..... (Original Signature of Member)

115TH CONGRESS 1ST SESSION



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

Ms. DEGETTE (for herself, Mrs. BROOKS of Indiana, and Mr. REED) introduced the following bill; which was referred to the Committee on

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".

1	SEC. 2. STRENGTHENING RULES IN CASE OF COMPETITION
2	FOR DIABETIC TESTING STRIPS.
3	(a) Special Rule in Case of Competition for
4	DIABETIC TESTING STRIPS.—
5	(1) IN GENERAL.—Paragraph (10) of section
6	1847(b) of the Social Security Act (42 U.S.C.
7	1395w–3(b)) is amended—
8	(A) in subparagraph (A), by striking the
9	second sentence and inserting the following new
10	sentence: "With respect to bids to furnish such
11	types of products on or after January 1, 2019,
12	the volume for such types of products shall be
13	determined by the Secretary through the use of
14	multiple sources of data, including market
15	based data measuring sales of diabetic testing
16	strip products described in section 1861(n) that
17	are not exclusively sold by, and marketed under
18	the name of, a single retailer that is not the
19	manufacturer of such products, from mail
20	order, non-mail order, Medicare, and non-Medi-
21	care markets."; and
22	(B) by adding at the end the following new
23	subparagraphs:
24	"(C) DEMONSTRATION OF ABILITY TO
25	FURNISH TYPES OF DIABETIC TESTING STRIP
26	PRODUCTS.—With respect to bids to furnish di-

1 abetic testing strip products on or after Janu-2 ary 1, 2019, under the program described in 3 subparagraph (A), the Secretary shall reject a 4 bid submitted by an entity if the entity does not 5 attest to the Secretary and demonstrate, 6 through letters of intent with manufacturers, 7 wholesalers, or other suppliers, or other evi-8 dence as the Secretary may specify, that the en-9 tity has the ability to obtain an inventory of the 10 types and quantities of diabetic testing strip 11 products that will allow the entity to furnish 12 such products in a manner consistent with its 13 bid.

14 "(D) USE OF UNLISTED TYPES IN CAL-CULATION OF PERCENTAGE.—With respect to 15 16 bids to furnish diabetic testing strip products 17 on or after January 1, 2019, in determining 18 under subparagraph (A) whether a bid sub-19 mitted by an entity under such subparagraph 20 covers 50 percent (or such higher percentage as 21 the Secretary may specify) of all types of dia-22 betic testing strip products, the Secretary may 23 not attribute a percentage to types of diabetic 24 testing strip products that the Secretary does

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not identify by brand, model, and market share volume.

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

14 "(ii) TERMINATION.—If the Secretary 15 determines that an entity described in clause (i) fails to maintain in inventory, or 16 17 otherwise maintain ready access to through 18 requirements contracts or otherwise, a type 19 of product included in the entity's bid, the 20 Secretary may terminate such contract un-21 less the Secretary finds that the failure of the entity to maintain inventory of, or 22 23 ready access to, the product is the result of the discontinuation of the product by the 24

1	product manufacturer or a market-wide
2	shortage of the product.".
3	(b) Codifying and Expanding Anti-switching
4	RULE.—Section 1847(b) of the Social Security Act (42
5	U.S.C. 1395w-3(b)), as amended by subsection (a)(1), is
6	further amended—
7	(1) by redesignating paragraph (11) as para-
8	graph (12) ; and
9	(2) by inserting after paragraph (10) the fol-
10	lowing new paragraph:
11	"(11) Additional special rules in case of
12	COMPETITION FOR DIABETIC TESTING STRIPS.—
13	"(A) IN GENERAL.—With respect to an en-
14	tity that is furnishing diabetic testing strip
15	products to individuals under a contract entered
16	into under the competitive acquisition program
17	established under this section, the entity shall
18	furnish to each individual a brand of such
19	strips that is compatible with the home blood
20	glucose monitor selected by the individual.
21	"(B) PROHIBITION ON INFLUENCING AND
22	INCENTIVIZING.—An entity described in sub-
23	paragraph (A) may not attempt to influence or
24	incentivize an individual to switch the brand of

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

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1	nish the brand of such product that is
2	compatible with the home blood glu-
3	cose monitor selected by the indi-
4	vidual; and
5	"(III) the right of the individual
6	to return diabetic testing strip prod-
7	ucts furnished to the individual by the
8	entity.
9	"(ii) REQUIREMENT.—With respect to
10	diabetic testing strip products furnished on
11	or after the date on which the Secretary
12	develops the standardized information
13	under clause (i), an entity described in
14	subparagraph (A) may not communicate
15	directly to an individual until the entity
16	has verbally provided the individual with
17	such standardized information.
18	"(D) Order refills.—With respect to
19	diabetic testing strip products furnished on or
20	after January 1, 2019, the Secretary shall re-
21	quire an entity furnishing diabetic testing strip
22	products to an individual to contact and receive
23	a request from the individual for such products
24	not more than 14 days prior to dispensing a re-
25	fill of such products to the individual.".

(c) IMPLEMENTATION; NON-APPLICATION OF THE
 PAPERWORK REDUCTION ACT.—

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

8 (2) NON-APPLICATION OF THE PAPERWORK RE-9 DUCTION ACT.—Chapter 35 of title 44, United 10 States Code (commonly referred to as the "Paper-11 work Reduction Act of 1995") shall not apply to this 12 section or the amendments made by this section.