I

115TH CONGRESS
1ST SESSION

H. R. 1775

To amend part D of title XVIII of the Social Security Act to direct the President to negotiate prescription drug prices and establish a formulary on behalf of Medicare beneficiaries, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 29, 2017

Mr. DEFAZIO (for himself and Mr. CONYERS) 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 part D of title XVIII of the Social Security Act to direct the President to negotiate prescription drug prices and establish a formulary on behalf of Medicare beneficiaries, and for other purposes.

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 Reduction in Costs for Everyone (PRICE) Act of 2017''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) The President has announced his intention to bring down prices of prescription drugs.

(2) The President has touted his negotiating skills and referred to himself as a ''master negotiator''.

SEC. 3. PRESIDENTIAL NEGOTIATION OF PRESCRIPTION DRUG PRICES.

(a) NEGOTIATION BY PRESIDENT.—Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended by striking subsection (i) (relating to noninterference) and inserting the following:

''(i) NEGOTIATION OF LOWER DRUG PRICES.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, the President shall negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and MA organizations for covered part D drugs for part D eligible individuals who are enrolled under a prescription drug plan or under an MA–PD plan.

''(2) NO CHANGE IN RULES FOR FORMULARIES.—

''(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to authorize the Presi-

dent to establish or require a particular formulary.

''(B) CONSTRUCTION.—Subparagraph (A) shall not be construed as affecting the President's authority to ensure appropriate and adequate access to covered part D drugs under prescription drug plans and under MA–PD plans, including compliance of such plans with formulary requirements under section 1860D–4(b)(3).

''(3) CONSTRUCTION.—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).

''(4) SEMI-ANNUAL REPORTS TO CONGRESS.—Not later than June 1, 2018, and every 6 months thereafter, the President shall submit to the Committees on Ways and Means, Energy and Commerce, and Oversight and Government Reform of the House of Representatives and the Committee on Finance of the Senate a report on negotiations conducted by the President to achieve lower prices for Medicare bene-

ficiaries, and the prices and price discounts achieved by the President as a result of such negotiations.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) 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, 2018.

SEC. 4. PRESIDENTIAL ESTABLISHMENT OF MEDICARE OPERATED PRESCRIPTION DRUG PLAN OPTION.

(a) IN GENERAL.—Subpart 2 of part D of title XVIII of the Social Security Act is amended by inserting after section 1860D–11 (42 U.S.C. 1395w–111) the following new section:

''MEDICARE OPERATED PRESCRIPTION DRUG PLAN OPTION

''SEC. 1860D–11A. (a) IN GENERAL.—Notwithstanding any other provision of this part, for each year (beginning with 2018), in addition to any plans offered under section 1860D–11, the President shall offer one or more Medicare operated prescription drug plans (as defined in subsection (c)) with a service area that consists of the entire United States and shall enter into negotiations in accordance with subsection (b) with pharmaceutical manufacturers to reduce the purchase cost of covered part D drugs for eligible part D individuals who enroll in such a plan.

''(b) NEGOTIATIONS.—For purposes of offering a Medicare operated prescription drug plan under this section, the President shall negotiate with pharmaceutical manufacturers with respect to the purchase price of covered part D drugs in a Medicare operated prescription drug plan and shall encourage the use of more affordable therapeutic equivalents to the extent such practices do not override medical necessity as determined by the prescribing physician. To the extent practicable and consistent with the previous sentence, the President shall implement strategies similar to those used by other Federal purchasers of prescription drugs, and other strategies, including the use of a formulary and formulary incentives in subsection (e), to reduce the purchase cost of covered part D drugs.

''(c) MEDICARE OPERATED PRESCRIPTION DRUG PLAN DEFINED.—For purposes of this part, the term 'Medicare operated prescription drug plan' means a prescription drug plan that offers qualified prescription drug coverage and access to negotiated prices described in section 1860D–2(a)(1)(A). Such a plan may offer supplemental prescription drug coverage in the same manner as other qualified prescription drug coverage offered by other prescription drug plans.

''(d) MONTHLY BENEFICIARY PREMIUM.—

''(1) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The monthly beneficiary premium for qualified prescription drug coverage and access to negotiated prices described in section 1860D–2(a)(1)(A) to be charged under a Medicare operated prescription drug plan shall be uniform nationally. Such premium for months in 2018 and each succeeding year shall be based on the average monthly per capita actuarial cost of offering the Medicare operated prescription drug plan for the year involved, including administrative expenses.

''(2) SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—Insofar as a Medicare operated prescription drug plan offers supplemental prescription drug coverage, the President may adjust the amount of the premium charged under paragraph (1).

''(e) USE OF A FORMULARY AND FORMULARY INCENTIVES.—

''(1) IN GENERAL.—With respect to the operation of a Medicare operated prescription drug plan, the President shall establish and apply a formulary (and may include formulary incentives described in paragraph (2)(C)(ii)) in accordance with this subsection in order to—

''(A) increase patient safety;

"(B) increase appropriate use and reduce inappropriate use of drugs; and

"(C) reward value.

"(2) DEVELOPMENT OF INITIAL FORMULARY.—

"(A) IN GENERAL.—In selecting covered part D drugs for inclusion in a formulary, the President shall consider clinical benefit and price.

