued to more than one employee shall be cleaned and disinfected before being worn by different individuals;

1910.134(h)(1)(iii)

Respirators maintained for emergency use shall be cleaned and disinfected after each use; and

1910.134(h)(1)(iv)
Respirators used in fit testing and training shall be cleaned and disinfected after each use.

1910.134(h)(2)
Storage. The employer shall ensure that respirators are stored as follows:

1910.134(h)(2)(i)
All respirators shall be stored to protect them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and they shall be packed or stored to prevent deformation of the facepiece and exhalation valve.

1910.134(h)(2)(ii)
In addition to the requirements of paragraph (h)(2)(i) of this section, emergency respirators shall be:

1910.134(h)(2)(ii)(A)
Kept accessible to the work area;

1910.134(h)(2)(ii)(B)
Stored in compartments or in covers that are clearly marked as containing emergency respirators; and

1910.134(h)(2)(ii)(C)
Stored in accordance with any applicable manufacturer instructions.

1910.134(h)(3)
Inspection.

1910.134(h)(3)(i)
The employer shall ensure that respirators are inspected as follows:

1910.134(h)(3)(i)(A)
All respirators used in routine situations shall be inspected before each use and during cleaning;

1910.134(h)(3)(i)(B)
All respirators maintained for use in emergency situations shall be inspected at least monthly and in accordance with the manufacturer's recommendations, and shall be checked for proper function before and after each use; and

1910.134(h)(3)(i)(C)
Emergency escape-only respirators shall be inspected before being carried into the workplace for use.

1910.134(h)(3)(ii)
The employer shall ensure that respirator inspections include the following:

1910.134(h)(3)(ii)(A)
A check of respirator function, tightness of connections, and the condition of the various parts including, but not limited to, the facepiece, head straps, valves, connecting tube, and cartridges, canisters or filters; and

1910.134(h)(3)(ii)(B)
A check of elastomeric parts for pliability and signs of deterioration.

1910.134(h)(3)(iii)

In addition to the requirements of paragraphs (h)(3)(i) and (ii) of this section, self-contained breathing apparatus shall be inspected monthly. Air and oxygen cylinders shall be maintained in a fully charged state and shall be recharged when the pressure falls to 90% of the manufacturer's recommended pressure level. The employer shall determine that the regulator and warning devices function properly.

1910.134(h)(3)(iv)

For respirators maintained for emergency use, the employer shall:

1910.134(h)(3)(iv)(A)

Certify the respirator by documenting the date the inspection was performed, the name (or signature) of the person who made the inspection, the findings, required remedial action, and a serial number or other means of identifying the inspected respirator; and

1910.134(h)(3)(iv)(B)

Provide this information on a tag or label that is attached to the storage compartment for the respirator, is kept with the respirator, or is included in inspection reports stored as paper or electronic files. This information shall be maintained until replaced following a subsequent certification.

1910.134(h)(4)

Repairs. The employer shall ensure that respirators that fail an inspection or are otherwise found to be defective are removed from service, and are discarded or repaired or adjusted in accordance with the following procedures:

1910.134(h)(4)(i)

Repairs or adjustments to respirators are to be made only by persons appropriately trained to perform such operations and shall use only the respirator manufacturer's NIOSH-approved parts designed for the respirator;

1910.134(h)(4)(ii)

Repairs shall be made according to the manufacturer's recommendations and specifications for the type and extent of repairs to be performed; and

1910.134(h)(4)(iii)

Reducing and admission valves, regulators, and alarms shall be adjusted or repaired only by the manufacturer or a technician trained by the manufacturer.

1910.134(i)

Breathing air quality and use. This paragraph requires the employer to provide employees using atmosphere-supplying respirators (supplied-air and SCBA) with breathing gases of high purity.

1910.134(i)(1)

The employer shall ensure that compressed air, compressed oxygen, liquid air, and liquid oxygen used for respiration accords with the following specifications:

1910.134(i)(1)(i)

Compressed and liquid oxygen shall meet the United States Pharmacopoeia requirements for medical or breathing oxygen; and

1910.134(i)(1)(ii)

Compressed breathing air shall meet at least the requirements for Grade D breathing air described in ANSI/Compressed Gas Association Commodity Specification for Air, G-7.1-1989, to include:

1910.134(i)(1)(ii)(A)
Oxygen content (v/v) of 19.5-23.5%;

1910.134(i)(1)(ii)(B)
Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

1910.134(i)(1)(ii)(C)
Carbon monoxide (CO) content of 10 ppm or less;

1910.134(i)(1)(ii)(D)
Carbon dioxide content of 1,000 ppm or less; and

1910.134(i)(1)(ii)(E)
Lack of noticeable odor.

1910.134(i)(2)
The employer shall ensure that compressed oxygen is not used in atmosphere-supplying respirators that have previously used compressed air.

1910.134(i)(3)
The employer shall ensure that oxygen concentrations greater than 23.5% are used only in equipment designed for oxygen service or distribution.

1910.134(i)(4)
The employer shall ensure that cylinders used to supply breathing air to respirators meet the following requirements:

1910.134(i)(4)(i)
Cylinders are tested and maintained as prescribed in the Shipping Container Specification Regulations of the Department of Transportation (49 CFR part 180);

1910.134(i)(4)(ii)
Cylinders of purchased breathing air have a certificate of analysis from the supplier that the breathing air meets the requirements for Grade D breathing air; and

1910.134(i)(4)(iii)
The moisture content in the cylinder does not exceed a dew point of -50 deg.F (-45.6 deg.C) at 1 atmosphere pressure.

1910.134(i)(5)
The employer shall ensure that compressors used to supply breathing air to respirators are constructed and situated so as to:

1910.134(i)(5)(i)
Prevent entry of contaminated air into the air-supply system;

1910.134(i)(5)(ii)
Minimize moisture content so that the dew point at 1 atmosphere pressure is 10 degrees F (5.56 deg.C) below the ambient temperature;

1910.134(i)(5)(iii)
Have suitable in-line air-purifying sorbent beds and filters to further ensure breathing air quality. Sorbent beds and

filters shall be maintained and replaced or refurbished periodically following the manufacturer's instructions.

1910.134(i)(5)(iv)
Have a tag containing the most recent change date and the signature of the person authorized by the employer to perform the change. The tag shall be maintained at the compressor.

1910.134(i)(6)
For compressors that are not oil-lubricated, the employer shall ensure that carbon monoxide levels in the breathing air do not exceed 10 ppm.

1910.134(i)(7)
For oil-lubricated compressors, the employer shall use a high-temperature or carbon monoxide alarm, or both, to monitor carbon monoxide levels. If only high-temperature alarms are used, the air supply shall be monitored at intervals sufficient to prevent carbon monoxide in the breathing air from exceeding 10 ppm.

1910.134(i)(8)
The employer shall ensure that breathing air couplings are incompatible with outlets for nonrespirable worksite air or other gas systems. No asphyxiating substance shall be introduced into breathing air lines.

1910.134(i)(9)
The employer shall use only the respirator manufacturer's NIOSH-approved breathing-gas containers,marked and maintained in accordance with the Quality Assurance provisions of the NIOSH approval for the SCBA as issued in accordance with the NIOSH respirator-certification standard at 42 CFR part 84.

1910.134(j)
Identification of filters, cartridges, and canisters. The employer shall ensure that all filters, cartridges and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible.

1910.134(k)
Training and information. This paragraph requires the employer to provide effective training to employees who are required to use respirators. The training must be comprehensive, understandable, and recur annually, and more often if necessary. This paragraph also requires the employer to provide the basic information on respirators in Appendix D of this section to employees who wear respirators when not required by this section or by the employer to do so.

1910.134(k)(1)
The employer shall ensure that each employee can demonstrate knowledge of at least the following:

1910.134(k)(1)(i)
Why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator;

1910.134(k)(1)(ii)
What the limitations and capabilities of the respirator are;

1910.134(k)(1)(iii)
How to use the respirator effectively in emergency situations, including situations in which the respirator malfunctions;

1910.134(k)(1)(iv)
How to inspect, put on and remove, use, and check the seals of the respirator;

1910.134(k)(1)(v)
What the procedures are for maintenance and storage of the respirator;

1910.134(k)(1)(vi)
How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators; and

1910.134(k)(1)(vii)
The general requirements of this section.

1910.134(k)(2)
The training shall be conducted in a manner that is understandable to the employee.

1910.134(k)(3)
The employer shall provide the training prior to requiring the employee to use a respirator in the workplace.

1910.134(k)(4)
An employer who is able to demonstrate that a new employee has received training within the last 12 months that addresses the elements specified in paragraph (k)(1)(i) through (vii) is not required to repeat such training provided that, as required by paragraph (k)(1), the employee can demonstrate knowledge of those element(s). Previous training not repeated initially by the employer must be provided no later than 12 months from the date of the previous training.

1910.134(k)(5)
Retraining shall be administered annually, and when the following situations occur:

1910.134(k)(5)(i)
Changes in the workplace or the type of respirator render previous training obsolete;

1910.134(k)(5)(ii)
Inadequacies in the employee's knowledge or use of the respirator indicate that the employee has not retained the requisite understanding or skill; or

1910.134(k)(5)(iii)
Any other situation arises in which retraining appears necessary to ensure safe respirator use.

1910.134(k)(6)
The basic advisory information on respirators, as presented in Appendix D of this section, shall be provided by the employer in any written or oral format, to employees who wear respirators when such use is not required by this section or by the employer.

1910.134(l)
Program evaluation. This section requires the employer to conduct evaluations of the workplace to ensure that the written respiratory protection program is being properly implemented, and to consult employees to ensure that they are using the respirators properly.

1910.134(l)(1)
The employer shall conduct evaluations of the workplace as necessary to ensure that the provisions of the current written program are being effectively implemented and that it continues to be effective.

1910.134(l)(2)
The employer shall regularly consult employees required to use respirators to assess the employees' views on program effectiveness and to identify any problems. Any problems that are identified during this assessment shall be

corrected. Factors to be assessed include, but are not limited to:

1910.134(l)(2)(i)
Respirator fit (including the ability to use the respirator without interfering with effective workplace performance);

1910.134(l)(2)(ii)
Appropriate respirator selection for the hazards to which the employee is exposed;

1910.134(l)(2)(iii)
Proper respirator use under the workplace conditions the employee encounters; and

1910.134(l)(2)(iv)
Proper respirator maintenance.

1910.134(m)
Recordkeeping. This section requires the employer to establish and retain written information regarding medical evaluations, fit testing, and the respirator program. This information will facilitate employee involvement in the respirator program, assist the employer in auditing the adequacy of the program, and provide a record for compliance determinations by OSHA.

1910.134(m)(1)
Medical evaluation. Records of medical evaluations required by this section must be retained and made available in accordance with 29 CFR 1910.1020.

1910.134(m)(2)
Fit testing.

1910.134(m)(2)(i)
The employer shall establish a record of the qualitative and quantitative fit tests administered to an employee including:

1910.134(m)(2)(i)(A)
The name or identification of the employee tested;

1910.134(m)(2)(i)(B)
Type of fit test performed;

1910.134(m)(2)(i)(C)
Specific make, model, style, and size of respirator tested;

1910.134(m)(2)(i)(D)
Date of test; and

1910.134(m)(2)(i)(E)
The pass/fail results for QLFTs or the fit factor and strip chart recording or other recording of the test results for QNFTs.

1910.134(m)(2)(ii)
Fit test records shall be retained for respirator users until the next fit test is administered.

1910.134(m)(3)

A written copy of the current respirator program shall be retained by the employer.

1910.134(m)(4)
Written materials required to be retained under this paragraph shall be made available upon request to affected employees and to the Assistant Secretary or designee for examination and copying.

1910.134(n)
Effective date. Paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) of this section become effective November 22, 2006.

1910.134(o)
Appendices. Compliance with Appendix A, Appendix B-1, Appendix B-2, Appendix C, and Appendix D to this section are mandatory.

[63 FR 1152, Jan. 8, 1998; 63 FR 20098, April 23, 1998; 71 FR 16672, April 3, 2006; 71 FR 50187, August 24, 2006; 73 FR 75584, Dec. 12, 2008; 76 FR 33606, June 8, 2011]

Plaintiff's Exhibit 472

By Standard Number / 1910.134 App C - OSHA Respirator Medical Evaluation Questionnaire (Mandatory).

- **Part Number:** 1910
- **Part Number Title:** Occupational Safety and Health Standards
- **Subpart:** 1910 Subpart I
- **Subpart Title:** Personal Protective Equipment
- **Standard Number:** 1910.134 App C
- **Title:** OSHA Respirator Medical Evaluation Questionnaire (Mandatory).
- **GPO Source:** e-CFR

Appendix C to Sec. 1910.134: OSHA Respirator Medical Evaluation Questionnaire (Mandatory)

To the employer: Answers to questions in Section 1, and to question 9 in Section 2 of Part A, do not require a medical examination.

To the employee:

Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.

Part A. Section 1. (Mandatory) The following information must be provided by every employee who has been selected to use any type of respirator (please print).

1. Today's date:_____

2. Your name:_____

3. Your age (to nearest year):_____

4. Sex (circle one): Male/Female

5. Your height: _____ ft. _____ in.

6. Your weight: _____ lbs.

7. Your job title:_____

8. A phone number where you can be reached by the health care professional who reviews this questionnaire (include the Area Code): _____

9. The best time to phone you at this number: _____

10. Has your employer told you how to contact the health care professional who will review this questionnaire (circle one): Yes/No

11. Check the type of respirator you will use (you can check more than one category):
a. _____ N, R, or P disposable respirator (filter-mask, non-cartridge type only).
b. _____ Other type (for example, half- or full-facepiece type, powered-air purifying, supplied-air, self-contained breathing apparatus).

12. Have you worn a respirator (circle one): Yes/No

If "yes," what type(s):_____
_____

Part A. Section 2. (Mandatory) Questions 1 through 9 below must be answered by every employee who has been selected to use any type of respirator (please circle "yes" or "no").

1. Do you *currently* smoke tobacco, or have you smoked tobacco in the last month: Yes/No

2. Have you *ever had* any of the following conditions?

a. Seizures: Yes/No

b. Diabetes (sugar disease): Yes/No

c. Allergic reactions that interfere with your breathing: Yes/No

d. Claustrophobia (fear of closed-in places): Yes/No

e. Trouble smelling odors: Yes/No

3. Have you *ever had* any of the following pulmonary or lung problems?

a. Asbestosis: Yes/No

b. Asthma: Yes/No

c. Chronic bronchitis: Yes/No

d. Emphysema: Yes/No

e. Pneumonia: Yes/No

f. Tuberculosis: Yes/No

g. Silicosis: Yes/No

h. Pneumothorax (collapsed lung): Yes/No

i. Lung cancer: Yes/No

j. Broken ribs: Yes/No

k. Any chest injuries or surgeries: Yes/No

l. Any other lung problem that you've been told about: Yes/No

4. Do you *currently* have any of the following symptoms of pulmonary or lung illness?

a. Shortness of breath: Yes/No

b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline: Yes/No

c. Shortness of breath when walking with other people at an ordinary pace on level ground: Yes/No

d. Have to stop for breath when walking at your own pace on level ground: Yes/No

e. Shortness of breath when washing or dressing yourself: Yes/No

f. Shortness of breath that interferes with your job: Yes/No

g. Coughing that produces phlegm (thick sputum): Yes/No

h. Coughing that wakes you early in the morning: Yes/No

i. Coughing that occurs mostly when you are lying down: Yes/No

j. Coughing up blood in the last month: Yes/No

k. Wheezing: Yes/No

l. Wheezing that interferes with your job: Yes/No

m. Chest pain when you breathe deeply: Yes/No

n. Any other symptoms that you think may be related to lung problems: Yes/No

5. Have you *ever had* any of the following cardiovascular or heart problems?

a. Heart attack: Yes/No

b. Stroke: Yes/No

c. Angina: Yes/No

d. Heart failure: Yes/No

e. Swelling in your legs or feet (not caused by walking): Yes/No

f. Heart arrhythmia (heart beating irregularly): Yes/No

g. High blood pressure: Yes/No

h. Any other heart problem that you've been told about: Yes/No

6. Have you *ever had* any of the following cardiovascular or heart symptoms?

a. Frequent pain or tightness in your chest: Yes/No

b. Pain or tightness in your chest during physical activity: Yes/No

c. Pain or tightness in your chest that interferes with your job: Yes/No

d. In the past two years, have you noticed your heart skipping or missing a beat: Yes/No

e. Heartburn or indigestion that is not related to eating: Yes/No

d. Any other symptoms that you think may be related to heart or circulation problems: Yes/No

7. Do you *currently* take medication for any of the following problems?

a. Breathing or lung problems: Yes/No

b. Heart trouble: Yes/No

c. Blood pressure: Yes/No

d. Seizures: Yes/No

8. If you've used a respirator, have you *ever had* any of the following problems? (If you've never used a respirator, check the following space and go to question 9:)

a. Eye irritation: Yes/No

b. Skin allergies or rashes: Yes/No

c. Anxiety: Yes/No

d. General weakness or fatigue: Yes/No

e. Any other problem that interferes with your use of a respirator: Yes/No

9. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire: Yes/No

Questions 10 to 15 below must be answered by every employee who has been selected to use either a full-facepiece respirator or a self-contained breathing apparatus (SCBA). For employees who have been selected to use other types of respirators, answering these questions is voluntary.

10. Have you *ever lost* vision in either eye (temporarily or permanently): Yes/No

11. Do you *currently* have any of the following vision problems?

a. Wear contact lenses: Yes/No

b. Wear glasses: Yes/No

c. Color blind: Yes/No

d. Any other eye or vision problem: Yes/No

12. Have you *ever had* an injury to your ears, including a broken ear drum: Yes/No

13. Do you *currently* have any of the following hearing problems?

a. Difficulty hearing: Yes/No

b. Wear a hearing aid: Yes/No

c. Any other hearing or ear problem: Yes/No

14. Have you *ever had* a back injury: Yes/No

15. Do you *currently* have any of the following musculoskeletal problems?

a. Weakness in any of your arms, hands, legs, or feet: Yes/No

b. Back pain: Yes/No

c. Difficulty fully moving your arms and legs: Yes/No

d. Pain or stiffness when you lean forward or backward at the waist: Yes/No

e. Difficulty fully moving your head up or down: Yes/No

f. Difficulty fully moving your head side to side: Yes/No

g. Difficulty bending at your knees: Yes/No

h. Difficulty squatting to the ground: Yes/No

i. Climbing a flight of stairs or a ladder carrying more than 25 lbs: Yes/No

j. Any other muscle or skeletal problem that interferes with using a respirator: Yes/No

Part B Any of the following questions, and other questions not listed, may be added to the questionnaire at the discretion of the health care professional who will review the questionnaire.

1. In your present job, are you working at high altitudes (over 5,000 feet) or in a place that has lower than normal amounts of oxygen: Yes/No

If "yes," do you have feelings of dizziness, shortness of breath, pounding in your chest, or other symptoms when you're working under these conditions: Yes/No

2. At work or at home, have you ever been exposed to hazardous solvents, hazardous airborne chemicals (e.g., gases, fumes, or dust), or have you come into skin contact with hazardous chemicals: Yes/No

If "yes," name the chemicals if you know them:_____
_____
_____

3. Have you ever worked with any of the materials, or under any of the conditions, listed below:

a. Asbestos: Yes/No

b. Silica (*e.g.*, in sandblasting): Yes/No

c. Tungsten/cobalt (e.g., grinding or welding this material): Yes/No

d. Beryllium: Yes/No

e. Aluminum: Yes/No

f. Coal (for example, mining): Yes/No

g. Iron: Yes/No

h. Tin: Yes/No

i. Dusty environments: Yes/No

j. Any other hazardous exposures: Yes/No

If "yes," describe these exposures:_____
_____
_____

4. List any second jobs or side businesses you have:_____
_____

5. List your previous occupations:_____
_____

6. List your current and previous hobbies:_____
_____

7. Have you been in the military services? Yes/No

If "yes," were you exposed to biological or chemical agents (either in training or combat): Yes/No

8. Have you ever worked on a HAZMAT team? Yes/No

9. Other than medications for breathing and lung problems, heart trouble, blood pressure, and seizures mentioned earlier in this questionnaire, are you taking any other medications for any reason (including over-the-counter

medications): Yes/No

If "yes," name the medications if you know them:_____

10. Will you be using any of the following items with your respirator(s)?

a. HEPA Filters: Yes/No

b. Canisters (for example, gas masks): Yes/No

c. Cartridges: Yes/No

11. How often are you expected to use the respirator(s) (circle "yes" or "no" for all answers that apply to you)?:

a. Escape only (no rescue): Yes/No

b. Emergency rescue only: Yes/No

c. Less than 5 hours *per week:* Yes/No

d. Less than 2 hours *per day:* Yes/No

e. 2 to 4 hours per day: Yes/No

f. Over 4 hours per day: Yes/No

12. During the period you are using the respirator(s), is your work effort:

a. *Light* (less than 200 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift:_____hrs._____mins.

Examples of a light work effort are *sitting* while writing, typing, drafting, or performing light assembly work; or *standing* while operating a drill press (1-3 lbs.) or controlling machines.

b. *Moderate* (200 to 350 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift:_____hrs._____mins.

Examples of moderate work effort are *sitting* while nailing or filing; *driving* a truck or bus in urban traffic; *standing* while drilling, nailing, performing assembly work, or transferring a moderate load (about 35 lbs.) at trunk level; *walking* on a level surface about 2 mph or down a 5-degree grade about 3 mph; or *pushing* a wheelbarrow with a heavy load (about 100 lbs.) on a level surface. c. *Heavy* (above 350 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift:_____hrs._____mins.

Examples of heavy work are *lifting* a heavy load (about 50 lbs.) from the floor to your waist or shoulder; working on a loading dock; *shoveling; standing* while bricklaying or chipping castings; *walking* up an 8-degree grade about 2 mph; climbing stairs with a heavy load (about 50 lbs.).

13. Will you be wearing protective clothing and/or equipment (other than the respirator) when you're using your respirator: Yes/No

If "yes," describe this protective clothing and/or equipment:_____
_____

14. Will you be working under hot conditions (temperature exceeding 77 deg. F): Yes/No

15. Will you be working under humid conditions: Yes/No

16. Describe the work you'll be doing while you're using your respirator(s):
_____
_____

17. Describe any special or hazardous conditions you might encounter when you're using your respirator(s) (for example, confined spaces, life-threatening gases):
_____
_____

18. Provide the following information, if you know it, for each toxic substance that you'll be exposed to when you're using your respirator(s):

Name of the first toxic substance:_____
Estimated maximum exposure level per shift:_____
Duration of exposure per shift:_____
Name of the second toxic substance:_____
Estimated maximum exposure level per shift:_____
Duration of exposure per shift:_____
Name of the third toxic substance:_____
Estimated maximum exposure level per shift:_____
Duration of exposure per shift:_____
The name of any other toxic substances that you'll be exposed to while using your respirator:
_____
_____
_____

19. Describe any special responsibilities you'll have while using your respirator(s) that may affect the safety and well-being of others (for example, rescue, security):
_____

[63 FR 1152, Jan. 8, 1998; 63 FR 20098, April 23, 1998; 76 FR 33607, June 8, 2011; 77 FR 46949, Aug. 7, 2012]

UNITED STATES
DEPARTMENT OF LABOR

Occupational Safety & Health Administration
200 Constitution Ave NW
Washington, DC 20210

MAJOR REQUIREMENTS OF OSHA'S RESPIRATORY PROTECTION STANDARD 29 CFR 1910.134

OSHA Office of Training and Education
Rev. December 2006

MAJOR REQUIREMENTS OF 29 CFR 1910.134

Introduction

- This standard applies to General Industry (Part 1910), Shipyards (Part 1915), Marine Terminals (Part 1917), Longshoring (Part 1918), and Construction (Part 1926).

(a) Permissible Practice

- Paragraph (a)(1) establishes OSHA's **hierarchy of controls** by requiring the use of **feasible engineering controls** as the primary means to control air contaminants. Respirators are required when "effective engineering controls are not feasible, or while they are being instituted."

- Paragraph (a)(2) requires employers to provide employees with respirators that are "applicable and suitable" for the purpose intended "when such equipment is necessary to protect the health of the employee."

(b) Definitions

This paragraph contains definitions of important terms used in the regulatory text.

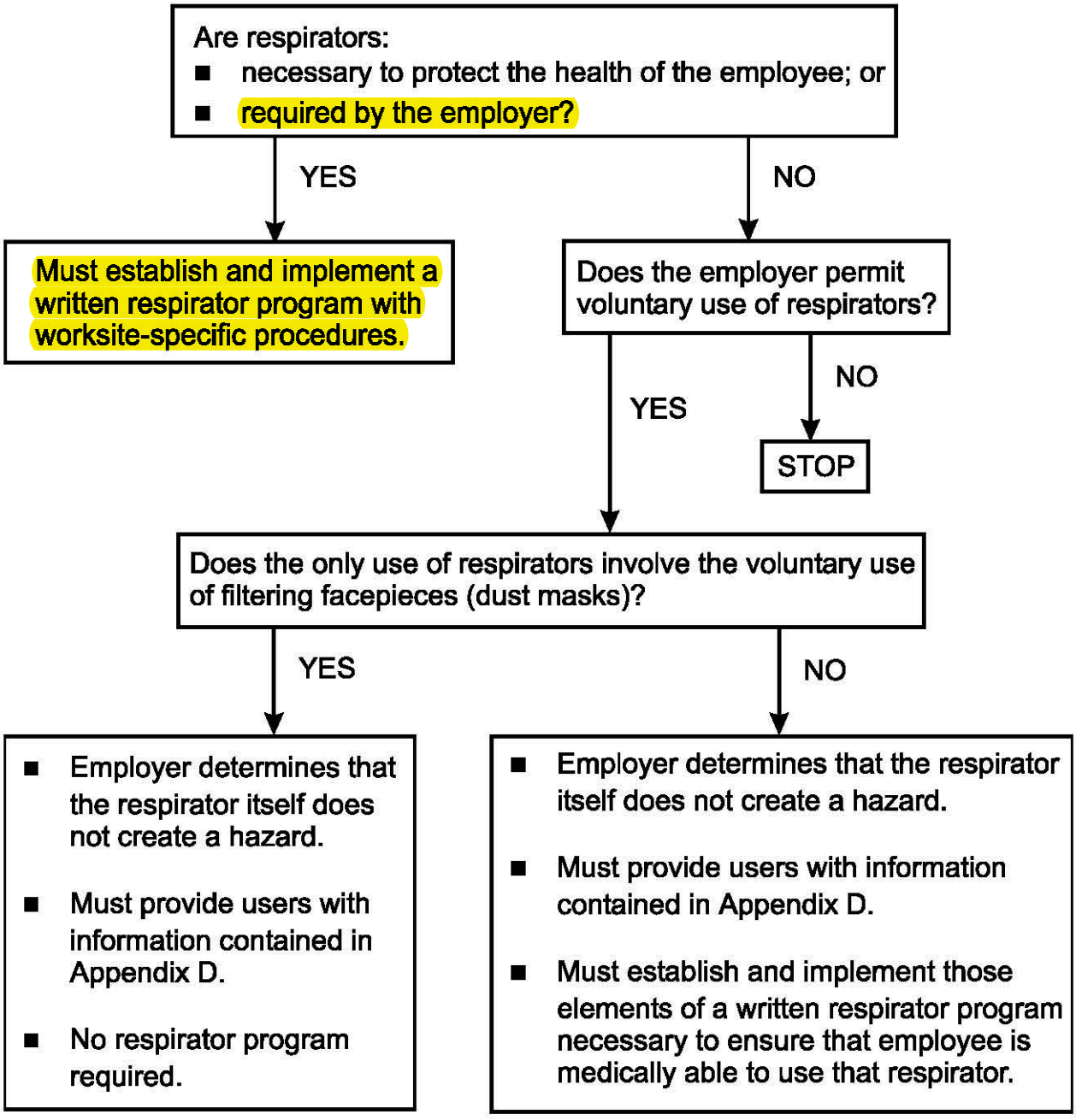
(c) Respiratory Protection Program

- Must designate a **qualified program administrator** to oversee the program.

- Must provide respirators, training, and medical evaluations **at no cost to the employee**.

- OSHA has prepared a *Small Entity Compliance Guide* that contains criteria for selection of a program administrator and a sample program.

Respirator-Use Requirements Flow Chart
29 CFR 1910.134(c)



(d) Selection of Respirators

- Must select a respirator **certified by the National Institute for Occupational Safety and Health (NIOSH)** which must be used in compliance with the conditions of its certification.

- Must identify and evaluate the respiratory hazards in the workplace, including a reasonable estimate of employee exposures and identification of the contaminant's chemical state and physical form.

- Where exposure cannot be identified or reasonably estimated, the atmosphere shall be considered immediately dangerous to life or health (IDLH).

- Respirators for IDLH atmospheres:
  - Approved respirators:
    - full facepiece pressure demand self-contained breathing apparatus (SCBA) certified by NIOSH for a minimum service life of thirty minutes, or
    - combination full facepiece pressure demand supplied-air respirator (SAR) with auxiliary self-contained air supply.
  - All **oxygen-deficient atmospheres (less than 19.5% O_2 by volume)** shall be considered IDLH.

    Exception: If the employer can demonstrate that, under all foreseeable conditions, oxygen levels in the work area can be maintained within the ranges specified in Table II (i.e., between 19.5% and a lower value that corresponds to an altitude-adjusted oxygen partial pressure equivalent to 16% oxygen at sea level), then *any* atmosphere-supplying respirator may be used.

- Respirators for non-IDLH atmospheres:
  - Employers must use the **assigned protection factors (APFs)** listed in Table 1 to select a respirator that meets or exceeds the required level of employee protection.
    - When using a combination respirator (e.g., airline respirators with an air-purifying filter), employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.
  - Must select a respirator for employee use that maintains the employee's exposure to the hazardous substance, when measured outside the respirator, at or below the **maximum use concentration (MUC)**.
    - Must not apply MUCs to conditions that are IDLH; instead must use respirators listed for IDLH conditions in paragraph (d)(2) of this standard.
    - When the calculated MUC exceeds the IDLH level or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.
    - The respirator selected shall be appropriate for the chemical state and physical form of the contaminant.

- For protection against gases and vapors, the employer shall provide:
  - an atmosphere-supplying respirator, or
  - an air-purifying respirator, provided that:
    - the respirator is equipped with an **end-of-service-life indicator (ESLI)** certified by NIOSH for the contaminant; or
    - if there is no ESLI appropriate for conditions of the employer's workplace, the employer implements a **change schedule** for canisters and cartridges that will ensure that they are changed before the end of their service life and describes in the respirator program the information and data relied upon and basis for the change schedule and reliance on the data.
- For protection against particulates, the employer shall provide:
  - an atmosphere-supplying respirator; or
  - an air-purifying respirator equipped with high efficiency particulate air (HEPA) filters certified by NIOSH under 30 CFR Part 11 or with filters certified for particulates under 42 CFR Part 84; or
  - an air-purifying respirator equipped with any filter certified for particulates by NIOSH for contaminants consisting primarily of particles with mass median aerodynamic diameters of at least 2 micrometers.

(e) Medical Evaluation

- Must provide a medical evaluation to determine employee's ability to use a respirator, **before fit testing and use**.

- Must identify a **physician or other licensed health care professional (PLHCP)** to perform medical evaluations using a medical questionnaire or an initial medical examination that obtains the same information as the medical questionnaire (information required is contained in mandatory Appendix C).

- Must obtain a **written recommendation** regarding the employee's ability to use the respirator from the PLHCP.

- Additional medical evaluations are required under certain circumstances, e.g.:
  - employee reports medical signs or symptoms related to ability to use respirator;
  - PLHCP, program administrator, or supervisor recommends reevaluation;
  - information from the respirator program, including observations made during fit testing and program evaluation, indicates a need; or
  - change occurs in workplace conditions that may substantially increase the physiological burden on an employee.

- Annual review of medical status is not required.

(f) Fit Testing

- All employees using a **negative or positive pressure tight-fitting facepiece** respirator must pass an appropriate **qualitative fit test (QLFT**) or **quantitative fit test (QNFT).**

- Fit testing is required prior to initial use, whenever a different respirator facepiece is used, and **at least annually thereafter**. An additional fit test is required whenever the employee reports, or the employer or PLHCP makes visual observations of, changes in the employee's physical condition that could affect respirator fit (e.g., facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight).

- The fit test shall be administered using an OSHA-accepted QLFT or QNFT protocol, as contained in mandatory Appendix A.
  - QLFT Protocols:
    - Isoamyl acetate
    - Saccharin
    - Bitrex
    - Irritant smoke
  - QNFT Protocols:
    - Generated Aerosol (corn oil, salt, DEHP)
    - Condensation Nuclei Counter (PortaCount)
    - Controlled Negative Pressure (Dynatech FitTester 3000)
    - Controlled Negative Pressure (CNP) REDON

- QLFT may only be used to fit test negative pressure air-purifying respirators (APRs) that must achieve a fit factor of 100 or less.

- If the fit factor determined through QNFT is ≥100 for tight-fitting half facepieces, or ≥500 for tight-fitting full facepieces, the QNFT has been passed with that respirator.

Note: If a particular OSHA standard (e.g., 29 CFR 1910.1001 Asbestos) requires the use of a full facepiece APR capable of providing protection in concentrations up to 50 times the Permissible Exposure Limit (PEL), this respirator must be QNFT. This is because a protection factor of 50 (50 X PEL) multiplied by a standard safety factor of 10 is equivalent to a fit factor of 500.

The safety factor of 10 is used because protection factors in the workplace tend to be much lower than the fit factors achieved during fit testing. The use of a safety factor is a standard practice supported by most experts to offset this limitation. This is discussed in the record at 63 FR 1225.

(g) Use of Respirators

- Tight-fitting respirators shall not be worn by employees who have facial hair or any condition that interferes with the face-to-facepiece seal or valve function.

- Personal protective equipment shall be worn in such a manner that does not interfere with the seal of the facepiece to the face of the user.

- Employees shall perform a user seal check **each time they put on a tight-fitting respirator** using the procedures in mandatory Appendix B-1 or equally effective manufacturer's procedures.

- Procedures for respirator use in IDLH atmospheres are stated. In addition to these requirements, interior structural firefighting requires the use of SCBAs and a protective practice known as "2-in/2-out" — at least two employees must enter and remain in visual or voice contact with one another at all times, and at least two employees must be located outside. (Note that this is not meant to preclude firefighters from performing emergency rescue activities before an entire team has assembled.)

(h) Maintenance and Care of Respirators

Must clean and disinfect respirators using the procedures in Appendix B-2, or equally effective manufacturer's procedures at the following intervals:

- as often as necessary to maintain a sanitary condition for exclusive use respirators,
- before being worn by different individuals when issued to more than one employee, and
- after each use for emergency use respirators **and those used in fit testing and training**.

(i) Breathing Air Quality and Use

Compressed breathing air shall meet the requirements for Type 1-Grade D breathing air as described in ANSI/CGA *Commodity Specification for Air*, G-7.1-1989.

(j) Identification of Filters, Cartridges, and Canisters

- All filters, cartridges, and canisters used in the workplace must be labeled and color coded with the NIOSH approval label.
- The label must not be removed and must remain legible.

(k) Training and Information

- Must provide effective training to respirator users, including:
  - why the respirator is necessary and how improper fit, use, or maintenance can compromise the protective effect of the respirator
  - limitations and capabilities of the respirator
  - use in emergency situations
  - how to inspect, put on and remove, use and check the seals
  - procedures for maintenance and storage
  - recognition of medical signs and symptoms that may limit or prevent effective use
  - general requirements of this standard
- Training required prior to initial use, unless acceptable training has been provided by another employer within the past 12 months.
- **Retraining required annually** and when:
  - workplace conditions change,
  - new types of respirator are used, or
  - inadequacies in the employee's knowledge or use indicates need.

- The basic advisory information in Appendix D shall be provided to employees who wear respirators when their use is not required.

(l) Program Evaluation

Employer must conduct evaluations of the workplace as necessary to ensure proper implementation of the program, and consult with employees to ensure proper use.

(m) Recordkeeping

- Records of medical evaluations must be retained and made available per 29 CFR 1910.1020.
- A record of fit tests must be established and retained until the next fit test.
- A written copy of the current program must be retained.

Plaintiff's Exhibit 474

- **Standard Number:** 1910.134

OSHA requirements are set by statute, standards and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules. Also, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at https://www.osha.gov.

December 20, 2017

Mr. John Boren
3633 Wareham Drive
Thompsons Station, TN 37179

Dear Mr. Boren:

Thank you for your letter to the Occupational Safety and Health Administration (OSHA). Your letter has been referred to the Directorate of Enforcement Programs for an answer to your question. Your letter requested clarification of OSHA's Respiratory Protection Standard, 29 CFR 1910.134, pertaining to the voluntary use of surgical masks. This letter constitutes OSHA's interpretation only of the requirements discussed herein, and may not be applicable to any questions not delineated within your original correspondence. Your paraphrased question and our response are below.

Question: Is it permissible to allow surgical masks to be worn on a voluntary basis when respiratory protection is not required to meet any OSHA standards? And if so, is it permissible for employers to provide surgical masks for voluntary use?

Response: Yes. The employer may allow the voluntary use of surgical masks even where an exposure assessment shows respirator use is not required and the employer may provide surgical masks for voluntary use. However, surgical masks may not be used in lieu of required respiratory protection. Surgical masks are not considered respirators by OSHA and, as such, are not covered by 29 CFR 1910.134. They are fluid resistant, disposable, and loose-fitting protection that create a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. They are commonly used in health care settings for the protection of the patient and they are also often used to prevent splashes from contacting the face of the wearer. However, surgical masks do not seal tightly to the wearer's face, nor do they provide a reliable level of protection from inhaling smaller airborne particles.

If the hazard to which your employees are exposed to is a combination of splashes and respirable contaminants, your company may want to consider NIOSH approved surgical N95 respirators which also are cleared by the Food and Drug Administration (FDA) for use as a surgical mask. Surgical N95s are filtering facepiece respirators equipped with spray- or splash-resistant facemask material on the outside to protect the wearer from splashes. Regardless of which type is used, the employees should be informed on the different varieties and their unique set of cautions, limitations, and restrictions of use. This information will facilitate employee involvement in the respirator program and/or the overall safety and health program.

For more information on surgical masks and surgical respirators, please review the *Hospital Respiratory Protection Program Toolkit* at https://www.osha.gov/Publications/OSHA3767.pdf. OSHA also has a fact sheet that compares

respirators and surgical masks titled Respiratory Infection Control: Respirators Versus Surgical Masks that is available at https://www.osha.gov/Publications/respirators-vs-surgicalmasks-factsheet.html.

Please be aware that the Tennessee Department of Labor and Workforce Development operates its own occupational safety and health program under an OSHA-approved State Plan. The Tennessee Occupational Safety and Health Administration (TOSHA) adopts and enforces standards and investigates safety and health concerns in workplaces throughout the state. State Plans are required to have standards and an enforcement program that are “at least as effective” as OSHA’s, but may have different or additional requirements. Please contact TOSHA directly at the address below, for further information and to discuss your specific compliance issue:

Tennessee Department of Labor and Workforce Development

220 French Landing Drive
Nashville, Tennessee
Telephone: (615) 741-2793
https://www.tn.gov/workforce/employees/safety-health/tosha.html

Thank you for your interest in occupational safety and health. We hope you find this information helpful. OSHA’s requirements are set by statute, standards, and regulations. Our letters of interpretation do not create new or additional requirements but rather explain these requirements and how they apply to particular circumstances. This letter constitutes OSHA’s interpretation of the requirements discussed. From time to time, letters are affected when the agency updates a standard, a legal decision impacts a standard, or changes in technology affect the interpretation. To assure that you are using the correct information and guidance, please consult OSHA’s website at http://www.osha.gov. If you have further questions, please feel free to contact the Office of Health Enforcement at (202) 693-2190.

Sincerely,

Thomas Galassi, Director
Directorate of Enforcement Programs

UNITED STATES
DEPARTMENT OF LABOR

Occupational Safety & Health Administration
200 Constitution Ave NW
Washington, DC 20210
800-321-6742 (OSHA)
TTY
www.OSHA.gov

FEDERAL GOVERNMENT

White House

Severe Storm and Flood Recovery Assistance

Disaster Recovery Assistance

DisasterAssistance.gov

Plaintiff's Exhibit 475

Carbon Dioxide
Health Hazard Information Sheet

What is carbon dioxide?

Carbon dioxide (CO_2) is a colorless, odorless, non-flammable gas that naturally occurs in the atmosphere. CO_2 is produced by body metabolism and is a normal component of exhaled breath. It also results from the burning of fossil fuels and natural sources such as volcanic eruptions. CO_2 levels in outdoor air typically range from 300 to 400 ppm (0.03% to 0.04%) but can be as high as 600-900 ppm in metropolitan areas. Although it is most commonly present as a gas, CO_2 can also exist in a solid (dry ice) form.

How are FSIS employees exposed to carbon dioxide?

The most common exposure to CO_2 for FSIS employees results from the off-gassing of CO_2 gas from the use of dry ice for chilling and packing product. Dry ice is also sometimes blended with meat product. CO_2 levels directly next to an open bin of dry ice can be as high as 11,000 to 13,000 ppm. When dry ice is used in rooms without adequate ventilation CO_2 has been measured as high as 25,000 to 30,000 ppm. However, levels at poultry plant inspection stations range from about 900 to 3,500 ppm (depending on how close the inspection station is to the dry ice use). In a few cases elevated levels, in excess of 5,000 ppm have been found at inspection stations.

CO_2 gas is also used to euthanize both poultry and swine. This process is typically fully contained and CO_2 is vented to the atmosphere (outside the building). In some cases, compressed CO_2 gas is added to plant water (eg. chillers) to make carbonic acid for pH regulation. CO_2 is denser than air and can collect in high concentrations in open pits, low lying areas and confined spaces where it can displace oxygen creating a serious health hazard.

What are the health effects of carbon dioxide?

CO_2 is considered to be minimally toxic by inhalation. The primary health effects caused by CO_2 are the result of its behavior as a simple asphyxiant. A simple asphyxiant is a gas which reduces or displaces the normal oxygen in breathing air.

Symptoms of mild CO_2 exposure may include headache and drowsiness. At higher levels, rapid breathing, confusion, increased cardiac output, elevated blood pressure and increased arrhythmias may occur.

Breathing oxygen depleted air caused by extreme CO_2 concentrations can lead to death by suffocation.

What are the symptoms of different levels of exposure?

5,000 ppm (0.5%)	OSHA Permissible Exposure Limit (PEL) and ACGIH Threshold Limit Value (TLV) for 8-hour exposure

10,000 ppm (1.0%)	Typically no effects, possible drowsiness
15,000 ppm (1.5%)	Mild respiratory stimulation for some people
30,000 ppm (3.0%)	Moderate respiratory stimulation, increased heart rate and blood pressure, ACGIH TLV-Short Term
40,000 ppm (4.0%)	Immediately Dangerous to Life or Health (IDLH)
50,000 ppm (5.0%)	Strong respiratory stimulation, dizziness, confusion, headache, shortness of breath
80,000 ppm (8.0%)	Dimmed sight, sweating, tremor, unconsciousness, and possible death

The response to CO2 inhalation various greatly even in healthy individuals. The seriousness of the symptoms is dependent on the concentration of CO2 and the length of time a person is exposed. Since CO2 is odorless and does not cause irritation, it is considered to have poor warning properties. Fortunately, conditions from low to moderate exposures are generally reversible when a person is removed from a high CO2 environment.

Another health hazard caused by CO2 is frostbite by contact with solid CO2 (dry ice) and vapors off-gassing from dry ice. Precautions should be taken to prevent direct skin and eye contact with dry ice or with vessels/bins containing dry ice. Similar effects may occur from compressed CO2 gas as it is being released from a cylinder if it comes in contact with the skin or eyes. CO2 gas at room temperature will not injure the skin or eyes.

What OSHA standards and exposure guidelines apply?

OSHA has established a Permissible Exposure Limit (PEL) for CO2 of 5,000 parts per million (ppm) (0.5% CO2 in air) averaged over an 8-hour work day (time-weighted average or TWA.) The American Conference of Governmental Industrial Hygienists (ACGIH) recommends an 8-hour TWA Threshold Limit Value (TLV) of 5,000 ppm and a Ceiling exposure limit (not to be exceeded) of 30,000 ppm for a 10-minute period. A value of 40,000 is considered immediately dangerous to life and health (IDLH value).

The TLVs are intended to minimize the potential for asphyxiation and undue metabolic stress. The ACGIH TLV supporting document states that: “Based on the long-term exposure studies, even though the majority of references are concerned with studies on physically fit males in confined spaces, a TLV-TWA of 5,000 ppm, is recommended. This value provides a good margin of safety from asphyxiation and from undue metabolic stress provided normal amounts of oxygen are present in the inhaled air.” The TLV-STEL is based on short-term studies which showed that “concentrations of 27,600 to 39,500 ppm produced increased pulmonary ventilation rates. Therefore, a TLV-STEL of 30,000 ppm is considered appropriate.”

How are occupational exposures monitored or measured?

CO2 concentrations in air can be measured using detector tubes (for immediate short term samples) and passive indicator tubes or dosimeters (for longer TWA full or partial shift sampling). The primary OSHA method for the sampling and analysis of CO2 involves using a

gas sampling bag followed by gas chromatography or infrared spectrophotometry analysis. If you would like to arrange for CO2 monitoring at your workplace, please contact your district's Occupational Safety and Health Specialist.

What are the safety precautions protect for carbon dioxide?

Employees should receive training and be knowledgeable of the potential sources and symptoms of exposure to CO2.

If you are working near any sources of dry ice and develop any of the symptoms of exposure, move to an area of fresh air immediately, and report the incident to your supervisor. (Fresh air or oxygen is the primary remedy for CO2 exposure.

If you are pregnant consult with your supervisor and your physician about limiting exposure to CO2.

If CO2 is used to euthanize poultry or livestock ensure that you are aware of the location of the gas sources and emission vents, alarm signals and any special precautions for working in those areas.

Do not enter areas where CO2 levels exceed 20,000 ppm until ventilation has been provided to bring the concentration down to safe levels.

Do not stand directly next to open bins that contain dry ice or in vapors from these bins. Do not touch dry ice or a bin containing dry ice.

How should training for this Health Hazard Information Sheet be recorded?

Per requirements found in FSIS Directive 4791.1 Section IX, all occupational health and safety training is to be recorded using either AgLearn or FSIS form 3530-12. Training records are to include the topics covered, date, and employee name. The Agency is to retain all training records for a minimum of five years."

Resources

For more information, see the OSHA website:
https://www.osha.gov/dts/chemicalsampling/data/CH_225400.html

About the ESHG

The FSIS Environmental Safety and Health Group (ESHG) is devoted to providing a safe and healthful work environment for FSIS employees. More information on safety topics can be found on the intranet site http://www.tinyurl.com/FSIS-ESHG or by email askemployeesafety@fsis.usda.gov

Plaintiff's Exhibit 476

vox.com

This is why flying on a plane makes you feel terrible

Joseph Stromberg

6-8 minutes

Do you feel inexplicably crappy — tired, dehydrated, and headachy — every time you fly?

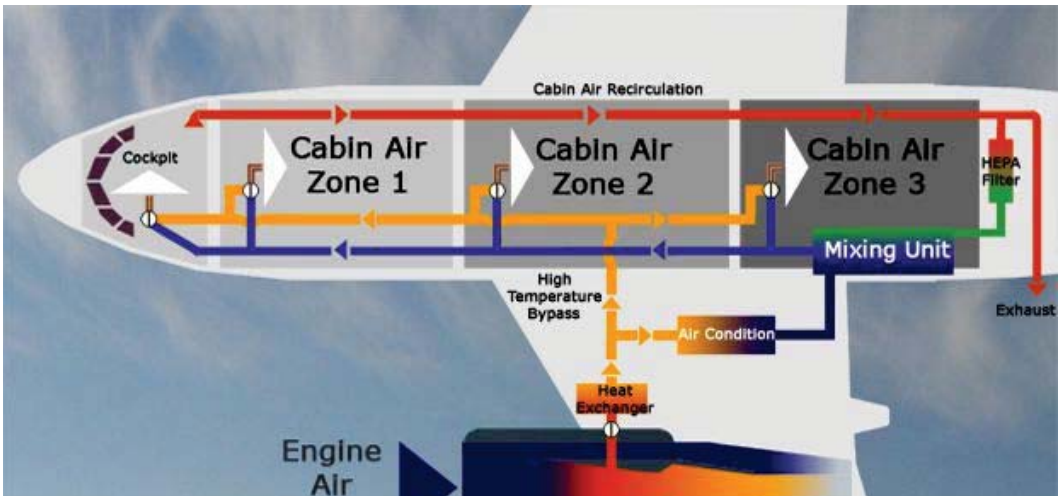
It's not your imagination. People talk a lot about the many awful aspects of flying nowadays, but one that gets less attention is the way that sitting in a small, pressurized metal tube at 35,000 feet for several hours wreaks havoc on your body.

"Anytime you fly, you're exposing yourself to a different environment than your body is used to," says Jeffrey Sventek, director of the Aerospace Medical Association and a longtime aerospace physiologist for the Air Force.

For some people, this environment — with lower oxygen levels than the ground, extremely little humidity, and sudden changes in air pressure — can cause a bunch of negative symptoms. This is how flying can make you feel terrible.

Planes have lower oxygen levels

As a plane flies, air that flows through the engine gets sucked in, compressed, cooled, filtered, and pumped into the cabin. If this didn't happen, everyone inside the plane would die, as the low air pressure at the elevations planes fly (typically 35,000 feet or so) means there isn't enough oxygen present for your body to function.



(Lufthansa)

Still, the amount of air pumped inside doesn't result in quite as much oxygen as you'd normally breathe at sea level. "The cabin is only pressurized to simulate an elevation of 6,000 to 8,000 feet on modern jets," says Brent Blue, a doctor and longtime pilot. In other words, to your body, flying is like sitting on a 6,000 to 8,000 foot mountain for several hours. As Blue says, "that's a significant difference for people who live at sea level, and aren't used to it."

For people with conditions — like heart or lung disease — that cause them to have special oxygen requirements, this is a big deal, and means they might need to fly with an oxygen concentrator, or not fly at all. But even for healthy people who are used to the abundant levels of oxygen present at sea level, it can have an effect.

"If you're flying for six hours and dropping your blood's oxygen saturation by five or ten percent, the fatigue factor is significant," Blue says. Even if they don't cause fatigue, reduced oxygen levels can also make your thinking a bit less sharp.

What's more, other aspects of the flying environment exacerbate this effect. Sitting for extended periods of time causes your blood to disproportionately pool in your thighs and feet, which means your body is less efficient at circulating and oxygenating the blood, and your brain gets even less oxygen.

Theoretically, planes could be somewhat more heavily pressurized to eliminate this effect. Federal regulations only require them to be pressurized to 8,000 feet, though some experts have criticized this as a substandard level.

Moreover, because planes are designed to be lightweight, they aren't nearly strong enough hold in enough air to simulate pressures that you'd find closer to sea level. (The new Boeing 787 Dreamliner, it's worth noting, will have slightly higher levels of air pressure and humidity.) Finally, intaking and pumping all this air uses fuel — so airlines are reluctant to pressurize any more than they need to.

What you can do to stay sharp

Though you can't solve this problem entirely, there are a few things you can do.

1) Don't drink alcohol. This makes the oxygen problem even worse, by interfering with your cells' metabolism so they too are less efficient at taking in oxygen. (This is also why

it's easier to get drunk on a plane, or for that matter, at high elevations on Earth.) Alcohol also exacerbates the problem of dehydration (more on that below).

2) Get up and walk around during flights, or do in-seat leg exercises if you don't want to deal with the dirty looks from flight attendants. This will improve circulation, and also reduce the chance of a blood clot in your legs.

3) Blue recommends taking an aspirin the day before and the day of flying, to further improve blood flow, and to wear support compression stockings, to reduce the amount of blood pooled in your legs.

How head colds make flying even worse

When a plane descends below 6,000 feet, this pressurization system is shut down. This causes the air pressure inside the plane to fluctuate as it matches the pressure outside the plane.

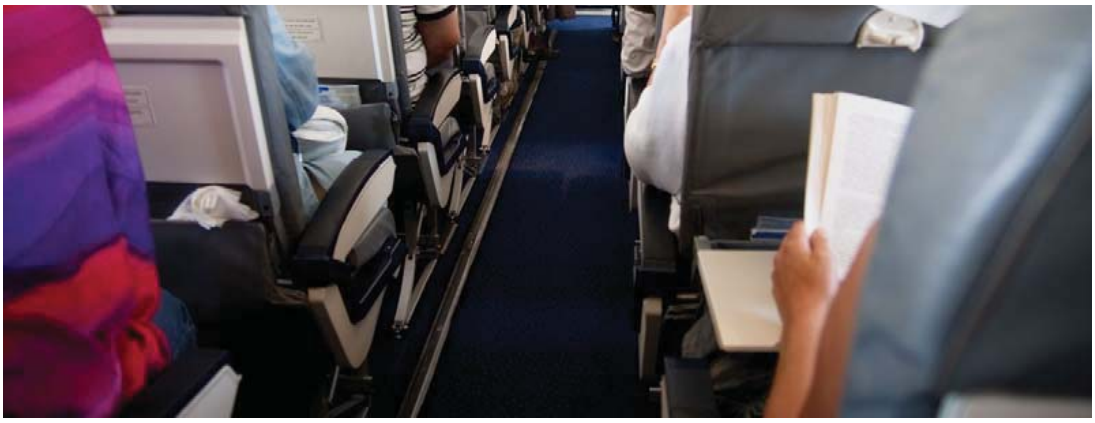
"As this happens, you'll notice your ears popping," Blue says. "That's a good thing — it's the opening and closing of the eustachian tubes, which connect the oral cavities to the middle ear." The air flowing through these tubes allows the pressure inside your middle ear to match the pressure outside your head.

If you have a head cold or sinus infection, however, these tubes won't open and close as easily — so the pressure won't be equalized as easily. This causes your eardrums to bulge inward, which hurts like hell. In extreme cases, this can even cause the eardrum to rupture.

(Merck Manuals)

If you're already very congested and scheduled to fly, Sventek recommends getting a prescription decongestant. Additionally, as your plane is descending, try to chew, yawn, or swallow repeatedly to get your eustachian tubes to open. If that doesn't work, you can try what scientists call the Valsalva maneuver: pinch your nose and forcefully exhale, which forces air into your middle ear.

Why planes make you dehydrated



(Shutterstock.com)

Because the air drawn into the plane to pressurize it comes from extremely dry, high-altitude regions of the atmosphere, the plane environment itself is drier than a desert. "About 30 minutes after takeoff, the relative humidity in the cabin drops down to nearly zero," Blue says. "This makes it relatively easy to get dehydrated, especially on long overseas trips.

The most obvious effect of this is dry mouth, as much of the moisture inside it is quickly evaporated into the surrounding air. But on longer flights, this effect — coupled with little water consumption — can cause your body as a whole to get dehydrated, leading to headaches and dizziness.

The key to avoiding this, Sventek says, is to hydrate *before* you fly, and keep drinking water when you're onboard. Bring a water bottle so you don't need to rely on flight attendants' refills. And don't drink alcohol or caffeinated beverages, because they act as diuretics and dehydrate you further.

Further reading: The Aerospace Medical Association has a number of detailed publications on the health effects of flying.

Rachel Orritt[1], Pippa Powell[1] and Isabel Saraiva[1], together with the European Industrial Gases Association[2]

Rachel.orritt@europeanlung.org

@EuropeanLung

Review

Why is medical oxygen a challenge for people travelling by air?

Cite as: Orritt R, Powell P, Saraiva I. Why is medical oxygen a challenge for people travelling by air? *Breathe* 2019; 15: 182–189.

There are currently 3.5 million people in Europe who require medical oxygen, and as life expectancies increase, this figure is likely to grow. At the same time, air travel is becoming more accessible to a wider range of people, as costs of flights fall, and airlines and airports make improvements to the accessibility of their services.

People who need medical oxygen to fly experience a wide range of difficulties when planning to travel by plane, and sometimes during or after the flight.

A European Commission Regulation (EC No 1107/2006) sets the standard for airlines when it comes to making air travel accessible, but healthcare professionals and oxygen providers can both help patients to navigate the various requirements for using medical oxygen when travelling.

In this review, we discuss the journey of the patient planning to travel by air, from initial consultation and fit-to-fly test, through to planning their air travel and oxygen supply, travelling, and arriving at their destination. We also highlight some common problems at each stage and suggest points for healthcare professionals to discuss with patients.

Introduction

Globally, the number of people using medical oxygen for respiratory conditions is increasing. There are 3.5 million people in Europe who need oxygen [1], and as people get older there will be more people living with chronic disease and more disabilities, meaning this a growing problem. In parallel, air travel is becoming more accessible for a greater range of people as the cost of tickets fall, and working and living styles change. However, there are still many barriers to air travel for passengers who need to use medical oxygen to fly, and a successful journey is contingent upon careful planning and support from both healthcare professionals and oxygen suppliers.

Difficulties associated with air travel for people with respiratory conditions is an equality issue, and is covered by the European Commission Regulation on the rights of disabled persons and persons with reduced mobility when travelling by air (EC No 1107/2006) [2].

This regulation states that:

- "Disabled persons and persons with reduced mobility, whether caused by disability, age or any other factor, should have opportunities for air travel comparable to those of other citizens"

@ERSpublications

Airlines have a responsibility to provide equal access to passengers who require medical oxygen, but many barriers remain. Healthcare professionals and oxygen suppliers can help patients plan their journey and reduce the risk associated with air travel. http://bit.ly/30wkCU4

- "Disabled persons and persons with reduced mobility should therefore be accepted for carriage and not refused transport on the grounds of their disability or lack of mobility, except for reasons which are justified on the grounds of safety and prescribed by law"
- "Assistance to meet [disabled persons'] needs should be provided at the airport as well as on board aircraft … the persons concerned should receive this assistance without additional charge"
- "[Airline] charges should be adopted and applied in full transparency" [2]

As well as travelling for personal and professional reasons, respiratory patients are called upon as patient advocates or speakers to share their experiences at international conferences and events, helping to provide the patient perspective on key topics in respiratory medicine.

Although there are still some respiratory conditions that prevent people from travelling by plane (for example, infectious tuberculosis, untreated pneumothorax and major haemoptysis) most people who require medical oxygen are able to fly.

Many of these individuals will use supplementary oxygen on a full-time or *ad hoc* basis in their everyday lives, but may need to increase the flow rate they receive when travelling by plane due to the reduced oxygen pressure in the cabin of an aircraft. Others who do not require medical oxygen elsewhere may need to use it when travelling by plane.

Conditions commonly associated with use of medical oxygen for air travel include chronic obstructive pulmonary disease (COPD), restrictive and interstitial lung diseases, bronchiectasis, cystic fibrosis and severe asthma. However, any person with a respiratory condition that could cause them to experience difficulties at reduced ambient oxygen levels should use supplementary oxygen when travelling by aircraft.

The percentage oxygen on a plane travelling around 2440 m is equivalent to 15.1% oxygen at sea level [3]. When considering the risk that the reduced partial pressure of oxygen in a travelling aircraft presents, it is useful to refer to the oxygen–haemoglobin dissociation curve. This curve shows the relationship between oxygen saturation of the haemoglobin molecules in the blood and partial pressure of oxygen (figure 1). Due to the sigmoidal shape of this curve, oxygen saturation in a healthy person only drops by about 10%, a decrease that is typically well tolerated [4]. However, in people with existing respiratory difficulties, there is a risk of hypoxia.

Despite commitments made by airlines to provide an equal service to all passengers including those with disabilities, there are still numerous barriers to air travel for people who require supplementary oxygen to fly. One of the biggest hurdles for these individuals is related to bringing their own portable oxygen concentrator

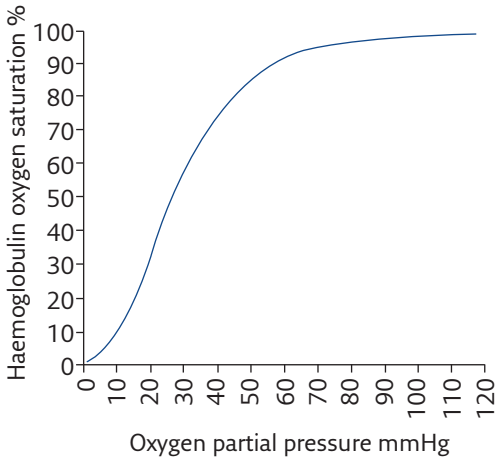


Figure 1 *Oxygen–haemoglobin dissociation curve.*

(POC) or oxygen cylinders. Airlines must adhere to strict regulations concerning use of portable electric devices and transport of dangerous goods. Due to the relative rarity of airline passengers with respiratory difficulties, airlines have historically been slow to consider the needs of these passengers and agree upon a standardised process and set of requirements.

The European Lung Foundation (ELF) started to work on the issue of air travel for people with oxygen in 2012, and have worked together with the European Federation of Asthma and Airways Diseases Patients (EFA) on the issue ever since [5, 6]. In 2016, ELF conducted a survey to ask people with respiratory conditions and their carers about the barriers they experienced when trying to travel by plane (unpublished survey and workshop by ELF). The results showed that the main obstacle was finding reliable information on airline oxygen policies (19%). Other obstacles experienced by at least 10% of survey participants included difficulties bringing their own POC, the perceived physical impact of travelling by plane, and other concerns related to logistics and planning.

Difficulties with air travel for these individuals are further compounded by stress at the airport and during the flight, extra exertion associated with travel to and around the airport and baggage handling, and immobility and cramped conditions on aircraft.

In this review article, we seek to outline the process through which a person with a respiratory condition can work with their healthcare team, oxygen supplier and airline to plan their journey, travel by plane, and arrange and use oxygen therapy at their destination. At each stage, potential barriers will be identified and examined, and recommendations for assisting a patient in overcoming these barriers will be provided. This article has been written together with EIGA (the European Industrial Gases Association), to provide a practical insight as to why there are so many challenges for people travelling with oxygen and how they can be overcome.

Planning

Timelines

Patients who might be required to use medical oxygen should plan their trip as far in advance as possible, and start the process for assessing and planning oxygen provision as soon as they know when they will be travelling. The time needed for organising air travel with medical oxygen depends on many different factors, so the absolute minimum time needed for planning will vary depending on the individual. As a guide, the process can take around 6 weeks after a patient has been advised that they are medically fit to fly.

Aside from the time taken for medical necessities (including the fit-to-fly test [7] and certificate provision) the factors that cause variation in timelines include: the destination of the patient, communication with the oxygen supplier at the final destination, and the support and requirements associated with the chosen airline.

Initial consultation

On first approaching their general practitioner or respiratory consultant about air travel, the patient should find out about the length of time needed for the fit-to-fly assessment and any other medical necessities, and begin planning their journey as soon as possible before they need to travel.

Patients should also be encouraged to consider other aspects of travelling with a lung condition, including:

- medical insurance
- additional oxygen equipment and batteries
- oxygen therapy at the destination
- compensation for additional expenses associated with travelling, if available from their healthcare provider
- vaccinations
- provision of emergency supplies of medication
- guidance about maximising respiratory performance on the flight (for example avoiding alcohol and sedatives, and strategies to reduce anxiety)

It may be useful to provide the patient with further written information about travelling by plane while using supplementary oxygen. ELF has produced a factsheet for this purpose, which is available in 18 languages and is written in clear, accessible language [8].

Researching airlines

The travelling patient or their carer should be encouraged to ask questions of the airlines they are considering travelling with in advance of booking their flight, to avoid unanticipated setbacks. They should ask about:

- the types of oxygen support devices that are permitted
- the rules surrounding batteries for portable electrical equipment
- any restriction the airline has per person for medical oxygen
- the process for boarding and disembarking
- the information required on their medical certificate
- any other paperwork that is needed

At this stage, it is also advisable to check for restrictions that apply to any other medical equipment or medicines the patient needs to travel with, for example continuous positive airway pressure (CPAP) machines, nebulisers and medicines.

The patient can then make an informed decision about which airline is best positioned to support them before and during their flight.

Fit-to-fly assessment

The assessment to determine if an individual is able to travel by plane and what flow rate of oxygen they will require is known as the fit-to-fly assessment or test. One of the most commonly discussed parts of this assessment is the hypoxic challenge test (HCT), in which an individual is actively monitored over a period of around 20 min while breathing levels of oxygen equivalent to those they will experience in a travelling aircraft.

When the arterial blood oxygen levels are expected to decline below 6.6 kPa while flying (the current recommended threshold for HCTs [9]), consideration of supplementary oxygen is advised. However, there has been mixed evidence for the predictive validity of the HCT in assessing the risk of adverse effects for people travelling by plane [9, 10]. Therefore, this assessment should be considered alongside other factors to determine what level of support, if any, an individual will need in the form of supplementary oxygen.

The patient's full medical history should be taken into account, alongside clinical considerations (including stability of their condition) and information about the patient's previous experiences of air travel. It may also be appropriate to conduct a walking test to further assess dyspnoea.

Finally, individual patient needs should be considered, including: any relevant comorbidities, patient age, general condition and the length of flight they would like to take. The person(s) conducting the assessment should also be confident that the patient or the patient's carer is be able to operate (or learn to operate) medical oxygen equipment safely.

The results of the fit-to-fly assessment should be shared with the home oxygen provider, and the oxygen provider the patient will use at their destination.

Assessments for children and infants

Assessment of infants should take into account prematurity. For infants that were born pre-term, medical oxygen should be considered, particularly if the infant is showing symptoms or has a peripheral capillary oxygen saturation (SpO_2) <85% [11].

For infants and children with chronic respiratory conditions, a full fit-to-fly assessment should be performed, and a specialist respiratory paediatrician should be consulted as part of this process.

Medical certificates

Medical certificates are requested by airlines to prove that the passenger is fit to fly, and to provide details that could be useful for the airline in facilitating the passenger's journey. The requirements for medical certificates differ between airlines, so it is advisable for the person travelling and their healthcare provider to discuss the specific requirements for the airline they will be most likely to travel with.

In addition to the information required by the airline, medical certificates should be specific about the passenger's condition, contain information about any accompanying person or carer, and indicate the required oxygen flow rate. Information about treatment and medication is not always necessary.

Booking flights

After choosing the airline that is best for their travel and medical needs, and speaking to the airline about their requirements, people who need oxygen when they are flying should book their flight as far in advance of the date of travel as possible. When booking, they may wish to consider choosing a seat that is adjacent to the aisle and in close proximity to the toilets. Some airlines will ask for additional information at this stage.

The patient should also share the details of their planned travel with their current oxygen supplier [12], including dates, travel itinerary, mode of travel and final destination. At this stage, their current oxygen supplier will be able to advise whether they will be able to provide oxygen for the duration of travel, or if another oxygen supplier should be sought.

Acquiring medical oxygen for travel

For those who already use medical oxygen, the next step involves contacting their current supplier about their travel arrangements, to plan or acquire additional oxygen for flying and a back-up battery if they are planning on using a POC.

For those who do not already use medical oxygen, their doctor or consultant should suggest an oxygen supplier to them. The new oxygen supplier will arrange for a technician to visit the individual in their own home and train them or their parent or carer so that they can operate the equipment safely and effectively. The technician should also conduct a risk assessment on their initial visit, and provide written instructions and details of an all-hours assistance phoneline.

This is also the time to plan and book oxygen for the destination, if needed. If the current oxygen supplier does not serve the destination country, they may be able to suggest another supplier that does.

The oxygen service provider at the destination is responsible for providing all the required training for the patient in using the equipment that they have provided prior to travel. They are also responsible for providing a back-up service in case of equipment failure.

Planning travel through the airport

It is advisable for the person travelling to contact airport assistance services at both the departure and arrival airports to arrange assistance prior to travel. These services may be able to provide transport around the terminal, wheelchairs and maps, or an in-person guide. They can also help to cater for any other disabilities.

Prior to travel, the journey through the airport should be planned, with particular attention given to where the assistance services are based, where power outlets are located in case of need to charge POCs, and where the toilets are. This process can also help the passenger to plan for the time needed to go through the airport and reach their gate safely and in time for their flight.

Travel to and from the airport should also be planned in advance to avoid unexpected issues.

Problems encountered during planning

Airline regulations with regards to the type of equipment that is permitted on their aircrafts, the use of equipment on board and during take-off and landing, and the paperwork required is highly variable. This is one of the main challenges for people who wish to travel by plane with medical oxygen. Even those that have flown before with similar requirements may find that each new flight presents its own challenges, particularly with respect to the requirements of a new airline.

Another variation is the cost. Some airlines will provide oxygen from the ring main or from their own cylinders free of charge, whereas others charge a lot of money for cylinders and will not allow passengers to bring their own.

A common problem for people who are seeking answers from airlines about travelling with medical oxygen is that they have difficulty finding the right person to speak to. Airline policies and charges are not

always clear on websites, and it can be difficult to find the right person to speak to when contacting airlines, particularly if the patient is prone to fatigue. Patients may find it useful to ask their carer or travelling partner to help them, and to make use of online resources such as ELF's airline index to find policies and contact details for the airline they are travelling with [13].

At the airport

Passengers travelling with medical oxygen should take all necessary paperwork relating to their oxygen devices or condition to the airport with them. This will include, but may not be limited to, physical copies of their medical certificate and information about their oxygen device (including instructions and warranty).

Using the assisted services at the airport can improve the experience of the individual, and reduce the fatigue and stress associated with plane travel. Once at the gate, the passenger should make themselves known to the airline employees, and ask to board first or last. They may also require assistance to board, particularly if access to the plane is *via* the stairs.

Problems encountered at the airport

It is important to note that not all operatives at the airport are trained to the same level. Some are employed by the airport, others by the airline, and some may be hired from a contracting agency (for example, security staff). Making contact with assisted services prior to arrival at the airport can increase the chances of receiving appropriate support.

Arriving at the airport can be a stressful experience, which may cause an exacerbation of symptoms. It may also lead to fatigue, which can decrease a person's ability to operate their device safely, and increase their respiratory rate, depleting their oxygen quickly. This stress can be mitigated by thorough planning and a timely arrival at the airport, but unexpected issues may still occur. Delays to flights will also deplete the oxygen supply if cylinders are being used, and this can cause additional stress.

Managing stress and anxiety should be part of the discussions between the person travelling and their healthcare professional prior to travel. Furthermore, a patient that is confident and practised in using and operating their POC will be better equipped to cope with any increases in anxiety at the airport.

During the flight

Types of oxygen that can be used on a plane

POCs concentrate oxygen from the ambient air to provide a supply of oxygen to the user. Therefore, so long as electrical power is not a limiting factor, they are unlimited in the supply of oxygen they provide. Although some aircrafts provide a power supply for passengers, it is strongly advised to carry a spare battery. POCs are the preferred device for many travelling by plane, and many models are accepted by airlines. Passengers usually use their own POC, and so benefit from the advantage of using familiar equipment. However, some airlines require them to be switched off for take-off and landing, because they are classed as a portable electronic device. For this reason, another supply of oxygen may also need to be used.

Cylinders are widely available, but subject to stricter requirements than POCs because of the perceived risks of transporting pressurised gases. They are not permitted on most airlines. However, some airlines will offer to provide cylinders, often for a cost. The passenger must ensure that they have enough oxygen to last them for the duration of the flight, taking into account flow rate and unanticipated delays.

The oxygen supplier can advise on a suitable oxygen supply, or more commonly, a POC for the flight, considering the passenger's required oxygen flow rate as specified in the results of their fit-to-fly assessment.

In some circumstances, passengers may use the ring main on the aircraft for their oxygen supply, which is fed by large cylinders in the aircraft hold. Using this method, there is no limit to the oxygen supply for the passenger, and the need for extra equipment in the cabin is removed. However, the flow rate may not be appropriate.

The length of the flight will determine the amount of supplementary oxygen required, and longer flights are associated with greater risk for passengers using supplementary oxygen because of the limited battery life and limitations in taking a backup battery.

Problems encountered during the flight

The main issue associated with using a POC for oxygen support while flying is battery life. Passengers should take the opportunity to recharge

Self-evaluation questions

1. Why might a person with a lung condition need medical oxygen on a plane, even if they do not require it in their daily lives?
2. What options does a patient have for oxygen supply when travelling by plane (oxygen devices, *etc.*)?
3. What additional considerations are there in a fit-to-fly assessment for an infant or child?
4. What should a patient do if they have a technical problem with their device but do not speak the languages spoken by their oxygen supplier's assistance phoneline operatives?

their device and any spare batteries before take-off, in the terminal if possible.

If the flight takes longer than expected, is delayed before take-off or landing, or passengers are held on the plane for any reason, the oxygen supply needs of the patient will increase. For this reason, individuals should carry a back-up battery for their POC or more oxygen than they anticipate using during the flight.

There is no possibility of contacting oxygen supplier assistance phonelines during the flight, and flight attendants typically do not have expertise in assisting patients using these devices. Any problems with the oxygen devices will have to be dealt with by the patient or their carer, which is why the manual or operating instructions should be kept accessible during the flight. It is also important to note that there is negligible risk to other passengers when the oxygen devices are used in accordance with the instructions.

It is useful for patients to remind flight attendants that they need to disembark first or last at the end of the flight.

At the destination

The same considerations apply at the destination airport as for the departure airport, including use of airport assistance services and planning onward travel.

The patient should have arranged for a delivery of medical oxygen at their destination, and they should make their way to the arranged drop-off point as soon as possible after their flight. If there are any problems with delivery, the passenger should make contact with the oxygen supplier that will be serving them at their destination.

Problems encountered at the destination

At the patient's destination, there may be a language barrier between the patient and the operatives from the oxygen supplier's assistance phoneline. These operatives will typically speak English and the language or languages of the country that their organisation operates in. If there is a language barrier and the patient has a technical problem with their device, they will be able to contact their home oxygen supplier for advice.

However, if the query pertains to something specific to the destination oxygen supplier (*e.g.* problems with delivery) this can present a problem. It is advised that the individual has access to a mobile device to be able to email the destination supplier so that online translation services can be used to facilitate communication. It is also helpful for the individual to ask their destination supplier about the languages that the assistance phoneline operatives can communicate in prior to travel.

Table 1 *Overview of recommendations for patients*

Stage	Recommendation
Planning air travel	Start to plan as far in advance of travel as possible
	Discuss other travel-related concerns with your doctor at an early stage (including medical insurance, other medications, oxygen therapy at destination, vaccinations, *etc.*)
	Research airlines to understand different travel policies and restrictions; use ELF's Airline Index to help you [13]
	Arrange a fit-to-fly assessment
	Ask the airline what information is required on the medical certificate and arrange for this to be produced
	When booking flights, choose an aisle seat that is close to the airplane door and toilets
	Share the travel itinerary with the oxygen provider
	Arrange oxygen supply for travel and at the destination
	Contact airport assistance services to plan travel through airports and avoid fatigue
At the airport	Take print outs of relevant paperwork with you, including medical certificate copies and instructions and warranty for oxygen equipment
	Use assistance services
	Make yourself known to airline employees at the gate, and ask to board first or last to avoid having to rush or queue
During the flight	Try to relax as much as possible once on the plane
	Keep the oxygen equipment instructions accessible in case they are needed
	Remind the flight attendant about disembarking first or last
At the destination	Use airport assistance services at the destination airport
	Make your way to the pre-arranged drop-off point for the destination oxygen equipment as soon as possible

Summary

For people who require medical oxygen, air travel can be a challenge. However, it is possible if planned carefully and in enough time. Table 1 gives an overview of recommendations discussed in this paper.

Doctors, oxygen suppliers and patients should proactively communicate with each other throughout the process. Although airlines have a responsibility under European Commission Regulations to provide equal access to passengers who require medical oxygen to fly, in reality barriers to air travel remain, many of which could be lessened by standardised procedures and requirements.

Affiliations

Rachel Orritt[1], Pippa Powell[1] and Isabel Saraiva[1], together with the European Industrial Gases Association[2]

[1]European Lung Foundation, Sheffield, UK. [2]European Industrial Gases Association AISBL, Brussels, Belgium.

Conflict of interest

R. Orritt is an employee of the European Lung Foundation. P. Powell is an employee of the European Lung Foundation. I. Saraiva is Chair of the European lung Foundation.

References

1. EFA. Air travel for patients requiring oxygen should be facilitated, not hindered. www.efanet.org/resources/library/2510-31press-release-world-copd-day-2014 Date last updated: July 27, 2015. Date last accessed: April 29, 2019.
2. Publications office of the European Union. Regulation (EC) No 1107/2006 of the European Parliament and of the Council of 5 July 2006 concerning the rights of disabled persons and persons with reduced mobility when travelling by air. https://eur-lex.europa.eu/eli/reg/2006/1107/oj Date last updated: August 15, 2006. Date last accessed: April 29, 2019.
3. Samuels MP. The effects of flight and altitude. *Arch Dis Child* 2004; 89: 448–455.
4. Geertsema C, Williams AB, Dzendrowskyj P, *et al.* Effect of commercial airline travel on oxygen saturation in athletes. *Br J Sports Med* 2008; 42: 877–881.
5. Brennan D, Palkonen S, Fink-Wagner AH, *et al.* Enabling air travel with oxygen in Europe. *Eur Respir J* 2014; 44: Suppl. 58, P1461.
6. EFA. Enabling air travel with medical oxygen. www.efanet.org/resources/42-library/campaign/2619-enabling-air-travel-with-medical-oxygen Date last updated: November 18, 2015. Date last accessed: April 30, 2019.
7. European Lung Foundation. Fit to fly? www.europeanlung.org/en/lung-disease-and-information/air-travel/fit-to-fly Date last updated: June 6, 2018. Date last accessed: April 30, 2019.
8. European Lung Foundation. Air travel when you have a lung condition. www.europeanlung.org/assets/files/en/publications/air-travel-web.pdf Date last updated: June 1, 2018. Date last accessed: April 30, 2019.
9. Patel S, Hastings RA, Lota HK, *et al.* Application of a predictive formula for hypoxic challenge testing in patients with interstitial lung disease. *Eur Respir J* 2018; 52: Suppl. 62, PA2912.
10. Isaac A, Noffsinger W, Singh B, *et al.* Hypoxic challenge testing in the UK and Australia and New Zealand. *Eur Respir J* 2018; 52: Suppl. 62, OA3776.
11. Udomittipong K, Stick SM, Verheggen M, *et al.* Pre-flight testing of preterm infants with neonatal lung disease: a retrospective review. *Thorax* 2006; 61: 343–347.
12. EIGA. Document 141/13 Planning Oxygen Supplies for Respiratory Patients when Travelling. www.eiga.eu/publications/eiga-documents/doc-14113-planning-oxygen-supplies-for-respiratory-patients-when-travelling/ Date last updated: 2014. Date last accessed: April 30, 2019.
13. European Lung Foundation. Airline index. www.europeanlung.org/en/lung-disease-and-information/air-travel/airline-index/ Date last updated: July 1, 2010. Date last accessed: July 18, 2019.

Suggested answers

1. The level of ambient oxygen in an aircraft travelling at altitude is significantly lower than at sea level.
2. POC, use of airline oxygen cannisters, use of "hold" oxygen on aircraft, bringing their own oxygen cannisters (the latter is very rarely permitted).
3. For infants, prematurity. For children and infants, a specialist respiratory paediatrician should be consulted.
4. They should call their home oxygen supplier's assistance phoneline.

Further reading

EIGA. Document 141/13 Planning Oxygen Supplies for Respiratory Patients when Travelling. www.eiga.eu/publications/eiga-documents/doc-14113-planning-oxygen-supplies-for-respiratory-patients-when-travelling/

A guide to organising medical oxygen supply for patients while travelling away from their home, and guidance that can be given to the patient about the safe use of medical oxygen on public transport and in public spaces.

European Lung Foundation. Air travel when you have a lung condition. www.europeanlung.org/assets/files/en/publications/air-travel-web.pdf

Information written in clear accessible language for people with a lung condition who are planning to travel. ELF factsheets are reviewed by patients and topic experts who are members of the European Respiratory Society.

Ergan B, Akgun M, Pacilli AMG, *et al.* Should I stay or should I go? COPD and air travel. *Eur Respir Rev* 2018; 27: 180030.

A recent review that evaluates potential risks of air travel for people with COPD and provides insight into planning safe air travel for these patients.

Plaintiff's Exhibit 478

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

LUCAS WALL,	:	
	:	
Plaintiff,	:	Case No. 6:21-cv-975-PGB-DCI
	:	
v.	:	District Judge Paul Byron
	:	
CENTERS FOR DISEASE CONTROL & PREVENTION *et al.*	:	Magistrate Judge Daniel Irick
	:	
Defendants.	:	

DECLARATION OF JEFFREY PENCE

I, Jeffrey Pence, declare as follows:

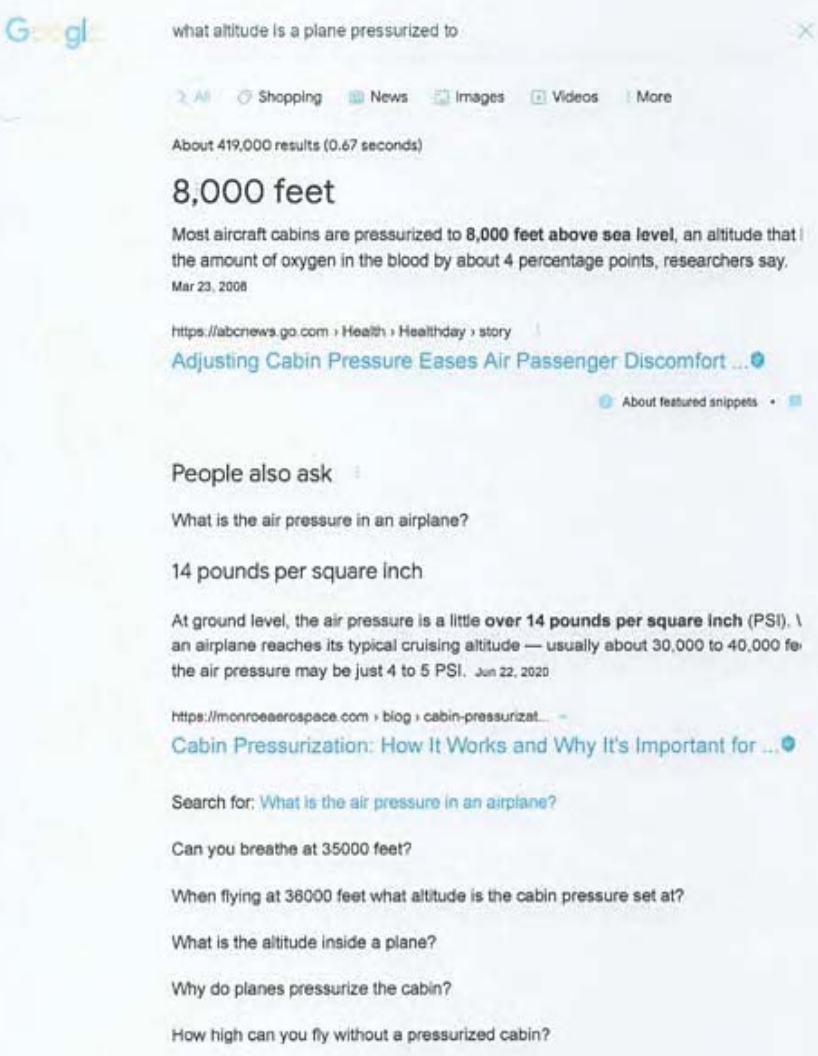
1. I am over the age of majority.
2. I could testify to the facts set out herein if called upon to do so via Zoom or other remote communications.
3. I reside at 26025 S. Cherry Hill Rd., Manhattan, IL 60442.
4. I make this declaration based on my personal knowledge to explain the dangers of wearing a mask/respirator (Personal Protective Equipment).
5. 29 CFR § 1910.134 governs respirators/masks and states that an oxygen deficient atmosphere is an area with an oxygen content below 19.5% by volume.
6. The pressurized atmosphere inside an aircraft is as if you were at an altitude of 8,000 feet. At that level the oxygen level is about 15.4%. Ex. A.

7. You cannot wear masks in this atmosphere because it can cause serious injury or death. This is also confirmed in the directions of a 3M N95 mask. Ex. B.
8. This is likely why the airlines are having customers who become violent or try to open the emergency exits at 35,000-plus feet. These people are experiencing hypoxemia due to oxygen deprivation from having their nose and mouth covered. Ex. C.

Pursuant to 28 USC 1746 I declare under penalty of perjury that the foregoing is true and correct to the best of my ability.

Executed Aug. 3, 2021.

/s/ Jeffrey Pence



Google

what altitude is a plane pressurized to

All Shopping News Images Videos More

About 419,000 results (0.67 seconds)

8,000 feet

Most aircraft cabins are pressurized to **8,000 feet above sea level**, an altitude that
the amount of oxygen in the blood by about 4 percentage points, researchers say.
Mar 23, 2008

https://abcnews.go.com › Health › Healthday › story

Adjusting Cabin Pressure Eases Air Passenger Discomfort ...

About featured snippets •

People also ask

What is the air pressure in an airplane?

14 pounds per square inch

At ground level, the air pressure is a little **over 14 pounds per square inch** (PSI). \
an airplane reaches its typical cruising altitude — usually about 30,000 to 40,000 fe
the air pressure may be just 4 to 5 PSI. Jun 22, 2020

https://monroeaerospace.com › blog › cabin-pressurizat...

Cabin Pressurization: How It Works and Why It's Important for ...

Search for: What is the air pressure in an airplane?

Can you breathe at 35000 feet?

When flying at 38000 feet what altitude is the cabin pressure set at?

What is the altitude inside a plane?

Why do planes pressurize the cabin?

How high can you fly without a pressurized cabin?

Exhibit A
Page 1 of 2

HYPOXICO
ALTITUDE TRAINING SYSTEMS

Hypoxico, Inc.
Altitude Training Systems

HYPOXICO ALTITUDE TO OXYGEN CHART

Altitude (Feet)	Altitude (Meters)	O2 Monitor Reading	Effective Oxygen Percentage	Similar Location
Sea Level	Sea Level	20.90%	20.90%	Hypoxico HQ - New York, NY
1,000'	304m	20.10%	20.10%	Tbilisi, Georgia (1,479' - 451m)
2,000'	609m	19.40%	19.40%	Canberra, Australia (1,984' - 605m)
3,000'	914m	18.60%	18.60%	Chamonix, France (3,264' - 995m)
4,000'	1219m	17.90%	17.90%	Salt Lake City, UT (4,226' - 1288m)
5,000'	1524m	17.30%	17.30%	Boulder, CO (5,430' - 1655m)
6,000'	1828m	16.60%	16.60%	Stanley, ID (6,253' - 1906m)
7,000'	2133m	16%	16%	Flagstaff, AZ (6,910' - 2106m)
8,000'	2438m	15.40%	15.40%	Aspen, CO (7,907' - 2410m)
9,000'	2743m	14.80%	14.80%	Bogata, Columbia (8,660' - 2640m)
10,000'	3048m	14.30%	14.30%	Leadville, CO (10,200' - 3109m)
11,000'	3352m	13.70%	13.70%	Cusco, Peru (11,152' - 3399m)
12,000'	3657m	13.20%	13.20%	La Paz, Bolivia (11,942' - 3640m)
13,000'	3962m	12.70%	12.70%	Yabuk Camp, Sikkim, India (12,467' - 3800m)
14,000'	4267m	12.30%	12.30%	Pikes Peak, CO (14,115' - 4302m)
15,000'	4572m	11.80%	11.80%	Mount Rainier, WA (14,411' - 4392m)
16,000'	4876m	11.40%	11.40%	Mount Blanc (15,777' - 4808m)
17,000'	5181m	11%	11%	Everest Base Camp (16,900 ft. - 5150m)
18,000'	5486m	10.50%	10.50%	Mount Elbrus (18,510' - 5642m)
19,000'	5791m	10.10%	10.10%	Mt. Kilimanjaro (19,341' - 5895m)
20,000'	6096m	9.70%	9.70%	Mt. Denali (20,310' - 6190m)
21,000'	6400m	9.40%	9.40%	Hypoxico Home Generator Max
22,000'	6705m	9%	9%	Ama Dablam (22,349' - 6812m)
23,000'	7010m	8.70%	8.70%	Aconcagua (22,841' - 6960m)
24,000'	7315m	8.40%	8.40%	K12, Pakistan (24,370' - 7428m)
25,000'	7620m	8.10%	8.10%	Chomo Lonzo, Himalayas (25,604' - 7804m)
26,000'	7924m	7.80%	7.80%	Annapurna (26,545' - 8091m)
27,000'	8229m	7.50%	7.50%	Cho Oyu (26,864 ft. - 8188m)
28,000'	8534m	7.20%	7.20%	K2 (28,251 ft. - 8611m)
29,000'	8839m	6.90%	6.90%	Mt. Everest (29,029 ft. - 8848m)
30,000'	9144m	6.30%	6.30%	Hypoxico K2 High Flow Max

Exhibit A
Page 2 of 2

Particulate Respirator N95

User Instructions
8210*Plus*/8210*Plus*MX/8210/
8210MX/07048/8110S

(EN) Particulate Respirator N95

User Instructions

IMPORTANT: Keep these *User Instructions* for reference.

(FR) Respirateur N95 contre les particules

Directives d'utilisation

IMPORTANT : Conserver ces *directives d'utilisation* à titre de référence.

(ES) Respirador para partículas N95

Instrucciones de uso

IMPORTANTE: Conserve estas *Instrucciones* para referencia futura.

(ZH) 粒狀物防護口罩, N95

使用說明

重要提示

使用前，使用者必須閱讀和瞭解本說明書。請保留此份使用說明以供參考

(MS) Partikulat Respirator, N95

Arahan Penggunaan

PENTING

Sila simpan *Arahan Penggunaan* ini bagi rujukan masa depan.

Exhibit B
Page 1 of [redacted]

98-0060-0097-4_4
34-8719-4197-6
34-8723-0284-9

Particulate Respirator N95

User Instructions
8210*Plus*/8210*Plus*MX/ 8210/8210MX/07048/8110S

⚠ WARNING

This respirator helps protect against certain particles. **Misuse may result in sickness or death.** For correct use, consult supervisor and these *User Instructions*, or call 3M in U.S.A., 1-800-247-3941. In Canada, call Technical Service at 1-800-267-4414. In Mexico, call 01-800-712-0646.

IMPORTANT

Before use, wearer must read and understand these *User Instructions*. Keep these instructions for reference.

Use For

Particles such as those from grinding, sanding, sweeping, sawing, bagging, or processing minerals, coal, iron ore, flour, metal, wood, pollen, and certain other substances. Liquid or non-oil based particles from sprays that do not also emit oil aerosols or vapors. Follow all applicable local regulations. For additional information on 3M use recommendations for this class of respirator please consult the 3M Respirator Selection Guide found on the Personal Safety web site at www.3M.com/respiratorselector or call 1-800-243-4630 in U.S.A. In Canada, call 1-800 267-4414.

Do Not Use For

Do not use for gases and vapors, oil aerosols, asbestos, or sandblasting; particulate concentrations that exceed either 10 times the occupational exposure limit or applicable government regulations, whichever is lower. In the United States, do not use when the U.S. Occupational Safety and Health Administration (OSHA) substance specific standards, such as those for arsenic, cadmium, lead in the construction industry, or 4,4'-methylene dianiline (MDA), specify other types of respiratory protection. This respirator does not supply oxygen.

Biological Particles

This respirator can help reduce inhalation exposures to certain airborne biological particles (e.g. mold, *Bacillus anthracis*, *Mycobacterium tuberculosis*, etc.) but cannot eliminate the risk of contracting infection, illness or disease. OSHA and other government agencies have not established safe exposure limits for these contaminants.

Use Instructions

1. Failure to follow all instructions and limitations on the use of this respirator and/or failure to wear this respirator during all times of exposure can reduce respirator effectiveness and **may result in sickness or death.**
2. In the U.S., before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the requirements of OSHA 29 CFR 1910.134, such as training, fit testing, medical evaluation, and applicable OSHA substance specific standards. In Canada, CSA standard Z94.4 requirements must be met and/or requirements of the applicable jurisdiction, as appropriate. Follow all applicable local regulations.
3. The particles which can be dangerous to your health include those so small that you cannot see them.
4. Leave the contaminated area immediately and contact supervisor if dizziness, irritation, or other distress occurs.
5. Store the respirator away from contaminated areas when not in use.
6. Inspect respirator before each use to ensure that it is in good operating condition. Examine all the respirator parts for signs of damage including the two headbands, attachment points, nose foam, and noseclip. The respirator should be disposed of immediately upon observation of damaged or missing parts. Filtering facepieces are to be inspected prior to each use to assure there are no holes in the breathing zone other than the punctures around staples and no damage has occurred. Enlarged holes resulting from ripped or torn filter material around staple punctures are considered damage. Immediately replace respirator if damaged. Staple perforations do not affect NIOSH approval (For 8110S only).
7. Conduct a user seal check before each use as specified in the Fitting Instructions section. **If you cannot achieve a proper seal, do not use the respirator.**
8. Dispose of used product in accordance with applicable regulations.

Use Limitations

1. This respirator does not supply oxygen. Do not use in atmospheres containing less than 19.5% oxygen.
2. Do not use when concentrations of contaminants are immediately dangerous to life and health, are unknown or when concentrations exceed 10 times the permissible exposure limit (PEL) or according to specific OSHA standards or applicable government regulations, whichever is lower.
3. Do not alter, wash, abuse or misuse this respirator.
4. Do not use with beards or other facial hair or other conditions that prevent a good seal between the face and the sealing surface of the respirator.
5. Respirators can help protect your lungs against certain airborne contaminants. They will not prevent entry through other routes such as the skin, which would require additional personal protective equipment (PPE).
6. This respirator is designed for occupational/professional use by adults who are properly trained in its use and limitations. This respirator is not designed to be used by children.

Exhibit B
page 2 of [redacted]

7. Individuals with a compromised respiratory system, such as asthma or emphysema, should consult a physician and must complete a medical evaluation prior to use.
8. When stored in accordance with temperature and humidity conditions specified below, the product may be used until the "use by" date specified on the packaging.

Storage Conditions and Shelf Life

Before use, store respirators in the original packaging away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals. When stored in accordance with temperature and humidity conditions specified below, the product may be used until the "use by" date specified on packaging. Always inspect product and conduct a user seal check before use as specified in the *User Instructions*. **If you cannot achieve a proper seal, do not use the respirator.**

End of Shelf Life
Use respirators before the "use by" date specified on packaging

Storage Temperature Range
-20°C (-4°F) to +30°C (+86°F).

Storage Maximum Relative Humidity
<80% RH

Time Use Limitation

If respirator becomes damaged, soiled or breathing becomes difficult, leave the contaminated area immediately and replace the respirator.

Fitting Instructions

Must be followed each time respirator is worn.

1. Prestretch top and bottom straps before placing respirator on the face (8210/8210MX only) (Fig. 1).
2. Cup the respirator in your hand, with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand (Fig. 2).
3. Position the respirator under your chin with the nosepiece up. Pull the top strap over your head resting it high at the top back of your head. Pull the bottom strap over your head and position it around the neck below the ears (Fig. 3).
4. Place your fingertips from both hands at the top of the metal nosepiece. Using two hands, mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece (Fig. 4).
   ⚠ Pinching the nosepiece using one hand may result in improper fit and less effective respirator performance. Use two hands.
5. Perform a User Seal Check prior to each wearing. To check the respirator-to-face seal, place both hands completely over the respirator and exhale sharply. Be careful not to disturb the position of the respirator. If air leaks around nose, readjust the nosepiece as described in step 4. If air leaks at the respirator edges, work the straps back along the sides of your head (Fig. 5). **If you CANNOT achieve a proper seal, DO NOT enter the contaminated area. See your supervisor.**


Fig. 1


Fig. 2


Fig. 3


Fig. 4


Fig. 5

Removal Instructions

See step 3 of *Fitting Instructions* and cup respirator in hand to maintain position on face. Pull bottom strap over head. Still holding respirator in position, pull top strap over head and remove respirator.

This respirator contains no components made from natural rubber latex.

Exhibit B
Page 3 of [redacted]

Symptoms

Hypoxemia

Causes

By Mayo Clinic Staff

Several factors are needed to continuously supply the cells and tissues in your body with oxygen:

- There must be enough oxygen in the air you are breathing
- Your lungs must be able to inhale the oxygen-containing air — and exhale carbon dioxide
- Your bloodstream must be able to circulate blood to your lungs, take up the oxygen and carry it throughout your body

A problem with any of these factors — for example, high altitude, asthma or heart disease — might result in hypoxemia, particularly under more extreme conditions, such as exercise or illness. When your blood oxygen falls below a certain level, you might experience shortness of breath, headache, and confusion or restlessness.

Common causes of hypoxemia include:

- Anemia
- ARDS (Acute respiratory distress syndrome)
- Asthma

Exhibit C
Page 1 of 3

- Pneumonia
- Pneumothorax (collapsed lung)
- Pulmonary edema (excess fluid in the lungs)
- Pulmonary embolism (blood clot in an artery in the lung)
- Pulmonary fibrosis (scarred and damaged lungs)
- Sleep apnea

Causes shown here are commonly associated with this symptom. Work with your doctor or other health care professional for an accurate diagnosis.

Definition When to see a doctor

Share Tweet

Dec. 01, 2018

Show references

Other Topics in Patient Care & Health Info

Diseases & Conditions A-Z | Symptoms A-Z | Tests & Procedures A-Z | Dr Su

Health Books | Healthy Living Program | Mayo Clinic Health Letter | Ma Ap

Exhibit C
Page 2 of 3

the Terms and Conditions and Privacy Policy linked below.

Exhibit C
Page 3 of 3

Plaintiffs' Exhibit 479

ice.gov

ICE, CBP seize more than 100,000 counterfeit surgical masks intended for hospital workers

3-4 minutes

December 9, 2020El Paso, TX, United StatesCOVID-19

EL PASO, Texas — More than 100,000 counterfeit 3M N95 surgical masks destined to be used by hospital workers were seized Dec. 7 by U.S. Immigration and Customs Enforcement's (ICE) Homeland Security Investigations (HSI) and U.S. Customs and Border Protection (CBP).

On Dec. 3, CBP officers at the Ysleta Cargo Facility initially intercepted the shipment of 100,080 3M N95 surgical masks with an MSRP of $600,480. The masks were in-transit at an El Paso bonded warehouse destined to a hospital on the East Coast.

ICE HSI special agents determined the masks were counterfeit after working with the National Intellectual Property Rights Coordination Center and 3M Company.

"The seizure of these counterfeit surgical masks not only ensures the health and safety of our frontline health care workers by preventing them from receiving inferior personal protective equipment, it also protects the integrity of the American economy. We will continue to aggressively investigate, arrest and prosecute criminal counterfeiters who show a total disregard for human life and take advantage of a relentless world pandemic for economic gain." said Erik P. Breitzke, acting special agent in charge of ICE HSI El Paso.

"HSI and CBP will continue to collaborate to prevent unauthorized and counterfeit products from getting to U.S. consumers to protect the health and safety of the American public and the American economy," said Ysleta Port

Director Arnoldo Gomez. “This large seizure of counterfeit surgical masks, destined for frontline medical workers, demonstrates the great collaborative effort between CBP and HSI. Counterfeit surgical masks pose a great risk to our medical community, and any individual who may use them.”

This shipment is in violation of Importation, Removal and Contrary to Law (19 U.S.C. 1595a(c)(2)(A)) and the Federal Food, Drug and Cosmetic Act. ICE HSI El Paso is investigating the seizure with assistance from CBP.

ICE HSI launched Operation Stolen Promise in April 2020 to protect U.S. consumers from the increasing and evolving threat posed by the pandemic. The operation involves various federal agencies, including CBP, the U.S. Department of Justice, U.S. Postal Inspection Service, U.S. Food and Drug Administration, the Internal Revenue Service, and multiple private sector partners, including Pfizer, 3M, Amazon and others.

Operation Stolen Promise combines ICE HSI’s expertise in global trade, financial fraud, international operations and cybercrime to investigate financial fraud schemes, the importation of prohibited pharmaceuticals and medical supplies, offending e-commerce schemes, and any other illicit criminal activities associated with the COVID-19 virus that may compromise legitimate trade, financial systems and/or endangers the public.

For more information or to report COVID fraud, visit the Operation Stolen Promise website.

Plaintiffs' Exhibit 480

fdaimports.com

DOJ Charges Manufacturer for Exporting Misbranded Masks

3-4 minutes

On June 5, 2020, the U.S. Department of Justice (DOJ) charged a Chinese manufacturer with exporting misbranded face masks, purported to be N95 respirators. The criminal complaint against King Year Printing and Packaging Co., Ltd. includes numerous allegations that it violated the Federal Food, Drug and Cosmetic Act (FDCA). U.S. Customs and Border Protection, together with the U.S. Food and Drug Administration (FDA), monitor imports for possible fraudulent or defective products.

Willful Violations of the Law

The DOJ filed a criminal complaint against King Year, alleging that King Year knew that the masks were noncompliant, and knowingly and willfully took various actions to cover this up. They falsely labeled the respirators, the complaint states, "with the intent to defraud U.S. consumers, including medical providers and state and local governments, into believing they were buying N95 respirators approved, cleared, or otherwise authorized" by FDA and National Institute for Occupational Safety and Health (NIOSH). Other allegations include the use of a false registration document and the use of a fictitious corporation as its U.S. agent in registration documents filed with FDA. As Attorney Jessica Rifkin observed, "This suit shows that the U.S. is going to aggressively pursue "bad actors" in this area, i.e. those who willfully violate the law."

Reminder to Importers: Conduct Due Diligence

The allegations include several problems that we have reported on previously, such as including the NIOSH logo and having N95 embroidered on the

respirators even though they were not NIOSH approved. A manufacturer must be listed on CDC's site if a mask has N95 marking on it or its box, or it is a counterfeit product and is subject to seizure. The defendant also stamped the FDA logo on their packaging according to the complaint. Any medical device that has the FDA logo on its label is misbranded. FDA recently sent a warning letter to a seller of purported COVID-19 test kits, based in part on the seller's use of the FDA logo on its website.

We continue to urge importers to ensure that PPE is accurately labeled to reduce the risk that an inappropriate mask, for example, is not used in a surgical setting. We remind importers and distributors that failure to conduct due diligence to ensure that the goods you are selling are not counterfeit or fraudulent could lead to civil actions such as detention, seizure, and penalties, or other governmental action.

Our firm has produced a COVID-19 Trade Resources page where you can access all of our blogs and other links. If you are in doubt as to whether the PPE (including face masks), testing kits, and other COVID-19 related products you want to import are properly classified and not counterfeit or otherwise fraudulent, and if they need FDA approval or facility registration, ask our team of regulatory consultants and affiliated attorneys. Contact us today.

Plaintiffs' Exhibit 481

ISO 13485, § 7.3.7 Requirements For Medical Devices

From: little one (wiidc@yahoo.com)

To: lucas.wall@yahoo.com

Date: Tuesday, August 24, 2021, 02:57 PM EDT

FDA adopted the International Standards Organization 13485 regulations for medical devices. Claiming that any face mask is a medical devise must have a “Design and development validation”, including a clinical evaluation. These requirements must be documented. Without meeting the ISO 13485 requirements, the product is not a valid medical devise and is not to be released to the customer(s).

ISO 13485 Medical Devices (2016 current)
www.iso.org/obp/ui/#iso:std:iso:13485:ed-3:v1:en

7.3.7 Design and development validation

Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.
The organization shall document validation plans that include methods, acceptance criteria and,
as appropriate, statistical techniques with rationale for sample size.
Design validation shall be conducted on representative product. Representative product includes
initial production units, batches or their equivalents. The rationale for the choice of product used
for validation shall be recorded (see 4.2.5).
As part of design and development validation, the organization shall perform clinical evaluations
or performance evaluations of the medical device in accordance with applicable regulatory
requirements. A medical device used for clinical evaluation or performance evaluation is not
considered to be released for use to the customer.
If the intended use requires that the medical device be connected to, or have an interface with,
other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced.
Validation shall be completed prior to release for use of the product to the customer.
Records of the results and conclusion of validation and necessary actions shall be maintained
(see 4.2.4 and 4.2.5).

Plaintiffs' Exhibit 482

troutman.com

Liability Considerations for Manufacturers of Face Masks Intended for Source Control in the Age of COVID-19

8-10 minutes

In April, the Centers for Disease Control and Prevention ("CDC") began recommending that the public wear face masks as "source control" to limit the spread of COVID-19.[1] In response to this recommendation, the Food and Drug Administration ("FDA") extended its prior Emergency Use Authorization ("EUA") to cover face masks intended for use as source control. In May 2020, FDA again updated its guidance documents and defined face masks used for source control as medical devices subject to FDA regulation and requirements. To aid in increasing the availability of products intended to help curb the spread of COVID-19, the Department of Health and Human Services ("HHS") issued a declaration that provides potential manufacturers of countermeasures with immunity from liability in certain cases. Now that FDA has defined face masks used for source control as medical devices covered by its EUA, face mask manufacturers may be able to claim protection under these immunity provisions. FDA regulation and potential civil products liability still pose legal risks, and would-be manufacturers should understand the regulatory requirements, immunities, and protections surrounding face mask manufacturing before wading into this highly regulated industry.

Manufacturing Guidance from FDA

In response to the CDC's recommendations that members of the public use face masks to cover their noses and mouths, FDA issued a Letter of Authorization for the use of face masks (hereafter "Authorization Letter").[2] Under FDA's most recent guidance, all face masks intended for use as "source control" are considered medical devices.[3] In this context, source control "refers to the use of a face mask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19."[4] Simply put: manufacturers producing even simple cloth face coverings are now producing medical devices regulated by FDA and must therefore comply with certain regulatory requirements.[5]

Although this may sound daunting, FDA's Authorization Letter makes compliance very straightforward. First, manufacturers acting under the Authorization Letter may only produce masks intended for source control.[6] In other words, the Authorization Letter does not permit a manufacturer to produce a face mask intended for another medical purpose, like a surgical mask or respirator. Second, they must comply with the following labeling requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);
2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection;
3. The product labeling includes recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high;
4. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction;
5. The product is not labeled as a respiratory protective device, and therefore should not be used for particulate filtration; and
6. The product is not labeled for use in high risk aerosol generating procedures.[7]

Finally, they must comply with the Conditions of Authorization as detailed in the Authorization Letter.[8] The Conditions of Authorization reiterate the labeling requirements while also requiring the manufacturer to (1) take steps to ensure that the labeling information is available to the end user; (2) include instructions regarding the recommended cleaning of the materials; (3) implement a process to report adverse events; (4) maintain records related to the Emergency Use Authorization; (4) maintain records related to the production and distribution of the masks; and (5) comply with certain requirements for advertising and promoting the masks.[9] If a manufacturer complies with these requirements, they "do not need to take any action . . . to be authorized under th[e] [Emergency Use Authorization]."[10]

Health and Human Services Liability Immunity

A byproduct of FDA's designation of face masks as medical devices covered by FDA's Letter of Authorization is that face mask manufacturers now may qualify for liability immunity under a declaration by HHS.[11] Under this declaration, manufacturers of "Covered Countermeasures" are immune from liability for all claims "under Federal and State law . . . for loss caused by, arising out of, relating to, or resulting from the

administration to or use by an individual of a covered countermeasure."[12] The only exception to this immunity is for "death or serious physical injury proximately caused by willful misconduct" on the part of the entity otherwise entitled to immunity.[13]

The term "Covered Countermeasure" includes, among other things,

a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act . . . .[14]

In this context, face masks for source control may qualify as "Covered Countermeasures" because FDA views face masks intended for this purpose as "devices"[15] and "authorized [them] for emergency use" in its Authorization Letter. Accordingly, face mask manufacturers may be able to take advantage of the broad liability immunity established by HHS's declaration.

Closing Thoughts

Despite FDA's efforts to simplify regulatory compliance for face mask manufacturers, liability and regulatory risks remain. Those interested in producing face masks should seek guidance from an attorney experienced in FDA and regulatory compliance to ensure full compliance with FDA's requirements, as well as an attorney experienced in issues surrounding products liability to ensure that the immunity protections provided by HHS will apply to the manufacturer's actions in producing face masks.

---

[1] See CDC's recommendations here: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html.

[2] *See* U.S. FOOD & DRUG ADMIN., FACE MASK LETTER OF AUTHORIZATION (April 24, 2020) (hereafter "AUTHORIZATION LETTER").

[3] MASK GUIDANCE, at 5 ("FDA pronounced that "[f]ace masks . . . are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19)."

[4] *Id.* at 4.

[5] Face masks not intended for a medical purpose are not considered medical devices. *See* MASK GUIDANCE, at 3-4. Accordingly, a manufacturer producing, for example, dust masks or masks intended for use in industrial applications, are not regulated by FDA's new face mask guidance. *See id.*

[6] AUTHORIZATION LETTER, at 3.

[7]*Id.* at 3-4.

[8]*Id.* at 5.

[9]*Id.* at 5-7.

[10]*Id.* at 4.

[11]*See* Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (March 17, 2020) (hereafter "Declaration").

[12] 42 U.S.C. §247d-6d(a)(1).

[13]*Id.* at § 247d-6d(d)(1).

[14]*Id. at* § 247d-6d(i)(1)(C) (footnote omitted).

[15] The term "device" is defined by the Food, Drug & Cosmetic Act as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals . . . ." 21 U.S.C. § 321(h)(2). As discussed above, FDA's Mask Guidance clearly states that face masks intended for source control are included in this definition. *See*, MASK GUIDANCE, at 5.

Product Responsibility Best Practices

SUBJECT
FDA Emergency Use Authorization

Plaintiffs' Exhibit 483

LAST UPDATE
January 2021

APPLIES TO
- Suppliers
- Distributors

FOCUS ON
Emergency FDA Guidance

QUICK LINKS
- PPAI Corporate Responsibility: ppai.org/corporate-responsibility/
- Consumer Product Safety Commission: www.cpsc.gov

Intended for intermediate compliance programs

Italic grey text indicates a hyperlink listed in the Online Resources section of this document.

The Food and Drug Administration (FDA) has employed regulatory flexibility to alleviate medical product shortages and augment the availability of medical products that are necessary for mitigating the impact of COVID-19. The FDA has two methods available to implement this policy. One option employed by the FDA is the Immediately-in-Effect (IIE) guidance, and the other option is the Emergency Use Authorization (EUA).

Immediately-In-Effect Guidance

The *FDA's IIE guidance* outlines the intended use of face masks for source control. According to the FDA, source control is described as preventing the transmission of infection through a person's respiratory secretions which are produced when speaking, coughing, or sneezing. Considering the public health emergency, and provided that a face mask does not create an undue risk, the FDA does not object to a mask's distribution and use intended for a medical purpose, even if the mask does not comply with specific regulations outlined in the guidance document. The normally applicable regulation includes a registration requirement, a quality system requirement, protocols for corrections and removals, and a unique device requirement. This guidance applies whether the mask is being used by medical personnel or the general public.

There are solutions available for determining whether a mask creates an undue risk. The product must be labeled as a face mask, not a surgical mask or respirator. The product must also include a list of body contacting materials, and not include any *drugs* or biologics. The product's label should include recommendations for further reducing the risk of use, for example not using the mask in a surgical setting. Another recommendation for minimizing risk associated with use of the product includes not using the mask if there could be exposure to hazardous fluids. It is also important to ensure the product does not have any additional antimicrobial or anti-viral claims made within its labelling.

Emergency Use Authorization

The FDA has also issued *Emergency Use Authorizations* regarding facemasks in pursuit of its policy related to COVID-19. FDA policies regarding facemasks include clarification that, in accordance with the federal *Food, Drug, and Cosmetic Act*, the masks comprise medical devices only when they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases. This is an important distinction; unlike respirators and surgical masks, face masks are not considered *Personal Protective Equipment (PPE)*.

Under the EUA, face masks are also intended to help stop the spread of COVID-19 by providing source control. Conditions for authorization include labeling requirements of the product and waivers of certain FDA requirements, including quality system regulation and the Unique Device Identifier (UDI). This is an "umbrella" EUA, which means the manufacturer does not need to take any further action and does not need to submit a request to the FDA for inclusion under the EUA. However, it is important to note that adverse event reporting and record keeping are still required.

When working under an EUA, the Department of Health and Human Services (HHS) provides liability coverage under the *Public Readiness and Emergency Preparedness (PREP) Act*. The PREP Act authorizes the HHS Secretary to make a declaration that provides immunity from potential liability, except for cases of intentional misconduct, regarding claims related to loss caused by using covered countermeasures associated with the public health emergency.

When the public health emergency is officially terminated for products that are either in use or in warehouses, the FDA will issue policies that outline the transition process. It is important to keep in mind that face masks are products that are exempt from the *premarket notification requirements* implemented under the Federal Food, Drug, and Cosmetic Act. That means

premarket submissions are not necessary with some face masks, however the other regulations that are waived during the public health emergency would be in effect. Some examples of those requirements include registration and listing, quality systems, and reports of corrections and removals. It will be important for companies to maintain compliance with those requirements if they intend to maintain products in the market, after the EUAs expire.

Online Resources:

FDA Regulated Face Masks: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/face-masks-including-surgical-masks-and-respirators-covid-19

FDA Enforcement Policy: https://www.fda.gov/media/136449/download

N95 Respirators, Surgical Masks, and Face Masks: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks

Importing Medical Devices During the COVID-19 Pandemic: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/importing-medical-devices-during-covid-19-pandemic

Surgical Masks - Premarket Notification [510(k)] Submissions: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks-premarket-notification-510k-submissions

PRODUCT™ RESPONSIBILITY
POWERED BY PPAI

Plaintiff's Exhibit 484

The John Marshall Journal of Information Technology & Privacy Law

Volume 30 | Issue 4 Article 1

Summer 2014

The Right To Travel And Privacy: Intersecting Fundamental Freedoms, 30 J. Marshall J. Info. Tech. & Privacy L. 639 (2014)

Richard Sobel

ARTICLES

THE RIGHT TO TRAVEL AND PRIVACY: INTERSECTING FUNDAMENTAL FREEDOMS*

RICHARD SOBEL+

ABSTRACT

As a fundamental right inherent in American citizenship and the nature of the federal union, the right to travel in the United States is basic to American liberty. The right precedes the creation of the United States and appears in the Articles of Confederation. The U.S. Constitution and Supreme Court recognize and protect the right to interstate travel. The travel right entails privacy and free domestic movement without governmental abridgement.

