

115TH CONGRESS
1ST SESSION

S. 348

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate lower covered part D drug prices on behalf of Medicare beneficiaries.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 9, 2017

Mr. FRANKEN (for himself, Mr. REED, and Mr. BROWN) 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 to require the Secretary of Health and Human Services to negotiate lower covered part D drug prices on behalf of Medicare beneficiaries.

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 “Prescription Drug and
5 Health Improvement Act of 2017”.

6 **SEC. 2. NEGOTIATING FAIR PRICES FOR MEDICARE PRE-**
7 **SCRIPTION DRUGS.**

8 (a) NEGOTIATING FAIR PRICES.—

1 (1) IN GENERAL.—Section 1860D–11 of the
 2 Social Security Act (42 U.S.C. 1395w–111) is
 3 amended by striking subsection (i) (relating to non-
 4 interference) and by inserting the following:

5 “(i) NEGOTIATING FAIR PRICES WITH DRUG MANU-
 6 FACTURERS.—

7 “(1) IN GENERAL.—Notwithstanding any other
 8 provision of law, in furtherance of the goals of pro-
 9 viding quality care and containing costs under this
 10 part, the Secretary shall, with respect to applicable
 11 covered part D drugs, and may, with respect to
 12 other covered part D drugs, negotiate, using the ne-
 13 gotiation technique that the Secretary determines
 14 will maximize savings and value for a covered part
 15 D drug and plan enrollees (in a manner that may
 16 be similar to Federal entities and that may include,
 17 but is not limited to, formularies, reference pricing,
 18 discounts, rebates, and other price concessions), with
 19 drug manufacturers the prices that may be charged
 20 to PDP sponsors and MA organizations for such
 21 drugs for part D eligible individuals who are enrolled
 22 in a prescription drug plan or in an MA–PD plan.
 23 In conducting such negotiations, the Secretary shall
 24 consider the drug’s current price, initial launch
 25 price, prevalence and usage, and approved indica-

tions, the number of similarly effective alternative treatments for each approved use of the drug, the budgetary impact of providing coverage under this part for such drug for all individuals who would likely benefit from the drug, and evidence on the drug's effectiveness compared to similar drugs.

“(2) USE OF LOWER OF VA OR BIG FOUR PRICE IF NEGOTIATIONS FAIL.—If, after attempting to negotiate for a price with respect to a covered part D drug under paragraph (1) for a period of 1 year, the Secretary is not successful in obtaining an appropriate price for the drug (as determined by the Secretary), the Secretary shall establish the price that may be charged to PDP sponsors and MA organizations for such drug for part D eligible individuals who are enrolled in a prescription drug plan or in an MA–PD plan at an amount equal to the lesser of—

“(A) the price paid by the Secretary of Veterans Affairs to procure the drug under the laws administered by the Secretary of Veterans Affairs; or

“(B) the price paid to procure the drug under section 8126 of title 38, United States Code.

1 “(3) APPLICABLE COVERED PART D DRUG DE-
 2 FINED.—For purposes of this subsection, the term
 3 ‘applicable covered part D drug’ means a covered
 4 part D drug that the Secretary determines to be ap-
 5 propriate for negotiation under paragraph (1) based
 6 on one or more of the following factors as applied
 7 to such drug:

8 “(A) Spending on a per beneficiary basis.

9 “(B) Spending under this title.

10 “(C) Unit price increases over the pre-
 11 ceding years.

12 “(D) Initial launch price.

13 “(E) Availability of similarly effective al-
 14 ternative treatments.

15 “(F) Status of the drug as a follow-on to
 16 previously approved drugs.

17 “(G) Any other criteria determined by the
 18 Secretary.

19 “(4) PDP SPONSORS AND MA ORGANIZATION
 20 MAY NEGOTIATE LOWER PRICES.—Nothing in this
 21 subsection shall be construed as preventing the spon-
 22 sor of a prescription drug plan, or an organization
 23 offering an MA–PD plan, from obtaining a discount
 24 or reduction of the price for a covered part D drug

below the price negotiated under paragraph (1) or the price established under paragraph (2).

