

114TH CONGRESS  
2D SESSION

# S. 4

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.

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## IN THE SENATE OF THE UNITED STATES

NOVEMBER 16, 2016

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

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## 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 2016”.

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—

4           (A) in subparagraph (A), by striking the  
5 second sentence and inserting the following new  
6 sentence: “With respect to bids to furnish such  
7 types of products on or after January 1, 2019,  
8 the volume for such types of products shall be  
9 determined by the Secretary through the use of  
10 multiple sources of data, including market  
11 based data measuring sales of diabetic testing  
12 strip products described in section 1861(n) that  
13 are not exclusively sold by, and marketed under  
14 the name of, a single retailer that is not the  
15 manufacturer of such products, from mail  
16 order, non-mail order, Medicare, and non-Medi-  
17 care markets.”; and

18           (B) by adding at the end the following new  
19 subparagraphs:

20           “(C) DEMONSTRATION OF ABILITY TO  
21 FURNISH TYPES OF DIABETIC TESTING STRIP  
22 PRODUCTS.—With respect to bids to furnish di-  
23 abetic testing strip products on or after Janu-  
24 ary 1, 2019, under the program described in  
25 subparagraph (A), the Secretary shall reject a

1 bid submitted by an entity if the entity does not  
2 attest to the Secretary and demonstrate,  
3 through letters of intent with manufacturers,  
4 wholesalers, or other suppliers, or other evi-  
5 dence as the Secretary may specify, that the en-  
6 tity has the ability to obtain an inventory of the  
7 types and quantities of diabetic testing strip  
8 products that will allow the entity to furnish  
9 such products in a manner consistent with its  
10 bid.

11 “(D) USE OF UNLISTED TYPES IN CAL-  
12 CULATION OF PERCENTAGE.—With respect to  
13 bids to furnish diabetic testing strip products  
14 on or after January 1, 2019, in determining  
15 under subparagraph (A) whether a bid sub-  
16 mitted by an entity under such subparagraph  
17 covers 50 percent (or such higher percentage as  
18 the Secretary may specify) of all types of dia-  
19 betic testing strip products, the Secretary may  
20 not attribute a percentage to types of diabetic  
21 testing strip products that the Secretary does  
22 not identify by brand, model, and market share  
23 volume.

24 “(E) ADHERENCE TO DEMONSTRATION.—

1           “(i) IN GENERAL.—In the case of an  
2           entity that is furnishing diabetic testing  
3           strip products on or after January 1,  
4           2019, under a contract entered into under  
5           the competition conducted pursuant to  
6           paragraph (1), the Secretary shall estab-  
7           lish a process to monitor, on an ongoing  
8           basis, the extent to which such entity con-  
9           tinues to cover the product types included  
10          in the entity’s bid.

11          “(ii) TERMINATION.—If the Secretary  
12          determines that an entity described in  
13          clause (i) fails to maintain in inventory, or  
14          otherwise maintain ready access to through  
15          requirements contracts or otherwise, a type  
16          of product included in the entity’s bid, the  
17          Secretary may terminate such contract un-  
18          less the Secretary finds that the failure of  
19          the entity to maintain inventory of, or  
20          ready access to, the product is the result of  
21          the discontinuation of the product by the  
22          product manufacturer or a market-wide  
23          shortage of the product.”.

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  
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  
15 strips that is compatible with the home blood  
16 glucose 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-  
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  
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                  (c) IMPLEMENTATION; NON-APPLICATION OF THE  
23                  PAPERWORK REDUCTION ACT.—

24                  (1) IMPLEMENTATION.—Notwithstanding any  
25                  other provision of law, the Secretary of Health and

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

4 (2) NON-APPLICATION OF THE PAPERWORK RE-  
5 DUCATION ACT.—Chapter 35 of title 44, United  
6 States Code (commonly referred to as the ‘Paper-  
7 work Reduction Act of 1995’) shall not apply to this  
8 section or the amendments made by this section.

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