115TH CONGRESS 1ST SESSION

S. 1914

To amend title XVIII of the Social Security Act in order to strengthen rules in case of competition for diabetic testing strips, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 4, 2017

Mr. Warner (for himself and Mr. Scott) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act in order to strengthen rules in case of competition for diabetic testing strips, 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 "Protecting Access to
- 5 Diabetes Supplies Act of 2017".
- 6 SEC. 2. STRENGTHENING RULES IN CASE OF COMPETITION
- 7 FOR DIABETIC TESTING STRIPS.
- 8 (a) Special Rule in Case of Competition for
- 9 Diabetic Testing Strips.—

- 1 (1) IN GENERAL.—Paragraph (10) of section 2 1847(b) of the Social Security Act (42 U.S.C. 3 1395w-3(b)) is amended—
 - (A) in subparagraph (A), by striking the second sentence and inserting the following new sentence: "With respect to bids to furnish such types of products on or after January 1, 2019, the volume for such types of products shall be determined by the Secretary through the use of multiple sources of data (from mail order and non-mail order Medicare markets), including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets."; and
 - (B) by adding at the end the following new subparagraphs:
 - "(C) Demonstration of ability to furnish types of diabetic testing strip products on or after January 1, 2019, under the program described in subparagraph (A), the Secretary shall reject a bid submitted by an entity if the entity does not attest to the Secretary and demonstrate,

through letters of intent with manufacturers, wholesalers, or other suppliers, or other evidence as the Secretary may specify, that the entity has the ability to obtain an inventory of the types and quantities of diabetic testing strip products that will allow the entity to furnish such products in a manner consistent with its bid.

"(D) USE OF UNLISTED TYPES IN CAL-CULATION OF PERCENTAGE.—With respect to bids to furnish diabetic testing strip products on or after January 1, 2019, in determining under subparagraph (A) whether a bid submitted by an entity under such subparagraph covers 50 percent (or such higher percentage as the Secretary may specify) of all types of diabetic testing strip products, the Secretary may not attribute a percentage to types of diabetic testing strip products that the Secretary does not identify by brand, model, and market share volume.

"(E) Adherence to Demonstration.—

"(i) IN GENERAL.—In the case of an entity that is furnishing diabetic testing strip products on or after January 1,

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2019, under a contract entered into under the competition conducted pursuant to paragraph (1), the Secretary shall establish a process to monitor, on an ongoing basis, the extent to which such entity continues to cover the product types included in the entity's bid.

> "(ii) Termination.—If the Secretary determines that an entity described in clause (i) fails to maintain in inventory, or otherwise maintain ready access to (through requirements contracts or otherwise) a type of product included in the entity's bid, the Secretary may terminate such contract unless the Secretary finds that the failure of the entity to maintain inventory of, or ready access to, the product is the result of the discontinuation of the product by the product manufacturer, a market-wide shortage of the product, or the introduction of a newer model or version of the product in the market involved.".

24 (b) Codifying and Expanding Anti-Switching 25 Rule.—Section 1847(b) of the Social Security Act (42

| 1 | U.S.C. 1395w-3(b)), as amended by subsection (a)(1), is |
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| 2 | further amended— |
| 3 | (1) by redesignating paragraph (11) as para- |
| 4 | graph (12); and |
| 5 | (2) by inserting after paragraph (10) the fol- |
| 6 | lowing new paragraph: |
| 7 | "(11) Additional special rules in case of |
| 8 | COMPETITION FOR DIABETIC TESTING STRIPS.— |
| 9 | "(A) IN GENERAL.—With respect to an en- |
| 10 | tity that is furnishing diabetic testing strip |
| 11 | products to individuals under a contract entered |
| 12 | into under the competitive acquisition program |
| 13 | established under this section, the entity shall |
| 14 | furnish to each individual a brand of such prod- |
| 15 | ucts that is compatible with the home blood glu- |
| 16 | cose monitor selected by the individual. |
| 17 | "(B) Prohibition on influencing and |
| 18 | INCENTIVIZING.—An entity described in sub- |
| 19 | paragraph (A) may not attempt to influence or |
| 20 | incentivize an individual to switch the brand of |
| 21 | glucose monitor or diabetic testing strip product |
| 22 | selected by the individual, including by— |
| 23 | "(i) persuading, pressuring, or advis- |
| 24 | ing the individual to switch; or |

| 1 | "(ii) furnishing information about al- |
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| 2 | ternative brands to the individual where |
| 3 | the individual has not requested such in- |
| 4 | formation. |
| 5 | "(C) Provision of Information.— |
| 6 | "(i) Standardized information.— |
| 7 | Not later than January 1, 2019, the Sec- |
| 8 | retary shall develop and make available to |
| 9 | entities described in subparagraph (A) |
| 10 | standardized information that describes |
| 11 | the rights of an individual with respect to |
| 12 | such an entity. The information described |
| 13 | in the preceding sentence shall include in- |
| 14 | formation regarding— |
| 15 | "(I) the requirements established |
| 16 | under subparagraphs (A) and (B); |
| 17 | "(II) the right of the individual |
| 18 | to purchase diabetic testing strip |
| 19 | products from another mail order sup- |
| 20 | plier of such products or a retail phar- |
| 21 | macy if the entity is not able to fur- |
| 22 | nish the brand of such product that is |
| 23 | compatible with the home blood glu- |
| 24 | cose monitor selected by the indi- |
| 25 | vidual; and |

| 1 | "(III) the right of the individual |
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| 2 | to return diabetic testing strip prod- |
| 3 | ucts furnished to the individual by the |
| 4 | entity. |
| 5 | "(ii) Requirement.—With respect to |
| 6 | diabetic testing strip products furnished on |
| 7 | or after the date on which the Secretary |
| 8 | develops the standardized information |
| 9 | under clause (i), an entity described in |
| 10 | subparagraph (A) may not communicate |
| 11 | directly to an individual until the entity |
| 12 | has verbally provided the individual with |
| 13 | such standardized information. |
| 14 | "(D) Order refills.—With respect to |
| 15 | diabetic testing strip products furnished on or |
| 16 | after January 1, 2019, the Secretary shall re- |
| 17 | quire an entity furnishing diabetic testing strip |
| 18 | products to an individual to contact and receive |
| 19 | a request from the individual for such products |
| 20 | not more than 14 days prior to dispensing a re- |
| 21 | fill of such products to the individual.". |
| 22 | (e) Implementation; Non-Application of the |
| 23 | Paperwork Reduction Act.— |
| 24 | (1) Implementation.—Notwithstanding any |
| 25 | other provision of law, the Secretary of Health and |

Human Services may implement the provisions of,
and amendments made by, this section by program
instruction or otherwise.

(2) Non-application of the Paperwork Reduction Act.—Chapter 35 of title 44, United States Code (commonly referred to as the 'Paperwork Reduction Act of 1995') shall not apply to this section or the amendments made by this section.

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