“(5) NO AFFECT ON EXISTING APPEALS PROCESS.—Nothing in this subsection shall be construed to affect the appeals procedures under subsections (g) and (h) of section 1860D–4.”.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date of the enactment of this Act and shall first apply to negotiations and prices for plan years beginning on January 1, 2019.

(b) REPORTS TO CONGRESS.—

(1) SECRETARY OF HHS.—

(A) IN GENERAL.—Not later than 3 years after the date of the enactment of this Act, and every 6 months thereafter, the Secretary of Health and Human Services shall submit to Congress a report on the following:

(i) The negotiations conducted by the Secretary under section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)), as amended by subsection (a), including a description of how such negotiations are achieving lower prices for covered part D drugs (as defined in section

1 1860D–2(e) of the Social Security Act (42
 2 U.S.C. 1395w–102(e))) for Medicare bene-
 3 ficiaries.

4 (ii) Data on spending under part D of
 5 the Medicare program on covered part D
 6 drugs, including data on covered part D
 7 drugs with—

8 (I) spending on a per beneficiary
 9 basis that is above the median spend-
 10 ing on other drugs in the same class
 11 or above the median spending of other
 12 drug classes; and

13 (II) high unit cost increases over
 14 the past five years, especially where
 15 such increases are greater than the
 16 increases for covered part D drugs in
 17 general.

18 (iii) A list of the covered part D drugs
 19 with no therapeutic substitute and data on
 20 spending under part D of the Medicare
 21 program on such drugs.

22 (iv) Access to covered part D drugs.

23 (v) Appeals by enrollees with respect
 24 to covered part D drugs not included on
 25 plan formularies.

1 (B) PUBLIC AVAILABILITY OF REPORT.—

2 The Secretary of Health and Human Services
3 shall publish on the Internet website of the
4 Centers for Medicare & Medicaid Services a
5 copy of each report submitted under subpara-
6 graph (A).

7 (2) MEDPAC.—

8 (A) STUDY.—The Comptroller General of
9 the United States shall conduct a study on the
10 negotiations conducted by the Secretary under
11 section 1860D–11(i) of the Social Security Act
12 (42 U.S.C. 1395w–111(i)), as amended by sub-
13 section (a), including a description of how such
14 negotiations are achieving lower prices for cov-
15 ered part D drugs (as defined in section
16 1860D–2(e) of the Social Security Act (42
17 U.S.C. 1395w–102(e))) for Medicare bene-
18 ficiaries.

19 (B) REPORT.—Not later than January 1,
20 2022, the Comptroller General of the United
21 States shall submit to Congress a report on the
22 study conducted under subparagraph (A), to-
23 gether with recommendations for improving
24 such negotiations.

1 (c) CMI TESTING OF NEGOTIATING DRUG AND BIO-
 2 LOGICAL PRICES TO IMPROVE VALUE.—Section
 3 1115A(b)(2) of the Social Security Act (42 U.S.C.
 4 1315a(b)(2)) is amended—

5 (1) in subparagraph (A), by adding at the end
 6 the following new sentence: “The models selected
 7 under this subparagraph shall include at least 3 of
 8 the models described in subparagraph (D), which
 9 shall be implemented by not later than 18 months
 10 after the date of the enactment of the Prescription
 11 Drug and Health Improvement Act of 2017”; and

12 (2) by adding at the end the following new sub-
 13 paragraph:

14 “(D) MODELS OF NEGOTIATING DRUG AND
 15 BIOLOGICAL PRICES TO IMPROVE VALUE.—The
 16 models described in this subparagraph are the
 17 following models for negotiating drug and bio-
 18 logical prices under the applicable titles (includ-
 19 ing under both parts B and D of title XVIII)
 20 in order to improve the value of payments for
 21 such drugs and biologicals under such titles:

22 “(i) Discounting or eliminating pa-
 23 tient cost-sharing on high-value drugs and
 24 biologicals.

25 “(ii) Value-based formularies.

1 “(iii) Indications-based pricing.

2 “(iv) Reference pricing.

3 “(v) Risk-sharing agreements based
4 on outcomes.

5 “(vi) Pricing based on comparative ef-
6 fectiveness research.

7 “(vii) Episode-based payments for
8 chemotherapy and other conditions deter-
9 mined appropriate by the Secretary.”.

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