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(Original Signature of Member)

116TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To amend title XVIII of the Social Security Act to exclude ventilators from competitive acquisition programs under the Medicare program for 5years, and for other purposes.

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**IN THE HOUSE OF REPRESENTATIVES**

Mr. GRIFFITH (for himself, Mr. WELCH, Mr. BILIRAKIS, Mr. SOTO, and Mr. LARSON of Connecticut) introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To amend title XVIII of the Social Security Act to exclude ventilators from competitive acquisition programs under the Medicare program for 5years, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Safeguarding Medicare  
5       Access to Respiratory Therapy Act of 2019”.

1 **SEC. 2. EXCLUDING VENTILATORS AND CERTAIN OTHER**  
2 **RESPIRATORY ITEMS FROM COMPETITIVE**  
3 **ACQUISITION PROGRAMS UNDER THE MEDI-**  
4 **CARE PROGRAM FOR 5YEARS.**

5 Section 1847(a)(2)(A) of the Social Security Act (42  
6 U.S.C. 1395w–3(a)(2)(A)) is amended by inserting “ex-  
7 cluding ventilators (whether invasive or noninvasive) and  
8 any other respiratory covered item (as defined in para-  
9 graph (13) of section 1834(a)) payable under paragraph  
10 (3) of such section and furnished on or after January 1,  
11 2020, and before January 1, 2025,” before “and excluding  
12 drugs and biologicals.”.

13 **SEC. 3. REQUIRING THE ESTABLISHMENT OF UPDATED NA-**  
14 **TIONAL COVERAGE POLICIES TO REFLECT**  
15 **INNOVATION IN TECHNOLOGY FOR HOME**  
16 **MECHANICAL VENTILATOR DEVICES UNDER**  
17 **THE MEDICARE PROGRAM.**

18 (a) IN GENERAL.—Section 1869(f) of the Social Se-  
19 curity Act (42 U.S.C. 1395ff(f)) is amended by adding  
20 at the end the following new paragraph:

21 “(9) TECHNICAL EXPERT PANEL REVIEW AND  
22 UPDATE OF NATIONAL COVERAGE DETERMINATIONS  
23 FOR HOME MECHANICAL VENTILATORS AND CER-  
24 TAIN OTHER RESPIRATORY DEVICES.—

25 “(A) IN GENERAL.—Not later than 90  
26 days after the date of the enactment of this

1 paragraph, the Secretary (through use of a con-  
2 tractor or otherwise) shall establish a technical  
3 expert panel for purposes of reviewing national  
4 coverage determinations with respect to cov-  
5 erage under part B for home invasive and  
6 noninvasive ventilators and other noninvasive  
7 respiratory devices (including respiratory de-  
8 vices with bi-level pressure capability) and mak-  
9 ing recommendations for revising such deter-  
10 minations.

11 “(B) REVIEW, ASSESSMENT, AND REC-  
12 OMMENDATIONS.—Not later than 1 year after  
13 the date the technical expert panel described in  
14 subparagraph (A) is established (and periodi-  
15 cally thereafter as the Secretary determines ap-  
16 propriate), the technical expert panel shall re-  
17 view stakeholder input and clinical literature  
18 and make recommendations to the Secretary,  
19 with respect to national coverage determina-  
20 tions described in such paragraph, relating to—

21 “(i) defining home invasive ventilators  
22 and home noninvasive ventilators;

23 “(ii) defining the term ‘respiratory  
24 failure’ for purposes of establishing criteria

1 for the appropriate use of home invasive or  
2 noninvasive ventilators;

3 “(iii) establishing medical necessity  
4 criteria for the use of home invasive and  
5 noninvasive ventilators for individuals en-  
6 rolled under part B diagnosed with res-  
7 piratory failure and for such individuals  
8 not diagnosed with respiratory failure;

9 “(iv) any other aspects of home ven-  
10 tilators and similar devices that the tech-  
11 nical expert panel determines are appro-  
12 priate to ensure access to medically appro-  
13 priate devices.

14 “(C) MEMBERSHIP.—In establishing the  
15 technical expert panel, the Secretary shall so-  
16 licit recommendations from interested stake-  
17 holders. The technical expert panel shall be  
18 composed of a minimum of 15 individuals with  
19 relevant expertise and perspectives, including  
20 the following:

21 “(i) Home invasive and noninvasive  
22 ventilator patients and caregivers.

23 “(ii) Experts with relevant clinical ex-  
24 perience and expertise, including research-  
25 ers in respiratory care, pulmonologists,

1 nurses, respiratory therapists, and other  
2 clinicians.

3 “(iii) Experts with subject matter ex-  
4 pertise in reimbursement systems and  
5 medical necessity requirements under this  
6 title.

7 “(iv) Experts in the supply of devices  
8 and services for home ventilation therapy.

9 “(v) Experts in the design, develop-  
10 ment, and manufacturing of home ventila-  
11 tion equipment.

12 “(D) USE OF THE RECOMMENDATIONS BY  
13 THE SECRETARY.—

14 “(i) IN GENERAL.—In consultation  
15 with stakeholders, the Secretary shall,  
16 based upon the recommendations described  
17 in subparagraph (B), update national cov-  
18 erage determinations for ventilators and  
19 devices described in paragraph (1).

20 “(ii) TIMING.—The Secretary shall fi-  
21 nalize and implement updated national  
22 coverage determinations described in clause  
23 (i), taking into account public comments  
24 made during the determination process,  
25 not later than 9 months after any date on

1                   which the Secretary receives recommenda-  
2                   tions described in subparagraph (B) from  
3                   the technical expert panel.

4                   “(E)   TRANSPARENCY.—The   Secretary  
5                   shall make the minutes of all meetings of the  
6                   technical expert panel and all documentation re-  
7                   lating to the formulation of recommendations  
8                   described in subparagraph (B) available to the  
9                   public through the Centers for Medicare & Med-  
10                  icaid Services website.”.