In the era of surveillance, the imposition of official photo identification for travel, watchlist prescreening programs, and invasive airport scans and searches unreasonably burden the right to travel. They undermine citizen rights to travel and to privacy. These regulations

---

* An earlier version of this research was presented by Richard Sobel & Ramon Torres as "The Right to Travel: Intersection with the Right to Privacy and a Personal Liberty," at the Northwestern University Transportation Center Seminar Series on January 6, 2011. It formed a basis for Sobel & Torres, *The Right to Travel a Fundamental Right of Citizenship*, in the Journal of Transportation Law, Logistics & Policy, Spring 2013. The current Article updates portions of the earlier presentation and publication. The author thanks Dawid Danek, Kevin Doran, Brian Kebbekus, Tim Lamoureux, Catherine Nance, Allison Trzop and Michael Zhang, for research assistance and comments on the Article. He also appreciates the insights and suggestions of Barry Horwitz, Gerald Jenkins, Diana Marek, Matthew Beamer, and Ramon Torres, and the assistance of the Buffett Center, Transportation Center, NICO, Hutchins Institute, Houston Institute, Journal of Transportation Law, Logistics & Policy, and The John Marshall Journal of Information Technology & Privacy Law.

+ Buffett Center for International and Comparative Studies, Northwestern University, at richard-sobel@northwestern.edu. In addition to being a Visiting Scholar at the Buffett Center, he is also a faculty affiliate of the Transportation Center at Northwestern, an associate of the Hutchins Institute, and a consultant to the Houston Institute at Harvard.

impermissibly require citizens to relinquish one fundamental right of privacy in order to exercise another fundamental right of travel. The government must preserve these rights in addressing policy goals.

The original conception of the right to travel embodies it as a broadly-based freedom that encompasses all modes of transport. Its explicit articulation in the Articles of Confederation became implicit in the Privileges and Immunities Clause of the Constitution. Contrary to the appellate "single mode doctrine," abridgement of any mode of transportation undermines the constitutionally enshrined travel right. The U.S. Supreme Court needs to rearticulate an originally consistent and politically robust multi-modal right to travel.

INTRODUCTION: TRAVEL AS A FUNDAMENTAL RIGHT OF CITIZENSHIP

As a foundational political liberty that precedes the adoption of the U.S. Constitution, the right to travel in the United States is inherent both in citizenship and in the nature of the federal union. The Constitution and the U.S. Supreme Court recognize and protect the right to interstate travel.[1]

The travel right empowers U.S. citizens to move interstate without abridgement by government interference. Laws and regulations that impede citizens' ability to exercise a fundamental right like travel to preserve another like privacy are inherently suspect. The Ninth Circuit stated in *United States v. Davis*, "exercise of the constitutional right to travel may not be conditioned upon the relinquishment of another constitutional right absent a compelling state interest."[2]

The original conception of the travel right is explicitly stated in Article IV of the Articles of Confederation and remains in force in the parallel article of the U.S. Constitution. Travel embodies a broadly based personal, political, and economic right that encompasses all modes of transportation and movement. Abridgement of any mode violates the right. The so-called "single mode doctrine," constructed by some circuit courts truncates the plenary scope of the travel right.[3] The imposition

---

1. *See* Saenz v. Roe, 526 U.S. 489, 498 (1999) (noting that the right to travel is "firmly embedded" within the jurisprudence of the Supreme Court); Shapiro v. Thompson, 394 U.S. 618, 630 (1969); RONALD D. ROTUNDA & JOHN E. NOWAK, TREATISE ON CONSTITUTIONAL LAW: SUBSTANCE AND PROCEDURE § 4.8 (4th ed. 2007).

2. United States v. Davis, 482 F.2d 893, 913 (9th Cir. 1973).

3. *See* John Doe No. 1 v. Ga. Dep't. of Pub. Safety, 147 F. Supp. 2d 1369, 1375 (N.D. Ga. 2001) ("[T]he denial of a single mode of transportation does not rise to the level of a violation of the fundamental right to interstate travel."); s*ee, e.g.*, Town of Southold v. Town of East Hampton, 477 F.3d 38, 54 (2d Cir. 2007); Gilmore v. Gonzales, 435 F.3d 1125, 1137 (9th Cir. 2006); Duncan v. Cone, 2000 WL 1828089 (6th Cir. 2000); Miller v. Reed, 176 F.3d 1202, 1205 (9th Cir.1999); Houston v. F.A.A., 679 F.2d 1184, 1198 (5th

of governmental requirements, such as official photo identification for travel, watch-list prescreening programs, no-fly lists, and intrusive airport scanning and searches, unreasonably burden the right to travel in privacy.

This Article traces the development of the travel right from its robust early conceptualization to its modern-day misconstruction. Part I presents the historical origins of the travel right. Part II conceptualizes the historic travel right around privacy concerns for the modern era. Part III critiques unjustified circuit court limitations on the rights to travel and privacy in a surveillance age. The Conclusion argues that the Supreme Court needs to reconstruct and rearticulate an originally consistent and expansive right to travel.

I. THE HISTORICAL ORIGINS OF THE RIGHT TO TRAVEL

The right to travel precedes the American union and the U.S. Constitution. In shaping medieval English law in 1215, the Magna Carta articulated travel rights for personal liberties and unfettered commerce in assuring "merchants are . . . safe and secure in . . . traveling in England."[48] Blackstone's 1795 *Commentaries on the Laws of England* identified freedom of movement as a natural liberty inherent by birth.[5] "This personal liberty consists in the power of locomotion, of changing situation, or removing one's person to whatsoever place one's own inclination may direct, unless by due course of law."[6] Blackstone defined it as a "strictly natural" right.[7]

The right to travel pervades U.S. history. In 1770, Thomas Jefferson argued that freedom of movement is a personal liberty by birth. "Under the law of nature, all men are born free, everyone comes into the world with a right to his own person, which includes the liberty of moving and using it at his own will. This is what is called a personal liberty."[8] The appearance in Article IV of the Articles of Confederation in 1777 of a right to travel informed its implicit incorporation in the

---

Cir. 1982); Monarch Travel Servs., Inc. v. Associated Cultural Clubs, Inc., 466 F.2d 552, 554 (9th Cir. 1972).

4. PETER LINEBAUGH, MAGNA CARTA MANIFESTO: LIBERTIES AND COMMONS FOR ALL 179 (2008); NICHOLAS VINCENT, MAGNA CARTA, A VERY SHORT INTRODUCTION, 118 (2012) ("All merchants are to be safe and secure in leaving and entering England, and in staying and traveling in England . . . ").

5. *See generally* SIR WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND: BOOK THE FIRST OF THE RIGHTS OF PERSONS (1765).

6. *Id.* at 130. The Delaware Chancery Court agreed with Blackstone, in *Douglass v. Stephens*, and established that freedom of movement is fundamental for "the enjoyment and defense of liberty." Douglass v. Stephens, 1 Del. Ch. 465, 471 (1821).

7. BLACKSTONE, *supra* note 5, at 130.

8. THOMAS JEFFERSON, ARGUMENT IN THE CASE OF HOWELL V. NETHERLAND, THE WRITINGS OF THOMAS JEFFERSON 474 (1892).

Privileges and Immunities Clause of Article IV of the U.S. Constitution in 1789. In short, the Confederation travel right was fundamentally inaugurated for the founding era and beyond.[9]

> The better to secure and perpetuate mutual friendship and intercourse among the people of the different States in this Union, the free inhabitants of each of these States . . . shall be entitled to all privileges and immunities of free citizens in the several States; and the people of each State shall have free ingress and regress to and from any other State, and shall enjoy therein all the privileges of trade and commerce. . . . [10]

Early courts explicated this broad conception. In the 1823 decision, *Corfield v. Coryell*,[11] the Supreme Court recognized the travel right in explaining the relationship between the "free ingress and regress" clause in Article IV of the Articles and the Privileges and Immunities Clause in the Constitution.[12] The Court affirmed that the privileges and immunities of citizenship encompass "the right of a citizen of one state to pass through, or to reside in any other state, for purposes of trade, agriculture, professional pursuit, or otherwise."[13] The imperative of free interstate travel was "better to secure and perpetuate mutual friendship" of the states.[14] Moreover, in 1824, the Supreme Court established in *Gibbons v. Ogden*, that commerce, as intercourse between the states, encompasses a right from the creation and adoption of the U.S. Constitution.[15]

The original expansive conception of the right to travel encompasses all available modes of transportation. The 1831 Court ruling in *Beckman v. Saratoga & Schenectady Railroad* established that whenever there is a compelling public interest in a technology available to the public, for instance, a new mode of transport like railways, then all citizens are equally entitled to enjoy its benefits and to access it and its instrumentalities.[16] This ruling established transportation service providers as common carriers,[17] and scheduled passenger transport of various kinds.

---

9. ARTICLES OF CONFEDERATION of 1781, art. IV.
10. *Id.*
11. Corfield v. Coryell, 6 F.Cas. 546, 550-51 (C.C.E.D. Pa. 1823).
12. U.S. CONST. art. IV, § 2.
13. *Corfield*, 6 F.Cas. at 552.
14. *Id.* (citing ARTICLES OF CONFEDERATION of 1781, art. IV).
15. Gibbons v. Ogden, 22 U.S. 1, 193(1824).
16. Beckman v. Saratoga & Schenectady R.R., Co., 3 Paige Ch. 45, 45 (N.Y. 1831).
17. "[T]he public [has] an interest in the use of the road, and the owners of the franchise are liable to respond in damages, if they refuse to transport an individual or his property upon such road, without any reasonable excuse, upon being paid the usual rate of fare." *Beckman*, 3 Paige Ch. at 75; *see* the section herein on common carriage and travel rights.

THE RIGHT TO TRAVEL ACROSS THE UNITED STATES

The right to interstate travel has connected the parts of the nation since its founding. Travel is fundamental and structural to maintaining a strong political and economic union of sovereign states. As Ronald Kahn articulated, "The [Supreme] Court views the concepts of the federal union and personal liberty rights in the Constitution as closely related. Their union requires that all citizens be free to travel, uninhibited by regulations that unreasonably burden their movement."[18]

Because the national government does not possess "general police power," its authority is restricted to what the Constitution expressly grants it.[19] The Ninth and Tenth Amendments reserve all other unenumerated rights to the states and the people to ensure that citizens may not be deprived of those rights not delegated to the federal and state governments without due process under the Fifth and Fourteenth Amendments.[20] The right to travel, inherent in intercourse among the states, is one of the implied and unemunerated rights reserved to the People.[21]

The 1849 *Passenger Cases* declared the right to travel may be exercised without interference. The Court established that state taxation of imports and exports unconstitutionally imposed on commerce and interstate travel.[22] It ruled against New York and Massachusetts' imposition of taxes on alien passengers arriving from ports out of state.[23] To ensure uniform treatment of citizens across the states, and to bind together the Union, the Constitution empowered Congress alone with the power to regulate commerce between the United States and among the States.[24]

The right to travel is "so rooted in the traditions and conscience of our people as to be ranked as fundamental."[25] The 1867 case of *Crandall v. Nevada*, for example, recognized that necessity for interstate travel to exercise other personal rights and liberties. A Nevada-imposed fee constituted "a tax on the passenger for the privilege of passing

18. RONALD KAHN, THE SUPREME COURT AND CONSTITUTIONAL THEORY, 1953-1993 50 (1994).

19. *See, e.g.*, LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW § 5-2 (1988).

20. *See* Griswold v. Connecticut, 381 U.S. 479, 487 (1965) (Goldberg, J., concurring); McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316, 372, (1819) (argument of counsel).

21. *See, e.g.*, Crandall v. Nevada, 73 U.S. 35, 48-49 (1867); Shapiro v. Thompson, 394 U.S. 618, 629-31 (1969).

22. The Passenger Cases, 48 U.S. 283, 283 (1849).

23. Congress may impose taxes on common carriers and ports. However, these taxes are regulated and uniform throughout the nation since, in accordance to the Constitution: "all duties, imposts and excises shall be uniform throughout the United States." U.S. CONST. art. 1, § 8, cl.1.

24. *The Passenger Cases*, 48 U.S. at 492 (Taney, C.J., dissenting).

25. Griswold v. Connecticut, 381 U.S. 479, 493 (1964) (citing Snyder v. Massachusetts, 291 U.S. 97, 105 (1934)).

through the State by the ordinary modes of transportation."[26] Even one state's imposition of a tax on those leaving the state could weaken the federation of states. "If one State can [levy such a tax], so can every other State. And thus one or more States covering the only practicable routes of travel from the east to the west, or from the north to the south, may totally prevent or seriously burden all transportation of passengers from one part of the country to the other."[27]

The *Crandall* court determined that Nevada's imposition of a per passenger tax on railroad or stagecoach companies for passengers transported out of the state unconstitutionally limited citizens' right to travel.[28] The tax levied by Nevada on passengers for the privilege of passing through the state unconstitutionally burdened the travel right.[29] "We are all citizens of the United States, and as members of the same community must have the right to pass and repass through every part of it without interruption, as freely as in our own States."[30] The tax hindered citizens' exercise of other fundamental rights, such as approaching the government for redress of grievances and accessing ports where commerce was conducted.[31]

As in *Corfield v. Coryell, The Slaughter House Cases*[32] in 1873 affirmed the right to travel by determining that "the privileges and immunities intended [in Articles IV of the Articles of Confederation and U.S. Constitution] are the same in each."[33] By asserting such a close link, the Court confirmed the right to interstate travel is protected, as in the Articles of Confederation, by the Constitution's Commerce Clause and as a Privilege and Immunity of citizens under Article IV.[34] In *Williams v. Fears*, the Supreme Court in 1900 declared, "[u]ndoubtedly the right of locomotion, the right to remove from one place to another according to inclination, is an attribute of personal liberty, and the right, ordinarily of free transit from or through the territory of any State is a right secured by the 14th amendment and by other provisions of the Constitution."[35]

---

26. Crandall v. Nevada, 73 U.S. 35, 49 (1867).
27. *Id.* at 35.
28. *Id.* at 44-45.
29. The Court described the tax power as "being in its nature unlimited," and interfering with powers of the federal government. *See id.* at 36, 46-48.
30. *Id.* at 49.
31. *See id.* at 43-44.
32. *The Slaughter House Cases*, 83 U.S. 36, 79 (1873).
33. *Id.* at 75.
34. *See generally* Ward v. Maryland, 79 U.S. 418 (1870); Hoxie v. New York, N.H. & H.R. Co., 82 Conn. 352 (1909).
35. Williams v. Fears, 179 U.S. 270, 274 (1900), *quoted in* Schactman v. Dulles, 225 F.2d 938, 944 (1955).

Complementing Fifth Amendment due process guarantees,[36] the Court established in *Edwards v. California* in 1941 that the Fourteenth Amendment extends due process protections to all citizens of the United States.[37] It thereby protects citizens from infringement by states and the federal government. In concurring, Justice Douglas held that "the right of persons to move from state to state occupies a more protected position in our constitutional system . . . "[38] As the Supreme Court affirmed in 1958 in *Kent v. Dulles*, "[t]he right to travel is a part of the 'liberty' of which the citizen cannot be deprived without due process of law."[39]

In 1966 in *United States v. Guest*, the Court rearticulated that the Constitution did not explicitly mention the right to travel because:

> a right so elementary was conceived from the beginning to be a necessary concomitant of the stronger Union the Constitution created. . . . The constitutional right to travel from one State to another . . . occupies a position so fundamental to the concept of our Federal Union. It is a right that has been firmly established and repeatedly recognized. . . .[40]

Indeed, *Guest* affirmed "[t]he constitutional right of interstate travel is virtually unqualified."[41] Today the travel right remains crucial to the formation and ongoing prosperity of the political union and common market.

The importance of such connectivity appears in *Shapiro v. Thompson* in 1969.[42] The *Shapiro* Court stated:

> This Court long ago recognized that the nature of our Federal Union and our constitutional concepts of personal liberty unite to require that all citizens be free to travel throughout the length and breadth of our land uninhibited by statutes, rules, or regulations which unreasonably burden or restrict this movement.[43]

The *Shapiro* decision highlighted that "[t]his constitutional right . . . is not a mere conditional liberty subject to regulation and control under conventional due process or equal protection standards." Furthermore, the decision reaffirmed the right to travel, as "a right broadly assertable

---

36. *See, e.g.,* United States v. Guest, 383 U.S. 745, 759 n.17 (1966); Kent v. Dulles, 357 U.S. 116, 125 (1958).
37. Edwards v. California, 314 U.S. 160, 176 (1941).
38. *Id.* at 177.
39. *Kent*, 357 U.S. at 125.
40. *Guest*, 383 U.S. at 757-58.
41. *Id.*
42. *See generally* Shapiro v. Thompson, 394 U.S. 618 (1969). As Justice Brennan added in his concurrence in *Zobel v. Williams*, the origin of the travel rights' "unmistakable essence [is] that document that transformed a loose confederation of States into one Nation." Zobel v. Williams, 457 U.S. 55, 67 (1982) (Brennan, J., concurring).
43. *Shapiro*, 394 U.S. at 629.

against private interference as well as governmental action."[44] In short, the travel right protects against both restrictive public and private actions, and it empowers those availing themselves of the right's protections. The right to travel constitutes a fundamental freedom government may not abridge.

Quoting *Guest* in *Dunn v. Blumstein* in 1972, the Supreme Court ruled that, "freedom to travel throughout the U.S. has long been recognized as a basic right under the Constitution."[45] The *Dunn* court held, "since the right to travel was a constitutionally protected right, any classification which serves to penalize the exercise of the right . . . is unconstitutional."[46]

The Court more recently affirmed the fundamental constitutional right to travel in 1999 in *Saenz v. Roe*.[47] The first of three components is most relevant to interstate travel: "citizens have the right to enter and leave another State."[48] The decision held unconstitutional a state welfare statute that discriminated against new residents.[49] The ruling agreed with *Shapiro* in that "a classification that has the effect of imposing a penalty on the right to travel violates the Equal Protection Clause 'absent a compelling governmental interest.'"[50] While *Saenz* focused on state-to-state travel, the holding was not specific to states alone. Thus, the case features a travel right that extends across the nation.

Travel is an instrumentality of commerce that Congress may regulate in order to encourage commercial activities and intercourse. *Kent* established that the Interstate Commerce Clause[51] protects interstate travel and its instrumentalities against governmental infringement.[52] *Guest* affirmed "[t]he constitutional right to travel from one State to another, and necessarily to use the highways and other instrumentalities

---

44. *Id.* at 630-31.

45. Dunn v. Blumstein, 405 U.S. 330, 338 (1972); United States v. Guest, 383 U.S. 745, 758 (1966).

46. *Dunn*, 405 at 338-39 (striking down a residency requirement restricting voting rights).

47. *See generally* Saenz v. Roe, 526 U.S. 489 (1999).

48. *Id.* at 500.

49. *Id.* at 507-08.

50. *Id.* at 490.

51. U.S. CONST., art. I, § 8, cl. 3; *see* Daniel A. Farber, *National Security, the Right to Travel, and the Court*, 1981 SUP. CT. REV. 263, 263-87 (1981).

52. President Woodrow Wilson would not abridge American citizens' rights to travel and engage in commerce, even during wartime. Responding to Senator W. J. Stone's letter that "this government tak[e] definite steps toward preventing American citizens from embarking upon armed merchant vessels," Wilson wrote, "[f]or my own part, I cannot consent to any abridgement of the rights of American citizens in any respect. . . . To forbid our people to exercise their rights for fear we might be called upon to vindicate them would be a deep humiliation indeed." *President Wilson's Letter to Senator Stone Announcing His Stand on Armed Liner Issue*, N.Y. TIMES, Feb. 25, 1916.

of interstate commerce in doing so, occupies a position fundamental to the concept of our Federal Union. It is a right that has been firmly established and repeatedly recognized."[53] The right to interstate commerce encompasses both the freedom of movement and the instrumentalities of transportation needed to so move.

Congress may not pass legislation that unreasonably burdens the right to travel. "One has the right, as against any prohibitory or other restrictive legislation, whether by Congress,[54] or by the States, to engage in the interstate or foreign commerce, that is, to transport persons or articles from State to State, or to or from a foreign country."[55] Thus, Congress must not infringe citizens' travel rights.

The travel right ensures the vitality of the government through the free movement of citizens in purposive travel. Specifically, the right preserves and facilitates citizens' ability to journey to their representative seats of government, both statewide and nationally, in order to petition under the First Amendment to have their grievances redressed. Foreclosing such a right would have offended the Founders in their suspicion of governmental overreaching into citizens' rights. Therefore, the Founders laid down protections for political speech and association inherent in the travel right. Even in an era of few travel modes, the Founders conceived the travel right as broad and plenary.

Consequently, domestic requirements for passports, identification, or permits for traveling in the United States hamper exercising the right to interstate travel. They also invert the proper consent relationship between citizens and government.[56] Government derives its "license" to operate from the people: when the government instead requires the people to obtain or present a license in order to travel domestically, it abrogates foundational rights. As Justice Ginsburg stated in a public forum: "[t]here is a right to travel. We have had a common market in that respect from the very beginning; you can go from one state to another without any passport."[57]

---

53. United States v. Guest, 383 U.S. 745, 758 (1966).

54. "Congress can set the regulations, conditions, or prohibitions regarding the permissibility of interstate travel or shipments if the law does not contravene a specific constitutional guarantee." ROTUNDA & NOWAK, *supra* note 1.

55. Frederick H. Cooke, *The Right to Engage in Interstate and Foreign Commerce as an Individual or as a Corporation*, 8 MICH. L. REV. 458, 459 (1910).

56. Richard Sobel & John A. Fennel, *Troubles with Hiibel: How the Court Inverted the Relationship between Citizens and the State*, 48 S. TEX. L. REV. 613, 639 (2007).

57. Associate Justice Ruth Bader Ginsburg, Remarks at the Northwestern University Law School (Sept. 15, 2009), *available at* http://www.c-spanvideo.org/program/288900-1 (responding in a public discussion to a question by Dr. Richard Sobel); *see* Louis Brandeis & Samuel Warren, *The Right to Privacy*, 4 HARV. L. REV. 193 (1890); *see also* Olmstead v. United States, 277 U.S. 438, 471-85 (1928) (Brandeis, J., dissenting); *see also* MELVIN UROFSKY, LOUIS D. BRANDEIS: A LIFE 562 (2009) (quoting Brandeis that the Fourteenth Amendment protects the right to travel: "the 14th

In short, the right to travel preceded modern means of transportation like railroads and airplanes. It was conceived as an inherent liberty within citizenship, personhood, and union. The right was not linked to a particular instrumentality for exercise of personal liberty. Accordingly, the right to travel is not tied to any specific mode of transportation. Consequently, it encompasses all means of travel.

THE RIGHT TO TRAVEL AS A FOUNDATION FOR CITIZENS AND UNION

From the perspective of individual rights, the ability to move freely in the United States is a personal liberty, inherent by birth and U.S. citizenship. The travel right is essential to guaranteeing equality of opportunities, and *the pursuit* of happiness for citizens of the federal union. Freedom of personal movement is a natural liberty that citizens exercise among fundamental rights and privileges.

Moreover, the right to interstate travel encompasses rights and privileges to personal, political, and commercial movement. This interconnection between the right of individuals and the character of the nation guarantees unrestricted geographical mobility to citizens in the American political and economic union. The right to interstate travel is based on the Founders' desire to structure a federal union under the Constitution to create a strong political union and a common market composed of sovereign states. By "place[ing] the citizens of each State upon the same footing with citizens of other States . . . ,"[58] the Privileges and Immunities Clause in Article IV of the U.S. Constitution guarantees the freedom to move from state to state and set up residence anywhere in the country. In securing that liberty, citizens of one state are entitled to the same privileges and immunities as the citizens of any other state.

An essential element in the notion that the states belong to a more perfect union manifests itself in the right to travel between the states on a basis of equality.[59] The Court recognized that without this constitutive dimension, "the Republic would have constituted little more than a league of States; it would not have constituted the Union which now exists."[60] Therefore, the right to travel is fundamental and structural to

---

amendment due process clause . . . had to be applied . . . to protect . . . fundamental rights—speech, education, choice of profession, and the right to travel . . . ").

58. Paul v. Virginia, 75 U.S. 168, 180 (1869); *see* Sonia Sotomayor, *Statehood and the Equal Footing Doctrine: The Case for Puerto Rican Seabed Rights*, 88 YALE L. J. 825, 835-51 (1979); *see also* Associate Justice Sonia Sotomayor, Address at the Northwestern University Law School (Mar. 7, 2011) (distinguishing travel rights for constitutional versus statutory citizenship).

59. Seth F. Kreimer, *The Law of Choice and Choice of Law: Abortion, the Right to Travel, and Extraterritorial Regulation in American Federalism*, 67 N.Y.U. L. REV. 451, 519 (1992).

60. *Paul,* 75 U.S. at 180.

a larger union because without it, the founding vision of a transcontinental nation could not be attained.

As a commercial union, the United States is a common market that enjoys the right of free interstate movement of people and goods in order to guarantee economic prosperity of the political union. The Founders had a desire to create one nation with regard to economic movement and change. Thus, the Founders established national control of commerce[61] to enable individuals to move from state to state for economic reasons.[62] In short, the commercial and political intersect.

American political history and Supreme Court jurisprudence crafted the right to travel as a fundamental one accruing naturally to every U.S. citizen and to the nation. The Court has consistently recognized a right to travel as one of citizenship preceding and contributing to the establishment of a federal constitution. Although the text of the Constitution no longer explicates the right to travel, Articles I and IV, and the First, Fifth, Ninth, Tenth, and Fourteenth Amendments protect the right. Here, facilitation of imports and exports (Article I, Section 9) coincides with the Privileges and Immunities of citizens of all states (Article IV). Due process and equal protection (Fifth and Fourteenth Amendments) intersect with rights reserved to the people and states (Ninth and Tenth Amendments).[63] In short, multiple constitutional provisions underlie and ally with the right to travel and related rights.

---

61. *See* U.S. CONST., art. I, § 8 (enumerating the powers of Congress to regulate commerce under § 9).

62. KAHN, *supra* note 18, at 39.

63. Freedom of movement within a country is internationally recognized as a right and embodied in national constitutions. *See* CONSTITUCIÓN POLÍTICA DE LOS ESTATOS UNIDOS MEXICANOS [C.P.] art. 11 (the right to travel is embedded in the Mexican Constitution, Article 11, guaranteeing the right of any person to enter, leave, or travel within the Mexican territory without the need of any means of identification); *see e.g*, Grundgesetz Fur Die Bundesrepublik Deutschland [GG] (GER), INDIA CONST., CONSTITUCIÓN NACIONAL [CONST. NAC.] (Arg.), CONSTITUCIÓN ESPAÑOLA [C.E.] (Spain), CONSTITUTION OF ROMANIA, USTAV REPUBLIKE HRVATSKE (Croat.), CONSTITUTION OF THE REPUBLIC OF TURKEY, and S. AFR. CONST (providing for the right to move freely within the respective countries). For the right to travel recognized in international law *see American Declaration of the Rights and Duties of Man*, OEA/Ser.L./V.II.23, doc. 21, rev. 6 (1948) (noting the right to travel in the Organization of American States); *see also Universal Declaration of Human Rights*, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (Dec. 10, 1948) (discussing right to travel in Article 12); *see also* Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, 213 U.N.T.S. 222; *see also* The Helsinksi Act, Aug. 1, 1975, 14 I.L.M. 1292 (the United States and thirty-five countries are signatories); *see also* African Charter on Human and Peoples' Rights, June 27, 1981, 1520 U.N.T.S. 217; *see also* International Covenant on Civil and Political Rights, Dec. 16, 1966, S. Exec. Rep. 102-23, 999 U.N.T.S. 171.

II. THE MODERN CONTEXT OF THE RIGHT TO TRAVEL

Fundamental rights must expand to encompass new technologies, and case law needs to evolve by retaining the essence of the basic protections. When the right to travel appeared in the Articles of Confederation, for example, it preceded the formulation of the related right to privacy. Yet, the expansive nature of the travel right drives the construction of privacy provisions. The travel right also preceded and catalyzed progressive non-discrimination policies included in current federal definitions of and access to common carriers. There, the government sought equal and uniform protection of rights to common carriage. The evolution of privacy and other rights parallels the protections inherent in the right to travel. Evolution may not, in short, fundamentally alter the original rights.

INTERSECTION OF THE RIGHT TO TRAVEL AND THE RIGHT TO PRIVACY

In a parallel path to the travel right, the right to privacy has evolved from a focus on the protection of an individual's physical property[64] to encompass a broader swath of privacy safeguards and expectations pertaining to an individual as a constitutionally-protected person in both private and public.[65] The oldest protections to personal privacy resides in the Fourth Amendment safeguards against unreasonable searches and seizures without probable cause of criminal activity.[66] These protections now intersect with travel rights.

The fundamental right to privacy protects individuals' choices to conduct their personal lives free from governmental interference.[67] In *Griswold* v. *Connecticut*, the Court established that the right to privacy protects individuals engaging in private acts from government

64. *See*, *e.g.,* Boyd v. United States, 116 U.S. 616, 622-23 (1886) (recognizing that a search and seizure was equivalent to a compulsory production of a man's private papers and was unreasonable within the meaning of the Fourth Amendment).

65. *See, e.g.,* Griswold v. Connecticut, 381 U.S. 479 (1964).

66. J. NOWAK & R. ROTUNDA, CONSTITUTIONAL LAW 734-35 (2d ed. 1983) ("the oldest constitutional right to privacy is that protected by the Fourth Amendment's restriction on governmental searches and seizures."); *see generally* Richard Sobel, Barry Horwitz, & Gerald Jenkins, *The Fourth Amendment beyond Katz, Kyllo and Jones: Reinstating Justifiable Reliance as a More Secure Constitutional Standard for Privacy*, 22 B.U. PUB. INT. L.J. 1 (2013).

67. Meyer v. Nebraska, 262 U.S. 390, 402-03 (1923) (using the right to privacy to protect the freedom of schools to teach subjects in languages other than English); *see* Pierce v. Soc'y of Sisters, 268 U.S. 510, 534-35 (1925) (using the right to privacy to protect parents' decision to have their children attend private schools); *see, e.g.*, Lawrence v. Texas, 539 U.S. 558 (2003); *see, e.g.,* Village of Belle Terre v. Boraas, 416 U.S. 1 (1974) (to protect the intimate and family lives of citizens).

interference.[68] The "emanations" of several constitutional rights protect a range of privacy interests.[69]

These constitutional rights also protect the right to privacy in travel.[70] The right to travel entails the right to privacy in its fundamental elements of individual choice regarding when, where, and how to move.[71] The intersection of the right to travel and the right to privacy as fundamental liberties allow individuals to engage in private and anonymous travel. Indeed, anonymous travel represents the concurrent exercise of these overlapping personal liberties.

The right to travel in anonymity, without having to identify oneself or carry identification documents, was articulated clearly in *Kolender v. Lawson*.[72] Edward Kolender was an African-American who frequently walked in white California neighborhoods where police repeatedly stopped, asked him for identification, and at times arrested him, even though he was pursuing legal activity.[73] In *Kolender*, the Court struck down the California statute that required "persons who loiter or wander on the streets to provide a 'credible and reliable' identification and to account for their presence when requested by a peace officer."[74] The Court invalidated the statute on the basis that it was "constitutionally vague within the meaning of the Due Process Clause of the Fourteenth Amendment by failing to clarify what is contemplated by the requirement that a suspect provide a 'credible and reliable' identification."[75]

The basis of *Kolender* on vagueness affirmed the Ninth Circuit's judgment that the statute violated the Fourth Amendment. "The appellate court determined that the statute was unconstitutional in that it violates the Fourth Amendment's proscription against unreasonable searches and seizures, it contains a vague enforcement standard that is susceptible to arbitrary enforcement, and it fails to give fair and adequate notice of the type of conduct prohibited."[76]

---

68. *Griswold*, 381 U.S. at 483; *see* Roe v. Wade, 410 U.S. 113, 153 (1973); *see also* Planned Parenthood v. Casey, 505 U.S. 822, 851 (1982) (upholding the bodily autonomy of individuals); *see also* Oral Argument Transcript at 43, Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S.Ct. 2566 (Mar. 27 2012) (referencing "means of travel").

69. *See* Doe v. Bolton, 410 U.S. 179, 209 (Douglas, J., concurring).

70. *See supra* Part I.

71. Kent v. Dulles, 357 U.S. 116, 125-26 (1958); Shapiro v. Thompson, 394 U.S. 618, 629 (1969). *Kent* and *Shapiro* established that the right to travel must be free from government interference, thus associating the right to privacy with the exercise of the right to travel. *Kent*, 357 U.S. at 125-26; *Shapiro*, 394 U.S. at 629.

72. Kolender v. Lawson, 461 U.S. 352, 353-54 (1983).

73. *Id.*

74. *Id.* at 353.

75. *Id.* at 353-54.

76. *Id.* at 355.

Moreover, in a telling concurrence, Justice Brennan clarified that the demand for identification was a search when he held that even if the statute had not been vague, it would still have violated the Fourth Amendment.[77] "Even if the defect identified by the Court were cured, however, I would hold that this statute violates the Fourth Amendment" because "States may not authorize the arrest . . . for failing to produce identification."[78] In short, the *Kolender* court struck down the requirement to provide identification when involved in legal behavior.

In *Hiibel v. Nevada*, the Supreme Court reaffirmed that unless there is reasonable suspicion of a crime and a state law requiring identification under that circumstance, police may not require individuals to provide identification.[79] Like previous cases where, for instance, Kolender had simply been walking, Hiibel was a pedestrian at roadside when confronted by the officer, though first pursued under reasonable suspicion based on an observer's report that an assault had been observed in a motor vehicle.[80] The Nevada statute, the Supreme Court ruled 5-4, required Hiibel to disclose his name, but not to produce an identification document.[81] Nonetheless, contrary to *Kolender,* the demand in *Hiibel* to produce a name as identification contradicts the now-famous principles in *Miranda v. Arizona*[82] and a series of cases of strong dicta that protect the right to remain silent.[83]

Thus, an individual moving around has the right to be private and anonymous in his or her affairs, free from government intrusion. Hence, the demand for identification, without probable cause that the individual is engaging in an illegal activity, interferes not only with privacy, but also with travel rights. In short, the travel right entails the right to privacy, and it encompasses freedom to travel anonymously and free

77. *Id.* at 362 (Brennan, J., concurring).
78. Kolender v. Lawson, 461 U.S. 352, 362 (1983) (Brennan, J., concurring).
79. Hiibel v. Sixth Jud. Dist. Ct. of Nev., 542 U.S. 177, 185 (2004).
80. *Id.* at 177.
81. *Id.* at 185.
82. *See generally* Miranda v. Arizona, 384 U.S. 436 (1966).
83. *See* Sobel & Fennell, *supra* note 56, at 618 (discussing the right to remain silent); *see* Terry v. Ohio, 392 U.S. 1, 34 (1968) (White, J., concurring) (discussing that "the person may be briefly detained against his will while pertinent questions are directed to him. Of course, the person stopped is not obliged to answer, answers may not be compelled, and refusal to answer furnishes no basis for an arrest"); *Kolender*, 461 U.S. at 365 (noting that a *Terry* suspect "must be free to leave after a short time and to decline to answer the questions put to him") (Brennan, J., concurring); Berkemer v. McCarty, 468 U.S. 420, 439-40 (1984) (stating that the "officer may ask the . . . detainee a moderate number of questions to determine his identity and to try to obtain information confirming or dispelling the officer's suspicions. But the detainee is not obliged to respond"); Illinois v. Wardlow, 538 U.S. 119, 125 (2000) (explaining that stopping a fleeing suspect "is quite consistent with the individual's right to go about his business or to stay put and remain silent in the face of police questioning").

from governmental infringement.[84]

In *The Right of Mobility*, Gerald Houseman identifies how the right to travel is essential for the exercise of other fundamental rights, including employment.[85] "Mobility is a right which makes many other rights we hold dear both tenable and possible—the rights of association, privacy, and equality of opportunity, for example."[86] He notes, a national identification system, including worker identification cards, constitute an "internal passport" which he calls the "hallmark of repressive regimes such as [Apartheid] South Africa, the [former] Soviet Union, or Nazi Germany."[87]

In the concurrent exercise of two fundamental rights, one right, for example travel (or employment, often travel-related), may not be conditioned on abrogating another right like privacy.[88] In summary, travel and privacy rights are intimately linked in their constitutional protections.

COMMON CARRIAGE IN TRAVEL RIGHTS[89]

The travel right also includes the right to movement on common carriers. "A carrier becomes a common carrier when it 'holds itself out' to the public, or to a segment of the public, as willing to furnish transportation within the limits of its facilities to any person who wants it."[90] That means that any individual or corporation becomes a common carrier by promoting to the public the ability and willingness to provide

84. GERALD L. HOUSEMAN, THE RIGHT OF MOBILITY 7 (1979). In the late 1970's, Congress first considered establishing "a system of 'forgery-proof' Social Security cards, complete with photographs . . . for everyone entitled to have one." *Id.* While its sponsors denied "that this could easily be turned into a national identification system, it is not difficult to imagine this being done in the name or bureaucratic efficiency, national security, or . . . to snoop and perhaps to limit mobility." *Id.* at 17. Houseman identified the proposed Social Security card as a national passport – internal passport – acting as a work ID. *Id.* "Any potential employer must then refuse to hire anyone who fails to produce this card." *Id.* at 42. Houseman argues that a national ID system confronts the American with "a totalitarian potential of invasion of privacy, harassment, and denial of mobility." *Id.* at 43. A national ID can easily become an internal passport as an instrument of "mobility control" and feature of totalitarian governments. *Id.*

85. *Id.*

86. *Id.* at 17.

87. *Id.*

88. United States v. Davis, 482 F.2d 893, 913 (9th Cir. 1973); *see also* United States v. Kroll, 481 F.2d 884, 886 (8th Cir.1973).

89. *See* Ramon L. Torres, The Right to Travel: Intersection with the Right to Privacy and a Personal Liberty (2010) (unpublished Master's Thesis, Northwestern University) (on file with author).

90. WILLIAM T. BRENNAN, FED. AVIATION ADMIN., PRIVATE CARRIAGE VERSUS COMMON CARRIAGE OF PERSONS OR PROPERTY, (Apr. 24, 1986), *available at* http://www.faa.gov/documentLibrary/media/Advisory_Circular/AC%20120-12A.pdf.

transportation service, including air travel.[91]

Air transport providers operating in, to, or from the United States act under common carrier rules.[92] "An air carrier or foreign air carrier may not subject a person in air transportation to discrimination on the basis of race, color, national origin, religion, sex, or ancestry."[93] If there are available places, the charge is paid, and there are no reasonable grounds to refuse the service to an individual, the air carrier is legally bound to provide the transportation of passengers or goods. Denying someone passage violates federal law.[94]

The national government has broad federal jurisdiction.[95] When vehicles engage in commerce, the United States has jurisdiction over them, even if they travel outside the specific U.S. areas.[96] Under aircraft jurisdiction in *Special Aircraft Jurisdiction of the United States*, the U.S. government exercises national jurisdiction over its territory and "in-flight" aircraft, even outside national airspace.[97] Thus, travel conducted between contiguous and non-contiguous United States by air remains within national jurisdiction. And its regulation requires following U.S. federal law and rules, the Constitution, and specific rights and privileges of citizenship. Accordingly, the expansiveness of this

---

91. *But see* Gonzales v. Williams, 192 U.S. 1, 13 (1904). In the related series of "Insular Cases," the Court considered whether or not to extend full constitutional protection to territories the United States gained in the Spanish-American War; it distinguished between travel rights for continental versus territorial citizens, *e.g.* a U.S. citizen traveling from the non-continental U.S. (e.g., Alaska or Hawaii) to the continental part would have more rights than a citizen of a territory or commonwealth like Puerto Rico traveling to the continental U.S. The distinction depends partly on the difference between birth, naturalized or granted (statutory) citizenship. *See generally* De Lima v. Bidwell, 182 U.S. 1 (1901); Goetze v. United States, 182 U.S. 221 (1901); Dooley v. United States, 182 U.S. 222 (1901); Armstrong v. United States, 182 U.S. 243 (1901); Downes v. Bidwell, 182 U.S. 244 (1901); Huus v. N.Y. & Peurto Rico Steamship Co., 182 U.S. 392 (1901); *see also* SONIA SOTOMAYOR, MY BELOVED WORLD 179 (2013).

92. Brennan, *supra* note 90.

93. 49 U.S.C. § 40127 (2006).

94. *Id.*

95. *See* 18 U.S.C. § 7 (2006) (defining "Special Maritime and Territorial Jurisdiction of the United States" and concluding that the United States has federal jurisdiction over their territory and any vessel registered, licensed, or enrolled under the United States).

96. *See* 49 U.S.C. §§ 10501, 13502(a), 13521(a) (2006). Rail vehicle carrier, motor carrier, and water carrier operations are subject to U.S. jurisdiction when operating within the area defined in 18 U.S.C. § 7 (2006) and outside it when traveling to/from/between U.S. destinations. *Id.* Motor carriers are exempt when traveling through Canada between Alaska and the contiguous United States. *Id.* at § 13502(a).

97. § 46501(2) (included in the special U.S. jurisdiction are any "in-flight" civil or military aircraft of the United States, as well as any aircraft in the United States, including foreign aircraft that are scheduled to land or last departed from the United States); *see id.* at § 46501 (explaining that an aircraft "in-flight" corresponds to an aircraft from the time the door is closed to when it is opened at the destination; the law also covers any aircraft leased to an American resident or business, even when the lease is made outside the United States and/or using a non-U.S. registered aircraft).

jurisdiction empowers citizens to exercise broadly their right to travel.[98]

Sovereignty and Use of Airspace assigned control of the airspace of the United States to the government, and it guarantees citizens the right to use and access the space.[99] Air commerce and safety regulations establish an air transportation network consistent with public convenience and necessity.[100] The air travel network is a part of the public infrastructure open for wide use and enjoyment. The national government advances these goals by ensuring by law that all citizens have adequate access to the air system.

U.S. law, pursuant to 49 U.S.C. § 40103, pertaining to sovereignty and the use of airspace holds under "Sovereignty and Public Right to Transit" that (1) "[t]he United States Government has exclusive sovereignty of airspace of the United States; (2) [a] citizen of the United States has a public right of transit through the navigable airspace."[101] Moreover, 49 U.S.C. § 40101, "Policy," notes under "General Safety Considerations" that in carrying out regulation, the administrator for the Federal Aviation Administration (FAA) shall consider "the public right to freedom of transit through the navigable airspace."[102] Therefore, under not only general U.S. sovereignty but also the public right of transit, freedom of travel includes air travel.

THE INFIRMITIES OF THE "SINGLE MODE DOCTRINE"

Historically and fundamentally, the right to travel in the United States is broad and encompasses all modes of transportation. In conflict, however, with the nature of this expansive right in a large Union, some circuit courts have maintained that limitations on one mode of transportation do not implicate the right to travel. A modern construction that inaptly degrades the travel right, however, is the so-called "single mode doctrine," which maintains that if someone can travel by any mode of transportation, his right to travel is sustained.[103]

---

98. This is applicable when travel adheres to the U.S. Code statutes for the mode of transportation. The same also applies to travel on common carriers by ground or water. The U.S. Code for transportation of goods and passenger differs across modes of transportation. Rail, coach buses, aircraft, and ships have different sets of rules and different situations where American jurisdiction applies. A motor coach, for example, is outside U.S. jurisdiction when traveling in or through Canada, even if the trip starts and ends in the United States.

99. § 40103(a)(2).

100. § 40101-46507.

101. § 40103.

102. § 40101.

103. *See* John Doe No. 1 v. Ga. Dep't of Pub. Safety, 147 F. Supp. 2d 1369, 1375 (N.D. Ga. 2001) ("[T]he denial of a single mode of transportation does not rise to the level of a violation of the fundamental right to interstate travel.").

In *Monarch Travel Services v. Associated Cultural Clubs* in 1972[104] the Ninth Circuit ruled that the inability of a person to pay the fare of a common carrier in the form of charter flight fees, was not an unconstitutional limitation of the person's travel rights, since there was no state action in government interference.[105] In 1999 in *Miller v. Reed*, the same circuit used the *Monarch* argument to construct what is now known as "the single mode doctrine."[106] The court asserted that "burdens on a single mode of transportation do not implicate the right to interstate travel."[107] Under the construction, Miller was deprived of his privilege to operate a motor vehicle, but not the right to ride as a passenger or to travel by other means.[108] When the circuit court proffered its doctrinal opinion, however, it created an unconstitutional limitation on the fundamental interstate travel right.[109] Moreover, the Ninth Circuit again inappropriately relied on the "single mode doctrine" in *Gilmore v. Gonzales* when it restricted freedom of movement based on John Gilmore's refusal to submit to an identification requirement in order to fly from California to the seat of government in Washington, D.C.[110]

---

104. *See generally* Monarch Travel Serv., Inc. v. Ass'n Cultural Clubs, Inc., 466 F.2d 552 (9th Cir. 1972).

105. The Court only mentioned limitations on travel derived from lack of personal wealth. *Id.* at 554; *see generally* Harris v. McRae, 448 U.S. 297 (1980) (establishing a similar economic argument as *Monarch* in that the government does not have to allocate funds or resources to facilitate the exercise of certain rights).

106. Miller v. Reed, 176 F.3d 1202, 1204 (9th Cir. 1999).

107. *Id. at* 1205.

108. *Id.* at 1206. Miller could still use his personal vehicle, but could not legally drive it, since he had no license (indicating the required skills to do so). He could, however, have someone else drive his vehicle for him. Miller could also ride public transit or other modes of transportation. *Id.*; *see generally* Roger I. Roots, *The Orphaned Right: The Right to Travel by Automobile, 1890-1950*, 30 OKLA. CITY. U. L. REV. 245 (2005) (discussing the right to drive); *see also* Karl Manheim, *The Right to Travel,* CON LAW II BLOG (Nov. 2, 2005), http://manheimk.lls.edu/blog/conlaw2/archives/2005/11/the_right_to_tr.html (noting that due to constitutional right to travel questions and strong protests, drivers were initially neither required to get license plates containing numbers for automobiles nor to obtain licenses to drive them).

109. The Ninth Circuit's holding conflicted with the Supreme Court's emphasis in *Shapiro* that the right to travel should be free of regulations that unreasonably burden or restrict it. *See* Shapiro v. Thompson, 394 U.S. 618, 638 (1969).

110. Gilmore v. Gonzales, 435 F.3d 1125, 1136-37 (9th Cir. 2006). However, in *Gilmore*, the government revealed that identification was not absolutely required in order to fly. "The identification policy requires that airline passengers either prevent identification or be subjected to a more extensive search." *Id.* at 1155. Philip Mocek was also arrested for declining to provide identification to fly (and photographing the TSA response) in Albuquerque, New Mexico. In the trial acquitting him on all charges, the government also acknowledged that people can fly on commercial airlines without providing identification. *See State of New Mexico v. Phillip Mocek (2011)*, PAPERSPLEASE.ORG, http://www.papersplease.org/wp/mocek/ (last visited May 25, 2014); *see also* Mocek v. City of Albuquerque, 2013 WL 312881 (D.N.M. Jan. 14, 2013). Commentary on the *Mocek* case notes under, "Do you have a right to travel by air? Answers Yes," how The Airline Deregulation Act of 1978 guarantees the "public right of freedom of transit" by air, and that the

The deficiencies of the "single mode doctrine" are particularly apparent when a citizen needs to travel between the contiguous and the non-contiguous United States.[111] Commercial air service is the only mode of passenger common carrier transportation available between many U.S. locations, especially American states and territories outside the continental union. Particularly for non-continental interstate travel, where the only viable means of travel is by airplane, the "single mode doctrine" imposes on citizens an onerous, unreasonable, and unjustifiable burden.[112] It cannot stand constitutional scrutiny.

In sum, contrary to the Ninth Circuit rulings, burdens on a single mode of transportation do implicate the right to interstate travel. This is clearest when there is only one mode of common carrier travel, such as flying by commercial airline, available between the two non-continental U.S. locations, for instance, between the mainland and Hawaii. It may also be an unconstitutional burden when there is only one practicable mode of travel for long distances. In *Gilmore*, for example, the only way for Gilmore to get to Washington, D.C. from California to petition the federal government in a timely manner was to travel by air.[113]

For non-continental travel, the only other hypothetical way to reach offshore locations is by ship, but commercial ship service by U.S. carriers rarely exists.[114] Here, the "single mode doctrine" proves deficient

---

TSA is required by federal law (49 USC § 40101) to consider this right when it issues regulations. *State of New Mexico v. Phillip Mocek*, PAPERSPLEASE.ORG, http://www.papersplease.org/wp/mocek/ (last visited May 25, 2014). Airlines are common carriers. Mocek's attempted trip was an exercise of "the right . . . peaceably to assemble" as guaranteed by the First Amendment. Freedom of movement is also guaranteed by Article 12 of the International Covenant on Civil and Political Rights, a human rights treaty signed and ratified by the United States. *Id.*; *see also Identity Project tells UN Human Rights Committee that US Violates the Right to Travel*, PAPERSPLEASE.ORG (Jan. 8, 2013), http://www.papersplease.org/wp/2013/01/08/identity-project-tells-un-human-rights-committee-that-us-violates-the-right-to-travel (discussing submissions to the UNHRC); *see also Update to the U.N. Human Rights Committee concerning Violations of the Right to Freedom of Movement (ICCPR Article 12) by the Government of the U.S.A.*, PAPERSPLEASE.ORG (Feb. 10, 2014), *available at* http://papersplease.org/wp/wp-content/uploads/2014/02/idp-iccpr-update-travel.pdf (Identity Project stating to the U.N. Human Rights Committee that the United States violates the right to travel).

111. The United States comprises the forty-eight contiguous states and the non-contiguous U.S. states of Alaska and Hawaii, plus Puerto Rico, Guam, the U.S. Virgin Islands, and other offshore territories.

112. Richard Sobel & Ramon L. Torres, *The Right to Travel*, 80 J. OF TRANSP. L., LOGISTICS & POL'Y 13 (2013).

113. *See Want to Fly? Papers Please*, PAPERSPLEASE.ORG, http://papersplease.org/gilmore/facts.html (last updated Aug. 16, 2006).

114. For example, common carrier passenger ship service does not exist between the continental United States and Puerto Rico. *See Tourist Information*, WELCOME TO PUERTO RICO, http://www.topuertorico.org/tinfo.shtml (last visited May 26, 2014). The Passenger Vessel Services Act of 1886 established that passenger transport within the United States could only be carried out on a U.S. registered vessel. This would make any common-

because burdens imposed on individuals whose only alternative is the one mode of air travel lose entirely their right to interstate travel. Especially in the non-contiguous United States, when a single mode becomes the sole mode of travel, a citizen's constitutional protections for travel are broadest. To be plenary and efficacious, the right to travel must include protections for using all possible modes of travel.

Indeed, the "single mode doctrine" is also inapt for travel within the contiguous United States. This is especially so because of limitations in national air transportation. The general provisions of the *Air Commerce and Safety Regulations*[115] recognize that it is in the public's interest[116] to have an air transportation network. This ensures "the availability of a variety of adequate, economic, efficient, and low-priced services without unreasonable discrimination or unfair or deceptive practices."[117] The federal government has invested broadly in creating and maintaining the requisite air network.

As Congress recognized through codification, there is a compelling public interest in maintaining a national air transportation network available to all citizens.[118] Therefore, as in *Beckman v. Saratoga*, the mandate that railroad common carrier services be available to all citizens analogously requires that U.S. air transportation network and air common carrier services be available to all American citizens domestically, regardless of location.[119] The "single mode doctrine" also contravenes this congressional intent.

Air transportation is not only typically the most convenient method of even moderately distant interstate travel, but in many cases, it is the only feasible mode of interstate and in some cases of intrastate travel.[120] The Eighth Circuit held in *United States v. Kroll* that "flying may

carrier scheduled ship passenger service expensive, unprofitable, and therefore nonexistent. 46 App. U.S.C. §289 (2006). For Puerto Rico, see the section pertaining to the transportation of passengers between Puerto Rico and other United States ports; foreign-flag vessels; unavailability of United States flag service. 46 App. U.S.C. § 289c (2006). This section authorizes passenger service between the contiguous U.S. and Puerto Rico under certain conditions. This allows cruise ship services to stop in Puerto Rico when traveling directly between U.S. territories. *Id.* But this does not constitute common carrier water passenger service between the contiguous U.S. and Puerto Rico. *Id.* Hence, leisure cruise ships do not provide service between non-contiguous parts of the U.S., since their business purpose and schedule are not intended for point-to-point passenger and freight transportation. *Id.*

115. 49 U.S.C. § 40101 (2006).

116. *Id.*

117. *Id.* at § 40101(a)(4).

118. *See id.* at § 40101, § 40103.

119. Beckman v. Saratoga & Schenectady R.R., Co., 3 Paige Ch. 45, 75 (N.Y. 1831).

120. Some cities within Alaska, for instance, the capital Junea, are only accessible by air or sea, air being the only timely mode. Intrastate travel in some states is more convenient by air for travel between cities within a state separated by great distances and/or natural barriers, e.g., California, Florida, Illinois, New York, and Texas.

be the only practical means of transportation;" when limited, it often deprives an individual of the right to travel.[121] Even if other modes of travel exist, the Second Circuit held in *United States v. Albarado,* it is not acceptable to force travelers to forego using air travel because "it would work a considerable hardship on many air travelers to be forced to utilize an alternate form of transportation, assuming one exists at all."[122] More recently, in *Mohamed v. Holder*, the district court held that:

> The impact on a citizen who cannot use a commercial aircraft is profound. He is restricted in his practical ability to travel substantial distances within a short period of time, and the inability to fly to a significant extent defines the geographical area in which he may live his life. . . . An inability to travel by air also restricts one's ability to associate more generally, and effectively limits educational, employment and professional opportunities. It is difficult to think of many job[s] . . . where an inability to fly would not affect the prospects for employment or advancement. . . . An inability to fly likewise affects the possibility of recreational and religious travel . . . particularly those who are employed.[123]

In short, courts recognize the unique nature of flight as a necessarily accessible and protected mode of transportation under the travel right and federal law.

Passenger travel by airline common carriage also constitutes the only mode for covering large distances in a timely manner within the continental United States. People today do not have the luxury to journey for days across widely disbursed coastal areas within the United States from California to Maine. Citizens have responsibilities, and time is valuable. Jobs do not allow people to spend a great amount of time traveling.[124] Exercising constitutional rights requires timely access to travel great distances for citizens to petition the national government and exercise political liberties.[125]

---

121. United States v. Kroll, 481 F.2d 884, 886 (8th Cir. 1973).

122. United States v. Alvarado, 495 F.2d 799, 806 (2d Cir. 1974). However, in *Town of Southold v. Town of East Hampton*, the Second Circuit stated that travelers do not have "a constitutional right to the most convenient way of travel" and that minor restrictions do not abridge the right to travel. 477 F.3d 38, 54 (2d Cir. 2007) (referencing City of Houston v. F.A.A., 679 F.2d 1184, 1198 (5th Cir.1982)). This decision conflicts with *Kroll* and *Alvarado*, and with the right of citizens to enjoy the benefits and access to all public transportation modes. *Alvarado*, 495 F.2d at 806.

123. Mohamed v. Holder, 2014 WL 243115, at *6 (E.D.Va. Jan. 22, 2014).

124. Air travel has allowed for Congress to remain in session more days throughout the year and for members to return home for every recess and even weekly. CAL JILLSON, AMERICAN GOVERNMENT: POLITICAL DEVELOPMENT AND INSTITUTIONAL CHANGE 234 (2009).

125. An individual needing to reach the seat of the federal government in Washington, D.C. or of the state government in Juneau to petition the government for redress of

Traveling long distances within the contiguous United States relies on only one mode of travel: commercial airlines. Therefore, restricting this single mode of travel, by air, abridges the right to travel and the right to exercise political and personal liberties. The single mode construction thus contravenes the right to travel within the U.S. territory.[126] By threatening to prevent the use of what is often the only viable method of transportation—airline travel—and by imposing corollary chilling effects on citizens' right to seek redress from government, the "single mode doctrine" abridges the right to interstate travel and freedoms of expression and assembly. In doing so, it undermines the right to travel that is broadly non-discriminatory. The "single mode doctrine" fails historically and constitutionally. If any single mode is limited, the right to travel is abridged. Instead, the travel right is a multi-modal one that encompasses all forms of transport.

III. ABRIDGING THE RIGHT TO TRAVEL

As *Shapiro* articulated, the right to travel is a "fundamental right" guaranteed by the Constitution.[127] "An individual's liberty may be harmed by an act that causes or reasonably threatens a loss of physical locomotion or bodily control."[128] As *Guest* found, the right is "virtually unqualified."[129]

Especially in the surveillance age after 9/11, federal impediments to domestic travel particularly by air have undermined and abridged the rights of millions of passengers.[130] The major limitations on travel rights consist in identification and informational requirements, as well as intrusive physical screening. On the one hand, these limitations involve official air identification requirements in order to fly, watchlists and "no-fly" designations, and passenger pre-screening schemes to get a reservation. On the other hand, they involve whole body scanning and

---

grievances, as guaranteed by the First Amendment, may require air traveling as the only available mode to reach the government.

126. The "single mode doctrine" also conflicts with federal law requiring that modes of transportation be accessible. The federal government mandates that most public buildings, including airports and train stations, be accessible to people with disabilities. *See* 49 U.S.C. § 40101 (2006) (addressing handicap accessibility); *id.* at § 41705 (addressing discrimination laws); *see also id.* at § 4151-57. Similarly, federal law ensures that citizens living in remote areas are entitled to subsidized scheduled air service. A regular, subsidized minimum air service is maintained to many small communities in the United States. *See State of New Mexico v. Phillip Mocek*, *supra* note 110.

127. Shapiro v. Thompson, 394 U.S. 618, 630-31 (1969) (overruled parts unrelated to the right to travel by *Edema v. Jordan*); *see generally* Edema v. Jordan, 415 U.S. 651 (1974).

128. ELIZABETH P. FOLEY, LIBERTY FOR ALL: RECLAIMING INDIVIDUAL PRIVACY IN A NEW ERA OF PUBLIC MORALITY 49 (2006).

129. United States v. Guest, 383 U.S. 745, 757 (1966).

130. Sobel & Torres, *supra* note 112.

"enhanced" pat down searches. Each burdens citizens' rights to travel and to privacy. They abrogate citizens' rights without materially improving security procedures.[131] Since 1996, air passengers have faced the requirement to provide official identification in order to board aircraft.[132] This essentially creates an internal passport requirement to fly in the United States, abridging the right to move freely around the nation.

Invasive scans and searches at the airports also violate the fundamental conception of the Fourth Amendment and the right to privacy.[133] These intrusions essentially function as mass searches without even the "protection" of the general warrants and writs that the Founding Fathers despised. During a trial challenging the use of writs of assistance in the pre-Revolutionary colonies, James Otis presciently "attacked the Writ of Assistance because its use placed the liberty of every man in the hands of every petty officer."[134] Quite simply, historically and today invasive general search schemes directly contradict the underpinning of the Fourth Amendment.

The intrusiveness of recent airport searches is currently sanctioned by another questionable doctrine of "administrative searches"[135] that further erodes Fourth Amendment protections.[136] Again, this administrative construction, like the "single mode doctrine's" undermining travel rights, degrades the fundamental Fourth Amendment protections by resurrecting the equivalent of governmental use of general warrants.[137]

Despite quoting John Adams as a signer of the Declaration of Independence, about the detriment of unreasonable searches without warrants, *Frank v. State of Maryland* in 1959 sanctioned non-criminal public safety searches that required no warrants.[138] This first major departure from the founding principles of the Fourth Amendment opened the door to further government intrusions. The Court held that a health

---

131. *See* Sobel & Torres, *The Right to Travel: Part III Unjustified Limitations on the Rights to Travel*, 80 J. OF TRANSP. L., LOGISTICS & POL'Y 13, 28 (2013).

132. *See* Sean Holstege, *Case Centers on Secret ID Directive*, INSIDE BAY AREA, Dec. 9 2005.

133. *See* United States v. Davis, 482 F.2d 893, 913 (9th Cir. 1973) (stating that the "election to submit to a search is essentially a 'consent' granting the government a license to do what it would otherwise be barred from doing by the Fourth Amendment").

134. Otis's argument so impressed his audience and the people of the Colonies that John Adams maintained that "American Independence was then and there born." Frank v. State of Md., 359 U.S. 360, 364 (1959).

135. Eva Primus, *Disentangling Administrative Searches*, 111 COLUMN. L. REV. 254, 262 (2011).

136. *See Frank*, 359 U.S. at 365; *compare e.g.*, FTC v. Am. Tobacco Co., 264 U.S. 298 (1924); Boyd v. United States, 116 U.S. 616 (1886); I.C.C. v. Brinson, 154 U.S. 447 (1894); Tropicana v. United States, 789 F. Supp. 1154 (Ct. Int'l Trade 1992).

137. *See Frank*, 359 U.S. at 364.

138. *Id.* at 366.

inspector may enter a home without a warrant to find a public health hazard.[139] The *Frank* holding began a series of expansions of invasion of privacy.[140]

Justice Douglas's dissent in *Frank* eloquently identifies the majority's mistake: the Fourth Amendment was not "designed to protect criminals only."[141] His dissent clarifies, "[t]he security of one's privacy against arbitrary intrusion by the police—which is at the core of the Fourth Amendment—is basic to a free society."[142] Douglas also highlights the confusion that arises when administrative searches can lead to criminal penalties or are carried out by a police force: "This is a strange deletion to make from the Fourth Amendment. In some States the health inspectors are none other than the police themselves. In some States the presence of unsanitary conditions gives rise to criminal prosecutions."[143]

The place of privacy against unreasonable personal searches has been apparent for over a century in the Supreme Court jurisprudence since the *Boyd* decision in 1886.[144] While the majority in *Frank* explored the relation of the Fourth Amendment and the Fifth Amendment in criminal law, Justice Frankfurter mistook criminality as the key to whether a search is reasonable.[145] Earlier decisions like *Boyd,* which Frankfurter cites, did not require criminality for a search to necessitate a warrant.[146] Instead, *Boyd* states all "official acts and proceedings" are subject to the Fourth Amendment.[147] *Boyd* placed the primary importance on the object of the search as "a material ingredient, and [it] affects the sole object and purpose of search and seizure," whether the case involved a crime was merely dicta.[148] The dilution of the distinction in administrative search doctrine by requiring criminality has weakened the Fourth Amendment, just as Justice Douglas warned in *Frank*.[149]

The Fourth Amendment protection against unwarranted government searches "applies to governmental actions."[150] The amendment is "intended as a restraint upon the activities of sovereign authority."[151]

---

139. *Id.* at 373.
140. *See* Frank v. State of Md., 359 U.S. 360, 375 (1959).
141. *Id.* at 377 (Douglas, J., dissenting).
142. *Id.* at 375.
143. *Id.*
144. Boyd v. United States, 116 U.S. 616, 633 (1886); *see* Griswold v. Connecticut, 381 U.S. 479, 484 (1964).
145. Frank v. State of Md., 359 U.S. 360, 372 (1959).
146. *See generally* Boyd v. United States, 116 U.S. 616 (1886).
147. *Id.* at 624.
148. *Id.* at 622.
149. *Frank*, 359 U.S. at 373.
150. Bureau v. McDowell, 256 U.S. 465, 475 (1921).
151. *Id.*

Searches or seizures, like those at airports, are "ordinarily unreasonable in the absence of individualized suspicion of wrongdoing."[152]

The privacy rights inherent in the Constitution have eroded over time as the Supreme Court continues to undervalue privacy rights. Some courts find exceptions to the Fourth Amendment based on administrative convenience or alleged necessity.[153] As Justice Scalia wrote in *Kyllo v. United States*, "[i]t would be foolish to contend that the degree of privacy secured to citizens by the Fourth Amendment has been entirely unaffected by the advance of technology."[154]

The Fourth Amendment has now been further eroded by choices made by the Court. Technology advances in myriad ways, some privacy enhancing and some privacy inhibiting. When the Court insists on keeping the protections of the Fourth Amendment intact, technology more likely advances in a way that simultaneously retains full Fourth Amendment protections and meets the alleged requirements of convenience and necessity. Necessity as the mother of invention will lead technology to follow different and more privacy enhancing courses if the Court makes full protection of the Fourth Amendment a necessity for technological innovations.

Despite the protections embodied in the Fourth Amendment, courts have diluted the historical search and seizure doctrine over time.[155] Now, the government may often search persons to find evidence of a crime without a warrant, probable cause, or reasonable suspicion.[156] Thus, even when the potential criminality making a warrant necessary in *Frank* is present, the administrative search concept allows searching a person's body without probable cause or a judicial warrant.[157]

In fact, the privacy associated with a person's house should extend to one's body, since it is in essence more private than the home.[158] In 1924, the Court stated in *Federal Trade Commission v. Interstate Tobacco Company*:

---

152. City of Indianapolis v. Edmond, 531 U.S. 32, 37 (2000); *see also* William W. Greengage, *In Defense of the 'Per Se' rule: Justice Stewart's Struggle to Preserve the Fourth Amendment's Warrant Clause*, 31 AM. CRIM. L. REV. 4, 10-14 (1994).

153. "Airport screening searches . . . are constitutionally reasonable administrative searches because they are conducted as part of a general regulatory scheme in furtherance of an administrative purpose, namely, to prevent the carrying of weapons or explosives aboard aircraft, and thereby to prevent hijackings." United States v. Davis, 482 F.2d 893, 908 (9th Cir. 1973); *but see* Katz v. United States, 389 U.S. 347, 357 (1967).

154. Kyllo v. United States, 533 U.S. 27, 33-34 (2001); *but see* Sobel, Horwitz, & Jenkins, *supra* note 66.

155. Primus, *supra* note 135.

156. Elec. Privacy Info. Ctr. v. U.S. Dept. of Homeland Sec., 653 F.3d 1, 1 (D.C. Cir. 2011).

157. *Id.* at 10.

158. *See* Frank v. State of Md., 359 U.S. 360, 375 (1959).

> Anyone who respects the spirit as well as the letter of the Fourth Amendment would be loath to believe that Congress intended to authorize one of its subordinate agencies to sweep all our traditions into the fire, and to direct fishing expeditions into private papers on the possibility that they may disclose evidence of crime.[159]

Wide-ranging searches into private papers and houses are anathema to liberty guaranteed by the Fourth Amendment. Expeditions into a person's body are even more repugnant to the Fourth Amendment's purposes as a cornerstone of liberty.[160] As the court stated in *McDonald v. United States*:

> The presence of a search warrant serves a high function. Absent some grave emergency, the Fourth Amendment has interposed a magistrate between the citizen and the police. This was done not to shield criminals, nor to make the home a safe haven for illegal activities. It was done so that an objective mind might weigh the need to invade that privacy in order to enforce the law. The right of privacy was deemed too precious to entrust to the discretion of those whose job is the detection of crime and the arrest of criminals. Power is a heady thing; and history shows that the police acting on their own cannot be trusted.[161]

The Supreme Court in *United States v. Lefkowitz* articulated the straightforward notion: "Security against unlawful searches is more likely to be attained by resort to search warrants than by reliance upon the caution and sagacity of petty officers while acting under the excitement that attends the capture of persons accused of crime."[162] In short, warrant requirements protect privacy. With each additional assault on the Fourth Amendment, Justice Douglas' prophetic dissent in *Frank* rings even truer now: "We live in an era 'when politically controlled officials have grown powerful through an ever increasing series of minor infractions of civil liberties.' One invasion of privacy by an official of government can be as oppressive as another."[163]

The efficacy of many technologies that intrude on the rights to travel and privacy are unproven. Instead, many air travel requirements and procedures represent what security expert Bruce Schneier has called "security theater."[164] They are mainly "measures that make people feel more secure without doing anything to actually improve their

---

159. FTC v. Am. Tobacco Co., 264 U.S. 298, 305-06 (1924) (citing I.C.C. v. Brinson, 154 U.S. 447, 479 (1894)).

160. York v. Story, 324 F.2d 450, 455 (9th Cir. 1963).

161. McDonald v. United States, 335 U.S. 451, 455-56 (1959).

162. United States v. Lefkowitz, 285 U.S. 452, 464 (1932).

163. *Frank*, 359 U.S. at 382 (1959) (citing *Health Inspection of Private Dwelling Without Search Warrant*, 17 U. CHI L. REV. 733, 740 (1950)).

164. Bruce Schneier, *Flying on Someone Else's Airplane Ticket*, SCHNEIER ON SECURITY (Feb. 8, 2005), *available at* http://www.schneier.com/blog/archives/2005/02/flying_on_someo_1.html.

security."[165] The key point is that each of these "requirements" and technologies infringes on the rights to travel and privacy. Yet, the burden in a free society is on the government when it pursues, for instance, security to find ways that preserve basic rights while addressing valid policy goals.

While the variety of assaults on the right to travel are the most obvious today in air travel, the intrusions are beginning to appear in other modes of transportation as the governmental agencies seek to extend their authority to other transportation modes and nodes.[166] These inaptly expand the scope of abridgement of the right to travel: what happens at the airport checkpoint can extend to the subway turnstile.[167]

CONCLUSION: TOWARD A ROBUST RIGHT TO TRAVEL

As a fundamental political liberty since the Magna Carta, Blackstone's *Commentaries*, and the Articles of Confederation, the right to travel is essential for individual freedom and national unity. Its interstate manifestation has been broadly based in the privileges and immunities since the Articles of Confederation and the U.S. Constitution and encompasses all modes of travel across the federal union.

The travel right encompasses personal, political, and commercial movement fundamental to the nature of the United States by effectively stitching the union together. The right to travel guarantees the free movement of people and goods throughout the nation. It allows citizens to exercise other fundamental rights guaranteed by the Constitution and the Bill of Rights, like petitioning for redress of grievances and

---

165. None of the 911 hijackers who used their real names were identified beforehand. The would-be terrorist traveling on Christmas 2009 under his own name hid powdered explosive compound, PETN, in his clothing, despite both the physical and watchlist layers of security. The failure of the security procedures to prevent him from trying to ignite the explosive, exemplifies the failings of the system. Investigators concluded body-scanning devices would likely have not detected the compound. *Id.*; *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-385, AVIATION SECURITY: COMPUTER-ASSISTED PASSENGER PRESCREENING SYSTEM FACES SIGNIFICANT IMPLEMENTATION CHALLENGES (2004).

166. Aviation and Transportation Security Act, Pub. L. No. 107-71, § 115 Stat. 579 (2001) (assigning responsibility to TSA for security in all modes of transportation). TSA could expand pre-screening like Secure Flight to trains, subways and buses, create similar "no-travel lists," and implement them on all possible modes of interstate travel, including Amtrak. This could abridge the right to travel by every single transportation mode. *See* Thom Patterson, *TSA Rail, Subway Spot-Checks Raise Privacy Issues*, CNN (Jan. 28, 2012); Jen Quraishi, *Surprise! TSA Is Searching Your Car, Subway, Ferry, Bus, AND Plane*, MOTHER JONES (June 20, 2011), http://www.motherjones.com/mojo/2011/06tsa-swarms-800-bus-stations-public-transit-systems-yearly; see also Gilmore v. Gonzales, 435 F.3d 1125 (9th Cir. 2006) (discussing the prospects of IDs on other modes of travel).

167. For a more detailed discussion of the conflict between the right to travel, air identification, Secure Flight, and Whole Body Scanning system, *see* Sobel & Torres, *supra* note 112.

protecting privacy. In short, the right to travel freely implies respect for other liberties and rights.

The federal government's extensive national jurisdiction provides American citizens with constitutional protection for traveling domestically on common carriers. The "single mode doctrine" fails for its inconsistencies with the potent original historical and political underpinnings of travel rights. It also fails for its undue burdens on long distance travel, especially from the non-continental United States, but also within the contiguous U.S. territory, necessary here to live and carry out economic and political activities.

The impositions of burdens and regulations, like government identification requirements, passenger watch-list matching and prescreening programs, undermine the nature and exercise of the travel right, what it means to be an American citizen, and personal privacy. These abridgments transform travel from a foundational right into a privilege requiring governmental permission. They form the basis for a domestic passport system that undermines the right to travel and other fundamental freedoms.

The travel right is multi-modal and encompasses all methods of transportation. Contrary to the inaptly constructed "single mode doctrine," if any mode of transportation is restricted, then the constitutionally enshrined right of travel is abridged. Moreover, the lawful and beneficial relationship between the government and those governed by their consent is inverted by requirements for government ID and permission to travel. In the post-9/11 era, overreaching government agencies have assaulted the foundational travel and privacy rights by replacing "consent of the governed" with "permission from the government."

Contrary to certain circuit courts' truncation of the broad scope and strength of the travel right, a plenary right to travel, enshrined in the Constitution strengthens both liberty of the individual citizen and the very nature of a more perfect union. The Supreme Court of these United States needs to correct the misplotted course in some appellate opinions by rearticulating a plenary, original, and multi-modal constitutional right to travel.

The New England Journal of Medicine

Special Article

FIFTY YEARS LATER: THE SIGNIFICANCE OF THE NUREMBERG CODE

EVELYNE SHUSTER, PH.D.

THE Nuremberg Code is the most important document in the history of the ethics of medical research.[1-6] The Code was formulated 50 years ago, in August 1947, in Nuremberg, Germany, by American judges sitting in judgment of Nazi doctors accused of conducting murderous and torturous human experiments in the concentration camps (the so-called Doctors' Trial).[7] It served as a blueprint for today's principles that ensure the rights of subjects in medical research. Because of its link with the horrors of World War II and the use of prisoners in Nazi concentration camps for medical experimentation, debate continues today about the authority of the Code, its applicability to modern medical research, and even its authorship.[1,2,4,5,8] The chief prosecutor at the Doctors' Trial, General Telford Taylor, believed that one of the three U.S. judges, Harold Sebring, was the author of the Code.[2] Two American physicians who helped prosecute the Nazi doctors at Nuremberg, Leo Alexander and Andrew Ivy, have each been identified as the Code's author.[5,8-11] A careful reading

From the Veterans Affairs Medical Center, University and Woodland Ave., Philadelphia, PA 19104, where reprint requests should be addressed to Dr. Shuster.

THE NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential.

   This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

of the transcript of the Doctors' Trial, background documents, and the final judgment reveals that authorship was shared and that the famous 10 principles of the Code grew out of the trial itself.

In this article I will explain the important role that physicians had in the prosecution of the Nazi doctors and in the formulation of the Nuremberg Code and summarize how medical researchers have used the Code as a guide over the past five decades.

THE DOCTORS' TRIAL

The main trial at Nuremberg after World War II was conducted by the International Military Tribunal. The tribunal was made up of judges from the four allied powers (the United States, Britain, France, and the former Soviet Union) and was charged with trying Germany's major war criminals. After this first-of-its-kind international trial, the United States conducted 12 additional trials of representative Nazis from various sectors of the Third Reich, including law, finance, ministry, and manufacturing, before American Military Tribunals, also at Nuremberg. The first of these trials, the Doctors' Trial, involved 23 defendants, all but 3 of whom were physicians accused of murder and torture in the conduct of medical experiments on concentration-camp inmates.[7]

The indictment of the defendants was filed on October 25, 1946, 25 days after the conclusion of the first Nuremberg trial by the International Military Tribunal. The Doctors' Trial began on December 9, 1946, and ended on July 19, 1947. The case was heard by three judges and one alternate. Thirty-two prosecution witnesses and 53 defense witnesses, including the 23 defendants, testified. A total of 1471 documents were introduced into the record. Sixteen of the 23 defendants were found guilty; 7 of them were sentenced to death by hanging, 5 to life imprisonment, 2 to imprisonment for 25 years, 1 to imprisonment for 15 years, and 1 to imprisonment for 10 years. Seven were acquitted. The sentences were confirmed by the military governor, and, after the U.S. Supreme Court declined to review the case, the executions were carried out at the Landsberg prison.

For the United States and its chief prosecutor, Telford Taylor, the trial was a murder trial (and murder had been identified by the International Military Tribunal as a crime against humanity). Nonetheless, as Taylor pointed out in his opening statement, this was "no mere murder trial," because the defendants were physicians who had sworn to "do no harm" and to abide by the Hippocratic Oath.[12] He told the judges that the people of the world needed to know "with conspicuous clarity" the ideas and motives that moved these doctors "to treat their fellow human beings as less than beasts," and that "brought about such savageries" so that they could be "cut out and exposed before they become a spreading cancer in the breast of humanity."[12] One recurring theme was the relevance of Hippocratic ethics to human experimentation and whether Hippocratic moral ideals could be an exclusive guide to the ethics of research without risk to the human rights of subjects. In the trial's exploration of ideas that shaped medical-research ethics, three physicians had central roles: Leo Alexander, an American neuropsychiatrist, Werner Leibbrand, a German psychiatrist and medical historian, and Andrew Ivy, a renowned American physiologist.

Leo Alexander

Leo Alexander, a Viennese-born American physician, had joined the U.S. Army Medical Corps in 1942, before being stationed in England at the American Eighth Air Force base. At the end of the war, Alexander was sent on a special mission under the Combined Intelligence Objectives Sub-Committee, an intelligence organization with members from several nations, and charged by orders from Supreme Headquarters of Allied Expeditionary Forces to gather evidence for the Nuremberg trials. Two days before the opening of the Doctors' Trial, Alexander gave Taylor a memorandum entitled "Ethical and Non-Ethical Experimentation on Human Beings," in which he identified three ethical, legal, and scientific requirements for the conduct of human experimentation.[9] The first requirement established the right of the competent experimental subject to consent or refuse to participate in these terms: "the subject should be willing to undergo the experiment of his own free will. . . ." The second focused on the duty of physicians as expressed in the Hippocratic Oath, which Alexander restated in research terms: "the medical Hippocratic attitude prohibits an experiment if the foregone conclusion, probability or a priori reason to believe exists that death or disabling injury of the experimental subject will occur." The third characterized good research practices.

On April 15, 1947, Alexander gave Taylor a second memorandum.[9,11] In it he set forth in greater detail six specific conditions for ethically and legally permissible experiments on human beings. The first stated that

> the legally valid voluntary consent of the experimental subject is essential. This requires specifically the absence of duress, sufficient disclosure on the part of the experimenter and sufficient understanding on the part of the experimental subject of the exact nature and consequences of the experiment for which he volunteers, to permit an enlightened consent.

The five other conditions established the humanitarian nature and purpose of the experiment and the scientific integrity and obligations of the investigator to the welfare of the subject.

Werner Leibbrand

On January 27, 1947, Werner Leibbrand, a German psychiatrist and medical historian at Erlangen University, opened the debate on medical ethics at Nuremberg.[12] He explained to the court that German physicians at the beginning of the 20th century had adopted a "biologic thinking" according to which a patient was a series of biologic events, and nothing more than "a mere object, like a mail package."[12] Leibbrand insisted that such a view precluded any human relation between physicians and their patients and that it represented a perversion of Hippocratic ethics and "a lack of morality and reverence for human life."[12] He strongly condemned physicians who conducted experiments on subjects without their consent, and testified that this was also the result of biologic thinking.

During cross-examination, defense lawyers asserted that "civilized" nations such as France, the Netherlands, Britain, and the United States had performed dangerous medical experiments on prisoners, often without their consent. They cited American malaria experiments[12-14] to argue that Nazi physicians had followed common research practices. Leibbrand replied that this American research also was wrong because "prisoners were in a forced situation and could not be volunteers."[12] Leibbrand insisted that "the morality of a physician is to hold back his natural research urge which may result in doing harm, in order to maintain his basic medical attitude that is laid down in the Oath of Hippocrates."[12] This strong accusation of American research by the prosecution's first medical-ethics witness created major unanticipated problems for the prosecution. It therefore became necessary to broaden the scope of the trial by defining the conditions under which risky human experimentation is ethically permissible.

Defense lawyers explained that Nazi doctors were ordered by the state to conduct such experiments as the high-altitude, hypothermia, and seawater experiments on inmates at the Dachau concentration camp to determine how best to protect and treat German fliers and soldiers. They contended that these experiments were necessary and that the "good of the state" takes precedence over that of the individual.[12] Leibbrand replied that "the state could order deadly experiments on human subjects, but the physicians remained responsible for [not] carrying them out."[12] Once these physiologic experiments became the centerpiece of the trial, reliance on psychiatrists alone was not possible. The prosecution needed a prestigious medical scientist who was an authority on research physiology and whose wartime scientific interests corresponded to those of the Nazi doctor defendants. This expert was Andrew Ivy.

Andrew Ivy

Andrew Ivy was an internationally known physiologist and a noted scientist. He also had first-hand knowledge of the Stateville Penitentiary experiments on malaria[12,13] in his home state of Illinois, which the Nazi defendants attempted to liken to those performed on concentration-camp inmates. When the secretary of war, through the surgeon general of the army, asked the board of trustees of the American Medical Association to nominate a medical advisor to the Nuremberg prosecution, Ivy emerged as the natural nominee. On June 12, 1947, Ivy came to Nuremberg for the third time, this time to testify in rebuttal for the prosecution. His testimony, the longest of the trial, lasted four days.[12]

In direct examination, Ivy presented to the judges three research principles that he had formulated at the request of the American Medical Association and which, he said, reflected common research practices.[12] His document entitled "Principles of Ethics Concerning Experimentation with Human Beings," adopted by the American Medical Association House of Delegates in December 1946, read in part:

> 1. Consent of the human subject must be obtained. All subjects have been volunteers in the absence of coercion in any form. Before volunteering, subjects have been informed of the hazards, if any. Small rewards in various forms have been provided as a rule.
> 2. The experiment to be performed must be based on the results of animal experimentation and on a knowledge of the natural history of the disease under study, and must be so designed that the anticipated results will justify the performance of the experiment. The experiment must be such as to yield results for the good of society, unprocurable by other methods of study, and must not be random and unnecessary in nature.
> 3. The experiment must be conducted only by scientifically qualified persons and so as to avoid all unnecessary physical and mental suffering and injury and only after the results of adequate animal experimentation have eliminated any *a priori* reason to believe that death or disabling injury will occur. . . .[15]

Ivy explained that these common-sense principles mirrored the understanding shared by everyone in practice in the medical community.[12] The first principle was that a physician would never do anything to a patient or subject before obtaining his or her consent. Ivy also asserted that, unlike Leibbrand, he did not consider prisoners to be in an inherently coercive situation and thus unable to give consent, because in democratic countries where the rights of individuals are respected, prisoners can always say yes or no without fear of being punished.[12] He testified:

> The American malaria experiments with 800 or more prisoners were absolutely justified, scientifically, legally and ethically even if they bring with them danger to human life. To treat malaria was an important scientific problem,

and so long as the subjects volunteer and are explained the hazards of the experiments, there is no ethical reason against it. . . . If prisoners condemned to death are volunteers, then it was ethical to do just that.[12]

During cross-examination, Ivy acknowledged that there were no written principles of research in the United States or elsewhere before December 1946 and that the principles adopted by the American Medical Association were expressly formulated for the Doctors' Trial.[12] Ivy also recognized that the right of the research subject to withdraw from an experiment may not always exist, as in the malaria experiments in which the subjects had already been infected, or in dangerous experiments in which the subjects could be severely injured or fatally harmed. Ivy agreed with Leibbrand that researchers must refuse to conduct experiments on human beings when ordered by the state in order "to save lives," because in such cases subjects would not be volunteers. He declared that "[t]here is no justification in killing five people in order to save the lives of five hundred" and that "no state or politician under the sun could force [him] to perform a medical experiment which [he] thought was morally unjustified."[12] Ivy also stressed that the state may not assume the moral responsibility of physicians to their patients or research subjects, arguing that "[E]very physician should be acquainted with the Hippocratic Oath [which] represents the Golden Rule of the medical profession in the United States, and, to [his] knowledge, throughout the world."[12] When, finally, defense counsel asked Ivy to reconcile the Hippocratic moral maxim that forbids physicians to "administer a poison to anyone even when asked to do so" with conducting potentially lethal experimental interventions on volunteer subjects, Ivy replied, "I believe this Hippocratic commandment refers to the function of the physician as a therapist, not as an experimentalist, and what refers to the Hippocratic Oath is that he must have respect for life and the human rights of his experimental patient."[12]

MEDICAL ETHICS AND HUMAN RIGHTS

The judges at Nuremberg, although they realized the importance of Hippocratic ethics and the maxim *primum non nocere*, recognized that more was necessary to protect human research subjects. Accordingly, the judges articulated a sophisticated set of 10 research principles centered not on the physician but on the research subject. These principles, which we know as the Nuremberg Code, included a new, comprehensive, and absolute requirement of informed consent (principle 1), and a new right of the subject to withdraw from participation in an experiment (principle 9). The judges adopted much of the language proposed by Alexander and Ivy but were more emphatic about the necessity and attributes of the subject's consent and explicitly added the subject's right to withdraw.

In the traditional Hippocratic doctor–patient relationship, the patient is silent and dutifully obedient to the beneficent and trusted physician.[16-18] Obviously, the patient must seek the physician's help and initiate the therapeutic relationship with the physician.[17] But once patients agree to be treated, they trust that the physician will act in their interest, or at least will do no harm.[17,18] In research, which is outside the beneficent context of the physician–patient relationship, this trust may be misplaced, because the physician's primary goal is not to treat; rather, it is to test a scientific hypothesis by following a protocol, regardless of the patient-subject's best interest. It is therefore only through a conflation of treatment and research that Alexander and Ivy believed they could expand on Hippocratic ethics to protect the rights of subjects in human experimentation.[19,20] Their Hippocratic view of medical research may have prevented them from adequately appreciating the risks to research subjects, which are many times greater than the risks to patients who are merely being treated.[21] Hippocratic ethics, even when supplemented with informed consent, tend to submerge the subject's autonomy into what the physician-investigator thinks is best for the subject.

Informed consent, the core of the Nuremberg Code, has rightly been viewed as the protection of subjects' human rights. The key contribution of Nuremberg was to merge Hippocratic ethics and the protection of human rights into a single code. The Nuremberg Code not only requires that physician-researchers protect the best interests of their subjects (principles 2 through 8 and 10) but also proclaims that subjects can actively protect themselves as well (principles 1 and 9). Most strikingly, for example, in Hippocratic ethics the subject relies on the physician to determine when it is in the subject's best interest to end his or her participation in an experiment. In the Nuremberg Code, the judges gave the subject as much authority as the physician-researcher to end the experiment before its conclusion (principle 9).

50 YEARS AFTER NUREMBERG

The Nuremberg Code has not been officially adopted in its entirety as law by any nation or as ethics by any major medical association. Nonetheless, its influence on global human-rights law and medical ethics has been profound.[6] Its basic requirement of informed consent, for example, has been universally accepted and is articulated in international law in Article 7 of the United Nations International Covenant on Civil and Political Rights (1966).[6,22] Informed consent, with specific reliance on the Nuremberg Code, is also the basis of the International Ethical Guidelines for Biomedical Research Involving Human Subjects, the most recent guidelines

promulgated by the World Health Organization and the Council for International Organizations of Medical Sciences (1993).[23]

The World Medical Association, established during World War II, has been accused of purposely trying to undermine Nuremberg in order to distance physicians from Nazi medical crimes.[24] The election of a former Nazi physician and SS member, Hans-Joachim Sewering, to the presidency of that organization in 1992 added credibility to that accusation.[24] (Because of public criticism, Sewering later withdrew.) Nonetheless, the various versions of the Declaration of Helsinki promulgated by the World Medical Association since 1964, although attempting to have peer review supplement informed consent and even supplant it as their central principle in the context of "therapeutic research," all implicitly acknowledge Nuremberg's authority. Both the Nuremberg Code and the Declaration of Helsinki served as models for the current U.S. federal research regulations, which require not only the informed consent of the research subject (with proxy consent sometimes acceptable, as for young children), but also prior peer review of research protocols by a committee (the institutional review board of the hospital or research institution) that includes a representative of the community.[25]

The Nuremberg Code focuses on the human rights of research subjects, the Declaration of Helsinki focuses on the obligations of physician-investigators to research subjects, and the federal regulations emphasize the obligations of research institutions that receive federal funds. Nonetheless, by insisting that medical investigators alone cannot set the rules for the ethical conduct of research, even when guided by beneficence and Hippocratic ethics, and by adopting a human-rights perspective that acknowledges the centrality of informed consent and the right of the subject to withdraw, the Nuremberg Code has changed forever the way both physicians and the public view the proper conduct of medical research on human subjects. Fifty years after Nuremberg, we recognize the human-rights legacy of the Nuremberg Code and are better able to face the critical challenge of applying the Code in its entirety and enforcing its human-rights provisions.

REFERENCES

1. Annas GJ, Grodin MA, eds. The Nazi doctors and the Nuremberg Code: human rights in human experimentation. New York: Oxford University Press, 1992.
2. Biomedical ethics and the shadow of Nazism: a conference on the proper use of the Nazi analogy in ethical debate/April 8, 1976. Hastings Cent Rep 1976;6(4):Suppl:1-20.
3. Katz J. The consent principle of the Nuremberg Code: its significance then and now. In: Annas GJ, Grodin MA, eds. The Nazi doctors and the Nuremberg Code: human rights in human experimentation. New York: Oxford University Press, 1992:227-39.
4. Ambroselli C. L'éthique médicale. Paris: Presses Universitaires de France, Que Sais-je?, 1988.
5. Advisory Committee on Human Radiation Experiments. Final report. Washington, D.C.: Government Printing Office, 1995.
6. Grodin MA, Annas GJ. Legacies of Nuremberg: medical ethics and human rights. JAMA 1996;276:1682-3.
7. International Military Tribunal. Trials of war criminals before the Nuremberg Military Tribunals under Control Council law no. 10. Washington, D.C.: Government Printing Office, 1950.
8. Moreno JD. Reassessing the influence of the Nuremberg Code on American medical ethics. J Contemp Health Law Policy 1997;13:347-60.
9. Alexander L. Ethics of human experimentation. Psychiatr J Univ Ottawa 1976;1:40-6.
10. Grodin MA. Historical origins of the Nuremberg Code. In: Annas GJ, Grodin MA, eds. The Nazi doctors and the Nuremberg Code: human rights in human experimentation. New York: Oxford University Press, 1992:121-44.
11. Bayle F. Croix gammée contre caducée: les expériences humaines en Allemagne pendant la Deuxième Guerre Mondiale. Berlin, Germany: Commission Scientifique des Crimes de Guerre, 1950.
12. Complete transcript of the Nuremberg Medical Trial: United States v. Karl Brandt et al. (Case 1). Washington, D.C.: National Archives, November 21, 1946–August 20, 1947. (Microfilm publication no. M887.)
13. Ethics governing the service of prisoners as subjects in medical experiments: report of a committee appointed by Governor Dwight H. Green of Illinois. JAMA 1948;136:457-8.
14. Annas GJ, Glantz LH, Katz BF. Informed consent to human experimentation: the subject's dilemma. Cambridge, Mass.: Ballinger Publishing, 1977.
15. Supplementary report of the Judicial Council. JAMA 1946;132:1090.
16. Hippocratic corpus: oath and epidemics 1. Jones WHS, trans. Cambridge, Mass.: Harvard University Press, 1923.
17. Aziza-Shuster E. Le médecin de soi-même. Paris: Presses Universitaires de France, 1972.
18. Katz J. The silent world of doctor and patient. New York: Free Press, 1984.
19. Alexander L. Medical science under dictatorship. N Engl J Med 1949; 241:39-47.
20. Ivy AC. Nazi war crimes of a medical nature. JAMA 1949;139:131-5.
21. Bacteriology and the end of nineteenth-century "medical theory." In: Canguilhem G. Ideology and rationality in the history of the life science. Goldhammer A, trans. Cambridge, Mass.: MIT Press, 1988:51-77.
22. The international covenant on civil and political rights. Suppl. 52. No. 16. Article 7. New York: United Nations Office of Public Information, 1966. (UN document no. A/6316.)
23. International ethical guidelines for biomedical research involving human subjects. Geneva: Council for International Organizations of Medical Sciences, 1993.
24. Grodin MA, Annas GJ, Glantz LH. Medicine and human rights: a proposal for international action. Hastings Cent Rep 1993;23(4):8-12.
25. National Institute of Health, Office for Protection from Research Risks, protection of human subjects, 45 C.F.R. 46 (1991).

Plaintiffs' Exhibit 486

International Covenant on Civil and Political Rights

Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, entry into force 23 March 1976, in accordance with Article 49

Preamble

The States Parties to the present Covenant,

Considering that, in accordance with the principles proclaimed in the Charter of the United Nations, recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world,

Recognizing that these rights derive from the inherent dignity of the human person,

Recognizing that, in accordance with the Universal Declaration of Human Rights, the ideal of free human beings enjoying civil and political freedom and freedom from fear and want can only be achieved if conditions are created whereby everyone may enjoy his civil and political rights, as well as his economic, social and cultural rights,

Considering the obligation of States under the Charter of the United Nations to promote universal respect for, and observance of, human rights and freedoms,

Realizing that the individual, having duties to other individuals and to the community to which he belongs, is under a responsibility to strive for the promotion and observance of the rights recognized in the present Covenant,

Agree upon the following articles:

PART I

Article 1

1. All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development.

2. All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law. In no case may a people be deprived of its own means of subsistence.

3. The States Parties to the present Covenant, including those having responsibility for the administration of Non-Self-Governing and Trust Territories, shall promote the realization of the right of self-determination, and shall respect that right, in conformity with the provisions of the Charter of the United Nations.

PART II

Article 2

1. Each State Party to the present Covenant undertakes to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

2. Where not already provided for by existing legislative or other measures, each State Party to the present Covenant undertakes to take the necessary steps, in accordance with its constitutional processes and with the provisions of the present Covenant, to adopt such laws or other measures as may be necessary to give effect to the rights recognized in the present Covenant.

3. Each State Party to the present Covenant undertakes:

(a) To ensure that any person whose rights or freedoms as herein recognized are violated shall have an effective remedy, notwithstanding that the violation has been committed by persons acting in an official capacity;

(b) To ensure that any person claiming such a remedy shall have his right thereto determined by competent judicial, administrative or legislative authorities, or by any other competent authority provided for by the legal system of the State, and to develop the possibilities of judicial remedy;

(c) To ensure that the competent authorities shall enforce such remedies when granted.

Article 3

The States Parties to the present Covenant undertake to ensure the equal right of men and women to the enjoyment of all civil and political rights set forth in the present Covenant.

Article 4

1 . In time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with their other obligations under international law and do not involve discrimination solely on the ground of race, colour, sex, language, religion or social origin.

2. No derogation from articles 6, 7, 8 (paragraphs I and 2), 11, 15, 16 and 18 may be made under this provision.

3. Any State Party to the present Covenant availing itself of the right of derogation shall immediately inform the other States Parties to the present Covenant, through the intermediary of the Secretary-General of the United Nations, of the provisions from which it has derogated and of the reasons by which it was actuated. A further communication shall be made, through the same intermediary, on the date on which it terminates such derogation.

Article 5

1. Nothing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or perform any act aimed at the destruction of any of the rights and freedoms recognized herein or at their limitation to a greater extent than is provided for in the present Covenant.

2. There shall be no restriction upon or derogation from any of the fundamental human rights recognized or existing in any State Party to the present Covenant pursuant to law, conventions, regulations or custom on the pretext that the present Covenant does not recognize such rights or that it recognizes them to a lesser extent.

PART III

Article 6

1. Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.

2. In countries which have not abolished the death penalty, sentence of death may be imposed only for the most serious crimes in accordance with the law in force at the time of the commission of the crime and not contrary to the provisions of the present Covenant and to the Convention on the Prevention and Punishment of the Crime of Genocide. This penalty can only be carried out pursuant to a final judgement rendered by a competent court.

3. When deprivation of life constitutes the crime of genocide, it is understood that nothing in this article shall authorize any State Party to the present Covenant to derogate in any way from any obligation assumed under the provisions of the Convention on the Prevention and Punishment of the Crime of Genocide.

4. Anyone sentenced to death shall have the right to seek pardon or commutation of the sentence. Amnesty, pardon or commutation of the sentence of death may be granted in all cases.

5. Sentence of death shall not be imposed for crimes committed by persons below eighteen years of age and shall not be carried out on pregnant women.

6. Nothing in this article shall be invoked to delay or to prevent the abolition of capital punishment by any State Party to the present Covenant.

Article 7

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

Article 8

1. No one shall be held in slavery; slavery and the slave-trade in all their forms shall be prohibited.

2. No one shall be held in servitude.

3.

(a) No one shall be required to perform forced or compulsory labour;

(b) Paragraph 3 (a) shall not be held to preclude, in countries where imprisonment with hard labour may be imposed as a punishment for a crime, the performance of hard labour in pursuance of a sentence to such punishment by a competent court;

(c) For the purpose of this paragraph the term "forced or compulsory labour" shall not include:

(i) Any work or service, not referred to in subparagraph (b), normally required of a person who is under detention in consequence of a lawful order of a court, or of a person during conditional release from such detention;

(ii) Any service of a military character and, in countries where conscientious objection is recognized, any national service required by law of conscientious objectors;

(iii) Any service exacted in cases of emergency or calamity threatening the life or well-being of the community;

(iv) Any work or service which forms part of normal civil obligations.

Article 9

1. Everyone has the right to liberty and security of person. No one shall be subjected to arbitrary arrest or detention. No one shall be deprived of his liberty except on such grounds and in accordance with such procedure as are established by law.

2. Anyone who is arrested shall be informed, at the time of arrest, of the reasons for his arrest and shall be promptly informed of any charges against him.

3. Anyone arrested or detained on a criminal charge shall be brought promptly before a judge or other officer authorized by law to exercise judicial power and shall be entitled to trial within a reasonable time or to release. It shall not be the general rule that persons awaiting trial shall be detained in custody, but release may be subject to guarantees to appear for trial, at any other stage of the judicial proceedings, and, should occasion arise, for execution of the judgement.

4. Anyone who is deprived of his liberty by arrest or detention shall be entitled to take proceedings before a court, in order that that court may decide without delay on the lawfulness of his detention and order his release if the detention is not lawful.

5. Anyone who has been the victim of unlawful arrest or detention shall have an enforceable right to compensation.

Article 10

1. All persons deprived of their liberty shall be treated with humanity and with respect for the inherent dignity of the human person.

2.

(a) Accused persons shall, save in exceptional circumstances, be segregated from convicted persons and shall be subject to separate treatment appropriate to their status as unconvicted persons;

(b) Accused juvenile persons shall be separated from adults and brought as speedily as possible for adjudication.

3. The penitentiary system shall comprise treatment of prisoners the essential aim of which shall be their reformation and social rehabilitation. Juvenile offenders shall be segregated from adults and be accorded treatment appropriate to their age and legal status.

Article 11

No one shall be imprisoned merely on the ground of inability to fulfil a contractual obligation. Article 12

1. Everyone lawfully within the territory of a State shall, within that territory, have the right to liberty of movement and freedom to choose his residence.

2. Everyone shall be free to leave any country, including his own.

3. The above-mentioned rights shall not be subject to any restrictions except those which are provided by law, are necessary to protect national security, public order (ordre public), public health or morals or the rights and freedoms of others, and are consistent with the other rights recognized in the present Covenant.

4. No one shall be arbitrarily deprived of the right to enter his own country.

Article 13

An alien lawfully in the territory of a State Party to the present Covenant may be expelled therefrom only in pursuance of a decision reached in accordance with law and shall, except where compelling reasons of national security otherwise require, be allowed to submit the reasons against his expulsion and to have his case reviewed by, and be represented for the purpose before, the competent authority or a person or persons especially designated by the competent authority.

Article 14

1. All persons shall be equal before the courts and tribunals. In the determination of any criminal charge against him, or of his rights and obligations in a suit at law, everyone shall be entitled to a fair and public hearing by a competent, independent and impartial tribunal established by law. The press and the public may be excluded from all or part of a trial for reasons of morals, public order (ordre public) or national security in a democratic society, or when the interest of the private lives of the parties so requires, or to the extent strictly necessary in the opinion of the court in special circumstances where publicity would prejudice the interests of justice; but any judgement rendered in a criminal case or in a suit at law shall be made public except where the interest of juvenile persons otherwise requires or the proceedings concern matrimonial disputes or the guardianship of children.

2. Everyone charged with a criminal offence shall have the right to be presumed innocent until proved guilty according to law.

3. In the determination of any criminal charge against him, everyone shall be entitled to the following minimum guarantees, in full equality: (a) To be informed promptly and in detail in a language which he understands of the nature and cause of the charge against him;

(b) To have adequate time and facilities for the preparation of his defence and to communicate with counsel of his own choosing;

(c) To be tried without undue delay;

(d) To be tried in his presence, and to defend himself in person or through legal assistance of his own choosing; to be informed, if he does not have legal assistance, of this right; and to have legal assistance assigned to him, in any case where the interests of justice so require, and without payment by him in any such case if he does not have sufficient means to pay for it;

(e) To examine, or have examined, the witnesses against him and to obtain the attendance and examination of witnesses on his behalf under the same conditions as witnesses against him;

(f) To have the free assistance of an interpreter if he cannot understand or speak the language used in court;

(g) Not to be compelled to testify against himself or to confess guilt.

4. In the case of juvenile persons, the procedure shall be such as will take account of their age and the desirability of promoting their rehabilitation. 5. Everyone convicted of a crime shall have the right to his conviction and sentence being reviewed by a higher tribunal according to law.

6. When a person has by a final decision been convicted of a criminal offence and when subsequently his conviction has been reversed or he has been pardoned on the ground that a new or newly discovered fact shows conclusively that there has been a miscarriage of justice, the person who has suffered punishment as a result of such conviction shall be compensated according to law, unless it is proved that the non-disclosure of the unknown fact in time is wholly or partly attributable to him.

7. No one shall be liable to be tried or punished again for an offence for which he has already been finally convicted or acquitted in accordance with the law and penal procedure of each country.

Article 15

1 . No one shall be held guilty of any criminal offence on account of any act or omission which did not constitute a criminal offence, under national or international law, at the time when it was committed. Nor shall a heavier penalty be imposed than the one that was applicable at the time when the criminal offence was committed. If, subsequent to the commission of the offence, provision is made by law for the imposition of the lighter penalty, the offender shall benefit thereby.

2. Nothing in this article shall prejudice the trial and punishment of any person for any act or omission which, at the time when it was committed, was criminal according to the general principles of law recognized by the community of nations.

Article 16

Everyone shall have the right to recognition everywhere as a person before the law.

Article 17

1. No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation.

2. Everyone has the right to the protection of the law against such interference or attacks.

Article 18

1. Everyone shall have the right to freedom of thought, conscience and religion. This right shall include freedom to have or to adopt a religion or belief of his choice, and freedom, either individually or in community with others and in public or private, to manifest his religion or belief in worship, observance, practice and teaching.

2. No one shall be subject to coercion which would impair his freedom to have or to adopt a religion or belief of his choice.

3. Freedom to manifest one's religion or beliefs may be subject only to such limitations as are prescribed by law and are necessary to protect public safety, order, health, or morals or the fundamental rights and freedoms of others.

Plaintiffs' Exhibit 487

WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the

researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

Universal Declaration of Human Rights

Preamble

Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world,

Whereas disregard and contempt for human rights have resulted in barbarous acts which have outraged the conscience of mankind, and the advent of a world in which human beings shall enjoy freedom of speech and belief and freedom from fear and want has been proclaimed as the highest aspiration of the common people,

Whereas it is essential, if man is not to be compelled to have recourse, as a last resort, to rebellion against tyranny and oppression, that human rights should be protected by the rule of law,

Whereas it is essential to promote the development of friendly relations between nations,

Whereas the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women and have determined to promote social progress and better standards of life in larger freedom,

Whereas Member States have pledged themselves to achieve, in cooperation with the United Nations, the promotion of universal respect for and observance of human rights and fundamental freedoms,

Whereas a common understanding of these rights and freedoms is of the greatest importance for the full realization of this pledge,

Now, therefore,

The General Assembly,

Proclaims this Universal Declaration of Human Rights as a common standard of achievement for all peoples and all nations, to the end that every individual and every organ of society, keeping this Declaration constantly in mind, shall strive by

teaching and education to promote respect for these rights and freedoms and by progressive measures, national and international, to secure their universal and effective recognition and observance, both among the peoples of Member States themselves and among the peoples of territories under their jurisdiction.

Article I

All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.

Article 2

Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. Furthermore, no distinction shall be made on the basis of the political, jurisdictional or international status of the country or territory to which a person belongs, whether it be independent, trust, non-self-governing or under any other limitation of sovereignty.

Article 3

Everyone has the right to life, liberty and the security of person.

Article 4

No one shall be held in slavery or servitude; slavery and the slave trade shall be prohibited in all their forms.

Article 5

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.

Article 6

Everyone has the right to recognition everywhere as a person before the law.

Article 7

All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination.

Article 8

Everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law.

Article 9

No one shall be subjected to arbitrary arrest, detention or exile.

Article 10

Everyone is entitled in full equality to a fair and public hearing by an independent and impartial tribunal, in the determination of his rights and obligations and of any criminal charge against him.

Article 11

1. Everyone charged with a penal offence has the right to be presumed innocent until proved guilty according to law in a public trial at which he has had all the guarantees necessary for his defence.
2. No one shall be held guilty of any penal offence on account of any act or omission which did not constitute a penal offence, under national or international law, at the time when it was committed. Nor shall a heavier

penalty be imposed than the one that was applicable at the time the penal offence was committed.

Article 12

No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks.

Article 13

1. Everyone has the right to freedom of movement and residence within the borders of each State.
2. Everyone has the right to leave any country, including his own, and to return to his country.

Article 14

1. Everyone has the right to seek and to enjoy in other countries asylum from persecution.
2. This right may not be invoked in the case of prosecutions genuinely arising from non-political crimes or from acts contrary to the purposes and principles of the United Nations.

Article 15

1. Everyone has the right to a nationality.
2. No one shall be arbitrarily deprived of his nationality nor denied the right to change his nationality.

Article 16

1. Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and to found a family. They are entitled to equal rights as to marriage, during marriage and at its dissolution.
2. Marriage shall be entered into only with the free and full consent of the intending spouses.
3. The family is the natural and fundamental group unit of society and is entitled to protection by society and the State.

Article 17

1. Everyone has the right to own property alone as well as in association with others.
2. No one shall be arbitrarily deprived of his property.

Article 18

Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance.

Article 19

Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers.

Article 20

1. Everyone has the right to freedom of peaceful assembly and association.
2. No one may be compelled to belong to an association.

Article 21

1. Everyone has the right to take part in the government of his country, directly or through freely chosen representatives.
2. Everyone has the right to equal access to public service in his country.
3. The will of the people shall be the basis of the authority of government; this will shall be expressed in periodic and genuine elections which shall be by universal and equal suffrage and shall be held by secret vote or by equivalent free voting procedures.

Article 22

Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality.

Article 23

1. Everyone has the right to work, to free choice of employment, to just and favourable conditions of work and to protection against unemployment.
2. Everyone, without any discrimination, has the right to equal pay for equal work.
3. Everyone who works has the right to just and favourable remuneration ensuring for himself and his family an existence worthy of human dignity, and supplemented, if necessary, by other means of social protection.
4. Everyone has the right to form and to join trade unions for the protection of his interests.

Article 24

Everyone has the right to rest and leisure, including reasonable limitation of working hours and periodic holidays with pay.

Article 25

1. Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.
2. Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.

Article 26

1. Everyone has the right to education. Education shall be free, at least in the elementary and fundamental stages. Elementary education shall be compulsory. Technical and professional education shall be made generally available and higher education shall be equally accessible to all on the basis of merit.
2. Education shall be directed to the full development of the human personality and to the strengthening of respect for human rights and fundamental freedoms. It shall promote understanding, tolerance and friendship among all nations, racial or religious groups, and shall further the activities of the United Nations for the maintenance of peace.
3. Parents have a prior right to choose the kind of education that shall be given to their children.

Article 27

1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Article 28

Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized.

Article 29

1. Everyone has duties to the community in which alone the free and full development of his personality is possible.
2. In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society.
3. These rights and freedoms may in no case be exercised contrary to the purposes and principles of the United Nations.

Article 30

Nothing in this Declaration may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms set forth herein.

CONVENTION ON INTERNATIONAL CIVIL AVIATION
SIGNED AT CHICAGO ON 7 DECEMBER 1944

Plaintiffs' Exhibit 489

Entry into force:	The Convention entered into force on 4 April 1947.
Status:	193 parties.
This list is based on information received from the depositary, the Government of the United States of America	

State	Date of deposit of instrument of ratification or notification of adherence (A)
Afghanistan	4 April 1947
Albania	28 March 1991 (A)
Algeria	7 May 1963 (A)
Andorra	26 January 2001 (A)
Angola	11 March 1977 (A)
Antigua and Barbuda	10 November 1981 (A)
Argentina	4 June 1946 (A)
Armenia	18 June 1992 (A)
Australia	1 March 1947
Austria	27 August 1948 (A)
Azerbaijan	9 October 1992 (A)
Bahamas	27 May 1975 (A)
Bahrain	20 August 1971 (A)
Bangladesh	22 December 1972 (A)
Barbados	21 March 1967 (A)
Belarus	4 June 1993 (A)
Belgium	5 May 1947
Belize	7 December 1990 (A)
Benin	29 May 1961 (A)
Bhutan	17 May 1989 (A)
Bolivia (Plurinational State of)	4 April 1947
Bosnia and Herzegovina	13 January 1993 (A)
Botswana	28 December 1978 (A)
Brazil	8 July 1946
Brunei Darussalam	4 December 1984 (A)
Bulgaria	8 June 1967 (A)
Burkina Faso	21 March 1962 (A)
Burundi	19 January 1968 (A)
Cabo Verde	19 August 1976 (A)
Cambodia	16 January 1956 (A)
Cameroon	15 January 1960 (A)
Canada	13 February 1946
Central African Republic	28 June 1961 (A)
Chad	3 July 1962 (A)
Chile	11 March 1947
China (1)	20 February 1946
Colombia	31 October 1947
Comoros	15 January 1985 (A)
Congo	26 April 1962 (A)
Cook Islands	20 August 1986 (A)
Costa Rica	1 May 1958
Côte d'Ivoire	31 October 1960 (A)
Croatia	9 April 1992 (A)
Cuba	11 May 1949
Cyprus	17 January 1961 (A)
Czech Republic	4 March 1993 (A)
Democratic People's Republic of Korea	16 August 1977 (A)
Democratic Republic of the Congo	27 July 1961 (A)
Denmark	28 February 1947

State	Date of deposit of instrument of ratification or notification of adherence (A)
Djibouti	30 June 1978 (A)
Dominica	14 March 2019 (A)
Dominican Republic	25 January 1946
Ecuador	20 August 1954
Egypt	13 March 1947
El Salvador	11 June 1947
Equatorial Guinea	22 February 1972 (A)
Eritrea	17 September 1993 (A)
Estonia	24 January 1992 (A)
Eswatini	14 February 1973 (A)
Ethiopia	1 March 1947
Fiji	5 March 1973 (A)
Finland	30 March 1949 (A)
France	25 March 1947
Gabon	18 January 1962 (A)
Gambia	13 May 1977 (A)
Georgia	21 January 1994 (A)
Germany (2)	9 May 1956 (A)
Ghana	9 May 1957 (A)
Greece	13 March 1947
Grenada	31 August 1981 (A)
Guatemala	28 April 1947
Guinea	27 March 1959 (A)
Guinea-Bissau	15 December 1977 (A)
Guyana	3 February 1967 (A)
Haiti	25 March 1948
Honduras	7 May 1953
Hungary	30 September 1969 (A)
Iceland	21 March 1947
India	1 March 1947
Indonesia	27 April 1950 (A)
Iran (Islamic Republic of)	19 April 1950
Iraq	2 June 1947
Ireland	31 October 1946
Israel	24 May 1949 (A)
Italy	31 October 1947 (A)
Jamaica	26 March 1963 (A)
Japan	8 September 1953 (A)
Jordan	18 March 1947 (A)
Kazakhstan	21 August 1992 (A)
Kenya	1 May 1964 (A)
Kiribati	14 April 1981 (A)
Kuwait	18 May 1960 (A)
Kyrgyzstan	25 February 1993 (A)
Lao People’s Democratic Republic	13 June 1955 (A)
Latvia	13 July 1992 (A)
Lebanon	19 September 1949
Lesotho	19 May 1975 (A)
Liberia	11 February 1947
Libya	29 January 1953 (A)
Lithuania	8 January 1992 (A)
Luxembourg	28 April 1948
Madagascar	14 April 1962 (A)
Malawi	11 September 1964 (A)
Malaysia	7 April 1958 (A)
Maldives	12 March 1974 (A)

State	Date of deposit of instrument of ratification or notification of adherence (A)
Mali	8 November 1960 (A)
Malta	5 January 1965 (A)
Marshall Islands	18 March 1988 (A)
Mauritania	13 January 1962 (A)
Mauritius	30 January 1970 (A)
Mexico	25 June 1946
Micronesia (Federated States of)	27 September 1988 (A)
Monaco	4 January 1980 (A)
Mongolia	7 September 1989 (A)
Montenegro	12 February 2007 (A)
Morocco	13 November 1956 (A)
Mozambique	5 January 1977 (A)
Myanmar	8 July 1948 (A)
Namibia	30 April 1991 (A)
Nauru	25 August 1975 (A)
Nepal	29 June 1960 (A)
Netherlands (3)	26 March 1947
New Zealand	7 March 1947
Nicaragua	28 December 1945
Niger	29 May 1961 (A)
Nigeria	14 November 1960 (A)
North Macedonia	10 December 1992 (A)
Norway	5 May 1947
Oman	24 January 1973 (A)
Pakistan	6 November 1947 (A)
Palau	4 October 1995 (A)
Panama (4)	18 January 1960 (A)
Papua New Guinea	15 December 1975 (A)
Paraguay	21 January 1946
Peru	8 April 1946
Philippines	1 March 1947
Poland	6 April 1945
Portugal	27 February 1947
Qatar	5 September 1971 (A)
Republic of Korea	11 November 1952 (A)
Republic of Moldova	1 June 1992 (A)
Romania	30 April 1965 (A)
Russian Federation	15 October 1970 (A)
Rwanda	3 February 1964 (A)
Saint Kitts and Nevis	21 May 2002 (A)
Saint Lucia	20 November 1979 (A)
Saint Vincent and the Grenadines	15 November 1983 (A)
Samoa	21 November 1996 (A)
San Marino	13 May 1988 (A)
Sao Tome and Principe	28 February 1977 (A)
Saudi Arabia	19 February 1962 (A)
Senegal	11 November 1960 (A)
Serbia (7)	14 December 2000 (A)
Seychelles	25 April 1977 (A)
Sierra Leone	22 November 1961 (A)
Singapore	20 May 1966 (A)
Slovakia	15 March 1993 (A)
Slovenia	13 May 1992 (A)
Solomon Islands	11 April 1985 (A)
Somalia	2 March 1964 (A)
South Africa	1 March 1947

State	Date of deposit of instrument of ratification or notification of adherence (A)
South Sudan	11 October 2011 (A)
Spain	5 March 1947
Sri Lanka	1 June 1948 (A)
Sudan	29 June 1956 (A)
Suriname	5 March 1976 (A)
Sweden	7 November 1946
Switzerland (5)	6 February 1947
Syrian Arab Republic	21 December 1949
Tajikistan	3 September 1993 (A)
Thailand	4 April 1947
Timor-Leste	4 August 2005 (A)
Togo	18 May 1965 (A)
Tonga	2 November 1984 (A)
Trinidad and Tobago	14 March 1963 (A)
Tunisia	18 November 1957 (A)
Turkey	20 December 1945
Turkmenistan	15 March 1993 (A)
Tuvalu	19 October 2017 (A)
Uganda	10 April 1967 (A)
Ukraine	10 August 1992 (A)
United Arab Emirates	25 April 1972 (A)
United Kingdom	1 March 1947
United Republic of Tanzania	23 April 1962 (A)
United States	9 August 1946
Uruguay	14 January 1954
Uzbekistan	13 October 1992 (A)
Vanuatu	17 August 1983 (A)
Venezuela (Bolivarian Republic of)	1 April 1947 (A)
Viet Nam	13 March 1980 (A)
Yemen (6)	17 April 1964 (A)
Zambia	30 October 1964 (A)
Zimbabwe	11 February 1981 (A)

(1) A letter dated 15 February 1974 from the Government of the People's Republic of China advised ICAO that "the Government of the People's Republic of China has decided to recognize the Convention on International Civil Aviation, which the then Government of China signed in Chicago on 9 December 1944 and of which an instrument of ratification was deposited by it on 20 February 1946".

