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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prescription Drug and Health Improvement Act of 2017''.

SEC. 2. NEGOTIATING FAIR PRICES FOR MEDICARE PRESCRIPTION DRUGS.

(a) NEGOTIATING FAIR PRICES.—

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

''(i) NEGOTIATING FAIR PRICES WITH DRUG MANUFACTURERS.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, in furtherance of the goals of providing quality care and containing costs under this part, the Secretary shall, with respect to applicable covered part D drugs, and may, with respect to other covered part D drugs, negotiate, using the negotiation technique that the Secretary determines will maximize savings and value for a covered part D drug and plan enrollees (in a manner that may be similar to Federal entities and that may include, but is not limited to, formularies, reference pricing, discounts, rebates, and other price concessions), with drug manufacturers the prices that may be charged to PDP sponsors and MA organizations for such drugs for part D eligible individuals who are enrolled in a prescription drug plan or in an MA–PD plan. In conducting such negotiations, the Secretary shall consider the drug's current price, initial launch 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.

"(3) APPLICABLE COVERED PART D DRUG DEFINED.—For purposes of this subsection, the term 'applicable covered part D drug' means a covered part D drug that the Secretary determines to be appropriate for negotiation under paragraph (1) based on one or more of the following factors as applied to such drug:

"(A) Spending on a per beneficiary basis.

"(B) Spending under this title.

"(C) Unit price increases over the preceding years.

"(D) Initial launch price.

"(E) Availability of similarly effective alternative treatments.

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

"(G) Any other criteria determined by the Secretary.

"(4) PDP SPONSORS AND MA ORGANIZATION MAY NEGOTIATE LOWER PRICES.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan, or an organization offering an MA–PD plan, from obtaining a discount 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

1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e))) for Medicare beneficiaries.

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

(I) spending on a per beneficiary basis that is above the median spending on other drugs in the same class or above the median spending of other drug classes; and

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

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

(iv) Access to covered part D drugs.

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

(B) PUBLIC AVAILABILITY OF REPORT.—The Secretary of Health and Human Services shall publish on the Internet website of the Centers for Medicare & Medicaid Services a copy of each report submitted under subparagraph (A).

(2) MEDPAC.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study on 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 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e))) for Medicare beneficiaries.

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

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

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

(2) by adding at the end the following new subparagraph:

''(D) MODELS OF NEGOTIATING DRUG AND BIOLOGICAL PRICES TO IMPROVE VALUE.—The models described in this subparagraph are the following models for negotiating drug and biological prices under the applicable titles (including under both parts B and D of title XVIII) in order to improve the value of payments for such drugs and biologicals under such titles:

''(i) Discounting or eliminating patient cost-sharing on high-value drugs and biologicals.

''(ii) Value-based formularies.

''(iii) Indications-based pricing.

''(iv) Reference pricing.

''(v) Risk-sharing agreements based on outcomes.

''(vi) Pricing based on comparative effectiveness research.

''(vii) Episode-based payments for chemotherapy and other conditions determined appropriate by the Secretary.''.

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