

Union Calendar No. 329

115TH CONGRESS
1ST SESSION

H. R. 3271

[Report No. 115–447, Part I]

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 HOUSE OF REPRESENTATIVES

JULY 17, 2017

Ms. DEGETTE (for herself, Mrs. BROOKS of Indiana, and Mr. REED) 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

DECEMBER 6, 2017

Additional sponsors: Mr. GUTHRIE, Mr. BILIRAKIS, Mr. RODNEY DAVIS of Illinois, Mr. JOHNSON of Ohio, Mr. BUCSHON, Mr. TIPTON, Mrs. WALORSKI, Mr. COSTELLO of Pennsylvania, Mr. LONG, and Mr. ROSKAM

DECEMBER 6, 2017

Reported from the Committee on Energy and Commerce with an amendment
[Strike out all after the enacting clause and insert the part printed in *italic*]

DECEMBER 6, 2017

The Committee on Ways and Means discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on July 17, 2017]

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 Dia-*
5 *betes 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 DI-*
9 *ABETIC TESTING STRIPS.—*

10 *(1) IN GENERAL.—Paragraph (10) of section*
11 *1847(b) of the Social Security Act (42 U.S.C. 1395w-*
12 *3(b)) is amended—*

13 *(A) in subparagraph (A), by striking the*
14 *second sentence and inserting the following new*
15 *sentence: “With respect to bids to furnish such*
16 *types of products on or after January 1, 2019,*
17 *the volume for such types of products shall be de-*
18 *termined by the Secretary through the use of*
19 *multiple sources of data (from mail order and*
20 *non-mail order Medicare markets), including*
21 *market-based data measuring sales of diabetic*
22 *testing strip products that are not exclusively*
23 *sold by a single retailer from such markets.”;*
24 *and*

1 (B) by adding at the end the following new
2 subparagraphs:

3 “(C) *DEMONSTRATION OF ABILITY TO FUR-*
4 *NISH TYPES OF DIABETIC TESTING STRIP PROD-*
5 *UCTS.—With respect to bids to furnish diabetic*
6 *testing strip products on or after January 1,*
7 *2019, under the program described in subpara-*
8 *graph (A), the Secretary shall reject a bid sub-*
9 *mitted by an entity if the entity does not attest*
10 *to the Secretary and demonstrate, through letters*
11 *of intent with manufacturers, wholesalers, or*
12 *other suppliers, or other evidence as the Sec-*
13 *retary may specify, that the entity has the abil-*
14 *ity to obtain an inventory of the types and*
15 *quantities of diabetic testing strip products that*
16 *will allow the entity to furnish such products in*
17 *a manner consistent with its bid.*

18 “(D) *USE OF UNLISTED TYPES IN CALCULA-*
19 *TION OF PERCENTAGE.—With respect to bids to*
20 *furnish diabetic testing strip products on or after*
21 *January 1, 2019, in determining under subpara-*
22 *graph (A) whether a bid submitted by an entity*
23 *under such subparagraph covers 50 percent (or*
24 *such higher percentage as the Secretary may*
25 *specify) of all types of diabetic testing strip*

1 *products, the Secretary may not attribute a per-*
2 *centage to types of diabetic testing strip products*
3 *that the Secretary does not identify by brand,*
4 *model, and market share volume.*

5 “(E) *ADHERENCE TO DEMONSTRATION.*—

6 “(i) *IN GENERAL.*—*In the case of an*
7 *entity that is furnishing diabetic testing*
8 *strip products on or after January 1, 2019,*
9 *under a contract entered into under the*
10 *competition conducted pursuant to para-*
11 *graph (1), the Secretary shall establish a*
12 *process to monitor, on an ongoing basis, the*
13 *extent to which such entity continues to*
14 *cover the product types included in the enti-*
15 *ty’s bid.*

16 “(ii) *TERMINATION.*—*If the Secretary*
17 *determines that an entity described in*
18 *clause (i) fails to maintain in inventory, or*
19 *otherwise maintain ready access to (through*
20 *requirements, contracts, or otherwise) a type*
21 *of product included in the entity’s bid, the*
22 *Secretary may terminate such contract un-*
23 *less the Secretary finds that the failure of*
24 *the entity to maintain inventory of, or*
25 *ready access to, the product is the result of*