(2) The German Democratic Republic, which adhered to the Convention on 2 April 1990, acceded to the Federal Republic of Germany on 3 October 1990.

(3) By a Note dated 9 January 1986 the Government of the Kingdom of the Netherlands informed the Government of the United States of America that as of 1 January 1986 the Convention is applicable to the Netherlands Antilles (without Aruba) and to Aruba.

(4) The accession of Panama contains the following statement designated as "reservation":
"La República de Panamá se adhiere a dicha CONVENCIÓN con la reserva de que la República de Panamá no da su asentimiento a la palabra *jurisdicción* que aparece en el Artículo 2 de la versión española de la Convención, como equivalente del término *suzerainty* que aparece en el texto ingles".
("The Republic of Panama accedes to the said Convention with the reservation that the Republic of Panama does not give its assent to the word *jurisdiction* appearing in Article 2 of the Convention as equivalent to the term *suzerainty* which appears in the English text.")

(5) The Minister of Switzerland made the following statement in the note transmitting the Swiss Instrument of Ratification: "My Government has instructed me to notify you that the authorities in Switzerland have agreed with the authorities in the Principality of Liechtenstein that this Convention will be applicable to the territory of the Principality as well as to that of the Swiss Confederation, as long as the Treaty of 29 March 1923 integrating the whole territory of Liechtenstein with the Swiss customs territory will remain in force".

(6) The People's Democratic Republic of Yemen, which adhered to the Convention on 28 January 1970, merged with the Yemen Arab Republic on 22 May 1990.

(7) On 4 February 2003, the name of the State of the Federal Republic of Yugoslavia was changed to Serbia and Montenegro. Following the Declaration of Independence adopted by the National Assembly of Montenegro on 3 June 2006, Serbia advised ICAO by a note dated 7 June 2006 that the membership of the state union of Serbia and Montenegro in ICAO is continued by the Republic of Serbia. Serbia subsequently advised ICAO by a note dated 13 July 2006 that the Republic of Serbia continues to exercise its rights and honour its commitments deriving from international treaties concluded by Serbia and Montenegro and requests that the Republic of Serbia be considered a party to all international agreements in force, instead of Serbia and Montenegro.

Doc 7300/9

Convention on International Civil Aviation

Convention relative à l'aviation civile internationale

Convenio sobre Aviación Civil Internacional

Конвенция о международной гражданской авиации

This document supersedes Doc 7300/8.
Le présent document annule et remplace le Doc 7300/8.
Este documento remplaza el Doc 7300/8.
Настоящий документ заменяет Doc 7300/8.

Ninth Edition – Neuvième édition – Novena edición – Издание девятое — 2006

International Civil Aviation Organization
Organisation de l'aviation civile internationale
Organización de Aviación Civil Internacional
Международная организация гражданской авиации

FOREWORD

This document contains the text of the Convention on International Civil Aviation, signed at Chicago on 7 December 1944 (hereinafter referred to as the "Convention"), in the English, French, Russian and Spanish languages. Each of these texts is equally authentic. The English text is the text adopted and signed at Chicago on 7 December 1944, amended as indicated below. The French and Spanish texts are the texts adopted by and annexed to the Protocol on the Authentic Trilingual Text of the Convention, signed at Buenos Aires on 24 September 1968 (hereinafter referred to as the "Buenos Aires Protocol"), amended as indicated below. The text of the Buenos Aires Protocol is reproduced in this document at pages 45 to 47. This Protocol came into force on 24 October 1968. The Russian text is the text adopted by and annexed to the Protocol on the Authentic Quadrilingual Text of the Convention, signed at Montreal on 30 September 1977 (hereinafter referred to as the "Protocol on the Authentic Quadrilingual Text"), amended as indicated below. This Protocol came into force on 16 September 1999. The text of the Protocol on the Authentic Quadrilingual Text is reproduced in this document at pages 48 to 51.

In the body of the above-mentioned texts of the Convention, in English, French, Russian and Spanish, as presented in this document, are incorporated all the amendments made to the Convention which were in force on 1 January 2006, namely in respect of:

a) Article 3 *bis* (non-use of weapons against civil aircraft in flight);

b) Article 45 (permanent seat of the Organization);

c) Article 48 *a)* (frequency of Assembly Sessions);

d) Article 49 *e)* (powers of Assembly relating to annual budgets);

e) Article 50 *a)* (composition and election of Council);

f) Article 56 (membership of Air Navigation Commission);

g) Article 61 (budget and apportionment of expenses);

h) Article 83 *bis* (transfer of certain functions and duties in cases of lease, charter or interchange of aircraft);

i) Article 93 *bis* (expulsion from the International Civil Aviation Organization or suspension of membership in it); and

j) the final paragraph, adding Russian to the authentic texts of the Convention.

AVANT-PROPOS

Le présent document comporte le texte de la Convention relative à l'aviation civile internationale, signé à Chicago le 7 décembre 1944 (appelé ci-après la «Convention»), en langues française, anglaise, espagnole et russe. Chacun de ces textes fait également foi. Le texte anglais est celui qui a été adopté et signé à Chicago le 7 décembre 1944, amendé de la manière indiquée ci-dessous. Les textes français et espagnol sont ceux qui ont été adoptés au moyen du Protocole concernant le texte authentique trilingue de la Convention, et qui sont annexés à ce protocole, signé à Buenos Aires le 24 septembre 1968 (appelé ci-après le «Protocole de Buenos Aires»), amendé de la manière indiquée ci-dessous. Le texte du Protocole de Buenos Aires est reproduit dans le présent document aux pages 45 à 47. Ce protocole est entré en vigueur le 24 octobre 1968. Le texte russe est celui qui a été adopté au moyen du Protocole concernant le texte authentique quadrilingue de la Convention, et qui est annexé à ce protocole, signé à Montréal le 30 septembre 1977 (appelé ci-après le «Protocole concernant le texte authentique quadrilingue»), amendé de la manière indiquée ci-dessous. Ce protocole est entré en vigueur le 16 septembre 1999. Le texte du Protocole concernant le texte authentique quadrilingue est reproduit dans le présent document aux pages 48 à 51.

Les textes français, anglais, espagnol et russe précités de la Convention, tels qu'ils figurent dans le présent document, comportent tous les amendements apportés à la Convention qui étaient en vigueur le 1er janvier 2006, et qui concernaient:

a) l'article 3 *bis* (non-utilisation d'armes contre des aéronefs civils en vol);

b) l'article 45 (siège permanent de l'Organisation);

c) l'article 48 *a)* (fréquence des sessions de l'Assemblée);

d) l'article 49 *e)* (pouvoirs de l'Assemblée en matière de budgets annuels);

e) l'article 50 *a)* (composition et élection du Conseil);

f) l'article 56 (membres de la Commission de navigation aérienne);

g) l'article 61 (budget et répartition des dépenses);

h) l'article 83 *bis* (transfert de certaines fonctions et obligations en cas de location, d'affrètement ou de banalisation d'aéronefs);

i) l'article 93 *bis* (exclusion d'un État de l'Organisation de l'aviation civile internationale ou suspension de sa qualité de membre de l'Organisation);

j) le dernier paragraphe (ajout du russe aux textes authentiques de la Convention).

Attention is invited to the footnotes to the above-mentioned amendments.

Further amendments to the Convention have been adopted but have not been incorporated in this document as they have not yet entered into force, namely in respect of:

a) the final paragraph of the Convention, adding Arabic to the authentic texts of the Convention, adopted by the 31st Session of the Assembly; and

b) the final paragraph of the Convention, adding Chinese to the authentic texts of the Convention, adopted by the 32nd Session of the Assembly.

On voudra bien se reporter aux notes de bas de page relatives aux amendements précités.

D'autres amendements de la Convention ont été adoptés mais n'ont pas été incorporés au présent document du fait qu'ils ne sont pas encore entrés en vigueur. Il s'agit:

a) d'un amendement du dernier paragraphe de la Convention qui ajoute l'arabe aux textes authentiques de la Convention et qui a été adopté par l'Assemblée à sa 31e session;

b) d'un amendement du dernier paragraphe de la Convention qui ajoute le chinois aux textes authentiques de la Convention et qui a été adopté par l'Assemblée à sa 32e session.

TABLE OF CONTENTS

TABLE DES MATIÈRES

CONVENTION[1]

ON INTERNATIONAL CIVIL AVIATION

Signed at Chicago, on 7 December 1944

PREAMBLE

WHEREAS the future development of international civil aviation can greatly help to create and preserve friendship and understanding among the nations and peoples of the world, yet its abuse can become a threat to the general security; and

WHEREAS it is desirable to avoid friction and to promote that cooperation between nations and peoples upon which the peace of the world depends;

THEREFORE, the undersigned governments having agreed on certain principles and arrangements in order that international civil aviation may be developed in a safe and orderly manner and that international air transport services may be established on the basis of equality of opportunity and operated soundly and economically;

Have accordingly concluded this Convention to that end.

1. Came into force on 4 April 1947, the thirtieth day after deposit with the Government of the United States of America of the twenty-sixth instrument of ratification thereof or notification of adherence thereto, in accordance with Article 91 *b)*.

CONVENTION[1]

RELATIVE À L'AVIATION CIVILE INTERNATIONALE

Signée à Chicago, le 7 décembre 1944

PRÉAMBULE

CONSIDÉRANT que le développement futur de l'aviation civile internationale peut grandement aider à créer et à préserver entre les nations et les peuples du monde l'amitié et la compréhension, alors que tout abus qui en serait fait peut devenir une menace pour la sécurité générale,

CONSIDÉRANT qu'il est désirable d'éviter toute mésentente entre les nations et les peuples et de promouvoir entre eux la coopération dont dépend la paix du monde,

EN CONSÉQUENCE, les Gouvernements soussignés étant convenus de certains principes et arrangements, afin que l'aviation civile internationale puisse se développer d'une manière sûre et ordonnée et que les services internationaux de transport aérien puissent être établis sur la base de l'égalité des chances et exploités d'une manière saine et économique,

Ont conclu la présente Convention à ces fins.

1. Entrée en vigueur le 4 avril 1947, trentième jour après le dépôt auprès du Gouvernement des États-Unis d'Amérique du vingt-sixième instrument de ratification ou notification d'adhésion, *conformément* à l'article 91 *b)*.

munitions of war or implements of war for the purposes of this Article, giving due consideration, for the purposes of uniformity, to such recommendations as the International Civil Aviation Organization may from time to time make.

b) Each contracting State reserves the right, for reasons of public order and safety, to regulate or prohibit the carriage in or above its territory of articles other than those enumerated in paragraph *a)*: provided that no distinction is made in this respect between its national aircraft engaged in international navigation and the aircraft of the other States so engaged; and provided further that no restriction shall be imposed which may interfere with the carriage and use on aircraft of apparatus necessary for the operation or navigation of the aircraft or the safety of the personnel or passengers.

par voie de règlement ce qu'il faut entendre par munitions de guerre ou matériel de guerre aux fins du présent article, en tenant dûment compte, dans un souci d'uniformité, des recommandations que l'Organisation de l'aviation civile internationale pourrait formuler le cas échéant.

b) Chaque État contractant se réserve le droit, pour des raisons d'ordre public et de sécurité, de réglementer ou d'interdire le transport, à l'intérieur ou au-dessus de son territoire, d'articles autres que ceux qui sont mentionnés au paragraphe *a)*, à condition qu'il ne soit fait aucune distinction à cet égard entre ses aéronefs nationaux employés à la navigation internationale et les aéronefs des autres États employés aux mêmes fins, et à condition aussi qu'il ne soit imposé aucune restriction pouvant gêner le transport et l'usage, à bord des aéronefs, des appareils nécessaires à l'exploitation ou à la navigation desdits aéronefs, ou à la sécurité du personnel ou des passagers.

Article 36

Photographic apparatus

Each contracting State may prohibit or regulate the use of photographic apparatus in aircraft over its territory.

Article 36

Appareils photographiques

Tout État contractant peut interdire ou réglementer l'usage d'appareils photographiques à bord des aéronefs survolant son territoire.

CHAPTER VI

INTERNATIONAL STANDARDS AND RECOMMENDED PRACTICES

Article 37

Adoption of international standards and procedures

Each contracting State undertakes to collaborate in securing the highest practicable degree of uniformity in regulations, standards, procedures, and organization in relation to aircraft, personnel, airways and auxiliary services in all matters in which such uniformity will facilitate and improve air navigation.

To this end the International Civil Aviation Organization shall adopt and amend from time to time, as may be necessary,

CHAPITRE VI

NORMES ET PRATIQUES RECOMMANDÉES INTERNATIONALES

Article 37

Adoption de normes et procédures internationales

Chaque État contractant s'engage à prêter son concours pour atteindre le plus haut degré réalisable d'uniformité dans les règlements, les normes, les procédures et l'organisation relatifs aux aéronefs, au personnel, aux voies aériennes et aux services auxiliaires, dans toutes les matières pour lesquelles une telle uniformité facilite et améliore la navigation aérienne.

À cette fin, l'Organisation de l'aviation civile internationale adopte et amende, selon les nécessités, les normes, pratiques

international standards and recommended practices and procedures dealing with:

a) Communications systems and air navigation aids, including ground marking;

b) Characteristics of airports and landing areas;

c) Rules of the air and air traffic control practices;

d) Licensing of operating and mechanical personnel;

e) Airworthiness of aircraft;

f) Registration and identification of aircraft;

g) Collection and exchange of meteorological information;

h) Log books;

i) Aeronautical maps and charts;

j) Customs and immigration procedures;

k) Aircraft in distress and investigation of accidents;

and such other matters concerned with the safety, regularity, and efficiency of air navigation as may from time to time appear appropriate.

recommandées et procédures internationales traitant des sujets suivants:

a) systèmes de communications et aides à la navigation aérienne, y compris le balisage au sol;

b) caractéristiques des aéroports et des aires d'atterrissage;

c) règles de l'air et pratiques de contrôle de la circulation aérienne;

d) licences et brevets du personnel technique d'exploitation et d'entretien;

e) navigabilité des aéronefs;

f) immatriculation et identification des aéronefs;

g) collecte et échange de renseignements météorologiques;

h) livres de bord;

i) cartes et plans aéronautiques;

j) formalités de douane et d'immigration;

k) aéronefs en détresse et enquêtes sur les accidents;

et, lorsqu'il paraît approprié de le faire, de tout autre sujet intéressant la sécurité, la régularité et l'efficacité de la navigation aérienne.

Article 38

Departures from international standards and procedures

Any State which finds it impracticable to comply in all respects with any such international standard or procedure, or to bring its own regulations or practices into full accord with any international standard or procedure after amendment of the latter, or which deems it necessary to adopt regulations or practices differing in any particular respect from those established by an international standard, shall give immediate notification to the International Civil Aviation Organization of the differences between its own practice and that established by the international standard. In the case of amendments to international standards, any State which does not make the appropriate amendments to its own regulations or practices shall give notice to the Council within sixty days of the adoption of the amendment to the international standard, or

Article 38

Dérogation aux normes et aux procédures internationales

Tout État qui estime ne pouvoir se conformer en tous points à l'une quelconque de ces normes ou procédures internationales, ou mettre ses propres règlements ou pratiques en complet accord avec une norme ou procédure internationale amendée, ou qui juge nécessaire d'adopter des règles ou des pratiques différant sur un point quelconque de celles qui sont établies par une norme internationale, notifie immédiatement à l'Organisation de l'aviation civile internationale les différences entre ses propres pratiques et celles qui sont établies par la norme internationale. Dans le cas d'amendements à des normes internationales, tout État qui n'apporte pas à ses propres règlements ou pratiques les amendements appropriés en avise le Conseil dans les soixante jours à compter de l'adoption de l'amendement à la norme internationale ou

indicate the action which it proposes to take. In any such case, the Council shall make immediate notification to all other states of the difference which exists between one or more features of an international standard and the corresponding national practice of that State.

indique les mesures qu'il se propose de prendre. En pareil cas, le Conseil notifie immédiatement à tous les autres États la différence existant entre un ou plusieurs points de la norme internationale et la pratique nationale correspondante de l'État en question.

Article 39

Endorsement of certificates and licenses

a) Any aircraft or part thereof with respect to which there exists an international standard of airworthiness or performance, and which failed in any respect to satisfy that standard at the time of its certification, shall have endorsed on or attached to its airworthiness certificate a complete enumeration of the details in respect of which it so failed.

b) Any person holding a license who does not satisfy in full the conditions laid down in the international standard relating to the class of license or certificate which he holds shall have endorsed on or attached to his license a complete enumeration of the particulars in which he does not satisfy such conditions.

Article 39

Annotation des certificats et licences

a) Tout aéronef ou élément d'aéronef au sujet duquel il existe une norme internationale de navigabilité ou de performance et qui n'a pas satisfait sur un point quelconque à cette norme lors de l'établissement de son certificat de navigabilité, doit avoir sous forme d'annotation sur son certificat de navigabilité, ou en annexe à celui-ci, l'énumération complète des détails sur lesquels l'aéronef ou l'élément d'aéronef s'écartait de cette norme.

b) Tout titulaire d'une licence qui ne satisfait pas entièrement aux conditions imposées par la norme internationale relative à la classe de la licence ou du brevet qu'il détient doit avoir sous forme d'annotation sur sa licence, ou en annexe à celle-ci, l'énumération complète des points sur lesquels il ne satisfait pas auxdites conditions.

Article 40

Validity of endorsed certificates and licenses

No aircraft or personnel having certificates or licenses so endorsed shall participate in international navigation, except with the permission of the State or States whose territory is entered. The registration or use of any such aircraft, or of any certificated aircraft part, in any State other than that in which it was originally certificated shall be at the discretion of the State into which the aircraft or part is imported.

Article 40

Validité des certificats et des licences annotés

Aucun aéronef ou membre du personnel dont le certificat ou la licence a été ainsi annoté ne peut participer à la navigation internationale si ce n'est avec la permission de l'État ou des États sur le territoire desquels il pénètre. L'immatriculation ou l'emploi d'un tel aéronef ou d'un élément certifié d'aéronef dans un État autre que celui où il a été certifié à l'origine, est laissé à la discrétion de l'État dans lequel cet aéronef ou élément est importé.

Article 41

Recognition of existing standards of airworthiness

The provisions of this Chapter shall not apply to aircraft and aircraft equipment of types of which the prototype is submitted

Article 41

Reconnaissance des normes de navigabilité existantes

Les dispositions du présent chapitre ne s'appliquent ni aux aéronefs ni au matériel d'aéronefs des types dont le prototype

PART II

THE INTERNATIONAL CIVIL AVIATION ORGANIZATION

CHAPTER VII

THE ORGANIZATION

Article 43

Name and composition

An organization to be named the International Civil Aviation Organization is formed by the Convention. It is made up of an Assembly, a Council, and such other bodies as may be necessary.

Article 44

Objectives

The aims and objectives of the Organization are to develop the principles and techniques of international air navigation and to foster the planning and development of international air transport so as to:

a) Insure the safe and orderly growth of international civil aviation throughout the world;

b) Encourage the arts of aircraft design and operation for peaceful purposes;

c) Encourage the development of airways, airports, and air navigation facilities for international civil aviation;

d) Meet the needs of the peoples of the world for safe, regular, efficient and economical air transport;

e) Prevent economic waste caused by unreasonable competition;

f) Insure that the rights of contracting States are fully respected and that every contracting State has a fair opportunity to operate international airlines;

DEUXIÈME PARTIE

L'ORGANISATION DE L'AVIATION CIVILE INTERNATIONALE

CHAPITRE VII

L'ORGANISATION

Article 43

Nom et composition

Il est institué par la présente Convention une organisation qui portera le nom d'Organisation de l'aviation civile internationale. Elle se compose d'une Assemblée, d'un Conseil et de tous autres organes qui pourraient être nécessaires.

Article 44

Objectifs

L'Organisation a pour buts et objectifs d'élaborer les principes et les techniques de la navigation aérienne internationale et de promouvoir la planification et le développement du transport aérien international de manière à:

a) assurer le développement ordonné et sûr de l'aviation civile internationale dans le monde entier;

b) encourager les techniques de conception et d'exploitation des aéronefs à des fins pacifiques;

c) encourager le développement des voies aériennes, des aéroports et des installations et services de navigation aérienne pour l'aviation civile internationale;

d) répondre aux besoins des peuples du monde en matière de transport aérien sûr, régulier, efficace et économique;

e) prévenir le gaspillage économique résultant d'une concurrence déraisonnable;

f) assurer le respect intégral des droits des États contractants et une possibilité équitable pour chaque État contractant d'exploiter des entreprises de transport aérien international;

g) Avoid discrimination between contracting States;

h) Promote safety of flight in international air navigation;

i) Promote generally the development of all aspects of international civil aeronautics.

Article 45*

Permanent seat

The permanent seat of the Organization shall be at such place as shall be determined at the final meeting of the Interim Assembly of the Provisional International Civil Aviation Organization set up by the Interim Agreement on International Civil Aviation signed at Chicago on December 7, 1944. The seat may be temporarily transferred elsewhere by decision of the Council, and otherwise than temporarily by decision of the Assembly, such decision to be taken by the number of votes specified by the Assembly. The number of votes so specified will not be less than three-fifths of the total number of contracting States.

Article 46

First meeting of Assembly

The first meeting of the Assembly shall be summoned by the Interim Council of the above-mentioned Provisional Organization as soon as the Convention has come into force, to meet at a time and place to be decided by the Interim Council.

* This is the text of the Article as amended by the 8th Session of the Assembly on 14 June 1954; it entered into force on 16 May 1958. The original text read as follows:

"The permanent seat of the Organization shall be at such place as shall be determined at the final meeting of the Interim Assembly of the Provisional International Civil Aviation Organization set up by the Interim Agreement on International Civil Aviation signed at Chicago on December 7, 1944. The seat may be temporarily transferred elsewhere by decision of the Council."

g) éviter la discrimination entre États contractants;

h) promouvoir la sécurité de vol dans la navigation aérienne internationale;

i) promouvoir, en général, le développement de l'aéronautique civile internationale sous tous ses aspects.

Article 45*

Siège permanent

L'Organisation aura son siège permanent au lieu que fixera, au cours de sa dernière session, l'Assemblée intérimaire de l'Organisation provisoire de l'aviation civile internationale, établie par l'Accord intérimaire sur l'aviation civile internationale signé à Chicago le 7 décembre 1944. Ce siège pourra être transféré provisoirement en tout autre lieu par décision du Conseil, et autrement que de façon provisoire par décision de l'Assemblée, cette décision devant recueillir le nombre des suffrages fixé par l'Assemblée. Le nombre des suffrages ainsi fixé ne sera pas inférieur aux trois cinquièmes du nombre total des États contractants.

Article 46

Première session de l'Assemblée

La première session de l'Assemblée sera convoquée par le Conseil intérimaire de l'Organisation provisoire précitée dès l'entrée en vigueur de la présente Convention et se tiendra à la date et au lieu que fixera le Conseil intérimaire.

* Ce texte est celui de l'article modifié lors de la 8e session de l'Assemblée, le 14 juin 1954; il est entré en vigueur le 16 mai 1958. Le texte original se lisait comme suit:

«L'Organisation aura son siège permanent au lieu que fixera, au cours de sa dernière session, l'Assemblée intérimaire de l'Organisation provisoire de l'aviation civile internationale, établie par l'Accord intérimaire sur l'aviation civile internationale signé à Chicago le 7 décembre 1944. Ce siège pourra être transféré provisoirement en tout autre lieu par décision du Conseil.»

Article 47

Legal capacity

The Organization shall enjoy in the territory of each contracting State such legal capacity as may be necessary for the performance of its functions. Full juridical personality shall be granted wherever compatible with the constitution and laws of the State concerned.

Article 47

Capacité juridique

Sur le territoire de chaque État contractant, l'Organisation jouit de la capacité juridique nécessaire à l'exercice de ses fonctions. La pleine personnalité juridique lui est accordée partout où elle est compatible avec la constitution et les lois de l'État intéressé.

CHAPTER VIII

THE ASSEMBLY

CHAPITRE VIII

L'ASSEMBLÉE

Article 48

Meetings of Assembly and voting

a) The Assembly shall meet not less than once in three years and shall be convened by the Council at a suitable time and place. An extraordinary meeting of the Assembly may be held at any time upon the call of the Council or at the request of not less than one-fifth of the total number of contracting States addressed to the Secretary General.*

b) All contracting States shall have an equal right to be represented at the meetings of the Assembly and each

Article 48

Sessions de l'Assemblée et vote

a) L'Assemblée se réunit au moins une fois tous les trois ans et est convoquée par le Conseil en temps et lieu utiles. Elle peut tenir une session extraordinaire à tout moment sur convocation du Conseil ou sur requête adressée au Secrétaire général par un nombre d'États contractants égal au cinquième au moins du nombre total de ces États*.

b) Tous les États contractants ont un droit égal d'être représentés aux sessions de l'Assemblée et chaque État

---

* This is the text of the Article as amended by the 14th Session of the Assembly on 15 September 1962; it entered into force on 11 September 1975. The previous text of this Article as amended by the 8th Session of the Assembly on 14 June 1954 and which entered into force on 12 December 1956 read as follows:

"*a)* The Assembly shall meet not less than once in three years and shall be convened by the Council at a suitable time and place. Extraordinary meetings of the Assembly may be held at any time upon the call of the Council or at the request of any ten contracting States addressed to the Secretary General."

The original unamended text of the Convention read as follows:

"*a)* The Assembly shall meet annually and shall be convened by the Council at a suitable time and place. Extraordinary meetings of the Assembly may be held at any time upon the call of the Council or at the request of any ten contracting States addressed to the Secretary General."

* Ce texte est celui de l'article modifié lors de la 14e session de l'Assemblée, le 15 septembre 1962; il est entré en vigueur le 11 septembre 1975. Le texte précédent de cet article établi par l'Assemblée à sa 8e session, le 14 juin 1954, et qui est entré en vigueur le 12 décembre 1956 se lisait comme suit:

«*a)* L'Assemblée se réunit au moins une fois tous les trois ans et est convoquée par le Conseil en temps et lieu utiles. Elle peut tenir des sessions extraordinaires à tout moment sur convocation du Conseil ou sur requête adressée au Secrétaire général par dix États contractants.»

Le texte original de cet article se lisait comme suit:

«*a)* L'Assemblée se réunit chaque année et est convoquée par le Conseil en temps et lieu utiles. Elle peut tenir des sessions extraordinaires à tout moment sur convocation du Conseil ou sur requête adressée au Secrétaire général par dix États contractants.»

Plaintiffs' Exhibit 491

un.org

UN Enable - Promoting the rights of Persons with Disabilities ICAO

22-28 minutes

Response

I wish to refer to your letter dated 30 January 2003, reference DESA/DIS03/2, requesting the views of the International Civil Aviation Organization (ICAO) on proposals for a Comprehensive and Integral International Convention on Protection and Promotion of the Rights and Dignity of Persons with Disabilities.

I would like to inform you that, pursuant to Article 37 of the *Convention on International Civil Aviation*, signed at Chicago on 7 December 1944 (the Chicago Convention), ICAO has adopted, *inter alia*, Annex 9 - *Facilitation* to the Chicago Convention, which contains provisions on facilitation of air transport, namely Standards and Recommended Practices (SARPS), including provisions on facilitation of the transport of passengers requiring special assistance. Attached is a copy of the Foreword of the Annex which explains in paragraph I of the General Information the status of SARPS.

Chapter 1 of Annex 9 defines "Person with disabilities" as "Any person whose mobility is reduced due to a physical incapacity (sensory or locomotor), an intellectual deficiency, age, illness or any other cause of disability when using transport and whose situation needs special attention and the adaptation to the person's needs of the services made available to all passengers."

Chapter 8 of Annex 9 contains two Standards and fifteen Recommended Practices that address accessibility to all elements of the air transport chain by persons with disabilities.

The Standards require that all airport facilities and services are adapted to the needs of persons with disabilities and that persons with disabilities have adequate access to air services:

Standard 8.27 Contracting States shall take the necessary steps to ensure that airport facilities and services are adapted to the needs of persons with disabilities.

Standard 8.34 Contracting States shall take the necessary steps to ensure that persons

with disabilities have adequate access to air services.

The Recommended Practices of Annex 9 provide that Contracting States should ensure, *inter alia*, that persons with disabilities, when travelling, be provided with special assistance to ensure they receive services customarily available to the general public; that all elements of a journey, from beginning to end, are made accessible to persons with disabilities; that persons with disabilities-particularly the hearing- and vision-impaired-are given all necessary information, by travel agents, airlines, airports, and ground handling operators, to help them in their travel; that adequate training programmes are established to ensure that trained personnel are available to assist persons with disabilities; that reserved points are located as close as possible to the main entrance of a terminal building, for ease of access for persons with disabilities; that aircraft have movable armrests, on-board wheelchairs, and other similarly user-friendly facilities for persons with disabilities; and that if such a person requires an escort, airlines are encouraged to offer discounts for the carriage of the escort. These Recommended Practices are reproduced at Attachment 2, for information.

Finally, ICAO has prepared guidance material, ICAO Circular 274 -*Access to Air Transport by Persons with Disabilities*, that elaborate on the Annex 9 Standards and Recommended Practices relating to persons with disabilities. The material is intended to assist the civil aviation community in the day-to-day application of these SARPs.

On the basis of the above-mentioned Standards and Recommended Practices, as complemented by guidance material, Contracting States have taken the necessary measures to make the system work satisfactorily. Airlines on a worldwide basis have standardized to a great extent, including by voluntary commitments, their procedures for acceptance and handling of disabled passengers. The International Air Transport Association (IATA) has also played an important role in the standardization and implementation of such procedures. The rights and dignity of persons with disabilities have been fully taken into account in all these efforts.

It should also be noted that, in accordance with the procedures established in Article 90 of the Chicago Convention, Standards and Recommended Practices can be amended without going through formal treaty amendment procedures to keep requirements in line with real needs. This seems to be the most appropriate way of dealing with measures to facilitate the transportation of persons with disabilities, as opposed to the adoption of treaty provisions, including by means of a convention as envisaged in General Assembly resolution 57/229, which would not allow for the required flexibility in this matter.

In closing, I would like to emphasize that, with regard to air transport, the existing system of facilitation of the transport of disabled passengers is deemed adequate, is working properly and can be amended swiftly to meet changing requirements as appropriate.

Accordingly, there would be in our view no requisite to provide for further international legislation in this respect.

Yours sincerely,

R.C. Costa Pereira

Return to top

ATTACHMENT 1

FOREWORD

Historical background

Standards and Recommended Practices on Facilitation were first adopted by the Council on 25 March 1949, pursuant to the provisions of Article 37 of the Convention on International Civil Aviation (Chicago, 1944), and designated as Annex 9 to the Convention with the title "Standards and Recommended Practices - Facilitation". They became effective on 1 September 1949. The Standards and Recommended Practices were based on recommendations of the First and Second Sessions of the Facilitation Division, held at Montreal in February 1946 and at Geneva in June 1948. They were expanded and amended comprehensively as a result of subsequent Sessions of the Division, i.e. the Third Session, held at Buenos Aires in December 1951, the Fourth Session,: held at Manila in October 1955, the Fifth Session, held at Rome-ml December 1959, the Sixth Session, held at Mexico City in March-April 1963, the Seventh Session, held at Montreal in May 1968, the Eighth Session, held at Dubrovnik in March 1973, the Ninth Session held at Montreal ,in April-May 1979 and the Tenth Session held at Montreal in September 1988. As a result of the Division's Recommendations, for amendment of Annex 9 and Council's action thereon, the Second: Edition of Annex 9 became effective on 1 March 1953, the Third Edition, on 1 November 1956, the Fourth Edition on 1 November 1960, the Fifth Edition on 1 April 1964, the Sixth Edition on 1 April 1969, the Seventh Edition on 15 Apri1 1974, the Eighth Edition on 15 July 1980, the Ninth Edition ón 151990 ember 1990 and the Tenth Edition on 30 April 1997.

Eleventh Edition.- The present edition incorporates, inter alia, provisions arising from recommendations of the Third Meeting of the Facilitation Panel (FAL.P/3).(Montreal . February 2001) which again resulted in the comprehensive expansion and amendment of Annex 9. This Eleventh Edition of Annex 9 became effective on 15 July 2002 and is to become applicable on 28 November 2002.

The Standards and Recommended-Practices on Facilitation are the outcome of Article 37 of the Convention, which provides, *inter alia*, that the "International Civil Aviation

ICAO

International Standards
and Recommended Practices

Annex 9 to the Convention on International Civil Aviation

Facilitation

Fifteenth Edition, October 2017

This edition incorporates all amendments adopted by the Council prior to 17 June 2017 and supersedes, on 23 February 2018, all previous editions of Annex 9.

For information regarding the applicability of the Standards and Recommended Practices, see Foreword.

INTERNATIONAL CIVIL AVIATION ORGANIZATION

Published in separate English, Arabic, Chinese, French, Russian
and Spanish editions by the
INTERNATIONAL CIVIL AVIATION ORGANIZATION
999 Robert-Bourassa Boulevard, Montréal, Quebec, Canada H3C 5H7

For ordering information and for a complete listing of sales agents
and booksellers, please go to the ICAO website at www.icao.int

First edition 1949
Fourteenth edition 2015
Fifteenth edition 2017

Annex 9 — Facilitation
Order Number: AN 9
ISBN 978-92-9258-301-9

TABLE OF CONTENTS

FOREWORD

Historical background

Standards and Recommended Practices on Facilitation were first adopted by the Council on 25 March 1949, pursuant to the provisions of Article 37 of the Convention on International Civil Aviation (Chicago, 1944), and designated as Annex 9 to the Convention with the title "Standards and Recommended Practices — Facilitation". They became effective on 1 September 1949. The Standards and Recommended Practices were based on recommendations of the First and Second Sessions of the Facilitation Division, held at Montréal in February 1946 and at Geneva in June 1948. They were expanded and amended comprehensively as a result of subsequent Sessions of the Division, i.e. the Third Session, held at Buenos Aires in December 1951, the Fourth Session, held at Manila in October 1955, the Fifth Session, held at Rome in December 1959, the Sixth Session, held at Mexico City in March-April 1963, the Seventh Session, held at Montréal in May 1968, the Eighth Session, held at Dubrovnik in March 1973, the Ninth Session held at Montréal in April-May 1979, the Tenth Session held at Montréal in September 1988 and the Eleventh Session held in Montréal in April 1995, and the Third Meeting of the Facilitation (FAL) Panel held in Montréal in February 2001. As a result of the Division's and FAL Panel's Recommendations for amendment of Annex 9 and Council's action thereon, the Second Edition of Annex 9 became effective on 1 March 1953, the Third Edition on 1 November 1956, the Fourth Edition on 1 November 1960, the Fifth Edition on 1 April 1964, the Sixth Edition on 1 April 1969, the Seventh Edition on 15 April 1974, the Eighth Edition on 15 July 1980, the Ninth Edition on 15 November 1990, the Tenth Edition on 30 April 1997, the Eleventh Edition on 15 July 2002, the Twelfth Edition on 11 July 2005, the Thirteenth Edition on 18 July 2011 and the Fourteenth Edition on 25 October 2015.

Fifteenth Edition.— The present edition incorporates, inter alia, provisions arising from the Ninth Meeting of the FAL Panel held in Montréal in April 2016 on issues such as Machine Readable Travel Documents (MRTDs), the transport of minors by air, passenger data exchange systems and the passenger manifest. This Fifteenth Edition of Annex 9 became effective on 23 October 2017 and is to become applicable on 23 February 2018. This edition also incorporates amendments arising from the Tenth Meeting of the FAL Panel held in Montréal in September 2018 on issues such as unaccompanied minors, the Passenger Data Single Window facility and trafficking in persons. Amendment 27 became effective on 21 October 2019 and is to become applicable on 21 February 2020.

The Standards and Recommended Practices on Facilitation are the outcome of Article 37 of the Convention, which provides, inter alia, that the "International Civil Aviation Organization shall adopt and amend from time to time, as may be necessary, international standards and recommended practices and procedures dealing with . . . customs and immigration procedures . . . and such other matters concerned with the safety, regularity and efficiency of air navigation as may from time to time appear appropriate". The policy with respect to the implementation by States of the Standards and Recommended Practices on Facilitation is strengthened by Article 22 of the Convention, which expresses the obligation accepted by each Contracting State "to adopt all practicable measures, through the issuance of special regulations or otherwise, to facilitate and expedite navigation by aircraft between the territories of contracting States, and to prevent unnecessary delays to aircraft, crews, passengers and cargo, especially in the administration of the laws relating to immigration, quarantine, customs and clearance", and by Article 23 of the Convention, which expresses the undertaking of each Contracting State "so far as it may find practicable, to establish customs and immigration procedures affecting international air navigation in accordance with the practices which may be established or recommended from time to time, pursuant to this Convention".*

* A number of other articles of the Convention have special pertinence to the provisions of the FAL Annex and have been taken into account in its preparation. In particular, persons responsible for the implementation of the provisions of this Annex should be familiar with the following articles in addition to Articles 22 and 23:
Article 10, Landing at customs airport; Article 11, Applicability of air regulations;
Article 13, Entry and clearance regulations; Article 14, Prevention of spread of disease;
Article 24, Customs duty; Article 29, Documents carried in aircraft;
Article 35, Cargo restrictions.

In addition to the Standards and Recommended Practices of Annex 9, the Organization's FAL Programme is based on the FAL Resolutions of the Assembly and B-type recommendations of FAL Division Sessions which are those recommendations which do not suggest amendments to the Annex provisions.

Table A shows the origin of the amendments to the Annex together with a list of the principal subjects involved and the dates on which the Annex and the amendments were adopted by the Council, when they became effective and when they became applicable.

Applicability

As indicated in Chapter 1, Section B, the Standards and Recommended Practices in this document apply to all categories of aircraft operation except where a particular provision specifically refers to one type of operation without mentioning other types of operations.

The Standards and Recommended Practices on Facilitation inevitably take two forms: first a "negative" form, e.g. that States shall not impose more than certain maximum requirements in the way of paperwork, restrictions of freedom of movement, etc., and second a "positive" form, e.g. that States shall provide certain minimum facilities for passenger convenience, for traffic which is merely passing through, etc. Whenever a question arises under a "negative" provision, it is assumed that States will, wherever possible, relax their requirements below the maximum set forth in the Standards and Recommended Practices. Wherever there is a "positive" provision, it is assumed that States will, wherever possible, furnish more than the minimum set forth in the Standards and Recommended Practices.

Action by Contracting States

Notification of differences. The attention of Contracting States is drawn to the obligation imposed by Article 38 of the Convention by which Contracting States are required to notify the Organization of any differences between their national regulations and practices and the International Standards contained in this Annex and any amendments thereto. Contracting States are invited to extend such notification of any differences from the Recommended Practices contained in this Annex, and any amendments thereto. Further, Contracting States are invited to keep the Organization currently informed of any differences which may subsequently occur, or of the withdrawal of any differences previously notified. A specific request for notification of differences will be sent to Contracting States immediately after the adoption of each Amendment to this Annex.

Attention of States is also drawn to the provision of Annex 15 related to the publication of significant differences between their national regulations and practices and the related ICAO Standards and Recommended Practices through the Aeronautical Information Service, in addition to the obligation of States under Article 38 of the Convention.

Promulgation of information. The establishment and withdrawal of and changes to facilities, services and procedures affecting aircraft operations provided in accordance with the Standards and Recommended Practices specified in this Annex should be notified and take effect in accordance with the provisions of Annex 15.

Contracting States should make every effort to publish the FAL information required by Annex 15 (as amplified by the *Aeronautical Information Services Manual* — Doc 8126) and, in particular, ensure that they conform with the requirements as to presentation and contents of such information prescribed by the Fourteenth Edition of Annex 15.

Use of the text of the Annex in national regulations. The Council, on 13 April 1948, adopted a resolution inviting the attention of Contracting States to the desirability of using in their own national regulations, as far as practicable, the precise language of those ICAO Standards that are of a regulatory character and also indicating departures from the Standards, including any additional national regulations that were important for the safety or regularity of air navigation. Wherever possible, the provisions of this Annex have been written in such a way as would facilitate incorporation, without major textual changes, into national legislation.

General information

An Annex is made up of the following component parts, not all of which, however, are necessarily found in every Annex; they have the status indicated:

1.— Material comprising the Annex proper

a) *Standards* and *Recommended Practices* adopted by the Council under the provisions of the Convention. They are defined, in the case of this Annex, as follows:

Standard: Any specification, the uniform observance of which has been recognized as practicable and as necessary to facilitate and improve some aspect of international air navigation, which has been adopted by the Council pursuant to Article 54 (*l*) of the Convention, and in respect of which non-compliance must be notified by Contracting States to the Council in accordance with Article 38.

Recommended Practice: Any specification, the observance of which has been recognized as generally practicable and as highly desirable to facilitate and improve some aspect of international air navigation, which has been adopted by the Council pursuant to Article 54 (*l*) of the Convention, and to which Contracting States will endeavour to conform in accordance with the Convention.

b) *Appendices* comprising material grouped separately for convenience but forming part of the Standards and Recommended Practices adopted by the Council.

c) *Definitions* of terms used in the Standards and Recommended Practices which are not self-explanatory in that they do not have accepted dictionary meanings. A definition does not have an independent status but it is an essential part of each Standard and Recommended Practice in which the term is used, since a change in the meaning of the term would affect the specification.

2.— *Material approved by the Council for publication in association with the Standards and Recommended Practices*

a) *Forewords* comprising historical and explanatory material based on the action of the Council and including an explanation of the obligations of States with regard to the application of the Standards and Recommended Practices ensuing from the Convention and the Resolution of Adoption.

b) *Introductions* comprising explanatory material introduced at the beginning of parts, chapters or sections of the Annex to assist in the understanding of the application of the text.

c) *Notes* included in the text, where appropriate, to give factual information or references bearing on the Standards or Recommended Practices in question, but not constituting part of the Standards or Recommended Practices.

d) *Attachments* comprising material supplementary to the Standards and Recommended Practices, or included as a guide to their application.

This Annex has been adopted in six languages — English, Arabic, Chinese, French, Russian and Spanish. Each Contracting State is requested to select one of those texts for the purpose of national implementation and for other effects provided for in the Convention, either through direct use or through translation into its own national language, and to notify the Organization accordingly.

The following practice has been adhered to in order to indicate at a glance the status of each statement: *Standards* have been printed in light face roman; *Recommended Practices* have been printed in light face italics, the status being indicated by the words **Recommended Practice**; *Notes* have been printed in light face italics, the status being indicated by the prefix *Note.*

Any reference to a portion of this document which is identified by a number includes all subdivisions of the portion.

Throughout this Annex, the use of the male gender should be understood to include male and female persons.

INTERNATIONAL STANDARDS AND RECOMMENDED PRACTICES

CHAPTER 1. DEFINITIONS AND GENERAL PRINCIPLES

A. Definitions

When the following terms are used in the Standards and Recommended Practices on Facilitation, they have the following meanings, for the purposes of this Annex:

Accompanying person. An adult who is travelling with a minor. This person will not necessarily be the parent or legal guardian of the minor.

Note.— It is to be noted that this definition might need to be applied in light of any obligation resulting from the application of national regulations on border checks.

Admission. The permission granted to a person to enter a State by the public authorities of that State in accordance with its national laws.

Advance Passenger Information (API) System. An electronic communications system whereby required data elements are collected and transmitted to border control agencies prior to flight departure or arrival and made available on the primary line at the airport of entry.

Aircraft equipment. Articles, including first-aid and survival equipment and commissary supplies, but not spare parts or stores, for use on board an aircraft during flight.

Aircraft operator. A person, organization or enterprise engaged in or offering to engage in an aircraft operation.

Aircraft operators' documents. Air waybills/consignment notes, passenger tickets and boarding passes, bank and agent settlement plan documents, excess baggage tickets, miscellaneous charges orders (M.C.O.), damage and irregularity reports, baggage and cargo labels, timetables, and weight and balance documents, for use by aircraft operators.

Airline. As provided in Article 96 of the Convention, any air transport enterprise offering or operating a scheduled international air service.

Authorized agent. A person who represents an aircraft operator and who is authorized by or on behalf of such operator to act on formalities connected with the entry and clearance of the operator's aircraft, crew, passengers, cargo, mail, baggage or stores and includes, where national law permits, a third party authorized to handle cargo on the aircraft.

Authorized Economic Operator. AEO is a party involved in the international movement of goods in whatever function that has been approved by or on behalf of a national Customs administration as complying with WCO or equivalent supply chain security standards. AEOs may include manufacturers, importers, exporters, brokers, carriers, consolidators, intermediaries, ports, airports, terminal operators, integrated operators, warehouses, distributors and freight forwarders.

Note.— The definition is aligned with that found in the World Customs Organization's "SAFE Framework of Standards to Secure and Facilitate Global Trade."

Automated Border Control (ABC). An automated system which authenticates the electronic machine readable travel document or token, establishes that the passenger is the rightful holder of the document or token, queries border control records, then determines eligibility for border crossing according to pre-defined rules.

Baggage. Personal property of passengers or crew carried on an aircraft by agreement with the operator.

Border integrity. The enforcement, by a State, of its laws and/or regulations concerning the movement of goods and/or persons across its borders.

Cargo. Any property carried on an aircraft other than mail, stores and accompanied or mishandled baggage.

Civil aviation inspector. A civil aviation inspector is an individual, designated by a Contracting State, who is charged with the inspection of the safety, security or related aspects of air transport operations as directed by the appropriate authority.

Note.— Examples of civil aviation inspectors include inspectors responsible for airworthiness, flight operations and other safety-related aspects, and security-related aspects, of air transport operations.

Clearance of goods. The accomplishment of the customs formalities necessary to allow goods to enter home use, to be exported or to be placed under another customs procedure.

Commencement of journey. The point at which the person began his journey, without taking into account any airport at which he stopped in direct transit, either on a through-flight or a connecting flight, if he did not leave the direct transit area of the airport in question.

Commissary supplies. Items, either disposable or intended for multiple use, that are used by the aircraft operator for provision of services during flights, in particular for catering, and for the comfort of passengers.

Crew member. A person assigned by an operator to duty on an aircraft during a flight duty period.

Declarant. Any person who makes a goods declaration or in whose name such a declaration is made.

Deportation order. A written order, issued by the competent authorities of a State and served upon a deportee, directing him to leave that State.

Deportee. A person who had legally been admitted to a State by its authorities or who had entered a State illegally, and who at some later time is formally ordered by the competent authorities to leave that State.

Direct transit area. A special area established in an international airport, approved by the public authorities concerned and under their direct supervision or control, where passengers can stay during transit or transfer without applying for entry to the State.

Direct transit arrangements. Special arrangements approved by the public authorities concerned by which traffic which is pausing briefly in its passage through the Contracting State may remain under their direct control.

Disembarkation. The leaving of an aircraft after a landing, except by crew or passengers continuing on the next stage of the same through-flight.

Disinfection. The procedure whereby health measures are taken to control or kill infectious agents on a human or animal body, in or on affected parts of aircraft, baggage, cargo, goods or containers, as required, by direct exposure to chemical or physical agents.

Disinsection. The procedure whereby health measures are taken to control or kill insects present in aircraft, baggage, cargo, containers, goods and mail.

Electronic Travel Systems (ETS). The automated process for the lodgement, acceptance and verification of a passenger's authorization to travel to a State, in lieu of the standard counterfoil paper visa.

Embarkation. The boarding of an aircraft for the purpose of commencing a flight, except by such crew or passengers as have embarked on a previous stage of the same through-flight.

eMRTD. An MRTD (passport, visa or card) that has a contactless integrated circuit embedded in it and the capability of being used for biometric identification of the MRTD holder in accordance with the standards specified in the relevant Part of Doc 9303 — *Machine Readable Travel Documents*.

Escort. An individual authorized by a Contracting State or an aircraft operator to accompany inadmissible persons or deportees being removed from that Contracting State.

Flight crew member. A licensed crew member charged with duties essential to the operation of an aircraft during a flight duty period.

Free zone. A part of the territory of a Contracting State where any goods introduced are generally regarded, insofar as import duties and taxes are concerned, as being outside the customs territory.

General aviation operation. An aircraft operation other than a commercial air transport operation or an aerial work operation.

Ground equipment. Articles of a specialized nature for use in the maintenance, repair and servicing of an aircraft on the ground, including testing equipment and cargo- and passenger-handling equipment.

ICAO Public Key Directory (ICAO PKD). The central database serving as the repository of Document Signer Certificates (C_{DS}) (containing Document Signer Public Keys), CSCA Master List (ML_{CSCA}), Country Signing CA Link Certificates (lC_{CSCA}) and Certificate Revocation Lists issued by Participants, together with a system for their distribution worldwide, maintained by ICAO on behalf of Participants in order to facilitate the validation of data in eMRTDs.

Immigration control. Measures adopted by States to control the entry into, transit through and departure from their territories of persons travelling by air.

Import duties and taxes. Customs duties and all other duties, taxes or charges, which are collected on or in connection with the importation of goods. Not included are any charges which are limited in amount to the approximate cost of services rendered or collected by the customs on behalf of another national authority.

Imposter. A person who impersonates the rightful holder of a genuine travel document.

Improperly documented person. A person who travels, or attempts to travel: (a) with an expired travel document or an invalid visa; (b) with a counterfeit, forged or altered travel document or visa; (c) with someone else's travel document or visa; (d) without a travel document; or (e) without a visa, if required.

Inadmissible person. A person who is or will be refused admission to a State by its authorities.

Interactive API (iAPI) system. An electronic system that transmits, during check-in, API data elements collected by the aircraft operator to public authorities who, within existing business processing times for passenger check-in, return to the operator a response message for each passenger and/or crew member.

International airport. Any airport designated by the Contracting State in whose territory it is situated as an airport of entry and departure for international air traffic, where the formalities incident to customs, immigration, public health, animal and plant quarantine and similar procedures are carried out.

Lading. The placing of cargo, mail, baggage or stores on board an aircraft to be carried on a flight.

Mail. Dispatches of correspondence and other items tendered by and intended for delivery to postal services in accordance with the rules of the Universal Postal Union (UPU).

Minor. A person who has not attained the age of majority as determined under the law applicable to the person.

Mishandled baggage. Baggage involuntarily, or inadvertently, separated from passengers or crew.

Narcotics control. Measures to control the illicit movement of narcotics and psychotropic substances by air.

Necessary precautions. Verifications carried out by adequately trained staff members of the aircraft operator or the company operating on behalf of the aircraft operator, at the point of embarkation, in order to ensure that every person holds a valid travel document and, where applicable, the visa or residence permit required to enter the State of transit and/or receiving State. These verifications are designed to ensure that irregularities (e.g. obvious document alteration) are detected.

Passenger amenities. Facilities provided for passengers which are not essential for passenger processing.

Passenger Data Single Window. A facility that allows parties involved in passenger transport by air to lodge standardized passenger information (i.e. API, iAPI and/or PNR) through a single data entry point to fulfil all regulatory requirements relating to the entry and/or exit of passengers that may be imposed by various agencies of the Contracting State.

Note.— The Passenger Data Single Window facility to support API/iAPI transmissions does not necessarily need to be the same facility used to support PNR data exchange.

Person with disabilities. Any person whose mobility is reduced due to a physical incapacity (sensory or locomotor), an intellectual deficiency, age, illness or any other cause of disability when using transport and whose situation needs special attention and the adaptation to the person's needs of the services made available to all passengers.

Pilot-in-command. The pilot responsible for the operation and safety of the aircraft during flight time.

Public authorities. The agencies or officials of a Contracting State responsible for the application and enforcement of the particular laws and regulations of that State which relate to any aspect of these Standards and Recommended Practices.

Public health emergency of international concern. An extraordinary event which is determined, as provided in the *International Health Regulations* (2005) of the World Health Organization: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.

Public health risk. A likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger.

Release of goods. The action by the customs authorities to permit goods undergoing clearance to be placed at the disposal of the persons concerned.

Relief flights. Flights operated for humanitarian purposes which carry relief personnel and relief supplies such as food, clothing, shelter, medical and other items during or after an emergency and/or disaster and/or are used to evacuate persons from a place where their life or health is threatened by such emergency and/or disaster to a safe haven in the same State or another State willing to receive such persons.

Removal of a person. Action by the public authorities of a State, in accordance with its laws, to direct a person to leave that State.

Removal order. A written order served by a State on the operator on whose flight an inadmissible person travelled into that State, directing the operator to remove that person from its territory.

Risk assessment. An assessment by a deporting State of a deportee's suitability for escorted or unescorted removal via commercial air services. The assessment should take into account all pertinent factors, including medical, mental and physical fitness for carriage on a commercial flight, willingness or unwillingness to travel, behavioural patterns and any history of violence.

Risk management. The systematic application of management procedures and practices which provide border inspection agencies with the necessary information to address movements or consignments which represent a risk.

Security equipment. Devices of a specialized nature for use, individually or as part of a system, in the prevention or detection of acts of unlawful interference with civil aviation and its facilities.

Single Window. A facility that allows parties involved in trade and transport to lodge standardized information and documents with a single entry point to fulfil all import, export, and transit-related regulatory requirements. If information is electronic then individual data elements should only be submitted once.

Spare parts. Articles, including engines and propellers, of a repair or replacement nature for incorporation in an aircraft.

State of Registry. The State on whose register the aircraft is entered.

Stores (Supplies). a) Stores (supplies) for consumption; and b) Stores (supplies) to be taken away.

Stores (Supplies) for consumption. Goods, whether or not sold, intended for consumption by the passengers and the crew on board aircraft, and goods necessary for the operation and maintenance of aircraft, including fuel and lubricants.

Stores (Supplies) to be taken away. Goods for sale to the passengers and the crew of aircraft with a view to being landed.

Temporary admission. The customs procedure under which certain goods can be brought into a customs territory conditionally relieved totally or partially from payment of import duties and taxes; such goods must be imported for a specific purpose and must be intended for re-exportation within a specified period and without having undergone any change except normal depreciation due to the use made of them.

Through-flight. A particular operation of aircraft, identified by the operator by the use throughout of the same symbol, from point of origin via any intermediate points to point of destination.

Travel document. A passport or other official document of identity issued by a State or organization, which may be used by the rightful holder for international travel.

Unaccompanied baggage. Baggage that is transported as cargo and may or may not be carried on the same aircraft with the person to whom it belongs.

Unaccompanied minor. A minor travelling alone or travelling only in the company of another minor.

Note.— It is to be noted that this definition might need to be applied in light of any obligation resulting from the application of national regulations on border checks.

Unclaimed baggage. Baggage that arrives at an airport and is not picked up or claimed by a passenger.

Unidentified baggage. Baggage at an airport, with or without a baggage tag, which is not picked up by or identified with a passenger.

Unlading. The removal of cargo, mail, baggage or stores from an aircraft after a landing.

Visitor. Any person who disembarks and enters the territory of a Contracting State other than that in which that person normally resides; remains there lawfully as prescribed by that Contracting State for legitimate non-immigrant purposes, such as touring, recreation, sports, health, family reasons, religious pilgrimages, or business; and does not take up any gainful occupation during his stay in the territory visited.

B. General principles

1.1 The Standards and Recommended Practices in this Annex shall apply to all categories of aircraft operation except where a particular provision refers specifically to only one type of operation.

1.2 Contracting States shall take necessary measures to ensure that:

a) the time required for the accomplishment of border controls in respect of persons and aircraft and for the release/clearance of goods is kept to the minimum;

b) minimum inconvenience is caused by the application of administrative and control requirements;

c) exchange of relevant information between Contracting States, operators and airports is fostered and promoted to the greatest extent possible; and

d) optimal levels of security, and compliance with the law, are attained.

1.3 Contracting States shall use risk management in the application of border control procedures for the release/clearance of goods.

1.4 Contracting States shall develop effective information technology to increase the efficiency and effectiveness of their procedures at airports.

1.5 The provisions of this Annex shall not preclude the application of national legislation with regard to aviation security measures or other necessary controls.

1.6 **Recommended Practice.—** *Contracting States and aircraft operators should exchange information as to the appropriate point(s) of contact(s) to whom border control and customs queries should be directed.*

G. Establishment of national facilitation programmes

8.17 Each Contracting State shall establish a national air transport facilitation programme based on the facilitation requirements of the Convention and of Annex 9 thereto.

8.18 Each Contracting State shall ensure that the objective of its national air transport facilitation programme shall be to adopt all practicable measures to facilitate the movement of aircraft, crews, passengers, cargo, mail and stores, by removing unnecessary obstacles and delays.

8.18.1 **Recommended Practice.—** *In establishing a national air transport facilitation programme, States should use the guidance material outlined in Appendix 12 and Doc 10042,* Model National Air Transport Facilitation Programme.

8.19 Each Contracting State shall establish a National Air Transport Facilitation Committee, and Airport Facilitation Committees as required, or similar coordinating bodies, for the purpose of coordinating facilitation activities between departments, agencies, and other organizations of the State concerned with, or responsible for, various aspects of international civil aviation as well as with airport and aircraft operators.

8.20 **Recommended Practice.—** *Contracting States should endeavour to establish close coordination, adapted to circumstances, between civil aviation security and facilitation programmes. To this end, certain members of Facilitation Committees should also be members of Security Committees.*

8.21 **Recommended Practice.—** *In establishing and operating National Air Transport and Airport Facilitation Committees, States should use the guidance material outlined in Appendices 11 and 12.*

H. Facilitation of the transport of persons with disabilities

I. General

8.22 **Recommended Practice.—** *When travelling, persons with disabilities should be provided with special assistance in order to ensure that they receive services customarily available to the general public. Assistance should be provided in a manner that respects the dignity of the individual.*

Note.— Attention is drawn to Doc 9984, Manual on Access to Air Transport by Persons with Disabilities, *developed for the purpose of elaborating on the Standards and Recommended Practices relating to the facilitation of the transport of persons with disabilities, and assisting the civil aviation community in their implementation.*

8.23 **Recommended Practice.—** *Contracting States should cooperate with a view to taking the necessary measures to make accessible to persons with disabilities all the elements of the chain of the person's journey, from arrival at the airport of departure to leaving the airport of destination.*

8.24 **Recommended Practice.—** *Contracting States should take the necessary steps with aircraft, airport and ground handling operators to establish and publish minimum uniform standards of accessibility with respect to transportation services for persons with disabilities, from arrival at the airport of departure to leaving the airport of destination.*

8.25 **Recommended Practice.—** *Contracting States should take the necessary steps with aircraft, airport and ground handling operators and travel agencies to ensure that persons with disabilities are given the information they need, in formats that are accessible to those with cognitive or sensory disabilities, and should take the necessary steps to ensure that airlines, airports and ground handling operators are in a position to give those passengers the assistance necessary for them, depending on their needs, to help them in their travel.*

8.26 **Recommended Practice.—** *Contracting States should take all necessary steps to secure the cooperation of aircraft, airport and ground handling operators in order to establish and coordinate training programmes to ensure that trained personnel are available to assist persons with disabilities.*

II. Access to airports

8.27 Contracting States shall take the necessary steps to ensure that airport facilities and services are adapted to the needs of persons with disabilities.

8.28 **Recommended Practice.—** *Contracting States should ensure that lifting systems or any other appropriate devices are made available in order to facilitate the movement of persons with disabilities between the aircraft and the terminal on both arrival and departure as required where telescopic passageways are not used.*

8.29 **Recommended Practice.—** *Measures should be taken to ensure that the hearing- and vision-impaired are able to obtain flight service-related information in accessible formats.*

8.30 **Recommended Practice.—** *Designated points for the pick-up and drop-off of persons with disabilities at a terminal building should be located as close as possible to main entrances and/or exits. To facilitate movement within the airport, access routes should be free of obstacles and be accessible.*

8.31 **Recommended Practice.—** *Where access to public services is limited, every effort should be made to provide accessible and reasonably priced ground transportation services by adapting current and planned public transit systems or by providing special transport services for people with mobility needs.*

8.32 **Recommended Practice.—** *Adequate parking facilities should be provided for people with mobility needs and appropriate measures taken to facilitate their movement between parking areas and the terminal buildings.*

8.33 **Recommended Practice.—** *When assistance is provided to transfer persons with disabilities from one aircraft to another, it should be provided as efficiently as possible, with due regard for connecting flights.*

III. Access to air services

8.34 Contracting States shall take the necessary steps to ensure that persons with disabilities have equivalent access to air services.

8.35 **Recommended Practice.—** *Contracting States should introduce provisions by which aircraft coming newly into service or after major refurbishment should conform, where aircraft type, size, and configuration permit, to minimum uniform standards of accessibility with respect to equipment on board aircraft which would include movable armrests, on-board wheelchairs, accessible washrooms and suitable lighting and signs.*

8.36 **Recommended Practice.—** *Disability aids required by persons with disabilities should be carried free of charge in the cabin where space, weight and safety requirements permit or should be carried free of charge and designated as priority baggage.*

8.37 **Recommended Practice.—** *Service animals accompanying persons with disabilities should be carried free of charge in the cabin, on the floor at the person's seat, subject to the application of any relevant national or aircraft operator regulations.*

8.38 Contracting States that restrict the transport of battery-powered devices, including mobility aids containing spillable batteries, shall notify ICAO promptly of such restrictions so that they can be included in Doc 9284, *Technical Instructions for the Safe Transport of Dangerous Goods by Air* and ensure that aircraft operators make such information publicly available and in accordance with Chapter 2, 2.5 of Annex 18.

8.39 **Recommended Practice.—** *In principle, persons with disabilities should be permitted to travel without the requirement for a medical clearance. Aircraft operators should only be permitted to require persons with disabilities to obtain a medical clearance in cases of a medical condition where it is not clear that they are fit to travel and could compromise their safety or well-being or that of other passengers.*

8.40 **Recommended Practice.—** *In principle, persons with disabilities should be permitted to determine whether or not they need an assistant. If the presence of an assistant is required, Contracting States should encourage aircraft operators to offer discounts for the carriage of that assistant. Aircraft operators should require an assistant only when it is clear that the person with a disability is not self-reliant and this could pose a risk to safety or the well-being of such person or that of other passengers.*

8.40.1 **Recommended Practice.—** *Advance notice should strongly be encouraged where assistance or lifting is required.*

I. Assistance to aircraft accident victims and their families

8.41 The State of Occurrence of an aircraft accident and adjacent States shall make arrangements to facilitate the entry into their territory on a temporary basis of family members of victims of an aircraft accident.

8.42 The State of Occurrence and adjacent States shall also make arrangements to facilitate the entry into their territory, on a temporary basis, of authorized representatives of the operator whose aircraft has met with the accident, or of the operator's alliance partner, in order to enable them to provide assistance to survivors and their family members, the family members of the deceased victims of the accident and the relevant authorities in these States.

Note.— Code-sharing and similar alliance agreements sometimes require alliance partners to act as "first responder" on behalf of an affected operator in case the alliance partner can get to the location of the accident quicker than the affected operator.

8.43 **Recommended Practice.—** *In arranging for the entry of the persons referred to in 8.41, the State of Occurrence and adjacent States should not require any other travel document than a passport, or an emergency travel document issued specifically to such persons, to enable them to travel to these States. In cases where the State of Occurrence of the accident or an adjacent State requires entrance visas for persons referred to in 8.41 and 8.42 above, it should expedite the issuance of such visas.*

8.44 Contracting States shall make arrangements to issue emergency travel documents, if required, to their nationals who have survived the accident.

8.45 Contracting States shall extend all necessary assistance, such as arranging transport and clearing customs, in the repatriation of human remains to their countries of origin, on request by family members of the deceased or the operator whose aircraft met with the accident.

8.46 **Recommended Practice.—** *Contracting States should establish legislation, regulations and/or policies in support of assistance to aircraft accident victims and their families.*

Note.— Attention is drawn to Doc 9998, ICAO Policy on Assistance to Aircraft Accident Victims and their Families *and Doc 9973,* Manual on Assistance to Aircraft Accident Victims and their Families.

Doc 9984

Manual on Access to Air Transport by Persons with Disabilities

Approved by the Secretary General and published under his authority

First Edition — 2013

International Civil Aviation Organization

Published in separate English, Arabic, Chinese, French, Russian
and Spanish editions by the
INTERNATIONAL CIVIL AVIATION ORGANIZATION
999 University Street, Montréal, Quebec, Canada H3C 5H7

For ordering information and for a complete listing of sales agents
and booksellers, please go to the ICAO website at www.icao.int

Doc 9984, ***Manual on Access to Air Transport by Persons with Disabilities***
Order Number: 9984
ISBN 978-92-9249-193-2

TABLE OF CONTENTS

FOREWORD

Persons with disabilities make up a significant and growing percentage of the world's population and constitute the world's largest minority. The World Health Organization (WHO) reports that this number is increasing through population growth, medical advances and the ageing process.

Aviation, like all other transport modes, needs to recognise and accommodate this growing passenger segment. Persons with disabilities have the same international rights as other citizens, such as accessibility, and full and effective participation and inclusion in society, including freedom of movement and freedom of choice (United Nations *Convention on the Rights of Persons with Disabilities*, articles 3.c and 3.f). Persons with disabilities should have equivalent access to air travel.

These international rights apply to air travel as to all areas of life. There have been many changes in the provision of accessible facilities and services to persons with disabilities in air transportation worldwide, and this trend requires renewed attention at an international level.

In keeping with the general obligations of States under the *Convention on the Rights of Persons with Disabilities*, to promote universal design, to provide accessible information, and to promote the training of professionals and staff working with persons with disabilities (article 4, paragraph 1, f, h, and i), this manual provides general guidance on services and features needed to meet the needs of persons with disabilities in air transportation. The guidance material in this manual was created by the Facilitation Panel's Working Group on Persons with Disabilities for the purpose of elaborating on the relevant Standards and Recommended Practices in Annex 9 — *Facilitation* and assisting the civil aviation community in their implementation.

This manual should be read in conjunction with other key documents in this field, which provide more detailed guidance, and the legal frameworks which apply to various jurisdictions.

DEFINITIONS

Person with disabilities. Any person whose mobility is reduced due to a physical incapacity (sensory or locomotor), an intellectual deficiency, age, illness or any other cause of disability when using transport and whose situation needs special attention and the adaptation to the person's needs of the services made available to all passengers.

Aircraft operator. A person, organization or enterprise engaged in or offering to engage in an aircraft operation. For the purposes of this manual, the term also includes operators operating under code sharing and wet-leasing arrangements.

Service animals. Animals, normally being dogs or other animals, specified in national regulations, for the purpose of accompanying persons with disabilities with the objective of providing them with physical or/and emotional support, being under the control of the person with disabilities and provided that their presence on board an aircraft:

a) does not endanger the safety of flight operations;

b) is not reasonably considered as a threat to other passengers; and

c) does not cause health concerns related to hygiene.

Member States should encourage aircraft and airport operators and travel agents to use common definitions for different categories of persons with disabilities. Such entities should follow the standard system of classification and codification developed by the International Air Transport Association (IATA) for this purpose, as amended from time to time.

Chapter 1

GENERAL ISSUES

ACCESSIBLE AIR TRAVEL

1.1 All procedures forming part of an air travel journey, including reservations, check-in, immigration and customs, security clearances, transfers within airports, embarkation and disembarkation, departure, carriage and arrival should be adapted to the needs of persons with disabilities in order to facilitate the clearance and air transportation of such persons in a dignified manner.

1.2 In some instances, the aircraft operator with whom the passenger enters into a contract of carriage may be a separate entity from the actual aircraft operator. Aircraft operators should ensure, as far as possible, that the services that they provide to persons with disabilities are also provided by the operator that operates their flights.

CONSULTATIONS WITH ORGANIZATIONS REPRESENTING PERSONS WITH DISABILITIES

1.3 Airport and aircraft operators should consult with organizations that represent persons with disabilities when developing services and training programmes and when designing facilities and equipment to ensure that persons with disabilities have equal access to air transportation. Airport and aircraft operators should consider involving organizations that represent persons with disabilities in evaluating services, training programmes, facilities and equipment.

SEAMLESS SERVICE

1.4 The service provided at the request of persons with disabilities should be professional and “seamless”, that is, with no points at which such persons may be left stranded or without assistance.

1.5 Seamless is a concept that includes a comfortable, safe and uninterrupted journey, with the provision of assistance that is adapted to the needs of each individual person with disabilities.

NO REFUSAL OF CARRIAGE EXCEPT FOR SAFETY REASONS

1.6 Aircraft operators should not refuse to transport persons with disabilities on the basis of their disabilities except for safety requirements.

NO CHARGE FOR ASSISTANCE

1.7 Assistance to meet disability-related needs should be provided without charge to persons with disabilities.

SERVICE LEVEL TARGETS

1.8 This manual presents the minimum recommended service level targets that Member States should meet, and urges them to exceed these service level targets wherever possible.

1.8.1 Recommended service level targets should be set for each request for assistance. These should be mutually agreed on by airport and aircraft operators, as well as by all other stakeholders. Organizations representing persons with disabilities should be consulted in the development of these service level targets which should be included in contractual arrangements.

ALLOCATION OF RESPONSIBILITIES

1.9 Some States' legislation and regulations assign responsibilities for providing accessible services at airports to airport operators, while others assign them to aircraft operators. Further references in the manual to airport and aircraft operators should be read in that context.

Plaintiff's Exhibit 494

zerohedge.com

German Judge Declares Mask Mandates Illegal And Harmful To Children

by Tyler Durden

5-7 minutes

Authored by Rocco Loiacono via The Epoch Times,

As reported in The Epoch Times recently, the Oklahoma Legislature recently passed a Bill banning mask mandates in schools. In Germany, mask mandates in schools have also been under the microscope, in particular in an extraordinary judgment given last month.

A woman wearing a protective face mask reading "dictatorship" protests against government restrictions, although the rally has been disallowed by a regional court, amid the CCP virus disease (COVID-19) outbreak, in Bremen, Germany, on Dec. 5, 2020. (Fabian Bimmer/Reuters)

On April 8, the Weimar District Court **banned two schools in that district from enforcing mask mandates, social distancing requirements, and rapid COVID-19 testing on their students**. The court also ordered the schools to no longer conduct distance learning.

The decision followed a legal action by the mother of two students, aged 8 and 14 respectively, at one of the schools, who argued that such measures were causing physical, psychological, and pedagogical harm to her children, as well as constituting an infringement of her children and parental rights under German and international law.

The judge, Christian Dettmar, upheld this argument (pdf), noting that mask mandates and social distancing requirements for children, were not only causing the harm mentioned above, but were in direct violation of Articles 2 and 6 of the German Constitution, which guarantee the rights to freedom of individual development, education, and parental assistance.

Members of the police stand guard as people protest against the government measures to curb the spread of the coronavirus disease (COVID-19), as the lower house of parliament Bundestag discusses amendments to the Infection Protection Act, in Berlin, Germany, on April 21, 2021. (Christian Mang/Reuters)

Accordingly, the judge held that the anti-COVID measures deployed were not proportional to the threat posed. This was in accordance with proportionality principles enshrined in Articles 20 and 28 of the German Constitution.

The court also referred to an October 2020 WHO Bulletin which featured a study by renowned medical science expert John Ioannidis, who found the death rate for coronavirus was 0.23 percent, the equivalent of a moderate influenza epidemic.

In examining expert medical, scientific (including biological) and psychological evidence, the judge found the use of masks and social distancing had no effect whatsoever on reducing infection, and cast serious doubt on the ability of asymptomatic persons—particularly children—to spread the virus. This was the first time evidence was presented to a German court regarding the scientific reasonableness and necessity of the prescribed anti-virus measures.

Judge Dettmar found that the anti-virus measures posed a danger to the mental, physical or psychological well-being of the children to such an extent that significant harm could be foreseen with a high degree of certainty. He wrote:

> **"The children are not only endangered in their mental, physical, and spiritual well-being by the obligation to wear face masks during school hours and to keep their distance**

> **from each other and from other persons, but, in addition, they are already being harmed. At the same time, this violates numerous rights of the children and their parents under the law, the constitution, and international conventions.**
>
> This applies in particular to the right to free development of the personality and to physical integrity from Article 2 of the (German Constitution) as well as to the right from Article 6 of the (Constitution) to upbringing and care by the parents (also with regard to measures for preventive health care and 'objects' to be carried by children) …"

The judge agreed with the experts' assessment that masks were not useful for viral protection, that PCR tests could not detect a disease-causing infection with necessary certainty, and that asymptomatic transmission played no detectable role epidemiologically with respect to coronavirus.

On the contrary, masks would have a negative impact on children's health due to handling-related contamination. Testing in school classes would be unnecessary, harmful and also extremely problematic in terms of data protection.

In conclusion, he stated, "100,000 elementary school students would have to put up with all the side effects of wearing masks for a week in order to prevent just one infection per week. To call this result merely disproportionate would be a wholly inadequate description. Rather, it shows that the state legislature regulating this area has fallen into a factual disconnect that has reached historic proportions."

Following this sensational decision, Judge Dettmar had his house, office, and car searched by police, and mobile phone confiscated.

The Weimar Administrative Court—a separate court with no jurisdiction over the District Court—issued a statement in response describing Dettmar's decision as unlawful (without giving reasons), and reiterated the importance of the mask mandate.

Do the actions of the police, court, and authorities suggest that the edifice of virus restrictions could be exposed as lacking proper epidemiological foundations?

Plaintiff's Exhibit 495

Weimar Local Court, Order dated 08.04.2021, Ref.: 9 F 148/21

the district court of Weimar by ...
by way of temporary injunction:

I. **The principals and teachers of the schools of the children A, born on ..., and B, born on ..., namely the Staatliche Regelschule X, Weimar, and the Staatliche Grundschule Y, Weimar, as well as the superiors of the principals are prohibited from ordering or prescribing the following for these and all other children and pupils taught at these schools:**

1. **to wear face masks of any kind, especially mouth-nose coverings, so-called qualified masks (OP mask or FFP2 mask) or others, in class and on school premises,**
2. **Maintain minimum distances from each other or from other persons beyond what was known prior to 2020,**
3. **Participate in rapid tests to detect the SARS-CoV-2 virus.**

II. **To the heads and teachers of the schools of the children A, born on ..., and B, born on ..., namely the Staatliche Regelschule X, Weimar, and the Staatliche Grundschule Y, Weimar, as well as to the superiors of the School administrators are offered to maintain face-to-face instruction at the school for these and all other children and students taught at these schools.**

III. **Court costs shall not be charged. The children involved shall not bear any costs. The parties shall bear their own out-of-court costs.**

IV. **The immediate effectiveness of the decision is ordered.**

Plaintiff's Exhibit 496

IN THE MATTER OF AN ARBITRATION

BETWEEN

Sault Area Hospital

("SAH" or "Hospital")

and

Ontario Hospital Association

("OHA")

and

Ontario Nurses' Association

("Union" or "ONA")

Re: 'Vaccinate or Mask' Policy

SOLE ARBITRATOR: James Hayes

APPEARANCES

OHA and SAH

John C. Field, Counsel
Dianne E. Jozefacki, Counsel
Dave McCoy, Manager, Labour Relations, OHA
Kim Lemay, Director, Human Resources, SAH
Chris Johns, Manager, Human Resources and Corporate Safety, SAH

ONA

Kate Hughes, Counsel
Philip Abbink, Counsel
Sharan Basran, Manager of Litigation, ONA
Glenda Hubley, President, Local 46
David Cheslock, Labour Relations Officer
Tyler Boggs, Law Student

Hearings on the merits were held on October 1, 2, and 9, 2014, and, in 2015, on January 26; May 11, 19- 21; June 6, 9, 22-26; July 7, 8.

AWARD

Introduction

1. ONA objects to a 'Vaccinate or Mask' ("VOM") policy introduced at the Sault Area Hospital, an acute care institution (the "Policy"). The Hospital requires that healthcare workers ("HCWs") wear surgical/procedure masks each year throughout the five to six month flu season if they have not received vaccination for influenza. The grievances allege that the VOM Policy is an unreasonable exercise of management rights and a breach of employee privacy rights.

2. The backdrop to these grievances is that certain distinguished Canadian academic physicians are divided on the VOM question. It appears to be unprecedented for leading infection prevention and control academic physicians at Mount Sinai Hospital and the University Health Network to oppose each other so directly in a litigation forum, as occurred here.

3. Grievances such as these are plainly grounded in a dispute over 'best practice' public health policy determination. It seems to me self-evident that medical judgments and policy decisions relating thereto should be located, primarily, elsewhere. One would think an expert medical forum, where contrary views are welcomed and consensus sought if not achieved, would be presumptively appropriate.[1] All the more so because it is almost certain that there will be future material change to the scientific fact pattern currently underpinning existing VOM policies.[2] Aspects of the relevant medical science remain in infancy or appear to be

[1] See Exhibit 66, p.14 where Dr. De Serres recommends: "a documented critique of available evidence by skilled experts who are independent of single option advocates, and with a full consideration of alternative approaches weighed against the usual policy analysis indicators (e.g. Erikson De Wals framework) is needed to ensure an optimal balance in protecting the safety and rights of both patients and HCWs"; See Exhibit 185, pp.44-45 where Dr. McGeer states her view that such a process was conducted by the Toronto Academic Health Science Network (TAHSN) between 2012 and 2014 resulting in a VOM recommendation; Dr. Gardam was extremely critical of the composition of the TAHSN Working Group: Transcript, May 21, 2015, pp.102-108

[2] There are ethical restrictions preventing the conduct of certain randomized controlled trials. See Exhibit 185, Report, A. McGeer, p. 26: "Assessing vaccine efficacy has also become more difficult over

incapable of formal proof, at the present time at least. The opinions of individual professionals continue to move with their understanding of the relevant evolving scientific research.[3] It is therefore scarcely surprising that there will be honest differences of expert opinion about the 'best' health policies and practices for a particular institution at any given point in time.

4. What is beyond doubt is that grievances of this type reach one extremity of labour relations adjudication. Whatever judicial deference may be paid to the collectively acquired expertise of labour arbitrators, labour arbitrators are not medical experts.

5. This is not to suggest that these grievances were misplaced. A trade union is typically entitled to challenge what it perceives to be an unreasonable exercise of a management right. ONA's members have a direct interest in VOM policies aimed at the conduct of their daily working lives. ONA reasonably objects to a Policy that it believes to be unwarranted. Whatever may be the limitations of a labour arbitration forum, ONA brought these grievances to the only place where it had the legal capacity to demand accountability.

6. These grievances, accordingly, raise an important issue about the appropriate engagement of a labour arbitrator with expert evidence. What approach should an arbitrator take when addressing a challenge to a policy relating to patient care, a subject matter that would normally be expected to fall within the primary domain of healthcare professionals?

---

time because once vaccine is recommended for a population group, it is no longer ethical to randomize people in that group to a placebo in clinical trials. This means that vaccine efficacy must be assessed by observational trials which are susceptible to many biases, and much more difficult to interpret than randomized controlled trials". See also: Transcript, July 8, 2015 for the OHA/SAH counsel's comment at p.129

[3] See for example: Transcript, May 21, 2015, M. Gardam, pp. 45-55. Dr Gardam was initially in favour of a mandatory flu shot policy. At p. 47: "when I started to change my mind was when I did the paper for Lancet Infectious Diseases and I realized that all the stuff that we're spouting about how flu is transmitted is actually based on the thinnest of evidence and we need to be much more critical".

7. Where a policy directly affecting employees' conditions of work connects with the delivery of fundamental health policy—and especially where the medical/scientific underpinnings of that policy continue to evolve—what is the role of a labour arbitrator? Should an arbitrator's preference for one credible expert opinion over another, following an adversarial process, necessarily be outcome determinative?

8. Alternatively, may this employer meet the labour relations test of reasonableness by simple proof that its VOM Policy is supported by medical opinion held by one group of leading academic physicians notwithstanding what may be the equally convincing opinion of another leading group? Put another way in labour law terms, in a *KVP*[4] case such as this one, is some version of *Dunsmuir*[5] deference owed to a credible expert opinion relied upon in good faith by an employer?

9. In approaching these questions I have borne in mind that counsel adopted one common legal position despite their disagreement about almost every other aspect of this case.

10. Both counsel stated that the resulting Award should choose between the contending scientific VOM evidence. Relying on her interpretation of *Meiorin*[6], and using *Suncor*[7] as a recent example, ONA counsel concluded: "that's the job".[8] OHA/SAH counsel referred to *Dunsmuir* as a guide to the meaning of reasonableness.[9] However, he also submitted that in considering reasonableness: "the task is to examine…all of the scientific evidence. In fact, we say that is the

---

[4] *KVP Co.* (1965), 16 L.A.C. 73 (Robinson)

[5] *Dunsmuir v. New Brunswick,* [2008] 1 S.C.R. 190

[6] *British Columbia (Public Service Employee Relations Commission),* [1999] 3 S.C.R. 3; 1999 CanLII 652 (SCC)

[7] *Suncor Energy Inc. Oil Sands,* (2014), 242 L.A.C. (4th) 1 (Hodges)

[8] Transcript, July 7, 2015, pp. 147-149; Transcript July 8, 2015, pp.4-6

[9] OHA/SAH Closing Argument, para. 346

evidence that will drive your analysis".[10] Counsel cited an observation made by Mr. Swan, a prominent Canadian labour arbitrator, in support:

> The one point that is clear from the case law is that the decision maker must reach a legal conclusion based on the scientific evidence and other evidence presented. It is not possible to simply decide that there has been a draw between the positions presented by both sides; it is necessary, when faced with two contradictory expert opinions, to decide which of the two is more likely on the balance of probabilities to be a correct statement of the actual circumstances being evaluated.[11]

11. I have proceeded therefore on the basis of the parties' joint expectation and reviewed the voluminous body of material presented by them albeit with trepidation. That will explain in part the unusual length of this Award. Nevertheless, an arbitration proceeding is not a medical colloquium. This forum remains a labour relations forum and I have sought to maintain an ultimate labour law lens.

12. In the result I conclude that counsel were correct. It is not sufficient for an employer to assert that it reasonably relied upon experts with superb curricula vitae. The calibre of the employer's experts will always be a crucial fact for consideration but demonstration of that fact is not *ipso facto* decisive in a contested labour law matter. *Dunsmuir* principles of judicial review should not be imported to first level rights determination. More is required in my opinion. And, while caution and some measure of regard may be appropriate in a given case, arbitral timidity is not.

13. On the merits I sustain the core of the Union position. I find that the Policy was introduced at SAH for the purpose of driving up vaccination rates. I also find that the weight of scientific evidence said to support the VOM Policy on patient

[10] Transcript, July 8, 2015, pp. 20, 26,153-154; See also: OHA/SAH Closing Argument, para. 12: "The critical analysis is with respect to the scientific evidence, which the OHA and SAH submit strongly supports the Policy and compels its implementation."

[11] *National Grocers* [2013] O.L.A.A. No. 354 (Swan); See: OHA/SAH Closing Argument, para.138; See also: Transcript, July 8, 2015, p. 67 referring to Mr. Swan's opinion: "And he makes the point that, I know recognizing as tough as it is, to reach a legal conclusion based on the scientific evidence as presented."

safety grounds is insufficient to warrant the imposition of a mask-wearing requirement for up to six months every year. Absent adequate support for the freestanding patient safety purpose alleged, I conclude that the Policy operates to coerce influenza immunization and, thereby, undermines the collective agreement right of employees to refuse vaccination. On all of the evidence, and for the reasons canvassed at length in this Award, I conclude that the VOM Policy is unreasonable.

Parties

14. ONA represents 60,000 registered nurses and allied health professionals and more than 14,000 nursing students providing care in Ontario in hospitals, long-term care facilities, clinics, and in industry, health and the community.[12]

15. The OHA is a member association that represents approximately 151 public hospitals in Ontario of which 135 are participating hospitals in the OHA's Central Collective Agreement with ONA.[13]

16. SAH provides care and services to residents in Sault Ste. Marie and the District of Algoma. SAH is an OHA member and a participating hospital. SAH and ONA are parties to a Local Collective Agreement.[14]

Grievances

17. ONA filed an Association policy grievance on December 13, 2013. ONA members filed a group grievance on January 14, 2014. These matters are consolidated.[15] They grieve the VOM Influenza Management Policy implemented at the Sault Area Hospital on January 1, 2014.

---

[12] Exhibit 12, para.3
[13] Exhibit 12, para.1; Exhibit 1, Tab 1
[14] Exhibit 12, para.2; Exhibit 1, Tab 2
[15] Exhibit 12, para.6; Exhibit 3, Tab A, 1 and 2

18. The Policy requires the following among other things:

> All persons carrying on activities at SAH, which includes employees, students, undergraduate and post-graduate medical trainees, physicians, volunteers and contract workers, **must receive annual influenza immunization or wear a surgical/procedure mask during the influenza season (typically from November to April)** when in a patient care/clinical area, or when engaged in work-related patient interactions in any area of the Hospital. [16] (bold added)

19. The Policy was applied without alteration for the remainder of the 2013-2014 flu season and throughout the following season in 2014-2015.

20. These grievances are *not* about mandatory immunization for influenza as a condition of employment. Nor do the grievances challenge the desirability of influenza vaccination for HCWs despite some witness differences as to what the scientific literature discloses concerning its short and long term efficacy.

21. During bargaining for the 2014-2016 Collective Agreement, the OHA and ONA entered into a Memorandum of Agreement ("MOA") dated March 19, 2014. Pursuant to the MOA, the OHA and ONA agreed to my appointment to an arbitration process to resolve some of the outstanding grievances related to influenza policies and practices at various participating hospitals.[17] The MOA included a provision that: "Sault Area Hospital shall proceed to arbitration first after which the parties will agree to the order in which the remaining grievances proceed."[18]

Arbitration Process

22. These grievances took a long time to try. The Memorandum objective of securing an expeditious outcome was not met. There were the usual prehearing disputes and scheduling exigencies, the details of which are unnecessary to record.

[16] Exhibit 12, para.5; Exhibit 3, Tab B, 4
[17] Exhibit 12, para.7; Exhibit 3, Tab A, 3
[18] Exhibit 3, Tab A, 3, para.4

Senior counsel conducted the case in the traditional adversarial manner. No time was wasted but neither was any stone left unturned.

23. The parties did agree to seek to achieve a Statement of Fact and Document Brief although the ultimate joint work product[19] was slim. Reports or will-say statements from proposed ONA experts were followed by reports from OHA expert witnesses and, finally, by ONA responses to those OHA opinions. Will-say statements for all other witnesses and copies of proposed exhibits were exchanged. Witnesses were permitted to adopt will-say statements and reports subject to the right to cross-examine. The parties retained a reporting service to ensure that complex medical testimony was taken efficiently and transcribed accurately.

24. Dr. Michael Gardam and Dr. Camille Lemieux of the University Health Network ("UHN") in Toronto testified under subpoenae in support of the grievances. Dr. Gardam is the Medical Director, Infection Prevention and Control, UHN and an Associate Professor, Infectious Diseases, in the Faculty of Medicine at the University of Toronto. Dr. Lemieux is the Associate Director, Infection Prevention and Control, UHN and an Assistant Professor of Medicine at the University of Toronto. She is also legally trained and a member of the Law Society of Upper Canada.

25. ONA also called Dr. Lisa Brosseau, currently a Professor in the Division of Environmental and Occupational Health Sciences and Director of the Industrial Hygiene Program at the University of Illinois in Chicago, and Dr. Gaston De Serres, MD, PhD who is a medical epidemiologist with the Scientific Group on Immunization at the Institut National de Santé Publique du Québec. Dr. De Serres is also a Professor of Epidemiology at the Department of Social and Preventive Medicine at Laval University. He works primarily on vaccine preventable diseases and states

[19] Exhibit 12

that he is "frequently called upon to contribute to systematic analyses to inform public policy".[20]

26. The OHA and SAH countered with Dr. Allison McGeer and Dr. Bonnie Henry. Dr. McGeer is the Director of Infection Control at Mount Sinai Hospital in Toronto and a Professor of Laboratory Medicine and Pathobiology, and of the Dalla Lana School of Public Health, at the University of Toronto. Dr. Henry is the Deputy Provincial Health Officer for the Province of British Columbia.

27. This arbitration process is indebted to the contributions of these distinguished professionals. Some of the evidence provided by them is later referred to, inevitably, in sharply abbreviated form. While the professional and research interests of the experts varied to some extent, their extraordinary qualifications, the depth of their experience, and their commitment to the medical profession and public health are beyond dispute. Their evidence was presented, as one would expect, with integrity. Their professional differences of opinion reflected no lack of respect for those with whom they disagreed. Professional courtesy however did not prevent them from vigorously expressing their opposing points of view.

28. In the result the hearing transcripts ran to more than 3500 pages. There were 249 exhibits several of which constituted substantial volumes of material in themselves. Among the exhibits were over 100 academic articles, reports, and commentaries from medical and scientific journals many containing complex statistical material designed to be understood by experts and professionals in the fields of their respective inquiries.

29. Some of these scientific journal articles contained meta-analyses: summaries, reviews and/or critical commentaries concerning the relative quality of randomized controlled trials, observational and experimental studies, investigations, and related

[20] Exhibit 66, Report of Dr. De Serres, p. 1

literature. The meta-analyses and literature reviews contained many conflicting evaluations and the experts who testified in this case, in turn, often differed about the conclusions they drew from those analyses and reviews.

Parties' Core Positions Briefly Stated[21]

ONA

30. ONA maintains that the evidence supporting masks is "weak".[22] Masks are of negligible use in the combat of influenza transmission by or to HCWs and patients. A VOM policy resting upon "objectively flawed" evidence for its "scientific foundation cannot be seen as a reasonable evidence based policy".[23]

31. The Hospital failed to reconsider the merits of the Policy when the extent of the extreme mismatch of the influenza vaccine with the most common 2014-2015 strain of influenza became known early in that flu season.[24] It did not then decide to mask all employees whether or not they had been vaccinated. That failure provides a further demonstration that the Policy is inherently illogical: an illogical policy is not a reasonable policy.

32. ONA submits that: "the process followed at SAH [concerning the Policy] goes directly to its reasonableness".[25] The VOM Policy was presented to the unions as a *fait accompli*. The Hospital provided no opportunity for affected health care professionals to engage in legitimate dialogue about the core of the Policy before its adoption was determined. There was internal professional opposition to VOM at the

[21] Both counsel filed lengthy written legal argument. Closing submissions required two days.
[22] Transcript, July 7, 2015, p.109
[23] ONA Final Argument Overview, para.107
[24] ONA Final Argument Overview, paras. 144-151
[25] ONA Final Argument Overview, para. 191; Transcript, July 7, 2015, pp.134-135

highest levels[26] at the outset. The Hospital failed to consult external consultants who were on retainer to provide that very advice.[27]

33. These fundamental flaws, says ONA, reveal the true purpose of the Policy; that is, to drive up vaccination rates through coercive means. The motive is illegitimate. It is unpleasant to wear masks for months at a time. The compulsory wearing of an unnecessary mask is imposed as a "consequence" for an employee's failure or refusal to accept or submit to vaccination. Such coercion undermines the individual right of employees to choose or decline to be vaccinated, a right that has been collectively bargained. Coercive intention is not reasonable intention.

34. The Policy violates employee privacy rights. A Hospital-wide posting[28] explains to the public that masks are required to be worn by unvaccinated employees. The mask requirement amounts to compulsory disclosure of personal medical information. *KVP* should be applied having regard to the framework set out in *Peace Country Health*[29]: "

> There must be compelling circumstances to justify an intrusion upon an employee's privacy. A policy is only reasonable if it is justifiable in the sense of adequate cause for infringement of the privacy right, and necessary in the sense that less intrusive rules would not suffice".[30]

35. For these reasons, the Hospital's adoption and implementation of VOM constitutes an unreasonable exercise of management rights. The Policy should be struck down on traditional *KVP* principles.

---

[26] Opposition from both the Chief of Staff/Director of Medical Care and the Chief Nursing Executive
[27] ONA Final Argument Overview, para. 195
[28] Exhibit 3, Tab G, 48
[29] *Peace Country Health v. United Nurses of Alberta,* (2007), 89 C.L.A.S. 107 (Sims)
[30] ONA Final Argument Overview, para. 4

OHA/SAH

36. The OHA and the Hospital defend the Policy as a valid patient safety measure[31] supported by highly credible experts. The primary purpose of a VOM policy is source control; that is, to prevent transmission from unvaccinated HCWs to their patients when shedding influenza virus prior to symptom onset, or, in cases of asymptomatic infection.[32] These parties submit that: "the Policy reasonably balances the interests in protecting patient safety against the potential deadly infectious disease of influenza with ONA members' personal autonomy and privacy". The Policy is "consistent with SAH's legal, contractual and ethical obligations as a public hospital".[33]

37. The OHA and the Hospital submit that the process issues raised by ONA are misguided and peripheral: "The critical analysis is with respect to the scientific evidence."[34] The Memorandum plainly envisages the challenge to the SAH Policy to be a lead case: "…it would be unreasonable to analyze the reasonableness of the Policy...by focusing on local evidence of development and implementation of the Policy or by focusing on evidence of the efficacy of the influenza vaccine in one influenza season".[35]

38. Citing *Dunsmuir* and other authorities concerning the standard of judicial review, the OHA and Hospital also submit that arbitral focus should be "to determine whether the Policy falls within a range of acceptable and rational solutions; it is not to assess whether the same policy would have been implemented by ONA", or, "whether SAH exhausted all possible alternatives".[36]

---

[31] OHA/SAH Closing Argument, para.379 citing *Public Hospitals Act—Hospital Management,* RRO 1990, Reg. 965, s.4
[32] Exhibit 185, Report, A. McGeer, p. 36; Transcript, June 24, 2015, A. McGeer, p. 154; Transcript, June 25, 2015, A. McGeer, p. 32
[33] OHA/SAH Closing Argument, para. 15
[34] OHA/SAH Closing Argument, para. 12
[35] OHA/SAH Closing Argument, para. 11
[36] OHA/SAH Closing Argument, paras. 353, 345

Relevant Provisions of Collective Agreement

39. The Central Collective Agreement and the Local Collective Agreement together constitute the collective agreement for each of the participating hospitals, including SAH (the "Collective Agreement"). The present Collective Agreement has a term of April 1, 2014 to March 31, 2016 and the previous Collective Agreement had the term of April 1, 2011 to March 31, 2014.[37]

40. The ONA/SAH Local Agreement contains the following management rights clause:

> B-1 The Association recognizes that the management of the Hospital and the direction of the working force are fixed exclusively in the Hospital and shall remain fully, with the Hospital except as limited by a provision of this Agreement. Without restricting the generality of the foregoing, the Association acknowledges that it is the exclusive function of the Hospital to:
> ....
>
> (e) discuss with the Association, make, enforce and alter from time to time reasonable rules and regulations to be observed by the nurses, provided that such rules and regulations shall not be inconsistent with the provisions of this Agreement. [38]

41. The ONA Central Agreement includes the following provisions:

> Article 1.02: It is recognized that nurses wish to work with the Hospital to secure the best possible nursing care and health protection for patients. Appropriate committees have been created under this Agreement to work towards this objective.
>
> Article 6.05(a): It is a mutual interest of the parties to promote health and safety in workplaces and to prevent and reduce the occurrence of workplace injuries and occupational diseases. The parties agree that health and safety is of the utmost importance and agree to promote health and safety and wellness throughout the organization.
>
> Article 6.05 (e) (vi): The Union agrees to endeavor to obtain the full cooperation of its membership in the observation of all safety rules and practices.
>
> Article 18.07: The parties agree that influenza vaccination may be beneficial for patients and nurses. Upon a recommendation pertaining to a facility or a

[37] Exhibit 12, para.4

[38] Exhibit 1, Tab 2, Appendix 5, Article B-1

specifically designated area(s) thereof from the Medical Officer of Health or in compliance with applicable provincial legislation, the following rules will apply:

a) Nurses shall, subject to the following, be required to be vaccinated for influenza.
b) Omitted
c) Hospitals recognize that nurses have the right to refuse any required vaccination.
d) If a nurse refuses to take the vaccine required under this provision, she may be placed on an unpaid leave of absence during an influenza outbreak in the hospital…
e) If a nurse refuses to take the vaccine because it is medically contraindicated, and where a medical certificate is provided to this effect, she or he will be reassigned during the outbreak period
f) Omitted
g) Omitted
h) This clause shall be interpreted in a manner consistent with the *Ontario Human Rights Code.* [39]

Diebolt Award

42. The specific VOM issue here in dispute has been addressed by a Canadian labour arbitrator once before. See: *Health Employers Assn. of British Columbia* (2013), 237 L.A.C. (4th) 1 (Diebolt) ["Diebolt Award"].

43. That Award records that the issue was heavily contested by an impressive group of expert witnesses, supported by a large body of documentary material. Dr. McGeer and Dr. Henry gave evidence in that earlier proceeding on behalf of the employers.

44. In the result, Arbitrator Diebolt sustained the challenged policy as "a valid exercise of the Employer's management rights" and dismissed all of the other objections that were raised. That VOM policy does not materially differ from the Policy disputed in the instant grievances. It appears that the arbitrator's general preference of the evidence of Dr. McGeer and Dr. Henry was a decisive factor in reaching the conclusion that he did.[40]

[39] Exhibit 1, Tab 1
[40] See Diebolt Award, para. 185: "given the areas of expertise of McGeer and Henry their evidence on the transmission issues have special relevance".

45. Counsel for the OHA/Hospital submits that the Diebolt Award was "a thorough and reasoned decision supported by a substantial body of expert evidence and jurisprudence". Citing numerous authorities including *Irving Pulp & Paper Ltd*[41] he submits that: "principles of certainty, consistency and predictability apply to ensure that adjudicators give appropriate consideration and weight to past decisions".[42] Counsel also referred to *University Health Network (CM-34)* where Arbitrator Surdykowski stated that: "Of course there is a first case on every issue, but even here an arbitrator will generally follow even a first reasoned decision on an issue unless he is convinced that it is wrong." [43]

46. I have paid close attention to the Diebolt Award. However, none of the ONA witnesses heard in this matter testified before Arbitrator Diebolt. As previously mentioned, the Union in the instant case called witnesses with expertise in epidemiology as well as infection control. While union witnesses before Arbitrator Diebolt had some training in epidemiology, their primary interests lay elsewhere as he noted. [44] The Diebolt Award does not disclose that the experts in that case were pressed in detail with each of the scientific and medical investigations, studies, and literature upon which their opinions were based as both counsel did here comprehensively with skill and determination.

47. Research and related commentary in the field has not stood still. In such a situation the precedential value of previous decisions will be more limited than the more typical second, third, or umpteenth view of a standard collective agreement provision. This is even more so where the statutory regimes governing the first and subsequent arbitrations differ, as is the case with the Diebolt Award and the present matter.

---

[41] 2013 SCC 34
[42] OHA/SAH Closing Argument, para. 299
[43] (2013) 115 C.L.A.S. 216, para. 48
[44] Diebolt Award, paras. 183-185

VOM Policy at SAH

48. As previously stated, ONA takes the position that the Policy was presented to Hospital employees as a 'done deal' with no room to consider the merits of a VOM policy. It says that this lack of process demonstrates that the Policy was never about the validity of a mask-wearing component and all about imposing a negative incentive upon employees to opt for what amounts to, for many of them, involuntary vaccination. The Union states that lack of process goes to the unreasonableness of the Policy.

49. On the other hand the OHA/SAH maintains that focus on local SAH evidence is a distraction. What these grievances require is an examination of the scientific evidence underpinning an evidence-based, patient safety VOM policy that has been introduced at many other Ontario hospitals.

50. Given the position taken by ONA on this issue, I find it preferable to outline what occurred at SAH at the outset of this Award.

The CEO's initial decision

51. Ron Gagnon[45], the Chief Executive Officer of SAH, testified by will-say Statement. He said that earlier disturbing critical incidents at the Hospital "shaped his beliefs and actions, and those of SAH, with regard to safety". He and his Senior Management Team ("SMT") were concerned about the low rates of influenza immunization at SAH for its employees, physicians, and volunteers. Mr. Gagnon stated that the Hospital's Human Resources Group was engaged to develop a policy.

52. Minutes of an SMT meeting held on January 30, 2013 record the following discussion:

[45] Exhibit 246

> R. Gagnon—recent report indicates that we are at 42% compliance on flu shot immunization (employees 46%, physicians 41%, volunteers 23%). **Need to determine the most aggressive stance that we can take, which will stand the test of arbitration, to either mandate staff to comply, or impose consequences (ie. masks that they would be charged for**). Also need to review IPAC best practices. (bold added)[46]

53. A Briefing Note prepared for the SMT meeting on February 6, 2013 supported a motion to approve "a new policy to be enforced in the fall of 2013 requiring all employees, physicians and volunteers that are involved in direct patient care to be immunized or wear a mask". *Inter alia*, reference was made to such a policy having been implemented at Health Sciences North in Sudbury.[47]

54. Minutes of the February 6, 2013 SMT meeting record the following:

> HR was asked to come up with most aggressive stance we could take regarding immunization of staff for influenza. HR recommendation to create a team to determine if and where we need a policy(s) and develop action plans related to those policies. Agreement that having a patient representative on the committee would be optimal. Recommended that immunization goal for 13/14 flu season should be 100%. [48]

55. Chris Johns, Manager, Human Resources and Corporate Safety, was asked in February 2013 by his Director "to make the policy more robust, to increase immunization rates, to protect the patients, and to look at the idea of a group plan implementation."[49] Mr. Johns is not a regulated health professional and has no infection control background. He was not then aware that the Hospital had infection control consultants on retainer.

56. The policy was first given to Occupational Health which deals with employee safety, not patient safety.[50] In February 2013 Mr. Johns asked Occupational Health Nurse Carolle Manzo "to do some research as to instituting a policy of getting influenza vaccination or wearing a mask for the season in patient care areas".[51]

---

[46] Exhibit 3, Tab D, 15
[47] Exhibit 3, Tab D, 16
[48] Exhibit 3, Tab E, 21
[49] Transcript, June 29, 2015, C. Johns, p. 66
[50] Transcript, June 29, 2015, C. Johns, p. 67; Transcript, June 9, 2015, C. Manzo, p. 83; Transcript, June 9, 2015, C. Manzo, pp. 53-56
[51] Transcript, June 9, 2015, C. Manzo, p. 20

Neither the normal process for policy development for occupational health, or for infection control matters, was followed.[52]

57. Ms. Manzo assumed that "the decision had been made that the policy would be a vaccinate or mask policy" when she and Mr. Johns were charged with drafting a policy in February 2013.[53]

Preparation of the draft policy

58. Ms. Manzo compiled literature and various policy statements and spoke with an occupational health colleague at Health Sciences North in Sudbury where a VOM policy had been instituted.[54] A first draft of a VOM policy was prepared based on Health Sciences North.[55] She was not asked to look into the human rights aspect of the policy.[56] She did not review the existing Hospital policy concerning Infection Prevention and Control ("IPAC").[57] She did not present or give to anyone copies of the research that she conducted.[58] Ms. Manzo prepared the VOM draft policy based on her understanding that influenza is transmitted by large droplets and aerosol generating procedures only.[59] No one asked her to look at the efficacy or effectiveness of the surgical masks for influenza.[60] She did not ask for assistance with respect to obtaining an expert opinion as to masks or the transmission of influenza.[61]

---

[52] Transcript, October 2, 2014, N. Marcello, p. 17; Transcript, June 29, 2015, C. Johns, pp. 73-74; Transcript, June 9, 2015, C. Manzo, p. 120, 170

[53] Transcript, June 9, 2015, C. Manzo, p. 68; See also pp. 81-2

[54] Transcript, June 9, 2015, C. Manzo, p. 21ff, p. 26; Exhibit 128A and B

[55] Transcript, June 9, 2015, C. Manzo, p. 28-29

[56] Transcript, June 9, 2015, C. Manzo, p. 70

[57] Exhibit 2; Transcript, June 9, 2015, C. Manzo, p. 58

[58] Transcript, June 9, 2015, C. Manzo, p. 104

[59] Transcript, June 9, 2015, C. Manzo, p. 106; Dr. Henry explained an aerosol medical generating procedure as "things we do to patients in the hospital that can produce these very small particles of aerosol", Transcript, June 22, 2015, p. 225

[60] Transcript, June 9, 2015, C. Manzo, p. 109

[61] Transcript, June 9, 2015, C. Manzo, p. 204

59. The SAH By-Laws provide for a standing committee called the IPAC Committee whose purpose is "to foster the prevention of infection, especially nosocomial infections in the hospital and patient safety".[62] The Committee was not asked to look into the issue of either transmission of influenza or whether the wearing of a mask would impact such transmission.[63] Nor did Mr. Johns conduct any research or look at any such evidence.[64]

60. On June 9, 2013 Mr. Johns sent an e-mail to the heads of all SAH bargaining agents including Glenda Hubley, President of ONA Local 46. The e-mail[65] included the following and indicated that a VOM policy would be in place:

> Sault Area Hospital is committed to maintaining a healthy and safety workplace. One step towards achieving this goal is the creation and implementation of an employee influenza management policy…
> ….
> The major change to be put in place this year is that employees who have not received the influenza vaccine will be required to wear a surgical mask in patient care areas for the duration of the influenza season. Later today, the Occupational Health Nurse will be reaching out to employees throughout the hospital, from various areas and levels (including the JHSC) requesting their representation on a committee to prepare and implement an influenza management policy at Sault Area Hospital. The goal for finalizing the policy and deal with logistic issues is the end of August. This will enable time for disseminating the information to all staff well before the 2013-2014 influenza season starts.[66]

61. Ms. Hubley responded to the e-mail on the same date advising that: "The Union reserves the right to grieve. Please be advised that any ONA member sitting on this committee is not a representative of the ONA and does not represent the ONA's view point or opinions on the matter."[67]

62. Responsibility for the Policy was transferred from Human Resources (Occupational Health) to IPAC in September 2013.[68] The SAH By-Laws provide for

---

[62] Transcript, June 9, 2015, C. Manzo, p. 17; Transcript, October 2, 2014, N. Marcello, p. 13
[63] Transcript, June 29, 2015, C. Johns, p. 76
[64] Transcript, June 29, 2015, C. Johns, p. 78, p. 128
[65] Exhibit 3, Tab F, 26
[66] Transcript, June 9, 2015, C. Manzo, p. 119
[67] Exhibit 3, Tab F, 26
[68] Transcript, October 2, 2014, N. Marcello, p. 44, p. 75; Transcript, June 29, 2015, C. Johns, pp. 29, 74; Transcript, June 9, 2015, C. Manzo, p. 38

such a standing committee.[69] An Influenza Planning Committee had been struck earlier. Occupational Health deals with employee safety while IPAC deals with patient safety.

Professional concerns about VOM

63. Minutes of the July 11, 2013 IPAC Committee Meeting include the following references to Dr. Heather O'Brien. Dr. O'Brien was and remains the Chief of Medical Staff and Director of Medical Care at the Hospital:

> Dr. O'Brien asked if direction for the requested change [the VOM policy] was received from Senior Management...**Dr. O'Brien indicated that she declined to participate on the influenza committee as she does not agree or support the policy change**...Dr. O'Brien sought confirmation on the intent of the influenza committee. **She noted that if the intent is to prevent the spread of the influenza virus then everyone should wear a mask; if the intent is to persuade everyone get** (*sic*) **the vaccine then the policy is reasonable. If you really don't want to pass the flu around everyone should wear a mask considering the vaccine is only 65% effective.** [70] (bold added)

64. The first meeting of the Influenza Planning Committee was held on July 18, 2013.[71]

65. A further meeting of the Influenza Planning Committee was held on July 29, 2013 but there were no additional meetings of that Committee in August, September, or October. There was no discussion about the following items: mask effectiveness, vaccine effectiveness, privacy issues, stickers, eye protection, surgical or procedural masks as opposed to respirators. No expert opinion was sought concerning masks. [72]

66. Mr. Johns and Ms. Manzo prepared a Briefing Note dated September 13, 2013 for the SMT "to update them on the progress of the Influenza Planning Committee, the policy that was developed during that committee. Also, the mask situation, the

[69] Exhibit 4, Tab D, Article 21.1 at p. 47
[70] Exhibit 4, Tab 7; See also: Transcript, June 9, 2015, C. Manzo, pp. 92-94, 96
[71] Transcript, June 29, 2015, C. Johns, p.25
[72] Transcript, June 9, 2015, C. Manzo, pp. 122-124

cost that would be involved in implementing the policy".[73] The Briefing Note included the following:

> In early 2013, a concern was raised at SMT hot topics regarding the immunization rate of employees, volunteers and physicians and subsequent risk to patients.
> In response to this discussion, Human Resources was asked to investigate, identify and recommend the most aggressive approach that could be taken to progress towards 100% compliance with influenza immunization
> ....
> In addition, bargaining agents were invited to participate on the work team, as well as given notice of the impending policy change. In response to this each bargaining agent responded stating they were not willing to participate as they did not agree with the direction and they reserved the right to grieve.[74]

67. SAH has a Consulting Services Agreement with UHN. Dr. Lemieux and Dr. Gardam are the UHN physicians responsible for providing "infection prevention and control consultation services to SAH". The appended Schedule to that Agreement includes but is not limited to the following "IPAC consultation on an as needed basis":

> Advise upon policy development or policy revision (does not include development or writing of policies)
> Provide expert advice to Infection Prevention and Control at SAH on specific infection control issues
> Advise upon Occupational Health issues as these relate to infectious diseases [influenza immunization is specifically referenced][75]

68. Dr. Lemieux and Dr. Gardam were not consulted by the Hospital concerning its VOM Policy[76] although infection control practitioners at SAH typically do so "especially in a situation of developing a new policy that hasn't historically been within the manual".[77]

69. On October 7, 2013 Natalie Marcello, who was the IPAC team lead at the time[78], advised Dr. Lemieux by e-mail[79] about the new VOM policy and received the following response less than two hours later:

---

[73] Transcript, June 9, 2015, C. Manzo, p.37
[74] Exhibit 3, Tab E, 22
[75] Exhibit 4, Tab 14
[76] Exhibit 20, para.6
[77] Transcript, October 2, 2014, N. Marcello, p. 15
[78] Transcript, October 2, 2014, p. 12
[79] Exhibit 4, tab 11

> I'm dismayed that the hospital has decided to go this route. It is very punitive and there is no literature substantiating that it does anything to minimize influenza transmission. But big jurisdictions like NY state are going to this.
> I would agree that the main 'benefit' of this is to drive immunization rates up (so an indirect benefit), given that few people would want to wear a mask for 6-7 months. However, aside from being coercive and punitive, the other big problem with this strategy is that to really be effective, you would have to mask everyone whether immunized or not—since the vaccine itself is not very effective and immunity appears to wane before the end of flu season. Being immunized does not mean you won't get the flu and then transmit it. [80]

70. On October 11, 2013 the Workers' Member Group of the Hospital's Joint Health and Safety Committee objected strongly to the draft VOM policy and proposed amendments that would have stripped it of its intended VOM purpose.[81]

Concerns about masks

71. An IPAC Committee Meeting was held on October 9, 2013 that included Johanne Messier-Mann as Chair. Ms. Messier-Mann was the Chief Nursing Executive at SAH and the Manager of the Hospital's IPAC Department. Also in attendance was Dr. Kim Barker who was then the Medical Officer of Health for the District of Algoma. Minutes of that meeting include the following excerpts from discussion of the immunization policy:

> - **The group noted that the policy should be honest and transparent and that in light of the fact that masks are not shown to be an effective means of decreasing the transmission of influenza the intention should be more clearly indicated as "to improve influenza immunization compliance"**
> ....
> - The IPAC committee members questioned why this policy is an IPAC policy rather than an Occupational Health and Safety as is the case in other hospitals who have implemented this type of policy. The purpose of the policy is to protect the patients; that is the role of IPAC. There was significant discussion where each member was asked for input; **without evidence that this will decrease transmission, the committee members do not support the policy. There is no evidence that wearing masks reduces transmission**. Masking appropriately for the duration of an outbreak can be very expensive for the organization and does not offer effective protection for the patients.
> The committee did not support the policy as an IPAC policy.... [82]
> (bold added)

[80] Exhibit 4, tab 11
[81] Exhibit 4, Tab 2
[82] Exhibit 4, Tab 7, p. 2

72. Ms. Marcello had been told prior to the October 9, 2015 meeting that any change to the existing policy would have the "mask piece" written into it.[83] She understood the group in attendance at that meeting agreed that the VOM policy should not be supported.[84]

73. Ms. Manzo was also in attendance at the October 9, 2015 meeting. She confirmed that the group as a whole thought that the purpose of the VOM policy was to get more people vaccinated.[85] She agreed that: "it wasn't that the mask was to protect the patients, but it was to up the immunization rate to protect the patients".[86]

74. Mr. Johns did no follow-up concerning the IPAC comment of October 9, 2013 that: "there is no evidence that wearing masks reduces transmission".[87]

Focus groups

75. Several focus groups were held with employees in various positions beginning on October 9, 2015. Mr. Johns stated that attendance was as low as two and as high as seven.[88] The number of participants represented a small fraction of the total number of SAH employees.

