

113TH CONGRESS
2^D SESSION

H. R. 5808

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

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 8, 2014

Ms. DEGETTE (for herself 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

A BILL

To amend title XVIII of the Social Security Act in order to strengthen rules applied 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 of 2014”.

1 **SEC. 2. STRENGTHENING RULES APPLIED IN CASE OF COM-**
2 **PETITION FOR DIABETIC TESTING STRIPS.**

3 (a) SPECIAL RULE APPLIED IN CASE OF COMPETI-
4 TION FOR 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: “The volume for such types of prod-
11 ucts shall be determined through the use of
12 multiple sources of data that measure consump-
13 tion and utilization of diabetic testing strips
14 among individuals in the United States.”; and

15 (B) by adding at the end the following new
16 subparagraphs:

17 “(C) DEMONSTRATION OF ABILITY TO
18 FURNISH TYPES OF DIABETIC TESTING
19 STRIPS.—With respect to the program de-
20 scribed in subparagraph (A), the Secretary shall
21 reject a bid submitted by an entity if the entity
22 does not, as part of the demonstration to the
23 Secretary described in such subparagraph sub-
24 mitted by the entity, demonstrate that the enti-
25 ty has an ability to furnish the types of diabetic
26 testing strips included in its bid, including an

1 ability to obtain and maintain an inventory of
2 such strips by volume in a manner consistent
3 with its bid.

4 “(D) USE OF UNLISTED TYPES IN CAL-
5 CULATION OF PERCENTAGE.—In determining
6 under subparagraph (A) whether a bid sub-
7 mitted by an entity under such subparagraph
8 covers 50 percent (or such higher percentage as
9 the Secretary may specify) of all types of dia-
10 betic testing strip products, the Secretary may
11 not attribute a percentage to types of diabetic
12 testing strips that the Secretary does not pro-
13 vide the entity with the option to identify by
14 type and market share volume.

15 “(E) CONTRACT REQUIREMENT.—Any con-
16 tract entered into with an entity for diabetic
17 testing strips under the competition conducted
18 pursuant to paragraph (1) shall include a re-
19 quirement that the entity offers, makes avail-
20 able to, and maintains in inventory of (or other-
21 wise has ready access to, such as through pur-
22 chasing contracts) each of the types of diabetic
23 testing strip products that is included in the bid
24 submitted by the entity. In the case that an en-
25 tity enters into such a contract with the Sec-

1 retary and fails to fulfill the requirement de-
2 scribed in the preceding sentence, the Secretary
3 shall terminate such contract.

4 “(F) MONITORING ADHERENCE TO DEM-
5 ONSTRATION.—The Secretary shall establish a
6 process to monitor, on an ongoing basis, the ex-
7 tent to which an entity that enters into a con-
8 tract with the Secretary for diabetic testing
9 strips under the competition conducted pursu-
10 ant to paragraph (1) adheres to the demonstra-
11 tion that the entity provided to the Secretary
12 under subparagraph (A).”.

13 (2) CONFORMING AMENDMENT.—Section
14 1847(b)(3)(A) of the Social Security Act (42 U.S.C.
15 1395w-3(b)(3)(A)) is amended by adding at the end
16 the following new sentence: “In the case that such
17 a contract is for diabetic testing strips, such con-
18 tract shall include the information required under
19 paragraph (10)(E).”

20 (b) CODIFYING AND EXPANDING ANTI-SWITCHING
21 RULE.—Section 1847(b) of the Social Security Act (42
22 U.S.C. 1395w-3(b)), as amended by subsection (a)(1), is
23 further amended—

24 (1) by redesignating paragraph (11) as para-
25 graph (12); and

1 (2) by inserting after paragraph (10) the fol-
2 lowing new paragraph:

3 “(11) ADDITIONAL SPECIAL RULE IN CASE OF
4 COMPETITION FOR DIABETIC TESTING STRIPS.—

5 “(A) IN GENERAL.—With respect to dia-
6 betic testing strips furnished by an entity to an
7 individual under the competitive acquisition
8 program established under this section, the en-
9 tity shall furnish to the individual the brand of
10 such strips that is compatible with the home
11 blood glucose monitor selected by the individual.

12 “(B) PROHIBITION ON INFLUENCING AND
13 INCENTIVIZING.—An entity described in sub-
14 paragraph (A) may not attempt to influence or
15 incentivize the individual described in such sub-
16 paragraph to switch the brand of glucose mon-
17 itor or testing strips selected by the individual,
18 including by—

19 “(i) persuading, pressuring, or advis-
20 ing the individual to switch such brand; or

21 “(ii) furnishing information about al-
22 ternative brands to the individual in the
23 case that the individual has not requested
24 such information.

1 “(C) PROVISION OF INFORMATION.—An
2 entity described in subparagraph (A) may not
3 communicate directly to an individual described
4 in such subparagraph until the entity has ver-
5 bally provided the individual with standardized
6 information, to be supplied to the entity by the
7 Secretary, that describes the rights of the indi-
8 vidual with respect to the entity. The informa-
9 tion described in the preceding sentence shall
10 include information regarding—

11 “(i) the requirements established in
12 subparagraphs (A) and (B);

13 “(ii) the right of the individual to con-
14 tact other mail order suppliers of diabetic
15 testing strips or to purchase such strips at
16 a retail pharmacy in the case that the enti-
17 ty is not able to furnish the brand of such
18 strips that is compatible with the home
19 blood glucose monitor selected by the indi-
20 vidual; and

21 “(iii) the right of the individual de-
22 scribed in subparagraph (D) to reject dia-
23 betic testing strips furnished to the indi-
24 vidual by the entity.

1 “(D) INDIVIDUALS ALLOWED TO SWITCH
2 FROM UNWANTED PRODUCTS.—

3 “(i) IN GENERAL.—The Secretary
4 shall establish a process under which an
5 individual furnished with diabetic testing
6 strips under the competitive acquisition
7 program established under this section
8 may reject the strips by notification, in-
9 cluding notification by telephone or elec-
10 tronic mail, to the supplier and to the Sec-
11 retary.

12 “(ii) CONSEQUENCES OF REJEC-
13 TION.—In the case that an individual re-
14 jects diabetic testing strips under clause
15 (i)—

16 “(I) any payment made to the
17 supplier under this title for a portion
18 of such strips furnished for use during
19 the period beginning with the date on
20 which the individual rejects the strips
21 shall be recovered by the Secretary;
22 and

23 “(II) the individual may obtain
24 different diabetic testing strips from a
25 supplier, and the Secretary shall proc-

1 ess a claim for such different diabetic
2 testing strips without regard to any
3 benefit or coverage limitations arising
4 from the fact that a claim has already
5 been submitted and payment made for
6 the rejected diabetic testing strips.

7 “(iii) PROHIBITION ON FUTURE
8 CLAIMS.—In the case that an individual re-
9 jects diabetic testing strips under clause
10 (i), the supplier who supplied the rejected
11 diabetic testing strips to the individual
12 may not submit additional claims for pay-
13 ment on behalf of the individual for the
14 type or brand of diabetic testing strips so
15 rejected by the individual, unless the indi-
16 vidual makes a separate expression of con-
17 sent to the supplier to be furnished with
18 such type or brand of diabetic testing
19 strips by the supplier.”.

20 (c) EFFECTIVE DATE.—The amendments made by
21 this section shall apply with respect to diabetic testing
22 strips furnished on or after July 1, 2016.

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