

116TH CONGRESS
1ST SESSION

H. R. 4945

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 31, 2019

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 Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

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

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; and

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,

nurses, respiratory therapists, and other clinicians.

“(iii) Experts with subject matter expertise in reimbursement systems and medical necessity requirements under this title.

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

“(v) Experts in the design, development, and manufacturing of home ventilation equipment.

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

“(i) IN GENERAL.—In consultation with stakeholders, the Secretary shall, based upon the recommendations described in subparagraph (B), update national coverage determinations for ventilators and devices described in paragraph (1).

“(ii) TIMING.—The Secretary shall finalize and implement updated national coverage determinations described in clause (i), taking into account public comments made during the determination process, 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.”.

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