76. A Briefing Note to the SMT dated November 6, 2013 was prepared by the Chief Nursing Executive Johanne Messier-Mann and Kim Lemay, SAH Director, Human Resources. The Note discloses approval by the Chief of Medical Staff Dr. O'Brien. It included the following:

---

[83] Transcript, October 2, 2014, p. 99
[84] Transcript, October 2, 2014, p. 108
[85] Transcript, June 9, 2015, C. Manzo, p. 129, line 22-p.130, line 1
[86] Transcript, June 9, 2015, C. Manzo, p. 129-30
[87] Transcript, June 29, 2015, C. Johns, p. 130
[88] Transcript, June 29, 2015, p. 92

Background:

- In early 2013, a concern was raised at SMT regarding the immunization rate of employees, volunteers and physicians and subsequent risk to patients. In response to this discussion, Human Resources was asked to investigate, identify and recommend the most aggressive approach that could be taken to progress towards 100% compliance with influenza immunization.
- Human Resources submitted a briefing note to SMT in February 2013 outlining a recommendation to enhance the existing influenza policy.

....

- A team worked through the required steps and actions to successfully implement the new policy for the 13/14 flu season. The revised policy was presented to SMT in September, 2013. SMT directed that further input be sought from the Infection Prevention and Control Committee, the Joint Health and Safety Committee, the MAC and by staff focus groups led by OH&S. All options were considered including wearing a mask.
- **The response from these groups was in support of working on increasing the immunization rates and overwhelmingly not in favour of creating a flu shot or mask policy.**

....

Analysis

Given the following points, it is recommended that SAH continue with the current immunization policy and work on increasing the immunization rates:

- Best practice stipulates that immunization is the best prevention for the spread of influenza;
- **There is no evidence that wearing masks reduces transmission**;
- The effort of implementing and monitoring compliance to an "if not immunized then mandatory mask" policy would require disproportionate management effort;
- **While other hospitals have seen increases in immunization rates with a flu shot or mask policy it is expected based on the initial feedback and reaction of staff that there would be a significant negative impact to employee and physician engagement which could persist for several years.** Given this due consideration, the staff and physicians need to commit to being vaccinated. **If the immunization rates do not reach a target of 80% for this influenza season, SMT may need to reconsider the implementation of an immunization or mask policy for next season.** [89] (bold added)

70% immunization rate or VOM

77. On November 13, 2013 Mr. Gagnon and Dr. O'Brien sent a Message to all SAH employees, physicians and volunteers that included the following:

> Last year only 50% of our staff, physicians and volunteers were immunized (or reported they had been immunized). In order to live our iCare values and be "best", we can—and must—do better.
>
> **In order to boost immunization rates, hospitals in Ontario and elsewhere have begun to adopt policies which require all employees, physicians and volunteers**

[89] Exhibit 3, Tab E, 23

> **(and in some cases, members of the public) to receive the annual flu vaccination or wear a mask**. The data from those who have adopted this policy indicates that it has had a dramatic impact in improving rates of immunization and protecting patients.
>
> ....
>
> **Given our low immunization rates last year, it is clear that we need to do something different.** While we seriously considered adopting the same "immunization or mask" policy for SAH at the beginning of this flu season, we also wanted to honour our commitment to hearing from you before making decisions which directly affect you or your work. We sought input from our staff, managers, physicians and others about this potential course of action as well as suggestions to significantly improve our rates of immunization using alternate approaches. There was universal agreement that immunization was important and that we must achieve higher rates of compliance. **In addition, it was strongly felt that moving to an "immunization or mask" policy without first trying other approaches and allowing our people the opportunity to demonstrate your commitment to our patients would be premature.**
> (bold above added)
> ....
> **Although we are committed to the success of the approaches suggested in our consultations, if we have not reached the 70% target by December 31, 2013, we will implement the "immunize or mask" policy beginning January 2014.** Also, should we not reach the 80% overall target by the end of March 2014, this policy will be implemented for the entire 2014/15 flu season. [90] (bold in the original)

78. Minutes of the December 13, 2013 Influenza Planning Committee record that: "Discussion ensued on the expected upsurge of staff who may want to receive their flu shot after the policy is implemented". [91]

79. The Policy was implemented on January 1, 2014 when the target 70% influenza vaccination rate was not met. Neither the Influenza Planning Committee nor the IPAC Committee was consulted about any best evidence concerning the 70% or 80% rates and those committees did not discuss those target rates.[92] Hospital employees had been kept apprised of the level of vaccination rates being achieved on an ongoing weekly basis by the publication of chart presented "flu shot thermometers".[93]

---

[90] Exhibit 3, Tab F, 30; See also Exhibit 246; Exhibit 4, Tab C, 11; Exhibit 3, Tab E, 24
[91] Exhibit 3, Tab C, 12
[92] Transcript, June 29, 2015, C. Johns, p. 85; Ms. Manzo is not aware of any empirical evidence to support selection of 70%. It was a decision taken by the SMT. See: Transcript, June 9, 2015, C. Manzo, pp. 181-2
[93] Exhibit 3, Tab E, 46; Transcript, June 9, 2015, C. Manzo, pp. 44-45

VOM roll-out: notices, stickers

80. On January 6, 2014 Mr. Gagnon and Dr. O'Brien issued a further message that included the following and also attached a media release announcing the VOM Policy:

> Those who have been immunized can be identified by a sticker on their ID badge indicating their status. Those who may choose not to wear the sticker will also be required to wear a mask as it's important for our patients to be able to immediately identify those who have taken this extra precaution against the flu. [94]

81. Notices were posted throughout the Hospital bearing the title "Attention Patients and Visitors". The purpose was to help explain to visitors why they would be seeing employees wearing masks and to encourage them to wear a mask if they had not been immunized.[95] The Notice began with the following statement:

> **You may see some Sault Area Hospital (SAH) personnel wearing masks.** To protect the well-being of patients, SAH has implemented a policy **requiring all personnel to either receive an influenza vaccination or wear a mask during the flu season.** (bold in original). [96]

82. The VOM Policy was maintained in force for the balance of the 2013-2014 flu season until the season was declared ended on April 30, 2014.[97]

2014-2015 flu season

83. The VOM Policy was in place in the following flu season from November 15, 2014[98] until May 6, 2015 when it was terminated following discussions with Algoma Public Health.[99] The Policy was maintained 'as is' throughout that season despite knowledge at an earlier date[100] that there was a significant mismatch of the vaccine

[94] Exhibit 3, Tab F, 38
[95] Transcript, June 29, 2015, C. Johns, p. 42
[96] Exhibit 3, Tab G, 48
[97] Exhibit 3, Tab F, 42; Transcript, June 29, 2015, C. Johns, p. 43
[98] Transcript, June 9, 2015, C. Manzo, p. 158
[99] Exhibit 245; Transcript, June 29, 2015, C. Johns, p.122
[100] Ms. Manzo was aware of a significant mismatch as early as mid-November. Transcript, June 9, 2015, C. Manzo, p. 174

with the most common strain of Influenza A then prevailing.[101] The Hospital did not require everyone to wear a mask whether immunized or not despite the known mismatch.[102]

Outbreaks

84. There were no outbreaks of influenza at the Hospital in 2013-2014 and no incidents of hospital acquired influenza.[103] There were three Influenza A outbreaks on three units during the 2014-2015 flu season[104]. Nine of the twelve patients affected had been vaccinated.[105] Three of the four staff who contracted influenza like illness had been vaccinated for influenza.[106] The measures taken did not require that all nurses wear masks.[107] The only prior influenza outbreak within the last five years had been at the antiquated Plummer site of the Hospital that has now been closed.[108]

Existing SAH policies

85. The Infection Prevention & Control Committee has issued various other policies over the years.

86. The OHA and the Hospital stress that masks are worn in numerous areas of SAH for many different reasons.[109] The existing SAH Infection Control Manual provides for "additional precautions" "to protect staff and patients" "based on the mode of transmission (e.g. contact, droplet, airborne)".[110] It requires that a surgical

[101] Transcript, June 29, 2015, C. Johns, p. 121, 124
[102] Transcript, June 9, 2015, C. Manzo, p. 174-5
[103] Exhibit 246
[104] Exhibit 248
[105] Exhibit 5; Transcript, October 2, 2014, N. Marcello, pp. 33-35
[106] Exhibit 138; Transcript, June 9, 2015, C. Manzo, pp. 211-212
[107] Transcript, June 9, 2015, C. Manzo, p. 213
[108] Transcript, June 29, 2015, C. Johns, p. 138; Exhibit 5
[109] OHA/SAH Closing Argument, para. 272, footnote 243
[110] Exhibit 2, Infection Prevention and Control Policy, 11-25, p. 1, Definition

mask and eye protection must be worn if within 2 metres of a patient as a droplet precaution:

- Used for microorganisms that are transmitted by large respiratory droplets
- Droplets can be generated when talking, coughing, or sneezing, and through some respiratory procedures (e.g. suctioning, bronchoscopy, nebulized therapies)
- Droplets are propelled from the patient's respiratory tract and can travel up to 2 metres.
- Droplets do not remain suspended in the air—once the microorganisms are deposited on surfaces in the patient's environment, they can be transmitted through contact with the contaminated surfaces
- Examples of microorganisms transmitted through the droplet route: respiratory syncytial virus (RSV), pertussis, influenza[111]

87. The Policy in issue likewise requires that employees infected with the influenza, who must continue to work, "should not work with high risk patients and must wear a mask and gloves and practice good hand hygiene during patient contact". [112]

A Road Map to Expert and Other Evidence

88. Compared to many other situations involving expert evidence, in this case most people will have some basic reference points that help in tracking the evidence. Virtually everyone has some direct personal experience with the flu. I expect therefore that most people understand at a basic level that: (i) flu is contagious, (ii) flu is more or less contagious at different points, (iii) some kind of transmission is required for flu to spread, (iv) steps may be taken to slow and/or reduce the spread. Against this backdrop, the expert evidence adduced in this matter, while complex, is not entirely inaccessible.

89. In reaching their differing conclusions about VOM policies, stated again in lay terms, the experts were in strong disagreement about the following issues: (i) the

[111] Exhibit 2, Infection Prevention and Control Policy, II-25, B. Droplet Precautions; See also: C, Droplet-N95 Precautions applicable to the event of a pandemic or emergence of a novel virus where staff must wear a fit tested N95 respirator if within 2 metres of a coughing patient and visitors must wear surgical masks.

[112] Exhibit 3, Tab A, 4, 2.4

extent that unvaccinated HCWs pose a risk to patients of giving them the flu, (ii) whether there is any serious risk that symptom-free HCWs will give patients the flu, (iii) whether masking HCWs serves any real purpose.

90. The following review of the evidence is organized in this way.

91. First, descriptions of influenza are provided. This section is not controversial but it is important to recognize the serious and complex public health challenge that the disease presents.

92. Second, the concept of transmission is explained. This is not a controversial topic either. One must understand the concept of transmission to appreciate why a masking policy is even considered.

93. Third, there is a general policy piece. It identifies the goal of VOM policies and outlines the elements involved. This section is a prelude to the controversy and identifies the experts' disagreement about key elements of the Policy. What is the burden of influenza disease acquired from unvaccinated HCWs? Is there a risk of asymptomatic HCWs spreading the disease to patients?

94. The fourth section relates to the efficacy of vaccination. The experts agree that vaccination is the best available option to combat influenza generally. They agree that the overall range of effectiveness of the vaccine is approximately 60%. But they do not agree that there is proof that the vaccination of HCWs reduces morbidity and mortality in acute care hospitals. This section contains a relatively deep dive, for lay purposes at least, into the medical/scientific evidence surrounding a fundamental precursor to the VOM dispute; namely, is it possible to identify an unvaccinated HCW problem?

95. The fifth section tackles the significant expert dispute over asymptomatic transmission. The OHA/SAH experts assert that the primary reason for requiring

HCWs to wear masks is that influenza virus may be shed asymptomatically. Is there evidence to show that this is true, or, sufficient evidence to demonstrate that there is a problem of sufficient proportion to warrant a VOM policy?

96. The sixth section addresses the crucial expert debate about the use of masks. Is there sufficient medical/scientific evidence to support a mask-wearing component? This section also includes a recitation of the fact evidence concerning the alleged adverse effects of masking, the alleged incursion into the privacy interests of employees, and the alleged inconsistent enforcement of the mask-wearing requirement.

97. The seventh section speaks to what happened in the 2014-2015 vaccine mismatch year. ONA claims that a large number of vaccinated employees, none of whom are required to mask, are as exposed to influenza as those who are unvaccinated. The Hospital's failure to require mask wearing by everyone, particularly in a mismatch year, is illogical says the Union. This section includes the experts' opinions concerning the 'why not mask everyone' question.

98. The eighth section shifts to the broader policy context in which the specific VOM Policy exists. Are there vaccination requirements for diseases other than influenza? Have there been other studies or recommendations? Do these speak to the reasonableness of the current Policy?

99. I turn now to the first section.

Influenza and Influenza Vaccine Efficacy

100. There is no dispute about the nature of influenza and the fact that the disease is complex.

101. Influenza is a subset of influenza-like illness ("ILI") that is, in turn, a subset of acute respiratory illness ("ARI"). Dr. De Serres estimated that influenza constitutes 30% of ILIs on average[113] and Dr. Henry stated that between one third and one half of ILIs were influenza depending on the season.[114] Dr. McGeer explained that the percentage of ILIs likely to be influenza may be higher than 20-35% depending on the point of the influenza season[115]. She went on to say:

> There are many viruses that cause respiratory infections. Influenza is by far the most serious of them, in that, it more often leads to complications or serious illness that require medical attention than many of the other upper respiratory infections and, importantly, it's one of the few that we do have a vaccine that prevents. There is a couple of others like parainfluenza and respiratory syncytial virus or RSV that also cause severe illness and outbreaks on long-term care, and in children in particular, but none of these are currently vaccine preventable.[116]

102. Dr. Henry explained in her initial Report:

> In basic terms influenza is an acute, primarily respiratory infection caused by the influenza virus….a respiratory infection caused by influenza A and B viruses. In Canada, it generally occurs each year in the late fall and winter months. Symptoms typically include the sudden onset of headache, chills, cough, fever, loss of appetite, muscle aches and fatigue, runny nose, sneezing, watery eyes and throat irritation. Nausea, vomiting and diarrhea may also occur, especially in children.
>
> Most people will recover within a week or ten days, but some—including those 65 years of age and older and adults and children with chronic conditions—are at greater risk of more severe complications, such as pneumonia. There are many factors which will affect how much impact influenza will have in any given season. One main factor is the circulating strain with influenza A H1N1 and B strains more likely to affect children and influenza A H3N2 having more severe effects on the elderly. In years when H3N2 is the predominant circulating strain of influenza, outbreaks in long term care (LTC) and in elderly populations, both in the community and in hospital, can be particularly severe.[117]

103. Dr. De Serres explained in his Report:

> Influenza is viral infectious disease, typically affecting the upper respiratory tract. Epidemics are usually caused by influenza type A or B, whereas type C is an infrequent cause of mostly mild human infection. In humans, type A influenza is further divided into two main subtypes (H1N1 and H3N2) whereas type B is divided into two lineages (Victoria and Yamagata). The hallmark of influenza illness is the abrupt onset of respiratory illness that classically includes fever and cough with extreme malaise and general body aches.

---

[113] Transcript, May 19, 2015, p. 87

[114] Transcript, June 23, 2015, p. 34

[115] Transcript, June 24, 2015, p. 82

[116] Transcript, June 22, 2015, p. 128

[117] Exhibit 141, p. 2

....

> During the winter season, in addition to influenza, many other respiratory viruses also cause influenza-like illness (ILI) including the respiratory syncytial virus (RSV), the human metapneumovirus (HMPV), the parainfluenza viruses, adenoviruses, enteroviruses, rhinoviruses, coronaviruses and several other viruses.[118]

104. Dr. McGeer explained that influenza preferentially infects the cells at the back of the nose and throat and is almost always limited to those cells; the virus co-opts those cells to reproduce and destroys them in the process. Symptoms start when there is local damage to those cells and immune response can cause inflammation and other systemic reactions. Bacterial pneumonia is a complication because one no longer has the intact lining of the throat for protection. There can be exacerbations of asthma. Complications arising from influenza are generally what cause the most burden of illness.[119] Issues may also arise for persons who have underlying lung disease, heart disease or who are receiving treatment for cancer.[120]

105. Dr. McGeer commented upon the seriousness of the disease in this way:

> So, when you study cohorts of people somewhere between one and eight, and one and twelve or fifteen people get infected with influenza every year, very common disease. And most of that disease is pretty mild. You get sick for a few days and then you get better and you go on with your life. But a big enough fraction of it is either severe or complicated that influenza is, in fact, the number one infectious disease cause of death in Canada, and somewhere in the top ten of total burden. We get into details about the argument about, you know, exactly how much influenza there is, and how you count it, but at the low end it's number eight, and at the high end it's number one. It's a big burden disease because of the frequency of infection and because of the complications.[121]

106. A and B strains of influenza, particularly the A strain, mutate quickly and can vary by geographic region. As a result a new vaccine is required annually and its composition must be determined well in advance of any upcoming flu season. The ability to predict what will become a predominant circulating strain is imperfect, in

---

[118] Exhibit 66, pp.2-3
[119] Transcript, June 24, 2015, pp. 74-77
[120] Transcript, June 22, 2015, B. Henry, p. 52
[121] Transcript, June 24, 2015, p.72

part because the circulating virus may drift so that the vaccine is no longer a match.[122] Dr. McGeer testified that:

> So, coming up to the 2015/16 season, we've got one strain of influenza A (H3N2), one strain of influenza A (H1N1), two different lineages of B, just to make your life difficult, and one or two of those will likely be the predominant influenza strain next winter...There's no way of knowing ahead of time which one. You can make some guesses based on the past years but you can't know for certain. [123]

107. There is no dispute that the best currently available method to prevent the transmission of influenza is the influenza vaccination albeit that the vaccine is not 100% effective. On average, based on all population ages and depending upon the number of years considered, the witnesses accepted that there is an overall range of effectiveness close to 60%.[124] And, notwithstanding debate about the level of proof concerning the measurable outcome of vaccinating health care workers, there is general agreement that present vaccines are the best intervention available for seasonal influenza.[125] There was some discussion by witnesses during the hearing about the possible negative impact of repeat vaccination but this issue appears to be a matter for continuing review.[126]

108. There is also no dispute that, with a vaccination efficacy rate in the range of 60%, many vaccinated HCWs will also contract influenza.[127] The level of protection afforded by the vaccine will depend upon how far the circulating strain has drifted

---

[122] Transcript, June 22, 2015, B. Henry, p. 48; See also: Exhibit 66, G. De Serres Report, p. 6

[123] Transcript, June 24, 2015, p. 79; See also: Transcript, May 21, 2015, M. Gardam, pp. 196-197

[124] Transcript, June 24, 2015, A. McGeer, p. 24; Exhibit 185, A. McGeer Report, p. 25; Transcript June 22, 2015, B. Henry, p. 59; Exhibit 141, B. Henry Report, p. 4; Transcript May 20, 2015, G. De Serres, pp. 190-191; Transcript, May 21, 2015, M. Gardam, p. 62; Transcript, July 8, 2015, OHA/SAH closing argument, pp. 79-81

[125] See Exhibit 73: Osterholm *et* al, "Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis", Lancet Infect Dis. 2012 Jan;12(1): 36-44; Some, as do Dr. McGeer and Dr. Henry, go further. See: Exhibit 157, Griffin, Editorial Commentary, "Influenza Vaccination of Healthcare Workers: Making the Grade for Action", CID 2014:58 (1 January), at p. 59: "Vaccination of healthcare workers to protect vulnerable patients and residents of long-term care facilities should be viewed as an evidence-based recommendation."

[126] See: Exhibit 23: McLean *et al,* "Impact of repeated vaccination on vaccine effectiveness against influenza A(H3N2) and B during 8 seasons", CID Advance Access published September 29, 2014; Exhibit 144: Neuzil, "How can we solve the enigma of influenza vaccine-induced protection?", Editorial Commentary, JID 2015:211:1517-8

[127] Transcript, May 19, 2015, G. De Serres, p. 103

from the vaccine components.[128] It will not protect against ILIs or ARIs that are not influenza.[129]

109. Nor is there any question that the range of effectiveness for the vaccine varies within age and population groups. Dr. Henry explained:

> ...vaccine provides good protection in healthy adults, which is mostly our health care worker community, and much more modest protection and paradoxically those who need it the most, and many of those people will be the patients, the residents in our health care facilities.[130]

110. Dr. McGeer testified that:

> So, if you vaccinate frail, elderly people in nursing homes, their protection against any influenza infection is somewhere probably in the mid 20s. Their protection against hospitalization due to influenza is something like 50 or 60 percent.
>
> So, influenza vaccine reduces the incidence of infection but it also mitigates disease. Part of the reason that may be important is that, when you talk about vaccinated and unvaccinated health care workers getting infection, there are in fact differences. So, vaccinated healthcare workers do get infections with influenza but, when they get infections, those infections will be less severe and they will shed less virus. So there may be some, in fact, some additional element of protection beyond the 60 percent reduction in infection that accrues because people are less ill from the influenza and consequently shedding less virus....
>
> I think the point is that you can, from an individual health care worker point of view, the benefits of influenza vaccination are not just in the prevention of influenza, they are also in the fact that you will be less ill if you do get it. From a transmission to a patient's point of view, it's hard to know what to do on that data.[131]

111. There is general recognition that development of an effective seasonal influenza vaccine is fraught with difficulty. Dr. McGeer repeated a comment in her evidence that sums it up: "Nancy Cox who just retired as the CDC's lead person on influenza is famous for saying, 'when you've seen one influenza season, you've seen one influenza season'".[132] The extent to which the influenza vaccine will be matched to circulating strains of influenza cannot be known until the season unfolds. The 2014-2015 flu season was a particularly bad mismatch year.

---

[128] Transcript, June 22, 2015, B. Henry, pp. 69-70
[129] Transcript, June 23, 2015, B. Henry, p. 34
[130] Transcript, June 22, 2015, p. 100
[131] Transcript, June 24, 2015, pp. 102-104
[132] Transcript, June 24, 2015, p.79

Transmission

112. It is important to understand the concept of transmission because a stated purpose of a mask is to prevent HCWs from giving patients the flu. As explained by Dr. Henry:

> The primary purpose of having health care providers wear a mask is to prevent transmission from them to their patients at times when they are shedding virus (prior to symptom onset, if they are working ill, or if they are asymptomatically infected). [133]

113. Transmission of influenza from one infected individual to another requires both shedding of virus and transportation. Shedding of virus is not the same thing as effective transmission to another. There must not only be shedding but also a sufficient amount of live replicating virus shed close enough to susceptible individuals to project the viruses onto receiving respiratory mucous.[134]

114. In her Report, Dr. Henry explained these concepts in this way:

> Humans have receptors for influenza viruses mostly in the mucosa that lines our nose and throat but also have some that are deep in the lungs. Transmission of infection occurs when influenza viruses penetrate a susceptible host's defences and are deposited on these viral receptors in the upper respiratory tract. To become infected with influenza we must be susceptible to the virus and be exposed to a sufficient concentration (infectious dose) of live particles of the virus. [135]

115. Dr. McGeer said that:

> The influenza has to go from acutely infected person to acutely infected person. It does not survive on a long-term basis in any one person so the continuous transmission is critical to its survival. And the one safe thing you can say about transmission of influenza is that being close to somebody with influenza is bad for you. After that, it's actually very difficult to parse what the components are to the transmission event…[136]

116. The point agreed upon by all of the experts is that virus shedding without transmission is of no concern. As explained by Dr. Lemieux:

> So shedding would be, I think, more closely aligned to the dissemination word. So shedding simply means that the virus is detected in, in this case, let's say, respiratory

---

[133] Exhibit 141, p. 6
[134] Transcript, June 23, 2015, B. Henry, pp. 92-93
[135] Exhibit 141, p. 3
[136] Transcript, June 24, 2015, p. 92

> secretions, the fact that it's being expelled from the body or being—it's actually in various body fluids or various secretions, but it in no way speaks to, again, that host or the person who has the illness transmitting to the recipient, who then develops clinical disease, very difficult. Right now I'm shedding bacteria, as an example. I'm sitting here, I'm shedding bacteria by the fact that I exist, but I'm not necessarily giving it to you, I'm not sharing it with you because the mode of transmission is not necessarily there.[137]

117. There are also important questions about proximity of a virus shedder to a potential recipient and about the size of droplets/particles that are produced.

118. When asked how influenza gets into a person's system, Dr. Henry explained that the receptors that allow the virus to attach to cells are very common in the back of the nose and throat but that there are some receptors deep in the lungs that are still under investigation.[138] She also testified that:

> For the most part though we think it's when somebody is in a short distance from somebody else and they are coughing, sneezing. Even things like singing and talking sometimes can transmit small droplets that you then inhale and they land on the receptors in the back of the nose and throat.[139]

119. Dr. De Serres said:

> Well, transmission is a complex issue because transmission means you have the virus, and you have a proper transportation for the virus because, if you have the virus and you cough, you sneeze, obviously you're producing lots of droplets.
>
> If you're not coughing, you're not sneezing, while speaking you produce some droplets but few, far fewer than when you're coughing, you know. Like when you're speaking you put your hand in front of you, you don't have your hand all wet. When you're coughing it is all wet.
>
> So, we're producing way more droplets which are the major way of transmission of influenza. So, it's not only the presence of the virus, it's also how many virus. If you have tons of virus, if you have few viruses that will be important in terms of transmission. If you have good transportation, so many droplets, that will be important for transmission. If you're close to people, again, that will account for transmission. So, it's the conjunction of that, plus, again, we're talking transmission, that's the acquisition of the infection by the other person but that person, if immune, will not be sick. [140]

120. Dr. McGeer testified that:

---

[137] Transcript, May 11, 2015, p. 101
[138] Transcript, June 22, 2015, p. 52
[139] Transcript, June 22, 2015, p. 53
[140] Transcript, May 19, 2015, p. 90

> I think in terms of small particles versus large particles...I think the majority of people believe that the weight of the evidence says that most transmission is by droplets, by larger particles but, you know, there is a range of acceptable opinion on that front.[141]

121. Dr. Henry said:

> ...we looked at a variety of different pieces of evidence and felt that the majority of transmission really from the evidence that we see is through larger droplets. And by large I mean larger than five microns which is tiny still. These are small droplets that you can't necessarily see. The droplets are deposited in the upper airways from people who are either coughing or talking or sneezing or certainly there's probably a lesser extent, people who touch something contaminated and rub their eyes, and that's the majority of transmission.
>
> With the exception of in health care settings when we do things to people that create what we call aerosols or smaller, less-than-five- micron particles, so things like putting in a breathing tube, that can generate these smaller particles and that probably leads to some transmission.
>
> The challenges that the influenza virus needs some—needs moisture to survive. So, as a particle gets smaller, it dries out. It dessicates in the air. And there is not a lot of good evidence to tell us whether those very tiny particles actually have live virus in them or just the virus RNA that we can detect with our testing but don't lead to infection because they are not actually live virus anymore. And in our opinion, from looking at this evidence, was that the majority of the infection are larger enough particles that the virus has some moisture to survive and those are the ones that are deposited in the upper airways.[142]

122. Dr. Gardam agreed that large droplets are a method of transmission[143] as did Dr. Lemieux[144] and Dr. De Serres[145]. When asked whether small droplets are considered to be a method of transmission, Dr. Gardam stated that:

> They are. I think they are still a bit more controversial in terms of their relative contribution that they provide. I think that is yet to be elucidated.....I think that they're out there. That's the reason why organizations went with N95 respirators for aerosol generating procedures during pandemics...I think we are going to need more research to figure out exactly how important they are and under what circumstances.[146]

[141] Transcript, June 24, 2014, p. 97
[142] Transcript, June 22, 2015, pp. 55-56
[143] Transcript, May 21, 2015, p. 198
[144] Transcript, May 11, 2015, p. 15; Exhibit 36
[145] Transcript, May 20, 2015, p. 48
[146] Transcript, May 21, 2015, p. 244

Evaluating VOM Policies

123. Before moving to assessing the merits of the VOM policy under review, it may be useful first to consider what might be termed 'best' practice for public health policy determination. In his initial Report, speaking generally about public policy analysis, Dr. De Serres explained that:

> By way of context, public policy analysis first requires an understanding of the premise of the proposed program—the problem it seeks to address, the program goals, objectives and a list of available options for achieving that. Establishing the goal is a critical first step because all subsequent evidence review and evaluation should be in relation to that specifically articulated program goal. Objectives may then include measurable changes related to outcome (e.g. reduction in illness or its severe consequences) or process (e.g. increasing vaccine uptake). For vaccine preventable diseases, the premise generally requires a substantial disease burden that can be prevented for which a program of immunization that is safe, effective, affordable and acceptable can achieve meaningful and measurable reduction.[147]

124. Dr. De Serres explained what is meant by "burden of disease":

> Well, the burden of disease is an expression to cover all aspects of the disease. So, it may be you become sick, but you stay home. You become sick and then have to consult a physician. You may need to be hospitalized or you may die. Obviously, dying from influenza is the most serious outcome…So, in the studies, for example, they are looking at different outcomes and it's important because the severity varies.
>
> But burden of disease is to encompass what happens in people who become sick, and we're talking about people who are sick, not people who are infected. Infected is just you're in contact, the virus multiplies, but it doesn't mean you're sick. You may become sick if you have insufficient protection or no protection, but if you have good protection from past exposure or from the vaccine, you may have no symptom.
>
> So, infection with no disease, with no symptom is not part of the burden of disease. You're not sick. You're not aware that anything has happened to you.[148]

125. Moving on to the specifics of a VOM policy for HCWs, Dr. De Serres stated that:

> The goal of that policy is ostensibly the reduction of disease burden among patients attributable to unvaccinated HCWs. Embedded within the premise of such a policy is that influenza vaccination will substantially reduce patient disease burden and there are no other practicable program or policy options for achieving the same or greater level of necessary patient protection.[149]

---

[147] Exhibit 66, p. 1

[148] Transcript, May 19, 2015, pp. 85-86

[149] Exhibit 66, p.3, para.5

126. He went on to identify as a threshold question the question of whether it is known that unvaccinated HCWs are infecting patients. In his words:

> Before assessing by how far patient disease burden can be reduced by the "vaccinate or mask" policy, we first need to know how many patients are being infected by unvaccinated (and/or unmasked) HCWs in the absence of the policy. We need to know how many patients are typically or on average infected by HCWs, and in particular those who are unvaccinated, during the seasonal influenza period which typically spans November to April in the northern hemisphere.[150]

127. In addition to the potential influenza disease burden of unvaccinated HCWs, Dr. De Serres also identified some other significant factors at play in any VOM analysis:

> The risk of influenza from unvaccinated HCWs to patients is the end result of a complex interaction of variables and conditions including: the frequency of influenza infections in HCWs; the proportion of infected HCWs with sufficient virus shedding to transmit; the amount of effective droplets produced by symptomatic or asymptomatic HCWs; the frequency, duration and closeness of contact between HCW and patients; and the level of pre-existing protective immunity in patients to protect themselves. Each of these factors will further vary for seasonal versus pandemic influenza, by seasonal subtype and by age, comorbidity etc. The risk to patients would be further reduced if HCW adopt other behaviours which also reduce the probability of transmission (e.g. staying home when sick, wearing a mask when in contact with patients, minimizing the time in close contact with patients).[151]

128. As will later be seen, at least two of these factors were the subject of serious disagreement by the experts who testified in this proceeding. They do not agree about the disease burden carried by unvaccinated HCWs. They do not agree about asymptomatic transmission.

HCW Disease Burden

129. The experts all agree that the question of the disease burden carried by unvaccinated HCWs is important because, at root, any VOM policy is ultimately grounded on the assumption that the disease burden from this source is significant. However, there is major disagreement about the medical/scientific evidence. The ONA experts do not accept that the evidence supports the proposition that

[150] Exhibit 66, p.3, para.7
[151] Exhibit 66, p.4, para.10

increasing HCW influenza immunization rates serves to protect patients from morbidity and mortality. The OHA/SAH experts maintain that the evidence is strong.

130. Dr. De Serres went on in his Report to explain more fully why he holds the view that accurate quantification of the disease burden of unvaccinated HCWs is important:

> I am not disputing that HCW have a professional duty to protect their patients, that healthcare acquired influenza exists, that the influenza vaccine protects or that unvaccinated HCW may occasionally transmit influenza to their patients. However, to justify a mandatory intervention abrogating HCW rights, the ethical dilemma and burden of proof rests on the proportionality, intrusiveness and effectiveness of the intervention in relation to the magnitude of the disease burden caused by unvaccinated HCW. My work as an epidemiologist is to quantify risks and my work as a policy analyst is to weight those risks against other considerations.
>
> After weighing the scientific evidence, I conclude that accurate quantification of the influenza disease burden in patients attributed to unvaccinated healthcare workers is missing. This information is fundamentally required in assessing the proportionality of the effectiveness of the intervention and the number or workers whose rights may be infringed each year by the 'vaccinate or mask' policy….
>
> Some may argue that in the absence of knowing the actual number of patients infected by unvaccinated HCWs, even a single patient potentially infected warrants any and every measure possible. However, such an extreme perspective is tantamount to a pursuit of 'zero risk'. Such 'zero risk' pursuits are elusive and slippery slopes that generally end in more and more draconian measures geared toward achieving the nearly impossible at a high cost in terms of target group trust and morale and professional credibility.[152]

131. Dr. McGeer has not estimated the number of hospital acquired deaths due to influenza and does not know the number.[153] She accepts that any VOM policy could only affect a subset of the annual total of influenza deaths.[154] She explained that:

> The preventable disease that is…The influenza that you would prevent with this policy is associated with the protection of patients from health care workers who either choose because of the vaccine-or-mask policy to be vaccinated when they might not otherwise have done so and health care workers who choose to wear a mask during the influenza season when in the absence of a policy they would not have done so.[155]

[152] Exhibit 66, p. 12, paras. 34-35

[153] Transcript, June 25, 2015, p. 86; Transcript, June 25, 2015, pp. 146-150

[154] Transcript, June25, 2015, p. 89

[155] Transcript, June 25, 2015, p. 122

132. The focus of the discussion here, to be clear, is upon unvaccinated HCWs. No one doubts that there are other potential vectors for the transmission of influenza to patients; for example: family members, other visitors, fellow patients, not to mention vaccinated HCWs who contract influenza nevertheless.

133. On an earlier occasion Dr. De Serres had joined Dr. Danuta Skowronski and Dr. David Patrick in a Letter to the Editor which included the following comment:

> Community-based statistics of influenza morbidity are mostly irrelevant to mandatory HCW immunization because this burden of disease is predominantly acquired outside of the health care setting. Estimates of patient disease burden within the nosocomial setting and specifically due to unvaccinated HCWs would be more relevant, but are not available.[156]

134. Dr. Henry agreed with this observation by Dr. Skowronski and Dr. Patrick who are her colleagues at the British Columbia Centre for Disease Control:

> I do agree, as we've discussed earlier, influenza is mostly transmitted in the community and we don't have data on the difference between vaccinated and unvaccinated healthcare workers and individual transmission events…in healthcare settings.[157]

135. Dr. Henry agreed that no VOM policy would influence influenza in the community[158]. Dr. McGeer denied that she had used or recommended the use of community burden in the assessment of development of such a policy.[159]

136. In the final analysis, Dr. McGeer accepted Dr. De Serres' concern about the difficulty of establishing the burden of disease attributable to unvaccinated HCWs but deemed it irrelevant because of her interpretation of the published randomized controlled trials ("RCTs") and other studies:

> Dr. De Serres approaches the question of the potential patient safety benefits of healthcare worker immunization by suggesting that we first need to establish the burden of hospital-acquired influenza in patients, and then understand what proportion of that burden is associated with unvaccinated health care workers. He points out, and very rightly, that this is an extraordinarily difficult challenge. I would, in fact, submit that it is even more difficult than he suggests, because of the complexity and communicability of influenza….

---

[156] Exhibit 93, Canadian Medical Association Journal, November 12, 2012.

[157] Transcript, June 23, 2015, pp. 155-156

[158] Transcript, June 23, 2015, pp. 163-164

[159] Transcript, June 24, 2015, p. 176

.....

> The fact that we have been unable to measure the specific burden of influenza caused by transmission from healthcare workers is no longer relevant—there is now compelling evidence from the strongest type of studies (5 randomized controlled trials) that vaccination of healthcare workers reduces patient mortality and morbidity.[160]

137. What Dr. McGeer's Report refers to as "now compelling evidence from the strongest type of studies (5 randomized controlled trials)" is completely rejected by the Union's experts. Indeed, accepting the assessment of its experts, ONA asserts that: without the RCTs[161] that they depend upon, the OHA/SAH case is "entirely unsubstantiated" and a VOM policy "which relies entirely on it as scientific foundation cannot be seen as reasonable evidence based policy".[162]

138. Dr. De Serres led the attack on the RCTs cited by the OHA/SAH experts and began by challenging the widely varying published estimates of deaths per year in Canada due to influenza.[163] Dr. De Serres cited meta-analyses published by others, conducted his own analyses, and provided a detailed critique of each RCT cited by the OHA/SAH experts.[164] It was his opinion that the long-term care RCTs "suffer from serious methodological problems and provide results that are mathematically impossible under any reasonable hypothesis"[165] and that the sole RCT conducted in an acute care setting "is a methodological mess with respect to the estimation of

---

[160] Exhibit 185, Report, A. McGeer, pp.45-46

[161] Exhibit 50: Potter *et al,* "Influenza vaccination of health care workers in long-term care hospitals reduces the mortality of elderly patients". J Infect Dis. Jan;175(1): 1-6; Exhibit 81: Carman *et al,* "Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomized controlled trial". Lancet. 2000 Jan8;355(9198):93-7; Exhibit 82: Hayward *et al*, "Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomized controlled trial". BMJ 2006 Dec 16;333(7581): 1241-6; Exhibit 83: Lemaitre *et al,* "Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial". J Am Geriatr Soc. 2009 Sep;57(9):1580-6; Exhibit 86: Riphagen-Dalhuisen *et al,* "Hospital-based cluster randomized controlled trial to assess effects of a multi-faceted programme on influenza vaccine coverage among hospital healthcare workers and nosocomial influenza in the Netherlands, 2009 to 2011". Euro Surveill. 2013 Jun 27;18(26):20512

[162] ONA Final Argument Overview, paras. 93, 107

[163] Exhibit 66, Report, G. De Serres, p.3, para. 8; Exhibit 70, Reply Report, G. De Serres, Part C

[164] Exhibit 66, pp.7-11

[165] Exhibit 70, p.32

benefit to patients".[166] He stated that: "Given the very serious flaws in the 4 RCTs conducted in LTCFs and the single RCT in acute care, I conclude that the scientific basis for the efficacy of increasing HCW vaccination to protect patients against deaths is extremely poor".[167] And, in his original Report, Dr. De Serres had concluded that:

> ..data about the effectiveness of vaccinating HCWs to protect patients is still of poor quality. A careful review of the RCTs conducted primarily in long term care settings reveals that most of the substantial all-cause mortality reduction after interventions to increase HCW immunization cannot possibly be attributed to the vaccine itself but rather relate to unknown factor(s) associated with implementing the intervention—what is known as methodologic bias….For acute care hospitals, the evidence that a policy mandating vaccination or mask in HCW would be effective to prevent patient influenza cases is also lacking and is at best indirect and also with strong indication of methodologic bias…In LTCF [long term care facilities], HCW provide prolonged and intense personal care to each patient, increasing the risk of influenza transmission. It is therefore likely that the risk of transmission from HCW to patients in acute care hospitals would be lower than in LTCF decreasing the benefit of the intervention if imposed equally in these settings.[168]

139. Dr. De Serres explained in detail why he preferred the conclusions of the Cochrane group[169] following their meta-analyses of the issue as opposed to those of the authors of a U.S. Centre for Disease Control publication.[170] [171] The 2010 Cochrane review concluded that: "there is no evidence that vaccinating HCWs prevents influenza in elderly residents in LTCFs".[172] The US CDC [Ahmed] review concluded that:

> Using GRADE the quality of the evidence for the effect of HCP [health care provider] vaccination on mortality and influenza cases in patients was *moderate* and *low* respectively. The evidence quality for the effect of HCP vaccination on patient hospitalization was *low*. The overall evidence quality was *moderate*.[173] (italics in original)

---

[166] Exhibit 70, p.33

[167] Exhibit 70, p.35

[168] Exhibit 66, pp.12-13, para. 36

[169] Exhibit 85, Thomas *et al*, "Influenza vaccination for healthcare workers who care for people aged 60 or older living in long-term care institutions", Cochrane Database Syst Rev.2013 Jul 22;7:CD005187; Exhibit 84, Thomas *et al,* "Influenza vaccination for healthcare workers who work with the elderly: a Cochrane review", Cochrane Database Syst Rev. 2010 Feb 17;(2):CD005187

[170] Exhibit 87, Ahmed *et al*, "Effect of Influenza Vaccination of Healthcare Personnel on Morbidity and Mortality Among Patients: Systematic Review and Grading of Evidence". Clin Infect Dis. 2013 Nov 13 Epub ahead of print

[171] Exhibits 66, 70

[172] Exhibit 84, Abstract

[173] Exhibit 87, Conclusions, p.50

140. ONA also points to other critiques of these trials and studies[174] emphasizing the World Health Organization report's assessment that the four long term care RCTs had "very serious" limitations in study design and other "serious" deficiencies concluding that: "Our confidence in the estimate of effect of influenza vaccination of HCW on influenza and related outcomes in elderly living in long term care facilities is low".

141. Dr. Gardam and Dr. Lemiux also raised concerns including questioning the applicability of long-term care studies to acute care settings.[175]

142. Dr. McGeer had quite a different opinion of the RCTs, one that she had maintained before Arbitrator Diebolt, and that she expressed with renewed vigour given a later commentary and meta-analysis, published after the Diebolt Award was released, that she saw as supportive.[176] Dr. McGeer was cross-examined extensively about the details of these studies and was prepared to concede some of their limitations but did not give ultimate ground. She explained her view that from a data perspective the Ahmed review and the Cochrane review say exactly the same thing.[177] She also tackled head on the reasons provided by the Cochrane investigators for their conclusion that the data should not be believed.[178] In her opinion:

---

[174] See: Exhibit 110, Osterholm *et al* [Center for Infectious Disease Research & Policy, CIDRAP] " The Compelling Need for Game Changing Influenza Vaccines: An Analysis of the Influenza Vaccine Enterprise and Recommendations for the Future", October 2012, cidrap.umn.edu; Exhibit 167, CMAJ 2012; Exhibit 147B, "Weekly epidemiological record", World Health Organization, 23; November 2012. No.47, 2012. 87. 461-476, Table 5b; Exhibit 93, De Serres, Skowronski, Patrick, Letter to the Editor, November 12, 2012, CMAJ

[175] Transcript, January 26, 2015, C. Lemieux, pp. 78-81; Transcript, May 21, 2015, M.Gardam, pp. 52, 126-127

[176] Ahmed at Exhibit 87; Exhibit 157, Griffin, "Influenza vaccination of healthcare workers: making the grade for action", Editorial Commentary, CID: 2014: 58

[177] Transcript, June 24, 2015, p. 124

[178] Exhibit 185, Report, A. McGeer, pp.28-35; See also Appendix B to Appendix C of Exhibit 185 where Dr. McGeer also provided extremely detailed commentary on the Cochrane Review some of which is set out in the Diebolt Award.

> In sum, there is no question that influenza vaccination of healthcare workers providing care for residents/patients in long term care protects residents from significant morbidity and mortality. This reduction is achieved by preventing the introduction of influenza into these facilities by staff, and by reducing the risk of transmission of influenza among staff and between staff and patients.
>
> The results of these four trials led many to ask whether the protection of patients would extend to patients in acute care and community care. The relevant differences between these settings and long term care facilities for the elderly are that some patients may not be as compromised as long term care facility residents, and that they may be more likely to have exposure to influenza external to patient care. However, the biologic rationale for healthcare worker immunization does not vary from one healthcare setting to another, and many patients in acute care hospitals and in the community are as vulnerable as those in long term care.
>
> ....
>
> Since an infected healthcare worker can transmit influenza to persons he or she comes into contact with, it must be true that preventing influenza in patient care staff reduces the risk that they will transmit influenza to patients. I believe that, because of the potential for other exposures to influenza in patients in the community, the protection afforded by vaccinating health care providers in community and acute care hospital settings is likely less than that provided by vaccinating health care providers in residential long term care. Nonetheless, while the size of the benefit to patients in ambulatory care settings is unknown, I believe that in almost all circumstances there would be some risk reduction.[179]

143. Dr. McGeer did acknowledge an important difference between long-term care and acute care settings however:

> ...as you move from a very enclosed setting of long-term care where health care workers may make a very large difference to ambulatory care at the far end where a patient has just taken the subway and might have children at home and has lots of other places they can be exposed to influenza, you clearly alter the balance of what's at risk from health care workers versus what's the risk from other people.
>
> Still within that though, if I'm a health care worker seeing you as a patient in my office, I think most of us would agree that we have some obligation, because of the nature of that relationship, not to be a part of your risk for influenza. And so, you know, even—it may well be true in an ambulatory care setting that protecting the patients from me does not alter their total risk of influenza because they may get it from other places, and so you may not be reducing it or you may be reducing it by a fairly small amount, I think many of us would agree that we still have an obligation because of the power and influence of that relationship to not be a source for our patients.[180]

[179] Exhibit 185, Report, A. McGeer, pp.34-35

[180] Transcript, June 24, 2015, pp.142-143

144. Dr. McGeer maintained her opinion[181] that the significance of the RCT conclusions should be considered supported by other observational and experimental studies[182] in addition to those referred to in the Ahmed meta-analysis.[183] She testified that:

> And while a lot of the observational evidence in different settings is not directly related to what happens in health care, it is always important in the interpretation of randomized controlled trials and data to have looked at all of the data and to ask whether there is consistency or variability across different settings and different situations...so the consistency of those findings I think is important in thinking through the evidence and assessing the extent to which the randomized controlled trials should be believed.[184]

145. In her Report Dr. Henry also referred to observational studies as supporting the data she said was derived from the RCTs[185] but acknowledged that these studies related to long term care and not acute care settings.[186] She was cross-examined at length concerning the studies referenced in this section of her Report[187], some that dealt with other closed community settings, and agreed that they were "clearly not referring to a healthcare setting".[188]

146. Witness commentary concerning the observational/experimental studies relied upon in the McGeer/Henry Reports is set out in Appendix A to this Award. I conclude from a review of these studies, and the expert witness commentary, that they do not disclose a consistent position. They address a wide range of issues in a

---

[181] Transcript, June 24, 2015, p. 140

[182] Exhibit 161, Vanhems *et al*, "Risk of Influenza-like illness in an acute health care setting during community influenza epidemics in 2004-2005, 2005-2006, and 2006-2007: a prospective study", Arch Internal Med 2011;171(2):151-157; Exhibit 159

[183] Exhibit 87, p. 54, Table 2: Oshitani *et al,* "Influenza vaccination levels and influenza-like illness in long-term facilities for elderly people in Niigata, Japan during an influenza A(H3N2) epidemic" Infect. Control Hosp Epidemiol 2000; 21:728-30; Enserink *et al,* "Absence of influenza A(H1N1) during seasonal and pandemic seasons in a sentinel nursing home surveillance network in the Netherlands", Am Geriatr Soc: 2011; 59:2301-5; Wendelboe *et al,* "Importance of employee vaccination against influenza in preventing cases in long term care facilities". Infect Control Hosp Epidemiol 2011; 32:990-7; Exhibit 161, Benet *et al,* "Influenza vaccination of healthcare workers in acute-care hospitals: a case control study of its effect on hospital acquired influenza among patients". BMC Infect Dis 2012; 12:30

[184] Transcript, June 24, 2015, p. 135

[185] Exhibit 141, p. 19

[186] Transcript, June 23, 2015, pp. 69-71

[187] Transcript, June 23, 2015, pp. 68-88

[188] Transcript, June 23, 2015, p. 88

wide range of settings. Some are not supportive of the OHA/SAH experts' claim. Some provide weak support at best. Some have nothing to do with the issue in question. Some have acknowledged study design limitations.

Asymptomatic Transmission

147. There was considerable expert disagreement about asymptomatic transmission although there was no dispute about the importance of the issue in assessing the merit of VOM policies.

148. To repeat, according to Dr. McGeer in her Report, the primary purpose of having unvaccinated HCWs wear a mask is to address transmission when they are shedding virus either prior to symptom onset or if they are asymptomatically infected.[189]

149. As will be seen, there is dispute as to the extent that asymptomatic transmission poses a theoretical risk, a minimal risk, or a real risk commanding a response. The parties do not agree as to the size of the window in which such transmission might occur. They do not agree about the likelihood, frequency, or strength of asymptomatic transmission and whether or not scientific study has progressed to a point where it can say anything meaningful in an evidence-based way about these matters.

150. In their joint Reply Report, Dr. Gardam and Dr. Lemieux explained the central importance of the issue in this way:

> A presumption that asymptomatic transmission is a significant factor is of great importance to Drs. McGeer and Henry's arguments. Without the significance of asymptomatic transmission, it is hard to understand how requiring otherwise well, unvaccinated staff to wear a mask during the entire influenza season will provide any significant protection for patients or other healthcare workers.[190]

[189] Exhibit 185, p. 36

[190] Exhibit 21, p. 7

151. ONA counsel highlighted the point in her final oral argument after posing a rhetorical question about whether the mask policy made sense:

> Because the mask policy is asking people for four to six months of the year to wear it when they're asymptomatic....they [OHA/SAH] are going to need to have legitimate evidence-based evidence that there is a concern about asymptomatic transmission because, if there isn't, then what's the point in wearing a mask? So, their case hinges on this.[191]

152. The question of asymptomatic transmission is made even more complex by the recognition that vaccinated, as well as unvaccinated, individuals may acquire influenza and that vaccinated persons may be protected from severe illness but still have attenuated illness.[192]

153. Dr. McGeer stated: "We know that people shed influenza in asymptomatic infections and before they develop symptoms....we need to worry about people who are asymptomatic or minimally symptomatic even if we are sending home people who are ill."[193] On the other hand Dr. McGeer also noted that the science was imperfect:

> ...there's still things about influenza transmission we just don't understand well...one of this issues is we are, in that model, currently we're getting more asymptomatic than symptomatic infections. It might be related to the dose somehow of what you're getting exposed to. So, it's complicated and we don't understand. We are a very long way I think is the short answer.[194]

154. One exchange of views is set out in the paragraphs immediately following.

155. Dr. De Serres acknowledged that a person may shed virus while asymptomatic[195] but commented in his Report that:

> There is scant evidence to support that such 'virus shedding' of influenza leads to effective transmission of the disease before an infected individual becomes symptomatic, and if it does occur, it is not the predominant concern. The transmission risk is greatest

[191] Transcript, July 7, 2015, p. 74
[192] Exhibit 66, p.7, para.19
[193] Transcript, June 24, 2015, pp. 156-157
[194] Transcript, June 24, 2015, p. 101
[195] Transcript, May 20, 2015, p. 120, p. 203

> when cases with influenza are symptomatic, notably with projectile symptoms such as cough or sneeze…[196]

156. Dr. McGeer responded this way:

> While it seems logical, as Dr. De Serres states, to conclude that transmission risk is greatest from individuals who are severely ill and coughing and sneezing, the truth is that we simply do not know much about transmission risk at a population level. For instance, individuals who are severely ill with coughing and sneezing may be much more likely to stay home and to practice respiratory etiquette, so may not actually contribute all that much to population transmission, and individual heterogeneity may mean that some asymptomatic high viral load shedders are very important in transmission.[197]

157. In his rebuttal Dr. De Serres relied upon a literature review stating that:

> From the Carrat review[198] we know that individuals with symptoms shed far more virus than individuals who remain free of symptoms (asymptomatic) and that the amount of virus shedding increases with the severity of symptoms
>
> …..
>
> [responding to Dr. McGeer's statement that 'the truth is we simply do not know much about transmission risk at a population level']
>
> If one does not know the proportion of influenza transmission caused by the pre-symptomatic, unvaccinated HCW then I reiterate that it is difficult to establish an ethical or evidence-based rationale to require mask wearing by unvaccinated HCWs every hour of every work day for nearly half the year, every year while remaining symptom free.

158. While giving oral testimony about possible asymptomatic transmission, citing Carrat *et al*[199] Dr. De Serres stated that:

> So, really, in this asymptomatic period, the time you're contagious, the amount of virus you have is lower than when you're contagious, and transportation…in terms of contagion, nobody can say exactly, okay, that day we have 25 percent of the transmission, this day we have 20 percent, this day we have 10 percent. We don't have that. But for influenza transportation, number of virus matter…you may say, well, they may transmit while asymptomatic, it's possible. I wouldn't deny that someone may because there are examples of people who did transmit while they were [as]symptomatic but that's generally not the case. The transmission will happen because you had enough virus, you have enough transportation.[200]

---

[196] Exhibit 66, p. 5, para.14

[197] Exhibit 185, p. 47

[198] See Exhibit 75: "Time Lines of Infection and Disease in Human Influenza: A Review of Volunteer Challenge Studies", American Journal of Epidemiology (January 29, 2008)

[199] Exhibit 75

[200] Transcript, May 19, 2015, pp. 138-139

159. Dr. Henry stated: "people can release virus into the community that's potentially transmissible to others even before they show symptoms themselves".[201] She also explained that: "it's absolutely clear that the first couple of days after symptoms start is when you're most transmissible to others. But there is evidence to support that it can be transmitted before you show symptoms yourself".[202]

160. In direct examination Dr. Henry stated that the pre-symptomatic period was "clearly not the most infectious period but we do know that it happens".[203] She also agreed in cross-examination that transmission required an element of proximity and a sufficient amount of live replicating virus.[204]

161. At another point, the following series of questions and answers ensued during Dr. Henry's cross-examination:

> Q. With respect to transmission while asymptomatic, and I want to deal with your authorities with respect to that, would you agree with me that there is scant evidence to support that virus shedding of influenza actually leads to effective transmission of the disease before somebody becomes symptomatic?
> A. I think we talked about that yesterday, that there is some evidence that people shed prior to being symptomatic, and there is some evidence of transmission, that leading to transmission, but I absolutely agree that that is not the highest time when shedding and transmission can occur.
>
> Q. So were you—I put it to you that there's scant evidence, and that was Dr. De Serres' evidence, so—but that there's very little evidence about that, do you agree?
> A. There is—as we talked about yesterday, there is not a lot of evidence around these pieces, I agree.
>
> Q. And clearly transmission risk is greatest when you're symptomatic, when you're able to cough or sneeze?
> A. Transmission risk is greatest, as we've said, when you're symptomatic, especially in the first day or two of symptom onset. [205]

162. Dr. McGeer commented that:

> It is true on balance that if I am ill and symptomatic I will be shedding more particles than if I am not. An individual coughs and sneezes create a great many more particles that can travel for long distances. What's not, I think, clear in that discussion is that there's a huge

[201] Transcript, June 22, 2015, p. 99; Exhibit 141, pp. 6-7
[202] Transcript, June 22, 2015, p. 155
[203] Transcript, June 22, 2015, p. 100
[204] Transcript, June 23, 2015, p. 91
[205] Transcript, June 23, 2015, pp. 91-92

> intra individual variability in the number of particles that are emitted by any one individual. And that variability is actually significantly greater than my internal variability when I go from asymptomatic to coughing and sneezing….some people shedding asymptomatic influenza will probably shed much more than other people who are severely symptomatic.[206]

163. Dr. Gardam agreed that: "there is a lead time of when you start to shed virus before you develop some symptoms"[207] but when asked if one produces large droplets when asymptomatic, replied:

> Not a lot. You have to be kind of spraying on people. The large droplets are things that are—typically they follow a ballistic trajectory, so if you're speaking or coughing and they land. The airborne ones go out and they float around the room. So if you think of the difference between me talking to you now, inevitably there are a couple of droplets coming out of my mouth and they are landing on the table versus me coughing or me sneezing, it would be orders of magnitude different. [208]

164. In their joint Reply Report Dr. Gardam and Dr. Lemieux disagreed strongly with Dr. McGeer's assessment of the importance of asymptomatic transmission of influenza. Relying upon a meta-analysis of human infection studies by Carrat *et al*[209], they opined that one could not say that asymptomatic transmission never occurs but that it was "unlikely to be of clinical significance". They noted that: "the production of virus and the development of symptoms are closely linked together, and that the vast majority of the time patients have high viral levels, they are also symptomatic". [210]

165. Dr. Gardam expressed this view of the asymptomatic justification for VOM when giving evidence:

> Well, asymptomatic flu transmission, that was something that didn't really, people didn't talk much about that until these policies started to come in place, and suddenly, frankly, I feel people needed a reason to get you to wear that mask. And the reason was, well, you might be developing the flu, you don't have symptoms yet, but you can still transmit it. Well, first of all, if that's true, given the effectiveness of the vaccine, everybody should wear the mask. Makes no sense to me.[211]

---

[206] Transcript, June 25, 2015, pp. 38-39

[207] Transcript, May 21, 2015, p. 134

[208] Transcript, May 21, 2015, pp. 244-245

[209] Exhibit 21, p. 6; Exhibit 75; Attachment to Exhibit 109

[210] Exhibit 21, p. 6

[211] Transcript, May 21, 2015, pp. 66-67

166. He went on to say:

> ...in order to figure this out, you need to know exactly when someone was infected. Essentially, yes, the virus in your nasal secretion starts to go up before you develop symptoms. But the two are actually quite parallel, they go up in parallel. And they go up on a log curve. So for each one to two, to three to four you're going up tenfold. So within a few hours of being infected and starting to have multiplying virus, you start to get some symptoms. So, yes, there's a little window in there where you don't have any symptoms and you've got a small amount of virus, but you have a thousandfold more virus once you have symptoms, and it can stay up there for several days, an that's the time when you're sneezing and coughing and ill. I have to think that that's the time when you're spreading most of your flu...I have to assume that's when you're most infectious. So masking when you're sick makes sense to me, but why are you masking when you're well—that just doesn't make sense to me.[212]

167. In oral testimony Dr. Lemieux gave her opinion that:

> In fact, the transmission of influenza is very tightly correlated with symptom onset. There is only a very, very brief period when the virus may be shed or may be created within the human body when you're not symptomatic. It is a very short window of time....During that very short period of time when you're asymptomatic, so even for that short window, which is at most a day, probably less than a day, if you're not symptomatic, it's very hard for virus to get from point "A" to point "B". I mean, it doesn't have legs. It doesn't walk on its own. It's not going to march over from myself to yourself. So it needs a vehicle to be transmitted. And if you're asymptomatic, that ability to take the virus from me and send it to you (sneezing, coughing, respiratory secretions) is not there. So even in that short window of time, the chance of it getting from me to you is pretty tenuous. The third part of that is, the levels of virus during that short period between shedding and symptom onset are much lower. The real peak of when we have lots of virus there ready to move is when we're symptomatic. [213]

168. Dr. Lemieux also stated more succinctly:

> And so the crux of saying that everybody has to wear a mask all the time when there is a tiny little period of time when virus may, and I'm stressing may be transmitted, and many reasons why it's less likely to be transmitted, again, seems very flawed to me.[214]

169. In cross-examination, ONA counsel reviewed the authorities relied upon by Dr. McGeer or Dr. Henry as the bases for their opinions on this issue together with some material not referenced by them: Loeb *et al* (2012)[215]; Suess *et al* (2011)[216] ;

---

[212] Transcript, May 21, 2015, pp. 67-68; Later on Dr. Gardam made it clear that "I'm not suggesting that there's evidence that it [wearing a surgical mask] works for preventing the asymptomatic spread of the flu": Transcript, May 21, 2015, pp. 98-99

[213] Transcript, January 26, 2015, p. 82-83

[214] Transcript, January 26, 2015, p.84

[215] Exhibit 106: "Longitudinal Study of Influenza Molecular Viral Shedding in Hutterite Communities", J Infect Dis. 2012)ct 1: 206(7): 1078-84

Freitas *et al* (2009)[217]; Esbenshade *et al* (2013)[218]; Wilde *et al* (1999)[219]; Elder *et al* (1996)[220]; Sheat (1992)[221]; Gu *et al* (2011)[222]; Carillo-Santisteve *et al* (2010)[223]; Lau *et al* (2010)[224]; Hermes *et al* (2011)[225]; Patrozou and Mermel (2009)[226].

170. ONA also introduced a Letter to the Editor of the Canadian Medical Association Journal dated November 12, 2012 that was co-authored by Dr. Danuta Skowronski. Dr. Skowronski is the medical lead for influenza and emerging respiratory infections who is part of Dr. Henry's team at the British Columbia Centre for Disease Control. Dr. Henry acknowledged that Dr. Skowronski had more experience with respect to vaccine effectiveness than herself.[227] The letter, co-authored by Dr. De Serres, included the following observation: "The evidence that pre-symptomatic or asymptomatic infections contribute substantially to influenza transmission remains scant."[228]

---

[216] Exhibit 107: "Comparison of shedding characteristics of seasonal influenza virus (sub) types and influenza A(H1N1) pdm09; Germany, 2007-2011", PLoS One. 2012; 7(12): e51653

[217] Exhibit 158: "Pre-symptomatic transmission of pandemic influenza H1N1 2009: investigation of a family cluster, Brazil", Epidemiol Infect. 2013 Apr: 141(4): 763-6

[218] Exhibit 170: "Respiratory virus shedding in a cohort of on-duty healthcare workers undergoing prospective surveillance", Infect Control Hosp Epidemiol 2013; 34(4); 373-378

[219] Exhibit 171: " Effectiveness of influenza vaccine in healthcare professionals: a randomized trial", JAMA. 1999 Mar1 0;281 (1 0): 908-13

[220] Exhibit 172: "Incidence and recall of influenza in a cohort of Glasgow healthcare workers during the 1993-4 epidemic: results of serum testing and questionnaire", BMJ 1996;313(7067): 1241-1242

[221] Exhibit 225: 'An investigation into an explosive outbreak of influenza-New Plymouth", Communicable Disease New Zealand 1992; 92:18-19

[222] Exhibit 226: "Pandemic (H1N1) 2009 transmission during presymptomatic phase, Japan", Emerg Infect Dis. 2011 Sep; 17(9):1737-9

[223] Exhibit 227: "2009 pandemic influenza A(H1N1) outbreak in a complex of schools in Paris, France, June 2009", Euro Surveill. 2010 Jun 24; 15(25)

[224] Exhibit 228: "Viral shedding and clinical illness in naturally acquired influenza virus infections", J Infect Dis. 2010 May 15; 201 (10): 1509-16

[225] Exhibit 229: "Lack of evidence for pre-symptomatic transmission of pandemic influenza virus A (H1N1) 2009 in an outbreak among teenagers; Germany, 2009", Influenza and Other Respiratory Viruses 5(6), e199-e503

[226] Exhibit 230: "Does Influenza Transmission Occur from Asymptomatic Infection or Prior to Symptom Onset?", Public Health Reports/ March-April 2009/Volume 124: 193-196

[227] Transcript, June 22, 2015, pp. 164-165

[228] Exhibit 93

171. The medical/scientific literature referred to or relied upon by the OHA/SAH on the asymptomatic question with witness commentary is set out in Appendix B. Once again, these studies/investigations were undertaken in a wide variety of settings most of which had nothing to do with HCWs and some of which involved a very few people. There were design limitations. Some of them expressed serious doubt about, or found no evidence of, asymptomatic transmission. The results were certainly not consistent.

Masking

172. The written submissions filed by the parties stake out polar opposite evaluations of the scientific evidence going to the key question of the use of masks to reduce the risk of transmission. Those positions were remarkably unconditional in their characterization.

173. The OHA and SAH submitted that: "The scientific evidence in this case provides a solid and compelling foundation for the reasonableness of the Policy".[229] ONA submitted that: "Though time consuming, we submit that the totality of evidence suggests there is no evidence in support of the mask policy."[230] "The mask element cannot be supported on any medical evidence as Dr. McGeer ultimately conceded."[231]

174. It must be noted that the witnesses called by the proponents of these opposing submissions were more nuanced and did not support such unconditional characterizations. While conceding that "there's quite a limited literature" on a key aspect of the issue[232], Dr. McGeer certainly did not concede that there was "no evidence in support of the mask policy".

[229] Closing Argument, para. 366
[230] Final Argument Overview, paras. 126, 128
[231] Final Argument Overview, para. 259
[232] Transcript, June 25, 2015, p. 32

175. Dr. McGeer explained that:

> Essentially all of the systematic studies of mask wearing have not met their primary end points. But in most of them there is some evidence of an effect. So, I think there are a couple of systematic reviews that are also referenced and generally people's conclusion is there is some evidence that wearing a mask will reduce your risk of influenza. It's not great evidence. It's clearly not complete protection, and it's hard to put a number on it, but you can't walk away from this saying there is no evidence that wearing a mask prevents you from influenza.[233]

176. Professor Brosseau agreed that there was qualitative evidence to support the conclusion that masks reduce the transmission of large droplets.[234] She acknowledged the 2007 consensus finding of an Expert Panel of which both she and Dr. Gardam were members, that: "Surgical masks worn by an infected person may play a role in the prevention of influenza transmission by reducing the amount of infectious material that is expelled into the environment."[235]

OHA/SAH evidence

177. Dr. McGeer and Dr. Henry presented the position of the OHA and the Hospital based upon their understanding of the relevant literature. Neither of them asserted that they had particular expertise with respect to masks or had conducted studies testing masks.[236]

178. On the subject of masks, after conceding that "I'm not a huge fan of the masking piece"[237], Dr. Henry ultimately concluded as follows:

> ...as my report says, there's not a lot of evidence to support mask use and that's why it is a secondary measure, where clearly the most important measure is immunization...However, I think there are some studies...that look at the potential for a mask to prevent the emission of droplets and then the potential for a mask to prevent somebody from inhaling droplets....I'd have to go back and look, but I agree, there's very

[233] Transcript, June 24, 2015, p. 152
[234] Transcript, June 6, 2015, p. 89; Exhibit 50: cover letter, L. Brosseau Report.
[235] Transcript, June 6, 2015, p.80;
[236] Transcript, June 25, 2015, A. McGeer, p. 234; Transcript, June 22, 2015, B. Henry, p. 163
[237] Transcript, June 23, 2015, p. 111

> scant evidence about the value of masks in preventing the transmission of influenza. The value of masks as source reduction has been proven.[238]

179. Dr. McGeer is of the view that "there is good evidence that wearing a mask limits the release of large droplets"[239] but was not as definitive as Dr. Henry about masks and proof of source control:

> ...when we talk about vaccine and mask policies the primary purpose of the vaccine mask policy is the protection of another person from somebody who's wearing a mask...when particles are emitted they come out large. When they're breathed in on the other end and they've had three or six feet to dry on the way and that makes a very substantial difference to the size and the distribution of those particles. So the truth of the matter is that none of us are really experts in source control. There's quite a limited literature. Dr. Milton, whose paper we've looked at, is probably one of the people who knows the most about it, having spent a lot of time in the last few years. But I don't think Dr. Brosseau would claim expertise in mask for source control.[240]

180. In final argument the OHA/SAH counsel put it succinctly this way: "It's [mask evidence] not as fulsome as all of the evidence about vaccination. But to answer your question, there is some evidence, so they fall on their own sword saying no evidence."[241]

181. On the focused question of the utility of masks for the stated Policy purpose of source control and the protection of patients, Dr. McGeer stated in her Report filed pre-hearing that:

> There is good evidence that wearing a medical mask reduces the volume of large and small particles that people routinely exhale. There is also experimental evidence from at least two studies that surgical masks, when worn by persons infected with influenza, reduce the concentration of influenza virus expelled into the ambient air.
> .....
>
> A second potential effect of masks is the protection of the wearer from droplets or aerosols in the air from a patient with influenza...
>
> .....
>
> Other clinical studies have suggested that masks, in association with adherence to good hand hygiene, have some impact on transmission of influenza infection. These studies are not definitive. No study has found a statistically significant effect for the primary trial

[238] Transcript, June 23, 2015, pp. 145-146
[239] Transcript, June 24, 2015, p. 148
[240] Transcript, June 25, 2015, p. 32
[241] Transcript, July 8, 2015, p.115, p.116

> question; however, all have limitations, and, most found some indication of effect in secondary analyses.
>
> Two systematic reviews of the protective effect of wearing masks on influenza concluded that there is evidence to support that wearing of masks or respirators during illness protect others, and a limited amount of data to support the use of masks or respirators to prevent becoming infected. (footnotes in original omitted)[242]

182. In support of these opinions, Dr. McGeer cited the following articles: Mansour and Smaldone (2013)[243]; Skaria and Smaldone (2014)[244]; Milton *et al* (2013)[245]; Johnson *et al* (2009)[246]; Canini *et al* (2010)[247]; Makison Booth *et* al (2013)[248]; Loeb *et al* (2009)[249]; MacIntyre *et al* (2011)[250]MacIntyre *et al* (2009)[251]; Cowling *et al* (2009)[252]; Simmerman *et al* (2011)[253]; Suess *et al* (2012)[254]; Larson *et*

[242] Exhibit 185, pp. 36-37 citing

[243] Exhibit 56: "Respiratory source control versus receiver protection: impact of facemask fit", J. Aerosol Med Pulm Drug Deliv. 2013 Jun; 26 (3): 131-7

[244] Exhibit 120: "Respiratory source control using surgical masks with nanofiber media", Ann Occup Hyg. 2014 Jul; 58(6): 771-81

[245] Exhibit 28: "Influenza virus aerosols in human exhaled breath: particle size, culturability, and effect of surgical masks", PLoS Pathog. 2013 Mar; 9(3): e1003205

[246] Exhibit 27: "A quantitative assessment of the efficacy of surgical and N95 masks to filter influenza virus in patients with acute influenza infection", Clin. Infect Dis. 2009 Jul 15; 49(2): 275-7

[247] Exhibit 215: "Surgical Mask to prevent influenza transmission in households: a cluster randomized trial", PLoS One. 2010 Nov 17; 5(11): e13998

[248] Exhibit 29: "Effectiveness of surgical masks against influenza bioaerosols", J Hosp Infect. 2013 May; 84(1): 22-6

[249] Exhibit 30: "Surgical Mask vs. N95 respirator for preventing influenza among healthcare workers: a randomized trial", JAMA. 2009 Nov 4; 302(17): 1865-71

[250] Exhibit 216: " A cluster randomized clinical trial comparing fit-tested and non-fit-tested N95 respirators to medical masks to prevent respiratory virus infection in healthcare workers", Influenza Other Respir Viruses. 2011 May; 5(3): 170-9

[251] Exhibit 217: "Face mask use and control of respirator virus transmission in households", Emerg Infect Dis. 2009 Feb; 1592): 233-41

[252] Exhibit 31: "Facemasks and hand hygiene to prevent influenza transmission in households: a cluster randomized trial", Ann Intern Med. 2009 Oct 6; 151 (7): 437-46

[253] Exhibit 218: "Findings from a household randomized controlled trial of hand washing and face masks to reduce influenza transmission in in Bangkok, Thailand", Influenza Other Respir Viruses. 2011 Jul; 5(4): 256-67

[254] Exhibit 32: "The role of facemasks and hand hygiene in the prevention of influenza transmission in households: results from a cluster randomized trial: Berlin, Germany 2009-2011", BMC Infect Dis. 2012 Jan 26; 12:26

al (2010)[255]; Aiello *et al* (2010)[256]; Cowling *et al* (2010)[257]; bin-Reza *et al* (2012)[258]; Zhang *et al* (2009).[259]

183. In responding to Dr. Brosseau in her pre-hearing Report she also cited the following additional references: Bridges *et al* (2003)[260]; McLure *et al* (2000)[261]; Bischoff *et al* (2007).[262]

184. In her pre-hearing Report Dr. Henry responded to a request that she discuss the evidence that masks protect patients from influenza this way:

> There is good evidence that surgical masks reduce the concentration of influenza virus expelled into the ambient air (a 3.4 fold overall reduction in a recent study) when they are worn by someone shedding influenza virus. There is also evidence that surgical masks reduce exposure to influenza in experimental conditions.
> ....
> Clinical studies have also suggested that masks, in association with hand hygiene, may have some impact on decreasing transmission of influenza infection. These studies are not definitive as they all had limitations. The household studies are limited by the fact that mask wearing did not start until influenza had been diagnosed and the patient/household was enrolled in the study, such that influenza may have been transmitted prior to enrollment. A study in student residences is limited by the fact that participants wore their mask for only approximately 5 hours per day. Two systematic reviews of the cumulative studies conclude that there is evidence to support that wearing of masks or respirators during illness protects others, and a very limited amount of data to support the use of masks or respirators to prevent becoming infected..
>
> In summary, there is evidence supporting the use of wearing of masks to reduce transmission of influenza from health care workers to patients. It is not conclusive, and

[255] Exhibit 219: "Impact of non-pharmaceutical interventions on URIs and influenza in crowded, urban households", Public Health Rep. 2010 Mar-Apr; 125(2): 178-91
[256] Exhibit 220: "Mask use, hand hygiene, and seasonal influenza-like illness among young adults: a randomized intervention trial", J Infect Dis. 2010 Feb 15; 201(4): 491-8
[257] Exhibit 121: "Face masks to prevent transmission of influenza virus: a systematic review", Epidemiol Infect. 2010 Apr; 138(4): 449-56
[258] Exhibit 122: "The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence", Influenza Other Respi Viruses. 2012 Jul; 6(4): 257-67
[259] Exhibit 33: "Protection by face masks against influenza A (H1N1) pdm09 virus on trans-Pacific passenger aircraft, 2009", Emerg Infect Dis. 2013; 19(9). Doi: 10.3201/eid 1909. 121765
[260] Exhibit 222: "Transmission of influenza: implications for control in health care settings", Clin Infect Dis. 2003 Oct 15; 37(8): 1094-1101
[261] Exhibit 223: "The effect of facial hair and sex on the dispersal of bacteria below a masked subject", Anaesthesia. 2000 Feb:55(2): 173-6
[262] Exhibit 224: "Preventing the airborne spread of *Staphylococcus aureus* by persons with the common cold: effect of surgical scrubs, gowns, and masks", Infect Control Hosp Epidemiol. 2007 Oct; 28(10): 1148-54

> not of the quality of evidence that supports influenza vaccination. Based on current evidence, patient safety would be best ensured by requiring healthcare providers to be vaccinated if they provide care during periods of influenza activity. However, if healthcare workers are unvaccinated, wearing masks almost certainly provides some degree of protection to their patients.[263] (footnotes in original omitted)

185. In rendering this opinion Dr. Henry relied upon many of the same authorities cited by Dr. McGeer[264] and also: Harnish *et al* (2013)[265].

186. Witness commentary concerning the mask and related literature is set out in Appendix C. It is fair to say, once again, that the findings of the authors vary considerably. Some studies are admittedly irrelevant. None of them present 'best' evidence. At best, there appears to be limited evidence of what to a layperson may seem obvious: a mask may prevent the transmission of large droplets.[266] Two literature reviews refer specifically to "limited data"[267] and to "the limited evidence base supporting the efficacy and effectiveness of face masks to reduce influenza virus transmission".[268]

ONA evidence

187. Citing a journal article[269] of which she was a co-author, Dr. Brosseau opined in her pre-hearing Report that:

> There are a very small number of studies examining the efficacy of surgical or medical masks for protecting patients from infection. In all cases, there were no significant differences in surgical wound infection rates with and without surgical masks. In modern surgical settings the most important controls for preventing infections are engineering or administrative in nature—including very high air exchange rates, well-designed air flow patterns that carry particles away from the patient and health care workers, aseptic techniques, hand-washing etc.

---

[263] Exhibit 141, pp. 6-7

[264] See: authorities cited at footnotes 243, 245, 246, 248, 249, 252-254, 256-258

[265] "Challenge of N95 filtering facepiece respirators with viable H1N1 influenza aerosols", Infect Control Hosp Epidemiol. 2013 May; 34(5): 494-9

[266] See: Exhibit 27, Johnson.

[267] See Exhibit 122, bin Reza, cited also in in Appendix C.

[268] See Exhibit 121, Cowling (2010), cited also in Appendix C.

[269] Exhibit 55: Oberg T, Brosseau L.M,"Surgical mask filter and fit performance", Am J Infect Control 2008; 36(4): 276-22

> Given their poor filter and fit characteristics, surgical masks are not likely to prevent the release of particle emitted by the wearer. Coughing, sneezing and talking produce a wide range of particle sizes, all of which can be infectious. The smaller-sized particles will easily bypass the filter and facepiece of a surgical mask—and are likely to remain airborne for long periods of time. Thus, it is very unlikely that wearing a surgical mask will lower the risk of patient illness from an infectious healthcare worker.[270] (footnote in original omitted)

188. In cross-examination Dr. Brosseau agreed, having been referred to the Johnson[271] study, that: "there is in fact qualitative evidence in support of reduction of transmission of large droplets".[272] Her Reply Report however explained her opinion more fully:

> However, large droplets that impact on the face are only one route for the transmission of influenza infections from one person to another. Seasonal influenza viruses cause disease by infecting receptor cells found in the epithelial tissues in the nose, throat and upper airways of the lungs.
>
> To transmit an infection by large droplets, cough or sneeze droplets would need to land directly in the open mouth or nose of a nearby patient. This is a very low probability event, as it is rare that a healthcare worker would sneeze or cough directly into the face of a patient. And in the rare event of such an occurrence, the patient will most likely have their mouth closed and their nostrils—by the nature of their geometry—facing away from the worker.[273]
>
> ....
>
> Milton's data[274] also illustrate that surgical masks offer little or no reduction in small infectious aerosols from the wearer.
>
> Surgical masks do not minimize the release of small inhalable particles. (underlining in original)

189. Dr. Brosseau had the following comments concerning mask performance generally:

> I have not tested these filters in particular, using what I would consider worst case, best practice kinds of tests. But based on my experience with examining the filtration performance of very similar types of masks that I've published, it is very likely that these masks [the type of masks used at SAH] these fitters will not have very good filter performance, filter efficiency.[275]

---

[270] Exhibit 47, p. 4

[271] Exhibit 27

[272] Transcript, June 6, 2015, p. 89

[273] Exhibit 50, Response to Comments, first unnumbered page

[274] Exhibit 28

[275] Transcript, May 11, 2015, p. 155

alleged adverse effects of masking/privacy/enforcement

190. Dr. Brosseau described a so-called 'grunge factor'. It was her opinion[276] that many people would not be able to wear either a respirator or mask for a full 8 hours "due to buildup of heat and humidity inside the facepiece":

> I have not worn a surgical mask in my own personal life. But based on what I know about their fit and filter performance, I would imagine, just as with the respirator, you'll get—you know, against your face, you'll get buildup of heat and humidity and, you know eventually it can be uncomfortable. Although the fact that it doesn't fit very well against the face means you'll have a lot of air movement through the internal part of the face. So, eventually, though, these will become what one of my colleagues refers to as the grunge factor. It just isn't something you want on your face any longer, because it's full of moisture, and so eventually you'll need to change it out.[277]

191. Dr. Brosseau's testimony and original Report also referred to an academic study[278] to support her own experience although she acknowledged[279] that she "has no experience with long-term surgical mask wearing and could locate few data":

> Based on my experience with half-mask respirators, wearing anything on the face that requires work during both inhalation and exhalation will eventually become uncomfortable. High temperature and relative humidity exhalation air will eventually lead to heat and moisture build-up inside the facepiece. When this type of respirator must be worn for lengthy periods of time, industrial hygienists recommend wearing a respirator with an exhalation valve, which decreases the work required during exhalation and alleviates the buildup of temperature and moisture.
>
> One might postulate that a surgical mask with poor filter performance (and thus low breathing resistance) and poor fit may be comfortable enough to tolerate for lengthy periods of time. The data do not support this hypothesis, however.[280]

192. Dr. Lemieux was asked why she commented that very few people would want to wear a mask for 6 – 7 months and replied, referring to her own experience with masks:

> First of all, there is the marking, here I am not having my flu shot, so there's a marking aspect of it, that people would be very hesitant to want to be labeled as a non-flu-immunized person.

---

[276] Transcript, May 21, 2015, pp. 177-178

[277] Transcript, May 21, 2015, p. 177

[278] Exhibit 32, p. 7; Transcript, May 21, 2015, p. 178

[279] Exhibit 50, p. 1

[280] Exhibit 47, p. 4

> But, secondly, masks are not that comfortable. I have worn them. I have worn them for extended periods in the operating room and they really are not comfortable. They pull at your ears, they make it difficult to take full breaths. If you have underlying respiratory problems, such as asthma, obstructive lung disease, it can make you distinctly short of breath to have these masks on. They pinch at your nose, to the point where people will frequently pull them down because they don't like the pressure on their nose. And I've certainly been in that camp where I've been pulling my mask down. And with prolonged wearing, because…they are essentially made of a tissue, paper-type substance, some masks being slightly more plasticized than others, but essentially it is paper, they get wet. And as you breathe, you're breathing out a lot of humidity and they get damp. So when you're wearing them for a number of hours, they get kind of soggy and they get even more heavy, more uncomfortable, and people will instinctively pull them down. They just are not pleasant to wear at all.[281]

193. Ann Cook RN testified by will-say statement[282] alone. She did not receive the influenza vaccination in 2014-2014 due to an allergy for which she provided medical documentation[283]. Her will-say included the following:

> RN Cook also experienced negative physical effects from wearing the mask. She found wearing the mask uncomfortable due to the build-up of heat and humidity from breathing her own trapped breath. She suffers from asthma and found that wearing the mask for many hours regularly made her feel dizzy, light-headed and very tired. In January and April 2014, RN Cook experienced bronchitis for two separate week-long periods. This was the first time she had been ill and taken sick days in 10 years (for one of those bouts as the other happened just prior to extended weekend vacation time) and she attributes her bronchitis in part to the mask-wearing requirement.[284]

194. Dr. McGeer expressed another opinion:

> The second issue is the potential issue of discomfort wearing masks. If you don't live in a hospital you may think that wearing a mask is something that we don't do on a regular basis but, in fact, there are lots of people in hospitals who wear masks all the time. In my hospital we do complex sarcoma surgery. There are times when a patient will be asleep under anesthetic for 30 hours continually and a series of teams of nurses and physicians and respiratory therapists will be operating. And all of those people are wearing asks for their entire shift except when they take breaks. And we expect them to be highly functional, able to communicate and we have never worried about that. The truth is that masks are not that uncomfortable to wear and the evidence is that you can communicate effectively in not all circumstances. There are clearly circumstances where you need to make exceptions. That's what medicine is all about. But in the great majority of circumstances they are neither terribly uncomfortable nor a significant impedance to communication.[285]

---

[281] Transcript, January 26, 2015, p. 64

[282] Exhibit 14

[283] Exhibit 14, para. 6

[284] Exhibit 14, para. 10

[285] Transcript, June 25, 2015, p. 33; See also: Exhibit 185, Report, A. McGeer, p. 42

195. Glenda Hubley acknowledged in cross-examination that she was "well aware that masks are worn by physicians, surgeons in the operating room, dentists, other healthcare workers in other parts of the hospital" and that she had never refused to work because she had to wear a mask in the operating room.[286]

196. Attached to Ms. Hubley's will-say[287] was a copy of a "Seasonal Influenza Vaccination Disclosure Form" that included provision for "consent to the release of my influenza immunization status to my manager (or designate) for the purpose of outbreak planning and management". That provision is contained in the section to be completed by employees who have received their immunization at a location other than the SAH Occupational Health and Safety Service. The same consent is required of employees who choose to decline influenza vaccination. It is preceded by the following statement that employees are required to acknowledge: "I, ___ understand that SAH is committed to offering employees the seasonal influenza vaccination because research indicates that employees who are not immunized pose a serious health risk to patients, family and community during influenza season". An "Influenza Vaccination Consent" form is also in place for all employees, physicians, volunteers, students, and 'other' at SAH. It includes the following: "I consent to the release of my influenza immunization/antiviral prophylaxis status to my manager (or designate) for the purposes of overseeing the influenza management policy and outbreak planning."[288]

197. Ms. Manzo agreed in cross-examination that "the use of a sticker…would then identify whether or not I as a healthcare worker have taken the vaccine" and that such a sticker would be visible to all, managers, visitors, and patients.[289]

---

[286] Transcript, October 9, 2014, p. 124
[287] Exhibit 17
[288] Exhibit 137
[289] Transcript, June 9, 2015, pp. 114, 138

198. Pam Poldmaa is a registered nurse who works at SAH in the Program for Assertive Community Treatment ("PACT"). The Program involves adult clients with complex bio-psycho-social needs due to severe and persistent mental illness. PACT nurses were instructed that the Policy made mandatory the wearing of procedure masks during all client contacts including in client homes, the nurse's car, in the PACT office waiting room, and during all outings in public places in the community.

199. Ms. Poldmaa testified about the negative impact of mask wearing upon the therapeutic nurse-patient relationship when dealing with paranoid suspicious people with a lot of fixed delusions.[290] She also described a particular safety concern that had arisen; she removed her mask when concerned that a patient might hurt her.[291] Ms. Poldmaa confirmed that she was subsequently advised that she was not required to wear a mask in public areas. She also stated that she told her manager that: "I felt I was being publicly put on display for choosing not to get the flu shot. I told her I felt I was being bullied into it and harassed."[292]

200. As previously noted, Ann Cook RN testified by way of will-say.[293] She stated that her role, as ONTrac Patient Blood Management Coordinator, consists primarily of assessing patients' health to determine readiness for surgery and providing health teaching about their blood transfusion options. She said that oral communication was extremely important and that the majority of her clients are elderly and many have difficulty hearing. She explained that she had experienced significant difficulty in effectively carrying out her nursing duties.

201. ONA also filed an academic study that included the following conclusion:

> The findings of this study are important in weighing up the benefits and risks of protective facemasks within doctor patient consultations and daily clinical practice. Facemasks offer limited protection in preventing infection and aerosol transmission through mucous membranes (ie. conjunctivae). Meanwhile, a negative impact on the

[290] Transcript, October 9, 2014, p. 15;
[291] Transcript, October 9, 2014, pp. 17-18
[292] Transcript, October 9, 2014, p. 14
[293] Exhibit 14

> patient's perceived empathy and relational continuity can reduce potential therapeutic effects…For countries in which wearing facemasks is uncommon care must be taken in conveying infection risk advice to healthcare professionals and caution in adopting guidelines regarding universal mask use (e.g. flu epidemics) particularly for medical physicians or other healthcare professionals where optimization of the therapeutic relationship is essential.[294]

202. Ms. Cook also asserted that she:

> Further experienced daily breaches of her privacy in her personal health information. Patients regularly asked her why she was wearing a mask, to which she replied that it was hospital policy because she was not able to have a required immunization shot. Many patients did not believe this explanation and believed RN Cook and others in the clinic also wearing masks were working while ill and therefore posing a risk to patients. One patient directly accused RN Cook of making him sick while working while ill…[295]

203. ONA also led evidence that it said supported the conclusion that the Policy was not consistently enforced. Ms. Marcello testified that she had seen employees wearing masks dangling underneath their chins[296] and with masks modified with the bottoms cut off so that they do not fit securely[297] to the knowledge of supervisors[298]. She said that she has raised concerns regarding masks being worn improperly with several different supervisors.[299] Mr. Johns did not take steps to see if the Policy was being complied with after hearing that evidence.[300] Ms. Manzo acknowledged in cross-examination that she had observed incidents where masks weren't being used properly. The responsibility for enforcing the Policy rests with managers. Audits have not been conducted nor auditors trained to monitor the use of masks.[301]

---

[294] Exhibit 221, Wong *et al*, "Effect of facemasks on empathy and relational continuity: a randomized controlled trial in primary care", BMC Family Practice 2013, 14:200

[295] Exhibit 14, para. 8

[296] Transcript, October 2, 2014, p. 79

[297] Transcript, October 2, 2014, p. 81

[298] Transcript, October 2, 2014, pp. 82, 118

[299] Transcript, October 2, 2014, p. 119

[300] Transcript, June 29, 2015, p. 117

[301] Transcript, June 9, 2015, pp. 192-195

2014-2015 Mismatch Year

204. In the 2014-2015 flu season there was a significant mismatch between the influenza vaccine and the dominant circulating virus in Canada, that is, A(H3N2).[302] Dr. Henry described the mismatch as "probably the biggest difference between the vaccine strain and the circulating strain that we [have] had in a long time".[303] ONA submits that the basic failure of the vaccine in that year left virtually all HCWs equally exposed to the flu whether or not they had been vaccinated. Therefore, the continued application of the VOM Policy only to unvaccinated HCWs made no sense.

205. Dr. McGeer acknowledged that:

> before the season, we knew that the H3N2 strain had drifted from what was in the vaccine and that drift was substantial…we didn't know before the season which influenza strain was going to be associated with infections, right, You can't tell that. It could still have been an H1N1 or B season and there was no way to be certain.[304]

206. For his part, Dr. De Serres testified that he advised the Ministry of Health in Quebec in the spring of 2014 that a "bad season", "most likely" a H3N2 season that would severely hit elderly people was anticipated. The components of the vaccine however had not been changed from the previous season. In the result the vaccine did not protect against H3N2; that is, there was "no protection". The bulk of influenza in the 2014-2015 season was H3N2 in Canada.[305] Dr. McGeer confirmed that: "what Dr. De Serres said was a surprise, was that that the degree of mismatch translated into our estimates in Canada of no protection".[306] Dr. Lemieux referred to

---

[302] Exhibit 62: Skowronski *et al,* " Interim Estimates of 2014/15 Vaccine Effectiveness Against Influenza A(H3N2) from Canada's Sentinal Physician Surveillance Network", Euro Surveillance (January 2015); Exhibit 63: McNeil *et al,* "Interim Estimates of 2014/15 Influenza Vaccine Effectiveness in Preventing Laboratory-Confirmed Influenza-Related Hospitalization from the Surveillance Network of the Canadian Immunization Research Network", Euro Surveillance (January 2015)

[303] Transcript, June 22, 2015, p. 62

[304] Transcript, June 24, 2015, p. 104; See also: Transcript, June 26, 2015, pp.112-113

[305] Transcript, May 19, 2015, pp. 56-61

[306] Transcript, June 26, 2015, p. 112

a sentinel surveillance report that indicated a vaccine effectiveness rate of 12-14% for people aged 18 to over 50 [the presumed age range of most HCWs].[307]

207. Dr. Henry agreed that, as early as November 2014, her colleague Dr. Skowronski had publicly indicated concern about a significant mismatch for the H3N2 strain, but stated that the vaccine also had the B strain and the H1N1 strain that were well matched. She agreed that the H3N2 strain causes the most morbidity and mortality in older people. She acknowledged that there was no change to the mask requirement in British Columbia nevertheless; that is, vaccinated as well as unvaccinated persons were not required to mask. She agreed that, against the dominating A(H3N2) virus, one nurse who had the vaccine would be no more protected than the nurse standing beside her who did not have the vaccine against that strain. [308]

208. In addressing this mismatch season Dr. McGeer commented as follows:

> So, when you knew that degree of mismatch was coming, you still didn't know what the degree of protection was going to be during the season and most people were—I think usually vaccine efficacy with mismatch drops to 40 or 50 percent. People looked at this and said this looks worse than usual. And so when the U.S. estimate of 20 percent came out at the beginning of January, that was within the range of what people thought it was going to be, okay. It's got an upper confidence limit of 35 percent, It's a bad mismatch but it's not no efficacy at all.
>
> And the Canadian data being no efficacy at all was I think a substantial surprise to everybody, probably not by the time the results came out…when your influenza vaccine fails to protect well against the big infecting strain, it's a really bad season, a lot of hospitalizations, a lot of deaths, a lot of outbreaks in hospitals and nursing homes. And so I think people were worried about what that number was but we really—we didn't know until the first week of February that our estimates for Canada were zero.[309]

209. Dr. McGeer was asked the following question in cross-examination: "And at your hospital then, knowing that there was a significant mismatch, did you ask that

[307] Transcript, January 26, 2015, p. 55; Exhibit 22

[308] Transcript, June 22, 2015, pp.249-254; Transcript, June 23, 2015, p. 188

[309] Transcript, June 24, 2015, p. 107

all the employees wear masks, not just unvaccinated ones?". Her reply was: "We did not, no."[310]

Why Not Mask Everyone?

210. ONA in evidence and in argument submitted repeatedly that the illogicality of the VOM policy was demonstrated by the failure of the Hospital to require the wearing of masks by everyone. The Union submitted that the failure of the Hospital to alter the application of the Policy when the extent of the 2014-2015 vaccine mismatch became known made this point stronger still.[311]

211. As early as July 11, 2013 the Chief of Staff at SAH is recorded as saying:

> If the intent is to prevent the spread of influenza virus then everyone should wear a mask; if the intent is to persuade everyone get the vaccine then the policy is reasonable. If you really don't want to pass the flu around everyone should wear a mask considering the vaccine is only 65% effective.[312]

212. Dr. Gardam expressed his point of view succinctly:

> The concept to me of asking people to wear a mask while doing work for the entire year because they didn't get the flu shot, when the CDC over the last 10 years has said the effectiveness is 40 percent, doesn't make sense to me. So if you get the flu shot, even though the majority of you are not protected, because that's the nature of our mediocre vaccine, you're okay, you don't need to wear a mask. But, if you didn't get it, you have to wear a mask the whole season…Given the effectiveness of the vaccine, that doesn't make sense to me. I mean, this year it was almost absurd, where you had a stated effectiveness of negative 8 percent in the Euro surveillance that came out, but you still don't have to wear a mask if you got your flu shot…That didn't make sense to me at all.[313]

213. Dr. Gardam also commented on the mismatch year in this way referring to the Toronto Academic Health Science Network ("TAHSN") implemented VOM policy:

> As we started to hear that the vaccine wasn't working this year, everything was to be forwarded to Alison [Dr. McGeer] to make comments upon. That's what I reacted to, is that there were opportunities to say stop the bus, let's think about what we're doing. Once we had a good sense, which we had back in December, that this was not going to be a good year for the flu shot. I would have loved to have seen a reassessment of the policy

[310] Transcript, June 26, 2015, p. 113

[311] ONA Final Argument Overview, paras. 130-135, 144

[312] Exhibit 4, Tab 6, p. 3

[313] Transcript, May 21, 2015, p. 66

> at that point, but obviously people had gone too far down that road to be able to back up…
> ….
>
> And some of the cognitive dissonance concepts of the idea you got a flu shot in a year when it didn't work, but you don't wear a mask—I can't understand that.[314]

214. Dr. De Serres put it this way in his reply Report:

> Notwithstanding that most of these unvaccinated HCWs will not be infected with influenza through the winter, the mask-wearing alternative is represented as a necessity to ensure patient safety. If, however, one is to buy the argument that unvaccinated HCWs should endure the ask in order to protect patients, one is compelled to extend that concern to the other multitude of equally dangerous viruses for which there is no vaccine (RSV, metapneumovirus etc.) as well as to the substantial proportion of HCWs who will remain susceptible to influenza despite having been immunized with influenza vaccine acknowledged by most experts to be suboptimal.[315]

215. Dr. De Serres said the following in his testimony after noting that vaccinated persons will shed virus if they get influenza. He was asked in that context if a VOM policy made sense that did not require the masking of everyone and responded:

> The short answer is it makes absolutely no sense. Well, you know it is meant to coerce health care workers. This year in British Columbia they were aware in January that the vaccine wasn't protecting. Was there anything about taking off the mask from unvaccinated individuals or what would be logical to force vaccinated health care workers to be masked? No, absolutely not. Only unvaccinated health care workers had to wear a mask. Why? Not because the others were better protected. Their risk was equivalent to unvaccinated health care workers. It was maintained to shame them, to impose a burden on them, not because it was about protecting patients. It's a way to try to get around, you know, having absolutely to get the vaccine, no option. We give you an option but, in fact, it's an option that is illogical. If we are logical, if we are talking about patient care, patient safety, even if you're vaccinated..if the mask you think is protecting, everybody should wear it because, you know, 40 to 50 percent of those who are vaccinated are as much at risk to acquire and shed virus as those who unvaccinated. So, for me, it is illogical, if it is done in good faith, but I think it's meant primarily to be coercive, to force vaccination.[316]

216. Dr. Lemieux expressed the same opinion.[317]

217. Dr. McGeer responded to the question of 'why not mask all HCWs' at some length:

---

[314] Transcript, May 21, 2015, pp. 238-239

[315] Exhibit 70, pp. 9-10

[316] Transcript, May 19, 2015, p. 146

[317] Transcript, January 26, 2015, p. 66

> Again, this gets back to policies and understanding seasons, and it's also partly about what the point of a policy is. So, this policy is about prevention of influenza. That's not to say, speaking of other respiratory viruses, that's not to say that other respiratory viruses aren't important. But when you're making changes in practice, you can't necessarily go for everything. You're making changes that are of specific benefit based on specific evidence. And the truth is that other respiratory viruses have a much lower burden. We don't have as good estimates. It's a little harder to justify policies about other respiratory viruses compared to influenza.
>
> So, if we're talking about policies to protect patients from influenza in a year with a good match between the vaccine and the virus, you will get protective efficacies in young, healthy adults that are…somewhere between 70 and 80 percent.
>
> In addition, you'll get less severe disease and, therefore, maybe less transmission when there is break-through disease. So, then in vaccinated health care workers there is not much benefit to be had from an influenza perspective in wearing a mask because you've already got 80 percent of your protection from just the vaccine…
>
> In a mismatch year, in a year like this year, there may very well be an argument for masking everybody. To my mind, we need more evidence in order to do that because the evidence for masking is not nearly as good as the evidence for vaccine, but I think it's actually something that we will talk about and start to think about and start to ask whether it might be a benefit. In a year in which protective efficacy is 40 or 50 percent, that is really difficult at the moment…
> ….
>
> And then do masks do the same thing as vaccination? And from that perspective, I think it's important to recognize that the mask as an alternative does not carry anything like the same evidence that if we mask everybody, that patient mortality would go down? The answer to that is no. We do not have that evidence. The masking alternative is honestly a somewhat desperate attempt to find the solution to the problem that we want to respect health care workers' choices about vaccination.[318]

218. During her cross-examination[319] Dr. Henry acknowledged that:

- unvaccinated persons are asked to wear a mask because they could be asymptomatically shedding virus
- asymptomatic shedding is less than when one has symptoms; "the major risk is when you're symptomatic"
- in the 2014-2015 mismatch influenza season, "the risk of being infected and therefore shedding asymptomatically would be the same" between two workers, one vaccinated and one unvaccinated but only the unvaccinated worker was required to wear a mask.

219. Dr. Henry answered the 'why not mask everyone' question this way:

---

[318] Transcript, June 24, 2015, pp. 109-112

[319] Transcript, June 23, 2015, pp. 99-101

> It is [influenza vaccination] by far, not perfect and it needs to be improved, but it reduces our risk from a hundred percent where we have no protection to somewhat lower. And there's nothing that I've found that shows there's an incremental benefit of adding a mask to that reduced risk.....there's no data that shows me that if we do our best to reduce that incremental risk, the risk of influenza, that adding a mask to that will provide any benefit. But if we don't have any protection then there might be some benefit when we know our risk is greater.
>
> When we look at individual strains circulating and what's happening, I think we need it to be consistent with the fact that there was nothing that gave us support that providing a mask to everybody all the time was going to give us any additional benefit over putting in place the other measures that we have for the policy. It's a tough one. You know, it varies by season.[320]
> .....
>
> It is a challenging issue and we've wrestled with it. I'm not a huge fan of the masking piece. I think it was felt to be a reasonable alternative where there was a need to do—to feel that we were doing the best we can to try and reduce risk.
>
> I tried to be quite clear in my report that the evidence to support masking is not as great and it is certainly not as good a measure.[321]

220. In final argument, referring to the mismatch year, the OHA/SAH counsel stressed that the mask is used as an alternative for those who choose not to vaccinate, that the Policy and its reasonableness can't be based on one-year assessments, that it was not "even by midstream absolutely clear that the vaccine against one strain was not going to provide any protection", and that "it's also not clear when it's providing protection against other strains".[322]

Broader Policy Requirements and Recommendations

221. The OHA/SAH also looks to positions taken by other institutions and bodies to support its selection of a VOM policy. I now turn to review some of them and others as well.

[320] Transcript, June 23, 2015, p. 108
[321] Transcript, June 23, 2015, p. 111
[322] Transcript, July 8, 2015, pp. 120-122

Statutory/regulatory requirements

222. By statute a medical officer of health has authority to settle requirements in an order "to decrease or eliminate the risk to health presented by the communicable disease".[323] What is noteworthy is what is missing. Neither mandatory influenza vaccination nor mask requirement orders have been made applicable for HCWs. There is however a requirement for proof of measles vaccination as a condition of employment.[324]

223. Subsection 6(1)(h) of the General Regulation under the *Ambulance Act* provides:

> 6. (1) An emergency medical attendant and paramedic employed, or engaged as a volunteer, in a land ambulance service shall,
> ....
>
> (h) hold a valid certificate signed by a physician that states that the person is immunized against diseases listed in Table 1 to the document entitled "Ambulance Service Communicable Disease Standards", published by the Ministry, as that document may be amended from time to time, or that such immunization is contra-indicated.[325]

224. At one time there was a specific requirement in Ontario that ambulance attendants have influenza vaccination, unless such vaccination was contra-indicated. This is no longer the case.[326]

225. The Ontario government has not designated influenza as a disease against which children must be vaccinated in order to attend school.[327] Measles, mumps, tetanus and other diseases are designated.

---

[323] *Health Protection and Promotion Act,* R.S.O. 1990, c. H.7, ss. 22(2)

[324] *Public Hospitals Act,* O. Reg. 965, ss. 4(2); Measles Surveillance Protocol for Ontario Hospitals, revised May 2014

[325] *Ambulance Act,* O. Reg. 257/00, ss. 6(1) (h), Ambulance Service Communicable Disease Standards, Table 1, Part A

[326] *North Bay General Hospital*, November 23, 2003 (Goodfellow)

[327] *Immunization of School Pupils Act,* R.S.O 1990, c. I.1, s. 1, s. 3; O. Reg. 261/13 "Designated Diseases"

226. The College of Nurses ("CNO") has not required that nurses secure influenza vaccination as a professional standard to be met nor have other provincial bodies with regulatory powers over healthcare professionals. The CNO 'Practice Guideline Influenza Vaccinations' (June 2009) states that: "The College does not establish the requirements for immunization of health care workers. These requirements are established by individual workplaces and by legislation."[328]

Other guides, reports, studies, recommendations

227. Dr. Brosseau was a member of the Council of Canadian Academies Expert Panel on Influenza and Personal Protective Respiratory Equipment. The Panel conducted "An Assessment of the Evidence" in 2007. Its consensus report included the following:

> Surgical masks worn by infected persons may play a role in the prevention of influenza by reducing the amount of infectious material that is released into the environment...Their biggest limitation is that they do not provide an effective seal to the face, thereby allowing inhalable particles access to the respiratory tract. In addition, the efficiency of the filters of surgical masks in blocking penetration of tracheobronchial or alveolar-sized particles is highly variable and their efficiency in blocking nasopharyngeal-sized particles is unknown.[329]

228. A 2012 Position Paper issued by AMMI Canada [Association of Medical Microbiology and Infectious Diseases Canada], of which Dr. McGeer was a joint author, took the position that vaccination against influenza is ethically justified as a condition of employment. The paper included no mention or discussion of the need for masking.[330]

229. A 2013 prospective cohort study performed during the 2009 influenza A(H1N1) pandemic was aimed to determine whether adults working in acute care hospitals were at higher risk than other working adults for influenza and to assess risk factors for influenza among HCWs. Dr. McGeer was lead author. There were no

[328] Attachment to Exhibit 17, Will-Say of Glenda Hubley

[329] Exhibit 123, p. 7; Transcript, June 6, 2015, L. Brosseau, pp. 76-81

[330] Exhibit 40

recommendations in the study of risk factors amongst healthcare workers that everyone be masked.[331]. *Inter alia* the study noted that:

> The mode of transmission of influenza remains a matter of ongoing debate. Although most experts believe that droplet and aerosol transmission are the most common modes of spread of influenza…Appropriate hand hygiene practice should continue to be recommended to prevent influenza transmission.[332]
>
> Within an HCW group, we were able to identify activities that could help focus prevention. Increasing efforts to improve hand hygiene and the use of protective equipment during aerosol-generating medical procedures would further reduce the risk for influenza among HCWs.[333]

230. A third edition of "Best Practices for Infection Prevention and Control Programs in Ontario" was published in May 2012 by the Provincial Infectious Diseases Advisory Committee ("PIDAC") of the Ontario Agency for Health Protection and Promotion.[334] There is no recommendation for a VOM policy among the numerous recommendations found in this document although PIDAC recommends annual influenza vaccination as a condition of continued employment in, or appointment to, health care organizations.[335]

231. A document, Annex F, "Prevention and Control of Influenza during a Pandemic for All Healthcare Settings"[336], produced by a working group of which Dr. Henry was a member[337], was produced for the Public Health Agency of Canada. This set of recommendations related to protection in a pandemic when the entire population is naïve to a newly circulating strain of influenza, meaning that everyone would be in the same situation as unvaccinated people in the context of seasonal influenza.[338] Dr. Henry agreed that this document did not recommend personal

---

[331] Transcript, June 26, 2015, A. McGeer, p. 116

[332] Exhibit 62 at p. 612: Kuster *et al,* "Risk Factors for Influenza among Health Care Workers during 2009 Pandemic, Toronto, Ontario, Canada', Emerging Infectious Diseases. Vol. 19, No.4, April 2013, pp. 608-615

[333] Exhibit 62, p. 614

[334] Exhibit 197

[335] Exhibit 197, p. 32

[336] Exhibit 143

[337] Transcript, June 22, 2015, B. Henry, p. 219ff

[338] Transcript, June 22, 2015, B. Henry, pp. 220-221

protective equipment for HCWs unless they were within two metres of a symptomatic person, permitted asymptomatic visitors without restrictions, indicated that asymptomatic personnel could safely work, and explicitly indicated that masks were *not* required for asymptomatic persons who had been exposed to infected roommates.[339] There were no recommendations for the use of masks outside of an outbreak situation.

232. A 2009 publication by the CDC (Centers for Disease Control and Prevention), "Interim Guidance for the Use of Masks to Control Influenza Transmission"[340] stated that: "no studies have definitively shown that mask use by either infectious patients or health-care personnel prevents influenza transmission" but recommended that "a surgical or procedure mask should be worn by health-care personnel who are in close contact(i.e. within 3 feet) with a patient who has symptoms of a respiratory infection, particularly if fever is present, as recommended for standard and droplet precautions".

Toronto Academic Health Science Network (TAHSN)

233. On February 24, 2014, the TAHSN Healthcare Worker Influenza Immunization Working Group released a Report that included recommendations and extensive commentary concerning vaccination and VOM policies.[341]

234. The TAHSN Report describes VOM policies as offering HCWs a choice between obtaining annual influenza vaccine and wearing a mask, a choice said to provide workers with more autonomy with respect to the management of influenza in their practices than would a vaccination-required policy[342]. It states that VOM policies "have been associated with reductions in the number of institutional

[339] Transcript, June 22, 2015, B. Henry, pp. 219-237
[340] Exhibit 11
[341] "Healthcare Worker Influenza Immunization", Attached as Appendix C to Exhibit 185, Report, A. McGeer. ("TAHSN Report")
[342] TAHSN Report, p. 16

outbreaks"[343]. It asserts that VOM policies "articulate conditions of employment very similar to those already in place for Diptheria, Tetanus, Pertussis, MMR, Varicella, and Hepatitis B".[344]

235. On the other hand, the TAHSN Report acknowledges a number of other issues including:

> Critics point to mixed evidence of the vaccine's efficacy, since the ethical defensibility of vaccination-required or vaccination-or-mask policies are linked to the vaccine's efficacy.
> ....
>
> At the level of the individual HCW the main ethical argument against vaccinate-or-mask policies is linked to respect for autonomy. Vaccinate-or-mask policies are generally considered to be a violation of autonomy. Constraints on autonomy are justified only if the benefits (i.e. prevention of serious harm) outweigh the harms, and only if those same benefits cannot be achieved without constraining freedom of choice. It is acknowledged that a vaccinate-or-mask policy is less of an infringement on autonomy than a vaccination-required policy.[345]

236. The Report went on to canvass what it described as Ethical Considerations in Operationalizing an Influenza Vaccination of HCWs Program. These included the following:

> **Duty not to harm others** – Generally speaking, HCWs have a moral obligation not to harm others and to contribute to a safe work environment. This implies a duty not to infect someone when one knows this can easily be prevented. While there are limits to what one could reasonably expect of a HCW in order to limit the chance that the worker would infect another, it would be ethically defensible to expect adherence to activities that are of minimal risk or burden to the HCW.
> ....
>
> **Proportionality** – Restrictions on freedom of staff are ethically defensible to the extent that they are proportionate to the risk they are intended to prevent. Restrictions to individual liberty and measures taken to protect the public from harm should not exceed what is necessary to address the actual level of risk to or critical needs of the community.
> ....
>
> **Individual liberty** – Restrictions to individual liberty may be necessary to protect the patients and other HCWs from serious harm. Restrictions to individual liberty should: be proportional, necessary, and relevant; employ the least restrictive means; and be applied equitably.
>
> **Privacy** – Individuals have a right to privacy in health care. When operationalizing a vaccination program, attention should be given to impact on disclosure of personal health

[343] TAHSN Report, p. 17
[344] TAHSN Report, p. 17
[345] TAHSN Report, p. 18

> information. For example, could there be challenges related to stigmatization against those who choose to wear a mask over vaccination, or families who only want caregivers who have been immunized.[346]

237. The Summary paragraphs on the VOM section of the Report included the following:

> It may be helpful to think of the ethical defensibility of influenza vaccination for HCWs programs as sitting along a continuum. Voluntary programs that include strong educational and incentive components would be the preferred first approach. If ineffective, policy could move along to stage of vaccinate-or-mask with careful attention to how to mitigate harms associated with potential pushback…
> ….
>
> When HCW immunization rates remain low in spite of state-of the-art educational and incentive programs, a vaccinate-or-mask approach would be ethically defensible.[347]

238. The Report went on at some length to consider what it termed Human Resources, Labour Relations and Legal Considerations and commented upon the Diebolt Award. The Report concluded that:

> The key requirements in formulating a "vaccination-or-mask" policy are reasonableness and consistency with the collective agreements. There are reasonable grounds to assert that both of those requirements can be met by Ontario hospitals. In order to do so, Ontario hospitals will need to establish key factual aspects, including the fact that the alternative use of a mask also reduces the risk of transmission of influenza to patients and the fact that the alternative use of the mask serves both patient safety and accommodation needs.[348]

239. The TAHSN Report contains numerous footnoted references that are said to support the propositions advanced. However, no references are cited concerning the use of a mask to reduce the risk of transmission of influenza to patients or that the introduction of VOM policies has been associated with reductions in the number of institutional influenza outbreaks. Nor does the Report note that influenza is not designated by Regulation for mandatory immunization unlike the other diseases referenced and said to be comparables.