1 *the discontinuation of the product by the*
2 *product manufacturer, a market-wide short-*
3 *age of the product, or the introduction of a*
4 *newer model or version of the product in the*
5 *market involved.”.*

6 **(b) CODIFYING AND EXPANDING ANTI-SWITCHING**
7 *RULE.—Section 1847(b) of the Social Security Act (42*
8 *U.S.C. 1395w–3(b)), as amended by subsection (a)(1), is*
9 *further amended—*

10 (1) *by redesignating paragraph (11) as para-*
11 *graph (12); and*

12 (2) *by inserting after paragraph (10) the fol-*
13 *lowing new paragraph:*

14 **“(11) ADDITIONAL SPECIAL RULES IN CASE OF**
15 **COMPETITION FOR DIABETIC TESTING STRIPS.—**

16 **“(A) IN GENERAL.—***With respect to an enti-*
17 *ty that is furnishing diabetic testing strip prod-*
18 *ucts to individuals under a contract entered into*
19 *under the competitive acquisition program estab-*
20 *lished under this section, the entity shall furnish*
21 *to each individual a brand of such products that*
22 *is compatible with the home blood glucose mon-*
23 *itor selected by the individual.*

24 **“(B) PROHIBITION ON INFLUENCING AND**
25 **INCENTIVIZING.—***An entity described in sub-*

1 paragraph (A) may not attempt to influence or
2 incentivize an individual to switch the brand of
3 glucose monitor or diabetic testing strip product
4 selected by the individual, including by—

5 “(i) persuading, pressuring, or advis-
6 ing the individual to switch; or

7 “(ii) furnishing information about al-
8 ternative brands to the individual where the
9 individual has not requested such informa-
10 tion.

11 “(C) PROVISION OF INFORMATION.—

12 “(i) STANDARDIZED INFORMATION.—
13 Not later than January 1, 2019, the Sec-
14 retary shall develop and make available to
15 entities described in subparagraph (A)
16 standardized information that describes the
17 rights of an individual with respect to such
18 an entity. The information described in the
19 preceding sentence shall include information
20 regarding—

21 “(I) the requirements established
22 under subparagraphs (A) and (B);

23 “(II) the right of the individual to
24 purchase diabetic testing strip products
25 from another mail order supplier of

1 *such products or a retail pharmacy if*
2 *the entity is not able to furnish the*
3 *brand of such product that is compat-*
4 *ible with the home blood glucose mon-*
5 *itor selected by the individual; and*

6 *“(III) the right of the individual*
7 *to return diabetic testing strip prod-*
8 *ucts furnished to the individual by the*
9 *entity.*

10 *“(ii) REQUIREMENT.—With respect to*
11 *diabetic testing strip products furnished on*
12 *or after the date on which the Secretary de-*
13 *velops the standardized information under*
14 *clause (i), an entity described in subpara-*
15 *graph (A) may not communicate directly to*
16 *an individual until the entity has verbally*
17 *provided the individual with such standard-*
18 *ized information.*

19 *“(D) ORDER REFILLS.—With respect to di-*
20 *abetic testing strip products furnished on or*
21 *after January 1, 2019, the Secretary shall re-*
22 *quire an entity furnishing diabetic testing strip*
23 *products to an individual to contact and receive*
24 *a request from the individual for such products*

1 *not more than 14 days prior to dispensing a re-*
2 *fill of such products to the individual.”.*

3 *(c) IMPLEMENTATION; NON-APPLICATION OF THE PA-*
4 *PERWORK REDUCTION ACT.—*

5 (1) *IMPLEMENTATION.—Notwithstanding any*
6 *other provision of law, the Secretary of Health and*
7 *Human Services may implement the provisions of,*
8 *and amendments made by, this section by program*
9 *instruction or otherwise.*

10 (2) *NON-APPLICATION OF THE PAPERWORK RE-*
11 *DUCTION ACT.—Chapter 35 of title 44, United States*
12 *Code (commonly referred to as the “Paperwork Re-*
13 *duction Act of 1995”), shall not apply to this section*
14 *or the amendments made by this section.*

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