240. In their joint Report dated December 5, 2014, Dr. Gardam and Dr. Lemieux had the following exceptionally blunt comments about the TAHSN process:

---

[346] TAHSN Report, p. 18
[347] TAHSN Report, p. 19
[348] TAHSN Report, p. 23

> ...we feel it important to illustrate how the process was in fact highly biased and determined at the outset to block any alternative viewpoints.
>
> Despite UHN being the largest TAHSN member, and the physicians within the UHN infection prevention and control department having expertise regarding influenza immunization (including one of us co-chairing the TAHSN pandemic influenza planning committee which was the forerunner of the staff vaccination committee), neither of us was included in the discussion regarding possible policy options. A UHN senior staff member did sit at the TAHSN table during policy discussions and repeatedly told the committee that there were alternative views and potentially more effective policies that should be considered. Our UHN senior staff member informed us that, despite these attempts, the TAHSN policy was not open for debate. Only two members of the TAHSN committee have infectious disease experience (Drs. McGeer and Kevin Katz, who share the same opinion of the policy) with the majority of the other members being senior administrators. The UHN representative on the committee has told us that, in her opinion, Dr. McGeer was solely relied upon to translate the evidence for the other members of the committee, few of whom had the requisite training to understand or critique the complexities. Any scientific questions that arose were directed exclusively to Dr. McGeer to answer from her authoritative position.[349]

241. Dr. Gardam also spoke about his concerns when he gave oral testimony.[350] In re-examination he explained:

> The process issues are very important to me because this is at the crux of all of this, is that we have a policy in front of us which that that support it say has ample evidence to support it, there really is no downside to that, yet this policy has been created in the organizations that I'm aware of, it's been created behind closed doors. There hasn't been a lot of open discussion about it. There aren't a lot of people that really have a lot of expertise in this area, so it's pretty easy to have discussion without people with expertise. And it's multiplying. And so it went from B.C.. it went to New Brunswick, now it's come to University of Toronto Hospitals, it's now in Saskatchewan. And it really bothers me because each place is saying, Well, these people adopted this policy, there is an inherent assumption that they went through all the process of really sorting that out. Because that's what we tend to do in medicine. Once it's been adopted three or four times, why do we have to go back and look at the original evidence anymore, you've done that....the next time it comes up, I want people to start over. I want them to actually bring in people from different opinions and get them in the room and really hash out what is the best way to protect our patients. Not what is the best way to get people vaccinated, but what is the best way to protect our patients, of which a component will be vaccination.[351]

242. Dr. Gardam referred to his own hospital, UHN:

> I think all of that relates to the fact that people didn't hear that there were other alternatives. In my own hospital, I spoke with my senior team for probably 10 minutes and they're like, okay, so there is another opinion. We want to think about this before we jump on board. So we decided for this year we weren't going to go along with the TAHSN

---

[349] Exhibit 21, p. 2

[350] See for example: Transcript, May 21, 2015, pp. 95, 103-107

[351] Transcript, May 21, 2015, pp. 235-236

report. I can't help but think if people heard alternative opinions that they may not have been quite so quick to jump on this.[352]

Legal Submissions

243. The following outline of the parties' very lengthy submissions [353] is necessarily very sharply abbreviated. It does not include most of the numerous authorities that were cited in their complementary written arguments.[354]

ONA

244. The Union submits that the Hospital has failed to meet its evidentiary burden to establish that the Policy is rationally connected to a legitimate purpose. It called no mask expert. The Policy does not meet accepted *KVP* requirements in that:

- It is inconsistent with the collective agreement.
- It is based on irrational considerations.
- It involves an infringement of employees' rights to privacy and personal autonomy.
- Less intrusive rules would suffice; the Policy is not proportionate.
- The Policy was not consistently enforced.

245. ONA argues that:

- The Policy undermines the negotiated right of employees to choose whether or not to be vaccinated by, in effect, coercing an election to vaccinate.
- The mask evidence asserted by the Hospital's experts disappears under close review.
- If the legitimate purpose of masking is to prevent transmission of influenza, then logically it should require everyone to mask. Moreover, the Hospital failed to apply its VOM Policy to vaccinated employees in 2014-2015 although it knew that the vaccine in that year was ineffective against the dominant influenza strain.
- The Policy is not applicable in all areas of the Hospital and to visitors.

[352] Transcript, May 21, 2015, pp. 239-240

[353] Transcript, July 7, 2015 (ONA); Transcript, July 8, 2015 (OHA/SAH)

[354] Final Argument Overview (ONA); Closing Argument of the OHA and SAH

- The process followed at SAH goes directly to the reasonableness of the Policy: the VOM policy was effectively determined at the outset by CEO Gagnon when he directed adoption of "the most aggressive stance we could take which will stand the test of arbitration"; the Hospital failed to consult its IPAC consultants and bypassed the IPAC department; the Chief of Medical Staff, the Chief Nursing Executive, and Medical Officer of Health expressed concerns; Mr. Gagnon's selection of a 70% required vaccination rate to forestall implementation was arbitrary.
- The Hospital's existing infection prevention and control policies were adequate.
- By placing a sticker on a public badge, by mandating the wearing of a mask if not vaccinated, by postings that advise patients and visitors that a mask can be equated to non-vaccination, the Hospital is infringing upon employees' right to privacy of their medical information.
- The consent form required is not sufficient to cover this public disclosure. It coerces consent in the sense that the negative consequence of mask wearing is the alternative.
- There are less intrusive measures that could be taken including non coercive measures to encourage vaccination, front line engagement tactics to have staff own the issue, policy development based on 'best evidence' of influenza transmission; a review of sick leave policies to encourage employees not to come to work if sick.

246. The Union refers to *Irving* and relies upon *Peace Country* Health [355] submitting that it provides the appropriate analytical framework for applying *KVP* where an employee's right to privacy and personal autonomy is involved. It suggests that an employer's valid business objectives and good intentions are insufficient justification to intrude upon employees' medical privacy: *Federated Cooperatives Ltd.*[356] An employer must provide sufficient objective evidence to establish a link between the policy and the employer's justification for the policy: for example, see: *West Lincoln Memorial Hospital* [357]; *Casino Niagara*[358].

[355] (2007), 89 C.L.A.S. 107 (Sims)
[356] (2010), 194 L.A.C. (4th) 326 (Ponak) at para. 30
[357] (2004), 126 L.A.C. (4th) 52 (Luborsky) at paras. 16-17
[358] (2005), 142 L.A.C. (4th) 78 (Knopf) at para. 12

247. ONA points as well to *Meiorin*[359] in support of its submission that it is not sufficient for an employer to claim a safety interest to support a workplace policy or practice. The Union submits that, although fitness tests for firefighters had a valid purpose in promoting safety, it was held that the research upon which the tests were based was incomplete, "impressionistic" and did not take into account human rights issues in establishing the required standard. The policy was struck down.

248. ONA refers to several leading authorities with respect to employee privacy rights: *Monarch Fine Foods Co. Ltd.*[360]; *Alberta (Information and Privacy Commissioner)*[361]; *St. Joseph's Health Centre*[362]. It also points to the provisions of a number of statutes: *Personal Health Information Protection Act, 2004*[363] ("*PHIPA*"); *Freedom of Information and Protection of Privacy Act,* s. 2[364] ("*FIPPA*"); *Occupational Health and Safety Act*, ss. 28(3), 63(2)[365]; *Health Care Consent Act,* s, 2, 10, 11[366]. As stated, the Union's theory concerning these issues is grounded on the submission that the medical vaccination status of employees is publically communicated both by the very fact of mask wearing and by the sticker on the badges they must wear. A Hospital posting advises patients and visitors of the VOM Policy and makes this clear. The argument is that a VOM policy that imposes consequences upon a refusal to vaccinate amounts, in effect, to coerced consent. Coerced consent is not proper consent.

249. The Union also submits that Dr. McGeer's evidence should be regarded as compromised given that she is "a fervent advocate for influenza vaccination"[367]. Dr. Henry was instrumental in the introduction of the VOM policy in British

---

[359] *British Columbia (Public Service Employee Relations Commission)*, [1999] 3 S.C.R. 3
[360] (1978), 20 L.A.C. (2d) 419 (M.Picher)
[361] 2013 SCC 62
[362] (2005), 76 O.R. (3d) 22 (Ont. Div. Ct.)
[363] S.O. 2004, c.3, Sch. A
[364] R.S.O. 1990, c. 31
[365] R.S.O. 1990, c. O.1
[366] S.O. 1996, c. 2, Sch A.
[367] Final Argument Overview, para. 84

Columbia.[368] It argues that an adverse inference should be drawn against the Hospital given that the following potential witnesses were not called: Joanne Messier-Mann, Chief Nursing Executive; Dr. Heather O'Brien, Chief of Staff; Dr. Kim Barker, Medical Officer of Health, Algoma; Kim Lemay, Director of Human Resources; Jack Willet, Manager and Influenza Planning Committee member.[369]

OHA/SAH

250. The OHA and the Hospital submit that the Policy relates to an important patient safety issue. They argue that the Diebolt Award is indistinguishable, good law, and should be followed. Arbitrator Diebolt has already determined that VOM policies meet the *KVP* test for reasonableness.

251. Insofar as *KVP* and *Irving* are concerned the OHA/SAH submit that the Policy meets accepted tests for reasonableness and that it appropriately balances the Hospital's interest with employee privacy interests. As previously found by Arbitrator Diebolt, influenza can be a serious, even fatal, disease and masking has a patient safety purpose. They submit that: "the scientific evidence in this case provides a solid and compelling foundation for the reasonableness of the Policy".[370] The ONA Central Collective Agreement recognizes a joint obligation to protect patient and employee health and safety. Implementation of the Policy was the exercise of a legitimate management right codified in the Local Collective Agreement.

252. Reasonableness should be assessed using the *Dunsmuir* approach for judicial review. Placing particular reliance upon comments by Arbitrator Hope quoted in *Canada Safeway Ltd.*[371], the OHA/SAH submit that: "the Arbitrator's focus is to

[368] Final Argument Overview, Appendix C, p. 61; Transcript, June 22, 2015, pp. 184, 188
[369] Final Argument Overview, para. 89
[370] OHA/SAH Closing Argument, para. 366
[371] [1998] B.C.C.A.A.A. No. 378 (Kelleher)

determine whether the Policy falls within a range of acceptable and rational solutions; it is not to assess whether the same policy would have been implemented by ONA".[372] The statutory framework also supports the conclusion that steps should be taken to eliminate "undue risks" and "minimize hazards inherent in the hospital environment".[373]

253. There is no evidence to provide a factual foundation for the allegation that there was no informed consent to vaccination, let alone to disclosure of immunization status. There are exclusion provisions in both *PHIPA*[374] and *FIPPA*[375] that preclude operation of those statutes. As a matter of fact, the sticker identifier shows only the SAH logo and the fiscal year and provides no information about immunization status.[376] Managers were given only a list of vaccinated employees who had consented to release of personal health information.[377] There is no evidence that informed consent was not given by any affected nurse.

Discussion

Experts

254. The relevant legal principles governing the admissibility of expert opinion evidence were well stated by the OHA/SAH[378] and are not disputed. The expert evidence adduced in this case was central to both positions. It would have been impossible to try the case properly without it. Each side however questions the weight that should be accorded the evidence provided by the other's experts.

---

[372] OHA/SAH Closing Argument, para. 353
[373] OHA/SAH Closing Argument, para. 379; *Public Hospitals Act*: *Hospital Management,* RRO 1990, Reg. 965, ss. 4(1) (d) (v)
[374] ss. 4(4)
[375] ss. 65(6)(3)
[376] Transcript, C. Johns, June 29, 2015, p. 156
[377] Transcript, C. Manzo, June 9, 2015, pp. 186-187
[378] OHA/SAH Closing Argument, paras. 88-97; *R. v. Mohan,* [1994] 2 SCR 9; *White Burgess Langille Inman v. Abbott and Haliburton Co.,* 2015 SCC 23 (CanLII).

255. The OHA/SAH suggest that the manner in which ONA secured its expert evidence was problematic.[379] It also challenges Dr. Brosseau's expertise if it is said to relate to the use of a mask to reduce influenza transmission from a HCW to a patient in an acute care hospital. It says that Dr. De Serres, Dr. Gardam, and Dr. Lemieux purported to opine on the very issue in this proceeding: whether the Policy is reasonable. Their description of the Policy as coercive and punitive constitutes the expression of personal views that mark their evidence as not "totally objective". Dr. De Serres has acknowledged that he has no expertise with respect to the use of a procedure/surgical mask. Dr. Gardam has not engaged in scientific research regarding the use of a mask in the prevention of HCW influenza transmission nor has Dr. Lemieux. Dr. Lemieux is tendered both as a fact and expert witness that the OHA/SAH also says is problematic.[380]

256. ONA notes that the OHA/SAH called no mask expert evidence at all. Dr. McGeer is a known advocate of mandatory influenza immunization and Dr. Henry was instrumental in the introduction of the VOM policy into British Columbia. Their objectivity is suspect. ONA says that: "Dr. McGeer has a history of making inflammatory and hyperbolic statements about the dangers of influenza and the risk caused by unvaccinated HCWs, specifically accusing them of having a 'license to kill'". [381]

257. I am satisfied that the evidence of all of these witnesses should be accepted as proper expert opinion evidence, albeit recognizing some inevitable limitations and ignoring some of the comments that might be seen as conclusory having regard to the issues in this case. The OHA/SAH raised concerns about "counsel-prepared" will-says and other objections at preliminary stages but I am satisfied that there has

[379] Transcript, July 8, 2015: "The use of a will-say for claimed expert opinion evidence…is highly problematic…It's not an answer to that, too, to say that the will-say statement was provided to the witness for review and comment. The fact remains it was prepared by an advocate."
[380] OHA/SAH Closing Argument, paras. 98-135; Transcript, July 8, 2015, p.54
[381] Final Argument Overview, Appendix C

been adequate compliance with the requirements of *Moore v. Getahun* 2015 ONCA 55, a judgment that issued subsequently to the preparation of this material. I also accept that ONA counsel faced practical difficulties when seeking the assistance of local expert witnesses that explains how their relationship unfolded. Dr. Gardam explained at some length why it was necessary that he testify under subpoena.[382]

258. The only witness for whom specialized mask expertise is claimed is Dr. Brosseau. I accept that the focus of her research has been industrial hygiene with focus on fit and filter, principally concerning respirators. I do not rely upon her opinion, to the extent that it was specifically expressed without corroboration, about the transmission of influenza from a HCW to a patient. I accept that she is as competent, and likely more competent, than the other experts to speak to such mask literature as exists.

259. I have no doubt about Dr. De Serres's expertise as a leading Canadian epidemiologist nor about that of Dr. McGeer. They have both conducted extensive research concerning influenza and related subjects. Dr. Henry, Dr. Gardam, and Dr. Lemieux are all actively engaged in the infectious diseases field and have major responsibilities in major health care institutions. They bring years of practical experience concerning influenza and other respiratory diseases and demonstrated deep knowledge of the currently available research and literature.[383] They collectively provided assistance in understanding the relevant research and literature in the only practical way possible; that is, by providing their informed opinions and by explaining the conclusions identified in their respective Reports by reference to that scientific material. The curricula vitae of these experts are truly remarkable.

---

[382] Transcript, May 21, 2015, pp.102-103

[383] OHA/SAH's description of Dr. Henry's expertise, having "engaged in a very substantial review of the relevant scientific literature regarding influenza, its transmission and the prevention of its transmission particularly given her significant practical experience" [OHA/SAH Closing Argument, para. 143; Transcript, July 8, 2015, p.69] is entirely apt and would apply in my view also to Dr. Gardam and Dr. Lemieux. OHA/SAH counsel agreed that Dr. Gardam has "considerable experience and expertise in infectious diseases". See: Transcript, July 8, 2015, p.61

260. As previously noted much earlier in this Award, Arbitrator Diebolt was also favoured with expert testimony. However, given the parallel expertise of Dr. De Serres, Dr. Gardam, and Dr. Lemieux, I am not able to reach the same conclusion as he did that the evidence of Dr. McGeer and Dr. Henry on transmission issues should be preferred as having what he called "special relevance".[384]

Experts and arbitrators: deference or choice

261. As noted at the outset of this Award, these grievances raise the issue of a labour arbitrator's engagement with expert evidence when assessing the reasonableness of workplace policies that establish terms and conditions of work for employees who are delivering patient care. The OHA/SAH, relying on *Dunsmuir* and other judicial review authorities, submit that some form of *Dunsmuir*-like deference should apply in assessing the expert evidence tendered in support of the VOM policy.

262. I disagree. *Dunsmuir* principles of deference should not be imported into first level rights adjudication. The analogy to *Dunsmuir* is misplaced. The nature and degree of that misplacement can be examined through the three concepts of deference, expertise, and reasonableness.

263. First, the OHA/SAH's position conflates *decision-making deference* with the question of what *weight* should be attached to an expert's evidence. These are very different projects.

264. The concept of and rationale for deference that apply in administrative law have no application to and are not transferrable to understanding an adjudicator's engagement with expert opinion evidence. In administrative law, the notion of

[384] Diebolt Award, para. 185

deference is integral to the very rationale for creating a rights-enforcement system composed of expert tribunals supervised by courts on judicial review. While administrative tribunals have particular contextual, subject matter, and/or technical expertise, what is crucial is that those tribunals and the supervising courts are both *legal decision-makers* that are engaged in the *same singular project of rights adjudication within a given legislative framework.* There, the concept of deference is grounded in principles of adjudicative economy and efficiency that recognize the rationale for creating expert tribunals while ensuring compliance with the constitutional requirement for judicial oversight. And in that context, deference is applied with considerable nuance and contextual sensitivity as the vast and subtle jurisprudence of administrative law well demonstrates.

265. The OHA/SAH's adoption of the notion of deference wrongly suggests that a labour arbitrator should defer to the choices or conclusions that a *witness* makes within their particular realm of expertise. The analogy is flawed because arbitrators and witnesses have different realms of expertise and are engaged in distinct 'decision-making' projects. A witness may make choices and reach conclusions within their area of expertise but the parameters, expertise and duties that inform those choices are different from the parameters, expertise and duties that are engaged by a legal claim that arbitrators must resolve in the course of rights adjudication. It is not a question of one decision maker (arbitrators) deferring to another (expert witnesses) because their mandates are completely distinct. To exercise that form of deference would be an abdication of a labour arbitrator's mandate and obligation to the parties.

266. Instead, it is better to understand the arbitrator's orientation towards expert evidence by remembering why expert opinion evidence is admissible as an exception to the exclusionary rule against opinion evidence and what role it plays in adjudication. Expert witnesses are permitted to provide opinion evidence because their specialized knowledge may be required to assist the adjudicator to reach true inferences from facts stated by witnesses.

267. Since its 1994 ruling in *R. v. Mohan,* and most recently in *White Burgess Langille Inman*, the Supreme Court of Canada has cautioned against the danger that in the face of expert evidence "the trier of fact will inappropriately defer to the expert's opinion rather than carefully evaluate it". [385] Instead, the Court has reiterated that "[t]he trier of fact must be able to use its 'informed judgment', not simply decide on the basis of an 'act of faith' in the expert's opinion". [386] In all cases, the role of the expert witness is to provide "fair, objective and non-partisan opinion evidence" that assists adjudicators in assessing all the evidence before them and drawing true inferences.[387]

268. But, the expert witness is not to substitute for the adjudicator's independent assessment of the legal issue to be decided. Accordingly, rather than "deference", the real questions are what *weight* should an arbitrator give to particular expert opinion evidence and does that expert opinion evidence assist in drawing inferences. As set out above, the parties agreed that it is necessary to assess and choose between the conflicting scientific evidence. That assessment and such choice are not questions of "deference" but an exercise of an arbitrator's normal judgment with respect to the weight, relevance and credibility of competing evidence.

269. Secondly, the OHA/SAH's adoption of the reasonableness test from *Dunsmuir* again risks confusing the question of deference and the limited scope of the expert witness' expertise and risks diluting the well-established *KVP* test.

270. The OHA/SAH's position suggests that as long as the VOM Policy is based on "some" expert evidence and "falls within a range of possible, acceptable outcomes" it will be compliant with a reasonable exercise of management rights. However, the articulation of what is "reasonable" in *Dunsmuir* is not a free-floating

---

[385] *White Burgess Langille Inman*, 2015 SCC 23, at para. 17
[386] *White Burgess,* at para. 18
[387] *White Burgess*, at paras. 2, 10

"reasonableness" test. It specifically describes what *degree of deference* is appropriate when taking into account the distinct roles played by an administrative tribunal of first instance and a reviewing court within a vertical process of rights adjudication and review. Also, the question of whether an expert witness' opinion is "reasonable" equally presents the wrong frame. It must be stressed that an expert witness' expertise has a different focus and is incomplete for the purposes of determining the legal rights at issue in a grievance. For example, an expert witness' opinion may be "reasonable" *in a colloquial sense* in view of the parameters that inform the specific scientific project to which the expertise relates. But this does not translate into a *legal conclusion of reasonableness.* It is important to use these terms with precision and to be very clear about the point in the decision-making process to which they relate.

271. At the end of the day, the well-established *KVP* test that identifies what is a reasonable exercise of management rights is the legal test that applies. As the Supreme Court of Canada stated in *Irving,* assessing what is reasonable requires a particular balancing of interests that is attuned to the labour relations context:

> Determining reasonableness requires labour arbitrators to apply their labour relations expertise, consider all of the surrounding circumstances, and determine whether the employer's policy strikes a reasonable balance. Assessing the reasonableness of an employer's policy can include assessing such things as the nature of the employer's interests, any less intrusive means available to address the employer's concerns, and the policy's impact on employees.[388]

KVP reasonableness

272. ONA and the OHA/SAH both present *Irving*'s explication of *KVP* reasonableness, just cited, as providing the appropriate foundation for the analysis that is required. [389]

[388] [2013] 2 S.C.R. 458, at para. 27; specifically acknowledging a submission of the Alberta Federation of Labour

[389] OHA/SAH Closing Argument, paras. 311-312; ONA Final Argument Overview, para. 3

273. Arbitrator Diebolt provided the following succinct descriptions that I readily adopt:

> The Policy, in my view, is a case of a unilaterally imposed set of rules. Therefore, it is necessary to establish that it is a legitimate exercise of the Employer's residual management rights recognized and retained in Article 4. That means the Policy must meet the tests set out in *KVP*. Further, because it contains elements that touch on privacy rights, it must meet the privacy tests articulated in *CEP, Local 30 v. Irving Pulp & Paper Ltd.,* 2013 SCC 34. If those tests are met the Policy will be a valid exercise of the Employer's management rights.[390]
>
> ....
>
> In any event, where privacy interests are affected by a unilateral policy implemented as an exercise of management rights, the most recent articulation of the relevant tests is set out by the Supreme Court of Canada in *Irving*, which addressed a policy of random alcohol breath testing in a dangerous work environment. The majority cited *KVP* with approval, noting both arbitrators and appellate courts have applied its reasonableness test. It wrote in part:
>
> > [24] The scope of management's unilateral rule-making authority under a collective agreement is persuasively set out in *Re Lumber & Sawmill Workers' Union, Local 2537, and KVP Co.* (1965), 16 L.A.C. 73 (Robinson). The heart of the "KVP" test, which is generally applied by arbitrators, is that any rule or policy unilaterally imposed by an employer and not subsequently agreed to by the Union, must be consistent with the collective agreement and be reasonable (Donald J.M. Brown and David Beatty, *Canadian Labour Arbitration* (4th ed. (loose-leaf), vol. 1, at topic 4:1520.
>
> More specifically, the majority reviewed with approval a number of past arbitral approaches to policies affecting employee privacy. It noted arbitrators have engaged in a "balancing of interests" approach. In the arbitration awards under review, the board weighed the employer's interest in random alcohol testing as a workplace safety measure against the harm to the privacy interests of employees. The board asked whether the benefit to the employer from random testing in the dangerous workplace was proportional to the harm to employee privacy. The majority of the Court also noted past decisions in which arbitrators had asked whether less intrusive measures had been exhausted.[391]

274. Arbitrators have also made clear, as the OHA/SAH submits[392], that the test for reasonableness is an objective one and does not depend upon the subjective views of the employer, the union or any employee or group of employees.[393]

---

[390] Diebolt Award, para. 155

[391] Diebolt Award, paras. 161-162

[392] OHA/SAH Closing Argument, para. 349

[393] York University (2012), 221 L.A.C. (4th) 48 (Surdykowski) at para. 32

275. As did Arbitrator Diebolt, I turn now to *KVP* where it was said that a unilateral employer rule must satisfy the following requisites:

> 1) It must not be inconsistent with the collective agreement.
> 2) It must not be unreasonable.
> 3) It must be clear and unequivocal.
> 4) It must be brought to the attention of the employee affected before the company can act on it.
> 5) The employee concerned must have been notified that a breach of such rule could result in his discharge if the rule is used as a foundation for discharge.
> 6) Such a rule should have been consistently enforced by the company from the time it was introduced.[394]

276. In the instant case, requirements #3 and #4 have been clearly met and #5 is not relevant. As far as #6 is concerned, I am satisfied that the limited evidence led alleging inconsistent enforcement is not nearly sufficient to support a finding of breach given the size of this Hospital and bargaining unit. I propose therefore to say no more about it.

277. The primary dispute between the parties concerned the reasonableness of the Policy. The Union raised challenges on a variety of grounds each of which will be addressed with abbreviated reference to the evidence adduced.

278. Before doing so, I identify certain non-controversial propositions disclosed in the evidence. No one doubts the obligation of the Hospital to take all reasonable precautions to protect the health and safety of patients. No one doubts that influenza is a serious disease that may lead to serious, even fatal, consequences for certain otherwise compromised patients. With varying levels of assent given the developing science, none of the experts appear to question the first sentence of the published Policy: "Influenza immunization is the single most effective way of

[394] *KVP Co.* (1965), 16 L.A.C. 73 (Robinson) at para. 34

preventing the spread and acquisition of influenza."[395] All of the experts accept that, depending upon the number of years considered, the overall vaccine effectiveness rate is about 60%; they agree that many vaccinated HCWs will also contract influenza albeit in attenuated form in some cases. They agree that the 2014-2015 influenza season was an exceptionally poor year for vaccine match with the strain of the disease then prevailing in Canada. The parties agree that the validity of a general VOM policy should not stand or fall on the basis of the experience of a single year.

Purpose of the Policy

279. As set out above, ONA asserts that the improper purpose of the Policy is to promote an increase in influenza immunization rates without an independent patient safety offset that would otherwise justify a mask-wearing requirement. To be clear, the Union does not contest the legitimacy of efforts properly made to encourage voluntary acceptance of vaccination by HCWs. Further, these grievances do not address outbreak situations specifically addressed by the Collective Agreement.

280. On the issue of driving an increase in vaccination rates, Arbitrator Diebolt had the following to say:

> Pausing here, in my view, the facts that: (1) influenza can be a serious, even fatal, disease; (2) that immunization reduces the probability of contracting the disease, and (3) that immunization of health care workers reduces transmission of influenza to patients all militate strongly in favour of a conclusion that an immunization program that increases the rate of healthcare immunization is a reasonable policy.
> ....
>
> **In sum, it is clear that a vaccination or masking policy will increase immunization rates. That said, it would be troubling if the only purpose or effect of the Policy's masking component were to motivate health care workers to immunize. In that event, masking would only be a coercive tool.** On all the evidence, however, I am persuaded that masking has a patient safety purpose and effect and also an

[395] Exhibit 3, Tab B, 4, p. 1.

> accommodative purpose for health care workers who conscientiously object to immunization.[396] (bold added)

281. I will come to the final part of Arbitrator Diebolt's second paragraph in due course but turn first to his first three sentences identified in bold.

282. The genesis of the VOM Policy at SAH cannot seriously be doubted on a documentary record that is extensive, detailed and supported by the uncontradicted oral evidence of several witnesses.

283. I credit without hesitation the statement in Mr. Gagnon's will-say that earlier "critical incidents have shaped his beliefs and actions, and those of SAH with regard to safety"[397]. His will-say was compelling. However, I also find that Mr. Gagnon had decided, by as early as January 2013, that a VOM policy would be introduced at SAH. Only VOM detail and a date for implementation remained. The bedrock VOM requirement had been determined. Notwithstanding questions raised at various times by the Chief of Staff, the Chief Nursing Executive, and the Algoma Medical Officer of Health, VOM was pursued without waver until the Policy was made effective on January 1, 2014. UHN experts retained "to provide expert advice to Infection Prevention and Control at SAH on specific infection control issues" were not consulted.

284. On the face of the record, I have little to no doubt that the dominant, likely sole, motivation for the introduction of the Policy at SAH was to drive up immunization rates. The concern was the risk to patient safety of influenza transmission. The response to that concern was to take all possible steps to increase vaccination rates at the Hospital. VOM was adopted as the vehicle to achieve that objective. What little doubt I have about this conclusion is allayed by what happened at the Hospital in the Fall of 2013. The record is plain that Mr.

---

[396] Diebolt Award, para. 188

[397] Exhibit 246, para.3

Gagnon determined that the Policy would be introduced if the target 70% immunization rate had not been reached by December 31, 2013. He also announced that the Policy would continue in 2014-2015 if an 80% target were not met by the end of March 2014. What is equally noteworthy is what is missing from the record. There is no discussion of any kind about the positive efficacy of masks throughout 2013 on the detailed record of events at SAH.

285. The motivation for VOM at SAH is entirely consistent with what has been acknowledged elsewhere. In her Report Dr. McGeer states that larger and more complex organizations have difficulty in achieving and sustaining superior rates of vaccination and that: "Programs which require that healthcare workers who choose not to be (or cannot be) vaccinated wear a mask when in patient care areas during the influenza season are associated with increases in vaccination rates."[398] In the TAHSN Report, the recommendation is to use voluntary programs as a "preferred first approach" and "if ineffective, policy could move along to [the] stage of vaccinate-or-mask...". [399] The TAHSN Report goes on to say: "When HCW immunization rates remain low in spite of state-of-the-art educational and incentive programs, a vaccinate-or-mask approach would be ethically defensible."[400]

286. The OHA/SAH accept at least the general tenor of this description. It is conceded that low influenza vaccination rates were the backdrop that "animated the implementation of the Policy at SAH"[401]. In final argument counsel, while disputing the relevance of the 70% vaccination rate for purposes of assessing reasonableness, stated that the Policy:

> was animated by the same considerations which occurred in BC Health [Diebolt Award], concerns on low influenza vaccination rates of healthcare workers in healthcare facilities. That backdrop animated the development of the policy at Sault Area Hospital as well.[402]

---

[398] Exhibit 185, p. 40
[399] TAHSN Report, Exhibit 185, Appendix C, p. 19
[400] TAHSN Report, Exhibit 185, Appendix C, p. 19
[401] OHA/SAH Closing Argument, para. 37
[402] Transcript, July 8, 2015, p.28; See also: p. 39

287. However, Dr. McGeer and Dr. Henry defended VOM policies on another basis. As previously stated, they assert that the primary purpose of VOM policies is to prevent transmission from unvaccinated HCWs to their patients prior to symptom onset, or, in cases of asymptomatic infection.

288. Review of this stated purpose requires an assessment of the evidence said to support it, to which I now turn. I have endeavoured earlier in this Award and in the Appendices to set out a summary of that evidence at least in outline form; there is no point in repetition.

Risk posed by unvaccinated HCWs

289. There was vigorous disagreement about the scientific merit, and relevance to acute care hospitals, of the findings of several RCTs conducted in long term care facilities. These RCTs are said to confirm that influenza vaccination of HCWs will produce substantial all-cause mortality reduction. Dr. McGeer and Dr. Henry also rely upon several observational and experimental studies in other settings. Dr. McGeer maintains that: "since an infected healthcare worker can transmit influenza to persons he or she comes into contact with, it must be true that preventing influenza in patient care staff reduces the risk that they will transmit influenza to patients".[403]

290. While the latter statement seems axiomatic, Dr. McGeer and Dr. Henry concede that there are differences between the very enclosed setting of long-term care and ambulatory or hospital care. These differences alter the balance of what is at risk from a HCW as opposed to from other people.[404] While the OHA/SAH experts opine that these observational and experimental studies provide support for the RCT findings, they appear to me in some cases to be quite remote and of extremely

[403] See above, at para. 142
[404] Transcript, June 24, 2015, A. McGeer, p. 142; See above, at para. 143

limited assistance. Other experts in the field have challenged their relevance and judged some of them harshly.

291. The RCTs have also been the object of detailed criticism from other reviewers and investigators as earlier related. Dr. McGeer and Dr. De Serres, to say the least, engaged in vigorous debate as to the merit and relevance of these RCTs. I do not propose to describe, let alone make any finding concerning the quite arcane aspects of their disagreement about Dr. De Serres' calculations as to the suggested numbers needed to vaccinate in order to prevent one death in Canadian acute care facilities, his application of the epidemiological dilution principle, and his explanation of why he supports the Cochrane Review's[405] highly critical assessment of the RCTs. I accept Dr. McGeer's observation that determining the proportion of hospital acquired influenza that is associated with HCWs is an extraordinarily difficult challenge given the complexity and communicability of influenza.

292. However, broad controversy concerning the merit of the subject RCTs arose in the scientific community well before the commencement of this litigation and has not dissipated since the release of the Diebolt Award notwithstanding the Ahmed review. Indeed the experts have continued to debate Ahmed itself.

293. On the evidence heard in this proceeding, I am not able to conclude that Dr. McGeer's opinion--that the specific burden of influenza caused by transmission from HCWs is no longer relevant given the RCT findings--should necessarily prevail to the extent that that issue is important to the outcome of this arbitration.

Asymptomatic transmission

294. The experts do not agree about this issue either although they do agree that the scientific evidence in support of the claim, that asymptomatic transmission is

[405] Exhibit 85

important, is limited. Dr. McGeer concedes that: "the truth is we simply do not know much about transmission risk at a population level".[406] Dr. Henry states that there is "some evidence that people shed prior to being symptomatic and some evidence of transmission" but "there is not a lot of evidence around these pieces".[407] Dr. De Serres says that there is "scant evidence".[408] Dr. Skowronski, whose expertise is acknowledged by Dr. Henry who is her colleague, co-authored a letter to the Canadian Medical Association Journal stating that: "The evidence that pre-symptomatic or asymptomatic infections contribute substantially to influenza transmission remains scant."[409]

295. The experts also commented upon the degree of risk attendant upon pre-symptomatic or asymptomatic virus shedding. Dr. Henry and Dr. McGeer concede that symptomatic patients will shed more particles but Dr. McGeer speculates that individual heterogeneity may mean that some asymptomatic high viral shedders are very important in transmission. On the other hand, Dr. De Serres, Dr. Gardam, and Dr. Lemieux all point to the Carrat meta-analysis to support their opinion that asymptomatic transmission is unlikely to be of clinical significance. Dr. Lemieux described the period of asymptomatic time to be a "very short window" of less than a day. Dr. Gardam said that an asymptomatic individual does not produce a lot of large droplets.

296. The several authorities relied upon by the OHA/SAH experts for their opinions on this subject, or to which they were referred, are identified previously in this Award. It is apparent that some of these studies were not about asymptomatic infection or were not cited in support of the proposition that influenza can lead to asymptomatic infection. Others concluded that viral shedding without apparent

[406] See above at para. 156
[407] See above at para. 161
[408] See above at para. 155
[409] See above at para. 170

symptoms was infrequent. There were household studies and others involving a very small number of people.

297. Based upon my review of this material noted above and canvassed in more detail in Appendix B, and bearing in mind the concessions made about the quality of this evidence by Dr. McGeer and Dr. Henry, it appears to me that conclusions stated in the Patrozou review remain accurate:

> Although asymptomatic individuals may shed influenza virus, studies have not determined if such people effectively transmit influenza…Based on the available literature, we found that there is scant, if any, evidence that asymptomatic or presymptomatic individuals play an important role in transmission. [410]

Use of masks to reduce transmission risk

298. The experts also agree that there is limited evidence on the significant point of the utility of masks in reducing transmission risk.

299. Although she referred to "good evidence" in her Report, Dr. McGeer gave oral testimony that: "It's not great evidence…it's hard to put a number on it, but you can't walk away from this saying there is no evidence that wearing a mask prevents you from influenza". She also said: "So the truth of the matter is that none of us are really experts in source control. There's quite a limited literature." [411]

300. Dr. Henry is "not a huge fan of the masking piece" and agreed that: "there's very scant evidence about the value of masks in preventing the transmission of influenza". It is her view however that, although the evidence is "not conclusive", "if healthcare workers are unvaccinated, wearing masks almost certainly provides some degree of protection to their patients".[412]

[410] Exhibit 230, Synopsis.
[411] See above at para. 179
[412] See above at paras. 178 and 184

301. Dr. Brosseau observed that "there are a very small number of studies examining the efficacy of surgical or medical masks for protecting patients from infection" although she conceded in cross-examination that "there is in fact qualitative evidence in support of reduction of transmission of large droplets", that she describes as a "very low probability event". She said that in her experience the masks used at SAH[413] would very likely not have very good filter performance or efficiency.[414]

302. The literature relied upon by Dr. McGeer and Dr. Henry, and the comments of the various experts thereon, have also been previously identified and are referenced in Appendix C. There is no point in repeating what has earlier been recorded about the testimony they gave. I conclude that the most that could be said is that there is agreement that a mask is likely to prevent the transmission of large droplets at close range. I accept on the evidence of all of the experts, as did Arbitrator Diebolt[415], that masking will act as a barrier and provide some patient protection when an infected person, coughing or sneezing, transmits large droplets to another person. Having said that, sick HCWs are not supposed to be at work although, of course, we know that this occurs.[416] I accept that the real life prospect of infected HCWs sneezing or coughing close to, or directly into, the face of patients is slim not to say that it could never occur.

303. Having considered that material and the witness commentary, I conclude as did the authors of the bin-Reza systematic review:

> There are limited data on the use of masks and respirators to reduce transmission of influenza... None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection.[417]

---

[413] Samples of the masks used at SAH were introduced into evidence: Exhibits 9, 10

[414] See above at paras. 188-189

[415] Diebolt Award, para.189

[416] As previously noted, the Policy actually contemplates that some infected employees must work (i.e. absence of worker poses a risk to patient safety): Exhibit 3, Tab A, 4, 2.4

[417] Exhibit 122. This was a "systematic review of the scientific evidence" published in 2011. The comment continues to be apt. It acknowledges that: "Some evidence suggests that mask use is best

Mask-wearing issues

304. Once again, the evidence on the impact on HCWs of long-term mask wearing has been previously reviewed above.

305. While I accept Dr. McGeer's explanation that surgical/procedure masks are worn routinely in hospitals in a variety of circumstances, the direct evidence particularly of RN Cook, that masks are unpleasant if worn for extended periods, persuades me. Her evidence, supported by the personal experiences of Dr. Lemieux and Dr. Gardam, seems to me to be irrefutable. It has a clear ring of practical truth.

306. Insofar as ONA's evidence concerning the difficulty of performing some nursing duties while wearing masks is concerned, I agree with the approach taken by Arbitrator Diebolt. If the Policy were sustained, I accept that such difficulties could and would be accommodated. If they were not, such issues could be made the subject of separate focused grievances. I do not believe that the general validity of the Policy should be tested by exceptional situations.

Why not mask everyone?

307. As previously explained, ONA submits that the illogicality of the VOM Policy at SAH is disclosed by the absence of a requirement to mask everyone. The Union does not of course agree that the Policy would be acceptable should the Hospital have done so.

308. Dr. De Serres, Dr. Gardam, and Dr. Lemieux provided sharp commentary on this issue in their pre-hearing material and in their testimony. It is argued that, with a vaccine efficacy rate of 60% on average, there are many vaccinated HCWs who

---

undertaken as a package of personal protection especially hand hygiene." See Appendix C, paras. 404-408 below.

stand in the same shoes as their unvaccinated colleagues insofar as risk of influenza is concerned. In a mismatch year, the number of equivalently situated persons only rises, potentially to the 2014-2015 extreme outcome. If hospital authorities were convinced about the utility of masks for the purpose alleged, why not mask everyone?

309. Dr. Henry and Dr. McGeer were asked this question and, with respect, I found their answers, set out in full above[418], to be less than convincing. Their more terse comments however seemed right to me. Dr. McGeer said: "The masking alternative [to vaccination] is honestly a somewhat desperate attempt to find the solution to the problem that we want to respect health care workers' choices about vaccination." Dr. Henry stated: "It's a challenging issue and we've wrestled with it. I'm not a huge fan of the masking piece. I think it was felt to be a reasonable alternative where there was a need to do—to feel that we were doing the best we can to try and reduce risk." Neither explained to my satisfaction, or to my understanding, why masking should not be required generally if the risk of HCW transmission is as serious as they maintain and if masks actually serve as an effective intervention. In my view their explanations do not adequately answer the contrary point of view expressed by Dr. Gardam, Dr. Lemieux, and Dr. De Serres.[419]

310. For the same reason, ONA also raises the issue of why the Policy does not apply to visitors and to HCW/patient interaction in other areas of the Hospital, for example, cafeterias.

Conclusion re reasonableness

311. Having considered all of the evidence led in this proceeding to the best of my ability, I reach a different conclusion than did Arbitrator Diebolt on the broad issue of reasonableness.

---

[418] See above para. 217 (A. McGeer); para. 219 (B. Henry)

[419] See above at paras. 212-216

312. In short, I am not satisfied that the patient safety purpose and effect of masking has been established as it was before Arbitrator Diebolt. In that circumstance, I am left to conclude that the VOM requirement reduces to "coercive tool", a situation that Arbitrator Diebolt said "would be troubling" if made out.

313. I find the Policy at SAH to be unreasonable for the following reasons.

purpose

314. The VOM Policy was introduced at SAH for the purpose of driving up immunization rates. The Hospital pursued a VOM policy despite concerns raised by senior medical staff including the Chief of Staff and the Chief Nursing Executive. The Hospital failed to consult with infectious prevention and control experts on retainer. CEO Gagnon announced that the Policy would be implemented should an immunization rate of 70% not be achieved. There is no evidence of any medical or scientific rationale for such a condition or for the 70% target rate selected.

315. In short, the laudable goal of preventing hospital-acquired influenza by enhancing vaccination rates was advanced by adoption of a VOM policy, what I see as a colourable means of accomplishing a legitimate objective. From the beginning masks were cast as a "consequence" for failure to vaccinate.[420] They were not advanced at SAH as useful instruments for patient safety in and of themselves.

[420] See: CEO Gagnon's reference to "consequences" as early as January 30, 2013, Exhibit 3, Tab D,15; See: Transcript, June 22, 2015. Dr. Henry commented in her direct examination that U.S. studies show that voluntary efforts to increase vaccination rates are of limited value. The only studies that show increased HCW immunization rates over a long time have included "consequences if people don't get immunized", vaccinate or wear a mask during influenza season; See also Exhibit 199, Dr. McGeer, "Why Vaccination Matters", mask requirement referred to as "consequence" for refusal to vaccinate, U.S. hospitals, pp.51-53

quality and weight of evidence

316. Arbitrator Diebolt preferred the employers' evidence before him on the question of whether the immunization of HCWs reduces transmission of the disease to patients. He did so for four reasons: (i) the union experts overlooked a considerable body of evidence beyond the RCTs, (ii) laboratory and ethical issues pose a barrier to the conduct of RCTs in acute care facilities and, therefore, it is sensible to have regard to other forms of evidence, (iii) because an infected HCW can transmit influenza to others it must be true that preventing influenza in HCWs reduce the risk of transmission to patients, (iv) "given the areas of expertise of McGeer and Henry their evidence on the transmission issues have special relevance".[421]

317. For reasons previously provided, I am unable to prefer the quality of the expert opinion advanced by the OHA/SAH employer to that of ONA on the basis of comparative expertise concerning the key issues in dispute. Fair recognition of the collective research and practical expertise of Dr. De Serres, Dr. Gardam, Dr. Lemieux, and Dr. Brosseau implies not the slightest disrespect to that of Dr. McGeer and Dr. Henry.

318. The testimony of the ONA experts supported the union expert evidence set out in some detail in the Diebolt Award. What is extremely clear is that the evidence underpinning an assessment of the burden of disease caused by unvaccinated HCWs has come under heavy criticism from several reputable sources apart from the experts who appeared in this case. Arbitrator Diebolt found that union witnesses overlooked transmission evidence beyond RCTs. The ONA experts did not overlook such evidence. In my opinion the extremely limited, not to say absolute lack of, assistance of such evidence was demonstrated. While I do not find it necessary to

[421] Diebolt Award, paras. 179-182

delve into the intricacies of the debate on this issue and to choose between the proponents, I am not able to prefer the views of Dr. McGeer and Dr. Henry.

319. The union position before Arbitrator Diebolt was that: "there is real doubt and little if any reliable evidence to show that silent shedders transmit influenza or that masking would inhibit such transmission."[422] After weighing the competing evidence before him, Arbitrator Diebolt concluded otherwise. On what appears to be a greater depth of evidence review conducted in this proceeding, I take the opposite point of view. In my opinion ONA has established, on its own evidence and through the admissions of the OHA/SAH experts in cross-examination, that there is scant scientific evidence concerning asymptomatic transmission, and, also, scant scientific evidence of the use of masks in reducing the transmission of influenza virus to patients.

320. A question arose about what should follow if the evidence on masks was weak: 'Is *any* evidence sufficient to sustain the policy or where is the line drawn?'[423] To paraphrase the answer of the Hospital: 'something has to be found if HCWs fail to vaccinate, some evidence of source control protection is sufficient'. To quote directly:

> You should be comforted that Arbitrator Diebolt had the same issue. And he said, it's not as fulsome, it's not as complete, there's not as many years studying this, there's some evidence. He found the qualitative evidence was there. In terms of the spectrum, I'm not sure whether it has to be some or any, but the point being it is absolutely not on to say there is no evidence…this is an acute care hospital with a number one obligation of patient safety—and I'll use the word that Dr. McGeer used—struggling, therefore with the fact that they have to recognize there's a collectively bargained provision in 18.07 that acknowledges a right to refuse, it's not required to vaccinate…But they are, therefore, having to recognize we have to find something, if you choose not to vaccinate, that provides we're comforted with some protection as source control…even if you said it's, to my view, not as strong as Arbitrator Diebolt says, that you still have to find there is some evidence and they're seeking some solution of protection.[424]

[422] Diebolt Award, para.190

[423] Transcript, July 8, 2015, p.126

[424] Transcript, July 8, 2015, pp.127-128

321. The word "some" of course is an adjective that may convey a wide range of meaning depending upon the context of its use. "Some" might mean 'very little' or 'quite a lot'. I am not able to conclude that "some" evidence, evidence as scant as appeared here, is sufficient to bear the weight of a Policy such as this one.

322. The assertion that a mask requirement serves a valuable or essential purpose, albeit that there is only "some" evidence, is also weakened by actual employer practice. If the mask evidence were as supportive as claimed, it would suggest that vaccinated HCWs should also wear masks given the limited efficacy of the vaccine even in relatively 'good' years. The SAH Chief of Medical Staff raised this question at the outset. The Hospital's failure to consider re-evaluating the Policy's application when the extent of the 2014-2015 vaccine mismatch became known raises the same issue. The OHA/SAH expert responses to these questions set out in full above[425] were short of satisfying.[426]

the 'ask'

323. Wearing a mask for an entire working shift, virtually everywhere, no matter the patient presenting circumstances, is most unpleasant. While I readily accept that the wearing of a mask for good reason may reasonably be expected of HCWs, an *Irving* "balancing of interests" is required. The Policy makes a significant 'ask' of unvaccinated employees; that is to wear an unpleasant mask for up to six months at a time. As noted, the evidence said to support the reason for the 'ask'—evidence concerning asymptomatic transmission and mask effectiveness--may be described at best as "some" and more accurately as "scant". I conclude that many of the articles footnoted in support of the strong opinions set out in the OHA/SAH expert

[425] See above at paras. 217 and 219

[426] The Policy's exceptions for visitors, and certain other HCW/patient areas of the Hospital, were not explained in evidence although the Union had raised these issues. OHA/SAH counsel speculated in an answer to a question in argument that there may have been enforcement considerations. See: Transcript, July 8, 2015. p.137

Reports provide very limited or no assistance to those views. The required balancing does not favour the Policy.

existing policies

324. There has been no showing as to why current Hospital policies are not adequate or could not be amended, if necessary to the extent necessary, to carry out the stated patient safety purpose of the Policy. They already speak to precautions required where there may be transmission of droplets to another person within two metres. There were no influenza outbreaks at the new Hospital site prior to the introduction of the Policy. Ironically, an outbreak, that occurred on three units after VOM implementation, affected 16 patients and staff of whom 75% had previously received influenza vaccination. The current Infection Control Manual that includes a mask component is said to apply to patients and staff although the focus is plainly upon patients with infection.[427]

inconsistency with collective agreement

325. I have found that the Policy was instituted for the purpose of increasing vaccination rates to a target figure deemed acceptable by the Hospital and that there is insufficient evidence to support its introduction on any other basis. In that circumstance, I conclude that the Union has established that the Policy is inconsistent with the collective agreement and therefore fails item #1 of the *KVP* test as well. The Policy is not a reasonable rule as would otherwise be permissible pursuant to Article B-1 (e) of the ONA/SAH Local Agreement.

326. ONA and the OHA/SAH have negotiated a detailed influenza outbreak protocol that includes recognition of the benefit of influenza vaccine. It also, in Article 18.07, recognizes the right of nurses to refuse any required vaccination. The

[427] Exhibit 2, IPAC Policy II-25, B and C

imposition of a mask requirement, without sufficient justification relating to the use of masks, is tantamount to an impermissible penalty upon a nurse choosing to exercise that right. In this regard, I note Dr. Henry's recognition that the wearing of a mask could be reasonably regarded as a "consequence" for failure to consent to vaccination.[428] The Policy is inconsistent with Article 18.07 (c) in that it operates to undermine the right of nurses to refuse any required vaccination.

accommodative purpose

327. Rather than finding, as did Arbitrator Diebolt, that a VOM policy provides a legitimate "accommodative purpose for health care workers who conscientiously object to immunization"[429], I conclude that the Policy more closely resembles an unacceptable Hobson's choice. I am not persuaded by Dr. McGeer's speculation that a VOM policy focuses employees' attention and may encourage truly voluntary immunization, nor, am I convinced that the continuance of a minority employee group who choose to mask disproves the effectively coercive aspect of VOM.[430] I note the evidence of RN Poldmaa who told her manager that: "I felt I was being publicly put on display for choosing not to get the flu shot. I told her I felt I was being bullied into it and harassed."[431]

practices elsewhere

328. I find little comfort in references to practices elsewhere.[432] Dr. Gardam's concerns about the TAHSN process and the recommendations of other bodies are

[428] See also Exhibit 199 where Dr. McGeer speaks to "consequences" also. See also references above at Footnote 420.
[429] Diebolt Award, para.188
[430] Transcript, July 8, 2015, pp. 123-124
[431] Transcript, October 9, 2014, p. 14
[432] See: Exhibit 185, A. McGeer Report, p. 54; See also: Diebolt Award at paras. 194-196

concerning[433] although I do not depend upon his extremely critical recitation. What I find more noteworthy is that the provincial authorities have not taken steps in Ontario to designate influenza for mandatory HCW immunization or to require or recommend the consideration or implementation of some form of a province-wide VOM policy. There is a clear statutory basis for the designation of diseases requiring vaccination.

Privacy issues

329. In view of my conclusion that the VOM Policy is unreasonable and contravenes *KVP* principles, it is not necessary that ONA objections to the Policy on the ground that it violates employee privacy rights be addressed. For reasons of completeness, if my conclusion concerning the Policy's reasonableness is in error, I make the following brief comments.

330. Assuming the validity of the Policy, and assuming the voluntariness of the employees' consent, I would have reached the same conclusion as Arbitrator Diebolt on the narrower privacy issue, albeit under separate provincial legislation.

331. In the face of these identified assumptions, I would have accepted the submission of the OHA/SAH that the information at issue would have been excluded from protection under the *Personal Health Information and Privacy Act* (*"PHIPA"*) by virtue of ss. 4(4) of that Act and would have been similarly excluded from protection by virtue of ss. 65(6) para. 3 of the *Freedom of Information and Protection of Privacy Act* ("FIPPA").

332. Subsection 4(4) of *PHIPA* excludes certain information from the application of the Act as follows:

[433] See above, paras 240-241; If Dr. Gardam's assessment is correct, there is a serious public health policy determination process problem concerning this issue.

> 4. (4) Personal health information does not include identifying information contained in a record that is in the custody or under the control of a health information custodian if,
>
> > (a) the identifying information contained in the record relates primarily to one or more employees or other agents of the custodian; and
> > (b) the record is maintained primarily for a purpose other than the provision of health care or assistance in providing health care to the employees or other agents.

333. Subsection 65(6) para. 3 of *FIPPA* similarly excludes certain information from the Act's ambit:

> 65. (6) Subject to subsection (7), this Act does not apply to records collected, prepared, maintained or used by or on behalf of an institution in relation to any of the following:
> ....
> > 3. Meetings, consultations, discussions or communications about labour relations or employment-related matters in which the institution has an interest.

334. While not binding, a decision of an analyst from the Office of the Information and Privacy Commissioner of Ontario is instructive on these points.[434] The decision deals with a nurse's complaint about a VOM policy at North York General Hospital in which individuals who received the influenza vaccine had identifying stickers on their badges or a lanyard of a different colour. The nurse argued that this improperly made her persona health information public knowledge. Broadly stated, under the VOM Policy, vaccination information is collected about employees and is maintained for a purpose other than the provision of health care to those employees. As a result, it is excluded under ss. 4(4) of *PHIPA.* The information is also collected, maintained and used by the SAH for the purpose of implementing a VOM Policy setting out terms and conditions of work and so relates broadly to labour relations or employment-related matters in which the institution has an interest. As a result, it is also excluded under ss. 65(6) of *FIPPA*.

335. Ultimately, though, these observations on the privacy legislation are *obiter* and do not affect the determination of these grievances because I have ruled that the VOM Policy as a whole fails to comply with *KVP* principles and so constitutes an unreasonable exercise of management rights. In the course of that determination, I

[434] Complaint HC 14-108 re North York General Hospital, March 26, 2015 (Rioux)

have also ruled that I am not convinced that the VOM Policy encourages truly voluntary immunization and/or disclosure of immunization status.

Final Comments

336. I return now to the issue raised at the outset of this Award.

337. Let there be no doubt that the intentions and opinions of CEO Gagnon, Dr. McGeer, and Dr. Henry are entitled to great respect. However, the VOM Policy—a mandated regimen for how patient care is to be delivered—is at the same time a unilaterally imposed term and condition of employment and it is properly and squarely within an arbitrator's jurisdiction to assess it as such. While this has not been an easy case because of the volume of expert evidence and the quality of the competing expertise, the only forum in which it can be required that labour relations considerations be addressed is before an arbitrator.

338. To review the labour relations implications of the VOM Policy does not disregard or discount the medical expertise. It simply recognizes that the medical expertise has a different focus that is incomplete for the purposes of the legal question at issue. While important in assessing what is reasonable, the medical expertise is not controlling in and of itself because it does not engage the labour/human rights/privacy expertise that balances employee rights with scientific information.[435]

339. It is surely the case that there are better ways of resolving complex policy issues such as this, in which many stakeholders have an interest, but this does not in any way displace or discredit the legitimate role of labour arbitration. It is very likely that the science will evolve and opinions about the prevention and control of influenza disease may coalesce into more of a consensus than has been achieved to

[435] The TAHSN Report acknowledges certain of these interests as noted above. See: Exhibit 185, Appendix C.

date. But, there are lines to be drawn in the meantime. Where their working lives are directly affected, the interests of employees require consideration, and, typically, their unions have recourse to rights arbitration to test judgments that have been made.

340. *Irving* balancing demands nuance and it is not sufficient to claim that scant, weak, "some", or imperfect data is better than nothing. While the precautionary principle ("reasonable efforts to reduce risk need not wait for scientific certainty"[436]) surely applies in truly exceptional circumstances, one could not live in a society where only 'zero risk' was tolerated. It cannot be right that a labour arbitrator should effectively abdicate by simply applying *Dunsmuir*-type deference to expert opinion planted in shallow soil.

341. It is also important to stress once again what this arbitration case was not about. The Award does not address the merits of influenza vaccination--a matter about which the experts agree and about which ONA and the OHA have reached specific agreement in the Central Collective Agreement. Nothing in this Award is intended to dissuade anyone from the benefit of annual influenza immunization whatever may be the vaccination efficacy rate in any particular year.

Decision

342. On the evidence before me, I find the VOM provisions of the SAH Policy to be unreasonable. Accordingly, for all of the foregoing reasons, I declare SAH to be in breach of Article B-1 (e) of the ONA/SAH Local Agreement and Article 18.07 (c) of the ONA Central Agreement.

[436] Cited in Diebolt Award, para. 196; See also: Transcript, January 26, 2015, pp.84-86 where Dr. Lemieux provides an extended explanation as to why the principle does not apply to influenza in her opinion where it would concerning SARS, Ebola, MERS and the like.

343. Any question concerning the need, if any, for additional relief is remitted to the parties for their consideration. I remain seized of remedial issues.

Dated at Toronto, this 8th day of September, 2015

James Hayes

APPENDIX C

Mask and related literature: witness commentary

Johnson[506]

387. As previously noted, with an important qualification, Dr. Brosseau confirmed the opinion of Dr. McGeer[507] and Dr. Henry that the study provides "some limited qualitative evidence" that a mask may prevent the release of large droplets. Dr. Henry testified that: "this study showed, in a small number of people, that both surgical masks and the respirator were good at trapping the droplets in, that they didn't come through the mask when somebody coughed".[508]

388. Dr. Brosseau noted that the study involved individuals coughing directly into Petri dishes with and without a mask. She stated that: "the Johnson study really gives you no data about the capture by a filter or a surgical mask of these smaller infectious particles".[509] She described the study this way:

> That Petri dish is probably just capturing the very large ones that are going straight out of the mouth…bases on my knowledge of aerosols and samplings and particle size, that it is those large droplets that are emitted straight outward during coughing that were captured by the Petri dish. Anything that was smaller that would have been emitted to the side or through the filter would not have been captured by that Petri dish…..this study offers qualitative support that a surgical mask may be able to stop the release of large particles greater than 5 to 10 microns from a person who is coughing or sneezing directly into the mask worn over their mouth and nose.[510]

[506] Exhibit 27
[507] Transcript, June 24, 2015, pp. 148-149
[508] Transcript, June 22, 2015, p. 84
[509] Transcript, May 11, 2015, p. 191
[510] Transcript, May 11, 2015, pp. 189-190

Milton[511]

389. The Abstract for this study reads in part:

> The CDC recommends that healthcare settings provide influenza patients with facemasks as a means of reducing transmission to staff and other patients and a recent report suggested that surgical masks can capture influenza virus in large droplet spray. However, there is minimal data on influenza virus aerosol shedding from patients with seasonal influenza….Overall, masks produced a 3.4 fold (95% CI 4.1 to 19) reduction in viral aerosol shedding….Surgical masks worn by patients reduce aerosols shedding of virus. The abundance of viral copies in fine particle aerosols and evidence of their infectiousness suggests an important role in seasonal influenza transmission. Monitoring exhaled virus aerosols will be important for validation of experimental transmission studies in humans.

390. Dr. Brosseau concluded that the Milton study demonstrated that surgical masks "offer little or no reduction in small infectious aerosols from the wearer".[512]

391. Dr. McGeer commented that a 3.4 fold reduction is:

> not a big enough reduction to really matter in her [Dr. Brosseau's] world of occupational hygiene…To me, living with influenza, where nothing is perfect, and everything has to be judged on its relative benefit a 3.5 fold reduction is not half bad, okay. So, I think it is incorrect to say the surgical mask does not reduce the emission of small, inhalable, infectious particles. It does reduce it. It just doesn't reduce it as completely as it reduces the emission of larger particles at the same time.[513]

Makison Booth[514]

392. The witnesses confirmed[515] that this study was conducted with dummies and focused on the performance of masks in protecting the wearer. Dr. Lemieux said that she did not view the article as "being particularly on point".[516]

---

[511] Exhibit 28

[512] Exhibit 50, Response to Comments, at first unnumbered page

[513] Transcript, June 24, 2015, pp. 98-99; See also: Transcript at pp. 149-150 where reference is made to a 2.8 fold reduction in small particles as a "non-trivial reduction".

[514] Exhibit 29

[515] Exhibit 50, Report, L. Brosseau, Response to Comments, at second unnumbered page; Transcript, June 26, 2015, p. 14

[516] Transcript, January 26, 2015, p. 163

Loeb[517]

393. Dr. Lemieux explained that this study was a non-inferiority trial stating that:

> This study simply looks at whether a surgical mask is any different than a N95 respirator preventing influenza among healthcare workers. It's really just comparing one to the other. And the only conclusion that can be drawn from this particular study is that a mask is as good as a N95…in terms of rates of laboratory confirmed influenza among healthcare workers. It says nothing about protecting patients. It says nothing about asymptomatic transmission and it really doesn't address the crux of any of the issues I think we're trying to get at today.[518]

394. Dr. Lemieux also went on to make an observation that she said applied to a number of studies, including *Loeb*, that she did not see as helpful to consideration of the merits of a VOM policy:

> These studies look at more than one intervention to control influenza transmission. If you're combining a number of interventions—and in this case, on the face of it, face masks and hand hygiene—it's virtually impossible to tease out what the relative impact is of one versus the other. We know that combined they have an impact. We can't specifically say that face masks had a predominant effect, we just know that both together did. I don't think it speaks at all to specifically whether masking as an intervention in healthcare workers will have a priority impact on transmission.[519]

Mansour[520]

395. Dr. Brosseau explained that the study involved placing types of masks and respirators with varying fits on mannequins, located about three feet away using small radioactive aerosols, with the source mannequin generating an aerosol. She testified that:

> So what they're basically saying is if you put anything on the source, a loose surgical mask, a tight fitting surgical mask, an N95 respirator or a sealed N95 respirator sealed to the face, the receiver gets no exposure, it's zero….if the infectious source, whether you're wearing a surgical mask or an N95 respirator and you seal the respirator to your face, you can reduce the amount of transmission basically at the receiver. Now I should be clear, while these are small particles, what we're not measuring is what is the size distribution of the particles at the point where the exposure is being measured…I wish they had just taken this one more step and measured the size distribution of the particles at the point where the exposure filter is, because that would have told us the story about large versus small particles. But what this is telling you is that a source can wear

[517] Exhibit 30

[518] Transcript, May 11, 2015, pp. 99-100

[519] Transcript, May 11, 2015, p. 104

[520] Exhibit 56

> anything, and that at least—and this agrees with what I've been saying, at least all the large particles are eliminated.[521]

396. Dr. Henry also noted the lack of exposure to droplets and stated further that the fit of a mask or respirator "made a difference in terms of preventing droplets from being expelled".[522]

397. Dr. McGeer noted that "as the fit gets better on either the source or receiver the number of particles that get through to the receiver's respiratory tract goes down".[523]

Cowling (2009)[524]

398. As explained by Dr. Henry, this was a randomized control trial done in household settings. She stated that: "not surprisingly", "Things like hand hygiene, cleaning your hands regularly were important but use of face mask along with hand hygiene seemed to provide some benefit in prevention of a whole host transmission of influenza".[525]

399. Dr. McGeer commented at some length on the applicability of studies not conducted in acute care settings:

> I think there is an argument that says that if you look at, you know, in this setting, in households, in university residences, on aircraft, if you look at the case control study there, all of them have some evidence that a mask provides some protection....I mean, they're unquestionably not the best evidence. I'm very sympathetic to Dr. Brosseau's world of order and organization, and you don't get that level of organization when you do studies in households. It's difficult to interpret studies when there are issues with adherence...but to my mind it doesn't alter the fact that there is some evidence that wearing a mask, particularly wearing a mask in combination with good hand hygiene, can reduce your risk of infection at least in some circumstances.[526]

---

[521] Transcript, May 11, 2015, pp. 201-203
[522] Transcript, June 22, 2014, pp. 88-9
[523] Transcript, June 25, 2015, p. 224
[524] Exhibit 31
[525] Transcript, June 22, 2015, p. 89
[526] Transcript, June 24, 2015, pp. 153-154

Suess[527]

400. This was a cluster randomized household trial conducted in Berlin unrelated to hospitals or healthcare. It concluded that: "household transmission of influenza can be reduced by the use of non-pharmaceutical interventions such as facemasks and intensified hand hygiene when implemented early and used diligently".[528]

Zhang[529]

401. This study concerned influenza infections that developed in passengers after travelling on flights from New York to China. The authors concluded that: "We recommend a more comprehensive intervention study to accurately estimate the protective effect of face masks for preventing influenza virus transmission on long-distance flights".[530]

402. When asked to comment on what this study has to say about VOM, Dr. Lemieux said that it indicates that wearing a mask will provide some level of protection against clinical disease around a person known to be symptomatic.[531]

403. As previously stated, Dr. McGeer conceded that this study was "unquestionably not the best evidence"[532]. She noted that the investigation self-reported several limitations.[533]

[527] Exhibit 32
[528] Exhibit 32, Abstract
[529] Exhibit 33
[530] Exhibit 33, p. 1408
[531] Transcript, May 11, 2015, p. 105
[532] Transcript, June 24, 2015, p. 154
[533] Transcript, June 26, 2015, p. 58

bin-Reza[534]

404. This 2011 article is titled "The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence". Included for review were "randomized controlled trials and quasi-experimental and observational studies of humans published in English with an outcome of laboratory-confirmed or clinically-diagnosed influenza and other viral respiratory infections".[535]

405. The Abstract of this systematic review noted that:

> There are limited data on the use of masks and respirators to reduce transmission of influenza.... None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection. Some evidence suggests that mask use is best undertaken as part of a package of personal protection especially hand hygiene.[536]

406. This was another study described by Dr. McGeer as "unquestionably not the best evidence" [in support of the Policy].[537] Dr. McGeer confirmed the conclusion of the authors that: "None of the studies established a conclusive relationship between masks/respirator use and protection against influenza infection."[538]

407. Dr. Henry stated that this article demonstrated that there was "not a lot of direct evidence" but that "there was some evidence that it provides some benefit". She explained that, because "there is not a lot of direct evidence...that's why I think why we include studies that are not necessarily in a health care setting".[539]

---

[534] Exhibit 122
[535] Exhibit 122, Abstract
[536] Exhibit 122, Abstract
[537] Transcript, June 24, 2015, p. 154
[538] Transcript, June 26, 2015, pp. 56-57
[539] Transcript, June 22, 2015, p. 91

408. Dr. Brosseau testified that: "this review also does not support the—it doesn't present any strong evidence for either surgical masks or N95 respirators mostly because the studies are not powered or not done correctly".[540]

Cowling (2010)[541]

409. This literature review under Discussion included the following conclusions that were reviewed with Dr. McGeer in her cross-examination:

> Our review highlights the limited evidence base supporting the efficacy or effectiveness of face masks to reduce influenza virus transmission....In future similar studies it would be important to consider the potential for leakage around the sides of the mask in addition to direct penetration of infectious viral particles through the mask, if the results are to have practical implications for reduction of transmission in community and other settings. Further studies are needed to investigate how mask and respirator performance varies with temperature and humidity, or under working conditions when moisture in exhaled breath or sweat may build up in face masks and hinder filtration or fit.[542]

Canini[543]

410. Dr. McGeer agreed that this study provides "no evidence at all" concerning the effectiveness of face masks in the context of seasonal epidemic".[544]

MacIntyre (2011)[545]

411. Dr. McGeer confirmed that this study, for the reason given by the authors[546], concluded that: "As a consequence, it is not possible to make any definitive judgment on the efficacy of masks on this basis."[547]

---

[540] Transcript, June 6, 2015, p. 16
[541] Exhibit 121
[542] Exhibit 121, p. 453-454
[543] Exhibit 215
[544] Transcript, June 25, 2015, p. 236
[545] Exhibit 216
[546] Exhibit 216, p. 176
[547] Transcript, June 26, 2015, p. 21

MacIntyre (2009)[548]

412. This was a household study concerning which Dr. McGeer confirmed that "the very authors of this report urge caution in applying it to healthcare settings"[549]:

> We urge caution in extrapolating our results to school, workplace, or community contexts, or where multiple, repeated exposures may occur, such as in healthcare settings. The exact mechanism of potential clinical effectiveness of face mask use may be the prevention of inhalation of repeated respiratory pathogens but may also be a reduction in hand-to-face contact. Our study could not determine the relative contribution of these mechanisms.[550]

Simmerman[551]

413. This randomized control household trial concluded that: "Influenza transmission was not reduced by interventions to promote hand washing and face mask use".[552]

414. Dr. McGeer said this about this study in cross-examination: "You can argue that because adherence was so poor, the negative trial really doesn't matter and maybe I should not have wasted people's time on it…"[553]

Larson[554]

415. This was another household study, one of primarily Hispanic households. The authors concluded that:

> There was no detectable additional benefit of hand sanitizer or face masks over targeted education on overall rates of upper respiratory infections but mask wearing was associated with secondary transmission and should be encouraged during outbreak situations.[555]

---

[548] Exhibit 217
[549] Transcript, June 26, 2015, p. 27
[550] Exhibit 217, p. 239
[551] Exhibit 218
[552] Exhibit 218, p. 256
[553] Transcript, June 26, 2015, p. 31
[554] Exhibit 219
[555] Exhibit 219, p. 178

416. Dr. McGeer commented that:

> I would rate it probably in this list of studies as second lowest on the list after Simmerman in terms of its value in assessing transmission but it is one of the studies that has recently been done that attempts to assess whether hand hygiene and masks alter the risk of transmission of influenza and other respiratory infections.[556]

Aiello[557]

417. Dr. McGeer agreed[558] that the authors concluded that: "Neither face mask use and hand hygiene nor face mask alone was associated with a significant reduction in the rate of ILI [influenza-like illness] cumulatively."[559]

Bridges[560]

418. Dr. McGeer agreed that this article does not assist in any way with respect to assessing the effectiveness of masks .[561]

McLure[562]

419. Dr. McGeer stated that this article is "additional evidence that face masks when worn by individuals prevent the egress of microbes, bacteria in this case, and viruses which are in the same emitted particles and contamination of the environment around them".[563]

---

[556] Transcript, June 26, 2015, pp. 37-38
[557] Exhibit 220
[558] Transcript, June 26, 2015, p. 42
[559] Exhibit 220, p. 491
[560] Exhibit 222
[561] Transcript, June 26, 2015, p. 62-63
[562] Exhibit 223
[563] Transcript, June 26, 2015, pp. 63-64

Bischoff[564]

420. This study related to the efficacy of surgical scrubs, gowns and masks. It concluded that: "In contrast to the efficacy of scrubs and gowns, there is only weak evidence of the efficacy of face masks".[565]

421. Dr. McGeer explained that:

> The point of this study is that for staph aureus, which colonizes the skin as well as the nose and mouth, in fact most of the shedding from healthcare workers occurs from the skin, it doesn't occur from the mouth. So it's not surprising that surgical masks don't have an impact on surgical site infections, particularly those due to staph aureus because, in that setting, protection from people's moth bacteria is not that important.[566]

[564] Exhibit 224

[565] Exhibit 224, p. 1152

[566] Transcript, June 26, 2015, p. 66

Plaintiff's Exhibit 497

IN THE MATTER OF AN ARBITRATION

BETWEEN:

St. Michael's Hospital and The Ontario Hospital Association

and

The Ontario Nurses' Association

2018 CanLII 82519 (ON LA)

Before: William Kaplan
Sole Arbitrator

Appearances

For St. Michael's Hospital & The Ontario Hospital Assn.
Roy C. Filion, QC
Melanie D. McNaught
Giovanna Di Sauro
Filion Wakely Thorup Angeletti LLP
Barristers & Solicitors

For the Ontario Nurses' Association:
Kate A. Hughes
Philip B. Abbink
Tyler Boggs
Cavalluzzo LLP
Barristers & Solicitors

The matters in dispute proceeded to a hearing in Toronto on August 9 and October 31, 2016, February 3, April 6, 29, 30, May 1, June 1, 2, 22, August 22, September 30, October 28, 29, and December 11, 2017, April 19, 21, 22, May 4, and July 16, 23, 2018.

Introduction

Summarily stated, this case concerns the reasonableness of the Vaccinate or Mask Policy (hereafter "VOM policy") that was introduced at St. Michael's Hospital (hereafter "St. Michael's") in 2014 for the 2014-2015 flu season and which has been in place ever since. Under the VOM policy, Health Care Workers and that group, of course, includes nurses (hereafter "HCWs"), who have not received the annual influenza vaccine, must, during all or most of the flu season, wear a surgical or procedural mask in areas where patients are present and/or patient care is delivered.

St. Michael's is one of a very small number of Ontario hospitals with a VOM policy: less than 10% of approximately 165 hospitals. The Ontario Nurses' Association (hereafter "the Association") immediately grieved the VOM policy in every hospital where it was introduced. It should be noted at the outset that the VOM policy has nothing to do with influenza outbreaks that are governed by an entirely different protocol, and one that is not at issue in this case.

This is not the first Ontario grievance taking issue with the VOM policy. The parties appropriately recognized that the matters in dispute were best decided through a lead case rather than through multiple proceedings at the minority of hospitals where the policy was in place. Accordingly, the Association grievance at the Sault Area Hospital was designated as that lead case and proceeded to a lengthy hearing before arbitrator James K.A. Hayes beginning in October 2014 and ending in July

2015. Arbitrator Hayes heard multiple days of evidence (replicated to some extent in this proceeding) and issued his decision, discussed further below, on September 8, 2015 (hereafter "the Hayes Award"). Arbitrator Hayes found that the Sault Area Hospital's VOM policy was inconsistent with the collective agreement and unreasonable. The grievance was, accordingly, upheld.

The Hayes Award

In the Sault Area Hospital case (SAH & OHA & ONA, [2015] O.L.A.A. No. 339), the Association asserted that the VOM policy, identical in all material respects to the one contested here, was inconsistent with the collective agreement and constituted an unreasonable exercise of management rights. The Association, in that case, took the position that there was insufficient scientific evidence supporting the VOM policy. Arbitrator Hayes agreed. He concluded that there was "scant" scientific evidence supporting the VOM policy and he upheld the grievance.

In particular, Arbitrator Hayes determined, following an exhaustive review of the scientific evidence, and the detailed and extensive submissions of the parties, as follows:

> On the merits, I sustain the core of the Union position. I find that the Policy was introduced at SAH for the purpose of driving up vaccination rates. I also find that the weight of scientific evidence said to support the VOM Policy on patient safety grounds is insufficient to warrant the imposition of a mask-wearing requirement for up to six months every year. Absent adequate support for the freestanding patient safety purpose alleged, I conclude that the Policy operates to coerce influenza immunization and, thereby, undermines the collective agreement right of employees to refuse vaccination. On all of the evidence, and for the reasons canvassed at length in this Award, I conclude that the VOM Policy is unreasonable (at para. 13).

Accordingly, Sault Area Hospital immediately discontinued its VOM policy, as did other hospitals. However, some hospitals, including a number of hospitals like St. Michael's, did not do so, necessitating this second proceeding. In order to ensure finality, the Ontario Hospital Association and the Association agreed on March 25, 2016, that the award in two St. Michael's VOM policy grievances would be binding on it and on a number of other scheduled hospitals (except to the extent that an issue raised by another policy was not addressed).

In light of the March 25, 2016 agreement, the matters in dispute proceeded to a hearing over a number of days in 2016, 2017 and 2018. The parties did not agree about much, although there was common ground that the contested scientific evidence had to be examined and then subjected to a legal assessment: did the VOM policy violate and/or conflict with the collective agreement, and was it reasonable?

Preliminary Observations

Some preliminary observations are appropriate starting with the following: St. Michael's effort to distinguish the Hayes award was unsuccessful. The new evidence that was introduced in the attempt to do so was not particularly helpful. Indeed, by and large, the same policy, the same legal issues, and some of the very same evidence that was introduced in this proceeding had earlier been put before Arbitrator Hayes. For reasons that will be elaborated below, and in general, the new evidence that was called by the Association corroborated and reconfirmed that which had been put before Arbitrator Hayes, while that called by St. Michael's was

not particularly persuasive, and as noted later, in the case of one report, has been completely disregarded.

VOM at St. Michael's – The TAHSN Report

The VOM policy was based on a recommendation drafted by a working group of the Toronto Area Health Sciences Network (hereafter "TAHSN"). TAHSN is composed of 13 Toronto-area teaching hospitals (and a number of associate hospital members).

The THASN report found as follows:

> There are several important infection control measures that help to prevent influenza transmission. These include: restricting HCWs with symptoms from attending the hospital, good hand hygiene practices, influenza vaccination, cough etiquette, early identification and management of infected patients, and appropriate outbreak management including prompt use of anti-viral medications for unvaccinated HCWs and exposed patients. The wearing of face masks can serve as a method of source control of infected HCWs who may or may not have symptoms. Masks may also prevent unvaccinated HCWs from as yet unrecognized infected patients or visitors. While all these measures are valuable and should be part of a comprehensive prevention program, vaccination remains the cornerstone of efforts to control influenza transmission.

The THASN report made it clear that voluntary efforts to increase influenza immunization had failed – 40% to 60% uptake "despite robust influenza education campaigns" – and that steps were necessary to address that failure and "to significantly improve healthcare worker influenza immunization rates." The report recommended that VOM policies "be part of a comprehensive prevention and control program aimed at preventing hospital-acquired influenza…." This recommendation was made in the admitted absence of direct evidence that mask-wearing HCWs protected patients from influenza; but on the basis of "indirect evidence [that] suggests it does." The only fair words to describe the evidence

advanced in support of the masking component of the VOM policy in the THASN report, and in this proceeding, are insufficient, inadequate, and completely unpersuasive.

The Collective Agreement

It is useful to set out certain provisions of the collective agreement:

6.05 Occupational Health & Safety

(a) It is a mutual interest of the parties to promote health and safety in workplaces and to prevent and reduce the occurrence of workplace injuries and occupational diseases. The parties agree that health and safety is of the utmost importance and agree to promote health and safety and wellness throughout the organization.

…

* When faced with occupational health and safety decisions, the Hospital will not await full scientific or absolute certainty before taking reasonable action(s) that reduces risk and protects employees.

…

* The employee shall use or wear the equipment, protective devices or clothing that the employer requires to be used or worn [*Occupational Health and Safety Act*, s. 28(1)(b).

…

(e) (vi) The Union agrees to endeavour to obtain the full cooperation of its membership in the observation of all safety rules and practices.

…

18.07 Influenza Vaccine

The parties agree that influenza vaccinations may be beneficial for patients and nurses. Upon a recommendation pertaining to a facility or a specifically designated area(s) thereof from the Medical Officer of Health or in compliance with applicable provincial legislation, the following rules will apply:

(a) Nurses shall, subject to the following, be required to be vaccinated for influenza.

…

(c) Hospitals recognize that nurses have the right to refuse any required vaccine.

One of the provisions of the local agreement is also relevant:

…the Association acknowledges that it is the exclusive function of the Hospital to…make and enforce and alter from time to time reasonable rules and regulations to be observed by nurses, provided that such rules and regulations shall not be inconsistent with the provisions of this Agreement.

Additional Preliminary Observations

Whatever its value, a labour arbitration is not an ideal forum by any intelligent measure to establish best practices in public health. In this case, a (second) hearing was made necessary by the continuing division of expert opinion, not to mention the disagreement in some quarters with the original arbitral outcome. In the result, questions that should normally be resolved by experts – based on the best possible evidence – must be decided by a decidedly inexpert tribunal through a collective agreement and labour law lens, albeit one that has been exceptionally well informed by a thoroughly argued case that included the evidence of internationally recognized experts, or persons with subject matter expertise.

There is no shortage of questions requiring answers, but two of the principal ones are the extent to which unvaccinated HCWs pose a risk to patients – a risk of transmitting influenza especially when they are asymptomatic – and whether masking appreciably reduces that risk.

The interests at issue are substantial. On the one hand, there is a hospital policy designed to ensure patient well-being by taking steps to prevent nosocomial – hospital acquired – influenza. If unvaccinated HCWs are infecting patients, and if wearing a surgical or procedural mask prevents the spread of influenza – meaning it prevents serious illness and death – that is, by any objective standard, a reasonable precaution even if the evidence is not all in. However, if the vaccination itself is of questionable utility, and if the masks are of limited value in preventing transmission of influenza by asymptomatic HCWs (symptomatic HCWS should not be at work), then the entire enterprise is put into question even if the motive underlying the policy is completely salutary.

It is clear and agreed that influenza is a serious and life-threatening illness. There is also consensus about other things. In general, the influenza vaccine is safe for most persons and has a "moderate" effectiveness for much of the population: up to 60%, (although in some years substantially less, and once in a while, vaccination provides virtually no protection). The vaccine has no effectiveness against influenza-like illnesses. The influenza virus mutates quickly, requiring annual development of a new vaccine. Vaccine effectiveness depends on the closeness of the match of the strains in the vaccine to the strains circulating in the season in which the vaccine is employed. For influenza to be transmitted, the virus must be both shed and transmitted. Contact – direct contact with the infected person, or indirect contact through infected surfaces – and droplets – particles that travel ballistically – and aerosol – particles suspended in the air – are the likely modes of transmission.

There is clearly a health benefit in vaccination. Except in years of a complete mismatch, the vaccine provides some protection against influenza. Indeed, the influenza vaccine is the best available intervention to prevent influenza (although repeated annual vaccinations reduces vaccine efficacy and this is known as the repeat vaccination effect). Effectiveness also varies with age and population groups. The general effectiveness of the vaccine, i.e., whether the vaccine is a match for circulating strains, is only ascertainable once the influenza season is underway, although early indications are available from the experience in the southern hemisphere. Because the vaccination provides only partial protection, unvaccinated HCWs contract influenza but so too do vaccinated HCWs – that is obvious given the effectiveness rate.

In the broadest possible terms, the issue to be decided, on the evidence, is whether a VOM policy for HCWs is reasonable. Stated somewhat differently, the question to be answered is whether the evidence supports the conclusion that the use of surgical or procedural masks, worn by unvaccinated HCWs for some or all of the flu season, actually results in reduction of harm to patients? Does it prevent the transmission of illness? Does it save lives? If the VOM policy prevented patient illness and saved patient lives, its reasonableness would be difficult to challenge. After all, preventing illness and saving lives is the core purpose of St. Michael's and other hospitals. It is central to the mission.

If, on the other hand, the evidence indicated that the policy did not achieve this objective, and if the science said to support it was unsound at best, then the reasonableness of the policy would be appropriately called into question.

This case was tried over multiple hearing days over three calendar years. The evidentiary record is extensive: Volumes of scientific articles – cluster randomized controlled trials (hereafter "cRCTs"), observational studies, summaries, critiques, literature reviews, meta-analyses, commentaries, etc. and numerous expert reports, more than one hundred and fifty exhibits and thousands of pages of transcript. Two Association members also testified about the impact of the VOM policy on them: their experience of being compelled to don a mask for days, weeks and months on end. But at the end of the day, the evidence adduced here leads to the very same conclusion reached by Arbitrator Hayes. The exhaustive evidentiary review in the Hayes award need not be repeated, or a similar exercise replicated here, although the key evidence and arguments must, of course, be appropriately addressed, and this follows.

Position of the Parties

Overview of Ontario Nurses' Association Submissions

The Association argued that the VOM policy must be set aside for a number of reasons including:

1. The VOM policy was inconsistent with and/or contrary to the collective agreement.

2. The TAHSN report – the basis for the VOM policy – was unreliable.

3. Evidence that masking as a source control results in any material reduction in transmission was scant, anecdotal, and, in the overall, lacking.

   In a related point, the Association argued that the evidence establishing asymptomatic transmission – that is transmission by HCWs when shedding virus either prior to symptom onset or when asymptomatically infected – was absent. The risk, based on the evidence, the Association argued, was theoretical or minimal and insufficient to justify the VOM policy on a reasonableness standard.

   In any event, if masking were effective, it would be required of all HCWs in addition to vaccination as all HCWs can acquire influenza whether vaccinated or not. The experience of mismatch years illustrated this point. From time to time the vaccine failed to work – it provided little or, rarely, no protection. In those years logic dictated a directive that everyone mask. But that was neither the policy nor the practice. The VOM policy was, in a word, "illogical."

4. There was no evidence of a problem; nor was there evidence that the "problem" was effectively addressed by the VOM policy "solution."

5. In all of these circumstances, requiring a HCW to wear a mask for each and every shift for up to six months was unwarranted and unjustifiable in light of the impact of doing so – the impact on HCWs, not to mention its adverse implications for patient care.

Inconsistent with and/or Contrary to the Collective Agreement

In the Association's submission, St. Michael's could issue rules and regulations, but they could not be inconsistent with and/or in conflict with the collective agreement. However, the VOM policy did just that by undermining and interfering with the categorical right of a nurse to refuse an unwanted vaccination. The VOM policy was unreasonable as it coerced HCWs into agreeing to vaccination by imposing on unvaccinated HCWs the obligation to wear a mask when it served no useful purpose.

The TAHSN Report was Unreliable

The justification for the VOM policy was the TAHSN report. However, that report cited no substantive evidence that VOM policies reduce influenza transmission, and the reason it failed to do so, in the Association's submission, was because there was no such evidence.

The initial focus of the working group that drafted the TAHSN report was on increasing vaccination rates and it went about its work, the Association argued, with that goal squarely in mind. Indeed, St. Michael's evidence established this, and specific reference was made to the testimony of some of its witnesses. It was

particularly noteworthy to the Association that the working group went out of its way to avoid hearing from experts who disagreed with what the Association characterized as a pre-determined outcome.

The TAHSN report substantially relied on four cRCTS: Potter, Carman, Hayward & Lemaitre (hereafter the "four cRCTs") conducted in long-term care (hereafter "LTC") facilities (not hospital settings like St. Michael's). These four cRCTS found that there was a substantial reduction in all-cause mortality in LTC facilities when HCWs were vaccinated. Stated in the simplest terms, these four cRCTs concluded that when HCW vaccination rates increased, patient deaths decreased. Additional evidence was cited by St. Michael's to support the following proposition: the risk of influenza outbreaks decreased when the rate of HCW immunization increased.

However, in the Association's view, the findings of the four cRCTs were inapplicable, implausible and unreliable (LTC vs. acute care hospital setting like St. Michael's, all-cause mortality vs. influenza-caused death, etc.), and had been thoroughly and conclusively debunked by the overwhelming weight of credible scientific evidence. (Discussion of the four cRCTs, it should be noted, occupied countless days of evidence engaging all of the experts but one.)

The fact of the matter was that the TAHSN report could not survive serious scrutiny given its manifest deficiencies. One example, the Association argued, amply illustrated this point.

Relying on the four cRCTs, the TAHSN report stated that for every 8 HCWs vaccinated 1 patient death would be prevented. This is known as the Number Needed to Vaccinate (hereafter "NNV"). But when carefully analyzed, this number was nonsensical and could not be sustained. In fact, St Michael's witnesses readily conceded limitations of the four cRCTs, while those for the Association completely rejected their findings – the experts testified that they were "controversial," "low grade," and "fundamentally flawed" – and could not serve a scientific foundation for a VOM policy. It was notable, the Association argued, that the College of Nurses did not require that nurses be vaccinated, that the Province of Ontario had not designated influenza for mandatory HCW immunization, nor had the Province of Quebec. Public Health Ontario's Provincial Infectious Disease Advisory Committee does not recommend a VOM policy (although masking for symptomatic individuals was a different matter).

Indeed, the Association made detailed reference in its submissions to the most compelling critiques of the four cRCTS, including the Cochrane Review, described by the Association as universally respected. It's finding, that the four cRCTs had a "high risk of bias" and that there was "no evidence…that vaccinating healthcare workers against influenza protects elderly people in their care," was material and directly on point.

This conclusion was supplemented by Association expert reports and peer-reviewed publications, most notably "*Influenza Vaccination of Healthcare Workers,"*

a 2017 *Plos One* article by Association expert Dr. Gaston De Serres (and others). Dr. De Serres was the principal Association witness. He has an MD and a PhD in epidemiology. His evidence, along with other leading studies, e.g., Osterholm, cast serious doubt on the validity of the four cRCTs and their various findings, including their applicability to the acute care hospital setting.

As Dr. Osterholm wrote: "The four randomized controlled trials…do not provide strong evidence to support an impact on patient mortality when increased numbers of healthcare workers are vaccinated. In fact, two of the studies do not support this claim…and the other two only weakly support it."

The De Serres article reached the following conclusion:

> The four cRCTs … attribute implausibly large reductions in patient risk to HCW vaccination, casting serious doubts on their validity. The impression that unvaccinated HCWs place their patients at great influenza peril is exaggerated. Instead, the HCW-attributable risk and vaccine-preventable fraction both remain unknown and the NNV to achieve patient benefit still requires better understanding. Although current scientific data are inadequate to support the ethical implementation of enforced HCW influenza vaccination, they do not refute approaches to support voluntary vaccination or other more broadly protective practices, such as staying home or masking when acutely ill.

The rest of the data relied on by St. Michael's, the Association submitted, fell far short of making a case – and this was reviewed in detail.

In summary, on this point, neither the TAHSN report, nor any of the evidence adduced by St. Michael's at the hearing, established that the use of surgical and procedural masks by unvaccinated nurses reduced the risk of transmission of

influenza to patients or led to a reduction in outbreaks. Arbitrator Hayes had concluded, given the absence of underlying scientific support, that the VOM policy was motivated by an improper purpose: it was, he found, a coercive practice designed to drive up vaccination rates, and the Association urged me to reach the same conclusion.

Masking Effectiveness

Influenza is transmitted in a number of ways, but primarily through droplets emitted by an infected person. The virus droplet has to be shed and then transported in sufficient amount and close enough to potential recipients to infect them (and evidence was led that explored this process in detail). The question to be asked here, and which the Association answered, was whether these masks effectively prevent influenza transmission: Are they an effective means of source control?

This answer to this question was "no," and the Association pointed to the report and evidence of masking expert Professor Lisa Brosseau. In her report, Professor Brosseau canvassed all of the relevant literature and wrote: "It is my opinion that the surgical masks required for unvaccinated staff at St. Michael's Hospital will offer no or a very low level of protection from infectious aerosols either for the wearer exposed to nearby patients or for patients exposed to an infected wearer." Referring specifically to surgical and procedural masks, she testified: "…none of the surgical masks exhibited adequate facial fit characteristics to be considered respiratory

protection devices." In particular, surgical and procedural masks did not prevent influenza transmission by an infected person: "In addition to having filters that do not perform very well, the fit of these masks on your face will allow a lot of leakage around the side."

In Professor Brosseau's opinion, coughing, sneezing and talking produced a wide range of particles, and in different sizes, all of which could be infectious. The smaller particles could bypass the filter, making it unlikely that a mask would lower the risk of nosocomial influenza from an infected HCW. Masks might prevent or impede large droplets, but that was only one of the ways in which influenza was transmitted. Other evidence, which the Association pointed to, supported this conclusion indicating that the influenza virus can bypass/penetrate surgical masks.

In the Association's submission (developed further below) masking did not stop the spread of influenza. For example, as the Centers for Disease Control (hereafter "CDC") observed, "no studies have definitively shown that mask use by…health care personnel prevents influenza transmission…." Masks were, as one of St. Michael's witnesses conceded, "the weak point (not much data that they work") and, as another agreed, "there really isn't data for using the mask in a way that we have used it in the VOM policy." These admissions alone, the Association argued, formed a sufficient factual and legal basis to uphold both grievances: they made the Association case.

For the VOM policy to survive arbitral review, it could not be arbitrary. There had to be a problem – nosocomial influenza from unvaccinated HCWs, and a link between it and the solution: the "ask", i.e., wearing the mask. No element of this test – legally or factually – the Association submitted, had been met. First, there was very little persuasive evidence about the existence, indeed, scope of the problem. Second, even assuming, for the sake of argument that the evidence about unvaccinated HCWs as a source of nosocomial influenza was accurate, the evidence about mask effectiveness as a solution was insufficient, at best, to support the VOM policy.

(It should be noted that on January 18, 2018, St. Michael's amended its *Influenza Prevention & Control & Inpatient Vaccination Guideline* by posting signs asking unvaccinated visitors to wear a mask while in patient care areas. The new policy was entirely voluntary and no visitor is asked about vaccination status. This new policy, in the Association's submission, did very little to address the logical flaws in the application of the VOM policy.)

Asymptomatic Transmission

Influenza is highly contagious and it can be transmitted by asymptomatic individuals. The Association did not dispute the possibility of asymptomatic transmission. However, the evidence indicated that the rate of asymptomatic transmission was low and "unlikely to be of clinical significance" as the production of the virus and the development of symptoms was linked. Data establishing asymptomatic infection was, the Association argued, extremely limited –

inconclusive at best – and certainly coming nowhere near establishing a problem requiring a solution. Numerous authorities were referred to in support of this submission.

Moreover, if there really was, as St. Michael's asserted, a problem with asymptomatic transmission, and if masking really worked, then universal masking would be required because both vaccinated and unvaccinated HCWs can become infected with influenza and, if infected and asymptomatic, can transmit it (albeit minimally, at best). Moreover, family members, police, ambulance drivers and many others who regularly pass through patient areas of the hospital are not required to vaccinate or mask. Why just HCWs, the Association asked? This, again, illustrated how illogical the VOM policy actually was and this went to the heart, the Association argued, of its unreasonableness.

On this point, the evidence further established that masking provided even less protection against transmission by asymptomatic individuals than the already low protection they provided in the case of symptomatic persons. Masking was not an effective means of source control in general, and, in particular, in the case of asymptomatic transmission.

Mismatch Years

Even in the best year – the best match – the influenza vaccination was only partially successful (and the Association argued was become increasingly less so because of

the repeat vaccination effect). During the 2017/2018 influenza season, for example, when it became apparent that there was a serious mismatch – meaning that the vaccine did not provide significant protection – St. Michael's did not impose a system-wide masking requirement. On an earlier occasion, the 2014/2015 influenza season, the vaccine had minimal effectiveness. In all circumstances, and in every year, both vaccinated and unvaccinated HCWs could transmit influenza to patients, but only unvaccinated individuals were required to mask.

The only conclusion that could be drawn in these circumstances, and it was one that the Association urged upon me, was to find that the true purpose of the VOM policy was to increase vaccination rates by offering up an unpalatable alternative – wearing close to useless, inconvenient and burdensome masks for months on end. By definition, this could not be reasonable.

No Evidence of a Problem

For a policy to be found to be reasonable, the Association argued, and where that policy must be balanced against employee interests, then the scale and nature of the issue must be known. The solution must actually address a real, not imaginary, problem. Here, the Association submitted, there was no evidence of the burden of disease – St. Michael's experts had admitted as much – no evidence of any demonstrated need, and no evidence of the degree to which unvaccinated HCWs were the cause of nosocomial influenza. Likewise, there was a complete absence of

quantification of the amount of influenza that was preventable by surgical and procedural masks.

Pre-existing Infection Protection and Control (IPAC) policies and practices at St. Michael's – which Association counsel described – were not only working and evidence-based, but accepted. There was no problem and no need for a solution, especially the masking solution that did not work. And that meant the policy was arbitrary. In these factual circumstances, the Association argued, the VOM policy could not be found to be reasonable.

Adverse Impacts on HCWs and Patients

Although challenged, the evidence was largely uncontradicted that wearing surgical and procedural masks over the course of an entire shift day in and day out for weeks and months on end was extremely uncomfortable for the nurse and problematic for patient care, a point established in the evidence of two long-service nurses. They testified about adverse reactions to the vaccine, the discomfort they experienced from wearing masks for prolonged periods, that wearing the masks attracted negative attention, that it seemed like a punishment for not being vaccinated, that it disturbed patients who were concerned whether they – the HCWs – were infectious, and that it frequently interfered with their care. They also spoke about their concerns about empathy and understanding and how masks undermined both – an issue raised in some of the literature. The VOM policy, in short, shamed and blamed,

and served no legitimate purpose, the Association argued, other than to coerce HCWs to submit to influenza vaccination.

Conclusion to Association Submissions

The only conclusion that the Association could draw, when all the evidence was examined, was that the VOM policy was not a legitimate and scientifically based employer response to an identified problem with a reasonable and targeted solution. Instead, it was clearly designed from the outset with one objective in mind: to increase influenza vaccination.

HCWs were given an unacceptable, unjustified and unwelcome choice, and it was one that had close to zero medical justification, demonstrating its ulterior purpose: driving up vaccination rates in the face of a clear collective agreement entitlement to refuse an unwanted vaccine. The VOM policy was contrary to the collective agreement, it conflicted with the collective agreement, and it was illogical and unreasonable. Arbitrator Hayes had concluded it was completely improper, and the Association urged that I reach the same result. The Association asked that both its grievances be upheld and the VOM policy struck. The Association asked me to remain seized with the implementation of my award.

Submissions of St. Michael's

In St. Michael's submission, the case for the VOM policy was straightforward: nosocomial influenza caused serious illness and sometimes death. HCWs can

transmit influenza to patients. Vaccination reduced the risk of HCWs becoming infected with influenza and, therefore, reduced the risk of HCWs transmitting influenza. Masks were effective as source control – they prevented transmission of influenza. And masks served as a reasonable alternative for HCWs who chose not to vaccinate.

Origin of the VOM policy at St. Michael's

The TAHSN working group that drafted the VOM policy was constituted to discuss options and make recommendations on how to best reduce nosocomial influenza. Increasing vaccination rates was the obvious first step because influenza vaccination provided protection. But the effort was unsuccessful. Notwithstanding various initiatives, influenza vaccination rates remained static. The working group exercise, involving a multi-disciplinary expert team, St. Michael's submitted, took the task seriously and directed considerable resources to it.

In the meantime, the evidence indicated – the four cRCTs in particular – that the burden of HCW-associated influenza was significant. One of the main contributors to the TAHSN report, and a witness called by St. Michael's, Dr. Allison McGeer, testified as follows: "Don't know that I can adequately represent hours and hours of discussion but I think that the focus of the committee became on what the least intrusive thing we could do…[to]...provide the best protection we could give to the patients in hospital from influenza." Dr. McGeer was looking for an alternative "to protect patients at the same time as trying to be the least intrusive to workers."

That meant masking. There was, Dr. McGeer testified, and wrote in her report: "…evidence that masks, especially when combined with good hygiene, reduce the risk of infection to exposed persons; that is, that they can be expected to confer some protection against healthcare-associated influenza in unvaccinated HCWs." Indeed there was evidence that masking worked to prevent transmission of influenza and it was quite possibly as "effective as vaccine in protecting patients from influenza." Masking was especially important, and necessary, St. Michael's argued, as some influenza was transmitted by asymptomatic HCWs. The VOM policy was, therefore, properly arrived at: grounded in scientific evidence and carefully calibrated to balance interests.

All of this, St. Michael's argued, had been established in the evidence of its witnesses – internationally recognized experts and persons with subject matter expertise – whose evidence St. Michael's counsel carefully and comprehensively reviewed. The TAHSN report was not uncritically accepted. Its findings were carefully reviewed by epidemiologist Dr. Matthew Muller, St. Michael's Director of Infection Prevention and Control.

As Dr. Muller testified, "when I saw the results…it really increased my urgency about the fact that…perhaps to some extent we had been complacent…and thought that, if these interventions can save patient lives in the manner that was demonstrated in those cluster randomized trials, this is something we should be taking a different approach to this problem and we should have started yesterday essentially." Dr.

Muller considered the differences in LTC facilities and acute hospitals and took notice of the biological plausibility of HCW vaccination reducing influenza among inpatients. He was also persuaded by some of the conclusions reached in some of the other literature including by Ahmed et al; indicating that HCW vaccination "can enhance patient safety."

Dr. Muller was not in favour of a mandatory vaccination program – although he understood that the only guaranteed method of substantially increasing influenza vaccination was by making it a condition of service – normative in the United States. He understood that a compromise position – VOM – had achieved some success in British Columbia – meaning that vaccination rates had increased – and determined that it was both a useful and appropriate compromise for St. Michael's. His research satisfied him that masks were a good means of source control and could interrupt influenza transmission. Simply put, "by wearing a mask, unvaccinated healthcare workers will protect patients from influenza, given the proven ability of masks to contain secretions, by preventing transmission of influenza from healthcare workers with asymptomatic or subclinical illness who are shedding virus, and from healthcare workers who continue to work despite significant symptoms of influenza."

Accordingly, Dr. Muller recommended that St. Michael's adopt a VOM policy, and a widespread and collegial process was then undertaken where the policy was

presented and discussed: "…we felt that both the vaccine and the mask would protect patients."

The VOM policy in Practice

It was, St. Michael's insisted, entirely up to individual HCWs to decide whether to vaccinate or mask, and nothing in the administration of the policy – discussed in the evidence and submissions – could be fairly described as intrusive or coercive. HCWs at St. Michael's, for example, were not required to mask for the entire season but only that part of the period when influenza activity was the most significant (on average about 10 weeks a year).

St. Michael's rejected the evidence of the nurses who testified about difficulties in wearing the mask as well as the asserted concerns about interference with patient care. It noted that no HCW has been disciplined for non-compliance. In terms of mismatch years, while timing was problematical – the mismatch may not be evident until later in the influenza season – the amended VOM policy allows St. Michael's to require universal masking, if need be. An amendment to a related policy, referred to above, invites unvaccinated visitors to the hospital to wear masks.

Justification

Much of the evidence, St. Michael's argued, was accepted and non-controversial. HCWs can be infected with influenza. HCWs can transmit influenza to their patients. Influenza causes serious illness and death. Nosocomial influenza is a serious

problem, and one that must be addressed even if precise numbers of patients infected by unvaccinated HCWs is not readily ascertainable.

At the very least, the four cRCTs provided evidence of the problem and pointed the way to a solution. Vaccination was the first step. Association witnesses acknowledged as much – it protected HCWs from influenza. Although not perfect, it was the best protection available. And even in mismatch years, except in the rare and extreme case of a complete mismatch, vaccinations provide some protection, and that is obviously better than no protection. But if an HCW decided against vaccination, then VOM was a reasonable alternative, one that conferred protection against nosocomial influenza.

The four cRCTs

The four cRCTs, followed by a fifth, referred to as the Dutch RCT, unambiguously established, in St. Michael's view, that vaccinating HCWs against influenza protected patients. While the Cochrane Review took issue with the four cRCTs, and found that the effect size was too big to be real, that criticism was, St. Michael's argued, unfounded. Dr. McGeer rebutted the Cochrane Review, and its finding that there was "no evidence" that vaccinating healthcare workers protects patients in their care in her appendix to the TAHSN report and in her evidence in these proceedings: "There is substantial evidence increasing vaccination rates in healthcare workers results in reduced mortality during influenza season in the residents they care for."

Others who had looked into it, and reference was made to various studies, concurred: influenza vaccination can and does enhance patient safety, a point which, St. Michael's noted, the Association experts did not dispute. Equally important, Dr. De Serres's conclusions in the *Plos One* article had been thoroughly rebutted by St. Michael's expert Dr. Reka Gustafson. St. Michael's urged me to adopt her evidence and conclude likewise. Additional data that St. Michael's reviewed – for example, some observational studies – supported the VOM policy.

Asymptomatic Transmission

People transmit influenza before they know they are sick. The extent of asymptomatic transmission is difficult to establish, but the weight of the evidence, nevertheless, St. Michael's argued, is that it occurs. It is also the case that some HCWs, even though it was contrary to established policy, work while sick (presenteeism). In St. Michael's view, this was another reason to require unvaccinated HCWS to mask: it protected patients.

Masking

In St. Michael's submission, masks prevent unvaccinated HCWs from transmitting influenza. It also protected them from acquiring it. While there was not a lot of evidence demonstrating the efficacy of masking as source control, what there was – and St. Michael's reviewed a number of studies – established that masking worked.

Standard of Care

The medical data supported HCW immunization but so too, increasingly, did the standard of care, and this was especially important in an acute care institution like St. Michael's, where the patient population was particularly vulnerable. The CDC recommended it. Canada's National Advisory Committee on Immunization described HCW influenza vaccination as "an essential component of the standard of care." The Provincial Infectious Diseases Advisory Committee of Public Health Ontario recommended that influenza vaccination be a condition of HCW employment. Other organizations indicating support of one kind or another included the Ontario Medical Association, Toronto Public Health, the Canadian Nurses Association and the Registered Nurses Association of Ontario. Standards of care, St. Michael's argued, matter, and there was little question that influenza vaccination was appropriate and approved.

Not Inconsistent with or Contrary to the Collective Agreement

In St. Michael's submission, there was no inconsistency between the VOM policy and the collective agreement, and it was definitely not contrary to any collective agreement provision. The VOM policy gave effect to the parties' shared obligation to provide the best possible care and health protection for patients. It was based on good evidence – and in health and safety matters absolute scientific certainty was not a precondition to taking steps to reduce risks to protect HCWs and patients. St. Michael's was well within its negotiated rights to require HCWs to wear protective equipment.

The parties agreed that the influenza vaccine may be beneficial for patients and HCWs – they said so in the collective agreement – and this expressed their shared view that it was an appropriate medical intervention and established that the VOM policy was not only collective agreement-compliant but reasonable. And perhaps most importantly of all, Article 18.07(c) was not impacted because the influenza vaccine was not "required". No one was ordered to take the vaccine. No one was disciplined for not taking the vaccine. There was no inconsistency, in St. Michael's view, between a policy that allows HCWs a choice between vaccination and masking and collective agreement provisions where the parties agree that vaccination may be beneficial for HCWs and patients.

VOM Policy Reasonable

The VOM policy provided HCWs with a choice: they could elect between two meaningful options. They could vaccinate or they could mask. Offering a choice, St. Michael's argued, was the exact opposite of coercion and exemplified reasonableness. All choice was subject to influence, but St. Michael's preference for vaccination did not affect the voluntariness of the decision being made. The choice may be difficult, but it was still a choice. That was the finding of Arbitrator Diebolt's in *Health Employers Assn. of B.C.* (2013) 237 LAC (4th) 1 ("the Diebolt Award").

The Diebolt Award

A VOM policy was introduced in British Columbia after efforts to increase voluntary influenza vaccination rates were unsuccessful. It was grieved. Arbitrator Diebolt found that programs that increased HCW influenza immunization were reasonable:

> Pausing here, in my view, the facts that: (1) influenza can be a serious, even fatal, disease; (2) that immunization reduces the probability of contracting the disease, and (3) that immunization of health care workers reduces transmission of influenza to patients all militate strongly in favour of a conclusion that an immunization program that increases the rate of healthcare immunization is a reasonable policy (at para. 205).

That left outstanding the contested policy: VOM. Arbitrator Diebolt accepted the evidence that had been led that VOM policies increase immunization rates. He also accepted that masking provided "some patient protection" (at para. 208).

> That said, it would be troubling if the only purpose or effect of the Policy's masking component were to motivate health care workers to immunize. In that event, masking would only be a coercive tool. On all the evidence, however, I am persuaded that masking has a patient safety purpose and effect and also an accommodative purpose for health care workers who conscientiously object to immunization (at para. 207).

Accordingly, Arbitrator Diebolt upheld the VOM policy and dismissed the grievance, and this result, for these reasons, was urged upon me in this case.

Speaking of arbitral results, St. Michael's argued that the Hayes Award not be followed. As indicated at the outset, I have concluded that the Hayes Award, in its most material respects, is on all fours with this case. That being said, there are some differences worth pointing out, especially as they go to Arbitrator Hayes characterizing the policy as coercive as a principal basis for his determination that the VOM policy was unreasonable (in contrast to the finding here).

The Sault Area Hospital set a 100% target vaccination rate. No target was set at St. Michael's. The Sault Area Hospital required VOM during the entire influenza season. St. Michael's requires it only during the most active phase. Sault Area Hospital actually implemented its VOM policy the month before the TAHSN report became effective. St. Michael's had an epidemiologist on staff who took the time to study it and consult with colleagues. St. Michael's counsel also pointed to some differences in the evidence of the HCWs who testified in the Sault Area Hospital case and the ones who testified in this proceeding and suggested that there was no evidence in this case of anything that could be remotely described as coercive. For all these reasons, and others, St. Michael's argued that the Hayes Award could not and should not be followed. Certainly, there was no basis to adopt that award's principal finding that the VOM policy in place at the Sault Area Hospital was coercive and that masks were cast as the consequence for non-compliance.

Conclusion to Saint Michael's Submissions

The VOM policy had one goal: putting patients first. It was grounded in the evidence, evidence that established that encouraging and increasing HCW vaccination rates reduced nosocomial influenza. Experience elsewhere indicated that vaccination rates rise in response to introduction of a VOM policy, and that additional protection was obtained by requiring unvaccinated HCWs to wear masks.

Ultimately, there was no final answer in science, but no reason to wait for better evidence or the perfect study. Doing nothing was not a satisfactory response when

active steps could and should be taken to promote patient welfare. The four cRCTS , and the other evidence St. Michael's relied upon, might not produce exact quantitative results that could be extrapolated across an entire health care system, but in total convincingly established that influenza transmission was reduced when HCWs vaccinate. The burden of preventable disease was addressed by encouraging influenza vaccination and by requiring masking for those HCWs who chose not to take advantage of the vaccine. Both provided protection against nosocomial influenza infection, a clearly desirable goal. And both did so in a reasonable and lawful manner that appropriately balanced all interests. St. Michael's asked that the grievances be dismissed.

Decision

Having carefully considered the evidence and arguments of the parties, I am of the view that the grievances must be allowed. The VOM policy – unilaterally developed and implemented by St. Michael's – comes directly within arbitral purview.

For the reasons that follow, the VOM policy is inconsistent with and contrary to the collective agreement and it is also unreasonable.

General Observations

The evidence establishes that, more or less, and other than the rare case of a complete mismatch year, influenza vaccination provides some – varying – degree of protection. It makes sense, therefore, that hospitals such as St. Michael's would want to encourage influenza vaccination as it is axiomatic that if one does not contract

influenza one cannot pass it on. It is hardly surprising, in these circumstances, that there is a general consensus in the medical establishment in favour of influenza vaccination. The parties have, however, agreed that HCWs can refuse an unwanted vaccination. And as Dr. Muller and others testified, individuals have all sorts of reasons to do so, the legitimacy of which has not been brought into question. Indeed, influenza vaccination is not required by St. Michael's.

The VOM policy, however, fails for a number of reasons: There is insufficient evidence of a problem to be addressed – nosocomial influenza transmitted by unvaccinated HCWs. There is insufficient evidence that asymptomatic or pre-symptomatic transmission is a significant source of infection. And there is insufficient evidence that masking prevents the spread of influenza.

In the face of all of this, the "ask" that HCWs wear a mask for their entire shift for possibly months on end when entirely free of symptoms is completely unreasonable and is contrary to the collective agreement.

In general, where matters of patient safety are concerned, caution is in order, and appropriate. Better to be safe than sorry. To be sure, one need not await all the evidence before taking appropriate steps. Nor is it necessary to await perfect evidence. Vaccinations are the best tool in the box to protect against influenza. A policy encouraging HCWs to vaccinate makes obvious sense (as does encouraging

hand washing hygiene, and discouraging people from coming to work when they are sick). However, the VOM policy fails for a number of reasons as set out below.

Before turning to the reasons why the grievances have been upheld, one assertion needs to be put to rest. The VOM policy, for all of its deficiencies, does not fail because it is coercive. That submission is completely rejected.

Not Coercive

It is correct that St. Michael's HCWs are not required to submit to the annual influenza vaccination. But their right to refuse the vaccine is interfered with by an unreasonable policy. However, unlike the Hayes Award, I cannot conclude that the VOM policy is coercive. This finding requires elaboration.

In the Hayes Award, the evidence clearly established that the Sault Area Hospital determined that there was a problem – low influenza vaccination rates – and went about devising a solution to address that problem. The minutes of a hospital meeting held on January 30, 2013 say it all: "Need to determine the most aggressive stance that we can take…to either mandate staff to comply, or impose consequences (i.e. masks that they would be charged for)" (at para. 52). Quite clearly, the solution to the problem at the Sault Area Hospital had nothing to do with using masks to prevent transmission and everything to do with using the threat of masking, and charging HCWs for them, to increase vaccination rates.

When an arbitrarily set voluntary immunization goal failed to be reached, the Sault Area Hospital implemented its policy. Little or no attention was paid to evidence about masking efficacy in preventing nosocomial influenza. Rather, when the carrot of encouraging voluntary vaccination failed, the decision was made to turn to the stick, and that was imposing a masking obligation on unvaccinated HCWs as a punitive and coercive measure.

Moreover, at Sault Area Hospital the VOM policy was pursued notwithstanding concerns raised by senior medical staff. If the target immunization rate of 70% was not achieved, the VOM policy would follow. And it was not, and it did. The target of 70% was an arbitrary number in and of itself. The objective – increasing HCW influenza vaccination – was there, and here, entirely legitimate, but the means employed there to achieve that objective was highly colourable, as Arbitrator Hayes found. The situation at St. Michael's – the backstory – is completely different.

In my view, the evidence is absolutely clear that the decision to introduce the VOM policy at St. Michael's was made in pursuit of entirely reasonable objectives: to increase vaccination levels and thereby prevent nosocomial influenza based on a good-faith belief that the four cRCTs established a persuasive link between increased HCW influenza vaccination and reduced morbidity and mortality, and that masking was a reasonable alternative, providing some protection for patients when HCWs declined influenza vaccination. That was, in a nutshell, the reasons that informed the decision that was made.

While Arbitrator Hayes concluded on the location-specific evidence before him that masking was intended to coerce Sault Area Hospital HCWs to vaccinate, I do not reach the same conclusion. I conclude that St. Michael's introduced and defended its policy because it believed it to be in the interest of patients. I accept Dr. Muller's evidence on this point:

> …I can say categorically that it was never my intention to shame or blame anyone by implementing this type of policy at St. Mikes. I would go further and say that on the different committees and groups that I've sat at where the policy was developed or presented or refined, every effort was made to avoid shaming or blaming, and the intention of the policy was always focused on patient and staff safety. So, I can say that absolutely.
>
> I think that the mask was selected because of our belief that it affords some protection against influenza, both to the person wearing the mask and the people around the person wearing the mask. So, again, it acts as a piece of personal protective equipment that protects the person but it's also a form of source control. So, if that person were to have asymptomatic flu or develop mild symptoms of flu which they don't recognize or to have more significant symptoms which they choose to ignore, for whatever reason, that this could protect the people around them.
>
> And I think we wanted to present health care workers with a real choice which means both choices had to be able to protect patients from flu, although our preference through all of this was to have more health care workers vaccinated.
>
> So, the best evidence for vaccinating health care workers, we have the four cluster randomized trials as well as the other evidence that we've gone over in detail. We don't have four cluster randomized trials of masking but we have I think sound biologic rationale and some study data showing that masks should be effective….
>
> So, by giving health care workers two choices, one is the vaccine and one is the mask, it means that every health care worker can make their own decision…

St. Michael's approved the VOM policy because vaccinations do (imperfectly) work and therefore reduce influenza incidence. Encouraging vaccination is a good thing. Masking may not provide perfect protection but it is better than nothing. Taken together, St. Michael's concluded that it could deal with a problem – nosocomial

influenza – and do so in a measured and balanced fashion. There is no evidence of coercion.

There is also no evidence that masking was identified as a punishment or stigma to encourage vaccination. Nevertheless, the VOM policy does impinge on the collective agreement, as set out above, and fails the reasonableness test. Acting in good faith is not enough alone to establish that a unilateral employer policy is reasonable where, as here, it is inconsistent with the collective agreement and where it sits on a shaky evidentiary foundation.

The Reasonableness Test

No one disputes that St. Michael's has the right and responsibility to take appropriate precautions to protect the health and safety of patients. But in this case, the steps taken – the VOM policy – are subject to a reasonableness test.

As is provided in the jurisprudence, and dealing with only the relevant parts of what is commonly referred to as *KVP* ((1965) 16 LAC 73), arbitrators must apply their labour relations expertise, consider context and decide whether a contested policy strikes a reasonable balance. In reaching a conclusion, among the factors to be considered is the nature of the interests at stake, whether there are less intrusive means available to achieve the objective, and the impact of the particular policy on employees. The policy must also not be inconsistent with or contrary to the collective agreement.

A VOM policy cannot be upheld simply because it is supported by good faith and some evidence. To satisfy a reasonableness test, objective evidence is required of a real problem that will be addressed by a specific solution. And when the evidence is examined, these factual and legal elements are absent. For the reasons that follow, I am left to conclude that the VOM policy violates, and is inconsistent, with the collective agreement, and is unreasonable.

Insufficient Evidence of a Problem

A useful starting point is the TAHSN report. It is, after all, the basis of the VOM policy. However, it cannot be relied upon because the evidence it cites as justification in support of the VOM policy does not withstand serious scrutiny. I am referring, of course, and in the main, to the four cRCTs.

As Dr. De Serres put it, "the four cRCTs…attribute implausibly large reductions in patient risk to HCW vaccination, casting serious doubts on their validity. (Notably, Dr. De Serres is in favour of influenza vaccination – he recommends it and is annually vaccinated.) Other persuasive evidence – for example, the Cochrane Review, generally understood to present the highest quality of analysis, supports this conclusion.

St. Michael's called Dr. Gustafson to rebut Dr. De Serres's expert evidence and publications. However, she was not an epidemiologist, and added virtually nothing to the discussion of vaccine efficacy, asymptomatic transmission, masking as source

control, or to protect the wearer, and minimal indirect evidence about the burden of nosocomial influenza in acute care. Her criticisms of Dr. De Serrres's work and conclusions fell short; they were entirely unpersuasive.

The suggestion that unvaccinated HCWs place patients at great influenza peril is, as Dr. De Serres testified, exaggerated. For example, the TAHSN report adopts the finding of one of the four cRCTS and concludes that for every 8 HCWs vaccinated, 1 patient life could be saved. If this were actually true, it would be hard to disagree with an assertion of an overwhelming public health interest in promoting influenza vaccination. But it is not true, for the reasons explained in the extremely detailed and persuasive evidence of Dr. De Serres, also as set out in his report, and in his *Plos One article*. I accept his conclusion that the assertion of 8/1 NNV is "preposterous." I accept his evidence that the four cRCTs provide impossible results from methodologically flawed studies that cannot be reasonably extrapolated and applied to an acute care hospital setting. Dr. McGeer conceded that NNV of 8/1 was incorrect. It was, another St. Michael's witness wrote, "a catchy phrase," but it is not a supportable one. Obviously, and even assuming there was persuasive data on the NNV, masking plays no role in the NNV.

To the extent that the four cRCTs have value, their value is surely limited to some extent by the fact that they arise in LTC, not in a major acute care hospital with a constant flow of personnel and visitors. Also, a reduction in all-cause mortality cannot be attributed to a higher vaccination rate. Influenza vaccines protect against

influenza, not all causes of death, and it is logically unpersuasive to suggest that an influenza vaccine has a much wider reach. The four cRCTs provide results that really are too good to be true. As Dr. McGeer wrote in one article, "vaccine efficacy is limited, and considerable morbidity and mortality occurs even in vaccinated persons."

The fact is, notwithstanding all of the studies, that no one can accurately report on how much, if any, nosocomial influenza is caused by unmasked or unvaccinated HCWs.

It is appropriate here to comment about some of the other new medical evidence (other than Gustafson, discussed above) relied on by St. Michael's. The new medical evidence, upon careful examination, was hardly new at all and/or subject to serious limitations and/or of questionable relevance – "smaller bricks", as one of the St. Michael's witnesses acknowledged. More seriously, some of the expert evidence advanced by St. Michael's was particularly problematic and actually inconsistent with the most basic academic norms.

It would serve no useful purpose to particularize this evidence in detail other than to observe that two of the principal experts advanced by St. Michael's put forward in their joint report propositions without evidentiary support, which was certainly troubling, but making matters worse, some of what they wrote was simply incorrect. On too many occasions their noted citations stood for the exact opposite of the point

being made – "I am going to agree with you that this is not the best reference…" – or, considered most favourably, completely overstated the proposition being advanced. There were too many apologies when errors were brought to their attention. As one of these witnesses testified, "we may have been sloppy…." Everyone makes mistakes, but this went beyond the pale. I completely disregard their report.

As the first step in establishing that the VOM policy is reasonable, St. Michael's had to establish that vaccination reduced transmission and/or that unvaccinated HCWs put patients at a greater risk of contracting influenza. It has not met this evidentiary burden.

There is no question that HCWs have an obligation to do what they can to protect their patients from nosocomial influenza. And there is no question that influenza vaccination provides some protection except in those circumstances when it provides no or little protection. However, on the evidence led in this proceeding, the burden of disease presented by unvaccinated HCWs is absent.

Vaccination obviously reduces some influenza transmission – except in complete mismatch years. But its efficacy varies, and every year both vaccinated and unvaccinated HCWs can transmit influenza while both asymptomatic and symptomatic. But the actual extent to which influenza vaccination reduces transmission is open to question and debate. As Dr. Michael Gardam wrote in his report, we are "only able to say with certainty that influenza transmission occurs

from close contact with infected individuals. The relative particulars of what this means…were unknown."

As one study indicated, mandatory influenza vaccination of HCWs is of "uncertain clinical impact." In another study, a hospital achieved a 97% influenza vaccination rate but experienced no reduction in sick leave. Another study noted, "we cannot say for certain whether there was a change due to influenza vaccination." Anecdotal evidence was presented that influenza outbreaks can occur in highly vaccinated and isolated populations. Needless to say, there are other studies indicating the exact opposite. On balance, though, the case establishing a link between vaccination and prevention of nosocomial influenza was not made.

It is also noteworthy that there is little evidence of any positive impact on patient care outcomes as a result of the VOM policy. Both prior to and after introduction of the policy, St. Michael's experienced, and continues to experience, influenza outbreaks. In particular, there was one influenza outbreak before the VOM policy was introduced – in 2011 – and there have been several since. The VOM policy, as earlier noted, was upheld in British Columbia, but evidence from that jurisdiction suggests that it does not achieve the stated objective. See *British Columbia Influenza Surveillance Bulletin, 2014-15, No. 21*.

The four cRCTs are controversial; so too are the studies taking issue with them. Even those studies and reviews supporting vaccination report that the quality of

evidence that HCW vaccination reduces mortality and influenza cases in patients of healthcare facilities is "moderate and low." At the end of the day, the evidence does not support the proposition that nosocomial influenza is associated with unvaccinated HCWs – the evidence simply does not demonstrate that there is a specific burden of disease associated with unvaccinated HCWs

While reasonable efforts to reduce risk in public health need not await scientific certainty, the fact of the matter is that the extent of the problem is unknown; we do not know the burden of disease for nosocomial influenza, and we do not know what proportion is caused by HCWs, vaccinated or not. We also do not know NNV. We do know that it is not 8/1, the number cited in the TAHSN report. All of this evidence – really absence of evidence – goes to the heart of reasonableness.

In any event, even assuming for the sake of argument that there was adequate or sufficient evidence that vaccination prevented or significantly reduced nosocomial influenza, the VOM policy still fails for a number of reasons, beginning with the fact that the evidence does not support masking as source control for unvaccinated HCWs, thereby putting the policy's reasonableness directly into question.

Masking – Not a Solution

There is no persuasive evidence establishing a conclusive relationship between the use of surgical and procedural masks and protection against influenza transmission. The logical flaws in the policy are discussed below.

St. Michael's did not call a masking expert, and urged me to reject the evidence of the expert called by the Association. However, the preponderance of the masking evidence is compelling – surgical and procedural masks are extremely limited in terms of source control: they do not prevent the transmission of the influenza virus. The two masks introduced into evidence clearly demonstrate why that would be the case. What protection they provide is self-evidently limited by their construction and how they sit on a human face.

I accept Professor Brosseau's evidence. She is an expert on masking. St. Michael's attempted to discredit her because of her advocacy for workers: "I am interested in protecting workers," she testified. And there is nothing in that, in my view, that undermines her testimony and expert report in any way: both were evidence-based, convincing and corroborated.

The bin-Reza systemic review concluded as follows: "None of the studies established a conclusive relationship between mask/respirator use and protection against influenza transmission." Dr. Gardam agreed: "The use of surgical or procedural masks is neither a viable nor scientifically supported alternative." And furthermore: "the evidence supporting people wearing a mask during flu season is far flimsier than the four cluster randomized controlled trials supporting influenza vaccination…." To quote one of the scientific articles, the studies supporting the use of masks as source control are "underpowered." As another study concluded, "there

is little good quality evidence to support surgical masks as an effective infection protection measure…."

Yet another study observed: "there is a lack of substantial evidence to support clams that face-masks protect either patient or surgeon from infectious contamination." The CDC is categorical: "No studies have definitively shown that mask use by either infectious patients or health-care personnel prevents influenza transmission." As the CDC also stated, "while a facemask may be effective in blocking splashes and large-particle droplets, a facemask, by design, does not filter or block very small particles in the air that may be transmitted by coughs, sneezes or certain medical procedures." As another study indicated, "overall, the evidence to inform policies on mask use in HCWs is poor, with a small number of studies that is prone to reporting biases and lack of statistical power."

The best case for masking is as follows: There is "ongoing debate" about the effectiveness of surgical and procedural masks as respiratory protection devices. The evidence in favour of masking is mostly "preliminary." Or, there is "some" evidence that surgical and procedural masks "may" reduce shedding and the concentration of the influenza virus in the air and environment around the wearer (with questions about actual transmission being entirely another matter). But the fact of the matter is, because of "leakage," surgical masks do not exhibit "adequate filter performance and facial fit characteristics to be considered respiratory protection devices."

On balance, and after the most thorough review of all of the testimony, studies and reports tendered in this proceeding, and with the greatest of respect to an accomplished and respected researcher and physician, I cannot conclude that the evidence comes even close to establishing that masking may be as "effective as vaccine in protecting patients from influenza."

Masking is the acknowledged and accepted standard of care when tending to an infected patient, but the expert evidence indicates that it is of limited value to anyone as a method of source control, particularly in case of an asymptomatic HCW. The fact that there is some evidence, for example, that masking can prevent transmission of large droplets – unlikely in asymptomatic transmission – is not enough to confer reasonableness on the policy. Little evidence – negligible evidence – cannot serve as the justification for this policy, all things considered, especially since the masking part of the VOM policy is not universalized in mismatch or bad match years. The "ask" is significant, but the benefit is so limited that the former cannot balance the latter. Independent of any other finding in this award, the VOM policy fails on a reasonableness basis for these reasons alone.

Asymptomatic Transmission Overstated

The argument was advanced by St. Michael's that masking was especially important to reduce the risk of nosocomial influenza by asymptomatic or pre-symptomatic HCWs. At best, the evidence indicates that asymptomatic transmission is not a significant factor in nosocomial influenza. As Dr. Muller testified, asymptomatic

transmission could not be ruled out, but "the likelihood of transmission is dramatically higher when you're coughing or sneezing." There is, nevertheless, some evidence that masking can prevent transmission of large droplets. However, in the same way that there is no credible quantification of the burden of disease attributable to unvaccinated HCWs, there is no credible quantification of the rate of infection that might occur in the asymptomatic period.

The degree to which asymptomatic individuals transmit influenza to others is, more or less, unknown: "Silent spreaders…may be less important in the spread of influenza epidemics than previously thought." As Dr. Eleni Patrozou concluded following her systemic review: "Based on the available literature, we found that there is scant, if any, evidence that asymptomatic or pre-symptomatic individuals play an important role in influenza transmission." As Dr. De Serres wrote, "The evidence that pre-symptomatic or asymptomatic infections contribute substantially to influenza transmission remains scant."

In general, secretion and symptoms are parallel, often rising up on a logarithmic curve. Carrat and others have demonstrated that asymptomatic transmission is unlikely to be of clinical significance. As Carrat observed, "viral shedding, the surrogate marker of infectiousness, was of moderate duration, and its dynamics largely overlapped those of systemic symptoms…." Best PPE practices indicate that individuals be required to wear protective equipment when it is necessary and appropriate for them to do so, and VOM while asymptomatic would not meet this

test. Symptomatic individuals, problems with presenteeism aside, should not be at work (and the policies requiring this should be vigorously enforced). Moreover, and to repeat, if masking really did prevent asymptomatic transmission, the only logical conclusion that should be drawn, given general vaccine effectiveness, is that everyone should mask all the time during the influenza season, whether vaccinated or not.

The masking "ask" is significant, but the benefit is so limited that the former cannot balance the latter. Two nurses testified about the impact of the VOM policy on them and their patients. I accept their evidence, which was corroborated in some of the literature. For example, Dr. Priya Sampathkumar, Chair of the Mayo Clinic's Immunization and Control Committee, has observed, "you get hot under the masks, patients can't understand what you're saying sometimes…they are not patient friendly, and they can be scary to patients." The Mayo Clinic does not require its 32,000 HCWs to mask if unvaccinated – approximately 8 or 9 percent of the eligible workforce. Infectious HCWs are told to stay home when they are getting sick, and when they are sick. There is no evidence before me that could lead me to find, as was the case with Arbitrator Diebolt, that wearing a mask is accommodative.

On balance, I am persuaded by the evidence and accept the conclusion of the experts that there is, indeed, scant evidence of asymptomatic nosocomial influenza transmission. It is unlikely to be of clinical significance. Accordingly, requiring unvaccinated HCWs to wear surgical or procedural masks – notwithstanding the

inherent illogicality of it all – is unreasonable, and so, therefore, is the policy compelling it.

Illogical and Unsustainable

Influenza is highly contagious. Hospital patients are highly vulnerable. These are reasons to encourage vaccination – generally regarded as safe and almost always providing some degree of protection. However, both vaccinated and unvaccinated HCWs can transmit it and asymptomatic transmission can occur. If donning a surgical or procedural mask provided protection, the conclusion should be inevitable that everyone should mask – at least until a vaccine with one hundred percent effectiveness, or close to it, becomes available. That is not, however, required illustrating how illogical the VOM policy actually is.

At the very least, in complete mismatch years, the only logical application of the VOM policy would require everyone to mask, as the vaccine confers no or little protection – but even that is not done. In years of a complete mismatch, or a generally ineffective vaccine, St. Michael's did not require all HCWs to mask. If the vaccine were ineffective, or exceptionally of almost no value, and if masking provided protection, the logical inference would be that all HCWs should don masks because vaccinated HCWs would be at least as susceptible to influenza as unvaccinated HCWs. But they were not required to do so, leading to the irresistible conclusion that the policy is illogical and makes no sense – the exact opposite of it

being reasonable. There are a number of collateral reasons that support this conclusion.

In January 2018, St. Michael's began asking unvaccinated visitors to mask, but its efforts in this regard – no questions are asked about visitor vaccination status – are hardly muscular. Unvaccinated visitors logically present the same risk, and possibly a greater one, than unvaccinated HCWs. If masking is truly effective as source control, how can it be that they too are not required to mask? The answer to this question reveals that the masking part of the policy is, as one St. Michael's witness admitted, "weak." As Dr. Muller also testified, "there's far more evidence supporting influenza vaccination itself to protect us from flu transmission than there is for a mask." To require only unvaccinated HCWs to mask in the case of a complete mismatch, or in a year when the vaccine is of marginal utility, is simply bizarre and completely inconsistent with any notion of reasonableness.

The VOM policy is also undermined by real questions of enforcement. Assuming an average St. Michael's vaccination rate of 70%, approximately 30% of HCWs, one would expect, would be wearing masks at one point or another. However, as Dr. Muller testified, "you ought to see 30 percent of people wearing a mask…people felt we didn't see 30 percent of people…." As Dr. Muller explained, differences in vaccination rates between full-, part-time and casual employees may provide some explanation, but one is left with the irresistible inference that on the masking side of the equation, enforcement was not a hospital priority. Clinical HCWs work throughout the hospital, and the policy is expansive in its geographic scope,

meaning that one would expect that if the policy were enforced unvaccinated HCWs would wear their masks virtually non-stop and would, therefore, be highly visible. And I can only conclude that all of this buttresses the evidence – and at least tacit understanding – about the true effectiveness of masks as source control.

Inconsistent with and/or Contrary to the Collective Agreement

The collective agreement is clear: Article 18.07(c) states: "Hospitals recognize that nurses have the right to refuse any required vaccine." That right is categorical but the VOM policy, I find, interferes with the exercise of that right. Accordingly, and to this limited extent, there is a breach, but it is one that is particularly made meaningful by the fact that the VOM policy itself is unreasonable. Taken together – a collective agreement breach – both central and local – and an unreasonable policy – the grievances must succeed.

Conclusion

It was noted at the outset that this case was, in large measure, a repeat of the one put before Arbitrator Hayes. It is not, therefore, surprising that there is an identical outcome. Ultimately, I agree with Arbitrator Hayes: "There is scant scientific evidence concerning asymptomatic transmission, and, also, scant scientific evidence of the use of masks in reducing the transmission of the virus to patients" (at para. 329). To be sure, there is another authority on point, and the decision in that case deserves respect. But it was a different case with a completely different evidentiary focus. It is not a result that can be followed.

One day, an influenza vaccine like MMR may be developed, one that is close to 100% effective. To paraphrase Dr. Gardam, if a better vaccine and more robust literature about influenza-specific patient outcomes were available, the entire matter might be appropriately revisited. For the time being, however, the case for the VOM policy fails and the grievances allowed. I find St. Michael's VOM policy contrary to the collective agreement and unreasonable. St. Michael's is required, immediately, to rescind its VOM policy. I remain seized with respect to the implementation of this award.

DATED at Toronto this 6th day of September 2018.

"William Kaplan"

William Kaplan, Sole Arbitrator

Plaintiffs' Exhibit 498

Congressional Research Service
Informing the legislative debate since 1914

INSIGHT

CARES Act Payroll Support to Air Carriers and Contractors

Updated October 22, 2020

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136), signed into law on March 27, 2020, provided assistance to consumers and businesses, including aid to air carriers and eligible contractors. Emergency funds also were provided to eligible airports. Assistance to air carriers in Division A, Title IV of the CARES Act included loans and loan guarantees, funds to support the pay and benefits of air carrier workers, and a suspension of aviation excise taxes on air transport of people, cargo, and aviation fuel through calendar year 2020. This Insight focuses on the payroll support program (PSP).

Section 4112 of the CARES Act provided $32 billion in payroll support to aviation workers. From this amount, the Secretary of the Treasury was authorized to provide up to

- $25 billion for passenger air carriers (any air carrier that, during the period from April 1, 2019, to September 30, 2020, derived more than 50% of its air transportation revenue from the transportation of passengers);
- $4 billion for cargo air carriers (any air carrier that, during the period from April 1, 2019, to September 30, 2020, derived more than 50% of its air transportation revenue from the transportation of property or mail, or both); and
- $3 billion for contractors who provide ground services directly to air carriers, such as catering services or on-airport functions.

The law specified that the amount received by each air carrier or contractor was to be based on its payroll expenses for the six-month period from April through September 2019, and that the payroll support funds must be used exclusively for continuing the payment of employee wages, salaries, and benefits. The law also required that air carriers or contractors receiving payroll support must refrain from conducting involuntary layoffs or furloughs or reducing pay rates and benefits from the day the payroll support agreement was executed until September 30, 2020.

According to the CARES Act, air carriers and contractors receiving payroll support also must comply with other program terms and conditions, including continuation of certain air service deemed necessary by the Secretary of Transportation, refraining from stock buybacks or dividend payments through September 30, 2021, and limiting the compensation of highly paid employees until March 24, 2022.

Congressional Research Service
https://crsreports.congress.gov
IN11482

Administered by the U.S. Treasury, PSP has generated considerable interest from airlines and contractors. Treasury data show that, by October 5, 2020, more than $28 billion in payroll support had been approved for disbursement to 610 recipients, including 352 passenger airlines (some operating unscheduled service), 38 cargo carriers, and 220 contractors.

Although Treasury set April 27, 2020, as the deadline for PSP applications, it agreed to accept and consider applications beyond the deadline, subject to the availability of funds. Program data indicate that Treasury accepted and approved applications in the months after the original deadline, as shown in **Table 1**.

Table 1. CARES Act Payroll Support Program (PSP)

(As of October 5, 2020)

	Passenger Airlines	Cargo Airlines	Contractors	Total
1st Agreement Date	04/20/2020	05/08/2020	05/15/2020	N/A
Number of Recipients	352	38	220	610
PSP Amount	$24,960,745,211	$826,478,739	$2,411,868,310	$28,199,092,260

Source: CRS analysis of U.S. Treasury CARES Act Payroll Support Program data (as viewed on October 21, 2020).

Treasury data indicate that the first group of agreements was reached with a number of passenger airlines on April 20, 2020, and about 72% of the passenger airlines payroll agreements occurred in April and May. The first batch of agreements with cargo airlines was reached on May 8, 2020, followed by contractors in mid-May (**Table 1**). Contractors' payroll support agreements were disbursed relatively evenly in May, June, and July. The timing of PSP agreements suggests that passenger airlines were the first group affected by the abrupt drop in air travel as a result of the COVID pandemic, followed by aviation contractors downstream. Air cargo carriers have been less affected.

The data also indicate that, as of October 5, 2020, over 99% of the $25 billion appropriated for payroll support to passenger airlines was committed, compared with approximately 80% of the $3 billion for contractors and over 20% of the $4 billion for cargo carriers. This also appears to agree with reports that cargo carriers have been faring better than passenger airlines.

As one of the PSP requirements prohibits involuntary furloughs or pay-rate reductions through September 2020, many airlines have asked employees to voluntarily take a leave of absence and/or begun to offer voluntary separation packages. Airlines also have warned employees about possible furloughs in October. Airlines and union groups have been advocating for continued federal aid.

However, the payroll support benefit did not expire on September 30, 2020. There is no deadline for a recipient to expend payroll support funds, as long as they are used exclusively for the continuation of employee wages, salaries, and benefits, as stated in a Treasury document. Since many payroll support agreements were approved and executed in May, June, July, or later, many employers are likely to have had funds available for payroll support beyond September 30, 2020. Meanwhile, airlines have been accessing additional capital in private markets and from Treasury's loan and loan guarantees program.

PSP has helped airlines and contractors to temporarily avert mass layoffs and furloughs due to the unprecedented drop in business. The number of passengers on U.S. airlines in April 2020 was 96% lower than in the same month in 2019. The number of U.S. airline passengers in mid-October 2020 remains about 65% lower than the 2019 level, and air travel is not expected to fully recover to pre-pandemic level for years. Congress could consider augmenting, extending, or reallocating undistributed PSP funds to passenger carriers that need more assistance. However, without immediate and significant improvement in passenger traffic, airlines may not have sufficient business to sustain current employment levels even

with short-term payroll assistance from the government. It is likely the airlines will need to restructure for survival and long-term growth.

Author Information

Rachel Y. Tang
Analyst in Transportation and Industry

Disclaimer

Plaintiffs' Exhibit 499

wheelchairtravel.org

The Government Has Leverage Over Airlines — Here's What They Should Do With It - Wheelchair Travel

John Morris

5-7 minutes

The CEO of American Airlines, Doug Parker, recently told CNBC that the coronavirus pandemic has been far worse for the airline industry than the 9/11 terrorist attacks. Demand has cratered and many carriers have cut capacity by more than 50% — but planes are still flying empty.

In the midst of this crisis which threatens the jobs of tens of thousands of employees, distressed airlines have turned to the federal government for financial assistance. Earlier this week, industry trade group Airlines for America asked for $50 billion in aid in the form of tax relief, grants and low-interest loans. At least half of that amount would not have to be repaid.

In recent years, when airline profits have been at an all-time high, carriers have spent nearly $45 billion on stock buybacks, rather than saving for a rainy day. Caught penniless and with their pants down, they want a government handout. Taxpayers will be forced to foot the bill.

Because the government holds all of the cards, it should take the following actions before handing over a single dollar.

Introduce passenger protections like those found in EC 261/2004.

European Union regulation EC 261/2004 provides compensation to airline passengers in the event of denied boarding, lengthy delays or flight cancellations. The compensation amount varies based on the length of the delay and flight distance, but ranges from €250 to €600 — a substantial payout, and an incentive for carriers to provide service as advertised.

The United States does regulate compensation for passengers who have been denied boarding due to oversales, but there is no requirement to make passengers whole in the

event of missed meetings or events due to a lengthy delay or flight cancellation.

Require accessible lavatories on all jet aircraft.

The Department of Transportation recently released a notice of proposed rulemaking or NPRM concerning the accessibility of lavatories on single-aisle aircraft. The proposed regulation would not require airlines to increase the size of lavatories on such aircraft, meaning wheelchair users (and many able-bodied passengers of larger size) will still be unable to use the toilet in the air.

Although the DOT does ultimately intend to require larger wheelchair accessible lavatories through a future rulemaking, that is still years away and would not apply to existing aircraft or any new aircraft delivered within the next 10 years. I propose that agreement to an expanded accessible lavatory regulation be a condition of any financial assistance offered to air carriers.

Set minimum standard for seat pitch.

Economy class is becoming uncomfortably cramped as airlines are installing more seats by reducing legroom. Some airlines offer as little as 28 inches of pitch — that's the measurement from the same position on two seats, one behind the other.

Many passenger rights groups have raised the alarm about the speed of airplane evacuations in an emergency with densified seating, and have called on Congress to take action. With airlines stuck between a rock and a hard place in the current economic climate, now is the time to set a minimum seat pitch standard for the benefit of all passengers.

Define accessibility requirements for business class seats.

As I wrote last month, airlines are restricting disabled passengers from business class seats by prioritizing privacy features over accessibility. They are literally erecting walls around seats which prevent safe, dignified and/or independent transfers from the onboard aisle chair.

While many long-haul aircraft are grounded around the world, the DOT should require dramatic accessibility improvements to recently installed seats that are largely inaccessible to disabled flyers. An agreement between U.S. airlines and the DOT should also be reached to draft a new rule that would better define requirements for accessible seating in premium cabins.

Add a private right of action to the Air Carrier Access Act.

At its annual meeting held last month, the American Bar Association voted to support a private right of action for airline passengers with disabilities.

When an airline violates the civil rights of a disabled passenger (outlined in the Air Carrier Access Act), that passenger cannot sue for damages or injunctive relief. The power of ACAA enforcement rests solely with the DOT, which rarely takes action.

Congress should attach a rider to any financial aid package for airlines, granting disabled air travelers the right to be heard in a court of law.

Final Thoughts

When the stock market closed on Friday, the combined market capitalization of the three largest U.S. airlines was just over $24 billion — American at $4.42 billion, Delta at $13.67 billion and United at $6.07 billion.

Given that the U.S. airline industry has asked for financial assistance equal to more than twice the value of those three airlines, it would be a dereliction of duty and a betrayal of taxpayers if Congress did not extract substantial concessions in return. The ball is in their court; let's hope they don't turn it over to the big corporations.

Featured image courtesy Philadelphia International Airport.

Section 504 of the Rehabilitation Act of 1973: Prohibiting Discrimination Against Individuals with Disabilities in Programs or Activities Receiving Federal Assistance

Cynthia Brougher, Coordinator
Legislative Attorney

September 29, 2010

Congressional Research Service
7-....
www.crs.gov
RL34041

CRS Report for Congress
Prepared for Members and Committees of Congress

Summary

Section 504 of the Rehabilitation Act of 1973 prohibits discrimination against an otherwise qualified individual with a disability solely by reason of disability in any program or activity receiving federal financial assistance or under any program or activity conducted by an executive agency or the U.S. Postal Service. Section 504 was the first federal civil rights law generally prohibiting discrimination against individuals with disabilities. This report examines Section 504, recent amendments to the definition of disability, Section 504's regulations, and Supreme Court interpretations. Section 504's differences with the ADA, and its relationship to the Individuals with Disabilities Education Act (IDEA), are also discussed.

Contents

Contacts

Introduction

Section 504 of the Rehabilitation Act of 1973[1] prohibits discrimination against an otherwise qualified individual with a disability solely by reason of disability in any program or activity receiving federal financial assistance or under any program or activity conducted by an executive agency or the U.S. Postal Service. Section 504 was the first federal civil rights law generally prohibiting discrimination against individuals with disabilities.[2] The concepts of Section 504 and its implementing regulations were used in crafting the Americans with Disabilities Act (ADA)[3] in 1990. The ADA and Section 504 are, therefore, very similar and have some overlapping coverage but also have several important distinctions. For example, Section 504 is limited to programs receiving federal funds or the executive agencies and the Postal Service while the ADA broadly covers the private sector regardless of whether federal funds are involved and does not cover the executive agencies or the Postal Service. The ADA Amendments Act of 2008, P.L. 110-325, amended the definition of disability in the ADA and the definition of disability applicable to Section 504.[4]

This report examines Section 504, the recent amendments to the definition of disability, Section 504's regulations, and Supreme Court interpretations. Section 504's differences with the ADA, and its relationship to the Individuals with Disabilities Education Act (IDEA), are also discussed.[5]

[1] 29 U.S.C. §794. Title V of the Rehabilitation Act contains other sections relating to disability discrimination law. Section 501, 29 U.S.C. §791, requires federal agencies to establish affirmative action program plans for the hiring, placement, and advancement of individuals with disabilities. Section 502, 29 U.S.C. §792, establishes the Architectural and Transportation Barriers Compliance Board (the Access Board), which in part provides technical guidance regarding architectural, transportation, and communication barriers. See http://www.access-board.gov/. Section 503, 29 U.S.C. §793, provides for affirmative action in employment of individuals with disabilities in certain federal contracts. The Rehabilitation also contains provisions authorizing the federal government to make grants to states and territories to provide vocational rehabilitation (VR) services to persons with disabilities who are interested in seeking and retaining employment. For a discussion of VR services see CRS Report RL34017, *Vocational Rehabilitation Grants to States and Territories: Overview and Analysis of the Allotment Formula*, by Scott Szymendera and (name redacted). This report focuses on section 504; a discussion of these provisions is beyond its scope.

[2] The National Council on Disability, the independent federal agency tasked with making recommendations to the President and Congress to enhance the quality of life for all Americans with disabilities and their families, stated: "Section 504 of the 1973 Rehabilitation Act is acknowledged as the first national civil rights law to view the exclusion and segregation of people with disabilities as discrimination and to declare that the Federal Government would take a central role in reversing and eliminating this discrimination." National Council on Disability, "Rehabilitating Section 504" (February 12, 2003), at http://www.ncd.gov/newsroom/publications/2003/section504.htm.

[3] 42 U.S.C. §12101 *et seq.* For a detailed discussion of the ADA see CRS Report 98-921, *The Americans with Disabilities Act (ADA): Statutory Language and Recent Issues*, by (name redacted).

[4] For a more detailed discussion of the ADA Amendments Act see CRS Report RL34691, *The ADA Amendments Act: P.L. 110-325*, by (name redacted).

[5] 20 U.S.C. §1400 et seq. For a discussion of IDEA, see CRS Report RS22590, *The Individuals with Disabilities Education Act (IDEA): Overview and Selected Issues*, by (name redacted) and (name redacted).

Overview of Section 504

Historical Background

Although Section 504 was the first federal statute that provided broad civil rights protections for individuals with disabilities, there was very little discussion of its meaning or importance during its enactment in 1973. The most detailed discussion was during congressional debate when Senator Humphrey observed,

> I am deeply gratified at the inclusion of these provisions which carry through the intent of original bills which I introduced, jointly with the Senator from Illinois (Mr. Percy), earlier this year, S. 3044 and S. 3458, to amend, respectively, Titles VI and VII of the Civil Rights Act of 1964, to guarantee the right of persons with a mental or physical handicap to participate in programs receiving Federal assistance, and to make discrimination in employment because of these handicaps, and in the absence of a bona fide occupational qualification, an unlawful employment practice. The time has come to firmly establish the right of these Americans to dignity and self-respect as equal and contributing members of society, and to end the virtual isolation of millions of children and adults from society.[6]

The implementation of Section 504 was not performed expeditiously. The then Department of Health, Education, and Welfare (HEW)[7] published regulations in 1978 only after a federal court held that HEW was required to promulgate regulations[8] and after demonstrations at HEW offices.[9] The year 1978 also saw major amendments to Section 504.[10] These amendments expanded Section 504 nondiscrimination requirements to programs or activities conducted by executive agencies, and added a new section 505[11] which applied the remedies, procedures and rights of Title VI of the Civil Rights Act of 1964[12] to Section 504 actions.

Statutory and Regulatory Provisions

Section 504 Statutory Provisions

Section 504 has been amended numerous times since its original enactment in 1973. The core requirement of the section is found in subsection (a). This subsection was amended by P.L. 95-602 which added the provisions regarding the regulations. Section 504(a) currently states the following:

---

[6] 118 CONG. REC. 32310 (September 26, 1972) (Remarks of Sen. Humphrey).

[7] HEW was divided into the current Department of Health and Human Services (HHS) and the current Department of Education (ED).

[8] *Cherry v. Mathews,* 419 F.Supp. 922 (D.D.C. 1976).

[9] National Council on Disability, "Rehabilitating Section 504" (February 12, 2003), at http://www.ncd.gov/newsroom/publications/2003/section504.htm.

[10] P.L. 95-602.

[11] 29 U.S.C. §794a.

[12] 42 U.S.C. §2000d *et seq.*

> (a) No otherwise qualified individual with a disability in the United States, as defined in section 705(20), shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service. The head of each such agency shall promulgate such regulations as may be necessary to carry out the amendments to this section made by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Act of 1978. Copies of any proposed regulation shall be submitted to appropriate authorizing committees of Congress, and such regulations may take effect no earlier than the thirtieth day after the date on which such regulation is so submitted to such committees.[13]

Subsection (b) of Section 504 defines the term "program or activity." This subsection was added by P.L. 100-259 in 1988 in response to the Supreme Court's narrow interpretation of the phrase "program or activity" in Title IX of the Education Amendments of 1972.[14] The amendment clarified that discrimination is prohibited throughout the entire institution if any part of the institution receives federal financial assistance.[15]

Subsection (c) of Section 504 was also added by P.L. 100-259 in 1988. It contains an exception for small providers so they are not required to make significant structural alterations to their existing facilities to render them accessible if alternative means of providing the services are available. This subsection was added to clarify that P.L. 100-259 does not add new requirements for architectural modification.[16]

Subsection (d) of Section 504 requires that the standards used to determine whether there has been a violation of Section 504 regarding employment discrimination complaints are the same as those in the Americans with Disabilities Act. This subsection was added by P.L. 102-569 in 1992. P.L. 102-569 also substituted the term "disability" for the term "handicap."

Definition of Disability

The definition of disability applicable to Section 504[17] was amended by the ADA Amendments Act of 2008 to conform with the new definition of disability for the ADA.[18] The Senate Statement of Managers noted the importance of maintaining uniform definitions in the two statutes so covered entities "will generally operate under one consistent standard, and the civil rights of individuals with disabilities will be protected in all settings."[19]

The ADA definition defines the term disability with respect to an individual as "(A) a physical or mental impairment that substantially limits one or more of the major life activities of such

---

[13] 29 U.S.C. §794(a).

[14] *Grove City College v. Bell*, 465 U.S. 555 (1984). See also *Consolidated Rail Corp. v. Darrone*, 465 U.S. 624 (1984).

[15] For a discussion of the purpose of the amendment see S.Rept. 100-64, 100th Cong., 2d Sess. (June 5, 1987), reprinted in 1988 U.S. CODE CONG. & AD. NEWS 3 (1988).

[16] *Id.*

[17] 29 U.S.C. §705.

[18] P.L. 110-325, §7. For a more detailed discussion of the ADA Amendments Act see CRS Report RL34691, *The ADA Amendments Act: P.L. 110-325*, by (name redacted).

[19] 153 CONG. REC. S. 8347 (Sept. 11, 2008)(Statement of Managers to Accompany S. 3406, the Americans with Disabilities Act Amendments Act of 2008).

individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment (as described in paragraph (3)).”[20] Although this is essentially the same statutory language as was in the original ADA, P.L. 110-325 contains new rules of construction regarding the definition of disability, which provide that

- the definition of disability shall be construed in favor of broad coverage to the maximum extent permitted by the terms of the act;
- the term “substantially limits” shall be interpreted consistently with the findings and purposes of the ADA Amendments Act;
- an impairment that substantially limits one major life activity need not limit other major life activities to be considered a disability;
- an impairment that is episodic or in remission is a disability if it would have substantially limited a major life activity when active; and
- the determination of whether an impairment substantially limits a major life activity shall be made without regard to the ameliorative effects of mitigating measures, except that the ameliorative effects of ordinary eyeglasses or contact lenses shall be considered.[21]

The ADA Amendments Act specifically lists examples of major life activities including caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, and working. The act also states that a major life activity includes the operation of a major bodily function.

Regulations

The first Section 504 regulations were promulgated by the then department of Health, Education, and Welfare (HEW) in January of 1978. Soon after this, the 1978 amendments to Section 504 were passed which applied Section 504 nondiscrimination requirements to programs or activities conducted by executive agencies, and added language requiring the promulgation of regulations. Each executive agency and the Postal Service now has its own Section 504 regulations which are tailored to the particular recipients of that agency’s programs. In addition, each executive agency and the Postal Service have regulations which delineate the coverage of Section 504 with regard to that agency’s own programs. In 1980, President Carter issued Executive Order 12250 which provided that the Department of Justice shall coordinate the implementation and enforcement of certain nondiscrimination provisions, including those of Section 504.[22]

Selected Supreme Court Decisions

The Supreme Court has examined Section 504 in numerous contexts and, since the enactment of the ADA in 1990, has often referenced Section 504 in its analysis of ADA cases. The first Section

[20] P.L. 110-325, §4(a), amending 42 U.S.C. §12102.

[21] Low vision devices are not included in the ordinary eyeglasses and contact lens exception.

[22] Executive Order 12250 (November 2, 1980), reprinted at http://www.usdoj.gov/crt/cor/byagency/eo12250.htm.

504 case to reach the Supreme Court was *Southeastern Community College v. Davis*.[23] In *Southeastern*, the plaintiff was a student with a serious hearing disability and who sought to be trained as a registered nurse. The college argued that she was not "otherwise qualified" as she could not understand speech except through lip reading and that this limitation made it unsafe for her to participate in the normal clinical program. The Supreme Court agreed with the college, noting that it was unlikely that she "could benefit from any affirmative action that the regulations reasonably could be interpreted as requiring."[24] The Court concluded that

> there was no violation of §504 when Southeastern concluded that respondent did not qualify for admission to its program. Nothing in the language or history of §504 reflects an intention to limit the freedom of an educational institution to require reasonable physical qualifications for admission to a clinical training program. Nor has there been any showing in this case that any action short of a substantial change in Southeastern's program would render unreasonable the qualifications it imposed.[25]

Similarly, in *Alexander v. Choate*[26] the Supreme Court found no violation of Section 504 where Medicaid recipients with disabilities claimed that a proposed 14-day limitation on in-patient coverage had a discriminatory effect on individuals with disabilities. The Court found that the limitation was neutral on its face as it would provide Medicaid users with or without disabilities with "identical and effective hospital services."[27] Section 504 did not require the state to alter its definition of the Medicaid benefit because individuals with disabilities have greater medical needs. Citing *Southeastern*, the Court observed that Section 504 requires even-handed treatment and an opportunity for individuals with disabilities to participate and benefit from programs receiving federal funds. "The Act does not, however, guarantee the handicapped equal results from the provision of state Medicaid, even assuming some measure of equality of health could be constructed."[28]

Consolidated Rail Corporation v. Darrone[29] raised the issue of whether an employment discrimination action under Section 504 was limited to situations where the primary objective of the federal financial assistance was to provide employment. The Supreme Court held that such actions were not limited since the primary goal of the Rehabilitation Act is to increase employment of individuals with disabilities. The fact that Congress chose to ban such employment discrimination only by the federal government and recipients of federal funds did not require that Section 504 be further limited.

In *Bowen v. American Hospital Association*[30] the Supreme Court addressed the issue of whether Section 504 regulations requiring the provision of health care to infants with disabilities were authorized by Section 504. This case began when the parents of a child with Down Syndrome requested that life-saving surgery not be performed.[31] In response to the death of the child, HHS

[23] 442 U.S. 397 (1979).

[24] *Id.* at 409.

[25] *Id.* at 414.

[26] 469 U.S. 297 (1985).

[27] *Id.* at 302.

[28] *Id.* at 304.

[29] 465 U.S. 624 (1984).

[30] 476 U.S. 610 (1986).

[31] This situation is generally referred to as the "Baby Doe" case.

promulgated a regulation under Section 504 stating that Section 504 required that nourishment and medically beneficial treatment should not be withheld from infants with disabilities.[32] Striking down these regulations, the Court noted that the legislative history of the Rehabilitation Act did not support the argument that federal officials can intervene in treatment decisions traditionally left by state law to the parents and attending physicians.[33]

School Board of Nassau County v. Arline[34] examined the issue of when an individual with a disability is "otherwise qualified" for a job if the individual has a contagious disease. Gene Arline taught elementary school until her employment was terminated after she suffered a third relapse of tuberculosis within two years. The Supreme Court held that an individual with a contagious disease may be a person with a disability under Section 504 but that a person who poses a significant risk of communicating an infectious disease to others that cannot be alleviated by reasonable accommodation will not be otherwise qualified for a job. This should be determined by findings of fact based on reasonable medical judgments about the nature of the risk, the duration of the risk, the severity of the risk, and the probabilities the disease will be transmitted and will cause harm.[35]

In *Traynor v. Turnage*[36] the Supreme Court examined the application of Section 504 to an executive agency, more specifically to the Veterans' Administration (VA). The veterans who brought the suit had been denied an extension of the time limit for the use of educational benefits due to disability on the ground that their alleged disability was due to alcoholism unrelated to a psychiatric condition. VA regulations prohibited the granting of a time extension because alcoholism unrelated to a psychiatric condition was considered willful misconduct.[37] 38 U.S.C. §211(a) bars judicial review of the Veterans' Administrators' decision "on any question of law or fact under any law administered by the Veterans' Administration providing benefits for veterans." The first question the Court addressed, then, was whether 38 U.S.C. §211(a) foreclosed the Court from considering whether the VA regulation violated Section 504. Holding that such suits were not precluded, the Supreme Court noted that

> Section 211(a) insulates from review decision of law and fact 'under any law administered by the Veterans' Administration,' that is, decisions made in interpreting or applying a particular provision of that statute to a particular set of facts... But the cases now before us involve the issue whether the law sought to be administered is valid in light of a subsequent statute whose enforcement is not the exclusive domain of the Veterans' Administration.[38]

The Court then examined the second issue in *Traynor*: whether the regulation was inconsistent with the requirements of Section 504. Finding that the regulation did not violate Section 504, the Court observed, "There is nothing in the Rehabilitation Act that requires that any benefit extended to one category of handicapped persons also be extended to all other categories of handicapped persons."[39] The Court also noted that "Congress is entitled to establish priorities for the allocation

[32] 45 C.F.R. §84.55(b) (1985).

[33] 476 U.S. 610, 645 (1986).

[34] 480 U.S. 273 (1987).

[35] *Id.* at 288.

[36] 485 U.S. 535 (1988).

[37] 28 C.F.R. §3.301(c)(2).

[38] 485 U.S. 535, 543-544 (1988).

[39] *Id.* at 549.

of the limited resources available for veterans' benefits, ... and thereby to conclude that veterans who bear some responsibility for their disabilities have no stronger claim to an extended eligibility period than do able-bodied veterans."

The Supreme Court in *Barnes v. Gorman*[40] held in a unanimous decision that punitive damages may not be awarded under Section 202[41] of the ADA and Section 504 of the Rehabilitation Act. Jeffrey Gorman uses a wheelchair and lacks voluntary control over his lower torso which necessitates the use of a catheter attached to a urine bag. He was arrested in 1992 after fighting with a bouncer at a nightclub and during his transport to the police station suffered significant injuries due to the manner in which he was transported. He sued the Kansas City police and was awarded over $1 million in compensatory damages and $1.2 million in punitive damages. The eighth circuit court of appeals upheld the award of punitive damages but the Supreme Court reversed. Although the Court was unanimous in the result, there were two concurring opinions, and the concurring opinion by Justice Stevens, joined by Justices Ginsburg and Breyer, disagreed with the reasoning used in Justice Scalia's opinion for the Court.

Justice Scalia observed that the remedies for violations of both Section 202 of the ADA and Section 504 of the Rehabilitation Act are "coextensive with the remedies available in a private cause of action brought under Title VI of the Civil Rights Act of 1964."[42] Neither Section 504 nor Title II of the ADA specifically mention punitive damages, rather they reference the remedies of Title VI of the Civil Rights Act. Title VI is based on the congressional power under the Spending Clause[43] to place conditions on grants. Justice Scalia noted that Spending Clause legislation is "much in the nature of a contract" and, in order to be a legitimate use of this power, the recipient must voluntarily and knowingly accept the terms of the "contract." "If Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously."[44] This contract law analogy was also found to be applicable to determining the scope of the damages remedies and, since punitive damages are generally not found to be available for a breach of contract, Justice Scalia found that they were not available under Title VI, Section 504, or the ADA.

Section 504 and the ADA

The Americans with Disabilities Act was modeled on the statutory language, regulations, and case law of Section 504. The ADA and Section 504 are, therefore, very similar and have some overlapping coverage but also have several important distinctions. Most significantly, Section 504 is limited to programs receiving federal funds or the executive agencies and the Postal Service while the ADA broadly covers the private sector regardless of whether federal funds are involved and does not cover the executive agencies or the Postal Service.

There are several other distinctions between the ADA and Section 504. For example, the ADA contains specific exemptions for religious entities.[45] There are no corresponding provisions in

[40] 536 U.S. 181 (2002).

[41] 42 U.S.C. §12132. Section 203, 42 U.S.C. §12133, contains the enforcement provisions.

[42] 42 U.S.C. §2000d *et seq.*

[43] U.S. Const., Art. I §8, cl.1.

[44] *Pennhurst State School and Hospital v. Halderman*, 451 U.S. 1, 17 (1981).

[45] 42 U.S.C. §§12113(c), 12187.

Section 504. Therefore, if a faith-based organization receives federal funds, it is prohibited from discriminating against an individual with a disability.[46]

Title I of the ADA prohibits employment discrimination which is also prohibited with regard to the entities covered by Section 504. However, the enforcement procedures for the two statutes are somewhat different. Enforcement of Title I of the ADA parallels that of Title VII of the Civil Rights Act of 1964 and includes the requirement that persons alleging discrimination file a charge with the EEOC.[47] However, under Section 504 an employment discrimination complaint may be filed with the Office of Civil Rights for the agency that provided the federal financial assistance or the Department of Justice. Administrative procedures do not have to be exhausted prior to filing suit in federal court.[48]

Section 504 and Education

Several federal statutes, notably the Individuals with Disabilities Education Act (IDEA),[49] Section 504, and the ADA, address the rights of individuals with disabilities to education.[50] Although there is overlap, particularly with Section 504 and the ADA, each statute plays a significant part in the education of individuals with disabilities. Generally, although there are some differences regarding K-12 schools, the Department of Education (ED) has interpreted the Section 504 compliance standards for schools to be the same as the basic requirements of IDEA.[51]

As discussed previously, the Rehabilitation Act is amended by the ADA Amendments Act to reference the definition of disability in the ADA. Section 504's coverage of education was a subject of discussion during the passage of the ADA Amendments Act, and the Senate Statement of Managers observed:

> We expect that the Secretary of Education will promulgate new regulations related to the definition of disability to be consistent with those issued by the Attorney General under this Act. We believe that other current regulations issued by the Department of Education Office of Civil Rights under Section 504 of the Rehabilitation Act are currently harmonious with Congressional intent under both the ADA and the Rehabilitation Act.[52]

The implications of the changes in the definition of disability under Section 504 and the ADA for the coverage of children in K-12 schools is not entirely clear. Perry Zirkel, a Lehigh University education and law professor, argues that the ADAAA would result in more students in K-12 education being given Section 504 plans, especially students with diabetes, asthma, food

[46] For a more detailed discussion of Section 504 requirements for faith-based organizations see http://www.dol.gov/odep/pubs/fact/faith.htm.

[47] 42 U.S.C. §12117(a), 42 U.S.C. §2000e-5.

[48] 29 U.S.C. §794a, 42 U.S.C. §2000d *et seq*.

[49] 20 U.S.C. §1400 et seq.

[50] For a more detailed discussion and comparison of the educational coverage of these statutes see CRS Report R40123, *Education of Individuals with Disabilities: The Individuals with Disabilities Education Act (IDEA), Section 504 of the Rehabilitation Act, and the Americans with Disabilities Act (ADA)*, by (name redacted) and (name redacted).

[51] These requirements include the provision of a free appropriate public education in the least restrictive setting. See 34 C.F.R. Part 104, Appx. A, Subpart D.

[52] *Id.*

allergies, dyslexia, and attention deficit disorder (ADD).[53] Another commentator noted that the addition of "reading" in the list of major life activities may be problematic since "there is no easy way to distinguish children who are unable to read because they have a disability from those who have simply received poor instruction."[54]

Author Contact Information

Cynthia Brougher, Coordinator
Legislative Attorney
/redacted/@crs.loc.gov, 7-....

Acknowledgments

Previous authors of this report include (name redacted) and (name redacted).

[53] "ADA Amendments Become Law, New Definitions Expand Protection," SECTION 504 COMPLIANCE HANDBOOK (Nov. 2008).

[54] "List of 'Major Life Activities" in ADA Bill Raises Questions About Reading," 24 THE SPECIAL EDUCATOR 3 (October 10, 2008).

Plaintiffs' Exhibit 501

Congressional Research Service
Informing the legislative debate since 1914

State and Federal Authority to Mandate COVID-19 Vaccination

April 2, 2021

Congressional Research Service
https://crsreports.congress.gov
R46745

CRS REPORT
Prepared for Members and
Committees of Congress

Congressional Research Service
Informing the legislative debate since 1914

SUMMARY

R46745

April 2, 2021

Wen W. Shen
Legislative Attorney

State and Federal Authority to Mandate COVID-19 Vaccination

The Coronavirus Disease 2019 (COVID-19) vaccines recently authorized by the U.S. Food and Drug Administration (FDA) are a critical tool to address the pandemic. After determining that these vaccines meet the applicable statutory standards and the Agency's specific safety and efficacy standards, FDA issued Emergency Use Authorizations (EUAs) under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In particular, data supporting the EUA requests show that the vaccines are effective at preventing symptomatic COVID-19 in vaccinated individuals. Given this data, many public health experts believe that promoting COVID-19 vaccination—along with continued engagement in community mitigation activities that prevent transmission, such as mask wearing and social distancing—should be a key component of the United States' pandemic response.

One available legal tool for increasing vaccination rates is for governments to require vaccination. Under the United States' federalist system, states and the federal government share regulatory authority over public health matters, with states traditionally exercising the bulk of the authority in this area pursuant to their general police power. This power authorizes states, within constitutional limits, to enact laws "to provide for the public health, safety, and morals" of the states' inhabitants. In contrast to this general power, the federal government's powers are confined to those enumerated in the Constitution.

This report provides an overview of state and federal authority to mandate vaccination. The first part of the report provides background on state and local authority to mandate vaccination under states' general police power. It discusses the Supreme Court's long-standing recognition of state and local authority to mandate vaccination as an exercise of their police power, as well as modern courts' analyses of more recent challenges to state vaccination mandates based on the First Amendment's Free Exercise Clause. The first part of the report closes with a look at how the COVID-19 vaccines' EUA status may affect a court's analysis of a potential mandate.

The second part of the report provides an overview of federal authority to mandate vaccination. It discusses one possible source of existing federal authority, Section 361 of the Public Health Service Act (PHSA), and reviews the extent of Congress's constitutional authority under the Constitution's Spending and Commerce Clauses to potentially mandate vaccination.

fines.[63] CDC has incorporated the higher fines into applicable regulations, which subject violating individuals to a fine up to $100,000 if the violation does not result in death, or a fine of up to $250,000 if the violation results in a death.[64] Violations by organizations are subject to a fine of up to $200,000 per event if the violation does not result in a death, or $500,000 per event if the violation results in a death.[65] Given the significant potential penalties, any mandate issued under the provision—assuming that it falls within the Agency's delegated authority—may be more appropriately structured as requirements on entities in interstate commerce, such as a requirement on entities to verify vaccination status.[66]

Congress's Authority to Mandate Vaccination

Although states have traditionally exercised the bulk of authority over public health matters, including vaccination, Congress shares certain concurrent authority in this area emanating from its enumerated powers in the Constitution.[67] This authority derives from, among other sources, the Constitution's Spending and Commerce Clauses.[68]

The Spending Clause empowers Congress to tax and spend for the general welfare.[69] Under this authority, which is subject to several limitations, Congress may offer federal funds to nonfederal entities and prescribe the terms and conditions under which the funds are accepted and used by recipients.[70] Over the past century, Congress has frequently invoked this authority in the public health context, including for purposes of controlling specified diseases, establishing neighborhood or community health centers, and creating federal health insurance programs, including Medicare and Medicaid.[71]

Applying its authority in the context of a vaccination mandate, Congress could encourage states to enact a vaccination mandate meeting certain federal requirements by imposing it as a condition of receiving certain federal funds.[72] This use of the Spending Clause authority, assuming it falls within the broad parameters of being for the "general welfare," would be permissible so long as (1) Congress provides clear notice of the vaccination mandate that states must enact; (2) the mandate is related to the purpose of the federal funds; (3) this conditional grant of funds is not

[63] *See* 18 U.S.C. §§ 3559, 3571(b)(5), 3571(c)(5).

[64] *See* 42 C.F.R. § 70.18(a).

[65] *See id.* § 70.18(b).

[66] For instance, CDC's public transit mask mandate was issued under Section 361 and includes an obligation on conveyance operators to require passengers to wear masks while also contemplating "widespread voluntary compliance" and enforcement support from other federal agencies with access to civil enforcement schemes. *See* 86 Fed. Reg. 8025, 8026, 8030 n.33 (Feb. 3, 2021). *See also* Abramson, *supra* note 17, at 24–27 (noting that some state vaccination mandates for health care workers are structured as a requirement on hospitals and health care facilities to ensure that their employees are vaccinated against specified vaccine-preventable diseases).

[67] McCuskey, *supra* note 6, at 113–20.

[68] *See id.* at 116–19.

[69] U.S. CONST. art. I, § 8, cl. 1.

[70] *See* Nolan & Lewis, *supra* note 8, at 29–31 (discussing South Dakota v. Dole, 483 U.S. 203, 207–08 (1987)).

[71] *See* James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 335–37 (1998); McCuskey, *supra* note 6, at 118–19.

[72] *See Dole*, 483 U.S. at 211–12 (holding that 23 U.S.C. § 158, which conditioned the provision of certain federal highway funds upon a state's enactment of a minimum drinking age of twenty-one, was a valid exercise of Congress's spending clause authority).

Plaintiffs' Exhibit 502

southwestada.org

DLRP May 2003 Legal E-Bulletin

13-16 minutes

Punitive Damages under § 504 of the Rehabilitation Act and Title II of the ADA.

In *Barnes v. Gorman*1, the Supreme Court ruled that punitive damages were not an available remedy in a private cause of action under Title II of the Americans with Disabilities Act or § 504 of the Rehabilitation Act. This case helped clarify an issue that many lower courts had disagreed - - whether money damages were even available with the lack of specific guidance provided by Congress in legislating Title II and § 504.

The plaintiff, Jeffrey Gorman lacks voluntary control over the lower half of his body and uses a wheelchair. He must also wear a catheter attached to a urine bag around his waist since he doesn't have control over his bladder. Gorman was involved in an altercation at a Kansas City nightclub and was arrested. While waiting for a police van to take him to the station, Gorman was denied permission to empty his urine bag in a restroom. The van that arrived was not wheelchair accessible and over Gorman's objections, the police officer removed him from his wheelchair and strapped him to a bench in the van with the seatbelt tightened over his urine bag. Gorman later released his seatbelt because of the pressure placed on his urine bag, ultimately falling off the bench. His wheelchair was also damaged in the ride. Gorman continues to suffer serious medical problems related to this incident.

Title II of the ADA prohibits discrimination on the basis of disability by state and local governmental entities while § 504 of the Rehabilitation Act prohibits discrimination by recipients of federal funding. The Kansas City police department is a public entity that receives federal funding. By failing to follow appropriate policies for the proper arrest and transportation of people with disabilities, they had in effect discriminated against Gorman.

Gorman sued the police for violating Title II and § 504 and received a jury verdict of $1 million in compensatory damages and $1.2 million in punitive damages. The district court vacated the punitive damages, holding that they were unavailable under Title II and § 504 respectively. The Federal Court of Appeals for the Eighth Circuit reversed this decision, contending that punitive damages are a traditional remedy available to the courts, and

their availability should not be disturbed unless Congress declares they are not available.

Punitive damages are a traditional court-ordered remedy designed to punish the defendant through their pocketbook as opposed to compensatory damages, which help compensate the victim. Courts will usually only award punitive damages when there has been intentional wrongdoing, wanton and reckless misconduct, or some sort of outrageous behavior.

If one looks at the statute prescribing remedies available under Title II2 , it refers to the statute discussing remedies for § 504 of Rehabilitation Act3. If one then looks at the Rehab Act statute, it states that the remedies are the same as those under Title VI of the Civil Rights Act4, which prohibits racial discrimination in federally funded programs and activities. So the remedies under both Title II and § 504 are the same as those available under Title VI.

This maddeningly convoluted attempt to find out what remedies are indeed available does not end there. Title VI doesn't mention any remedies in a private cause of action. However, the Supreme Court had interpreted Title IX of the Education Amendments of 19725 consistent with Title VI and ruled that monetary damages were available in a private cause of action under Title IX in *Franklin v. Gwinnett County Public Schools*6 : "Absent clear direction to the contrary by Congress, the federal courts have the power to award any appropriate relief in a cognizable cause of action brought pursuant to a federal statute." The Eighth Circuit had relied on Franklin and justified punitive damages as being "appropriate relief" for the courts to award under Title II. The Supreme Court stepped in and overruled.

Justice Scalia, in writing for a unanimous Supreme Court, noted that *Franklin* never defined the scope of "appropriate relief" available. Congress first passed Title VI and later the Rehabilitation Act under the Spending Clause of the United States Constitution. The Supreme Court likened legislation that utilizes the Spending Clause to a contract. Under the Spending Clause, Congress can place certain conditions upon granting federal funds. Under Title VI, the recipient agrees not to discriminate on the grounds of race by accepting the money. A similar analogy applies to § 504 with disability discrimination. When a recipient of federal funds discriminates, he is essentially breaking his agreement with Congress.

"A funding recipient is generally on notice that it is subject not only to those remedies explicitly provided in the relevant legislation, but also to those remedies traditionally available in suits for breach of contract." (citing *Franklin*)

So the proper scope of remedies available under Title VI is the traditional remedies available in a breach of contract. The Supreme Court reiterated that punitive damages, unlike compensatory damages or injunctions, are traditionally not available in a breach of

contract. Since compensatory damages by themselves can sometime exceed a recipient's level of federal funding, the Supreme Court reasoned that the recipient would never have accepted the money if they were to be additionally exposed to punitive liability. Therefore, punitive damages are not an available remedy under Title VI. Since both Title II and § 504's remedies derive from Title VI, punitive damages aren't available for Mr. Gorman either.

This decision exposes a tragic oversight by Congress when it fashioned Title II's remedial scheme after § 504's [remedial scheme] and ultimately Title VI's. Technically, as Justice Stevens noted in his concurring opinion, Title II, unlike Title VI and § 504 was not passed under the Spending Clause. Congress had passed the ADA using its power under the Fourteenth Amendment to enact legislation that enforces equal protection under the law. Public entities don't really have much of a choice when told not to discriminate under Title II, and this mandate is not conditioned on the receipt of federal funds. So the contract analogy would not have worked had Title II's remedies not been derived from § 504's. If Congress had intended punitive damages to be an available remedy under Title II, it could have explicitly legislated that as *Franklin* suggested rather than allow the courts to guess and possibly undermine their original intentions.

It is clear from the *Barnes* decision that punitive damages are not an available remedy under Title II and Section 504. The Supreme Court did not disturb Gorman's compensatory damage award.

Presumably, compensatory damages will remain an available remedy since compensatory damages are "traditionally available for a breach of contract." Two important obstacles still remain in obtaining compensatory damages. The first is that many courts require the showing of intentional discrimination before the award of such compensation. Many § 504 and Title II violations by state and local government are often due to ignorance and indifference to the obstacles that people with disabilities face in obtaining services and programs. The second obstacle in acquiring compensatory damages is the sovereign immunity issue. Courts are divided on whether state governments are even liable for money damages under Title II or Section 504 when sued by private individuals. A discussion on the contentious issue of sovereign immunity and its impact on civil rights legislation is outside the scope of this E-bulletin. The important thing to know is that only states have this immunity. Individuals can still recover compensation for local government violations of the ADA or Rehabilitation Act as long as such compensation is deemed "proper" by the courts.

---

1. 536 U.S. 181 (2002)
2. 42 U.S.C. § 12133
3. 29 U.S.C. § 794a(a)(2)

Plaintiffs' Exhibit 503

15. CONVENTION ON THE RIGHTS OF PERSONS WITH DISABILITIES

New York, 13 December 2006

ENTRY INTO FORCE: 3 May 2008, in accordance with article 45(1).

REGISTRATION: 3 May 2008, No. 44910.

STATUS: Signatories: 164. Parties: 184.

TEXT: United Nations, *Treaty Series*, vol. 2515, p. 3;

Note: The above Convention was adopted on 13 December 2006 during the sixty-first session of the General Assembly by resolution A/RES/61/106. In accordance with its article 42, the Convention shall be open for signature by all States and by regional integration organizations at United Nations Headquarters in New York as of 30 March 2007.

Participant	*Signature*	*Formal confirmation(c), Accession(a), Ratification*
Afghanistan		18 Sep 2012 a
Albania	22 Dec 2009	11 Feb 2013
Algeria	30 Mar 2007	4 Dec 2009
Andorra	27 Apr 2007	11 Mar 2014
Angola		19 May 2014 a
Antigua and Barbuda	30 Mar 2007	7 Jan 2016
Argentina	30 Mar 2007	2 Sep 2008
Armenia	30 Mar 2007	22 Sep 2010
Australia	30 Mar 2007	17 Jul 2008
Austria	30 Mar 2007	26 Sep 2008
Azerbaijan	9 Jan 2008	28 Jan 2009
Bahamas	24 Sep 2013	28 Sep 2015
Bahrain	25 Jun 2007	22 Sep 2011
Bangladesh	9 May 2007	30 Nov 2007
Barbados	19 Jul 2007	27 Feb 2013
Belarus	28 Sep 2015	29 Nov 2016
Belgium	30 Mar 2007	2 Jul 2009
Belize	9 May 2011	2 Jun 2011
Benin	8 Feb 2008	5 Jul 2012
Bhutan	21 Sep 2010	
Bolivia (Plurinational State of)[1]	13 Aug 2007	16 Nov 2009
Bosnia and Herzegovina	29 Jul 2009	12 Mar 2010
Botswana		12 Jul 2021 a
Brazil	30 Mar 2007	1 Aug 2008
Brunei Darussalam	18 Dec 2007	11 Apr 2016
Bulgaria	27 Sep 2007	22 Mar 2012
Burkina Faso	23 May 2007	23 Jul 2009
Burundi	26 Apr 2007	22 May 2014
Cabo Verde	30 Mar 2007	10 Oct 2011
Cambodia	1 Oct 2007	20 Dec 2012
Cameroon	1 Oct 2008	
Canada	30 Mar 2007	11 Mar 2010
Central African Republic	9 May 2007	11 Oct 2016
Chad	26 Sep 2012	20 Jun 2019
Chile	30 Mar 2007	29 Jul 2008
China[2]	30 Mar 2007	1 Aug 2008
Colombia	30 Mar 2007	10 May 2011
Comoros	26 Sep 2007	16 Jun 2016
Congo	30 Mar 2007	2 Sep 2014
Cook Islands		8 May 2009 a
Costa Rica	30 Mar 2007	1 Oct 2008
Côte d'Ivoire	7 Jun 2007	10 Jan 2014
Croatia	30 Mar 2007	15 Aug 2007
Cuba	26 Apr 2007	6 Sep 2007
Cyprus	30 Mar 2007	27 Jun 2011
Czech Republic	30 Mar 2007	28 Sep 2009
Democratic People's Republic of Korea	3 Jul 2013	6 Dec 2016
Democratic Republic of the Congo		30 Sep 2015 a
Denmark	30 Mar 2007	24 Jul 2009
Djibouti		18 Jun 2012 a
Dominica	30 Mar 2007	1 Oct 2012
Dominican Republic	30 Mar 2007	18 Aug 2009
Ecuador	30 Mar 2007	3 Apr 2008
Egypt	4 Apr 2007	14 Apr 2008
El Salvador	30 Mar 2007	14 Dec 2007

Participant	*Signature*	*Formal confirmation(c), Accession(a), Ratification*
Estonia	25 Sep 2007	30 May 2012
Eswatini	25 Sep 2007	24 Sep 2012
Ethiopia	30 Mar 2007	7 Jul 2010
European Union	30 Mar 2007	23 Dec 2010 c
Fiji	2 Jun 2010	7 Jun 2017
Finland	30 Mar 2007	11 May 2016
France	30 Mar 2007	18 Feb 2010
Gabon	30 Mar 2007	1 Oct 2007
Gambia		6 Jul 2015 a
Georgia	10 Jul 2009	13 Mar 2014
Germany	30 Mar 2007	24 Feb 2009
Ghana	30 Mar 2007	31 Jul 2012
Greece	30 Mar 2007	31 May 2012
Grenada	12 Jul 2010	27 Aug 2014
Guatemala[3]	30 Mar 2007	7 Apr 2009
Guinea	16 May 2007	8 Feb 2008
Guinea-Bissau	24 Sep 2013	24 Sep 2014
Guyana	11 Apr 2007	10 Sep 2014
Haiti		23 Jul 2009 a
Honduras	30 Mar 2007	14 Apr 2008
Hungary	30 Mar 2007	20 Jul 2007
Iceland	30 Mar 2007	23 Sep 2016
India	30 Mar 2007	1 Oct 2007
Indonesia	30 Mar 2007	30 Nov 2011
Iran (Islamic Republic of)		23 Oct 2009 a
Iraq		20 Mar 2013 a
Ireland	30 Mar 2007	20 Mar 2018
Israel	30 Mar 2007	28 Sep 2012
Italy	30 Mar 2007	15 May 2009
Jamaica	30 Mar 2007	30 Mar 2007
Japan	28 Sep 2007	20 Jan 2014
Jordan	30 Mar 2007	31 Mar 2008
Kazakhstan	11 Dec 2008	21 Apr 2015
Kenya	30 Mar 2007	19 May 2008
Kiribati		27 Sep 2013 a
Kuwait		22 Aug 2013 a
Kyrgyzstan	21 Sep 2011	16 May 2019
Lao People's Democratic Republic	15 Jan 2008	25 Sep 2009
Latvia	18 Jul 2008	1 Mar 2010
Lebanon	14 Jun 2007	
Lesotho		2 Dec 2008 a

Participant	*Signature*	*Formal confirmation(c), Accession(a), Ratification*
Liberia	30 Mar 2007	26 Jul 2012
Libya	1 May 2008	13 Feb 2018
Liechtenstein	8 Sep 2020	
Lithuania	30 Mar 2007	18 Aug 2010
Luxembourg	30 Mar 2007	26 Sep 2011
Madagascar	25 Sep 2007	12 Jun 2015
Malawi	27 Sep 2007	27 Aug 2009
Malaysia	8 Apr 2008	19 Jul 2010
Maldives	2 Oct 2007	5 Apr 2010
Mali	15 May 2007	7 Apr 2008
Malta	30 Mar 2007	10 Oct 2012
Marshall Islands		17 Mar 2015 a
Mauritania		3 Apr 2012 a
Mauritius	25 Sep 2007	8 Jan 2010
Mexico	30 Mar 2007	17 Dec 2007
Micronesia (Federated States of)	23 Sep 2011	7 Dec 2016
Monaco	23 Sep 2009	19 Sep 2017
Mongolia		13 May 2009 a
Montenegro	27 Sep 2007	2 Nov 2009
Morocco	30 Mar 2007	8 Apr 2009
Mozambique	30 Mar 2007	30 Jan 2012
Myanmar		7 Dec 2011 a
Namibia	25 Apr 2007	4 Dec 2007
Nauru		27 Jun 2012 a
Nepal	3 Jan 2008	7 May 2010
Netherlands[4]	30 Mar 2007	14 Jun 2016
New Zealand[5]	30 Mar 2007	25 Sep 2008
Nicaragua	30 Mar 2007	7 Dec 2007
Niger	30 Mar 2007	24 Jun 2008
Nigeria	30 Mar 2007	24 Sep 2010
North Macedonia	30 Mar 2007	29 Dec 2011
Norway	30 Mar 2007	3 Jun 2013
Oman	17 Mar 2008	6 Jan 2009
Pakistan	25 Sep 2008	5 Jul 2011
Palau	20 Sep 2011	11 Jun 2013
Panama	30 Mar 2007	7 Aug 2007
Papua New Guinea	2 Jun 2011	26 Sep 2013
Paraguay	30 Mar 2007	3 Sep 2008
Peru	30 Mar 2007	30 Jan 2008
Philippines	25 Sep 2007	15 Apr 2008
Poland	30 Mar 2007	25 Sep 2012
Portugal	30 Mar 2007	23 Sep 2009
Qatar	9 Jul 2007	13 May 2008

Participant	*Signature*	*Formal confirmation(c), Accession(a), Ratification*
Republic of Korea	30 Mar 2007	11 Dec 2008
Republic of Moldova	30 Mar 2007	21 Sep 2010
Romania	26 Sep 2007	31 Jan 2011
Russian Federation	24 Sep 2008	25 Sep 2012
Rwanda		15 Dec 2008 a
Samoa	24 Sep 2014	2 Dec 2016
San Marino	30 Mar 2007	22 Feb 2008
Sao Tome and Principe		5 Nov 2015 a
Saudi Arabia		24 Jun 2008 a
Senegal	25 Apr 2007	7 Sep 2010
Serbia	17 Dec 2007	31 Jul 2009
Seychelles	30 Mar 2007	2 Oct 2009
Sierra Leone	30 Mar 2007	4 Oct 2010
Singapore	30 Nov 2012	18 Jul 2013
Slovakia	26 Sep 2007	26 May 2010
Slovenia	30 Mar 2007	24 Apr 2008
Solomon Islands	23 Sep 2008	
Somalia	2 Oct 2018	6 Aug 2019
South Africa	30 Mar 2007	30 Nov 2007
Spain	30 Mar 2007	3 Dec 2007
Sri Lanka	30 Mar 2007	8 Feb 2016
St. Kitts and Nevis	27 Sep 2019	17 Oct 2019
St. Lucia	22 Sep 2011	11 Jun 2020
St. Vincent and the Grenadines		29 Oct 2010 a
State of Palestine		2 Apr 2014 a
Sudan	30 Mar 2007	24 Apr 2009
Suriname	30 Mar 2007	29 Mar 2017
Sweden	30 Mar 2007	15 Dec 2008
Switzerland		15 Apr 2014 a
Syrian Arab Republic	30 Mar 2007	10 Jul 2009
Tajikistan	22 Mar 2018	
Thailand	30 Mar 2007	29 Jul 2008
Togo	23 Sep 2008	1 Mar 2011
Tonga	15 Nov 2007	
Trinidad and Tobago	27 Sep 2007	25 Jun 2015
Tunisia	30 Mar 2007	2 Apr 2008
Turkey	30 Mar 2007	28 Sep 2009
Turkmenistan		4 Sep 2008 a
Tuvalu		18 Dec 2013 a
Uganda	30 Mar 2007	25 Sep 2008
Ukraine	24 Sep 2008	4 Feb 2010
United Arab Emirates	8 Feb 2008	19 Mar 2010
United Kingdom of Great Britain and Northern Ireland	30 Mar 2007	8 Jun 2009
United Republic of Tanzania	30 Mar 2007	10 Nov 2009
United States of America	30 Jul 2009	
Uruguay	3 Apr 2007	11 Feb 2009
Uzbekistan	27 Feb 2009	28 Jun 2021
Vanuatu	17 May 2007	23 Oct 2008
Venezuela (Bolivarian Republic of)		24 Sep 2013 a
Viet Nam	22 Oct 2007	5 Feb 2015
Yemen	30 Mar 2007	26 Mar 2009
Zambia	9 May 2008	1 Feb 2010
Zimbabwe		23 Sep 2013 a

Declarations and Reservations

(Unless otherwise indicated, the declarations and reservations were made upon ratification, formal confirmation or accession.)

AUSTRALIA

"Australia recognizes that persons with disability enjoy legal capacity on an equal basis with others in all aspects of life. Australia declares its understanding that the Convention allows for fully supported or substituted decision-making arrangements, which provide for decisions to be made on behalf of a person, only where such arrangements are necessary, as a last resort and subject to safeguards;

Australia recognizes that every person with disability has a right to respect for his or her physical and mental integrity on an equal basis with others. Australia further declares its understanding that the Convention allows for compulsory assistance or treatment of persons, including measures taken for the treatment of mental disability, where such treatment is necessary, as a last resort and subject to safeguards;

Australia recognizes the rights of persons with disability to liberty of movement, to freedom to choose their residence and to a nationality, on an equal basis with others. Australia further declares its understanding that the Convention does not create a right for a person to enter or remain in a country of which he or she is not a national, nor impact on Australia's health requirements for non-nationals seeking to enter or remain in Australia, where these requirements are based on legitimate, objective and reasonable criteria."

Plaintiffs' Exhibit 504

CONVENTION ON THE RIGHTS OF PERSONS WITH DISABILITIES

UNITED NATIONS
2007

CONVENTION ON THE RIGHTS OF PERSONS WITH DISABILITIES

Preamble

The States Parties to the present Convention,

(*a*) *Recalling* the principles proclaimed in the Charter of the United Nations which recognize the inherent dignity and worth and the equal and inalienable rights of all members of the human family as the foundation of freedom, justice and peace in the world,

(*b*) *Recognizing* that the United Nations, in the Universal Declaration of Human Rights and in the International Covenants on Human Rights, has proclaimed and agreed that everyone is entitled to all the rights and freedoms set forth therein, without distinction of any kind,

(*c*) *Reaffirming* the universality, indivisibility, interdependence and interrelatedness of all human rights and fundamental freedoms and the need for persons with disabilities to be guaranteed their full enjoyment without discrimination,

(*d*) *Recalling* the International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights, the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination against Women, the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, the Convention on the Rights of the Child, and the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families,

(*e*) *Recognizing* that disability is an evolving concept and that disability results from the interaction between persons with impairments and attitudinal and environmental barriers that hinders their full and effective participation in society on an equal basis with others,

(*f*) *Recognizing* the importance of the principles and policy guidelines contained in the World Programme of Action concerning Disabled Persons and in the Standard Rules on the Equalization of Opportunities for Persons with Disabilities in influencing the promotion, formulation and evaluation of the policies, plans, programmes and actions at the national, regional and international levels to further equalize opportunities for persons with disabilities,

(*g*) *Emphasizing* the importance of mainstreaming disability issues as an integral part of relevant strategies of sustainable development,

(*h*) *Recognizing also* that discrimination against any person on the basis of disability is a violation of the inherent dignity and worth of the human person,

(*i*) *Recognizing further* the diversity of persons with disabilities,

(*j*) *Recognizing* the need to promote and protect the human rights of all persons with disabilities, including those who require more intensive support,

(*k*) *Concerned* that, despite these various instruments and undertakings, persons with disabilities continue to face barriers in their participation as equal members of society and violations of their human rights in all parts of the world,

(*l*) *Recognizing* the importance of international cooperation for improving the living conditions of persons with disabilities in every country, particularly in developing countries,

(*m*) *Recognizing* the valued existing and potential contributions made by persons with disabilities to the overall well-being and diversity of their communities, and that the promotion of the full enjoyment by persons with disabilities of their human rights and fundamental freedoms and of full participation by persons with disabilities will result in their enhanced sense of belonging and in significant advances in the human, social and economic development of society and the eradication of poverty,

(*n*) *Recognizing* the importance for persons with disabilities of their individual autonomy and independence, including the freedom to make their own choices,

(*o*) *Considering* that persons with disabilities should have the opportunity to be actively involved in decision-making processes about policies and programmes, including those directly concerning them,

(*p*) *Concerned* about the difficult conditions faced by persons with disabilities who are subject to multiple or aggravated forms of discrimination on the basis of race, colour, sex, language, religion, political or other opinion, national, ethnic, indigenous or social origin, property, birth, age or other status,

(*q*) *Recognizing* that women and girls with disabilities are often at greater risk, both within and outside the home, of violence, injury or abuse, neglect or negligent treatment, maltreatment or exploitation,

(*r*) *Recognizing* that children with disabilities should have full enjoyment of all human rights and fundamental freedoms on an equal basis

with other children, and recalling obligations to that end undertaken by States Parties to the Convention on the Rights of the Child,

(*s*) *Emphasizing* the need to incorporate a gender perspective in all efforts to promote the full enjoyment of human rights and fundamental freedoms by persons with disabilities,

(*t*) *Highlighting* the fact that the majority of persons with disabilities live in conditions of poverty, and in this regard recognizing the critical need to address the negative impact of poverty on persons with disabilities,

(*u*) *Bearing in mind* that conditions of peace and security based on full respect for the purposes and principles contained in the Charter of the United Nations and observance of applicable human rights instruments are indispensable for the full protection of persons with disabilities, in particular during armed conflicts and foreign occupation,

(*v*) *Recognizing* the importance of accessibility to the physical, social, economic and cultural environment, to health and education and to information and communication, in enabling persons with disabilities to fully enjoy all human rights and fundamental freedoms,

(*w*) *Realizing* that the individual, having duties to other individuals and to the community to which he or she belongs, is under a responsibility to strive for the promotion and observance of the rights recognized in the International Bill of Human Rights,

(*x*) *Convinced* that the family is the natural and fundamental group unit of society and is entitled to protection by society and the State, and that persons with disabilities and their family members should receive the necessary protection and assistance to enable families to contribute towards the full and equal enjoyment of the rights of persons with disabilities,

(*y*) *Convinced* that a comprehensive and integral international convention to promote and protect the rights and dignity of persons with disabilities will make a significant contribution to redressing the profound social disadvantage of persons with disabilities and promote their participation in the civil, political, economic, social and cultural spheres with equal opportunities, in both developing and developed countries,

Have agreed as follows:

Article 1
Purpose

The purpose of the present Convention is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity.

Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others.

Article 2
Definitions

For the purposes of the present Convention:

"Communication" includes languages, display of text, Braille, tactile communication, large print, accessible multimedia as well as written, audio, plain-language, human-reader and augmentative and alternative modes, means and formats of communication, including accessible information and communication technology;

"Language" includes spoken and signed languages and other forms of non spoken languages;

"Discrimination on the basis of disability" means any distinction, exclusion or restriction on the basis of disability which has the purpose or effect of impairing or nullifying the recognition, enjoyment or exercise, on an equal basis with others, of all human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field. It includes all forms of discrimination, including denial of reasonable accommodation;

"Reasonable accommodation" means necessary and appropriate modification and adjustments not imposing a disproportionate or undue burden, where needed in a particular case, to ensure to persons with disabilities the enjoyment or exercise on an equal basis with others of all human rights and fundamental freedoms;

"Universal design" means the design of products, environments, programmes and services to be usable by all people, to the greatest extent possible, without the need for adaptation or specialized design. "Universal design" shall not exclude assistive devices for particular groups of persons with disabilities where this is needed.

Article 3
General principles

The principles of the present Convention shall be:

(*a*) Respect for inherent dignity, individual autonomy including the freedom to make one's own choices, and independence of persons;

(*b*) Non-discrimination;

(*c*) Full and effective participation and inclusion in society;

(*d*) Respect for difference and acceptance of persons with disabilities as part of human diversity and humanity;

(*e*) Equality of opportunity;

(*f*) Accessibility;

(*g*) Equality between men and women;

(*h*) Respect for the evolving capacities of children with disabilities and respect for the right of children with disabilities to preserve their identities.

Article 4
General obligations

1. States Parties undertake to ensure and promote the full realization of all human rights and fundamental freedoms for all persons with disabilities without discrimination of any kind on the basis of disability. To this end, States Parties undertake:

(*a*) To adopt all appropriate legislative, administrative and other measures for the implementation of the rights recognized in the present Convention;

(*b*) To take all appropriate measures, including legislation, to modify or abolish existing laws, regulations, customs and practices that constitute discrimination against persons with disabilities;

(*c*) To take into account the protection and promotion of the human rights of persons with disabilities in all policies and programmes;

(*d*) To refrain from engaging in any act or practice that is inconsistent with the present Convention and to ensure that public authorities and institutions act in conformity with the present Convention;

(*e*) To take all appropriate measures to eliminate discrimination on the basis of disability by any person, organization or private enterprise;

(*f*) To undertake or promote research and development of universally designed goods, services, equipment and facilities, as defined in article 2 of the present Convention, which should require the minimum possible adaptation and the least cost to meet the specific needs of a person with disabilities, to promote their availability and use, and to promote universal design in the development of standards and guidelines;

(*g*) To undertake or promote research and development of, and to promote the availability and use of new technologies, including information and communications technologies, mobility aids, devices and assistive technologies, suitable for persons with disabilities, giving priority to technologies at an affordable cost;

(*h*) To provide accessible information to persons with disabilities about mobility aids, devices and assistive technologies, including new technologies, as well as other forms of assistance, support services and facilities;

(*i*) To promote the training of professionals and staff working with persons with disabilities in the rights recognized in the present Convention so as to better provide the assistance and services guaranteed by those rights.

2. With regard to economic, social and cultural rights, each State Party undertakes to take measures to the maximum of its available resources and, where needed, within the framework of international cooperation, with a view to achieving progressively the full realization of these rights, without prejudice to those obligations contained in the present Convention that are immediately applicable according to international law.

3. In the development and implementation of legislation and policies to implement the present Convention, and in other decision-making processes concerning issues relating to persons with disabilities, States Parties shall closely consult with and actively involve persons with disabilities, including children with disabilities, through their representative organizations.

4. Nothing in the present Convention shall affect any provisions which are more conducive to the realization of the rights of persons with disabilities and which may be contained in the law of a State Party or international law in force for that State. There shall be no restriction upon or derogation from any of the

human rights and fundamental freedoms recognized or existing in any State Party to the present Convention pursuant to law, conventions, regulation or custom on the pretext that the present Convention does not recognize such rights or freedoms or that it recognizes them to a lesser extent.

5. The provisions of the present Convention shall extend to all parts of federal States without any limitations or exceptions.

Article 5
Equality and non-discrimination

1. States Parties recognize that all persons are equal before and under the law and are entitled without any discrimination to the equal protection and equal benefit of the law.

2. States Parties shall prohibit all discrimination on the basis of disability and guarantee to persons with disabilities equal and effective legal protection against discrimination on all grounds.

3. In order to promote equality and eliminate discrimination, States Parties shall take all appropriate steps to ensure that reasonable accommodation is provided.

4. Specific measures which are necessary to accelerate or achieve de facto equality of persons with disabilities shall not be considered discrimination under the terms of the present Convention.

Article 6
Women with disabilities

1. States Parties recognize that women and girls with disabilities are subject to multiple discrimination, and in this regard shall take measures to ensure the full and equal enjoyment by them of all human rights and fundamental freedoms.

2. States Parties shall take all appropriate measures to ensure the full development, advancement and empowerment of women, for the purpose of guaranteeing them the exercise and enjoyment of the human rights and fundamental freedoms set out in the present Convention.

Article 7
Children with disabilities

1. States Parties shall take all necessary measures to ensure the full enjoyment by children with disabilities of all human rights and fundamental freedoms on an equal basis with other children.

2. In all actions concerning children with disabilities, the best interests of the child shall be a primary consideration.

3. States Parties shall ensure that children with disabilities have the right to express their views freely on all matters affecting them, their views being given due weight in accordance with their age and maturity, on an equal basis with other children, and to be provided with disability and age-appropriate assistance to realize that right.

Article 8
Awareness-raising

1. States Parties undertake to adopt immediate, effective and appropriate measures:

(*a*) To raise awareness throughout society, including at the family level, regarding persons with disabilities, and to foster respect for the rights and dignity of persons with disabilities;

(*b*) To combat stereotypes, prejudices and harmful practices relating to persons with disabilities, including those based on sex and age, in all areas of life;

(*c*) To promote awareness of the capabilities and contributions of persons with disabilities.

2. Measures to this end include:

(*a*) Initiating and maintaining effective public awareness campaigns designed:

(i) To nurture receptiveness to the rights of persons with disabilities;

(ii) To promote positive perceptions and greater social awareness towards persons with disabilities;

(iii) To promote recognition of the skills, merits and abilities of persons with disabilities, and of their contributions to the workplace and the labour market;

(*b*) Fostering at all levels of the education system, including in all children from an early age, an attitude of respect for the rights of persons with disabilities;

(*c*) Encouraging all organs of the media to portray persons with disabilities in a manner consistent with the purpose of the present Convention;

(*d*) Promoting awareness-training programmes regarding persons with disabilities and the rights of persons with disabilities.

Article 9
Accessibility

1. To enable persons with disabilities to live independently and participate fully in all aspects of life, States Parties shall take appropriate measures to ensure to persons with disabilities access, on an equal basis with others, to the physical environment, to transportation, to information and communications, including information and communications technologies and systems, and to other facilities and services open or provided to the public, both in urban and in rural areas. These measures, which shall include the identification and elimination of obstacles and barriers to accessibility, shall apply to, inter alia:

(*a*) Buildings, roads, transportation and other indoor and outdoor facilities, including schools, housing, medical facilities and workplaces;

(*b*) Information, communications and other services, including electronic services and emergency services.

2. States Parties shall also take appropriate measures:

(*a*) To develop, promulgate and monitor the implementation of minimum standards and guidelines for the accessibility of facilities and services open or provided to the public;

(*b*) To ensure that private entities that offer facilities and services which are open or provided to the public take into account all aspects of accessibility for persons with disabilities;

(*c*) To provide training for stakeholders on accessibility issues facing persons with disabilities;

(*d*) To provide in buildings and other facilities open to the public signage in Braille and in easy to read and understand forms;

(*e*) To provide forms of live assistance and intermediaries, including guides, readers and professional sign language interpreters, to facilitate accessibility to buildings and other facilities open to the public;

(*f*) To promote other appropriate forms of assistance and support to persons with disabilities to ensure their access to information;

(*g*) To promote access for persons with disabilities to new information and communications technologies and systems, including the Internet;

(*h*) To promote the design, development, production and distribution of accessible information and communications technologies and systems at an early stage, so that these technologies and systems become accessible at minimum cost.

Article 10
Right to life

States Parties reaffirm that every human being has the inherent right to life and shall take all necessary measures to ensure its effective enjoyment by persons with disabilities on an equal basis with others.

Article 11
Situations of risk and humanitarian emergencies

States Parties shall take, in accordance with their obligations under international law, including international humanitarian law and international human rights law, all necessary measures to ensure the protection and safety of persons with disabilities in situations of risk, including situations of armed conflict, humanitarian emergencies and the occurrence of natural disasters.

Article 12
Equal recognition before the law

1. States Parties reaffirm that persons with disabilities have the right to recognition everywhere as persons before the law.

2. States Parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life.

3. States Parties shall take appropriate measures to provide access by persons with disabilities to the support they may require in exercising their legal capacity.

4. States Parties shall ensure that all measures that relate to the exercise of legal capacity provide for appropriate and effective safeguards to prevent abuse in accordance with international human rights law. Such safeguards shall ensure that measures relating to the exercise of legal capacity respect the rights, will and preferences of the person, are free of conflict of interest and undue influence, are proportional and tailored to the person's circumstances, apply for the shortest time possible and are subject to regular review by a competent, independent and impartial authority or judicial body. The

safeguards shall be proportional to the degree to which such measures affect the person's rights and interests.

5. Subject to the provisions of this article, States Parties shall take all appropriate and effective measures to ensure the equal right of persons with disabilities to own or inherit property, to control their own financial affairs and to have equal access to bank loans, mortgages and other forms of financial credit, and shall ensure that persons with disabilities are not arbitrarily deprived of their property.

Article 13
Access to justice

1. States Parties shall ensure effective access to justice for persons with disabilities on an equal basis with others, including through the provision of procédural and age-appropriate accommodations, in order to facilitate their effective role as direct and indirect participants, including as witnesses, in all legal proceedings, including at investigative and other preliminary stages.

2. In order to help to ensure effective access to justice for persons with disabilities, States Parties shall promote appropriate training for those working in the field of administration of justice, including police and prison staff.

Article 14
Liberty and security of person

1. States Parties shall ensure that persons with disabilities, on an equal basis with others:

(*a*) Enjoy the right to liberty and security of person;

(*b*) Are not deprived of their liberty unlawfully or arbitrarily, and that any deprivation of liberty is in conformity with the law, and that the existence of a disability shall in no case justify a deprivation of liberty.

2. States Parties shall ensure that if persons with disabilities are deprived of their liberty through any process, they are, on an equal basis with others, entitled to guarantees in accordance with international human rights law and shall be treated in compliance with the objectives and principles of the present Convention, including by provision of reasonable accommodation.

Article 15
Freedom from torture or cruel, inhuman or degrading treatment or punishment

1. No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his or her free consent to medical or scientific experimentation.

2. States Parties shall take all effective legislative, administrative, judicial or other measures to prevent persons with disabilities, on an equal basis with others, from being subjected to torture or cruel, inhuman or degrading treatment or punishment.

Article 16
Freedom from exploitation, violence and abuse

1. States Parties shall take all appropriate legislative, administrative, social, educational and other measures to protect persons with disabilities, both within and outside the home, from all forms of exploitation, violence and abuse, including their gender-based aspects.

2. States Parties shall also take all appropriate measures to prevent all forms of exploitation, violence and abuse by ensuring, inter alia, appropriate forms of gender- and age-sensitive assistance and support for persons with disabilities and their families and caregivers, including through the provision of information and education on how to avoid, recognize and report instances of exploitation, violence and abuse. States Parties shall ensure that protection services are age-, gender- and disability-sensitive.

3. In order to prevent the occurrence of all forms of exploitation, violence and abuse, States Parties shall ensure that all facilities and programmes designed to serve persons with disabilities are effectively monitored by independent authorities.

4. States Parties shall take all appropriate measures to promote the physical, cognitive and psychological recovery, rehabilitation and social reintegration of persons with disabilities who become victims of any form of exploitation, violence or abuse, including through the provision of protection services. Such recovery and reintegration shall take place in an environment that fosters the health, welfare, self-respect, dignity and autonomy of the person and takes into account gender- and age-specific needs.

5. States Parties shall put in place effective legislation and policies, including women- and child-focused legislation and policies, to ensure that instances of exploitation, violence and abuse against persons with disabilities are identified, investigated and, where appropriate, prosecuted.

Article 17
Protecting the integrity of the person

Every person with disabilities has a right to respect for his or her physical and mental integrity on an equal basis with others.

Article 18
Liberty of movement and nationality

1. States Parties shall recognize the rights of persons with disabilities to liberty of movement, to freedom to choose their residence and to a nationality, on an equal basis with others, including by ensuring that persons with disabilities:

(*a*) Have the right to acquire and change a nationality and are not deprived of their nationality arbitrarily or on the basis of disability;

(*b*) Are not deprived, on the basis of disability, of their ability to obtain, possess and utilize documentation of their nationality or other documentation of identification, or to utilize relevant processes such as immigration proceedings, that may be needed to facilitate exercise of the right to liberty of movement;

(*c*) Are free to leave any country, including their own;

(*d*) Are not deprived, arbitrarily or on the basis of disability, of the right to enter their own country.

2. Children with disabilities shall be registered immediately after birth and shall have the right from birth to a name, the right to acquire a nationality and, as far as possible, the right to know and be cared for by their parents.

Article 19
Living independently and being included in the community

States Parties to the present Convention recognize the equal right of all persons with disabilities to live in the community, with choices equal to others, and shall take effective and appropriate measures to facilitate full enjoyment by persons with disabilities of this right and their full inclusion and participation in the community, including by ensuring that:

(*a*) Persons with disabilities have the opportunity to choose their place of residence and where and with whom they live on an equal basis with others and are not obliged to live in a particular living arrangement;

(*b*) Persons with disabilities have access to a range of in-home, residential and other community support services, including personal assistance necessary to support living and inclusion in the community, and to prevent isolation or segregation from the community;

(*c*) Community services and facilities for the general population are available on an equal basis to persons with disabilities and are responsive to their needs.

Article 20
Personal mobility

States Parties shall take effective measures to ensure personal mobility with the greatest possible independence for persons with disabilities, including by:

(*a*) Facilitating the personal mobility of persons with disabilities in the manner and at the time of their choice, and at affordable cost;

(*b*) Facilitating access by persons with disabilities to quality mobility aids, devices, assistive technologies and forms of live assistance and intermediaries, including by making them available at affordable cost;

(*c*) Providing training in mobility skills to persons with disabilities and to specialist staff working with persons with disabilities;

(*d*) Encouraging entities that produce mobility aids, devices and assistive technologies to take into account all aspects of mobility for persons with disabilities.

Article 21
Freedom of expression and opinion, and access to information

States Parties shall take all appropriate measures to ensure that persons with disabilities can exercise the right to freedom of expression and opinion, including the freedom to seek, receive and impart information and ideas on an equal basis with others and through all forms of communication of their choice, as defined in article 2 of the present Convention, including by:

(*a*) Providing information intended for the general public to persons with disabilities in accessible formats and technologies appropriate to different kinds of disabilities in a timely manner and without additional cost;

(*b*) Accepting and facilitating the use of sign languages, Braille, augmentative and alternative communication, and all other accessible means,

modes and formats of communication of their choice by persons with disabilities in official interactions;

(*c*) Urging private entities that provide services to the general public, including through the Internet, to provide information and services in accessible and usable formats for persons with disabilities;

(*d*) Encouraging the mass media, including providers of information through the Internet, to make their services accessible to persons with disabilities;

(*e*) Recognizing and promoting the use of sign languages.

Article 22
Respect for privacy

1. No person with disabilities, regardless of place of residence or living arrangements, shall be subjected to arbitrary or unlawful interference with his or her privacy, family, home or correspondence or other types of communication or to unlawful attacks on his or her honour and reputation. Persons with disabilities have the right to the protection of the law against such interference or attacks.

2. States Parties shall protect the privacy of personal, health and rehabilitation information of persons with disabilities on an equal basis with others.

Article 23
Respect for home and the family

1. States Parties shall take effective and appropriate measures to eliminate discrimination against persons with disabilities in all matters relating to marriage, family, parenthood and relationships, on an equal basis with others, so as to ensure that:

(*a*) The right of all persons with disabilities who are of marriageable age to marry and to found a family on the basis of free and full consent of the intending spouses is recognized;

(*b*) The rights of persons with disabilities to decide freely and responsibly on the number and spacing of their children and to have access to age-appropriate information, reproductive and family planning education are recognized, and the means necessary to enable them to exercise these rights are provided;

Plaintiffs' Exhibit 505

orlandosentinel.com

Disability rights U.N. treaty should be ratified by U.S.

Michael E. Burke

5-6 minutes

When the disc between her seventh and eight thoracic vertebrae severed her spinal column, my mother became a paraplegic and would remain so for the last 34 years of her life. My family's experience was unique in that it affected my mother; but, at the same time, more than 700 million people around the world have a disability, including at least 60 million in the U.S. According to the Centers for Disease Control, just over 28% of adult Floridians have a disability. The number of people affected by a disability, such as family members of a person with a disability, is even higher.

The United States used to lead in the promotion and protection of human rights, including on disability rights. The United Nations Convention on the Rights of Persons with Disabilities is the primary international treaty on the subject.

During its drafting, the U.S. drew on experience with the and Americans with Disabilities Act (ADA) to build the Convention's foundational principles. Celebrating its 30th anniversary, the ADA helped my mother and millions of others secure their basic rights under the Constitution and started the process in the U.S. of addressing and improving inclusion and equity for Americans with disabilities.

The United States signed the Convention on July 31, 2009. A December 2012 Senate vote on ratification garnered bipartisan support with 61 'yes' votes, still short of the two-thirds supermajority required for approval. One hundred and eight-two countries have ratified the Convention, but the U.S. is keeping company with Libya and North Korea on this key human rights issue.

The Trump Administration does not support ratification of the Convention and has shown examples of remaining hostile towards America's disabled community.

In December 2017, the Justice Department stopped rulemaking under the ADA that would have improved accessible medical treatment standards for disabled Americans.

The Social Security Administration, in November 2019, proposed rules that would make it

harder for those with chronic conditions to receive benefits under the Supplemental Security Income program and the Social Security Disability Insurance program.

In August 2020, new rules issued by the Department of Health and Human Services under Section 1557 of the Affordable Care Act exempted certain insurance companies and health plans from complying with the statute's nondiscrimination protections that benefit persons with disabilities.

I was Chair of the American Bar Association's (ABA) International Law Section in 2011-2012, and also was the principal author of ABA Policy 108B that urges the U.S. to ratify and implement the Convention. Only one-third of all countries have laws similar to the ADA, leaving the human rights of persons with disabilities systematically unaddressed.

In jurisdictions without such laws, people like my mother suffer discrimination in education, employment, housing, transport, cultural life and access to public places and services. Such discrimination nullifies the recognition, enjoyment, and exercise by persons with disabilities of their fundamental human rights. I saw how the ADA positively impacted my mother's life, and each person with a disability, wherever located, is endowed with and entitled to equal dignity.

Ratification of the Convention should not be controversial because the rights referenced therein are drawn from the ADA and existing human rights treaties the U.S. helped develop over the past 75 years.

Specifically, the Convention provides that all persons, regardless of disability status, are equal before and under the law and are entitled, without discrimination, to the equal protection and equal benefit of the law. Further, the Convention holds that persons with disabilities are entitled to full and effective participation and inclusion in society.

U.S. ratification of the Convention would reinforce the treaty's core principles.

While much of existing U.S. law is consistent with the Convention's requirements, ratification of the Convention would improve existing U.S. disability law. Specifically, ratification would require us to improve antidiscrimination laws protecting women with disabilities and children with disabilities. Further, ratification would force the U.S. to take additional steps to ensure that reasonable accommodation is provided for persons with disabilities achieve equality.

The United States should ratify the Convention to start to restore our place as a global leader in protecting and promoting the rights of persons with disabilities, and to improve U.S. law. My mother's memory deserves nothing less.

Michael E. Burke was Chair of the ABA International Law Section in 2011-2012 and currently serves in the ABA House of Delegates. He works in Washington, D.C.

Plaintiffs' Exhibit 506

ncd.gov

National Council on Disability Topical Overviews - Access to Transportation by People with Disabilities Illustrations of Implementation from the United States

35-44 minutes

Lex Frieden, Chairperson

Publication date: August 2, 2005

Foreword

The National Council on Disability (NCD) is an independent Federal agency with 15 members appointed by the President of the United States and confirmed by the U.S. Senate. The overall purpose of NCD is to promote policies, programs, practices, and procedures that guarantee equal opportunity for all individuals with disabilities regardless of the nature or significance of the disability and to empower individuals with disabilities to achieve economic self-sufficiency, independent living, and inclusion and integration into all aspects of society. This topic paper is part of a series of topic papers designed to provide brief background information on United States disability policy for use by the delegates in their deliberations on the United Nations Ad Hoc Committee on a Comprehensive and Integral International Convention on Protection and Promotion of the Rights and Dignity of Persons with Disabilities.

I. Introduction

The ability to access transportation is a precondition to the full enjoyment of many human rights by people with disabilities. Inadequate transportation to places of work, education, healthcare, recreation, polling stations and countless other venues constitutes a significant barrier to the enjoyment of human rights by people with disabilities, and consequently their full participation and inclusion in our communities and societies. This fact is recognized in Draft Article 19 (Accessibility) of a proposed UN convention/treaty,[1] which would require States to take appropriate measures to ensure that transportation is accessible to people with disabilities.

As governments and other actors undertake the drafting and implementation of this new

human rights convention, it may be helpful to consider the experience of other countries in ensuring access to transportation by people with disabilities. This paper seeks to provide illustrations from the experience of the United States, and provides examples of legislative and other initiatives that have been undertaken to increase the accessibility of transportation. It is not the intent to argue that the approach adopted in the United States are the best or only way of ensuring access for people with disabilities, but instead to provide this information as a resource to those engaged in ultimately implementing the new convention. Although it is beyond the scope of this paper to provide an in-depth assessment of the impact of the legislation, programs, policies, and practices described here, documents providing such assessments are available and referenced in the footnotes for those interested in learning more.

Specifically, the paper seeks to:

- • provide an overview of human rights concepts related to transportation and their relevance for supporting the enjoyment of human rights by people with disabilities;
- • provide an overview of barriers which can impede access to transportation by people with disabilities;
- • provide examples of legislation, programs, policies and practices that promote access to transportation by people with disabilities; and
- • provide some recommendations for the convention context

II. Access to transportation by people with disabilities

- a) What concepts in international human rights instruments are relevant to this issue?

International human rights law does not recognize a 'right to transportation' per se. Rather, it guarantees the right to liberty of movement, which is elaborated in Article 12 of the International Covenant on Civil and Political Rights (ICCPR).[2] Specifically, Article 12 states:

1) Everyone lawfully within the territory of a State shall, within that territory, have the right to liberty of movement and freedom to choose his residence,

2) Everyone shall be free to leave any country, including his own,

3) The above-mentioned rights shall not be subject to any restrictions except those which are provided by law, are necessary to protect national security, public order (ordre public), public health or morals or the rights and freedoms of others, and are consistent with the other rights recognized in the present Covenant,

4) No one shall be arbitrarily deprived of the right to enter his own country.

The Human Rights Committee, which is mandated to interpret the implementation of the

ICCPR by States Parties, has noted, "Liberty of movement is an indispensable condition for the free development of a person." [3] As long as a person is lawfully within a State, the State must not place restrictions on their liberty of movement, save those permitted under specific circumstances as outlined in Article 12(3).[4] Thus, the duty of the State is to ensure the removal of barriers and other restrictions that impermissibly interfere with the individual's liberty or freedom of movement. Moreover, the enjoyment of the right should not be dependent upon the individual providing any particular reason for wanting to leave or stay in a place,[5] or be dependent upon the decision of a third party, such as a relative.[6]

Transportation constitutes an important means of exercising the right to freedom of movement, and as noted by the Committee on Economic, Social and Cultural Rights, adequate "transportation is crucial to the realization by persons with disabilities of virtually all the rights recognized in the Covenant." [7] Failure to provide accessible transportation that truly facilitates freedom of movement for people with disabilities not only inhibits their ability to fully enjoy human rights, it seriously undermines the very dignity and autonomy of people with disabilities.[8]

- b) What barriers can inhibit the enjoyment of this right by people with disabilities?

  If lack of transportation can constitute a barrier to the enjoyment of other rights, what can operate as barriers to the provision of adequate transportation for people with disabilities? Barriers may include:[9]

  • Physical barriers – such as vehicle thresholds that do not permit entry by people with disabilities, sidewalks and streets that do not permit access to vehicles or independent mobility by people with disabilities, transport facilities (such as train and bus stations) that do not permit access by people with disabilities or that limit full access to services (including, e.g. restrooms, lounges) by people with disabilities;
  • Informational barriers – such as signage or announcements that cannot be easily understood by those with sensory or developmental disabilities, insufficient information regarding the nature and availability of transportation services;
  • Legal barriers – such as legislative prohibitions against people with disabilities operating or using certain kinds of transport, or laws that prohibit people with disabilities from obtaining and using legal papers (such as passports or other forms of identification) that may be needed to facilitate travel;
  • Attitudinal barriers – such as the beliefs of transport operators and employees that people with disabilities do not or should not wish to utilize their services, or that it is sufficient to provide services for people with disabilities that are not of the same quality and functionality as services for the rest of the public.

  III. Illustrations of implementation of accessible transportation in the United States

On February 1, 2001, President Bush announced the "New Freedom Initiative," which is a comprehensive national plan to remove barriers to community living for people with disabilities.[10] Because of the key role that transportation plays in linking Americans with disabilities to jobs, education, healthcare services and many other aspects of community living, expanding transportation options for people with disabilities is a core component of the New Freedom Initiative.[11] Below is an examination of the core legislative frameworks that exist to promote accessible transportation for people with disabilities in the United States, as well as several examples of inter-agency collaborations designed to increase effectiveness of transportation initiatives, and also address specific issues, such as the needs of rural populations.

a. Americans with Disabilities Act of 1990 (ADA)

In recognition of the importance of transportation in the lives of people with disabilities, Congress included in Title II of the Americans with Disabilities Act a part dealing exclusively with the prevention of discrimination against people with disabilities in their access to public transportation.[12] With the exception of air carriers (who must comply instead with the Air Carrier Access Act of 1986, addressed below), Title II requires public entities to ensure that "no individual shall be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination" by public entities providing transportation services, on the basis of disability.[13] The subparts of Title II then address entities providing different forms of transport, with Subpart i addressing fixed route systems (such as buses and certain types of rail that run on fixed schedules), paratransit, and demand response systems (such as taxis, that do not run on fixed schedules), and Subpart ii addressing intercity and commuter rail. Public entities providing these services include requirements that: transit systems purchase and lease vehicles "readily accessible to and usable by individuals with disabilities, including individuals who use wheelchairs;" [14] that paratransit be provided as a complement to fixed route systems[15] and that people with disabilities using such mode of transit be allowed to be accompanied by one other person;[16] that entities alter existing facilities to make them accessible to people with disabilities[17] and ensure the accessibility of new facilities;[18] and that at least one car per intercity rail transportation be accessible to people with disabilities.[19] Regulations on each subpart of Title II of the ADA have been issued by both the Department of Justice[20](DOJ) (relating to Subtitle A of Title II) and the Department of Transportation[21] (relating to Subtitle B of Title II) which share responsibility for enforcement.

Title III of the ADA (Public Accommodations and Services Operated by Private Entities) also has application in the context of transportation, as it contains provisions explicitly

prohibiting discrimination on the basis of disability by private entities "primarily engaged in the business of transporting people."[22] Essentially, failure to provide services and equipment accessible to people with disabilities constitutes discrimination,[23] and relevant private entities are obliged to purchase or lease equipment accessible to people with disabilities, and to remanufacture vehicles (to extend their usable life by 10 years or more) in a manner that makes the vehicles readily accessible to people with disabilities.[24] The Department of Transportation has promulgated regulations giving specificity to the provisions of Title III.[25] The Department of Justice has also promulgated regulations,[26] and has also published a technical assistance manual providing advice to entities seeking to comply with Title III.[27]

As noted already, the Department of Transportation and Department of Justice have authority for promulgating regulations and enforcing various aspects of the ADA's provisions related to transportation. In addition, private individuals may initiate lawsuits and may also approach relevant agencies to investigate alleged violations of the ADA. For example, a number of individuals approached DOJ to ask them to investigate possible violations of Title III by Greyhound Lines, Inc., alleging that Greyhound had failed to remove barriers to people with disabilities at some of its facilities, and that Greyhound staff had failed on certain occasions to provide appropriate assistance to people with disabilities. To avoid litigation, expedite payment of compensatory damages to the individuals affected by the alleged violations, and effect the removal of barriers and changes in service to comply with Title III, Greyhound entered into a settlement agreement with DOJ.[28] As a result of this agreement, Greyhound undertook actions such as improvements to its internal dispute resolution procedures, training of its employees regarding ADA requirements, and creation of an advisory committee on disability issues that included representatives of organizations advocating for the rights of people with disabilities or specializing in travel for people with disabilities.[29]

b. Air Carrier Access Act of 1986 (ACAA)

As noted above, Title II (B)(I) of the ADA expressly exempts coverage of aircraft, which are instead addressed by the Air Carrier Access Act (ACAA).[30] The stated purpose of the ACAA is to prevent discrimination against people with disabilities by air carriers in the provision of air transportation,[31] and it achieves this by elaborating a "general prohibition of discrimination," [32] and also by placing specific requirements on relevant air transport facilities and services in order to ensure their accessibility to people with disabilities. It should be noted that while foreign air carriers need not comply with the specific accessibility provisions of the ACAA, following amendments in 2000, they are compelled to comply with the general prohibition against discrimination.[33] Similarly, contracts that

carriers have with contractors must include a clause guaranteeing that the contractor will not discriminate on the basis of disability in the course of performing activities on behalf of the carrier.[34]

Issues of accessibility relevant to both aircraft and air transportation facilities are addressed with great specificity in the ACAA, thus decreasing ambiguity for those seeking to comply with the Act. For example, on aircraft (of specified size and age) there are requirements addressing the provision of folding aisle armrests, in-cabin stowage for folding wheelchairs, accessible lavatories, and wheelchairs for on-board use.[35] In addition, there are provisions specifying that activities to refurbish air cabins should not decrease accessibility below the level specified.[36] Airports must be accessible to people with disabilities (including wheelchair users), and carriers are deemed in compliance if they comply with Department of Justice Regulations implementing Title III of the Americans with Disabilities Act.[37]

Even greater detail is provided regarding services, such as those related to seat assignments, boarding assistance, stowage of personal equipment, passenger information, treatment of mobility aids and assistive devices, accommodations for people with hearing impairments, and advance notice requirements.[38] The ACAA does not permit carriers to refuse carriage on the basis of a person's disability,[39] or "solely because the person's disability results in appearance or involuntary behavior that may offend, annoy, or inconvenience crewmembers or other passengers."[40] Furthermore, the carrier may not restrict the number of people with disabilities on any given flight.[41] Essentially, as long as carriage of a given individual does not violate Federal Aviation Administration regulations,[42] the carrier may not refuse transport for a given traveler with disabilities, nor may the carrier require that the individual travel with an attendant.[43] Furthermore, the carrier may not charge travelers with disabilities for the use of equipment or services required by the regulations.[44] The application of these provisions is bolstered by the requirement that carriers train their personnel in how to comply with the regulations, and also provide awareness-raising training on how to appropriately address disability-related issues.[45]

The Department of Transportation (DOT) is mandated to enforce the ACAA, and requires carriers to implement a complaint resolution mechanism and report regularly to DOT regarding complaints filed against the carrier.[46] DOT is also authorized to take enforcement actions against air carriers alleged to be in violation of the ACAA and related regulations, and in January 2004 DOT began issuing a biannual report of steps it has taken to enforce the ACAA.[47] DOT also provides information to consumers on how to file

Plaintiffs' Exhibit 507

iclg.com

International Comparative Legal Guides

Global Legal Group

65-83 minutes

USA: Aviation Laws and Regulations 2021

ICLG - Aviation Laws and Regulations - USA covers common issues in aviation laws and regulations - including aircraft trading, finance and leasing, litigation and dispute resolution – in 27 jurisdictions

Published: 02/02/2021

Hot off the press

Chapter Content Free Access

1. General

1.1 Please list and briefly describe the principal legislation and regulatory bodies which apply to and/or regulate aviation in your jurisdiction.

Aviation is principally regulated by the following:

on March 27, 2020, the bipartisan Coronavirus Aid Relief and Economic Security ("CARES") Act was signed into law which included $58 billion in aid to airlines ($29 billion in payroll grants for workers and $29 billion in loans for the airlines).

4.7 Are state subsidies available in respect of particular routes? What criteria apply to obtaining these subsidies?

The Essential Air Service ("EAS") Program permits the US government to subsidise air carriers to serve small, rural communities to maintain a minimal level of scheduled air service to those communities. Generally, the DOT will subsidise between two round trips per day with a 30- to 50-seat aircraft between an EAS community and a major hub airport. In selecting a carrier, the DOT considers: (1) service reliability; (2) contractual and marketing arrangements with a larger carrier at the hub; (3) interline arrangements with a larger carrier at the hub; and (4) community views (49 USC §§ 41731–41732).

The Alternative Essential Air Service Program designates funds directly to the municipality or airport authority instead of to the carrier, and allows them to forego their EAS for a certain amount of time and allocate the grant money in ways that may better suit their individual needs, but that would not otherwise meet EAS guidelines.

The Small Community Air Service Development Program ("SCASDP") is a grant program to provide financial assistance to small communities that address air service and airfare issues (49 USC § 41743). SCASDP's eligibility criteria are broader than EAS and provide a grant applicant the opportunity to self-identify its air service deficiencies and propose an appropriate solution. To be eligible, the airport serving the community cannot be larger than a small hub airport and the community must demonstrate that it has insufficient air carrier service, or unreasonably high airfares. The DOT may provide assistance to an air carrier to subsidise service to and from an underserved airport for a period of up to three years, or it may provide assistance to an underserved airport. SCASDP can involve, for example, revenue guarantees, financial assistance for marketing programs, start-up costs and studies. There is no limit on the amounts of the grants, which vary depending upon the features and merits of proposals. To date, grant sizes have ranged from $20,000 to nearly $1.6 million.

4.8 What are the main regulatory instruments governing the acquisition, retention and use of passenger data, and what rights do passengers have in respect of their data which is held by airlines and airports?

For purposes of security screening, the Intelligence Reform and Terrorism Prevention Act of 2004 (49 USC § 114) and the TSA's Secure Flight Program (49 CFR Parts 1540 and 1560) require airlines that operate flights to and from the US to collect passenger name records ("PNR data"), which includes the passenger's full name, date of birth, and gender. Records of passengers who are not potential or confirmed matches on the No Fly List are

4.14 To what extent does general consumer protection legislation apply to the relationship between the airport operator and the passenger?

Airports must be accessible to passengers with disabilities through compliance with the applicable sections of the Americans with Disabilities Act of 1990 (49 USC §§ 12101–12213), Section 405 of the Rehabilitation Act of 1973 (29 USC § 794), and the Air Carrier Access Act of 1986 (40 USC § 41705, 14 CFR Part 382). Airlines are also required to provide: assistance to passengers with disabilities, such as wheelchair or other guided assistance to board, deplane, or connect to another flight; seating accommodation assistance that meets passengers' disability-related needs; and assistance with the loading and stowing of assistive devices.

In addition, when airport owners and operators accept federal grants, such as through the AIP, the Federal Aid to Airports Program, or the Airport Development Air Program, they agree to operate their facilities in a safe and efficient manner and to comply with certain conditions and assurances. These assurances include that the airport will be available for public use on fair and reasonable terms without unjust discrimination.

4.15 What global distribution suppliers (GDSs) operate in your jurisdiction?

The GDSs that operate in the US include Amadeus, Sabre, and Travelport (parent company of GDS systems Galileo, Apollo, and Worldspan).

4.16 Are there any ownership requirements pertaining to GDSs operating in your jurisdiction?

No. However, the DOT can monitor the actions of GDSs under its unfair and deceptive practice statute, 49 USC § 41712.

4.17 Is vertical integration permitted between air operators and airports (and, if so, under what conditions)?

There are patterns of vertical integration in the US, especially with multiple major operators contracting with smaller operators at regional airports. Generally, however, operators enter into lease agreements with airports and there is federal oversight because of competition concerns given that airports are natural monopolies. "Local" competition in the New York area (with JFK, Newark, and LaGuardia airports being in competition with each other and JFK's multiple terminals being operated individually by multiple different carriers and non-carriers) may be viewed as an exception.

4.18 Are there any nationality requirements for entities applying for an Air Operator's Certificate in your jurisdiction or operators of aircraft generally into and out of your jurisdiction?

Yes. Under the FAA's enabling statute, a US air carrier must be deemed a US citizen by

remains to be seen with many of the defendant airlines moving to dismiss the actions. However, a significant decision was recently issued in *Ward v. American Airlines, Inc.* wherein the US District Court of Northern Texas rejected America Airline's argument that the breach-of-contract claims were preempted by the ADA.

On a different note, there has been a call for the overhaul of the FAA's aircraft certification process that will affect aircraft manufacturers going forward. In October 2018 and March 2019, Boeing's 737 Max jets were involved in two deadly crashes prompting lawmakers to push to enact legislation that would impose stricter requirements on the Federal Aviation Administration's aircraft certification process. In October 2018, Lion Air Flight 610 crashed in the Kava Sea, resulting in 189 deaths, and was followed by the crash of Ethiopian Airlines Flight 302 in March 2019, resulting in 157 deaths. Since the March 2019 crash, the fleet has been grounded. On November 17, 2020, the House passed the bipartisan Aircraft Certification Reform and Accountability Act, which includes nearly 30 provisions aimed at strengthening the aircraft certification process, ensuring transparency and accountability, incorporating improvements in the analysis of human factors, and imposing stricter requirements for disclosing "safety-critical information" to the FAA. The bill will also require the FAA to revise and improve its process for issuing amended type certificates to older airplanes and implement an added layer of oversight for the FAA's Organization Designation Authorization ("ODA") program, which currently delegates certain tasks of the aircraft certification process to the plane manufacturers themselves. The bill would require the FAA to approve any employees who are selected by manufacturers to perform delegated tasks under the program and assign FAA engineers or inspectors to be advisors to the employees participating in the ODA program.

Acknowledgment

The authors thank Jean Cunningham, an associate in Fox's Aviation Practice Group in New York, for her assistance with the preparation of this USA chapter. Ms. Cunningham helps clients resolve a broad range of aviation, product liability and commercial matters.

In the Name of Hate: Examining the Federal Government's Role in Responding to Hate Crimes

Briefing Before

The United States Commission on Civil Rights

Held in Washington, D.C.

Briefing Report

UNITED STATES COMMISSION ON CIVIL RIGHTS

1331 Pennsylvania Ave., NW • Suite 1150 • Washington, DC 20425 www.usccr.gov

Letter of Transmittal

November 13, 2019

President Donald J. Trump
Vice President Mike Pence
Speaker of the House Nancy Pelosi

On behalf of the United States Commission on Civil Rights ("the Commission"), I am pleased to transmit our briefing report, *In the Name of Hate: Examining the Federal Government's Role in Responding to Hate Crimes*. The report is also available in full on the Commission's website at www.usccr.gov.

In response to increased recent reports of hate crimes including horrific acts of violence, the Commission voted to investigate the federal government's role in combating hate crimes. Recent hate crimes resulting in the death of people of color, such as the mass shooting in El Paso, Texas in 2019, demonstrate the ongoing urgency and the work that is needed to prevent bias-based attacks on individuals and communities.

In this report, the Commission examined three areas: (1) federal law enforcement's hate crimes reporting practices and local policies being developed to encourage greater reporting; (2) federal prosecution and enforcement of laws regarding hate crimes and bias-motivated incidents; and (3) prevention of federal crimes based on race, national origin, ethnicity, disability, religion, gender, sexual orientation, or gender identity. Further, the Commission also explored the increase in reported hate incidents in American schools and in the public realm, along with current and potential civil rights tools that may be used to protect students and others against hateful, hostile, or threatening speech, including online speech, within the bounds of the First Amendment.

The Commission majority approved key findings including the following: Available evidence suggests hate crimes are increasing in America. Many Americans are negatively impacted by hate crimes and are fearful of the heightened expression of hate and bigotry in the United States. As of the time of this writing, 46 states and the District of Columbia have some form of hate crime statute, leaving Arkansas, Georgia, South Carolina, and Wyoming as states without such statutes.

The highest percent of reported post-2016 election hate incidents were in K-12 schools, and the majority of these incidents involved racial discrimination. Educators, researchers, parents and students should pay attention to bullying and hate-related incidents in schools and actively work with students and school communities to prevent them.

The Commission majority voted for key recommendations, including the following: Congress should pass legislation and provide adequate funding that would incentivize local and state law enforcement to more accurately report hate crimes to the FBI, and promote greater transparency and accountability, which would aid in building community trust. Congress should also pass legislation to ensure that federal law enforcement agencies collect and report their hate crime data to the FBI. To ensure that states are accurately reporting hate crime data they receive from local law enforcement agencies in their jurisdiction, the federal government should condition federal funding on reporting and publication of data, undergoing data auditing for accuracy, and working with community groups to report hate crimes even where a victim does not want to move forward with criminal prosecution.

Additionally, the Commission recommends that the Trump Administration reinstate groups within the Department of Homeland Security who analyze the threat of domestic terrorism and reinstate grants awarded to groups who counter white supremacist terror. The DOJ should provide grants, training materials, and resources for police departments to receive cultural competency and sensitivity training related to hate crimes and bias-motivated incidents. Congress should allocate additional funding towards anti-bias training for law enforcement officers.

Congress should pass legislation that includes hate crime prevention and response programs at higher education institutions and ensures that students and faculty are aware of related safety concerns on and around campuses. The Department of Education's Office for Civil Rights must vigorously enforce the protections against harassment that federal civil rights laws guarantee to students and provide the necessary leadership for school officials and administrators at primary, secondary, and higher education institutions to protect their students from bias-related incidents.

We at the Commission are pleased to share our views, informed by careful research and investigation as well as civil rights expertise, to help ensure that all Americans enjoy civil rights protections to which we are entitled.

For the Commission,

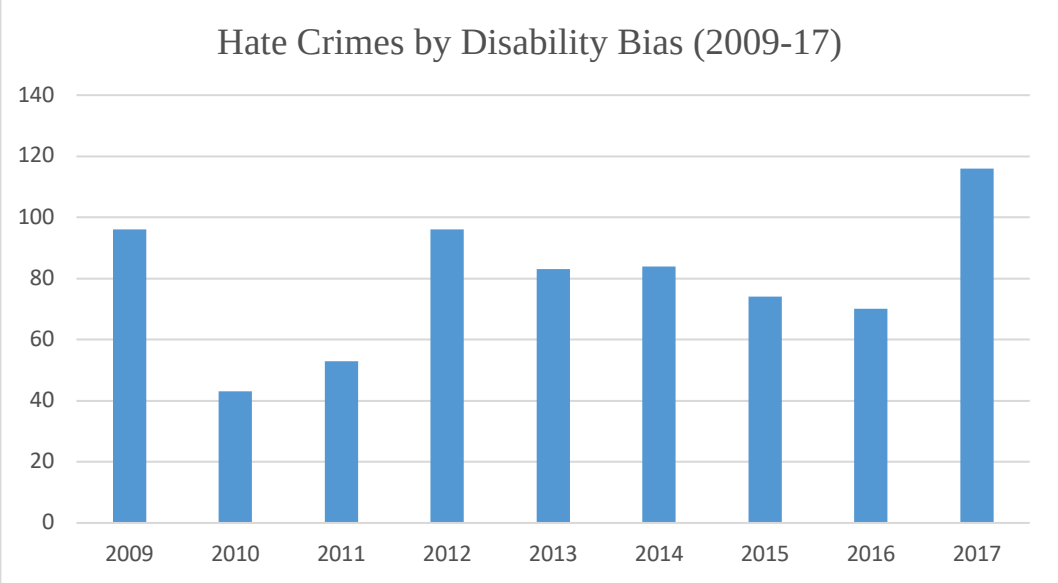
Catherine E. Lhamon
Chair

Disability Bias Hate Crimes

Hate-motivated violence against individuals with disabilities is also a serious concern. According to the Bureau of Justice Statistics, in 2014, the rate of violent victimization against persons with disabilities was 2.5 times higher than similarly aged persons without disabilities (31.7 victimization per 1,000 persons age 12 or older compared to 12.5 per 1,000, respectively).[721] This rate remained nearly constant from 2009-2014, during which time the victimization rate against individuals with disabilities was at least twice the rate for similarly aged individuals without disabilities. Further, "one in five violent crime victims with disabilities believed they were targeted because of their disability."[722] The rate of violent victimization was higher for individuals with disabilities for both women and men, as well as for each racial or ethnic group that was measured (i.e., black, Latinx, white, multiracial, and other, which includes Native American or Alaska Native, Asian, Native Hawaiian, or other Pacific Islander) compared to similarly aged persons without disabilities in 2010-14.[723]

FBI data from 2017 show that reported hate crimes against individuals with disabilities have also increased compared to 2016 reported numbers. In 2017, law enforcement reported 116 incidents compared to 70 reported incidents in 2016, which is a 65 percent increase in a single year.[724]

Chart 14: Reported Hate Crimes by Disability Status



Source: FBI, UCR, Hate Crime Statistics; data compiled and chart created by Commission staff

[721] Erika Harrell, "Crime Against Persons with Disabilities, 2009-2014," U.S. Dep't of Justice, Bureau of Justice Statistics, Nov. 2016, 1, https://www.bjs.gov/content/pub/pdf/capd0914st.pdf.
[722] Ibid, 4.
[723] Ibid, 4-5. The difference in rates of violent victimization between women and men with disabilities was not statistically significant (30.3 per 1,000, 31.2 per 1,000, respectively). Among the racial groups examined, persons with disabilities who identified as of two or more races had the highest rates of violent victimization among persons with disabilities (101.4 per 1,000), but there was no statistically significant difference in the rates between whites (29.7 per 1,000), blacks (28.8 per 1,000), Latinx (28.6 per 1,000), and persons of other races (28.0 per 1,000) with disabilities. Ibid.
[724] FBI, "FBI Releases 2017 Hate Crime Statistics," https://www.justice.gov/hatecrimes/hate-crime-statistics.

However, many advocates point out that these numbers are likely lower than the actual victimization rate, since crimes against persons with disabilities are often underreported.[725]

At the Commission's briefing, Nicole Jorwic, Director of Rights Policy at The Arc, testified that underreporting happens for many reasons. She explained that a "key factor is lack of understanding of stakeholders. Often, individuals with disabilities, their family members, allies, don't know what constitutes a hate crime and there is little outreach about this topic to the disability community specifically. . . . Without that knowledge, reporting will continue to be lower, despite the actual incidence not necessarily being less.[726] Further, Jorwic explained that local law enforcement are often not trained to handle bias crimes against victims with disabilities and also may hold negative impressions of individuals with disabilities, believing that victims with disabilities "lack credibility," which also leads to crimes going unreported.[727] And these negative beliefs about individuals with disabilities are further perpetuated in the court system where "cases of abuse and torture can sometimes be categorized as pranks or bullying, instead of calling them for what they are, hate crimes."[728] The disvaluing of the lives of people with disabilities is in part why hate crimes occur against these communities in the first place. For example, in 2010, Jennifer Daugherty, a 30 year-old woman with intellectual disabilities was attacked, humiliated, and brutalized by six roommates in Greensburg, Pennsylvania for many days before she was stabbed to death. Pennsylvania's hate crime laws do not extend protections to the disability community, and none of her attackers were charged with federal hate crimes; but they were prosecuted and received sentences varying from decades in prison, to life without parole, to the death penalty.[729]

---

[725] *See e.g.,* American Network of Community Options and Resources, "Hate Crimes Against People with Disabilities Increase in 2017," Nov. 19, 2018, https://ancor.org/newsroom/news/hate-crimes-against-people-disabilities-increase-2017; Debra McKinney, "The Invisible Hate Crime," Southern Poverty Law Center, Aug. 5, 2018, https://www.splcenter.org/fighting-hate/intelligence-report/2018/invisible-hate-crime; OSCE Office for Democratic Institutions and Human Rights, "Hate Crime against People with Disabilities," https://www.osce.org/odihr/hate-crime-against-people-with-disabilities?download=true.

[726] Nicole Jorwic, Director of Rights Policy at The Arc, testimony, *Briefing Transcript* pp. 109-10.

[727] Ibid, 110.

[728] Ibid, 111.

[729] Peggy Miller and Robert Masters pleaded guilty to third-degree murder charges; Miller is serving a 35 to 74 year prison sentence and Masters is serving 30 to 70 year sentence. Angela Marinucci who was 17 at the time, was convicted of first-degree murder and sentenced to life in prison, but her sentence was overturned and she is expected to appear in court in 2019 for a new penalty hearing. Ricky Smyrnes was convicted of first-degree murder and given the death penalty, which he appealed, however in 2017 the state Supreme Court upheld the first-degree murder conviction and the death penalty. Melvin Knight pleaded guilty and was given the death penalty, however the sentence was overturned in 2016, but in November 2018 he was again given the death penalty. Amber Meidinger was originally charged with first-degree murder and other offenses, but her sentence was lessened after testifying in other trials; she was allowed to plead guilty to lesser charges and was sentenced to prison for 40 to 80 years. *See* Rich Cholodofsky, "Roommate gives jurors gruesome details of 2010 torture-murder in Greensburg," *Trib Live*, Nov. 8, 2018; Ross Guidotti, "Jury Sentences 'Greensburg 6' Member Melvin Knight to Death," *KDKA-TV*, Nov. 15, 2018, https://pittsburgh.cbslocal.com/2018/11/15/greensburg-6-melvin-knight-jury-deliberations/; KDKA, "State High Court Upholds Death Penalty For 'Greensburg 6' Ringleader," Feb. 23, 2017, https://pittsburgh.cbslocal.com/2017/02/23/state-high-court-upholds-death-penalty-for-greensburg-6-ringleader/; Tribune-Review, "Woman convicted in Greensburg torture case faces 3rd sentencing hearing," *Trib Live*, April 27, 2018, https://archive.triblive.com/local/westmoreland/woman-convicted-in-greensburg-torture-case-faces-3rd-sentencing-hearing/.

Another reason why these crimes may go under- or unreported that is not as common in other hate crimes is that many times the victim knows the person who is harassing or abusing the victim.[730] For instance, the NCVS found that "a higher percentage of violence against persons with disabilities (40 percent) was committed by persons the victim knew well or who were casual acquaintances than against persons without disabilities (32 percent)."[731] Jorwic argues that this factor further highlights how outreach by law enforcement is crucial for victims to feel supported and be willing to report these crimes.[732] Data from the NCVS further show that victims who are targeted because of their actual or perceived disability (among others, such as LGBT victims) were much more likely to report these crimes when surveyed than they were to law enforcement.

In light of these concerns about reporting and investigating hate crimes against people with disabilities, Robert Moossy, Deputy Assistant Attorney General at the Justice Department, testified that DOJ has started to conduct more outreach to the disability community, especially as these bias crimes are on the rise. Deputy AG Moossy stated that:

> We're often prosecuting cases today that happened three or four years ago, just because of the time it takes to report, investigate, and prepare for prosecution. But I can say internally, we've noted the same thing. We feel like we're seeing too few transgender and disability matters and we want to do better at that. That is definitely an area where we want to improve.[733]

Another challenge in prosecuting hate crimes targeting persons with disabilities is that state laws vary in whether they offer protections to these communities. While the passage of HCPA expanded hate crime protections to include disability status in 2009, 18 states still do not have any specific hate crime law protections for people with disabilities.[734] For the states that do have protections for the disability community, crimes are more likely to be investigated and potentially prosecuted as a hate crime. For example, in May 2018, a woman in Staten Island, New York was charged with "two counts of burglary as a hate crime, along with multiple counts of burglary, grand larceny and stolen-property possession" after she intentionally tried to rob a visually impaired man in his home.[735] The New York Hate Crime Act of 2000 states that "a person commits a hate crime when he or she commits a specified offense" on the basis of the victim's actual or perceived identity category; the protected statuses include: race, religion, color, gender, national origin, ancestry, sexual orientation, or disability status.[736] Nicole Jorwic stated that it was "an awful situation, [b]ut a strong sign that the prosecutor labeled her crime as a hate crime. This case highlights that there are individuals who take advantage of perceived vulnerabilities of people with disabilities. And

---

[730] Nicole Jorwic, Director of Rights Policy at The Arc, testimony, *Briefing Transcript* p. 111.
[731] Erika Harrell, "Crime Against Persons with Disabilities, 2009-2014," U.S. Dep't of Justice, Bureau of Justice Statistics, Nov. 2016, 6, https://www.bjs.gov/content/pub/pdf/capd0914st.pdf.
[732] Nicole Jorwic, Director of Rights Policy at The Arc, testimony, *Briefing Transcript* p. 112.
[733] Robert Moossy, Deputy Assistant Attorney General at the Justice Department, testimony, *Briefing Transcript* p. 55.
[734] States without disability protections: Arkansas, Georgia, Idaho, Indiana, Kansas, Kentucky, Michigan, Mississippi, Montana, North Carolina, North Dakota, Ohio, Pennsylvania, South Carolina, South Dakota, Virginia, West Virginia, and Wyoming. *See* ADL Hate Crime Map, https://www.adl.org/adl-hate-crime-map.
[735] Frank Donnelly, "Woman charged with hate crimes for allegedly targeting sight-impaired man," *Staten Island Advance*, May 2, 2018, https://www.silive.com/northshore/2018/05/woman_charged_with_hate_crime.html.
[736] N.Y. PENAL LAW § 485.05 (McKinney 2019); New York State Senate, Section 485.05 Hate Crimes, Nov. 1, 2019, https://www.nysenate.gov/legislation/laws/PEN/485.05.

that needs to be called out and prosecuted as a hate crime so we can continue to improve the status of individuals with disabilities in our community."[737]

Emeritus Professor of Sociology at Northeastern University Jack Levin asserts that the majority of society does not think about hate crimes against the disability community. He explains that:

> [W]hen people think of hate crimes they think of neo-Nazis, they think of racism, they think of homophobia, they just don't seem to think of people with disabilities as being a protected category… I call it the invisible hate crime… [T]here are people very hostile towards people with disabilities. The sadism indicates some kind of need to feel powerful and special and important by targeting someone seen as inferior.[738]

While the passage of HCPA in 2009 extended protections for people with disabilities, gaining those rights was difficult. Curt Decker, executive director of the National Disability Rights Network, explained that the inclusion of people with disabilities received a lot of pushback. He told the SPLC that:

> In the political arena, there was a fair amount of conversation around, "People don't hate people with disabilities, they're very sympathetic." And it was like, "No, actually that's not necessarily true." And then we went through a series of discussions like, "Well, isn't it more a crime of opportunity? You rob a blind person or attack someone because they can't run away? That's not really hate, that's just convenience." It was a constant struggle throughout the whole process.[739]

In 2011, the first federal disability hate crime case tried under the HCPA that became known as the "Tacony Dungeon" case occurred in Philadelphia, Pennsylvania.[740] Five people admitted to kidnapping, torturing, and confining six individuals with mental disabilities for over a decade in subhuman conditions, and two of the victims died as a result of the mistreatment.[741] The group, referred to as "The Weston family" by prosecutors, stole over $200,000 in Social Security benefits from their captives and forced some into prostitution. The defendants in the case received varying sentences. Linda Weston, considered the ringleader in the case, was charged with 196 criminal counts and sentenced to life in prison plus an additional 80 years;[742] Jean McIntosh was sentenced

---

[737] Debra McKinney, "New York woman faces hate crime charges for targeting a visually impaired man in a burglary," Southern Poverty Law Center, July 20, 2018, https://www.splcenter.org/hatewatch/2018/07/20/new-york-woman-faces-hate-crime-charges-targeting-visually-impaired-man-burglary.
[738] Debra McKinney, "The Invisible Hate Crime," Southern Poverty Law Center, Aug. 5, 2018, https://www.splcenter.org/fighting-hate/intelligence-report/2018/invisible-hate-crime.
[739] Debra McKinney, "The Invisible Hate Crime," Southern Poverty Law Center, Aug. 5, 2018, https://www.splcenter.org/fighting-hate/intelligence-report/2018/invisible-hate-crime.
[740] *United States v. Weston, et al.* 2:13-CR-25 (E.D. Pa. 2013).
[741] Jeremy Stahl, "The Details of the 'Tacony Dungeon' Case Are Almost Beyond Belief," *Slate*, Nov. 6, 2015, https://slate.com/news-and-politics/2015/11/the-details-of-the-tacony-dungeon-case-are-almost-beyond-belief-linda-weston-sentenced-to-life.html.
[742] U.S. Dep't of Justice, U.S. Attorney's Office, Eastern District of Pennsylvania, "Guilty Plea In Case of Disabled Adults Held Captive In Subhuman Conditions," Sept. 9, 2015, https://www.justice.gov/usao-edpa/pr/guilty-plea-case-disabled-adults-held-captive-subhuman-conditions.

to 40 years in prison;[743] Nicklaus Woodard received 27 years in prison for his role;[744] Eddie Wright was also sentenced to 27 years in prison;[745] and at the time of this writing, Gregory Thomas still awaits sentencing.[746]

In a press release DOJ issued after the McIntosh sentencing, U.S. Attorney William McSwain stated that:

> It is hard to fathom this kind of disregard for the dignity of human life. The stomach-turning details of this case and unspeakable acts of cruelty McIntosh inflicted on her helpless victims serve as a stark reminder that pure evil does exist in the world. My sincere hope is that today's sentence brings some measure of closure to the victims and their families.[747]

The Special Agent in Charge of the FBI's Philadelphia Division, Michael Harpster mirrored McSwain's sentiments stating that:

> The actions of Jean McIntosh and 'The Weston Family' were nothing short of monstrous. With money as their motive, they used and abused some of society's most vulnerable. The torture inflicted upon their victims is unthinkable; the pain and the fear they caused, incalculable. Right now, my thoughts are with all who suffered at their hands—the survivors, as well as those who lost their lives.[748]

Hate crimes and bias-motivated incidents against people with disabilities can also occur on the basis of multiple aspects of their identities. For example, Dominick Evans, a transgender man who also has progressive spinal muscular atrophy, was the victim of a bias-motivated incident that occurred at his high school.[749] He explained that upon returning to school after undergoing an intensive back surgery, he utilized a wheelchair and relied on an elevator to navigate the school. Evans stated that it was well-known that he was the only student allowed to use the elevator on a daily basis, and as a "prank" a group of football players covered the elevator floor with dead mice.[750] Evan told SPLC researchers that:

---

[743] U.S. Dep't of Justice, U.S. Attorney's Office, Eastern District of Pennsylvania, "'Tacony Dungeon' Defendant Jean McIntosh Sentenced to 40 Years Imprisonment," Aug. 21, 2018, https://www.justice.gov/usao-edpa/pr/tacony-dungeon-defendant-jean-mcintosh-sentenced-40-years-imprisonment.
[744] Kristen Johnson, "Man Sentenced to 27 years for role in 'Basement of Horrors' case," *KYW News*, Sept. 11, 2018, https://kywnewsradio.radio.com/articles/news/man-sentenced-27-years-role-basement-horrors-case.
[745] CBS Philly, "Self-Described Preacher Sentenced to 27 Years in Prison in 'Basement of Horrors' Case," *CBS Philly*, Sept. 13, 2018, https://philadelphia.cbslocal.com/2018/09/13/self-described-preacher-sentenced-to-27-years-in-prison-in-basement-of-horrors-case/.
[746] Chris Palmer, "'Pastor Wright' codefendant in Tacony dungeon case, gets 27 years in prison," *The Inquirer*, Sept. 13, 2018, https://www.philly.com/philly/news/crime/linda-weston-pastor-eddie-wright-sentenced-27-years-tacony-dungeon-federal-prison-philadelphia-20180913.html.
[747] U.S. Dep't of Justice, "'Tacony Dungeon' Defendant Jean McIntosh Sentenced to 40 Years Imprisonment," U.S. Attorney's Office, Eastern District of Pennsylvania, Aug. 21, 2018, https://www.justice.gov/usao-edpa/pr/tacony-dungeon-defendant-jean-mcintosh-sentenced-40-years-imprisonment.
[748] Ibid.
[749] Debra McKinney, "The Invisible Hate Crime," Southern Poverty Law Center, Aug. 5, 2018, https://www.splcenter.org/fighting-hate/intelligence-report/2018/invisible-hate-crime.
[750] Ibid.

> They thought it would be funny to take the one disabled kid in their school and make them the senior prank. I spent sixth and seventh period hiding out in the disabled (restroom) stall because I couldn't stand to go to class and they wouldn't let me go home. I just cried. I felt like there was no place for me, that my life had no value… Nobody cared about what happened to me; that's how I felt, that nobody cared.[751]

Evans stated that this incident contributed to a suicide attempt a few years later.[752]

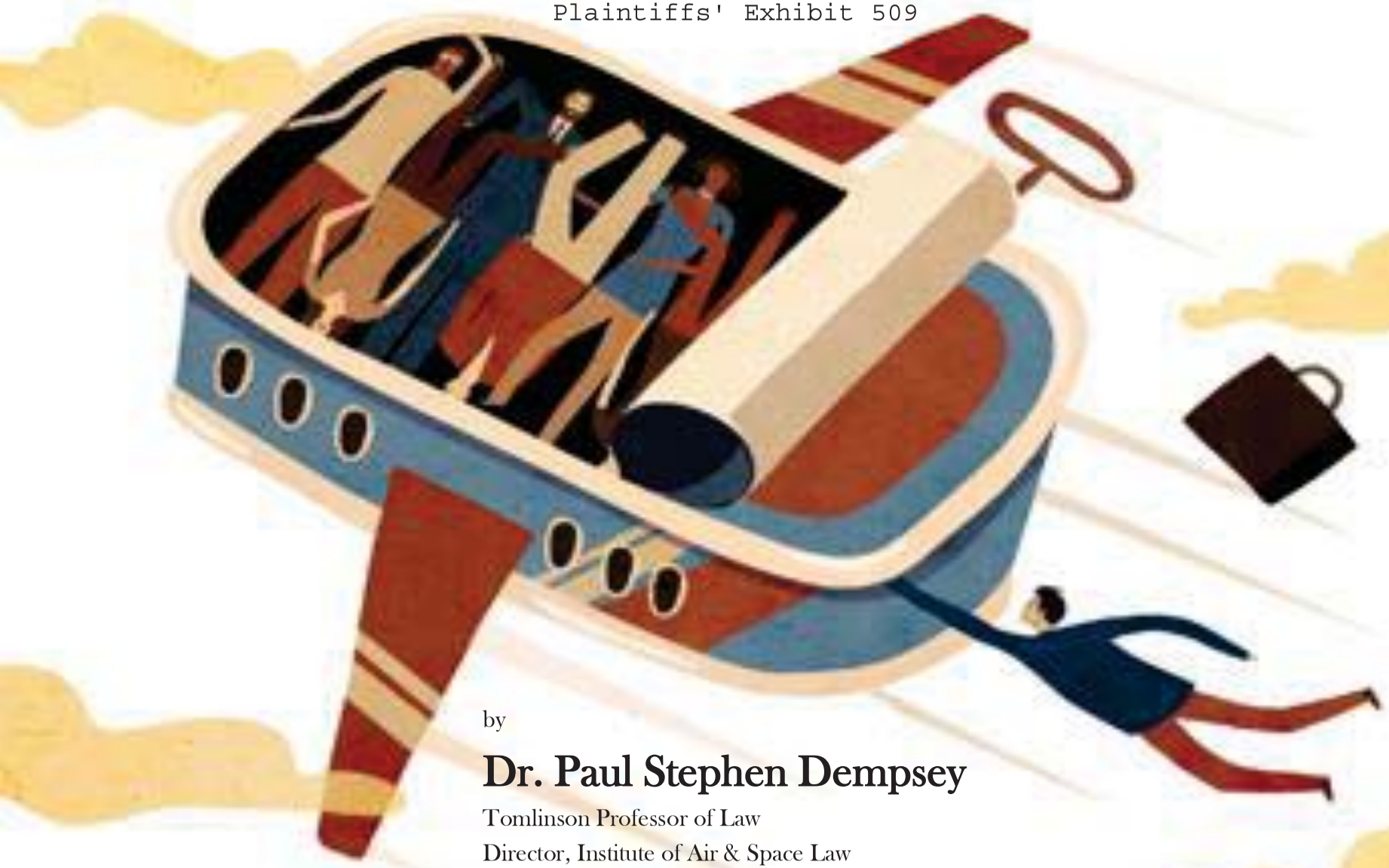
Another case that also occurred at a high school was in 2015 in Dietrich, Idaho, where a white high school football player, John R.K. Howard, was accused of kicking a coat hanger into the rectum of a black teammate with an intellectual disability.[753] According to the victim's testimony, Howard also repeatedly called him the n-word and taught him a song glorifying the KKK and the lynching of black people; other teammates also allegedly used other racial slurs, calling him "fried chicken," "watermelon," "Kool-Aid," and "grape soda."[754] Howard was initially charged with sexual assault, but those charges were dropped and he was sentenced to probation and community service for felony injury to a child. Two other football players were also charged, however since they were juveniles at the time the incident occurred, the charges in those cases were private.[755] The victim's family filed a lawsuit against the school alleging that the school was aware of the bullying and did not do enough to intervene to prevent the assault. In October 2017, the school settled the federal lawsuit, however the school maintained that officials were not aware of any alleged abuse or racist behavior until after the sexual assault was reported.[756]

As shown above, while there have been some significant strides to increase reporting (such as the expansion of reporting to include hate crimes against persons with disabilities), which can lead to more thorough investigation and prosecution efforts, hate crimes are still largely underreported in many communities. This underreporting has far-reaching deleterious effects in terms of investigations and also for prevention efforts for all.

---

[751] Ibid.
[752] Ibid.
[753] Camila Domonoske, "No Jail Time For 19-Year-Old In Idaho Coat-Hanger Assault Case," *NPR*, Feb. 27, 2017, https://www.npr.org/sections/thetwo-way/2017/02/27/517510627/no-jail-time-for-19-year-old-in-idaho-coat-hanger-assault-case; Debra McKinney, "The Invisible Hate Crime," Southern Poverty Law Center, Aug. 5, 2018, https://www.splcenter.org/fighting-hate/intelligence-report/2018/invisible-hate-crime.
[754] Camila Domonoske, "No Jail Time For 19-Year-Old In Idaho Coat-Hanger Assault Case," *NPR*, Feb. 27, 2017, https://www.npr.org/sections/thetwo-way/2017/02/27/517510627/no-jail-time-for-19-year-old-in-idaho-coat-hanger-assault-case; Alex Riggins, "Texas teen sentenced in Dietrich assault, but victim's deposition highlights case's murky facts," *Magic Valley*, Feb. 25, 2017, https://magicvalley.com/news/local/crime-and-courts/texas-teen-sentenced-in-dietrich-assault-but-victim-s-deposition/article_4a0ddb88-aaa6-5c3e-9f6a-ee398bc391df.html.
[755] Camila Domonoske, "No Jail Time For 19-Year-Old In Idaho Coat-Hanger Assault Case," *NPR*, Feb. 27, 2017, https://www.npr.org/sections/thetwo-way/2017/02/27/517510627/no-jail-time-for-19-year-old-in-idaho-coat-hanger-assault-case.
[756] Kimberlee Kruesi, "Idaho school settles in locker room assault case," *The Salt Lake Tribune*, Oct. 3, 2017, https://www.sltrib.com/news/2017/10/03/idaho-school-settles-in-locker-room-assault-case/.

CONSUMER PROTECTION IN THE AIRLINE INDUSTRY



by

Dr. Paul Stephen Dempsey

Tomlinson Professor of Law

Director, Institute of Air & Space Law

McGill University

The Civil Aeronautics Board

- Prior to the Airline Deregulation Act of 1978, carriers filed their Contracts of Carriage in tariffs, which were reviewed by the CAB, and approved if "just and reasonable."
- After deregulation, carrier Contracts of Carriage were no longer subjected to governmental review and approval.
- However, provisions in the carriers' Contracts of Carriage were void if they conflicted with federal law or regulation.
- Prior to deregulation, the economic health of airlines was not as stressed. Load factors were lower, and carriers offered other carriers discounted fares if they needed to reaccommodate passengers stranded by delays or flight cancellations.
- After deregulation, load factors increased so there were fewer empty seats, and some carriers became less willing to accommodate passengers of other airlines.

Plaintiffs' Exhibit 510

Children's Health Defense

NOTICE FOR EMPLOYERS, UNIVERSITIES AND OTHER INSTITUTIONS MANDATING COVID-19 MASKS

April 26, 2021

This serves as notice that the mandate for any individual to wear a mask against COVID-19 for employment or attendance at a university or other institution violates federal law. All COVID-19 masks, whether surgical, N95 or other respirators, are authorized, not approved or licensed, by the federal government; they are Emergency Use Authorization (EUA) only. They merely "may be effective." Federal law states:

Title 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) states:

> **individuals to whom the product is administered are informed—**
>
> **(I)** that the Secretary has authorized the emergency use of the product;
> **(II)** of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
> **(III) of the option to accept or refuse administration of the product,** of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

EUA products are by definition experimental and thus require the right to refuse. Under the Nuremberg Code, the foundation of ethical medicine, no one may be coerced to participate in a medical experiment. Consent of the individual is "absolutely essential." A federal court held that even the U.S. military could not mandate EUA vaccines to soldiers. *Doe #1 v. Rumsfeld*, 297 F.Supp.2d 119 (2003).

In a letter dated April 24, 2020, the Food and Drug Administration stated that authorized face masks must be labelled accurately and may not be labeled in a way that misrepresents the product's intended use as "source control to help prevent the spread of SARS-CoV-2." The letter specifies that the labeling "may not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction." Any EUA mandate requiring individuals to wear face masks conflicts with Section 360bbb-3(e)(1)(A)(ii)(I-III), which provides that the person must be informed of the option to refuse to wear the device.

Liability for forced participation in a medical experiment, including possible injury, may be incalculable. Children's Health Defense urges U.S. employers, universities and other institutions to respect and uphold the rights of individuals to refuse to wear EUA masks.

HEALTH FREEDOM DEFENSE FUND

Plaintiffs' Exhibit 511

FREQUENTLY ASKED QUESTIONS RE MASKS

1. Q: Can my employer force me to wear a mask at this time?

A: Currently, masks are authorized for use by the general public as "investigational products" under an Emergency Use Authorization ("EUA"). They are not an approved product, and are referred to in the law as "unapproved products" because they have not been fully tested and approved for use by the FDA. Under the federal law that allows the FDA to issue EUAs (21 U.S.C. § 360bbb-3), you cannot be forced to wear a mask. The law provides that recipients of a product authorized for use under and EUA can refuse to take the product. In this instance, the mask is the product.

2. Q: Can my employer fire me for refusing to wear a mask?

A: This issue has yet to be decided by the courts. Some attorneys take the position that employers can fire employees who refuse to wear a mask. However, this conclusion conflicts with the language of the critical statute, 21 U.S.C. § 360bbb-3, which provides that an unapproved product authorized for emergency use only, such as masks, can only be used if:

> **(i)** Appropriate conditions designed to ensure that health care professionals administering the product are informed—
>
> > **(I)** that the Secretary has authorized the emergency use of the product;
> >
> > **(II)** of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and
> >
> > **(III)** of the alternatives to the product that are available, and of their benefits and risks.
>
> **(ii)** Appropriate conditions designed to ensure that **individuals to whom the product is administered are informed—**
>
> > **(I)** that the Secretary has authorized the emergency use of the product;
> >
> > **(II)** of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
> >
> > **(III) of the option to accept or refuse administration of the product**, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.
>
> **(iii)** Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(emphasis added)

Note that the recipient of the product (the mask) must be informed of the option to refuse administration of the product. An employer who fires an employee for refusing to wear a mask would therefore be firing an employee for asserting a right guaranteed under federal law. Moreover, the health care professionals administering the product would be administering the

product in violation of federal law, and beyond the scope of the authorized use of the product. We therefore conclude that employers may not fire employees who refuse to wear a mask at this time.

3. Q: Can my employer subject me to special treatment, such as forcing me to work from home, or work in separate areas should I refuse to wear a mask.

A: This question has not been addressed by any court to date. An employer taking actions of nature noted above would seem to be punishing an employee for asserting the federally protected right of refusing to wear an emergency device that has yet to be approved by the FDA. The employer subjecting a healthy person, exhibiting no signs of illness or contagion, differently than other employees simply because that person asserted the federally protected right to refuse to wear a mask could be seen as attempting to coerce that employee into wearing a mask against their will, a violation of the federal law quoted above.

4. Q: What should I do if my employer tries to force me to wear a mask?

A: You should provide your employer with the HFDF Employer Mask Notice, that can be downloaded HERE. If your employer continues to insist that you wear a mask, please contact us by email, and we will attempt to refer you to a lawyer in your area who has been educated on this issue who may be able to assist you. We cannot guarantee that we will be able to assist every person who contacts us, but we will do our best to try to help you.

5. Q: My employer says that I am threatening the health of my co-workers because I refuse to wear a mask. What should I do?

A: Your employer is incorrect that the masks have been authorized by the FDA on the basis that they prevent the transmission of a virus like COVID-19. Here is a quote from the FDA's emergency use authorization for the use of masks by the general public:

> Authorized face masks must meet the following requirements:
>
> 1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);
>
> 2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection;
>
> 3. The product labeling includes recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high;
>
> 4. **The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction**;
>
> (emphasis added)

Thus, any statement by your employer that the mask is required to protect against microbes or viruses, or is required to prevent or reduce infection is contrary to the use authorization for masks.

Plaintiffs' Exhibit 512

HEALTH FREEDOM DEFENSE FUND

NOTICE TO EMPLOYERS

March 2, 2021

This serves as notice to all employers that any compulsory face mask requirement imposed upon an employee violates federal law.[1] Title 21, Section 360bbb-3 of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") vests the Secretary of Health and Human Services with the permissive authority to grant Emergency Use Authorizations ("EUAs"). However, the statute requires that:

> **individuals to whom the product is administered are informed—**
>
> **(I)** that the Secretary has authorized the emergency use of the product;
> **(II)** of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
> **(III)** **of the option to accept or refuse administration of the product**, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

On April 24, 2020 the Food and Drug Administration ("FDA") issued an EUA letter to all "Manufacturers of Face Masks; Health Care Personnel; Hospital Purchasing Departments and Distributors; and Any Other Stakeholders," allowing manufacturers to produce cloth and non-surgical face masks to sell and distribute to the general public and health care practitioners, so long as, "[the] product is not labeled in such a manner that would misrepresent the product's intended use; for example, **the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction[.]**"

Thus, by the FDA's own admission, face masks such as those in common use by the public are not intended to protect the wearer or others from the COVID-19 virus, ***as they do not prevent or reduce infection.***

Even if wearing a face mask were effective enough to protect the wearer and the general public from COVID-19, which they are not, the EUAs issued pursuant to FD&C Act's authority are extremely limited in legal scope and effect. Specifically, as long as EUAs pertaining to face masks remain in force and effect, any mandate requiring employees to wear face masks would conflict with Section 360bbb-3(e)(1)(A)(ii)(I-III), ***which requires that the employee be informed of the option to refuse the wearing of such 'device.'***

We at the Health Freedom Defense Fund urge U.S. employers to comply with the FD&C Act, not misrepresent the use of a mask as being intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction, and advise all employees that they have the right to refuse to wear a mask as a measure to prevent or reduce infection from COVID-19. Any other course of action is contrary to federal law.

---

[1] Title 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III).

Plaintiffs' Exhibit 513

icandecide.org

ICAN RESPONDS TO THE DOJ'S INCORRECT CONCLUSION THAT AN EMERGENCY USE VACCINE CAN BE MANDATED

3-4 minutes

Aug 05, 2021, 21:40ET

ICAN | LEGAL UPDATE

ICAN RESPONDS TO DOJ'S OPINION REGARDING VACCINE MANDATES DURING EMERGENCY USE AUTHORIZATION AND EXPLAINS WHY THE DOJ REACHED THE WRONG CONCLUSION

Since the three COVID-19 vaccines were granted emergency use authorization (**EUA**) in the U.S., the question of whether employers, schools, and others can mandate the vaccines has been heavily debated. At the crux of the debate is Section 564 of the Food, Drug, and Cosmetic Act (**FDCA**), codified at 21 U.S.C. § 360bbb-3 (**Section 564**), which provides "required conditions" for EUA products including that:

> the Secretary … shall … establish … [a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed … of **the option to accept or refuse administration of the product**, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

On July 26, 2021, an opinion written by the Acting Assistant Attorney General of the

Department of Justice ("**DOJ**") was released to the public. The opinion was addressed to the Deputy Counsel to the President, part of an administration whose stated goal is to vaccinate as many Americans as possible, and concludes "that section 564 of the FDCA does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs."

ICAN promptly and thoroughly responded in a letter to the DOJ. ICAN's attorneys explain in careful detail how this conclusion runs contrary to the text of Section 564, its statutory framework, the history surrounding its passage, and its consistent interpretation by the FDA, Centers for Disease Control and Prevention (**CDC**), the Department of Defense (**DOD**), and other federal agencies. ICAN's response highlights the experimental nature of EUA products and the long settled legal precedent which establishes that it is not legal to coerce an individual to accept an experimental product.

It further provides the historical background and evidence that Congress' intent in enacting Section 564 was to provide only one limited exception to the option to accept or refuse EUA products – that exception applies only to military personnel and only when national security is at risk. Federal agencies have also historically interpreted Section 564 as a prohibition on mandates of EUA products, and ICAN's letter highlights these interpretations from the CDC, FDA, DOD, and the U.S. General Services Administration.

ICAN also pointed out it would be illogical that Congress would require that individuals be informed of a freedom of choice if that choice is illusory at the whim of any public or private entity, and concluded its letter by urging the DOJ to revise its Slip Opinion and enforce Section 564 by making clear that it **prohibits** entities from requiring the use of an EUA product.

Read the full letter here and share it far and wide so that the correct interpretation of Section 564 and the fundamental right to be free from coercion with respect to unlicensed medical products ultimately prevails.

Plaintiffs' Exhibit 514

Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT | DENVER

200 Park Avenue, 17th Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

August 4, 2021

VIA EMAIL AND FEDERAL EXPRESS

The Honorable Dawn Johnsen
Acting Assistant Attorney General
Office of Legal Counsel
United States Department of Justice
Washington, DC 20530
dawn.johnsen@usdoj.gov

Re: Slip Opinion: *Whether Section 564 of the FDCA Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization*

Dear Ms. Johnsen:

We write on behalf of our client, the Informed Consent Action Network, regarding your Slip Opinion to the Deputy Counsel to the President, titled "Whether Section 564 of the FDCA Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization," (the "**Slip Opinion**") released to the public on July 26, 2021.

Section 564 of the Food, Drug, and Cosmetic Act ("**FDCA**"), codified at 21 U.S.C. § 360bbb-3 ("**Section 564**"), permits the Food and Drug Administration ("**FDA**") to issue an emergency use authorization ("**EUA**") for a medical product prior to licensure by the FDA. In your Slip Opinion, you conclude that Section 564 "does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs."[1] This conclusion runs contrary to the text of Section 564, its statutory framework, the history surrounding its passage and its consistent interpretation by the FDA, Centers for Disease Control and Prevention ("**CDC**"), the Department of Defense ("**DOD**"), and other federal agencies. Our client strongly urges you to reconsider your interpretation and guidance regarding Section 564, revise your Slip Opinion, and enforce Section 564 by making clear that it prohibits entities from requiring the use of an EUA product.

The Question Answered by Your Slip Opinion

Your Slip Opinion states that the Deputy Counsel to the President asked "whether the 'option to accept or refuse' condition in section 564 prohibits entities from imposing …

[1] https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf.

vaccination requirements while the only available vaccines for COVID-19 remain subject to EUAs." The "option to accept or refuse" refers to one of the "[r]equired conditions" in Section 564 for each EUA product. As provided in Section 564:

> the Secretary … shall … establish … [a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed … of **the option to accept or refuse administration of the product**, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

Section 564, 21 U.S.C. § 360bbb-3(e)(1)(A) (emphasis added). The Department of Justice ("**DOJ**") is the entity primarily tasked with enforcing Section 564. *See* 21 U.S.C. § 337. Nevertheless, your Slip Opinion circumvents any enforcement of the foregoing required condition by concluding that the "language of section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements."[2] As discussed below, this conclusion is incorrect.

Entrenched Principle to Not Coerce Acceptance of Unlicensed Medical Products

To be licensed, the FDA must find that a medical product is "safe for use and … effective in use."[3] Until licensed, a medical product remains investigational, even after issuance of an EUA. As the National Institutes of Health ("**NIH**") explains with regard to a vaccine granted EUA: "The issuance of an EUA is different than an FDA approval (licensure) of a vaccine. A vaccine available under emergency use authorization is still considered investigational."[4] And as the FDA explains, "an investigational drug can also be called an experimental drug" because these two terms are synonymous.[5] For example, the EUA fact sheet for an intravenous drug to treat H1N1 granted EUA by the FDA explains that it is "an experimental drug."[6] Similarly, after an EUA was granted

---

[2] *Id*.

[3] 21 U.S.C. § 355(b)(1)(A)(i) (an application for licensure requires "full reports of investigations which have been made to show that such drug is safe for use and whether such drug is effective in use").

[4] https://www.niaid.nih.gov/diseases-conditions/covid-19-vaccine-faq.

[5] Until a medical product's Investigational New Drug Application is approved by the FDA, and hence licensed, it is considered experimental. https://www.fda.gov/media/138490/download ("an investigational drug can also be called an experimental drug"); https://www.northwell.edu/coronavirus-covid-19/vaccine/frequently-asked-questions ("Vaccines that receive EUA are considered experimental until the FDA formally approves it.").

[6] https://web.archive.org/web/20100222172129/http:/www.cdc.gov/h1n1flu/eua/pdf/patient_fact_sheet_peramivir_IV_23Oct2009.pdf. Peer review studies found that using the term "experimental" in reference to an EUA medical product reduced their uptake and hence advised against informing the public that these products are still "experimental." *See*, *e.g.*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7893369/ ("A 2010 survey examining the acceptance of peramivir, approved as an EUA, found that use of the term 'experimental' on the fact sheet decreased willingness across the board. … FDA and the sponsor must … avoid language that stimulates negative responses (i.e., experimental)."); https://pubmed.ncbi.nlm.nih.gov/25882123/ ("In late 2009, peramivir was granted an EUA" and its "CDC fact sheet" stated it is an "experimental drug" but the study found that "the use of the term experimental, while necessary and accurate, presented real impediments for willingness" to take the EUA product.).

for the COVID-19 vaccine co-developed by the NIH and Moderna, it was described by the NIH as an "[e]xperimental coronavirus vaccine."[7]

Long settled legal precedent establishes that it is not legal to coerce an individual to accept an unlicensed, and hence experimental, medical product. An individual must voluntarily agree, free from any undue influence, to accept same. This principle was first codified long-ago by American jurists.[8] It was then incorporated into the United States Code, the Code of Federal Regulations, and guidance from federal health agencies. *See e.g.*, 21 U.S.C. § 360bbb-0a (Even for patients with a life-threatening condition, an unlicensed medical product cannot be coerced, rather Congress required obtaining the patient's "written informed consent.") 42 U.S.C. § 9501 (Same for mental health patients);[9] 45 C.F.R. § 46.116 (For an unlicensed medical product, the "Basic elements of informed consent" include that "participation is voluntary," "refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled" and that consent be obtained without "coercion or undue influence.");[10] FDA *Information Sheet: Informed Consent* ("Coercion occurs when an overt threat of harm [such as expulsion from school or employment] is intentionally presented by one person to another in order to obtain compliance.")[11]

The principle that individuals should not be coerced to receive an unlicensed medical product is also codified in the law of at least 84 countries and is an accepted principle of international common law. *See, e.g.*, *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 184 (2nd Cir. 2009) ("We have little trouble concluding that a norm forbidding nonconsensual human medical experimentation [which includes unlicensed medical products] is every bit as concrete – indeed even more so – than the norm prohibiting piracy…. The Nuremberg Code, Article 7 of the ICCPR, the Declaration of Helsinki, the Convention on Human Rights and Biomedicine, the Universal Declaration on Bioethics and Human Rights, the 2001 Clinical Trial Directive, and the domestic laws of at least eighty-four States all uniformly and unmistakably prohibit medical experiments on human beings without their consent, thereby providing concrete content for the norm.").

In your Slip Opinion, you assert that expulsion from a job, school, and civil society are only "secondary consequences" which does not remove the "option to accept or refuse." Not only does this argument defy common sense, but Section 564's history, statutory framework, and

---

[7] https://www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-highly-effective.

[8] "The Nuremberg Code is the most important document in the history of the ethics of medical research. The Code was formulated 50 years ago, in August 1947 … by American judges … It served as a blueprint for today's principles that ensure the rights of subjects in medical research [which includes unlicensed medical products]." https://www.nejm.org/doi/full/10.1056/NEJM199711133372006. *See also* https://history.nih.gov/display/history/Nuremberg+Code, 313 BMJ 1448 (1996) ("The voluntary consent of the human subject is absolutely essential [for unlicensed medical interventions]. This means that the person … [is] able to exercise free power of choice, without the intervention of any element of … coercion.").

[9] *See also* 38 U.S.C. § 7331 (Same for veterans); 42 U.S.C § 300ff-61 ("in testing for HIV/AIDS, the applicant will test an individual only after the individual confirms that the decision of the individual with respect to undergoing such testing is voluntarily made").

[10] *See also* 21 C.F.R § 50.20 (sets forth conditions for obtaining informed consent for use of an unlicensed medical product and reiterating that consent should be free from "coercion or undue influence")

[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent#coercion

implementation all reflect that "the option to accept or refuse" was intended to continue the longstanding principle that it is not permissible to coerce anyone to receive an unlicensed medical product.

Section 564 Incorporates the Principle that Unlicensed Medical Products Cannot be Mandated

Section 564 was enacted after the United States experienced September 11, 2001, and subsequent acts of terror, including envelopes with anthrax being sent through the United States Postal Service.[12] To create a legal route to distribute an unlicensed and therefore, experimental, medical product in the event of bioterrorism, or a similar emergency, and create a narrow exception to allow mandates of such a product to members of the military, Congress passed Section 564 (permitting an EUA) and 10 U.S.C. § 1107a ("**Section 1107a**") (permitting the President to waive "the option to accept or refuse" requirement in Section 564 for members of the military under limited circumstances of national security).

i. Congress' Intent When Passing Section 564

There is no indication that Congress, in passing Section 564 and Section 1107a, intended to deviate from the long-standing principle and entrenched state, federal, and international principle that unlicensed medical products generally cannot be anything but completely voluntary. That this principle was carried forward when Congress included the words "the right to accept or refuse" in Section 564 is reinforced by the legislative discussions surrounding the passing of Section 564. On July 16, 2003, in deliberating Section 564, Representative Hays said, without any objection, that:

> …any authority to actually use experimental drugs or medical devices in emergency situations has to be defined and wielded with nothing less than surgical precision. Prior informed consent in connection with the administration of experimental therapy is a basic human right, a right no one should be asked to surrender…[13]

Similarly, on May 19, 2004, Senator Kennedy said while deliberating regarding Section 564 that "[t]he authorization for the emergency use of unapproved products also includes strong provisions on informed consent for patients."[14]

---

[12] *See* https://wwwnc.cdc.gov/eid/article/13/7/06-1188_article (detailing "the need for and genesis of the EUA, its requirements, its broad application to civilian and military populations, and its features of particular importance to physicians and public health officials.").

[13] https://www.congress.gov/congressional-record/2003/7/16/house-section/article/h6908-1.

[14] https://www.congress.gov/congressional-record/2004/05/19/senate-section/article/S5744-1. This same Senator also reiterated that Section 564 "allows the FDA to authorize the emergency use of medicines under the tightly controlled conditions outlined in this legislation." *Id.* Those conditions are, of course, specifically outlined in Section 564. In a congressional hearing on Section 564 held a few months later, Representative Maloney added that "unapproved drugs and devices, whose risks and benefits are not fully tested, impose an unprecedented responsibility on the government. The FDA must be vigilant in protecting the public against unnecessary risks from these products. In part because of these concerns, the bill has been modified to require that health care providers and patients be informed that the products have not been approved and of their risks. … These conditions [in Section 564] are essential

ii. The Exception that Proves the Rule

That Congress intended "the option to accept or refuse" as a prohibition on mandating an unlicensed medical product comes into sharp focus by the fact that Congress specifically carved out only one exception for when an individual would not have "the option to accept or refuse administration of the product." Congress permitted required use of an EUA product when the President of the United States finds that providing an individual in the military with the option to accept or refuse the product would not be in the interests of national security. As provided in Section 1107a:

> In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.

Thus, Congress so highly valued the right to individual choice that it allowed only a threat to national security to trump that right, and even then, only with regard to military personnel. As your Slip Opinion admits, this is how members of Congress understood Section 564 and Section 1107a when they were enacted. *See* Slip Opinion at 16-17. It is also how the DOD understood these sections following their enactment, stating in DOD Instruction 6200.02 § E3.4, adopted February 27, 2008:

> In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients **are provided an option** to refuse administration of the product, the President may … waive **the option** to refuse … administration of the medical product to members of the armed forces.[15]

Your interpretation of Section 564 renders Section 1107a meaningless and nonsensical. If the military was permitted to create any consequences it deemed appropriate in the event an armed forces member refused an EUA vaccine, it would be unnecessary to create a separate statute and require a written presidential national security finding to remove a requirement that, in your words, "concerns only the provision of information[.]"

---

for the safe use of unapproved products, and they should be imposed in all cases, except in truly extraordinary circumstances." https://www.congress.gov/congressional-record/2004/07/14/house-section/article/H5721-3

[15] https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/620002p.pdf (emphasis added).

iii. Consistent Agency Interpretation of Section 564

The FDA likewise viewed Section 564 as providing a substantive right to refuse when it explained the military exception:

> [A]s a general rule, persons **must be made aware of their right to refuse the product** (or to refuse it for their children or others without the capacity to consent) and of the potential consequences, if any, of this choice. An exception to this rule is that the president, as commander in chief, **can waive military personnel's right to refuse this product**. If the right is not specifically waived by the president for a particular product given under EUA, military personnel **have the same right to refuse as civilians**.[16]

The FDA thus makes clear that Section 564 provides a substantive right to refuse, and this right does not exist in the presence of a requirement that imposes negative consequences for refusing.

Similarly, the CDC's Advisory Committee on Immunization Practices ("**ACIP**") has interpreted Section 564 as a consent provision and not merely a requirement to inform. When responding to an inquiry regarding whether the COVID-19 vaccines can be required, the Executive Secretary of ACIP publicly stated that "under an EUA, vaccines are not allowed to be mandatory. Therefore, early in the vaccination phase individuals **will have to be consented** and **cannot be mandated to be vaccinated**."[17] ACIP's Executive Secretary then reaffirmed to the FDA's Vaccine and Related Biological Products Advisory Committee that no organization, public or private – including hospitals – can mandate the EUA COVID-19 Vaccines:

> Organizations, such as hospitals, with licensed products do have [the] capability of asking their workers to get the vaccine. But in the setting of an EUA, patients and individuals will have **the right to refuse** the vaccine.[18]

Consistent with the foregoing, the U.S. General Services Administration's ("**GSA**") Safer Federal Workforce website, applicable to all federal employees and contractors, expressly provided that the EUA COVID-19 vaccines cannot be mandatory, stating:

> Employees should receive paid time off to be vaccinated and to deal with any side effects. At present, COVID-19 vaccination should generally not be a pre-condition for employees or contractors at executive departments and agencies … to work in-person in Federal buildings, on Federal lands, and in other settings as required by their job duties. Federal employees and contractors may voluntarily share

[16] Nightingale SL, Prasher JM, Simonson S. Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States. *Emerging Infectious Diseases*. 2007;13(7):1046. doi:10.3201/eid1307.061188 available at https://wwwnc.cdc.gov/eid/article/13/7/06-1188_article#r1 (emphasis added).

[17] https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508.pdf at 56 (emphasis added).

[18] https://www.fda.gov/media/143982/download at 156 (emphasis added).

> information about their vaccination status, but agencies should not require federal employees or contractors to disclose such information.[19]

The GSA only changed this interpretation *after* you released your Slip Opinion.

The foregoing consistent guidance from the FDA, CDC, DOD, and GSA all reflect the fact that federal agencies have long understood that an EUA product cannot be mandatory.

iv. Section 564 Prohibits Consequences Beyond Those Authorized by the Secretary

In line with the foregoing, Congress provided in Section 564 that only the Secretary of the U.S. Department of Health and Human Services (the "**Secretary**") may provide consequences for refusing an EUA product. As provided in that section, "the Secretary … shall … establish … the consequences, if any, of refusing administration of the product." The FDA makes plain that "the option to accept or refuse" and the "consequences" for refusing an EUA product established by the Secretary cannot be modified or added to:

> … section 564 does provide EUA conditions to ensure that recipients are informed about the MCM [medical countermeasure] they receive under an EUA. For an unapproved product … the statute requires that FDA ensure that recipients are informed … [t]hat they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product. The President may under certain circumstances waive the option for members of the armed forces to accept or refuse administration of an EUA product…
>
> In an emergency, **it is critical that the conditions that are part of the EUA … be strictly followed, and that no additional conditions be imposed**.[20]

The authorized labeling (the "**Fact Sheets**") for each EUA COVID-19 vaccine includes a question and answer section that expressly asks the question: "What if I decide not to get the … COVID-19 vaccine?," and the response reflects that the Secretary chose to not provide any "consequences" for refusing these products when it states: "Should you decide to not receive it, it will not change your standard of medical care."[21] Consistent with Section 564, and as reflected in the FDA's guidance, the required conditions on the Fact Sheets for each EUA COVID-19 vaccine are to "be strictly followed" and "no additional conditions [may] be imposed." And the Secretary's

[19] https://web.archive.org/web/20210727233714/https:/www.saferfederalworkforce.gov/faq/vaccinations/.

[20] https://www.fda.gov/media/97321/download (emphasis added).

[21] https://www.fda.gov/media/144414/download (Pfizer); https://www.fda.gov/media/144638/download (Moderna); https://www.fda.gov/media/146305/download (Janssen).

conditions for each EUA COVID-19 vaccine provide that there will not be any consequences for refusing this product.[22]

The interpretation of Section 564 that you apply in your Slip Opinion is therefore incorrect in stating that "[n]either the statutory conditions of authorization nor the Fact Sheet itself purports to restrict public or private entities from insisting upon vaccination in any context." The Slip Opinion runs directly counter to Section 564 and the FDA's guidance by permitting additional conditions on a person's refusal to receive an EUA product. For example, it would permit public or private entities to impose conditions such as a person's continued employment, or their right to receive certain benefits, on that person's acquiescence to receive an EUA product. These are obviously additional conditions beyond those established by the EUA for the COVID-19 vaccines, and as such, these conditions are not permitted. [23]

v. The Dictionary and Common Sense

Your Slip Opinion cites to the dictionary definition of "inform" but ignores the definition of the more important word "option" in Section 564 which the dictionary defines as "the power or right to choose; freedom of choice."[24] The Slip Opinion's interpretation of Section 564 would permit eliminating any real "freedom of choice." It is illogical that Congress would require that individuals be informed of a freedom of choice if that choice is illusory at the whim of any public or private entity.

If not clear on its face from Section 564, it is certainly made clear by the fact that Congress found it necessary to craft an exception to this freedom of choice for the military. If the "option to accept or refuse" were not a substantive right, there would be no need for the President to make a national security finding to require the military to receive an EUA product. The military exception was also unnecessary if Congress intended to permit any entity to impose its own "consequences" for refusing an EUA product.

vi. Putting it All Together

In sum, your reading of Section 564 as a requirement that an individual be informed that they have a "choice" while at the same time allowing the product to be mandated is illogical and contrary to the plain meaning, intent, and history of Section 564. There is no logical way to interpret Section 1107a other than as creating the only exception to the general rule in Section 564 that no one can be mandated to receive an EUA product except for the military in the event of a national security threat. Section 564 requires that this be an actual choice, which is incompatible

[22] *Id*. While the Secretary may include "consequences," consistent with the remainder of Section 564 and its statutory framework, those consequences cannot be coercive or unduly influence consent to an EUA product.

[23] The Slip Opinion focuses on the language "to the extent practicable given the applicable circumstances" to indicate the Secretary could potentially even eliminate the "required condition" of informing of "the option to accept or refuse." However, the "to the extent practicable" language plainly modifies the words "appropriate conditions" that the Secretary can impose, but those appropriate conditions must still "ensure that individuals to whom the product is administered are informed … of the option to accept or refuse."

[24] https://www.merriam-webster.com/dictionary/option.

with levying serious adverse consequences if someone refuses an EUA product, such as expulsion from school, employment, or the armed forces.

Your Slip Opinion did not meaningfully consider the foregoing in concluding that the "language of section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements."[25]

Conclusion

Rights exist to limit those in power. Congress entrusts the DOJ with the duty to enforce the long-standing principal that no individual should be coerced or unduly influenced to accept an unlicensed medical product. Whatever short term gain the Office of the President and the DOJ officials who authored the Slip Opinion believe will be achieved by casting aside this fundamental right pales in comparison to the harm likely to result from its elimination over the long arc of our great nation.[26]

We live in an unprecedented time, making it all the more important to hold tight to the principles that we have learned from history. We respectfully request that the DOJ officials that drafted the Slip Opinion reconsider their interpretation and guidance regarding Section 564, that you revise the Slip Opinion to accord with the foregoing, and that the DOJ fulfill its duty by enforcing this provision which prohibits mandates of an EUA product, rather than casting this important and longstanding right aside.

Sincerely Yours,

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Caroline Tucker, Esq.
Allison Lucas, Esq.
Gabrielle Palmer, Esq.
Jessica Wallace, Esq.

cc: Danielle Conley, Deputy Counsel to the President

[25] https://www.justice.gov/sites/default/files/opinions/attachments/2021/07/26/2021-07-06-mand-vax.pdf.

[26] Most medical products have historically been given to a small segment of the population, and hence when an unexpected result occurs, only a small segment of the population is impacted. Recent innovations have made it feasible and affordable to deploy drugs to large portions of the population. Unexpected consequences from an EUA product can therefore have far wider implications. This makes it even more important to hold fast to the longstanding principal that nobody should be coerced to take an unlicensed medical product.

Plaintiffs' Exhibit 515

law360.com

Takeaways From FDA's Relaxed Rules For Making Face Masks - Law360

12-16 minutes

By **Denise Bense and Karl Neumann**

Law360 is providing free access to its coronavirus coverage to make sure all members of the legal community have accurate information in this time of uncertainty and change. Use the form below to sign up for any of our weekly newsletters. Signing up for any of our section newsletters will opt you in to the weekly Coronavirus briefing.

Law360 (April 13, 2020, 5:47 PM EDT) --

Persistent headlines keep reminding us that the U.S. has run out of masks. Health officials have implored retailers to practice corporate generosity and donate what is left on their shelves. The surgeon general is asking lay people not to buy or hoard them. And the shortage has led to investigations into what some are calling unethical price-gouging.

The U.S.' strategic national stockpile includes roughly 12 million medical-grade N95 masks and 30 million surgical masks.[1] That is only approximately 1% of the estimated 3.5 billion that the U.S. Department of Health and Human Services estimates would be necessary if the COVID-19 pandemic lasts over a year.[2] With now more than 550,000 confirmed cases in the U.S. alone,[3] the shortage presents yet another obstacle for health care workers in the fight against the virus.

Ascending from this shortage has been a grassroots-meets-industry mobilization to help wage war on the virus. Lay people and manufacturers of just about every type of business are lending assistance to create masks. Companies that once made mattresses, shoes, apparel and many other products are now turning efforts toward the manufacturing face masks.[4] Even a business that manufactures sports jerseys for professional athletes is now making masks using the same jersey material from its products.

A recurring question from manufacturers wanting to assist in these efforts is, "What regulations exist and to what extent are they being enforced?" In light of this and an effort to increase availability of masks, the U.S. Food and Drug Administration recently issued an updated guidance policy for face masks and respirators.[5] At its core, the policy's

purpose is to ease compliance requirements that manufacturers would typically have to meet before distributing masks.

The guidance remains in effect for the duration of the public health emergency as declared by HHS.[6] For those businesses wanting to start manufacturing face masks, understanding the FDA's regulation of face masks generally and in light of recent circumstances will prove helpful in manufacturing efforts.

When is a face mask a medical device?

There are many types of face masks out on the market used in different industries and for varying purposes. The FDA regulates face masks when they meet the definition of a device under Section 201(h) of the Federal Food, Drug and Cosmetic Act.

A face mask is a device subject to regulation when it is intended for a medical purpose, or otherwise "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[7] The masks that are subject to regulation cover a range of masks and include masks used by the general public in public health emergencies,[8] to more robust masks like surgical masks with antiviral agents.[9]

In determining whether the products are intended for a medical purpose, the FDA will consider whether the mask (1) is labeled or intended for use by a health care professional; (2) is labeled or intended to be used in a health care-associated environment; and (3) includes any drugs, biologics, anti-microbial or anti-viral agents.[10] This list is nonexhaustive.

When face masks are not intended for medical use, they are not classified as a medical device and, therefore, neither FDA device marketing authorization nor the requirements under the Federal Food, Drug and Cosmetic Act apply.

The FDA is lifting typical production and distribution requirements.

In light of the ongoing need for masks, the FDA is suspending[11] enforcement of premarket requirements for certain face masks: the "FDA does not intend to object to individuals' distribution and use of improvised PPE when no alternatives, such as FDA-cleared masks or respirators, are available."[12]

More specifically, the FDA is waiving regulatory requirements, including submission of premarket notification under the 510(k) process, registration and listing requirements, quality system regulation requirements, reports or corrections and removals, and unique device identification requirements.[13]

The major caveat is that any face mask manufactured cannot "create an undue risk in light of the public health emergency."[14] For face masks intended for medical purposes, but not intended to provide liquid barrier protection, no undue risk is seen where:

- The product includes accurate labeling describing the product as a face mask. For example, the face mask should not be labeled as a surgical mask.

- The labeling includes a list of the material that makes contact with the body. The contacting materials may not include any drugs or biologics.

- The labeling makes recommendations that would sufficiently reduce any risks of usage. For example, it could include a recommendation against use in a surgical setting or against use in environments with increased exposure to fluids or high intensity heat sources.

- The product is not intended for any use that would create an undue risk in light of the public health emergency. For example, the labeling should not include that the mask can be used for antimicrobial or antiviral protection or be used for infection prevention.

  The FDA takes a similar approach with surgical masks that are intended to provide liquid barrier protection. Surgical masks are Class II devices that cover the user's nose and mouth while also providing a barrier to fluids and particulate materials. They are also tested for flammability and biocompatibility. The FDA is lifting the same requirements as those noted above for masks not intended to provide liquid barrier protection.[15]

  Such devices are not believed to create an undue risk under similar circumstance to above with a few additional variables:

- The product meets fluid resistance testing consistent with ASTM F1962.

- The mask meets Class I or Class II flammability requirements pursuant to Title 16 of Code of Federal Regulations Part 1610. This does not apply if the mask is labeled with an explicit recommendation against use in the presence of high-intensity heat sources.

- The product includes accurate labeling describing the product as a surgical mask.

- The product includes a list of materials contacting the body, which do not include drugs or biologics within the materials.

- The product is not intended for any use that would create an undue risk in light of the public health emergency.

Similarly, the FDA states it does not intend to object to companies importing and distributing alternative respirators identified in CDC recommendations.[16] The Centers for Disease Control and Prevention recommends use of alternative face masks approved under standards used in other countries when FDA-cleared or National Institute for Occupational Safety and Health-approved N95 respirators are unavailable.[17]

However, the FDA notes that because it cannot confirm the authenticity of any alternative respirators from abroad, it recommends that people take appropriate steps to verify the authenticity of the products before importing them.

The FDA is seeking collaboration, and companies should be familiar with compliance.

In the recent guidance update, the FDA is now welcoming the opportunity to work with any manufacturer with interest in manufacturing masks and respirators — even if the manufacturer has no previous experience in medical device manufacturing. For example, the FDA would like to work collaboratively with manufacturers on device-specific emergency use authorizations.

Likewise, the FDA guidance also addresses the reprocessing of otherwise disposable N95 particulate filtering facepiece respirators (or other similar filtering facepiece respirators). Under normal circumstances, a reprocessor would need to obtain 510(k) clearance to reprocess single-use medical devices. The FDA is seeking input from companies to facilitate the safe reuse and conservation of such devices.

The FDA recognizes that because of the short supply of masks, companies need to act quickly despite not being well-versed in mask construction and regulation. The FDA's guidelines will help increase the supply of alternative face masks during the ongoing pandemic. Worth noting, the FDA's guidance does not establish any enforceable rights or responsibilities — i.e., it is merely the FDA's current thinking and any guidance are at most suggestions or recommendations.

That said, companies attempting to manufacture or distribute face masks should not only review the entirety of the FDA's guidance but also be familiar with other FDA compliance measures that may still be applicable. The FDA's guidance document is not necessarily an exhaustive list of what should be done when manufacturing masks, and a full understanding of FDA regulations is required.

So long as the masks are not created with undue risk, efforts by various companies will serve as another vehicle toward preserving the workforce that is on the front lines in the fight against the virus.

Denise Bense is a member and Karl Neumann is an associate at Cozen O'Connor.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firms, their clients, or any of its or their respective affiliates. This article is for purposes of general information and is not intended to be and should not be taken as legal advice.

[1] Abby Goodnough, Some Hospitals Are Close to Running Out of Crucial Masks for Coronavirus (March 9, 2020), https://www.nytimes.com/2020/03/09/health/coronavirus-n95-face-masks.html.

[2] Dep't of Health and Human Servs., HHS to Procure N95 Respirators to Support Healthcare Workers in COVID-19 Outbreaks (March 4, 2020), https://www.hhs.gov/about/news/2020/03/04/hhs-to-procure-n95-respirators-to-support-healthcare-workers-in-covid-19-outbreaks.html.

[3] Centers for Disease Control and Prevention, Cases in U.S. (Updated April 13, 2020), https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.

[4] Ingrid Schmidt, Fashion Brands Are Making Face Masks, Medical Gowns for the Coronavirus Crisis, Los Angeles Times (March 24, 2020), https://www.latimes.com/lifestyle/story/2020-03-24/fashion-brands-face-masks-medical-surgical-gowns-coronavirus; Nicole Yang, New Balance is Working to Manufacture Facial Masks During Coronavirus Pandemic (March 28, 2020), https://www.bostonglobe.com/2020/03/28/sports/new-balance-is-working-manufacture-facial-masks/.

[5] See U.S. Food and Drug Admin., Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised), Guidance for Industry and Food and Drug Administration Staff (April 2020), https://www.fda.gov/media/136449/download.

[6] On January 31, 2020, the Secretary of Health and Human Services, Alex Azar II, determined that a nationwide public health emergency began on January 27, 2020. Dep't of Health and Human Services, Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus (January 31, 2020), https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html.

[7] Section 201(h) of the Food, Drug & Cosmetic Act.

[8] 21 CFR 880.6260 (General Hospital and Personal Use Devices).

[9] 21 CFR 878.4040 (Surgical Apparel).

[10] See U.S. Food and Drug Admin., Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised), Guidance for Industry and Food and Drug Administration Staff (April 2020),

https://www.fda.gov/media/136449/download.

[11] Id.

[12] Id.

[13] Id.

[14] Id.

[15] The FDA's updated guidance also addresses face shields for medical use. While outside the scope of this article, face shields are Class I devices and exempt from premarket notification requirements under the 510(k) process. See 21 CFR 878.4040.

[16] See Centers for Disease Control and Prevention, Strategies for optimizing the Supply of N95 Respirators During the COVID-19 Response, cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html ("Use alternatives to N95 respirators where feasible (e.g.,other disposable filtering facepiece respirators, elastomeric respirators with appropriate filters or cartridges, powered air purifying respirators)").

[17] Notably, even state health departments are releasing interim guidance on alternative facemasks Minnesota Dep't of Health, Interim Guidance on Alternative Facemasks (March 27, 2020), https://www.health.state.mn.us/diseases/coronavirus/hcp/masksalt.pdf.

Plaintiffs' Exhibit 516

butzel.com

The House Forwards Legislation Expanding the FDA's Authority to Manage Counterfeit Medical Devices

8-10 minutes

A bill expanding the authority of the Food and Drug Administration (FDA) may provide safer medical devices to the American public amid the Covid-19 pandemic, as well as support manufacturers of legitimate medical devices, by addressing a loophole in the Food, Drug, and Cosmetic Act. Counterfeit medical devices have been a danger in the U.S. supply chain for years, but their presence has been especially of concern during the current pandemic, when there have been shortages of products considered to be medical devices by the FDA, such as medical masks, surgical gowns and gloves, respirators, and other products. Counterfeit medical devices may include various products like those mentioned above, but often depend on the intended use and labeling.

Background

Many products used during the Covid-19 pandemic are considered to be medical devices by the FDA. The FDA has issued special guidance concerning medical masks, distinguishing those that are regulated by the FDA where they are intended for medical uses versus industrial uses. The FDA has also issued a number of guidance documents concerning various types of masks that may be considered medical devices.[i]

The FDA has already identified numerous hand sanitizers from China that were found to be packaged in a way that could be confused with drinks and cause serious injury.[ii] The FDA has also recalled many hand sanitizers due to methanol contamination as well.

FDA and Counterfeit Products

The FDA has had the power to seize and destroy counterfeit medicines, ensuring that they will not end up in American homes and endangering public health. The FDA does not, currently, however, have this same authority when regulating counterfeit medical devices. Additionally, drugs attached to medical devices, like a syringe, are technically considered "medical devices," creating a large loophole. In response, Republican Congressman Brett Guthrie and Democratic Congressman Eliot Engel introduced the bipartisan bill known as

the Safeguarding Therapeutics Act of 2020 ("the Act") in January of this year.

While counterfeit medical devices have been problematic for years, the Act is especially relevant this year in light of the ongoing pandemic that has increased demand for many of these products. Manufacturers of counterfeit devices have certainly taken advantage of the Covid-19 pandemic by seizing the opportunity to sell counterfeit devices amidst shortages and fearful consumers. Manufacturers of counterfeit devices have been producing and shipping fake Covid-19 tests, products that claim to cure Covid-19, and counterfeit medical supplies to the U.S. For example, in March, U.S. Customs and Border Protection at the Los Angeles International Airport and Chicago O'Hare International Airport confiscated counterfeit Covid-19 tests. In September, over 500,000 counterfeit N-95 masks were seized at the Chicago O'Hare International Airport. These counterfeit devices would only contribute to misleading and improperly protecting consumers, a significant threat during a pandemic. Although the FDA has the power to store items or send them back, it has been unable to *destroy* counterfeit devices to ensure that they do not reach medical providers and consumers. The Safeguarding Therapeutics Act aims to change that.

On September 21, 2020, the U.S. House of Representatives passed the bill, allowing it to move along in the legislative process to the Senate. It was received in the Senate, read twice, and was referred to the Committee on Health, Education, Labor, and Pensions on September 22, 2020. From there, little or no activity appears to have occurred in the Committee. There has not been a reference to a subcommittee nor has there been a markup session.

There is, however, a Senate companion bill (S4225), titled "Safeguarding Therapeutics Act of 2020." S4225 was introduced in July 2020 and was referred to the Committee on Health, Education, Labor, and Pensions. It has three sponsors: Maggie Hassan (D) from New Hampshire, Rick Scott (R) from Florida, and Mike Enzi (R) from Wyoming.

The legislation seeks to amend the Food, Drug, and Cosmetic Act and address the loophole that has limited the FDA's power to target and regulate the increasing number of counterfeit medical devices in the U.S. supply chain. The bill defines "counterfeit medical devices" as:

a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark, imprint, or symbol, or any likeness thereof, or is manufactured using a design, of a device manufacturer, packer, or distributor other than the person or persons who in fact manufactured, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, packer, or distributor.

Although the proposed changes are few, they would have significant impacts on the FDA's authority and effectiveness in regulating counterfeit medical devices. The Act would add the phrase "or counterfeit device" to 28 U.S.C. 381(a), which currently gives the FDA the authority to refuse admission of a counterfeit drug. The Act also includes an amendment that would give the FDA the authority to destroy counterfeit devices valued at $2,500 or less, which the FDA has been able to do with counterfeit drugs. Currently, the FDA may refuse admission of the devices, but cannot seize or destroy devices deemed as counterfeit because owners must first be provided the opportunity to export the product. The FDA is thus left with the choice of storing or returning the counterfeit medical devices. This results in the FDA often returning the counterfeit medical devices to their senders, who often repackage the devices and send them back to the U.S. If they are not caught, the counterfeit devices enter the supply chain. Thus, counterfeit devices are often not fully intercepted and prevented from entering the market and endangering the health of consumers.

Lastly, besides protecting the public from counterfeit devices, increased regulation may support manufacturers of legitimate medical devices by helping curb the counterfeit medical devices on the market. Manufacturers of legitimate medical devices may benefit from a decreased need for spending and by being able to invest less in anti-counterfeiting measures, such as tracking devices and having systems in place that allow for reporting counterfeits. These measures may still be needed to different extents depending on each manufacturer's situation, but the enactment of the Safeguarding Therapeutics Act would likely assist manufacturers in their anti-counterfeiting efforts. Lastly, while the law would not provide a cause of action for manufacturers of genuine devices, it would offer support for their position against manufacturers of counterfeit devices in litigation.

Counterfeiting is a major problem that affects many U.S. businesses. Fortunately, the U.S. Customs and Border Protection (CBP) also provide protection against counterfeiting by allowing U.S. companies that hold registered trademarks and copyrights to record them with CBP, and suspected counterfeits are detained at the border.[iii] This would be in addition to the remedies set out in the proposed Safeguarding Therapeutics Act. Butzel Long attorneys have extensive experience in assisting clients against counterfeit imports.

It is yet to be seen whether this Act will get signed into law and—if it does—whether it will be in its current version. But Butzel Long will continue to monitor this Act and report back to our clients on how this may impact you and your businesses.

Leslie Alan Glick
202.454.2839
glick@butzel.com

T.R. Eppel

Federal Civil Rights Statutes: A Primer

name redacted
Legislative Attorney

November 21, 2012

Congressional Research Service
7-....
www.crs.gov
RL33386

CRS Report for Congress
Prepared for Members and Committees of Congress

For additional information on GINA, see CRS Report RL34584, *The Genetic Information Nondiscrimination Act of 2008 (GINA)*, by (name redacted) and (name redacted); CRS Report R41527, *The Genetic Information Nondiscrimination Act (GINA): Final Employment Regulations*, by (name redacted); and CRS Report R41314, *The Genetic Information Nondiscrimination Act of 2008 and the Patient Protection and Affordable Care Act of 2010: Overview and Legal Analysis of Potential Interactions*, coordinated by (name redacted).

Reconstruction Statutes

In the wake of the Civil War, Congress enacted a series of statutes—most notably the Civil Rights Act of 1866 and the Civil Rights Act of 1871—that were intended to enforce the Thirteenth, Fourteenth, and Fifteenth Amendments, which prohibited slavery and enshrined equal protection and voting rights in the U.S. Constitution. Designed to provide private remedies to individuals deprived of their civil rights, these statutes were written in general terms that have been interpreted broadly to protect individuals from a wide range of discriminatory conduct. The relevant provisions, as codified, include 42 U.S.C. Sections 1981, 1982, 1983, and 1985.

- 42 U.S.C. Section 1981 provides, in part, that all persons shall have the same right to "make and enforce contracts" as is enjoyed by white citizens.[40] As a result, Section 1981's coverage extends to prohibit discrimination in a wide range of public and private contractual relationships, including the provision of services and the sale of goods. Indeed, since employment relationships are based on contracts, Section 1981 has been interpreted to prohibit intentional discrimination on the basis of race, color, or citizenship by private employers. Because Section 1981 refers to "white citizens," however, the provision does not prohibit discrimination on the basis of sex, religion, or national origin, unless a claim based on national origin or religion has a racial component.
- Under 42 U.S.C. Section 1982, "[a]ll citizens of the United States shall have the same right, in every State and Territory, as is enjoyed by white citizens thereof to inherit, purchase, lease, sell, hold, and convey real and personal property." Like Section 1981, Section 1982 prohibits intentional discrimination in both the public and private sectors, but unlike Section 1981, the coverage of Section 1982 is limited to discrimination on the basis of race and applies only to transactions involving real or personal property.
- 42 U.S.C. Section 1983, which provides a remedy for deprivation of rights under color of state law, creates no new substantive rights but rather provides relief where state law is inadequate.[41] Thus, individuals who sue under Section 1983

(...continued)

http://www.eeoc.gov/.

[40] Section 1981 provides, in pertinent part:

> All persons within the jurisdiction of the United States shall have the same right in every State and Territory to make and enforce contracts, to sue, be parties, give evidence, and to the full and equal benefit of all laws and proceedings for the security of persons and property as is enjoyed by white citizens, and shall be subject to like punishments, pains, penalties, taxes, licenses, and exactions of every kind, and to no other.

[41] Section 1983 states in full:

> Every person who, under color of any statute, ordinance, regulation, custom or usage, of any State

(continued...)

Plaintiffs' Exhibit 518

ada.gov

A Guide to Disability Rights Laws

27-35 minutes

U.S. Department of Justice
Civil Rights Division
Disability Rights Section

February 2020

TABLE OF CONTENTS

For persons with disabilities, this document is available in large print, Braille, and CD.

This guide provides an overview of Federal civil rights laws that ensure equal opportunity for people with disabilities. To find out more about how these laws may apply to you, contact the agencies and organizations listed below.

Americans with Disabilities Act (ADA)

The ADA prohibits discrimination on the basis of disability in employment, State and local government, public accommodations, commercial facilities, transportation, and telecommunications. It also applies to the United States Congress.

To be protected by the ADA, one must have a disability or have a relationship or association with an individual with a disability. An individual with a disability is defined by the ADA as a person who has a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such an impairment, or a person who is perceived by others as having such an impairment. The ADA does not specifically name all of the impairments that are covered.

ADA Title I: Employment

Housing Accessibility FIRST at:

www.fairhousingfirst.org

(888) 341-7781 (voice/TTY)

For publications, you may call the Housing and Urban Development Customer Service Center at:

(800) 767-7468 (voice/relay)

Additionally, the Department of Justice can file cases involving a pattern or practice of discrimination. The Fair Housing Act may also be enforced through private lawsuits.

Air Carrier Access Act

The Air Carrier Access Act prohibits discrimination in air transportation by domestic and foreign air carriers against qualified individuals with physical or mental impairments. It applies only to air carriers that provide regularly scheduled services for hire to the public. Requirements address a wide range of issues including boarding assistance and certain accessibility features in newly built aircraft and new or altered airport facilities. People may enforce rights under the Air Carrier Access Act by filing a complaint with the U.S. Department of Transportation, or by bringing a lawsuit in Federal court. For more information or to file a complaint, contact:

Aviation Consumer Protection Division, C-75
U.S. Department of Transportation
1200 New Jersey Avenue, S.E.
Washington, D.C. 20590

https://www.transportation.gov/airconsumer/disability

(202) 366-2220 (voice)
(202) 366-0511 (TTY)

(800) 778-4838 (voice)
(800) 455-9880 (TTY)

Voting Accessibility for the Elderly and Handicapped Act

The Voting Accessibility for the Elderly and Handicapped Act of 1984 generally requires polling places across the United States to be physically accessible to people with disabilities for federal elections. Where no accessible location is available to serve as a polling place, a political subdivision must provide an alternate means of casting a ballot on the day of the election. This law also requires states to make available registration and voting aids for disabled and elderly voters, including information by TTYs or similar devices. For more information, contact:

U.S. Department of Justice
Civil Rights Division
950 Pennsylvania Avenue, N.W.
Voting Section - Room 7254 NWB
Washington, D.C. 20530

(800) 253-3931 (voice/TTY)

National Voter Registration Act

The National Voter Registration Act of 1993, also known as the "Motor Voter Act," makes it easier for all Americans to exercise their fundamental right to vote. One of the basic purposes of the Act is to increase the historically low registration rates of minorities and persons with disabilities that have resulted from discrimination. The Motor Voter Act requires all offices of State-funded programs that are primarily engaged in providing services to persons with disabilities to provide all program applicants with voter registration forms, to assist them in completing the forms, and to transmit completed forms to the appropriate State official. For more information, contact:

U.S. Department of Justice
Civil Rights Division
950 Pennsylvania Avenue, N.W.
Voting Section - Room 7254-NWB
Washington, D.C. 20530

www.usdoj.gov/crt/voting

(800) 253-3931 (voice/TTY)

Civil Rights of Institutionalized Persons Act

The Civil Rights of Institutionalized Persons Act (CRIPA) authorizes the U.S. Attorney General to investigate conditions of confinement at State and local government institutions such as prisons, jails, pretrial detention centers, juvenile correctional facilities, publicly operated nursing homes, and institutions for people with psychiatric or developmental disabilities. Its purpose is to allow the Attorney General to uncover and correct widespread deficiencies that seriously jeopardize the health and safety of residents of institutions. The Attorney General does not have authority under CRIPA to investigate isolated incidents or to represent individual institutionalized persons.

The Attorney General may initiate civil law suits where there is reasonable cause to believe that conditions are "egregious or flagrant," that they are subjecting residents to "grievous harm," and that they are part of a "pattern or practice" of resistance to residents' full enjoyment of constitutional or Federal rights, including title II of the ADA and section

504 of the Rehabilitation Act. For more information or to bring a matter to the Department of Justice's attention, contact:

U.S. Department of Justice
Civil Rights Division
950 Pennsylvania Avenue, N.W.
Special Litigation Section
Washington, D.C. 20530

https://www.justice.gov/crt/civil-rights-institutionalized-persons

(877) 218-5228 (voice/TTY)

Individuals with Disabilities Education Act

The Individuals with Disabilities Education Act (IDEA) (formerly called P.L. 94-142 or the Education for all Handicapped Children Act of 1975) requires public schools to make available to all eligible children with disabilities a free appropriate public education in the least restrictive environment appropriate to their individual needs.

IDEA requires public school systems to develop appropriate Individualized Education Programs (IEP's) for each child. The specific special education and related services outlined in each IEP reflect the individualized needs of each student.

IDEA also mandates that particular procedures be followed in the development of the IEP. Each student's IEP must be developed by a team of knowledgeable persons and must be at least reviewed annually. The team includes the child's teacher; the parents, subject to certain limited exceptions; the child, if determined appropriate; an agency representative who is qualified to provide or supervise the provision of special education; and other individuals at the parents' or agency's discretion.

If parents disagree with the proposed IEP, they can request a due process hearing and a review from the State educational agency if applicable in that state. They also can appeal the State agency's decision to State or Federal court. For more information, contact:

Office of Special Education and Rehabilitative Services
U.S. Department of Education
400 Maryland Avenue, S.W.
Washington, D.C. 20202-7100

www.ed.gov/about/offices/list/osers/osep

(202) 245-7459 (voice/TTY)

Rehabilitation Act

The Rehabilitation Act prohibits discrimination on the basis of disability in programs

conducted by Federal agencies, in programs receiving Federal financial assistance, in Federal employment, and in the employment practices of Federal contractors. The standards for determining employment discrimination under the Rehabilitation Act are the same as those used in title I of the Americans with Disabilities Act.

Section 501

Section 501 requires affirmative action and nondiscrimination in employment by Federal agencies of the executive branch. To obtain more information or to file a complaint, employees should contact their agency's Equal Employment Opportunity Office.

Section 503

Section 503 requires affirmative action and prohibits employment discrimination by Federal government contractors and subcontractors with contracts of more than $10,000. For more information on section 503, contact:

Office of Federal Contract Compliance Programs
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

www.dol.gov/agencies/ofccp

(800) 397-6251 (voice)
(877) 889-5627 (TTY)

Section 504

Section 504 states that "no qualified individual with a disability in the United States shall be excluded from, denied the benefits of, or be subjected to discrimination under" any program or activity that either receives Federal financial assistance or is conducted by any Executive agency or the United States Postal Service.

Each Federal agency has its own set of section 504 regulations that apply to its own programs. Agencies that provide Federal financial assistance also have section 504 regulations covering entities that receive Federal aid. Requirements common to these regulations include reasonable accommodation for employees with disabilities; program accessibility; effective communication with people who have hearing or vision disabilities; and accessible new construction and alterations. Each agency is responsible for enforcing its own regulations. Section 504 may also be enforced through private lawsuits. It is not necessary to file a complaint with a Federal agency or to receive a "right-to-sue" letter before going to court.

For information on how to file 504 complaints with the appropriate agency, contact:

Plaintiffs' Exhibit 519

yaktrinews.com

Escalator fall death: Airline to pay Spokane family $3.2M - YakTriNews.com

Melissa Luck,

3-4 minutes

Alaska Airlines ordered to pay Spokane family for mother's death from escalator injury

February 22, 2021 7:20 PM

Posted: February 22, 2021 7:20 PM

Updated: February 22, 2021 7:35 PM

KXLY 4 News Now

SEATTLE, Wash. — In a case delayed by COVID-19, a jury Monday ruled in favor of a Spokane family and ordered Alaska Airlines to pay nearly $3.2 million for their mother's wrongful death from an injury suffered in a fall down an escalator.

Bernice Kekona, 75, was traveling to Hawaii to visit family. Because of her age and

physical condition, her family arranged for her to have an Alaska Airlines escort from gate to gate. They did not provide one and Kekona became disoriented. On video from Portland International Airport, you can see Kekona in her wheelchair falling down 21 steps of a moving escalator.

*space*play / pause

*q*unload | stop

*f*fullscreen

shift + ←→slower / faster

←→seek

. seek to previous

12… *6* seek to 10%, 20% … 60%

X

Color Settings

- Aa
- Aa
- Aa
- Aa

Text

Background

-
-
-
-
-
-
-

Opacity Settings

Text

Background

Reset

Kekona suffered serious injuries in the fall, including a leg wound that never properly healed and ultimately led to her death.

PAST COVERAGE: Spokane family sues Alaska Airlines for mother's escalator fall

Kekona's family sued Alaska Airlines under the Air Carrier Access Act. After delays due to the pandemic, the trial was finally held completely over Zoom.

The jury came back with its verdict Monday afternoon, finding Alaska Airlines responsible for her wrongful death.

RELATED: Judge: Suit against Alaska Airlines can go forward for woman who fell down escalator in wheelchair

Kekona suffered multiple injuries in the fall, including escalator teeth marks on her face and trauma to her head and chest.

KXLY 4 News Now

A cut to her Achilles tendon never healed, despite thousands of dollars in medical care.

“She’d lay in bed screaming, banging on the walls, pounding on her other [prothstetic] leg to take away the pain,” Kekona’s granddaughter Desiree Kekahuna told 4 News Now in 2017.

KXLY 4 News Now

The wound went septic. Doctors amputated the leg and Kekona died the next day.

The family’s attorneys maintained the federal Air Carrier Access Act lays out protections for disabled passengers. It says “airlines are required to provide assistance with boarding, deplaning and making connections.”

Plaintiffs' Exhibit 520

aviationpros.com

Alaska Airlines Ordered to Pay $3.2M to Family of Woman Who Died After Escalator Fall

By Heidi Groover Source The Seattle Times (TNS)

4-5 minutes 2-24-21

Feb. 24—Alaska Airlines was ordered this week to pay $3.2 million to the family of a 75-year-old woman who died after falling down an escalator in an electric wheelchair at Portland International Airport in 2017.

The family of the woman, Bernice Kekona, alleged that Alaska failed to ensure she received the gate-to-gate escort the family requested multiple times.

After a trial in King County Superior Court this month, a jury found Alaska violated the Air Carrier Access Act, which requires airlines to provide certain assistance for passengers with disabilities, including with boarding, deplaning and making connections. .

Kekona arrived in Portland on her way home to Spokane from Maui, where she was visiting family.

According to the family's court filings, Kekona and her family members had requested multiple times that she receive a gate-to-gate escort because she was elderly, hard of hearing and sometimes became confused in unfamiliar places, among other reasons. The family alleged that Alaska failed to communicate those requests to a contractor that would have provided the escort.

Robert Gellatly, an attorney for the family, said Kekona's death was "a tragic failure of communication."

Alaska said in a statement Tuesday, "We're disappointed in the ruling and are evaluating next steps. There is no more important responsibility than the safety and wellbeing of our guests, whether they're in our care or the care of a vendor."

The fall down the escalator left Kekona with multiple injuries, including an Achilles tendon injury that led to an infection, according to the family's attorneys. Doctors later amputated her leg, but she died soon after from infection.

Kekona had traveled before, receiving gate-to-gate help and having "no problems," said

her daughter, Darlene Bloyed.

Kekona was "the head of the household," Bloyed said. "She was special to us. She was not just a nobody."

With the jury's decision, Bloyed said, "we got justice."

In court filings, attorneys for the family and the company disagreed about what happened after Kekona landed in Portland.

Alaska Airlines said in a 2019 court filing that Kekona "declined multiple offers of additional assistance and promptly drove away from her arrival gate."

"Passengers often decline previously requested services, as is their right," attorneys for the company wrote.

Attorneys for the family disputed that Kekona declined offers of help. They argued the wheelchair attendants for the contractor, Huntleigh, did not know she needed gate-to-gate assistance, with one of them believing Portland was her final destination.

After the injuries, Kekona told her daughters the wheelchair attendants "put her in her wheelchair in the sky bridge, pointed toward the top of the sky bridge, and when she got to the top of the sky bridge nobody was there to escort her and she became confused. She also told them she mistakenly took the escalator while looking for the elevator," the family's attorneys wrote.

Bloyed said in an interview she spoke to her mother after the fall. "She told me nobody was there," Bloyed said. "She just needed that little bit of help to get to the next gate and she would have been home with me in Spokane."

Alaska did not respond to a question Tuesday about whether it implemented any policy changes in response to Kekona's death. Gellatly, the attorney for the family, said he believes Alaska later began using a digital system in Portland to better communicate requests for assistance.

Gellatly said he expects Alaska to appeal the jury's decision.

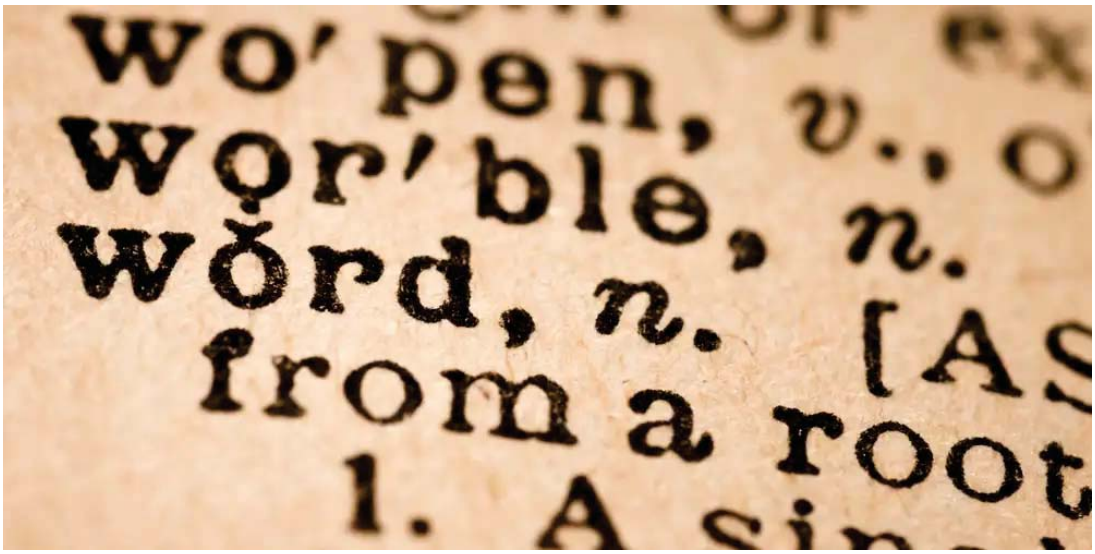
___

Plaintiffs' Exhibit 521

lawsintexas.com

Federal Court Civil Causes of Action | Laws In Texas

62-78 minutes



Appellate Circuit

Federal Court Civil Causes of Action

This complete Cause of Action codes table is issued by the Administrative Office of the U.S. Courts.

CIVIL Cause of Action (CoA) Codes Reference

This complete Cause of Action codes table is issued by the Administrative Office of the U.S. Courts. However, not all CoA codes may be available for selection by attorney e-filers in CM/ECF. Please contact the Clerk's Office at (317) 229-3700 for assistance with CoA codes.

MAY 11, 2018 | REPUBLISHED BY LIT: APR 25, 2021

Cause Code	***Description***

28:1331at	**Fed. Question: Anti-trust**

28:1331au	**Fed. Question: Auto Negligence**
28:1331b	**Fed. Question: Bivens Act**
28:1331bc	**Fed. Question: Breach of Contract**
28:1331bv	**Fed. Question: Bivens-Prisoner**
28:1331ca	**Fed Question: Fed Communications Act**
28:1331cm	**Fed. Question: Interstate Commerce Act**
28:1331cv	**Fed. Question: Other Civil Rights**
28:1331cr	**Fed. Question: Civil Rights (Race Discrimination)**
28:1331dd	**Fed. Question: Discovery Disputes (conversion case)**
28:1331dj	**Fed. Question: Declaratory Judgment**
28:1331dp	**Fed. Question: Violation of Due Process**
28:1331ed	**Fed. Question: Employment Discrimination**
28:1331ef	**Fed. Question: Civil Rights Violation (Excess Force)**
28:1331ej	**Fed. Question: Enforcement of Judgment**
28:1331es	**Fed. Question: Enforcement of Administrative Subpoena**
28:1331fa	**Fed. Question: Civil Rights Violation-False Arrest**
28:1331fl	**Fed. Question: Fair Labor Standards**
28:1331fm	**Fed. Question: Family and Medical Leave Act**

28:1332wd	Diversity-Wrongful Death
28:1333ad	Admiralty
28:1333in	Personal Injury
28:1333mc	Marine Contract
28:1333pd	Property Damage
28:1333pi	Marine Personal Injury
28:1334	Bankruptcy Appeal
28:1334(b)	Proceeding arising/related to case under title 11
28:1334(c)	R&R re motions for abstention
28:1335	Interpleader Action
28:1337sc	Sherman-Clayton Act
28:1338cp	Copyright Infringement
28:1338pt	Patent Infringement
28:1338tr	Trademark Infringement
28:1339	Postal matters
28:1340tp	Jurisdiction of Internal Revenue Matters; Customs Duties
28:1341	Taxes by States
28:1343	Violation of Civil Rights
28:1344	Election disputes
28:1345	U.S. Plaintiff
28:1345co	Replevin & Conversion
28:1345db	Debt to US – FHA/HUD Title I
28:1345df	Default of Promissory Note

29:794	Job Discrimination (Handicap)
29:1001	E.R.I.S.A.: Employee Retirement
29:1002	E.R.I.S.A.: Employee Retirement (Definitions)
29:1055	E.R.I.S.A., Employee Retirement (Joint and Survivor Annuity)
29:1101	E.R.I.S.A.: Coverage
29:1104	E.R.I.S.A.: Recovery of Benefits to Employee
29:1109	E.R.I.S.A.: Breach of Fiduciary Duties
29:1132	E.R.I.S.A.: Civil Enforcement of Employee Benefits
29:1145	E.R.I.S.A.: Delinquent Contributions
29:1149	E.R.I.S.A.: Prohibition on False Statements and Representations
29:1161	COBRA – Continuation Coverage
29:1162	COBRA – Continuation Coverage
29:1303	PBGC: Operation of Corporation
29:1362	E.R.I.S.A.: Liability for Termination of Single Employer Plans
29:1381	E.R.I.S.A.: Withdrawal Liability
29:1401(b)(2)	E.R.I.S.A.: Resolution of Disputes – Appeal of Arbitration Award
29:1451	E.R.I.S.A.: Enforcement – Civil Actions
29:1801	Farmworker Rights
29:1854	Migrant & Seasonal Agri Worker Protect Act (AWPA)
29:1916	Spec. Rule for Longshoremen & Harborworkers
29:2001	Employee Polygraph Protection Act
29:2101	Worker Adjustment and Retraining Notification Act
29:2104	Worker Adjustment & Retraining Notification (WARN)
29:2601	FMLA: Family and Medical Leave Act (Findings and Purposes)

42:1973	Voting Rights Act
42:1973gg-2	Nat'l. Voter Registration Act of 1993 (NVRA)
42:1981a	Damages in cases of intentional discrim. in employment
42:1981cv	Civil Rights
42:1981hs	Housing Discrimination
42:1981jb	Job Discrimination (Race)
42:1981ra	Race Discrimination
42:1981sx	Sex Discrimination
42:1982hs	Discrimination re property rights (housing)
42:1982ra	Discrimination re property rights (race)
42:1982sx	Discrimination re property rights (sex)
42:1983bv	Bivens Non-Prisoner
42:1983cv	Civil Rights Act – Civil Action for Deprivation of Rights
42:1983cvp	Civil Rights (Personal Property)
42:1983d	Civil Rights (Death)
42:1983dp	Civil Right Denial of Due Process
42:1983ed	Civil Rights (Employment Discrimination)
42:1983pr	Prisoner Civil Rights
42:1983vp	Violation of Due Process and Equal Protection
42:1985	Consipracy to interfere with civil rights
42:1986	Neglect of Duty
42:1987	Prosecution of violations of certain laws (violations of sec 1990 or 5506 to 5516 or 5518 to 5532)
42:1988	Proceedings in Vindication of Civil Rights

42:1997	Institutionalized Persons Act of 1980
42:2000a-3pa	Discrimination, segregation; public accommodation – Injunctive Relief
42:2000bea	Equal access to public facilities
42:2000c-6ed	Discrimination in Education
42:2000e-2ag	Job Discrimination (Age)
42:2000e-2e	Job Discrimination (Unlawful Employment Practices)
42:2000e-2no	Job Discrimination (National Origin)
42:2000e-2ot	Job Discrimination (other)
42:2000e-2pb	Job Discrimination (Public Accommodations)
42:2000e-2ra	Job Discrimination (Race)
42:2000e-2rl	Job Discrimination (religion)
42:2000e-2sh	Job Discrimination (Sexual Harassment)
42:2000e-2sx	Job Discrimination (Sex)
42:2000e-5eeo	Petition to Enforce EEOC Subpoena
42:2000ad	Job Discrimination (Disability Act)
42:2000bb	Religious Freedom Restoration Act of 1993
42:2000cc	Religious Land Use & Institutionalized Persons Act of 2000
42:2000d	Federally Assisted Programs
42:2003	Regulations of Indian Hospitals
42:2005	financial assistance to Indian tribes

42:10801	Protection & Advocacy for Individuals with Mental Illness Act of 1986 (PAIMI)
42:10805	Protection and Advocacy Systems
42:11001	Emergency Plan. & Comm. Right to Know Act (EPCRA)
42:11046	Fed Emer Plan Comm Right-to-know Act (EPCRA) – civil actions
42:11101	Health Care Quality Improvement Act of 1986
42:11112	Health Care Quality Improvement Act (Standards for Professional Review Actions)
42:11601	International Child Abduction Remedies Act
42:11603(b)	Int'l. Child Abduction Remedies Act (ICARA) – Judicial Remedies
42:12101	The Americans with Disabilities Act of 1990
42:12102	Americans with Disabilities Act (ADA) Disability Definition
42:12111	Americans with Disabilities Act – Employment
42:12112	Americans with Disabilities Act – Employment Discrimination
42:12117	Americans with Disabilities Act – Enforcement
42:12132	Americans with Disabilities Act – Discrimination
42:12188	Americans With Disabilities Act – Civil Enforcement Actions
42:13981	Violence Against Women Act (Civil Rights)
42:14135	DNA Backlog Grant Program
42:14901	Intercountry Adoptions
42:15483	Help America Vote Act
43:421	Complaint in Condemnation – Eminent Domain
43:945a	Compensation for Land Condemnation
43:945b	Complaint in Condemnation – Easements
43:946	Complaint in Condemnation – Right of Way for Irrigation and Drainage Projects
43:1331	Outer Continental Shelf Lands Act (Definitions)

49:31114	Access to Interstate System/Commercial Motor Vehicle
49:31502	Motor Carrier Safety: Requirements for Qualifications
49:32101	Motor Vehicle Information and Costs Savings Act
49:32701	Odometer Requirements Act
49:40101	Federal Aviation Act
49:40102	Airline Deregulation Actv(definitions of air and commerce safety)
49:40105	Warsaw Convention
49:41705	Air Carrier Access Act (discrimination against handicapped individuals)
49:41713	Airline Deregulation Actv (premp of authority over prices, routes, and service)
49:44709	Noise Control Act of 1972
49:44715	Noise Control Act of 1972
49:46507	False information and threats
49:47101	Airport and Airway Improvement Act of 1982
49:47501	Aviation Safety & Noise Abatement Act of 1979
49:49101	Wrongful Termination in Contravention of Published Regulations
49:49104	Breach of Lease by Metro. Wash. Airport Auth.
49:60101	Pipeline Safety Act of 1994
49:60102	Hazardous Liquid Pipeline Safety Act of 1979 (HLPSA)
49:80102	Bills of Lading – Application
49:80302	Contraband – Prohibitions
49:80303	Seizure and forfeiture of vessel or aircraft conveying contraband
50:1701-1706	International Emergency Economic Powers Act

Plaintiffs' Exhibit 522

transportation.gov

Fly Rights

61-77 minutes

A Consumer Guide to Air Travel

CONTENTS

Notice: We make every effort to keep *Fly-Rights* up to date, but airlines frequently change the way they do business. So by the time you read this, a few procedures we explain may be different.

Introduction

The elimination of government regulation of airline fares and routes has resulted in lower fares and a wide variety of price/service options. In this new commercial environment, consumers have had to take a more active role in choosing their air service by learning to

- Keep your ticket (or email confirmation) and your boarding passes until you receive a statement from the frequent-flyer program reflecting the correct mileage earnings for that trip. If a problem arises, get the names of the people you speak with and keep notes of your conversations.

Contract Terms

Throughout this booklet, we have tried to provide you general information about airline travel. It is important to realize, however, that each airline has specific rules that make up your contract of carriage. These rules may differ among carriers. They include provisions such as check-in deadlines, refund procedures, responsibility for delayed flights, and many other things.

Domestic Travel

For domestic travel, an airline may provide all of its contract terms on or with your ticket at the time you buy it. Some small "commuter" carriers use this system. Other airlines may elect to "incorporate terms by reference." This means that you are not given all the airline's rules with your ticket - most of them are contained in a separate document which you can inspect on request or on the airline's web site. If an airline elects to "incorporate by reference" it must provide conspicuous written notice with each ticket that: 1) it incorporates terms by reference, and 2) these terms may include liability limitations, claim-filing deadlines, check-in deadlines, and certain other key terms. The airline must also:

- Ensure that passengers can receive an explanation of key terms identified on the ticket from any location where the carrier's tickets are sold, including travel agencies;
- Make available for inspection the full text of its contract of carriage at each of its own airport and city ticket offices;
- Mail a free copy of the full text of its contract of carriage upon request.

DOT also requires most U.S.airlines to post their contracts of carriage on their web site, if they have one.

There are additional notice requirements for contract terms that affect your air fare. Airlines must provide a conspicuous written notice on or with the ticket concerning any "incorporated" contract terms that restrict refunds, impose monetary penalties, or permit the airline to raise the price after you've bought the ticket.

If an airline incorporates contract terms by reference and fails to provide you the required notice about a particular rule, you will not be bound by that rule. In addition, a DOT rule prohibits airlines from changing a term in your contract after you buy your ticket if the change will have a significant negative effect on you.

Plaintiffs' Exhibit 523

Airline Passenger Rights: The Federal Role in Aviation Consumer Protection

Rachel Y. Tang
Analyst in Transportation and Industry

August 17, 2016

Congressional Research Service
7-5700
www.crs.gov
R43078

CRS REPORT
Prepared for Members and
Committees of Congress

Summary

The 1978 deregulation of the airline industry in the United States eliminated federal control over many airline business practices, including pricing and domestic route selection. However, the federal government continues to legislate and enforce certain consumer protections for airline passengers. Congress largely determines the degree to which the rights of airline passengers are codified in law or developed through regulatory rulemaking.

The House Committee on Transportation and Infrastructure and the Senate Committee on Commerce, Science, and Transportation are the primary congressional committees of jurisdiction over airline passenger rights. Congress can authorize or require the U.S. Department of Transportation (DOT) to enact rules on certain issues, and it can enact requirements for airlines through direct legislation. In specific cases, DOT may take enforcement actions against air carriers that violate consumer protection rules.

Most of DOT's consumer rules are based on 49 U.S.C. §41712, which directs it to "protect consumers from unfair or deceptive practices." Some are based on DOT's authority to require air carriers in interstate transportation to provide "safe and adequate service" (49 U.S.C. §41702). The interpretation of the phrase "unfair or deceptive" can significantly affect the scope of DOT's enforcement authority.

In December 2009, DOT issued a comprehensive final rule, "Enhancing Airline Passenger Protections," that expanded regulatory protections for aviation consumers. The rule established procedures related to extended ground delays involving aircraft with passengers aboard, required air carriers to address chronically delayed flights, and mandated more information disclosure to consumers. In April 2011, DOT completed a further rulemaking that strengthened the rights of air travelers in the event of oversales, flight cancellations, and delays. The rule also required consumer access to accurate and adequate information when selecting flights, and improvements in agency responsiveness to customer complaints. A key provision of the 2011 rules, requiring airlines to prominently disclose to the consumer the total cost of a flight, including all government and airline taxes and fees, was upheld in the federal courts.

The FAA Extension, Safety, and Security Act of 2016 (P.L. 114-190), signed into law by the President on July 15, 2016, included a few provisions regarding the rights of airline passengers and created a firmer statutory basis for certain rules already adopted by DOT. However, the legislation did not address a number of consumer-related subjects, including disclosure of code-share arrangements on domestic flights, compensation of passengers "bumped" from oversold flights, and disclosure of ancillary fees. Proposals to overturn a DOT policy requiring that airline and travel websites give most prominent display to the total cost of a flight, including taxes and fees, were not included in the act. Such action would have allowed airlines to advertise base airfares, even though consumers would not be able to purchase transportation at those prices.

Contents

Figures

Contacts

Introduction

The deregulation of the airline industry in the United States in 1978 eliminated governmental control over most business practices of airlines. However, the federal government continues to regulate certain practices for the protection of the airlines' customers, in addition to its long-standing role in overseeing air safety.

Congressional interest in the rights of airline passengers became intense between 2007 and 2009, when a series of delays stranded passengers aboard airplanes at U.S. airports for 10 hours or longer. Since then, Congress has strengthened passengers' rights under federal law, and many Members of Congress have continued to follow aviation consumer issues closely.

This report examines aviation consumer protections in the post-deregulation era. It explains the roles of Congress and the U.S. Department of Transportation (DOT) in protecting airline consumers, and discusses some major passenger rights issues and related laws and regulations.

Three Levels of Airline Passenger Protection

The rights of domestic airline passengers are set forth at three different levels: in federal laws, in regulations, and in the airlines' own policies. Congress, under its constitutional power to "regulate Commerce with foreign Nations, and among the several States,"[1] has authority over airline passengers' rights. State and local governments are generally preempted by law from regulating "price, route, or service of an air carrier."[2]

The Role of Congress

By and large, the rights of airline passengers are defined by Congress. Congress determines the extent to which airline consumer rights are codified in law, authorizes federal agencies to enforce those rights, and directs or authorizes federal agencies to define and enforce passenger rights that are not specifically enumerated in legislation. The House Committee on Transportation and Infrastructure and the Senate Committee on Commerce, Science, and Transportation are the primary congressional committees of jurisdiction, and exercise routine oversight over DOT, the principal department responsible for executing and enforcing airline passenger rights laws. In many cases, Members of Congress become aware of passenger rights issues by receiving complaints from constituents, and congressional office staff members are often called upon to advise constituents about their rights as air passengers, to provide guidance on filing complaints with DOT, and to communicate with DOT about constituent concerns.

The controversy surrounding tarmac delays illustrates the ways in which Congress exercises its oversight authority. Between 2007 and 2009, hundreds of incidents occurred in which passengers were held aboard planes that had either departed airport gates but were not allowed to take off or had landed but were not allowed to disembark passengers. These incidents were extensively reported in the news media, and congressional offices received numerous complaints from

[1] U.S. Constitution, Article I, Section 8.

[2] 49 U.S.C. §41713(b) (1). Consumers may sue airlines for damages or breach of contract in a state or local court, but state or local consumer protection laws generally do not apply to air carriers. In one recent case, a federal court dismissed a lawsuit filed in a New York state court by passengers who claimed to have been stranded for more than seven hours aboard JetBlue flights on October 29, 2011, under "inhumane and intolerable" conditions. The court ruled that all the claims were preempted by federal law. *Joseph v. JetBlue*, No. 5:11-CV-1387 (TJM/ATB), April 11, 2012.

constituents who had been aboard planes that were unable to provide passengers with drinking water or on which lavatories stopped functioning. Congressional hearings ensued in 2009.[3] In the wake of this attention, DOT issued rules on tarmac delays in 2010. Language on this subject, providing a firmer statutory footing for the federal rules that had already entered into effect, was incorporated into the FAA Modernization and Reform Act of 2012 (P.L. 112-95). The 2016 FAA reauthorization incorporated language that defined excessive tarmac delays, but also altered how the tarmac delay threshold is measured, which could afford airlines more leeway in dealing with delayed flights.

Some Members of Congress also have expressed concern about issues related to flight schedules, aircraft capacity, and frequency of service. Although these matters are no longer subject to federal regulation, they are often raised in the context of business dealings between air carriers that do require federal approval, such as mergers and code-share arrangements. For example, the proposed merger between American Airlines and US Airways led to objections that the combination would reduce competition and limit consumer choices. These concerns were expressed by some Members of Congress and witnesses during congressional hearings in February and March 2013,[4] before completion of the merger in December 2013 and the final court approval of a settlement between the airlines and the U.S. Department of Justice Antitrust Division was granted in April 2014.

The Role of the U.S. Department of Transportation (DOT)

DOT Regulatory Authority

DOT is responsible for executing and enforcing airline consumer rights laws established by Congress. It may also develop regulations based on more general statutory authority, giving it broad powers to prescribe regulations, standards, and procedures related to air travel.[5] More specifically, DOT has authority "under 49 U.S.C. Section 41712, in concert with 49 U.S.C. Sections 40101(a)(4), 40101(a)(9), and 41702 to protect consumers from unfair or deceptive practices and to ensure safe and adequate service in air transportation."[6] DOT's authority in this

[3] Congressional Testimony, Airline Delays and Consumer Issues; Committee: House Transportation and Infrastructure; Subcommittee: Aviation, May 20, 2009; Bill McGee, "Passenger rights debate on glide path to Congress," *USA Today*, September 30, 2009.

[4] House Committee on the Judiciary, Subcommittee on Regulatory Reform, Commercial, and Antitrust Law, hearing on "Competition and Bankruptcy in the Airline Industry: The Proposed Merger of American Airlines and US Airways," February 26, 2013; Senate Judiciary Committee, Subcommittee on Antitrust, Competition Policy, and Consumer Rights, hearing on "The American Airlines/US Airways Merger: Consolidation, Competition, and Consumers," March 19, 2013.

[5] 49 U.S.C. §40113.

[6] Department of Transportation, "Enhancing Airline Passenger Protections," 74 *Federal Register* 68982-69004, December 30, 2009. DOT may also issue passenger protection rules governing international flights to and from the United States, depending on practicality and within the bounds of international agreements and treaties. Liability issues, such as compensation for lost baggage and passenger injury on international flights, are generally covered by international agreements ratified by the United States, notably the Montreal Convention of 1999, rather than by U.S. laws or regulations. Itineraries between certain countries may be subject to the older Warsaw Convention. DOT consumer-protection regulations may not apply to flights between foreign points undertaken by U.S. carriers' code-share partners, even if the flight carries a U.S. airline's flight number. For example, a United Airlines passenger traveling from Newark, NJ, to Istanbul, Turkey, might be booked from Newark to Munich, Germany, aboard a United flight, and then from Munich to Istanbul aboard a flight operated with a United flight number by Lufthansa, a German carrier. In such a case, the flight between Munich and Istanbul would not be subject to U.S. regulations concerning tarmac delays, overbooking, and other consumer matters.

area is exercised by the Office of the Secretary, not by the Federal Aviation Administration (FAA), which is responsible for aviation safety. DOT does not have authority over matters related to aviation security and airport security screening, which are administered by the Transportation Security Administration (TSA), an agency of the Department of Homeland Security.

DOT's statutory authority is generally used as the basis for rulemaking. Occasionally, it is also used in direct enforcement actions. Most of DOT's consumer rules are based on the "unfair or deceptive practices" provision, with a few based on the "ensure safe and adequate service" provision. The definition and interpretation of the phrase "unfair or deceptive practices" can significantly affect the scope of DOT's rulemaking and enforcement authorities.

Separately, DOT enforces regulations to ensure that individuals with disabilities have nondiscriminatory access to the air transportation system, and that airlines do not subject passengers to unlawful discrimination on the basis of race, gender, religion, or national origin.[7]

The DOT Aviation Consumer Protection Division's booklet *Fly-Rights: A Consumer Guide to Air Travel* is published online. It covers a wide array of topics, from flight delays and cancellations to travel scams. It also provides information about DOT rules on consumer complaints.[8]

DOT Enforcement Authority

The Office of the Assistant General Counsel for Aviation Enforcement and Proceedings in DOT (OAEP), including its Aviation Consumer Protection Division, monitors airline compliance, investigates reported violations of DOT regulations, and enforces rules and regulations. It may negotiate consent orders with air carriers and fine violators. In 2015, DOT issued 15 consent orders related to aviation consumer rule violations and assessed $2,435,000 in civil penalties.

OAEP considers a number of factors in determining the civil penalty it would seek in an enforcement proceeding, such as the harm caused by the violations, the alleged violator's compliance disposition, the alleged violator's financial condition and ability to pay, how long the violations continued, and the strength of the case.[9] Currently, air carriers are subject to a maximum civil penalty of $32,140 per violation, under 49 U.S.C. §46301 and 14 C.F.R. §383. Small businesses[10] or individuals are subject to a maximum penalty of $1,414. Notwithstanding this limit, small businesses and individuals are subject to higher maximum penalties for discrimination ($12,856 per violation) and for engaging in unfair or deceptive practices ($3,214 per violation).[11]

OAEP may look into possible violations based on complaints from individuals, groups, other government agencies, or its own staff members' observations and research. Usually, its first action is to send a letter to the air carrier, setting forth the complaint or issues involved and requesting a response. This gives the air carrier a chance to look into the matter and to resolve the complaint, deny the complaint, or provide an explanation. This may be the end of the process, but

[7] 14 C.F.R. §382.

[8] http://www.dot.gov/airconsumer/fly-rights.

[9] Office of Aviation Enforcement and Proceedings, DOT, "Answers to Frequently Asked Questions Concerning the Enforcement of the Final Rule on Enhancing Airline Passenger Protections," April 28, 2010, p. 2.

[10] A domestic or foreign air carrier is a small business if it provides air transportation only with small aircraft (i.e., aircraft with up to 60 seats/18,000-pound payload capacity). See 14 C.F.R. 399.73 Definition of small business for Regulatory Flexibility Act.

[11] 14 C.F.R. §383.2 (b). The penalty amounts were adjusted August 10, 2016; see *Federal Register*, Vol. 81, No. 154, pp. 52763-52766.

OAEP may issue a warning letter if it concludes violations occurred but were inadvertent or minor.

If OAEP believes enforcement action is appropriate, it would seek a civil penalty and consent order. A consent order typically relates the facts of the case to law and regulation, sets forth the penalty the violator has agreed to pay, and incorporates language ordering the air carrier to cease and desist from further violations. If the air carrier refuses to settle, the case may go to an enforcement hearing before a DOT administrative law judge.[12] DOT also may request injunctive relief from a federal district court, although this is unusual.

Airline Deregulation and Contracts of Carriage

The third source of airline passengers' rights is each air carrier's "Contract of Carriage," the legal agreement between an airline and its ticket holders. Contracts of carriage typically define the rights, duties, and liabilities of parties to the contract. For example, United Airlines' contract of carriage lists 30 rules, covering matters from reservations and ticketing to cancellation and refund policies to medical ground transfer services.[13]

Before the age of electronic tickets, contracts of carriage were usually evidenced by standard terms and conditions printed on the reverse of paper tickets. Now, they are often available for download via airlines' websites or at an airline's ticketing facilities. Passengers may take legal action in federal courts based on the contracts.

Contracts of carriage replace the pre-deregulation-era-rules "tariffs" that were subject to approval by the Civil Aeronautics Board (CAB).[14] The CAB could take action against an air carrier that violated its approved tariffs. Since the economic deregulation of the domestic airline industry in 1978, the federal government no longer has control over airlines' prices or routes, and contracts of carriage are not subject to federal review or approval. However, a contract of carriage that conflicts with federal laws or regulations may not be enforceable by the airline.

With respect to passenger rights, the deregulated environment differs from the former regulated environment in two major ways. First, under regulation, the CAB had authority to approve carriers' proposed fares and even to set fares itself. The airlines' profitability was protected by this price setting and by barriers to the entry of new competitors. Airlines, for the most part, competed on service and frequency rather than price. Since deregulation, and especially with the advent of low-cost carriers, the primary means of competition has become price, not service.

In recent years airlines have "unbundled" their offerings, charging separately for services that once were included in the price of a ticket. Among these charges are fees for checked baggage, early/priority boarding, and seat change on a flight. Such ancillary fees have become major causes of consumer complaints.

Second, because the CAB used a cost-plus basis for approving fares, airlines could afford to maintain a significant amount of extra capacity, which made it relatively simple for them to deal with problems arising from flight delays or cancellations. Carriers' treatment of passengers booked on delayed or canceled flights is now a major cause of complaints (see **Text Box**).

[12] This is a simplified description of the process. Underlying this process is usually an ongoing process of negotiation between OAEP and the air carriers and OAEP and the complainants.

[13] https://www.united.com/web/format/pdf/Contract_of_Carriage.pdf, viewed on August 3, 2016.

[14] Pursuant to the Airline Deregulation Act of 1978, the CAB ceased operations on December 31, 1984.

Clarification of "Rule 240" and Rerouting of Stranded Passengers

During the era of regulation, Tariff Rule 240 was the number commonly used in air carrier tariffs that stated the airline's rules on rerouting of passengers when a flight was canceled or delayed. Since airfares and routes were then regulated, airlines generally had comparable price structures. This made it easier for them to enter and/or honor interline agreements for rerouting passengers at times of service disruption. Although Tariff Rule 240 has often been referred to in the press as a "federal rule,"[15] it was not. Each airline's version of Tariff Rule 240 was written by the carrier itself, although it was subject to CAB approval.

Today, competing airlines' fares on a given route may differ, and the fares paid by passengers on any single plane may vary widely, depending upon the date of purchase, the passenger's ability to change flights without penalty, and other factors. Although some airlines maintain interline agreements with other carriers allowing passenger rebooking in the event of cancellation or delay, others, particularly "low-cost" carriers, may not have such agreements. An airline that cancels a flight may be unable to rebook its passengers aboard another carrier without significant costs, which it may be unwilling to incur.

Additionally, in a deregulated environment in which profitability is not guaranteed, market forces have led many airlines to reduce the number of seats they offer to improve load factors. According to DOT's Bureau of Transportation Statistics (BTS), air carriers' average load factor on domestic flights in 2015 was nearly 85%, meaning that many flights operated at or near capacity. The lack of spare capacity can make it difficult for carriers to accommodate passengers in the event of flight disruptions. Consequently, today's airline contracts of carriage are less likely to provide for rerouting of passengers on competing airlines' flights than was the case prior to deregulation.

Major Passenger Air Service Provisions in 2016 FAA Reauthorization

The FAA Extension, Safety, and Security Act of 2016 (P.L. 114-190), signed into law on July 15, 2016, included a few provisions relating to passenger rights.[16] Some of the passenger-rights provisions put forth during the debate over FAA reauthorization were not included in the final bill, as similar protections had meanwhile been implemented through the DOT rulemaking process. Relevant passenger-rights provisions of P.L. 114-190 are summarized below.

Training Policies Regarding Assistance for Persons with Disabilities

Section 2107 requires the Government Accountability Office to submit a report to Congress assessing air carrier personnel and contractor training programs regarding assistance to persons with disabilities, as well as reporting instances since 2005 in which DOT has requested an air carrier to take corrective action following a review of its training programs.

Section 2107 also requires DOT to disseminate to air carriers such best practices as it deems necessary to improve the reviewed training programs.

Air Travel Accessibility

Section 2108 requires DOT, no later than one year from enactment of the law, to issue a supplemental notice of proposed rulemaking regarding accessibility-related matters such as pressurized oxygen in a tank, transport of service animals, and provision of accessible lavatories.

[15] *Wall Street Journal*, "Passenger Rights? What Passenger Rights?," March 28, 2013.

[16] P.L. 112-95, Title IV Air Service Improvements, Subtitle A—Passenger Air Service Improvements.

Refunds for Delayed Baggage

Section 2305 requires DOT to issue a final rule requiring domestic and foreign airlines to provide a refund of a checked-bag fee if a bag is delayed 12 hours or longer on a domestic flight or 15 hours on an international flight.

The provision provides DOT latitude to expand the aforementioned window (up to 18 hours for domestic flights and up to 30 hours for international flights), if the Secretary decides that a shorter time frame is not feasible or would adversely affect consumers in certain cases.

Tarmac Delays

Section 2308 amends 49 U.S.C. §42301, which addresses airline tarmac delays. It specifies that "excessive tarmac delay" means a delay that lasts more than three hours for an interstate flight or more than four hours for an international flight. The section directs DOT to issue regulations to implement the statute.

Language in Section 2308(a) alters how excessive tarmac delays are defined. Under existing DOT regulations (14 C.F.R. §259.4), excessive delay is measured from the time that passengers last have an opportunity to deplane, which could be well before an aircraft actually departs the gate to the point at which the air carrier permits passengers to deplane in the event of delay. The statutory change requires that delay be measured from the time the main aircraft door is closed in preparation for departure to the point at which the air carrier "shall begin to return the aircraft to a suitable disembarkation point." Depending upon the length of time required to move the aircraft from its position during the delay to a disembarkation point such as a gate at the terminal, the actual amount of delay permitted before passengers are allowed to disembark may be significantly greater than under the previous regulations.

In addition, the new legislation does not specify the maximum time an air carrier has to complete the deplaning of passengers after returning to a disembarkation point. This may require a change in the existing DOT rule, which simply requires that passengers be given the opportunity to deplane no later than the three-hour or four-hour point in a tarmac delay.

Family Seating

Section 2309 requires DOT to review and, if appropriate, to establish a policy directing airlines to establish policies that would enable a child who is age 13 or under to be seated adjacent to an accompanying family member over age 13 "to the maximum extent practicable" at no additional cost.

This requirement would not apply when assignment to an adjacent seat would require an upgrade to another cabin class or a seat with extra legroom or seat pitch for which additional payment is normally required.

Advisory Committee for Aviation Consumer Protection

Section 1102(j) extends the Advisory Committee for Aviation Consumer Protection through FY2017. This advisory committee was established by the Secretary of Transportation in 2012, fulfilling the requirement in the 2012 FAA reauthorization to establish a four-member committee

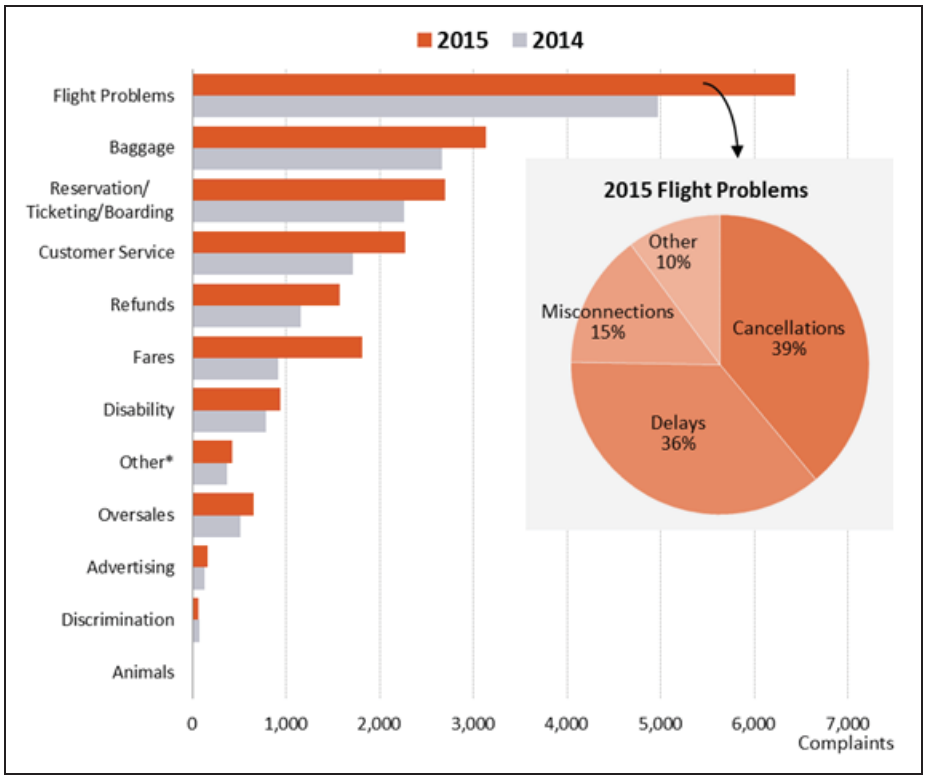
for aviation consumer protection to advise the Secretary in carrying out passenger service improvements.[17]

Consumer Complaints to DOT

Despite the fact that the 15 largest U.S. airlines' on-time arrival rate was nearly 80% in calendar year 2015, flight delays and cancellations continue to be a prevalent passenger complaint to DOT. In 2015, there were about 6,433 such complaints in total, accounting for nearly 32% of all complaints.[18] Mishandled baggage, problems with reservations, ticketing, and boarding, customer service, and refunds are also among the most frequent complaints (see **Figure 1**).

Figure 1. Number of Airline Consumer Complaints Filed with DOT

2014-2015



Source: U.S. Department of Transportation, Air Travel Consumer Report (February 2016), p. 43.

Note: "Other" includes complaints regarding frequent flyer programs, smoking, cargo problems, airport facilities, security, etc.

While DOT continues to receive many complaints about mishandled baggage, improved tracking systems have helped U.S. air carriers reduce the proportion of bags that are lost or sent to the wrong destinations. In 2015, the U.S. carriers reported 4.04 mishandled bags per 1,000

[17] See http://www.gpo.gov/fdsys/pkg/FR-2012-06-13/html/2012-14456.htm.

[18] Flight-related problems are predominantly delays and cancellations, but also include any other deviations from schedule.

passengers, which was among the lowest annual rates of mishandled baggage since DOT first collected data on the subject in 1987.[19]

How DOT Handles Aviation Consumer Complaints

When DOT receives a consumer complaint about an airline, it sends a copy to the airline and asks it to reply directly to the customer. If it is a complaint about a subject covered by DOT rules, DOT requires the airline to send DOT a copy of its response to the consumer, which DOT may evaluate to determine if the reply complies with DOT rules. A pattern of violations of a rule as reflected in complaints can lead to enforcement action. Even where no rule applies, if DOT determines an airline's practice, as reflected in complaints, to be deceptive, it may conduct an investigation, initiate a rulemaking, or commence enforcement action. This possibility gives airlines an incentive to monitor complaints made to DOT.

On the other hand, airlines often receive complaints directly from customers. The number of consumer complaints submitted directly to the air carriers is believed to be much higher than the number filed with DOT. However, airlines are not required by law to report consumer complaints to DOT, except those related to treatment of disabled passengers. The Air Carrier Access Act (49 U.S.C. §41705) prohibits discriminatory treatment of persons with disabilities in air transportation. The Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (P.L. 106-181) requires the Secretary of Transportation to "regularly review all complaints received by air carriers alleging discrimination on the basis of disability" and "report annually to Congress on the results of such review."

DOT's annual reports to Congress on disability-related air travel complaints are available on its website: http://www.transportation.gov/airconsumer/annual-report-disability-related-air-travel-complaints. In 2014, a total of 27,556 such disability-related complaints were submitted to DOT by airlines, of which 24,044 came from U.S. carriers.[20]

DOT Regulatory Actions

Airline flight delays and cancellations were addressed in a final rule issued in December 2009 by DOT, "Enhancing Airline Passenger Protections."[21] The rule expanded on previous regulations to address tarmac delays and chronically delayed flights and to require greater information disclosure to consumers. While language in the FAA Extension, Safety, and Security Act of 2016 (P.L. 114-190) alters how tarmac delays are measured, the rest of the tarmac delay rule is unaffected by the statutory change.

The existing rule requires large U.S. carriers to provide assurance that they will not permit an aircraft to remain on the tarmac for more than three hours without providing passengers an opportunity to deplane. An air carrier's failure to comply subjects the carrier to civil penalties of up to $32,140 per passenger.[22] This final rule contains the following mandates:

- Each air carrier is required to develop and implement a contingency plan for lengthy tarmac delays.
- Each contingency plan must include an assurance that, for domestic flights, the air carrier will not allow a tarmac delay to exceed three hours unless the pilot-in-

[19] Data pertain to all U.S. airlines with at least 1% of total domestic scheduled-service passenger revenues, as determined by DOT's Bureau of Transportation Statistics (BTS). More information on rules, guidance, and other related issues regarding aviation baggage can be found on the DOT website: http://www.dot.gov/airconsumer/baggage. The lowest annual rate of mishandled baggage since 1987 was the 2012 rate of 3.09 mishandled bags per 1,000 passengers. In 2015, the rate of mishandled baggage was 4.04 mishandled bags per 1,000 passengers. See U.S. Department of Transportation, Air Travel Consumer Report (February 2016), p. 30.

[20] https://www.transportation.gov/airconsumer/2014-disability-related-complaints-overview.

[21] http://www.dot.gov/airconsumer/final-rule-enhancing-airline-passenger-protections.

[22] Ibid.

command determines there is a safety-related or security-related impediment to deplaning passengers, or unless air traffic control has advised the pilot-in-command that deplaning would significantly disrupt airport operations. The plan must include assurance that adequate food and water will be provided within two hours after the aircraft leaves the gate, as well as assurance of operable lavatory facilities and adequate medical attention.

- For international flights, air carriers must commit to a set number of on-tarmac hours to be determined by air carrier and set forth in its plan.[23]

The tarmac delay rule took effect for domestic flights in April 2010. There has been a significant reduction in lengthy tarmac delays since the rule was published. In 2014, airlines reported the lowest number of tarmac delays longer than three hours on record—30 domestic flights with tarmac delays longer than three hours and nine international flights with tarmac delays longer than four hours at U.S. airports.[24]

- The rule issued in December 2009 also contained several other consumer protection provisions: Air carriers must display flight delay information for each domestic flight they operate on their websites and designate employees to monitor the impacts of flight delays and cancellations, respond to consumer complaints, and tell consumers where and how to file complaints.
- Air carriers are prohibited from applying changes to their contracts of carriage retroactively.
- Under the rule, any chronically delayed flight[25] scheduled by an air carrier is considered an unfair and deceptive practice and an unfair method of competition within the meaning of 40 U.S.C. §41712.

On April 25, 2011, DOT issued a further rulemaking to strengthen the rights of air travelers in the event of oversales, flight cancellations, and delays; to ensure consumers have accurate and adequate information when selecting flights; and to improve responsiveness to customer complaints.[26] These rules, fully effective January 26, 2012, include the following:

- Baggage fees must be reimbursed for lost bags;
- Additional fees must be prominently disclosed on airline websites; and
- The ban on excessive tarmac delay is expanded to foreign airlines' operations at U.S. airports, with a four-hour limit on international flights.

[23] A year later, the ban on lengthy tarmac delays was expanded to foreign airlines' operations at U.S. airports, with a limit of four-hour delay set for international flights.

[24] DOT press release DOT 13-15, February 10, 2015. See http://www.rita.dot.gov/bts/press_releases/dot013_15. However, critics have argued that the rule may have caused more cancellations by air carriers, as cancelling a flight eliminates the risk that it might be delayed extensively after boarding.

[25] A chronically delayed flight is defined as any domestic flight that is operated at least 10 times a month, and arrives more than 30 minutes late (including canceled flights) more than 50% of the time during that month (http://www.gpo.gov/fdsys/pkg/CFR-2012-title14-vol4/pdf/CFR-2012-title14-vol4-sec399-81.pdf).

[26] http://www.dot.gov/airconsumer/rule-two-amendment-concerning-baggage-and-other-consumer-issues-pdf.

Ongoing Airline Passenger Consumer Issues

Code-Share Agreements[27]

Over the past few decades, large U.S. carriers (also known as mainline carriers) have increasingly moved to joint marketing agreements, known as "code-share agreements." In domestic code-share agreements, mainline carriers, such as Delta and American Airlines, purchase seat capacity from regional airlines or contract for the services of regional carriers to fly passengers to their hub airports. Such agreements often allow a regional carrier to (1) use the mainline carrier's airline designator code to identify flights and fares in computer reservation systems; (2) use the mainline carrier's brand—for example, logos and uniforms; and (3) participate in joint promotion and advertising activities.

It is also common for major U.S. carriers to establish international alliances with foreign carriers, which almost always include a code-share component, although in international code-share agreements there is no distinctive large or mainline carrier. The DOT code-share disclosure rule (14 C.F.R. §257) applies equally to domestic and international air transportation to and from the United States. It requires that U.S. airlines and foreign air carriers that participate in code-share agreements or long-term "wet leases" tell consumers clearly when the air transportation involves such an agreement, and that they disclose the transporting carrier's identity.[28]

DOT does not review most domestic code-share agreements,[29] but does require ticket sellers to disclose which airline is operating the flight prior to booking to ensure consumer transparency.[30] However, some confusion still appears to exist among passengers because airlines, travel agencies, and advertisers may disclose this information differently. In some cases, the name of the operating carrier may not be displayed prominently. Also, some regional carriers have code-share agreements with multiple mainline carriers and use different "doing business as" names when operating on different domestic routes.[31]

---

[27] More information on disclosure of code-share air service can be found on the DOT website, http://www.dot.gov/airconsumer/notice-codeshare.

[28] 14 C.F.R. §257.3 (e); long-term wet lease means a lease by which the lessor provides both an aircraft and crew dedicated to a particular route(s) for more than 60 days or is part of a series of such leases that amounts to a continuing arrangement lasting more than 60 days.

[29] Under 49 U.S.C. §41720, DOT's Office of the Secretary (OST) must review any agreement "between two or more major air carriers that affects more than 15 percent of the total number of available seat miles offered by the major air carriers." OST is required to assess the potential economic impact on competition of domestic code-share agreements between major carriers. An international code-share agreement, on the other hand, needs DOT approval. For more information, see https://www.transportation.gov/policy/aviation-policy/competition-data-analysis/alliance-codeshares.

[30] In 2011, DOT added a new subsection (c) to 49 U.S.C. §41712 that specifically requires airlines and ticket agents to disclose in any oral, written, or electronic communication to the public, prior to a ticket sale, the name of the carrier providing the service of each segment of a passenger's itinerary. In addition, the amendment explicitly requires that on websites, disclosure must be made "on the first display of the Web site following a search of a requested itinerary in a format that is easily visible to a viewer." Office of the Secretary, DOT, "Guidance on Disclosure of Code-Share Service Under Recent Amendments to 49 U.S.C. §41712," January 14, 2011 (http://www.dot.gov/airconsumer/notice-codeshare).

[31] Office of Inspector General, U.S. Department of Transportation, "Growth of Domestic Airline Code Sharing Warrants Increased Attention," report AV-2013-045, February 14, 2013, p. 4.

Oversale/Overbooking[32]

Most airlines overbook their scheduled flights to a certain degree to compensate for "no-shows." Such oversale or overbooking is not illegal. When a flight is oversold, DOT requires airlines to ask passengers to give up their seats voluntarily (voluntary bumping), in exchange for compensation, before bumping anyone involuntarily.

A DOT rule (14 C.F.R. §250) requires airlines to properly inform and compensate passengers who are bumped involuntarily. Air carriers are required to establish and disclose boarding priority rules and criteria for determining which passengers shall be denied boarding on an oversold flight. Boarding priority criteria may include factors such as a passenger's time of check-in, the fare paid, and passenger's frequent flyer status.[33]

In April 2011, DOT issued an amended final rule to address issues regarding denied boarding or involuntary bumping compensation, especially inadequate denied boarding compensation to passengers. The amendment increased denied boarding compensation rates and dollar limits, with dollar limits subject to inflation-related adjustment every two years. When a passenger is bumped involuntarily and the airline arranges substitute transportation that is scheduled to reach the passenger's final destination within one hour of the original arrival time, no compensation is required. However, if the scheduled arrival time via substitute transportation[34] is more than one hour later than the original arrival time, the following rules apply:

- If the substitute domestic transportation arranged by the airlines is scheduled to arrive between one and two hours later than the original arrival time, the airline must pay the passenger an amount equal to 200% of the one-way fare (including all taxes and mandatory fees), with a $675 maximum, effective August 25, 2015.[35] On international flights departing the United States, this limit applies when a bumped passenger is delayed up to four hours.
- If the substitute transportation is scheduled to arrive more than two hours later on domestic flights (four hours on international flights), or if the airline does not make any substitute transportation arrangements for the passenger, the compensation doubles to 400% of the one-way fare, with a $1,350 maximum, effective August 25, 2015.[36]
- An air carrier must refund any unused ancillary fees for optional services paid by a passenger if he or she was denied boarding, voluntarily or involuntarily.

Ancillary Fees and Disclosure of Full Fares[37]

Many U.S. air carriers have held down ticket prices by advertising cheap base airfares and adding separate optional fees for services that traditionally have been included in the price of a ticket. These ancillary charges, including checked baggage fees, reservation cancellation or change fees,

[32] More information on oversales can be found at http://www.dot.gov/airconsumer/oversales.

[33] http://www.ecfr.gov/cgi-bin/text-idx?SID=54358562bcfe8b187765c7395f37bc33&mc=true&node=se14.4.250_13&rgn=div8.

[34] Substitute transportation may involve flights by the same or another carrier or transportation by train or bus.

[35] http://www.transportation.gov/sites/dot.gov/files/docs/Inflation_2015.pdf.

[36] Ibid.

[37] More information on this topic can be found on DOT websites, http://www.dot.gov/airconsumer/advertising and http://www.dot.gov/airconsumer/baggage-optional-fees.

seat selection fees, priority boarding fees, and charges for in-flight meals, are generating considerable revenue. In 2015, the U.S. passenger airline industry collected more than $3.8 billion in baggage fees[38] and over $3 billion in reservation cancellation/change fees.[39]

In order to make it easier for consumers to know how much they will have to pay for airline transportation and to ensure that airlines' fee-related practices are fair and transparent, the DOT rule issued in 2011 requires that an airline's most prominently advertised airfare must be the full cost of the ticket, with government taxes, mandatory fees, and optional surcharges included. For both domestic and international markets, carriers must disclose the full price to be paid, including government taxes and fees and any carrier surcharges, in their advertising, on their websites, and on the passenger's e-ticket confirmation. In addition, carriers must disclose all fees for optional services through a prominent link on their home pages, and must include information on e-ticket confirmations about the free baggage allowance and applicable fees for the first and second checked bags and carry-on bags. Airlines must refund charges for lost bags.

Spirit Airlines, Allegiant Air, and Southwest Airlines challenged in federal court that portion of DOT's April 2011 rule that requires airlines and ticket agents to most prominently display the total cost of a ticket, including taxes, when advertising airfares. In July 2012, the U.S. Court of Appeals for the Washington, DC, circuit rejected the airlines' contention that the rule violates their rights to engage in commercial and political speech and is an effort by the government to conceal taxes in airfares.[40] The airlines subsequently appealed to the U.S. Supreme Court, which, on April 1, 2013, refused to consider their challenge and left the rule intact.

On July 28, 2014, the House of Representatives passed the Transparent Airfares Act of 2014 (H.R. 4156, 113th Congress) by a voice vote. The bill would have allowed airlines' advertisements and websites to give greatest prominence to "base airfare," as long as they "clearly and separately" disclose government taxes and fees and the total cost of air transportation. While the bill would have enabled airlines to call greater attention to the many government taxes and fees on passenger aviation, it could have made price comparisons more difficult, as some advertisements or websites might have displayed the "base airfare" most prominently while others might have advertised the after-tax price. The Senate did not act on the legislation.

The FAA Extension, Safety, and Security Act of 2016 (P.L. 114-190), signed into law on July 15, 2016, did not address disclosure of ancillary fees.

Author Contact Information

Rachel Y. Tang
Analyst in Transportation and Industry
rtang@crs.loc.gov, 7-7875

[38] ttp://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/subject_areas/airline_information/baggage_fees/html/2015.html.

[39] http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/subject_areas/airline_information/reservation_cancellation_change_fees/html/2015.html.

[40] *Spirit Airlines v. U.S. DOT*, 402 U.S. App. D.C. 70, July 24, 2012.

(Lat. 46°36′24″ N, long. 111°59′0.0″ W)

That airspace extending upward from the surface within an area bounded by a line beginning at Lat. 46°34′18.57″ N, long. 111°51′30.319″ W, to Lat. 46°38′5.89″ N, Long. 111°51′24.53 ″ W, to Lat. 46°37′12.53″ N, long. 111°45′24.67 ″ W, to Lat. 46°32′22.72″ N, Long. 111°46′31.44″ W, to Lat. 46°33′24.13″ N, Long. 111°54′20.01″ W, then counter-clockwise along the 4.4-mile radius of the airport to Lat. 46°34′20.01″ N, long. 111°53′22.03″ W, then to the point of beginning, and within an area bounded by a line beginning at Lat. 46°38′39.95″ N, long. 112°06′47.50″ W, to Lat. 46°36′47.49″ N, long. 112°07′53.41″ W, to Lat. 46°37′22.52″ N, long. 112°11′37.80″ W, to Lat. 46°39′19.40″ N, long. 112°10′58.64″ W, then to the point of beginning west of Helena Regional Airport.

Paragraph 6005. Class E Airspace Areas Extending Upward from 700 feet or more above the Surface of the Earth.

* * * * *

ANM MT E5 Helena, MT [Amended]

Helena Regional Airport, MT

(Lat. 46°36′24″ N, long. 111°59′0.0″ W)

That airspace extending upward from 700 feet above the surface within an 8.3-mile radius of the airport, and within 1 mile each side of the 103° bearing from the airport, extending from the 8.3-mile radius to 10.7 miles east of the airport, and within 1.8 miles each side of the 281° bearing from the airport, extending from the 8.3-mile radius to 18.1 miles west of the airport; and that airspace extending upward from 1,200 feet above the surface within a 36-mile radius of Helena Regional Airport.

Issued in Seattle, Washington, on December 1, 2020.

B. G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2020–26816 Filed 12–4–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 399

[Docket No. DOT–OST–2019–0182]

RIN 2105–AE72

Defining Unfair or Deceptive Practices

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The U.S. Department of Transportation (DOT or Department) is issuing a final rule codifying its longstanding definitions for the terms ''unfair'' and ''deceptive'' in the Department's regulations implementing its aviation consumer protection statute. The final rule also describes the Department's procedural requirements for its rulemaking and enforcement actions when based on the Department's authority to prohibit unfair or deceptive practices. Most of the Department's aviation consumer protection regulations, such as the Department's rules on overbooking, are based on the Department's authority to prohibit unfair or deceptive practices. This rule is intended to provide regulated entities and other stakeholders with greater clarity and certainty about the Department's interpretation of unfair or deceptive practices and the Department's process for making such determinations in the context of aviation consumer protection rulemaking and enforcement actions.

DATES: Effective on January 6, 2021.

FOR FURTHER INFORMATION CONTACT: Robert Gorman, Kimberly Graber, or Blane Workie, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, 202–366–9342, 202–366–7152 (fax); *robert.gorman@dot.gov; kimberly.graber@dot.gov; blane.workie@dot.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Rulemaking Background

Much of the background information presented here also appears in the preamble to the Department's Notice of Proposed Rulemaking on Defining Unfair and Deceptive Practices published on February 28, 2020.[1] We have presented background information again here to assist the public in understanding the issues involved.

A. The Department's Unfair and Deceptive Practices Statute

The Department's authority to regulate unfair and deceptive practices in air transportation or the sale of air transportation is found at 49 U.S.C. 41712 (''Section 41712'') in conjunction with its rulemaking authority under 49 U.S.C. 40113, which states that the Department may take action that it considers necessary to carry out this part, including prescribing regulations. Section 41712 gives the Department the authority to investigate and decide whether an air carrier, foreign air carrier, or ticket agent is engaged in an unfair or deceptive practice in air transportation or the sale of air transportation. Under Section 41712, after notice and an opportunity for a hearing, the Department has the authority to issue orders to stop an unfair or deceptive practice. A different statute, 49 U.S.C. 46301, gives the Department the authority to issue civil penalties for violations of Section 41712 or for any regulation issued under the authority of Section 41712.

B. Request for Regulatory Reform

On February 24, 2017, President Trump signed Executive Order 13777, Enforcing the Regulatory Reform Agenda, which requires each Federal agency to establish a Regulatory Reform Task Force to evaluate existing regulations, and make recommendations for their repeal, replacement, or modification. As part of this process, the Department is directed to seek input and assistance from entities significantly affected by its regulations. On October 1, 2017, the Department issued a Notice of Regulatory Reform seeking written input from the public on existing regulations and other actions that are good candidates for repeal, replacement, or modification.[2] In response to the Notice, Airlines for America (A4A), an airline trade association, urged the Department to adopt policies defining unfairness and deception in Section 41712 consistent with principles articulated in Federal Trade Commission (FTC) and Federal court precedent interpreting those terms.[3] A4A also urged the Department to adopt various procedures which would, in its view, ensure that the Department's enforcement and rulemaking activities were rooted in fairness, due process, and an adequate factual foundation.

C. Department's Comprehensive Update of Rulemaking and Enforcement Procedures

On December 27, 2019, the Department issued a comprehensive update and consolidation of its procedural requirements for the Department's rulemaking and enforcement actions.[4] This update reflects the Department's policy that regulations should be straightforward and clear, incorporate best practices for economic analyses, and provide for appropriate public participation.[5] It also reflects the Department's policy that enforcement actions should satisfy principles of due process and remain

[1] ''Defining Unfair or Deceptive Practices,'' 85 FR 11881 (February 28, 2020).

[2] ''Notification of Regulatory Review,'' 82 FR 45750 (October 1, 2017).

[3] See Comment of A4A, Docket DOT–OST–2017–0069–2753, available at *www.regulations.gov*.

[4] ''Administrative Rulemaking, Guidance, and Enforcement Procedures,'' 84 FR 71714 (December 27, 2019), amending 49 CFR part 5 and other provisions.

[5] 84 FR 71718–71826.

lawful, reasonable, and consistent with Administration policy.[6]

D. Summary of Notice of Proposed Rulemaking (NPRM)

On February 28, 2020, the Department published an NPRM proposing to define the terms ''unfair'' and ''deceptive'' found in Section 41712, the Department's aviation consumer protection statute. The NPRM also proposed a series of amendments to the Department's aviation consumer protection procedures with respect to both regulation and enforcement. The proposals were issued to provide greater clarity, transparency, and due process in future aviation consumer protection rulemakings and enforcement actions.

By way of background, the Department described the origin of section 41712 and explained how it was modeled on Section 5 of the Federal Trade Commission (FTC) Act. The Department explained that while Section 5 vests the FTC with broad authority to prohibit unfair or deceptive practices in most industries, Congress granted the Department the exclusive authority to prohibit unfair or deceptive practices of air carriers and foreign air carriers. The Department noted that DOT and FTC share the authority to prohibit unfair or deceptive practices by ticket agents in the *sale* of air transportation.

Next, the Department explained that in December 1980, the FTC issued a Policy Statement to Congress, which articulated general principles drawn from FTC decisions and rulemakings that the Commission applies in enforcing its mandate to address unfairness under the FTC Act.[7] These principles were applied in FTC enforcement cases and rulemakings, and approved by reviewing Federal courts.[8] The FTC explained that unjustified consumer injury is the primary focus of the FTC Act. This concept contains three basic elements. An act or practice is unfair where it: (1) Causes or is likely to cause substantial injury to consumers; (2) cannot be reasonably avoided by consumers; and (3) is not outweighed by countervailing benefits to consumers or to competition. The FTC also considers public policy, as established by statute, regulation, or judicial decisions, along with other evidence in determining whether an act or practice is unfair.

These principles are now reflected in the FTC Act itself. In 1994, Congress enacted 15 U.S.C. 45(n), which states that the FTC shall have no enforcement authority or rulemaking authority to declare an act or practice unfair unless it is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. Congress further provided in Section 45(n) that the FTC could rely on public policy, along with other evidence, for making a determination of unfairness, but public policy may not be the primary basis of its decision.

Next, the Department explained that in 1983, the FTC issued a Policy Statement on Deception.[9] Like the 1980 Policy Statement on Unfairness, the 1983 Policy Statement clarified the general principles that the FTC applies in enforcing its mandate to address deception under the FTC Act. As explained in the Policy Statement, an act or practice is deceptive where: (1) A representation, omission, or practice misleads or is likely to mislead the consumer; (2) a consumer's interpretation of the representation, omission, or practice is considered reasonable under the circumstances; and (3) the misleading representation, omission, or practice is material.

In the NPRM, the Department proposed to adopt definitions of ''unfair'' and ''deceptive'' that echo FTC precedent. The Department explained that adopting these definitions would simply codify existing practice and would not reflect a change of policy, because the Department's Office of Aviation Consumer Protection (formerly known as the Office of Aviation Enforcement and Proceedings), a unit within the Office of the General Counsel that enforces aviation consumer protection requirements, has often explicitly relied on those definitions in its enforcement orders.

Next, the Department proposed a set of procedural rules that would govern the Department's future discretionary rulemaking and enforcement efforts in the area of aviation consumer protection. With respect to rulemaking actions, the Department proposed three measures. First, future rulemakings declaring certain practices to be ''unfair'' or ''deceptive'' would use the Department's proposed definitions of those terms.[10] In prior rulemakings, the Department tended to make a conclusory statement that a practice was unfair or deceptive and did not provide its reasoning for that conclusion. In arriving at these conclusions that certain practices were unfair or deceptive, DOT employed the same definitions that are set forth in this rule, though that analysis was done informally at the Department and not further described in rule preambles.

Second, future discretionary rulemakings would be subject to a hearing procedure. Specifically, if the Department proposes that a practice was unfair or deceptive in a rulemaking, and that rulemaking raised scientific, technical, economic, or other factual issues that are genuinely in dispute, then interested parties may request an evidentiary hearing to gather evidence on those disputed issues of fact. Third, future rulemakings would explain the Department's basis for finding a practice to be unfair or deceptive.

With respect to enforcement, the Department proposed three measures. First, when taking enforcement action against an airline or ticket agent for unfair or deceptive practices, the Department would use the proposed definitions of ''unfair'' and ''deceptive'' set forth above (unless a specific regulation issued under the authority of section 41712 applied to the practice in question, in which case the terms of the specific regulation would apply). Second, in future enforcement actions, the Department would provide the airline or ticket agent with the opportunity to be heard and to present mitigating evidence. This final rule codifies the longstanding practice of allowing regulated entities to present mitigating evidence during the course of informal DOT enforcement actions. In a typical enforcement action, the Office of Aviation Consumer Protection issues an investigation letter to an airline or ticket agent, seeking information about the extent and nature of the violations. During that process, the Office also allows airlines and ticket agents to present mitigating evidence (*e.g.,* that consumer harm was low, or that the airline or ticket agent has taken steps to mitigate the harm to consumers). While the rule now makes this process explicit, we do not expect an *expansion* in its usage; instead, we expect that it

[6] 84 FR 71729–71733.

[7] Letter from the FTC to Hon. Wendell Ford and Hon. John Danforth, Committee on Commerce, Science and Transportation, United States Senate, Commission Statement of Policy on the Scope of Consumer Unfairness Jurisdiction (December 17, 1980), appended to *International Harvester Co.,* 104 F.T.C. 949, 1070, 1073 (1984).

[8] See, *e.g., International Harvester,* 104 F.T.C. 949 (1984); Credit Practices Rule, Statement of Basis and Purpose, 49 FR 7740 (1984) (''Credit Practices Rule SBP''); *Orkin Exterminating Co.,* Inc., 108 F.T.C. 263 (1986); aff'd, *FTC* v. *Orkin,* 849 F.2d 1354 (11th Cir. 1988).

[9] FTC Policy Statement on Deception (Oct. 14, 1983), 103 F.T.C. 174, 175 (1984) (appended to *Cliffdale Assocs., Inc.,* 103 F.T.C. 110 (1984)).

[10] The proposal recognized that if Congress directed the Department to issue a rule declaring a specific practice to be unfair or deceptive, then the Department would do so without reference to the Department's own definitions.

will continue unchanged after the issuance of this final rule. Third, in future enforcement orders, if a specific regulation does not apply to the practice in question, the Department would explain the basis for its finding that a practice was unfair or deceptive. The Department is of the view that these measures generally codify existing practice.

In addition, the Department solicited comment on related matters. For example, the Department asked whether the term ''practice'' should be defined. The Department also noted that it relies on its general unfair and deceptive practices authority in certain specialized areas (*e.g.,* privacy, frequent flyer programs, and air ambulance service) and asked whether the proposed general definitions of ''unfair'' or ''deceptive'' were sufficient to provide stakeholders sufficient notice of what constitutes an unfair or deceptive practice in these or other subject areas.

The comment period for the NPRM was originally scheduled to expire on April 28, 2020. However, in response to a request by consumer advocacy organizations, the comment period was extended to May 28, 2020.

II. Summary of NPRM Comments and the Department's Responses

A. Overview

The Department received a total of 224 comments by the end of the comment period. Approximately 180 comments were filed by individual consumers, who almost uniformly opposed the NPRM. Individual consumers typically did not comment on any specific provision, but instead opposed the NPRM as a whole, viewing it as a weakening of aviation consumer protection. Many consumers noted with disapproval that the NPRM was initiated at the request of airlines, which in their view engage in practices that are anti-consumer.

Consumer advocacy organizations [11] and two FTC Commissioners [12] generally opposed the proposals on the ground that they were either unnecessary or weakened consumer protection. Four Senators and one Member of Congress [13] urged the Department to discontinue the NPRM for many of the same reasons identified by consumer advocates and the FTC Commissioners.

Airline associations, individual airlines, and a nonprofit public policy organization [14] broadly supported the proposals in the NPRM on the ground that they provided greater transparency and due process in the Department's rulemaking and enforcement activities. Airlines also suggested that the Department adopt additional provisions, which will be discussed in greater detail below.

Travel agent representatives and a large travel agency [15] generally supported the NPRM for the reasons expressed by airlines; however, they opposed the proposal to adopt hearing procedures relating to discretionary aviation consumer protection rulemakings.

We will discuss the comments in further detail below.

B. Definitions

1. Definitions of ''Unfair'' and ''Deceptive''

Consumer advocacy organizations generally recognized that the proposed definitions of ''unfair'' and ''deceptive'' mirror the FTC's interpretation of those terms. They argued, however, that the Department should not limit itself to those specific definitions. They contended that the flexibility of undefined terms serves as a deterrent to engaging in practices that do not fit within the proposed definitions, but which may nevertheless be unfair or deceptive.

They argued that this flexibility is especially important in the field of air transportation because the Airline Deregulation Act (ADA) prohibits States from regulating the unfair and deceptive practices of airlines. They contended that outside of the field of aviation, State consumer protection laws serve as a backstop to the FTC's authority, and that many consumer protection agencies take aggressive and successful action under State law with respect to practices that would not qualify as unfair or deceptive under the FTC's definitions. They also observed that because of ADA preemption, relief in court is generally limited to Federal class-actions or small claims. Consumer organizations concluded that the FTC definitions may be used for guidance, but should not be transformed into regulatory text.

FTC Commissioner Chopra urged the Department not to adopt the FTC's definitions, for many of the reasons identified by consumer advocacy organizations. He also raised several additional concerns. First, he argued that after the FTC adopted its Policy Statement on Unfairness in 1980, the Commission's ''number of enforcement actions and rulemakings plummeted, leaving a vacuum that hobbled development of the law.'' [16] Commissioner Chopra also argued that ''the key planks undergirding the FTC's unfairness definition—competitive markets, consumer choice, and a de-emphasis on public policy—are poorly suited to airline regulation,'' because the aviation market is not competitive, in his view, and because the Transportation Code affirmatively requires the Secretary to emphasize certain public policies.[17] He also argued that the proposed definitions do not adequately take these policies into account.

Airlines and travel agents supported the proposed definitions, arguing that they provide much-needed transparency and predictability to regulated industries. Southwest Airlines argued that the lack of clear definitions has led DOT to overreach in certain past rulemakings and enforcement actions. Southwest also argued that the third prong of the unfairness definition (*i.e.,* that the harm of the practice ''is not outweighed by countervailing benefits to consumers or to competition'') correctly reflects departmental policy to place ''maximum reliance on competitive market forces and on actual and potential competition.'' [18] Spirit Airlines suggested that the proposed definition of ''deceptive,'' which currently refers to misleading a singular ''consumer'' acting reasonably under the circumstances, should be written in the plural to reflect that the practice must be misleading to ''consumers'' in the aggregate. Travel agents argued that because DOT and FTC share jurisdiction over them, it is important for the two regulatory standards to be harmonious.

[11] Travelers United, Flyersrights.org, National Consumers League, Consumer Action, American Association for Justice (formerly American Trial Lawyers' Association), Travel Fairness Now, Consumer Reports, Consumer Federation of America, and US PIRG.

[12] Commissioners Rebecca Kelly Slaughter and Rohit Chopra.

[13] Senators Edward J. Markey, Tammy Baldwin, Maria Cantwell, and Richard Blumenthal and Representative Katie Porter.

[14] Airlines for America (A4A), International Air Transport Association (IATA), National Business Aviation Association (NBAA), U.S. Tour Operators Association (USTOA), Spirit Airlines, Southwest Airlines, and the Competitive Enterprise Institute (CEI).

[15] Travel Tech and BCD Travel USA.

[16] Comment of Commissioner Chopra at 2. He particularly noted that in the years after adoption of the Policy Statement, the FTC failed to take action against predatory lending and the deceptive practices of the tobacco industry; instead, states took the lead, and the FTC's authority over consumer lending practices was transferred to the Consumer Financial Protection Bureau (CFPB), which has a broader standard for taking enforcement action than the FTC. *Id.* at 6–8.

[17] *Id.* at 10.

[18] Southwest comment at 4, citing 49 U.S.C. 40101(a)(6), (12).

After reviewing the comments, the Department remains of the view that it should adopt the definitions of ''unfair'' and ''deceptive'' as proposed. We are guided by the principles set forth in our recent final rule, ''Administrative Rulemaking, Guidance, and Enforcement Procedures,'' which seeks to provide greater transparency to regulated entities when conducting enforcement actions and adjudications.[19] Offering clear definitions of ''unfair'' and ''deceptive'' will serve this goal. We note that transparency and clarity is particularly needed with respect to ticket agents, which are subject to both FTC and DOT jurisdiction.

We stress that the definitions that we adopt do not reflect a substantive departure from past DOT practice. As we explained in the NPRM, DOT has traditionally relied on these definitions when taking enforcement and discretionary rulemaking actions. Therefore, the Department is not of the view that codifying these definitions will diminish the Department's authority to take enforcement action or to regulate effectively.

We recognize the argument of consumer advocacy organizations and Commissioner Chopra that the ADA preempts State consumer protection agencies from acting as a more aggressive backstop to DOT action. At present, however, we are of the view that the proposed definitions are adequate to ensure regulations continue to prohibit unfair and deceptive practices while at the same time providing necessary transparency to the regulated industry. We also recognize that under FTC practice, the role of public policy is explicitly deemphasized,[20] while Congress has directed the Department to take into account a variety of policies in conducting economic regulation of air transportation.[21] We are not convinced that this distinction compels a different result. While the definitions of ''unfair'' and ''deceptive'' will remain the guiding principles for regulation and enforcement, in doing so, the Department recognizes its statutory responsibility to consider the public policies enumerated by Congress. These policies include safety, ensuring economic competition, *and* preventing unfair and deceptive practices.[22]

2. Intent as an Element of Unfairness or Deception

The proposed rule would clarify that intent is not an element of either unfairness or deception. We received relatively few comments on this issue. FTC Commissioners Chopra and Slaughter both expressed the view that the Department's position was legally correct. A4A and IATA, however, urged the Department to adopt an ''intent to deceive'' standard for both unfairness and deception. In the alternative, they urged the Department to give lack of intent ''significant weight'' when exercising its enforcement discretion.

We remain of the view that intent is not an element of either unfairness or deception.[23] We also reject A4A and IATA's suggestion to adopt an intent requirement. Such a requirement would place the Department's view of unfairness and deception substantially out of step with FTC precedent. It would also limit the Department's consumer protection actions to only those matters where parties establish and the Department can substantiate the private intent of carriers and ticket agents. In light of the revisions to the Department's rulemaking and enforcement procedures adopted in this final rule to enhance the justifications for actions taken under the Department's statutory authority, we view this as an unnecessary and unacceptably high bar. We also decline to include in the regulation the weight that lack of intent should be given in any future enforcement action, because the proper exercise of enforcement discretion generally involves an individualized consideration of a variety of factors.[24]

3. Definition of Additional Terms

Airlines urged the Department to define further the component elements of unfairness and deception, such as ''substantial harm,'' ''likely to mislead,'' ''reasonably avoidable,'' and ''acting reasonably under the circumstances.'' In general, airlines asked the Department to adapt into regulatory text certain aspects (but not all of the aspects) of the FTC's guidance on these terms, as found in the 1980 Policy Statement on Unfairness and the 1983 Policy Statement on Deception. We decline this invitation, because the regulatory text adequately explains the necessary elements of unfairness and deception.[25] The Department will continue to look to the FTC Policy Statements, as well as FTC precedent and the Department's own precedent, for guidance in determining whether any specific practice meets all of the component elements of unfairness and deception.

4. Definition of ''Practice''

In the NPRM, the Department noted that neither the DOT nor the FTC Act defines ''practice.'' The Department indicated that it did not believe that a definition of ''practice'' was necessary, because its aviation consumer protection regulations are always directed to ''practices'' rather than individual acts. The Department also explained that its enforcement efforts include a determination that the conduct in question reflects a practice or policy affecting multiple consumers, rather than an isolated incident. We concluded that ''in general, the Department is of the view that proof of a practice in the aviation consumer

[19] 84 FR 71716, citing Executive Order 13892, ''Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication'' (October 9, 2019).

[20] As noted above, pursuant to 15 U.S.C. 45(n), the FTC may rely on public policy, along with other evidence, for making a determination of unfairness, but public policy may not be the primary basis of its decision.

[21] 49 U.S.C. 40101 (directing the Department, when engaging in economic regulation of air transportation, to consider 16 matters, ''among others, as being in the public interest and consistent with public convenience and necessity.'')

[22] See 49 U.S.C. 40101(a)(1), (4), (6), (7), (9), and (12).

[23] See 85 FR 11885 (intent is not required under Federal case law interpreting the FTC Act, and noting that the definition of ''false advertisement'' in the FTC Act makes no reference to intent to deceive).

[24] See 49 CFR 5.97 (''Where applicable statutes vest the agency with discretion with regard to the amount or type of penalty sought or imposed, the penalty should reflect due regard for fairness, the scale of the violation, the violator's knowledge and intent, and any mitigating factors (such as whether the violator is a small business)'').

[25] For example, A4A/IATA asks the Department to define ''substantial harm'' as not involving merely trivial or speculative harm. A4A/IATA comment at 6, citing 1980 FTC Policy Statement on Unfairness. We are of the view that this clarification is unnecessary because the term ''substantial harm'' would necessarily exclude ''trivial or speculative harm.'' (We also observe, however, that in keeping with 15 U.S.C. 45(n), a practice is unfair not only if it causes substantial harm, but if also it is *likely* to cause substantial harm.)

Similarly, A4A/IATA asks us to define ''not reasonably avoided'' as excluding circumstances where a consumer's willful, intentional, or reckless conduct leads to harm (for example, by intentionally taking advantage of a mistakenly published fare). We are of the view that in general, the term ''not reasonably avoided'' would necessarily exclude the types of self-imposed harms described by A4A and IATA. We also note that mistaken fares are governed by a specific regulation relating to post-purchase price increases (14 CFR 399.88). The Department has issued guidance with respect to mistaken fares at *https://www.transportation.gov/sites/dot.gov/files/docs/Mistaken_Fare_Policy_Statement_05082015_0.pdf.*

Finally, A4A, IATA, Southwest, and Spirit all stress under the 1983 FTC Policy Statement on Deception, deception should be judged by reference to reasonable consumers as a whole, and that a single consumer's unreasonable interpretation of a statement does not make it deceptive. We agree that deception is judged in reference to a reasonable consumer and believe that these concepts are adequately reflected in the phrase ''acting reasonably under the circumstances,'' regardless of whether the word ''consumer'' is singular or plural.

protection context requires more than a single isolated incident. On the other hand, even a single incident may be indicative of a practice if it reflects company policy, training, or lack of training.'' [26] We sought comment, however, on whether a definition of ''practice'' was necessary.

We received relatively few comments on this issue. Consumer advocacy organizations largely did not address it. Spirit, Travel Tech, and FTC Commissioner Slaughter opined that a definition was not necessary. The NBAA and USTOA urged the Department to adopt a definition that reflected the Department's current understanding, described above. A4A and IATA urged the Department to define ''practice'' as ''a pattern of repetitive conduct that harmed multiple consumers rather than a single act.'' [27] A4A and IATA stated that under this standard, one ''mistaken advertisement'' would not be a practice even if the same advertisement runs multiple times.[28] Relatedly, A4A and IATA urged the Department to refrain from taking enforcement action with respect to ''a single act or isolated acts by a carrier,'' and instead take action only if the conduct is repeated after a warning.[29]

After reviewing the comments on this issue, we remain of the view that it is not necessary to define ''practice.'' The Department notes that this issue will arise in relatively rare instances where the Department seeks to take enforcement action in an area where no specific regulation applies, and where there is a reasonable disagreement over whether the conduct reflects a truly isolated incident. In such cases, regulated entities will have the opportunity to be heard and to present evidence that the conduct at issue does not constitute a practice, as set forth in this rule.

C. Rulemaking Proposals

In the NPRM, the Department proposed a hearing procedure that would be available when the Department proposed a discretionary aviation consumer protection rulemaking declaring a practice to be unfair or deceptive. To summarize, after the issuance of an NPRM, interested parties could request a formal hearing on the ground that the proposed rule raised one or more disputed technical, scientific, economic, or other complex factual issues. The General Counsel would have the authority to grant or deny the hearing using criteria set forth in this rule. If the hearing is granted, an Administrative Law Judge or other neutral hearing officer would conduct the formal hearing using procedures adapted from the Administrative Procedure Act (APA) or similar rules adopted by the Secretary. The hearing officer would issue a detailed report on the disputed factual issue(s), after which the General Counsel would determine whether the proposed rule should be continued, amended, or terminated.

Consumer advocacy organizations strongly urged the Department not to adopt these hearing procedures. They argued that the Department did not demonstrate that the typical notice-and-comment procedures of the APA were inadequate to gather a proper factual basis for discretionary rulemakings. Some commenters noted that these hearing procedures were unnecessary given the updates to the Department's general rulemaking procedures in 49 CFR part 5. They also contended that formal hearing procedures will inevitably create lengthy delays and numerous opportunities for regulated entities to lobby against the proposed rule. Some commenters argued that the proposed rulemaking has more liberal standards for granting a hearing than there are for denying a hearing; as a result, hearings will threaten to become the norm. Other advocates observed that the proposal does not have a clear mechanism for consumers to argue that a hearing is not necessary.

FTC Commissioner Slaughter commented on the FTC's own experience with similar formal hearing procedures, which were imposed by Congress, known as ''Mag-Moss'' procedures.[30] Commissioner Slaughter argued that such hearing procedures do not make rulemaking impossible, but ''the great difficulty of undergoing a Mag-Moss rulemaking compared with rulemaking under the APA should not be understated. The additional procedural requirements represent an enormous drain on staff resources, to say nothing of the additional time and effort they require of stakeholders.'' [31] She argued that there is a growing bipartisan consensus for the FTC to issue privacy regulations not under Mag-Moss, but instead under APA procedures. Commissioner Slaughter argued that if the Department issues its own privacy regulations using the proposed formal hearing procedures, the Department will ''create a regulatory incongruence in which the Department is the slowest and least capable regulator in the privacy arena.'' [32]

Ticket agents also urged the Department not to adopt formal hearing procedures, for many of the reasons cited by consumer advocates and Commissioner Slaughter. Travel Tech noted the incongruity of the Department requiring heightened hearing procedures only for its highest-cost rules and for discretionary aviation consumer protection rules, which generally do not impose nearly such a high economic burden.[33] Travel Tech also argued that the Department's institutional expertise in aviation consumer protection matters ensures that formal hearing will generally not be necessary. Travel Tech contended that formal hearings should only be required when directed by Congress or under very limited and unusual circumstances.[34]

Airlines generally favored the proposal on the ground that it provides regulated entities with an opportunity to test thoroughly the factual assumptions on which discretionary consumer protections are based. They argued that such hearings are helpful to determine whether a market failure has taken place such that regulation is necessary.[35]

After careful review of the comments in this area, the Department has decided to retain a hearing procedure that would be available when the Department proposes a discretionary aviation consumer protection rulemaking declaring a practice to be unfair or deceptive. This is consistent with section 41712, which requires notice and an opportunity for a hearing before a finding that an air carrier, foreign air carrier, or ticket agent is engaged in an

[26] 85 FR 11885.

[27] Comment of A4A/IATA at 12.

[28] *Id.*

[29] *Id.* at 13.

[30] See 15 U.S.C. 57a (codifying the Magnuson-Moss Warranty—Federal Trade Commission Improvement Act of 1975, Public Law 93–637 (''Mag-Moss'').

[31] Comment of Commissioner Slaughter at 3.

[32] *Id.* at 4.

[33] Comment of Travel Tech at 6–7.

[34] *Id.* at 9 (''Travel Tech thus proposes that a formal fact-finding hearing would only be appropriate in the very unusual circumstance when either Congress directs that a specific rule be adopted only after an on the record hearing or when the agency's General Counsel finds that a specific factual issue critical to a claim that a particular practice is unfair or deceptive (and not an economic or policy consideration) is in dispute and cannot be adequately resolved through the usual notice-and-comment process.)''

[35] A4A Comment at 16, citing 49 CFR 5.11 (before initiating a rulemaking, the Department should identify ''the need for the regulation, including a description of the market failure or statutory mandate necessitating the rulemaking''). See also comment of Spirit Airlines (arguing that the Department's repealed NPRM on dissemination of ancillary fees to third party ticket sellers was based on conflicting/misleading information regarding passengers' ability to get this information). Spirit also argued that the Department should engage in Advance Notice of Proposed Rulemaking (ANPRM) to gather comment on whether practices are unfair or deceptive.

unfair or deceptive practice or an unfair method of competition. The Department sees value in offering additional hearing procedures for low-cost discretionary aviation consumer protection rules where scientific, technical, economic, or other factual issues are genuinely in dispute. At the same time, the Department recognizes the concerns raised by commenters that formal hearing procedures may add time to the rulemaking process. As such, the hearing procedures for discretionary aviation consumer protection rules set forth in this final rule differ from the procedures set forth in the Department's general rulemaking procedures in 49 CFR part 5 for the Department's high-impact or economically significant rules. For example, under this final rule, the General Counsel would be free to adopt more flexible rules for the hearing than would be required for a high-impact or economically significant rulemaking. The General Counsel also has more flexibility with respect to appointing an appropriate hearing officer for such hearings. Finally, the presiding officer is not required to issue a report; the officer need only place on the docket minutes of the hearing with sufficient detail as to reflect fully the evidence and arguments presented on the disputed issues of fact, along with proposed findings addressing those issues. By adopting hearing procedures for discretionary aviation consumer protection rulemakings that are less stringent and more flexible than the formal hearing procedures for high impact or economically significant rules, the Department ensures that interested parties have an opportunity to test factual assumptions on which discretionary consumer protection rulemaking actions are based, consistent with the underlying statutory authority under which the Department is regulating, while minimizing the likelihood of extensive delays or a drain on staff resources.

These procedures, as modified, reflect the Department's continued view that interested parties should have the opportunity to be heard when the Department proposes discretionary rulemakings that may be based on complex and disputed economic, technical, or other factual issues. We also note that the ordinary notice and comment procedures of the APA remain the default process: To obtain a hearing, the party requesting the hearing has the initial burden of showing that, among other factors, the ordinary notice and comment procedures are unlikely to provide an adequate examination of the issues to permit a fully informed judgment. The rule retains the safeguard that the General Counsel may decline a hearing if it would unreasonably delay the rulemaking. We also generally disagree with commenters who stated that the standards for granting a hearing are necessarily more lenient than the standards for denying them.

We also note that the Department's use of similar procedures to supplement traditional notice-and-comment is not new.[36] For example, in 2011, the Department's Bureau of Transportation Statistics held a public meeting to gather information about industry practices for processing and accounting for baggage and wheelchairs, in connection with a pending rulemaking.[37] More recently, the Department asked the Architectural and Transportation Barriers Compliance Board (Access Board) to hold a hearing to gather public input on potential new standards for on-board wheelchairs, also in connection with a pending rulemaking.[38] The Department recognizes certain differences between the public meetings that sometimes were held in the context of earlier rulemakings [39] and the hearings contemplated by this rule. For example, hearings will be held before a neutral officer, who must make findings on the record, while public meetings were previously led by staff from the government office involved in the rulemaking and findings were not separately summarized and placed on the record but rather were noted in the preamble if they were relied on in the rulemaking. Moreover, this rule clearly identifies procedures to all interested persons that hearings may be requested, while previously there was no formal process to request a public meeting so they were more likely to have been instituted by the Department or requested only by those parties that knew that the Department was open to holding public meetings in appropriate instances. In sum, while the hearing procedures reflected in the final rule may result in some additional delays to the rulemaking process beyond what was experienced with public meetings, on the whole the new procedures will promote fairness, due process, and well-informed rulemaking, without unduly delaying the proceeding itself, and represent a reasonable and balanced approach consistent with the Department's rulemaking and enforcement policies.

D. Enforcement Proposals

In the NPRM, the Department proposed to codify certain enforcement practices. First, the Department proposed that before the Office of Aviation Consumer Protection determined how to resolve a matter involving a potential unfair or deceptive practice, it would provide an opportunity for the alleged violator to be heard and to present relevant evidence in its defense. Such evidence would include, but not be limited to, the following: (1) Evidence that the consumer protection regulation at issue was not violated; (2) evidence that the conduct was not unfair or deceptive (if no specific regulation applied); and (3) evidence that that consumer harm was limited or that the alleged violator has taken steps to mitigate the harm. The Department also proposed that when the Office issued a consent order declaring that a practice was unfair or deceptive, and no specific regulation applied to the conduct at issue, then the Office would explain the basis for its finding that the conduct was unfair or deceptive, using the definitions set forth in this rule. Finally, the Department clarified that if the Office took enforcement action against a regulated entity by filing a complaint with an Administrative Law Judge, then the entity would have the opportunity for notice and a hearing as set forth in 14 CFR part 302. We noted that these procedures reflected the longstanding practices of the Office of Aviation Consumer Protection.

We received few comments on this element of the proposed rule. Most consumer advocates did not opine on the issue, while National Consumers League and Consumer Action advised that they were unnecessary. Travel Fairness Now generally did not object to the measures, but urged the Department to declare that an unfair or deceptive practice with limited consumer harm would still be subject to enforcement action. Airlines and ticket agents generally supported these proposals.

In the final rule, we will adopt these measures as proposed in the NPRM. They reflect current practice, and afford reasonable due process to regulated entities. These specific measures are also consistent with the general principles set forth in the Department's

[36] See *https://cms7.dot.gov/regulations/rulemaking-process,* under ''May an agency supplement the APA requirements?'' (''We may use public meetings or hearings before or after a proposal is issued for a variety of reasons. Public meetings allow us to ask questions. They allow for interaction among participants with different views on the issues involved, and they provide a better opportunity for members of the public who believe they are more effective making oral presentations than submitting written comments.'')

[37] See *https://www.regulations.gov/document?D=RITA-2011-0001-0280.*

[38] 84 FR 43100 (August 20, 2019); see *https://www.regulations.gov/document?D=ATBCB-2019-0002-0001.*

[39] *E.g.,* 77 FR 25105 (April 27, 2012).

recent final rule relating to enforcement.[40]

E. Privacy, Air Ambulance, and Frequent Flyer Programs

The Department solicited comment on whether the general definitions of ''unfair'' or ''deceptive'' were sufficient to give notice to stakeholders of what constitutes unfair or deceptive practices with respect to the specialized fields of privacy, air ambulance service, and frequent flyer programs. While we did not receive specific comments related to frequent flyer programs, we did receive comment with respect to privacy and air ambulance service.

A4A asked the Department to declare that the Department has exclusive jurisdiction over airlines with respect to privacy practices. A4A also asked the Department to adopt detailed privacy regulations. A4A's proposal would declare that ''mishandling private information may be considered an unfair or deceptive practice,'' and that ''specific examples of unfair or deceptive practices with regard to the private information of consumers include'' violating the terms of the airline's privacy policy, failing to maintain reasonable data security measures for passengers' private information, and violating various privacy statutes.

We generally agree with the substance of A4A's proposal; indeed, it appears to be adapted from the privacy page of the Department's consumer protection website, which recites many of these principles.[41] Nevertheless, we decline to adopt it for procedural reasons. As noted above, one of the Department's stated policies is to improve transparency and public participation in the rulemaking process. If the Department were to adopt detailed privacy regulations affecting air transportation and the sale of air transportation, it should first engage in the full notice-and-comment procedures of the APA, as well as the procedures set forth in this final rule.

Next, we received comments from insurers, air ambulance providers, and other interested parties about the regulation of air ambulance providers. The National Association of Insurance Commissioners and nine researchers on health law, economics, and policy[42] urged the Department to declare that balance billing is an unfair practice because it imposes substantial harm on patients who had no ability to avoid the charges, without countervailing benefits to consumers or to competition. Separately, the researchers urged the Department to find that charging full out-of-network prices for air ambulance service is an unfair practice, in part because of its effect on the private insurance market. Air ambulance operators[43] argued that specific regulation of air ambulance providers in this rulemaking would be premature at best, because the Air Ambulance and Patient Billing (AAPB) Advisory Committee has been established to address these issues comprehensively. Air ambulance operators also argued that balance billing should not be considered an unfair or deceptive practice. They contend that much of the consumer harm from balance billing arises from the practices of insurers, rather than air ambulance providers (for example, by under paying out-of-network air ambulance bills, or denying claims that were medically necessary). They also argue that many patients who receive a large balance bill ultimately pay a small fraction of that amount out-of-pocket.

After consideration of the comments submitted on this issue, we decline to adopt specific regulations relating to air ambulance providers. Section 418 of the FAA Reauthorization Act of 2018 (FAA Reauthorization Act) requires the Secretary, in consultation with the Secretary of Health and Human Services, to establish an advisory committee to review options to improve the disclosure of charges and fees for air medical services, better inform consumers of insurance options for such services, and protect consumers from balance billing. The FAA Reauthorization Act also contemplates that the Advisory Committee's report and recommendations will serve as the basis for future regulations or other guidance as deemed necessary to provide other consumer protections for customers of air ambulance providers.[44] We agree that the most prudent course of action is to allow the work of the AAPB Advisory Committee to run its course, rather than to issue more detailed regulations relating to air ambulance providers in this final rule.

F. Other Comments

We will address briefly a number of comments that do not fall squarely within the categories described above. First, A4A and IATA urge the Department to adopt a ''clear and convincing evidence'' standard for enforcement of unfair and deceptive practices. We decline to enact such a burden of proof standard here, particularly in light of the fact that most enforcement cases are adjudicated not through the courts, but rather through voluntary consent orders. We also note that during these informal proceedings, regulated entities have the opportunity to present mitigating evidence as set forth above.

Next, A4A and IATA urge the Department to require the Office of Aviation Consumer Protection to present evidence on all of the elements of unfairness and deception, even in cases where a specific regulation enacted under the authority of section 41712 applies to the conduct in question. We decline this request because doing so would be unduly burdensome with limited or no benefit. By enacting a regulation under the authority of section 41712, the Department has already determined, after notice and comment, that the conduct in question is unfair or deceptive; in such cases, it should be sufficient to establish that the regulation itself was violated.[45] A4A and IATA also urge that they should be able to present mitigating evidence with respect to all of the prongs of unfairness and deception. We note that in informal enforcement proceedings involving the violation of specific regulations, regulated entities would have the opportunity to present relevant evidence, including evidence that consumer harm was limited.

Next, A4A and IATA argue that the Office of Aviation Consumer Protection should affirmatively furnish ''exculpatory evidence'' in its possession. We agree with this practice, and the Office is required to do so under the Department's existing enforcement procedures, which are set forth in another rule.[46]

[40] See, *e.g.,* 49 CFR 5.57 (''Enforcement adjudications require the opportunity for participation by directly affected parties and the right to present a response to a decision maker, including relevant evidence and reasoned arguments''); 49 CFR 5.59 (Department's enforcement action should conclude with, among other things, a ''well-documented decision as to violations alleged and any violations found to have been committed.'')

[41] *https://www.transportation.gov/individuals/aviation-consumer-protection/privacy.*

[42] See *https://www.regulations.gov/document?D=DOT-OST-2019-0182-0193.*

[43] Association of Air Medical Services, Air Methods, and PHI Health, LLC.

[44] For further information about the AAPB Advisory Committee, see *https://www.transportation.gov/airconsumer/AAPB* and the Committee's docket, available at *https://www.regulations.gov/docket?D=DOT-OST-2018-0206.*

[45] See Comment of Travel Fairness Now (urging the Department to clarify that it will not use this final rule as a vehicle for repealing existing regulations, because they were well justified).

[46] 49 CFR 5.89 (duty to disclose exculpatory evidence).

G. Formal Enforcement Proceedings

In the NPRM, the Department proposed to clarify that if regulated entities do not enter into a negotiated settlement with the Office of Aviation Consumer Protection with respect to potential violations of section 41712, then the Office may initiate a formal enforcement proceeding, and that hearings are available through this process. The Department did not receive comments on this provision, which restates current procedures found in 14 CFR part 302. In this final rule, the Department has made nonsubstantive editorial changes to the regulatory text such as adding a citation to a specific section of part 302. The Department has determined that good cause exists to dispense with notice and comment for these nonsubstantive editorial changes because they are ministerial in nature; therefore, public comment is unnecessary under 5 U.S.C. 553(b)(B).

III. Regulatory Analyses and Notices

A. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs), Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures (49 CFR Part 5)

This final rule is a significant regulatory action under section 3(f) of E.O. 12866, ''Regulatory Planning and Review'' (Oct. 4, 1993), supplemented by E.O. 13563, ''Improving Regulation and Regulatory Review'' (Jan. 21, 2011). Accordingly, the Office of Management and Budget (OMB) has reviewed it under that Order. This final rule is issued in accordance with the Department's rulemaking procedures found in 49 CFR part 5 and DOT Order 2100.6.

This rule primarily involves agency procedure and interpretation. It clarifies how the Department interprets the terms ''unfair'' and ''deceptive'' and requires enhanced departmental procedures for regulation and enforcement in the area of aviation consumer protection. Clarifying and explicitly defining terminology advances the Department's goal of improved transparency. Adopting enhanced procedures for future rulemaking and enforcement activities will help to ensure that the activities are rooted in fairness, due process, and an adequate factual foundation. These goals are described in the Department's final rule, ''Administrative Rulemaking, Guidance, and Enforcement Procedures.'' [47]

This rule aligns the Department's policies and rules involving unfairness and deception in aviation consumer protection explicitly with principles adopted by the FTC. In the Department's view, aligning the terms ''unfair'' and ''deceptive'' does not represent a substantive departure from past DOT practice. The definitions simply provide additional clarification to the public and regulated industries, and are not expected to affect the Department's ability to prohibit unfair and deceptive practices. While clarifying the terms is not expected to lead to changes that would impact the Department, public, or any regulated entity, it provides a foundation for the other elements of this rule pertaining to future rulemaking and enforcement actions.

Effects on Future Rulemakings

This final rule will require the Department to use specific definitions of the terms ''unfair'' and ''deceptive'' when declaring certain practices to be unfair or deceptive in future discretionary rulemakings.

Specifically, this final rule requires the Department to support a finding of an ''unfair'' practice by demonstrating that the harm to consumers is (1) substantial; (2) not reasonably avoidable; and (3) not outweighed by offsetting benefits to consumers or competition. Similarly, it requires the Department to support a finding that a practice is ''deceptive'' by showing that: (1) The practice actually misleads or is likely to mislead consumers; (2) who are acting reasonably under the circumstances; (3) with respect to a material matter.

The Department has declared certain practices to be unfair or deceptive in several prior rulemakings, including the full fare advertising rule (14 CFR 399.84) and oversales rule (14 CFR part 250). In the supporting analysis for these rulemakings, the Department justified its finding of unfairness or deception without using the full three-pronged analysis for unfairness or deception found in this final rule.[48]

In other instances, the Department has based its discretionary regulations on both section 41712 and other statutes. For example, the rule requiring on-time performance information during booking (14 CFR 234.11(b)) was based on both section 41712 and section 41702 (requiring carriers to provide safe and adequate interstate air transportation).[49] While the Department partly relied on a finding of consumer harm under section 41712 as the basis for that requirement, it did not engage in the full three-part analysis for unfairness found in this final rule.

Demonstrating support for findings of unfairness or deception requires an analysis of data, which is generally collected and organized as part of a regulatory impact analysis (RIA). Factors such as potential harm to consumers, benefits to consumers or competition, whether a consumer can avoid harm, and whether a harm is ''material'' relate to the economic benefits and costs of regulating a practice. These benefits and costs are analyzed in an RIA and offer a rationale for finding a practice ''unfair'' or ''deceptive.''

The Department customarily prepares a RIA or other regulatory evaluation as part of the E.O. 12866 review process for rulemakings involving aviation consumer protection. Further, the Department's final rule on ''Administrative Rulemaking, Guidance, and Enforcement Procedures'' requires that all rulemakings including a supporting economic analysis. The Department will therefore need to continue to collect, organize, and analyze data and facts to address economic impacts.

The Department's current practice of collecting and analyzing data, either for E.O. 12866 or departmental review, allows it to generate the necessary factual basis to support an explicit discussion of unfair or deceptive findings with little additional effort. While this final rule may result in the Department expending additional resources to prepare future discretionary aviation consumer protection rules and supporting analyses, the resources are expected to be small and more than justified by better, more deliberative internal decisions. Better internal decisions will improve rulemaking efficiency by reducing the resources needed to follow E.O. 12866 processes. The additional procedures required by this rule are expected to result in improved regulations that achieve their goals of protecting consumers without imposing any more burdens on regulated industry than necessary.

This rule does not require that the Department review existing rules to determine whether previous ''unfair'' or ''deceptive'' declarations would have been supported by the criteria described above. Existing rules are subject to retrospective review requirements under the Department's rulemaking procedures found in 49 CFR part 5, DOT Order 2100.6, and other legal requirements, as applicable. The Department will consider whether

[47] 84 FR 71714 (Dec. 27, 2019).

[48] See 76 FR 23110 (April 25, 2011).

[49] See 73 FR 74586 (December 8, 2008) (NPRM: ''Enhancing Passenger Airline Protections'').

existing discretionary aviation consumer protection rules such as full fare advertising, oversales and refunds meet the standards found in this rule when performing the retrospective reviews, but it is not possible to judge the impact of this rule on the rules until the Department conducts the reviews. The Department considers many factors when conducting its retrospective reviews, including the continuing need for the rule and whether the rule has achieved its intended outcomes. It is unlikely that an existing rule would fail the standards set forth in this rule without failing existing standards that would prompt the Department to revise or rescind the rule. Judging the impact of this rule is confounded further because some existing rules do not rely solely on section 41712, as is the case with the rule requiring on-time performance information during booking noted above.

Under this rule, future discretionary rulemakings could be subject to a hearing procedure. The rule allows interested parties to request a hearing when the Department proposes a rule to classify a practice as unfair or deceptive, when the issuance of the NPRM raises one or more disputed technical, scientific, economic, or other complex factual issues, or when the NPRM may not satisfy the requirements of the Information Quality Act. Allowing interested parties an opportunity for a hearing ensures that they can test the information informing discretionary consumer protection regulations. However, following this rule's requirements to provide a sufficient factual basis to support an ''unfair'' or ''deceptive'' finding should reduce the need for the Department to hold such hearings.

Nevertheless, requests for hearings are expected to occur occasionally. While the Department lacks data that would allow it to distinguish the costs and time of conducting the hearings from the costs of conducting its normal business operations, the Department believes that any incremental costs and time would be small relative to the baseline scenario in which the Department did not enact the rule. Previous discretionary rulemakings involving unfair and deceptive practices in aviation consumer protection have attracted substantial interest from consumer advocates, airline industry advocates, and the general public. The Department engaged with these interested parties without the benefit of a formal process, and the engagements required investments of time and resources by the Department and interested parties. Because these engagements were informal and with uncertain scopes, they were not as efficient as would be expected under a more formal process as would be the case under this rule. Without a formal process, parties tend to overinvest in preparation, incurring unnecessary costs, or underinvest, leading to additional engagements and administrative costs. For future rulemakings, establishing formal hearing procedures may reduce costs and time for both groups by increasing certainty about opportunities for engagement.

The hearing procedures established in this final rule are less stringent and more flexible than the hearing procedures for high-impact or economically significant rules detailed in the Department's general rulemaking procedures in 49 CFR part 5 and DOT Order 2100.6. In addition, the Department has experience using hearing procedures to supplement traditional notice-and-comment rulemaking, as described earlier for baggage and wheelchair accounting and for potential on-board wheelchair standards. Finally, the hearing procedures will provide consistency in the Department's exercise of its 41712 authority by mirroring the statute's hearing requirement to ensure rulemakings enacted under the same authority ensure due process, and are grounded in fairness and supported by an adequate factual foundation.

The Department believes that its experience with hearings, coupled with reduced complexity of the hearing procedures, will limit the additional staff resources needed to comply with the requirement and prevent it from leading to excessive delays in issuing aviation consumer protection rules. The General Counsel may also decline a hearing request if following the procedures would unreasonably delay the rulemaking. When deciding to decline a hearing request, the General Counsel will balance the impact of the hearing on departmental resources against the potential value of any information to be collected during the hearing process, and consider the quality of evidence presented, including but not limited to that presented by interested parties and in the Department's RIA and other supporting analyses.

Effects on Future Enforcement Actions

This final rule adds requirements for future enforcement actions analogous to the requirements for discretionary aviation consumer protection rulemakings. The Department will use the same definitions of unfair and deceptive when taking enforcement action against an airline or ticket agent for unfair or deceptive practices. In future enforcement actions, the Department would also provide the airline or ticket agent with the opportunity to be heard and to present mitigating evidence. The opportunity for a hearing before a finding that any air carrier, foreign air carrier, or ticket agent is engaged in an unfair or deceptive practice or an unfair method of competition already exists under section 41712. Finally, in future enforcement orders, if a specific regulation does not apply to the practice in question, the Department would explain the basis for its finding that a practice was unfair or deceptive.

As explained in the NPRM, the Department views these measures as a codification of existing practice, rather than a change in policy, because the Department has typically relied on the explicit definitions of ''unfair'' and ''deceptive'' in prior enforcement orders. Applying these terms and providing an opportunity for a hearing in enforcement proceedings is largely noncontroversial, and the Department received few comments on this element of the rule at the NPRM stage. The Department does not expect to need to expend additional resources in aviation consumer protection proceedings due to this rule, or expect that the rule will increase the amount of time needed to come to resolution. The Department believes that regulated entities could see some benefit, however, from upfront clarification of the guidelines and criteria that the Department follows when enforcing aviation consumer protection regulations involving unfair and deceptive practices.

This rule is not an E.O. 13771 regulatory action because it is does not impose any more than *de minimis* regulatory costs. This final rule provides an additional mechanism for industry to provide input to the Department on its discretionary aviation consumer protection rulemakings. Private industry should not experience more than minimal additional costs relative to the status quo because it already engages in significant information exchange with the Department. Industry has the option of continuing use of historical mechanisms for providing input to discretionary aviation consumer protection, and is not required to make use of the alternatives set forth in this rule. The Department should not experience significant additional costs because it has considerable experience conducting analysis in support of aviation consumer protection rules as well as hearings analogous to those in

this rule. Such efforts are consistent with the Department's normal business operations, and any additional resources needs could be accommodated through a simple and temporary realignment of internal resources.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities. A direct air carrier or foreign air carrier is a small business if it provides air transportation only with small aircraft (*i.e.,* aircraft with up to 60 seats/18,000-pound payload capacity). See 14 CFR 399.73. The Department has determined that this rule does not have a significant economic impact on a substantial number of small entities.

C. Executive Order 13132 (Federalism)

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This final rule does not include any provision that: (1) Has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government; (2) imposes substantial direct compliance costs on State and local governments; or (3) preempts State law. States are already preempted from regulating in this area by the Airline Deregulation Act, 49 U.S.C. 41713. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13175

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). Because this final rule does not significantly or uniquely affect the communities of the Indian Tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13175 do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that DOT consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from the Office of Management and Budget (OMB) for each collection of information it conducts, sponsors, or requires through regulations. The DOT has determined there are no new information collection requirements associated with this final rule.

F. Unfunded Mandates Reform Act

The Department has determined that the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply to this rulemaking.

G. National Environmental Policy Act

The Department has analyzed the environmental impacts of this final rule pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). *See* 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. Id. Paragraph 10.c.16.h of DOT Order 5610.1D categorically excludes ''[a]ctions relating to consumer protection, including regulations.'' Since this rulemaking relates to the definition of unfair and deceptive practices under Section 41712, the Department's central consumer protection statute, this is a consumer protection rulemaking. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

H. Privacy Act

Anyone may search the electronic form of all comments received into any of OST's dockets by the name of the individual submitting the comment, or signing the comment if submitted on behalf of an association, business, labor union, or any other entity. You may review USDOT's complete Privacy Act Statement published in the **Federal Register** on April 11, 2000, at 65 FR 19477–8.

I. Statutory/Legal Authority for This Rulemaking

This rulemaking is issued under the authority of 49 U.S.C. 40113(a), which grants the Secretary the authority to take action that the Secretary considers necessary to carry out 49 U.S.C. Subtitle VII (Aviation Programs), including conducting investigations, prescribing regulations, standards, and procedures, and issuing orders.

J. Regulation Identifier Number

A Regulation Identifier Number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in Spring and Fall of each year. The RIN set forth in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 14 CFR Part 399

Consumer protection, Policies, Rulemaking proceedings, Enforcement, Unfair or deceptive practices.

For the reasons discussed in the preamble, the Department amends 14 CFR part 399 as follows:

PART 399—STATEMENTS OF GENERAL POLICY

■ 1. The authority citation for part 399 is revised to read as follows:

Authority: 49 U.S.C. 41712, 40113(a).

Subpart F—Policies Relating to Rulemaking Proceedings

■ 2. Section 399.75 is added to subpart F to read as follows:

§ 399.75 Rulemakings relating to unfair and deceptive practices.

(a) *General.* When issuing a proposed or final regulation declaring a practice in air transportation or the sale of air transportation to be unfair or deceptive to consumers under the authority of 49 U.S.C. 41712(a), unless the regulation is specifically required by statute, the Department shall employ the definitions of ''unfair'' and ''deceptive'' set forth in § 399.79.

(b) *Procedural requirements.* When issuing a proposed regulation under paragraph (a) of this section that is defined as high impact or economically significant within the meaning of 49 CFR 5.17(a), the Department shall follow the procedural requirements set forth in 49 CFR 5.17. When issuing a proposed regulation under paragraph (a) of this section that is not defined as high impact or economically significant within the meaning of 49 CFR 5.17(a), unless the regulation is specifically required by statute, the Department shall adhere to the following procedural requirements:

(1) *Request for a hearing.* Following publication of a proposed regulation, and before the close of the comment

period, any interested party may file in the rulemaking docket a petition, directed to the General Counsel, to hold a hearing on the proposed regulation.

(2) *Grant of petition for hearing.* Except as provided in paragraph (b)(3) of this section, the petition shall be granted if the petitioner makes a plausible prima facie showing that:

(i) The proposed rule depends on conclusions concerning one or more specific scientific, technical, economic, or other factual issues that are genuinely in dispute or that may not satisfy the requirements of the Information Quality Act;

(ii) The ordinary public comment process is unlikely to provide an adequate examination of the issues to permit a fully informed judgment; and

(iii) The resolution of the disputed factual issues would likely have a material effect on the costs and benefits of the proposed rule.

(3) *Denial of petition for hearing.* A petition meeting the requirements of paragraph (b)(2) of this section may be denied if the General Counsel determines that:

(i) The requested hearing would not advance the consideration of the proposed rule and the General Counsel's ability to make the rulemaking determinations required by this section; or

(ii) The hearing would unreasonably delay completion of the rulemaking.

(4) *Explanation of denial.* If a petition is denied in whole or in part, the General Counsel shall include a detailed explanation of the factual basis for the denial, including findings on each of the relevant factors identified in paragraph (b)(2) or (3) of this section.

(5) *Hearing notice.* If the General Counsel grants the petition, the General Counsel shall publish notification of the hearing in the **Federal Register**. The document shall specify the proposed rule at issue and the specific factual issues to be considered at the hearing. The scope of the hearing shall be limited to the factual issues specified in the notice.

(6) *Hearing process.* (i) A hearing under this section shall be conducted using procedures approved by the General Counsel, and interested parties shall have a reasonable opportunity to participate in the hearing through the presentation of testimony and written submissions.

(ii) The General Counsel shall arrange for a neutral officer to preside over the hearing and shall provide a reasonable opportunity to question the presenters.

(iii) After the hearing and after the record of the hearing is closed, the hearing officer shall place on the docket minutes of the hearing with sufficient detail as to fully reflect the evidence and arguments presented on the issues, along with proposed findings addressing the disputed issues of fact identified in the hearing notice.

(iv) Interested parties who participated in the hearing shall be given an opportunity to file statements of agreement or objection in response to the hearing officer's proposed findings. The complete record of the hearing shall be made part of the rulemaking record.

(7) *Actions following hearing.* (i) Following the completion of the hearing process, the General Counsel shall consider the record of the hearing, including the hearing officer's proposed findings, and shall make a reasoned determination whether to terminate the rulemaking; to proceed with the rulemaking as proposed; or to modify the proposed rule.

(ii) If the General Counsel decides to terminate the rulemaking, the General Counsel shall publish a document in the **Federal Register** announcing the decision and explaining the reasons for the decision.

(iii) If the General Counsel decides to finalize the proposed rule without material modifications, the General Counsel shall explain the reasons for the decision and its responses to the hearing record in the preamble to the final rule.

(iv) If the General Counsel decides to modify the proposed rule in material respects, the General Counsel shall publish a new or supplemental notice of proposed rulemaking in the **Federal Register** explaining the General Counsel's responses to and analysis of the hearing record, setting forth the modifications to the proposed rule, and providing additional reasonable opportunity for public comment on the proposed modified rule.

(8) *Interagency review process.* The hearing procedures under this paragraph (b)(8) shall not impede or interfere with the interagency review process of the Office of Information and Regulatory Affairs for the proposed rulemaking.

(c) *Basis for rulemaking.* When issuing a proposed or final regulation declaring a practice in air transportation or the sale of air transportation to be unfair or deceptive to consumers under the authority of 49 U.S.C. 41712(a), unless the regulation is specifically required by statute, the Department shall articulate the basis for concluding that the practice is unfair or deceptive to consumers as defined in § 399.79.

Subpart G—Policies Relating to Enforcement

■ 3. Section 399.79 is added to subpart G to read as follows:

§ 399.79 Policies relating to unfair and deceptive practices.

(a) *Applicability.* This policy shall apply to the Department's aviation consumer protection actions pursuant to 49 U.S.C. 41712(a).

(b) *Definitions.* (1) A practice is ''unfair'' to consumers if it causes or is likely to cause substantial injury, which is not reasonably avoidable, and the harm is not outweighed by benefits to consumers or competition.

(2) A practice is ''deceptive'' to consumers if it is likely to mislead a consumer, acting reasonably under the circumstances, with respect to a material matter. A matter is material if it is likely to have affected the consumer's conduct or decision with respect to a product or service.

(c) *Intent.* Proof of intent is not necessary to establish unfairness or deception for purposes of 49 U.S.C. 41712(a).

(d) *Specific regulations prevail.* Where an existing regulation applies to the practice of an air carrier, foreign air carrier, or ticket agent, the terms of that regulation apply rather than the general definitions set forth in this section.

(e) *Informal enforcement proceedings* (1) Informal enforcement proceedings will be conducted pursuant to the policies and procedures found in 49 CFR part 5, subpart D. Before any determination is made on how to resolve a matter involving a potential unfair or deceptive practice, the U.S. Department of Transportation's Office of Aviation Consumer Protection will provide an opportunity for the alleged violator to be heard and present relevant evidence, including but not limited to:

(i) In cases where a specific regulation applies, evidence tending to establish that the regulation at issue was not violated and, if applicable, that mitigating circumstances apply;

(ii) In cases where a specific regulation does not apply, evidence tending to establish that the conduct at issue was not unfair or deceptive as defined in paragraph (b) of this section; and

(iii) Evidence tending to establish that consumer harm was limited, or that the air carrier, foreign air carrier, or ticket agent has taken steps to mitigate consumer harm.

(2) During this informal process, if the Office of Aviation Consumer Protection reaches agreement with the alleged violator to resolve the matter with the

issuance of an order declaring a practice in air transportation or the sale of air transportation to be unfair or deceptive to consumers under the authority of 49 U.S.C. 41712(a), and when a regulation issued under the authority of section 41712 does not apply to the practice at issue, then the Department shall articulate in the order the basis for concluding that the practice is unfair or deceptive to consumers as defined in this section.

(f) *Formal enforcement proceedings.* When there are reasonable grounds to believe that an airline or ticket agent has violated 49 U.S.C. 41712, and efforts to settle the matter have failed, the Office of Aviation Consumer Protection may issue a notice instituting an enforcement proceeding before an administrative law judge pursuant to 14 CFR 302.407. After the issues have been formulated, if the matter has not been resolved through pleadings or otherwise, the parties will receive reasonable written notice of the time and place of the hearing as set forth in 14 CFR 302.415.

Issued this 24th day of November, 2020, in Washington, DC, under authority delegated in 49 CFR 1.27(n).

Steven G. Bradbury,

General Counsel.

[FR Doc. 2020–26416 Filed 12–4–20; 8:45 am]

BILLING CODE 4910–9X–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 3

RIN 3038–AE46

Exemption From Registration for Certain Foreign Intermediaries

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (CFTC or Commission) is adopting amendments (Final Rule) revising the conditions set forth in the Commission regulation under which a person located outside of the United States (each, a foreign located person) engaged in the activity of a commodity pool operator (CPO) in connection with commodity interest transactions on behalf of persons located outside the United States (collectively, an offshore commodity pool or offshore pool) would qualify for an exemption from CPO registration and regulation with respect to that offshore pool. The Final Rule provides that the exemption under the applicable Commission regulation for foreign located persons acting as a CPO (a non-U.S. CPO) on behalf of offshore commodity pools may be claimed by such non-U.S. CPOs on a pool-by-pool basis. The Commission is also adopting a provision clarifying that a non-U.S. CPO may claim an exemption from registration under the applicable Commission regulation with respect to a qualifying offshore commodity pool, while maintaining another exemption from CPO registration, relying on a CPO exclusion, or even registering as a CPO, with respect to its operation of other commodity pools. Additionally, the Commission is adopting a safe harbor by which a non-U.S. CPO of an offshore pool may rely upon that exemption, if it satisfies several enumerated factors related to its operation of the offshore commodity pool. The Commission is also adopting an amendment permitting U.S. affiliates of a non-U.S. CPO to contribute initial capital to such non-U.S. CPO's offshore pools, without affecting the eligibility of the non-U.S. CPO for an exemption from registration under the applicable Commission regulation. The Commission is also adopting amendments to the applicable Commission regulation originally proposed in 2016 that clarify whether clearing of commodity interest transactions through a registered futures commission merchant (FCM) is required as a condition of the registration exemptions for foreign intermediaries, and whether such exemption is available for foreign intermediaries acting on behalf of international financial institutions.

DATES: The effective date for this Final Rule is February 5, 2021.

FOR FURTHER INFORMATION CONTACT: Joshua B. Sterling, Director, at 202–418–6056, *jsterling@cftc.gov;* with respect to the finalization of the 2016 Proposal: Frank N. Fisanich, Chief Counsel, at 202–418–5949 or *ffisanich@cftc.gov;* with respect to all other aspects of this release: Amanda Lesher Olear, Deputy Director, at 202–418–5283 or *aolear@cftc.gov;* Pamela Geraghty, Associate Director, at 202–418–5634 or *pgeraghty@cftc.gov;* Elizabeth Groover, Special Counsel, at 202–418–5985 or *egroover@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1151 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

A. Statutory and Regulatory Background

Section 1a(11) of the Commodity Exchange Act (CEA or Act) [1] defines the term ''commodity pool operator'' as any

[1] 7 U.S.C. 1a(11). *See also* 17 CFR 1.3 (defining ''commodity interest'' to include, inter alia, any contract for the purchase or sale of a commodity for future delivery, and any swap as defined in the CEA); Adaptation of Regulations to Incorporate Swaps, 77 FR 66288, 66295 (Nov. 2, 2012) (discussing the modification of the term ''commodity interest'' to include swaps). The Act is found at 7 U.S.C. 1, *et seq.* (2018), and the Commission's regulations are found at 17 CFR Ch. I (2020). Both are accessible through the Commission's website, *https://www.cftc.gov.*

Plaintiffs' Exhibit 525

GAO
Accountability * Integrity * Reliability

United States General Accounting Office
Washington, DC 20548

Resources, Community, and
Economic Development Division

B-283477

September 10, 1999

The Honorable Ron Wyden
United States Senate

Subject: Aviation: Comparison of Airline "Customer Service Commitment" With Contracts of Carriage and Federal Law

Dear Senator Wyden:

Airlines transport their passengers in accordance with various terms and conditions as well as federal statutes and regulations. These terms and conditions are referred to as conditions of contracts or more commonly as contracts of carriage. A contract of carriage is the agreement between the passenger and the airline that encompasses all contractual rights, liabilities, and duties of the two parties. For example, contracts of carriage include such provisions as airline liability limits for lost baggage and passenger entitlements when flights are delayed or canceled. Any term or condition of this contract is legally binding on the airline and the passenger and may be enforced in state court.[1] Federal regulations[2] require that airlines retain a copy of their contracts of carriage at each of their ticket offices for review by passengers requesting to do so.[3]

In addition to being able to sue an airline for breach of contract, a passenger could file a complaint with the Department of Transportation (DOT) alleging that an airline has violated a federal statute or regulation. For example, a passenger could claim that an airline engaged in an unfair or deceptive practice. As a result of such a complaint, DOT could bring an enforcement action against the airline.

In June 1999, the Air Transport Association[4] (ATA), responding to Congress's interest in ensuring that airlines make every effort to provide passengers with the best service available, announced its "Customer Service Commitment." The Commitment, developed in consultation with congressional leaders and DOT, consisted of several general measures designed to improve customer service. According to ATA officials, each of its member airlines will develop detailed customer service plans on the basis of the ATA proposal by September 15, 1999, and implement them by December 15, 1999.

---

[1] American Airlines v. Wolens, 513 U.S. 219 (1995).
[2] 14 C.F.R. § 253.4.
[3] The full text of contracts of carriage for the airlines we reviewed varied from 25 to 45 pages and can be obtained from an airline upon written request to the airline's headquarters.
[4] The Association is a trade organization representing the principal U.S. airlines.

162738

You requested that we compare the airlines' existing contracts of carriage with ATA's Customer Service Commitment. We performed this comparison for the 10 major U.S. passenger airlines. We also compared the airlines' contracts of carriage and the Customer Service Commitment with the federal statutes and regulations to determine what provisions, if any, are required by statutes or regulations.

Summary of Comparisons

ATA's Customer Service Commitment extends the airlines' commitment beyond the current contracts of carriage by either adding new provisions or augmenting existing terms. The Customer Service Commitment includes new provisions concerning reservations; offering the lowest fare available over the telephone, refunds, and on-time baggage delivery; meeting customers' needs during on-aircraft extended delays; and handling customer complaints. For example, airlines are to allow passengers to hold a reservation for 24 hours or cancel a reservation within 24 hours without penalty.

Several other measures in the Customer Service Commitment (notifying customers about known delays, cancellations, and diversions; petitioning DOT for an increase in the minimum baggage liability limits; disclosing information on various airline policies; and ensuring customer service for code-share partners[5]) augment terms provided for in the contracts of carriage. The remaining measures (accommodating special needs passengers and fairly handling "bumped" passengers) are currently included in the contracts of carriage. Enclosure I summarizes our comparison of the measures contained in the Customer Service Commitment.

The officials at the 10 major airlines that we contacted[6] indicated that they were considering revisions to their contracts of carriage to reflect at least some aspects of their customer service plans. However, these officials said that the decision about what specific changes to make would involve a side-by-side comparison of their current contracts of carriage and their final customer service plan. Because the plans are still being developed, the officials could not say to what extent the contracts would be revised. One airline official, however, did say that the minimum baggage liability limit would certainly be changed to reflect the anticipated regulatory change in the baggage liability minimum.[7] Most of these officials believed that any revisions to their airline's contracts of carriage would be made by the end of 1999.

Federal statutes and regulations have a significant impact on a number of the measures in the Customer Service Commitment, such as the following: providing baggage liability, providing prompt ticket refunds, accommodating special needs passengers, handling bumped passengers, notifying customers about aircraft changes and aircraft type and configuration, and ensuring customer service from an airline's code-sharing partners. Several of these measures (fairly handling bumped passengers, ensuring customer service from an airline's code-sharing partners, providing prompt ticket refunds, accommodating special needs

[5]Code-sharing allows an airline to sell seats on another airline's airplanes, as if they were its own. This enables the airlines that have partnered to expand their route networks without adding any airplanes.

[6]The 10 major passenger airlines, each with more than a billion dollars in annual revenues, are Alaska, American, America West, Continental, Delta, Northwest, Southwest, Trans World, United, and U.S. Airways.

[7]DOT has proposed that the minimum baggage liability be increased from $1,250 to $2,500, 64 Fed. Reg. 34592, June 28, 1999.

passengers, and providing passengers with information on airline policies and aircraft configuration) reflect what is in the statutes and regulations.

In addition, the Customer Service Commitment seeks to change the current minimum baggage liability limit regulation. In June of 1999, DOT issued a supplemental notice proposing to raise the minimum baggage liability limit from $1,250 to $2,500. DOT has yet to finalize this proposed rule. One of the ATA measures calls for airline officials to petition DOT to increase its minimum baggage liability limit.

DOT officials said that under federal law, DOT could bring an enforcement action against an airline that engages in what it considers an unfair and deceptive trade practice.[8] As examples of unfair and deceptive trade practices, DOT cited an airline's failure to (1) follow through on promises that would be made in an airline's customer service plan; (2) provide the lowest fare available over the telephone to a passenger who requests it; (3) adhere to promised flight schedules that have been changed as a result of flight cancellations due to economic considerations; and (4) provide passengers with cash refunds within 20 days of receiving complete claim information.

Scope and Methodology

We interviewed ATA officials to better understand the context in which the Customer Service Commitment was developed. We also interviewed officials from the 10 major passenger airlines to determine if they intended to incorporate their customer service plans into their contracts of carriage. We did not determine the extent to which existing contracts of carriage reflect actual airline practices. In addition, we interviewed DOT officials to determine the Department's interpretation of the pertinent federal statutes and regulations. However, we did not review all federal involvement in airline operations such as DOT enforcement decisions and federal law outside of DOT's and the Federal Aviation Administration's statutes and regulations.

We discussed the information in this report with DOT and ATA officials. They provided technical corrections, which we incorporated into the report as appropriate.

Our work was performed from July through August 1999 in accordance with generally accepted government auditing standards.

We are sending copies of this report to the Honorable Rodney E. Slater, Secretary of Transportation; appropriate congressional committees; and other interested parties. We will make copies available to others upon request.

[8] 49 U.S.C. § 41712.

If you have any further questions, please contact me at (202) 512-3650. Major contributors to this report were David Hooper, Paul Lacey, Richard Scott, and Robert White.

Sincerely yours,

Gerald L. Dillingham
Associate Director,
Transportation Issues

Enclosure I

Comparison of Customer Service Commitment With Contracts of Carriage and Federal Law

Each airline has its own contract of carriage, which sets out the terms and conditions of the agreement between the passenger and the airline when a passenger purchases an airline ticket. Because of the similarity among the contracts, we have summarized them and indicate major differences in the notes to table I.1.

Table I.1: Comparison of Customer Service Commitment With Airlines' DomesticContracts of Carriage and Pertinent Federal Statutes and Regulations

Customer Service Commitment	Airlines' domestic contracts of carriage	Pertinent federal statutes and regulations
The lowest fare that a customer is entitled to will be offered through the telephone reservations system.	Service not addressed.[a]	According to DOT officials, it would be an unfair and deceptive trade practice under 49 U.S.C. § 41712 for an airline to provide other than the lowest fare available by telephone to a customer if requested to do so.
Customers will be informed about delays, cancellations, and diversions in a timely manner.	Service not addressed.	According to DOT officials, it would be an unfair and deceptive trade practice under 49 U.S.C. § 41712 for an airline to inform passengers that cancellations were due to weather, mechanical reasons, etc., when, in fact, the cancellations were due to economic reasons.
Clear and concise policies regarding accommodations for passengers delayed overnight will be established and made available to them.	The airlines will provide amenities (including overnight accommodations) for passengers whose flight has been diverted to an unscheduled point. Hotel accommodations are provided if the delay exceeds 4 hours during the period of 10 p.m. to 6 a.m.[b]	Service not addressed.
Every reasonable effort will be made to return checked baggage to passengers within 24 hours and to contact any passenger whose unclaimed checked luggage contains a name and address or telephone number.	Service not addressed.	Service not addressed.
Airlines will petition DOT to increase the current minimum baggage liability.[c]	Contracts reflect federal regulation's minimum liability limit of $1,250.[d]	Federal regulations currently set the minimum amounts for the airlines liability limits at $1,250 for each passenger.[e] The airlines are required to provide passengers with written notice (included on or with a ticket) of such monetary limits on baggage liability.
Airlines will issue credit card refunds within 7 days and cash refunds within 20 days.	Service not addressed.[f]	Under federal regulations,[g] a creditor (in this case the airline) has 7 business days to provide a refund for tickets purchased with a credit card. In addition, DOT has taken

Enclosure I

Customer Service Commitment	Airlines' domestic contracts of carriage	Pertinent federal statutes and regulations
		enforcement actions against airlines for failure to provide refunds for tickets purchased with cash or check within 20 business days. DOT officials consider any period longer than 20 days to be an unfair and deceptive trade practice under 49 U.S.C. § 41712.
Airlines will disclose policies and procedures for accommodating unaccompanied minors.	Contracts specify the age that an unaccompanied child will be accepted for travel and address the requirements for such travel on both nonstop and connecting flights.	Service not addressed.
Airlines will disclose policies and procedures for accommodating disabled persons.	Contracts reflect federal regulations requiring airlines to provide specific services and facilities for passengers with disabilities. Contracts include former legal liability limit for assistive devices such as wheelchairs.	Federal regulations require airlines to provide specific services and facilities to accommodate passengers with disabilities both in the airport and on the aircraft. Airlines are required to make available, on request, information on facilities and services. Currently, airlines may not limit liability for assistive devices.[h]
Airlines will make reasonable efforts to provide food, water, restroom facilities, and access to medical treatment for passengers aboard an aircraft that is grounded for an extended period of time without access to the terminal consistent with passenger and employee safety and security concerns. Each airline will prepare contingency plans to address such circumstances.	Service not addressed.	Service not addressed.
Airlines will establish and disclose to customers the policies and procedures, including applicable requirements such as check-in deadlines, for managing their inability to board all passengers with confirmed reservations.	Under federal regulations, all airlines have established policies (and incorporated such policies into the contracts of carriage) for managing their inability to board all passengers with confirmed reservations. The provisions in each airline's conditions of contract, with respect to bumped passengers, are virtually identical and mirror the requirements and procedures found in the regulations.	Federal regulations specify policies for handling passengers who are denied boarding because of overbooking by the airline. Each airline must • request volunteers who will agree not to board an airplane before using any other boarding priority;[i] • establish criteria for determining which passengers shall be denied boarding; • compensate qualified passengers[j] who are involuntarily denied boarding;[k] • display a sign located so as to

Enclosure I

Customer Service Commitment	Airlines' domestic contracts of carriage	Pertinent federal statutes and regulations
		be clearly visible and readable to the traveling public, describing the airline's deliberate overbooking policy; and • furnish passengers with a written statement explaining the terms, conditions, and limitations of compensation for denied boarding.
Each airline will disclose to the customer any change of aircraft on a single flight with the same flight number.	Service not addressed.	Federal regulations require that a change of aircraft on a single flight number be disclosed directly to passengers.[l]
Each airline will disclose its cancellation policies due to passengers' failure to use flight segment coupons.	Some airlines[m] specifically prohibit "hidden city" ticketing[n] in their contracts of carriage. All airlines prohibit "back-to-back" ticketing.[o] If the passenger fails to comply with these restrictions, the airline has the right to cancel or confiscate the unused portion of the passenger's ticket.[p]	Federal regulations require airlines to make copies of the contracts of carriage available at airports and ticket offices so that passengers may view the full text of the contracts upon request.[q] Many contracts of carriage include airlines' rules with regard to unused flight segments. In addition, according to DOT officials, misrepresentations regarding airline policies would be prohibited as unfair and deceptive practices under 49 U.S.C. § 41712.
Rules, restrictions, and an annual report on frequent flyer program redemptions.	Service not addressed.	According to DOT officials, misrepresentations regarding airline policies would be prohibited as unfair and deceptive practices under 49 U.S.C. § 41712.
Information regarding aircraft configuration, including seat size and pitch.	Service not addressed.	For international flights, each tariff[r] must include the type of aircraft and the seating configuration for each class of passenger service, including the number of seats abreast, the seat pitch, and the number of lounge seats.[s] In addition, according to DOT officials, misrepresentations regarding airline policies would be prohibited as unfair and deceptive practices under 49 U.S.C. § 41712.
Each airline will ensure that domestic code-share partners make a commitment to provide comparable consumer plans and policies.	Airlines limit their responsibility to transportation over their own lines.[t] When an airline issues a ticket, checks baggage, or makes other arrangements for transportation over the lines of another carrier, it will act only as an agent for the other and will not assume responsibility for the acts or omissions of the other carrier.	Service not addressed.

Enclosure I

Customer Service Commitment	Airlines' domestic contracts of carriage	Pertinent federal statutes and regulations
Each airline will • assign a customer service representative to handle passenger complaints and ensure a response to written complaints within 60 days; • develop and implement a customer service plan within 6 months; • publish and make the customer service plans available on the Internet, at airports, at ticket offices, and with travel agents; and • respond fully to Congress's request for the periodic review of compliance with the Customer Service Commitment.	Service not addressed.	Federal regulations require that a carrier respond to a disability complaint within 30 days of its receipt.[u] According to DOT officials, it would be an unfair and deceptive practice under 49 U.S.C. § 41712 for an airline to engage in a practice of providing false or deceptive responses to complaints.

Legend

DOT = Department of Transportation

---

[a]All airlines (except Southwest and U.S. Airways) state that if, after purchasing a ticket, the fare decreases, the passenger will be reimbursed the difference upon request.
[b]Neither American Airlines nor Southwest Airlines includes provisions for overnight accommodations for passengers with flights that are diverted to unscheduled points.
[c] The $1,250 amount in the DOT rule is a minimum limit that sets the floor for an airline's liability.
[d]The Airline Transportation Association filed a petition with DOT on August 27, 1999, supporting the Department in raising the current domestic baggage minimum liability limit. Docket OST-1996-1340-38.
[e]The current liability limitation is found in 14 C.F.R. Part 254; however, DOT has proposed increasing the airlines' liability limit from $1,250 to $2,500. (See 64 Fed. Reg. 34592 (1999).)
[f]The airlines specify the circumstances in which refunds are permitted but do not address the promptness with which the passenger will receive the refund.
[g]12 C.F.R., Part 226.12(c) and 14 C.F.R. Part 374.
[h] DOT recently lifted the $2,500 liability limit for mobility aids making liability unlimited (64 Fed. Reg. 41781, Aug. 2, 1999). This regulation became effective Sept. 1, 1999 (14 C.F.R. § 382.43).
[i] 4 C.F.R. § 250.2b.
[j]The federal regulations require compensation only for those passengers who comply with the terms in the carrier's contract of carriage regarding ticketing, reconfirmation, and check-in times. Compensation is also not required if comparable transportation permits the passenger to arrive within 1 hour of the original arrival time. (See 14 C.F.R. § 250.6.)
[k]If the carrier arranges for comparable transportation that arrives within 2 hours of the original arrival time (4 hours on an international flight), the maximum compensation is $200; otherwise, the maximum compensation is $400. (See 14 C.F.R. § 250.5.)
[l]14 C.F.R. Part 258.5(b) and (c).
[m]Delta, Trans World, American, Continental, and U.S. Airways specifically prohibit hidden city ticketing in the contracts of carriage.
[n]Hidden city ticketing occurs when a passenger purchases a ticket with a stopover/connecting flight at a specific destination, intending only to begin or end his travel at this destination and not continue or use the remaining segments of the purchased flight.
[o]Back-to-back ticketing occurs when a passenger purchases two roundtrip tickets, intending to use only one segment of each ticket to circumvent minimum stay requirements.
[p]In addition to specifically addressing "back-to-back" ticketing, all airlines assert a general right to dishonor any or all portions of the ticket if a passenger fails to occupy space that has been reserved.
[q]14 C.F.R. § 253.5.

[r]A tariff is a public document that sets forth rates and charges with respect to international services and governing rules and regulations and practices relating to those services.
[s]14 C.F.R. § 221.38.
[t] Southwest Airlines does not have a provision in its contracts of carriage concerning responsibility/liability for a passenger's travel with another carrier. Southwest also does not currently code-share with any other airline.
[u]14 C.F.R. § 382.65.

(348186)