"(B) ROLE OF AHRQ.—The Director of the Agency for Healthcare Research and Quality shall be responsible for assessing the clinical benefit of covered part D drugs and making recommendations to the President regarding which drugs should be included in the formulary. In conducting such assessments and making such recommendations, the Director shall—

"(i) consider safety concerns including those identified by the Federal Food and Drug Administration;

"(ii) use available data and evaluations, with priority given to randomized controlled trials, to examine clinical effectiveness, comparative effectiveness, safety,

and enhanced compliance with a drug regimen;

''(iii) use the same classes of drugs developed by United States Pharmacopeia for this part;

''(iv) consider evaluations made by—

''(I) the Director under section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;

''(II) other Federal entities, such as the Secretary of Veterans Affairs; and

''(III) other private and public entities, such as the Drug Effectiveness Review Project and Medicaid programs; and

''(v) recommend to the President—

''(I) those drugs in a class that provide a greater clinical benefit, including fewer safety concerns or less risk of side effects, than another drug in the same class that should be included in the formulary;

''(II) those drugs in a class that provide less clinical benefit, including greater safety concerns or a greater risk of side effects, than another drug in the same class that should be excluded from the formulary; and

''(III) drugs in a class with same or similar clinical benefit for which it would be appropriate for the Secretary to competitively bid (or negotiate) for placement on the formulary.

''(C) CONSIDERATION OF AHRQ RECOMMENDATIONS.—

''(i) IN GENERAL.—The President, after taking into consideration the recommendations under subparagraph (B)(v), shall establish a formulary, and formulary incentives, to encourage use of covered part D drugs that—

''(I) have a lower cost and provide a greater clinical benefit than other drugs;

''(II) have a lower cost than other drugs with same or similar clinical benefit; and

''(III) have the same cost but provide greater clinical benefit than other drugs.

''(ii) FORMULARY INCENTIVES.—The formulary incentives under clause (i) may be in the form of one or more of the following:

''(I) Tiered copayments.

''(II) Reference pricing.

''(III) Prior authorization.

''(IV) Step therapy.

''(V) Medication therapy management.

''(VI) Generic drug substitution.

''(iii) FLEXIBILITY.—In applying such formulary incentives the President may decide not to impose any cost-sharing for a covered part D drug for which—

''(I) the elimination of cost sharing would be expected to increase compliance with a drug regimen; and

''(II) compliance would be expected to produce savings under part A or B or both.

''(3) LIMITATIONS ON FORMULARY.—In any formulary established under this subsection, the formulary may not be changed during a year, except—

''(A) to add a generic version of a covered part D drug that entered the market;

''(B) to remove such a drug for which a safety problem is found; and

''(C) to add a drug that the President identifies as a drug which treats a condition for which there has not previously been a treatment option or for which a clear and significant benefit has been demonstrated over other covered part D drugs.

''(4) ADDING DRUGS TO THE INITIAL FORMULARY.—

''(A) USE OF ADVISORY COMMITTEE.—The President shall establish and appoint an advisory committee (in this paragraph referred to as the 'advisory committee')—

''(i) to review petitions from drug manufacturers, health care provider organizations, patient groups, and other entities for inclusion of a drug in, or other changes to, such formulary; and

"(ii) to recommend any changes to the formulary established under this subsection.

"(B) COMPOSITION.—The advisory committee shall be composed of 9 members and shall include representatives of physicians, pharmacists, and consumers and others with expertise in evaluating prescription drugs. The President shall select members based on their knowledge of pharmaceuticals and the Medicare population. Members shall be deemed to be special Government employees for purposes of applying the conflict of interest provisions under section 208 of title 18, United States Code, and no waiver of such provisions for such a member shall be permitted.

"(C) CONSULTATION.—The advisory committee shall consult, as necessary, with physicians who are specialists in treating the disease for which a drug is being considered.

"(D) REQUEST FOR STUDIES.—The advisory committee may request the Agency for Healthcare Research and Quality or an academic or research institution to study and make

a report on a petition described in subparagraph (A)(ii) in order to assess—

"(i) clinical effectiveness;

"(ii) comparative effectiveness;

"(iii) safety; and

"(iv) enhanced compliance with a drug regimen.

"(E) RECOMMENDATIONS.—The advisory committee shall make recommendations to the President regarding—

"(i) whether a covered part D drug is found to provide a greater clinical benefit, including fewer safety concerns or less risk of side effects, than another drug in the same class that is currently included in the formulary and should be included in the formulary;

"(ii) whether a covered part D drug is found to provide less clinical benefit, including greater safety concerns or a greater risk of side effects, than another drug in the same class that is currently included in the formulary and should not be included in the formulary; and

"(iii) whether a covered part D drug has the same or similar clinical benefit to a drug in the same class that is currently included in the formulary and whether the drug should be included in the formulary.

"(F) LIMITATIONS ON REVIEW OF MANUFACTURER PETITIONS.—The advisory committee shall not review a petition of a drug manufacturer under subparagraph (A)(ii) with respect to a covered part D drug unless the petition is accompanied by the following:

"(i) Raw data from clinical trials on the safety and effectiveness of the drug.

"(ii) Any data from clinical trials conducted using active controls on the drug or drugs that are the current standard of care.

"(iii) Any available data on comparative effectiveness of the drug.

"(iv) Any other information the President requires for the advisory committee to complete its review.

"(G) RESPONSE TO RECOMMENDATIONS.—The President shall review the recommendations of the advisory committee and if the

President accepts such recommendations the President shall modify the formulary established under this subsection accordingly. Nothing in this section shall preclude the President from adding to the formulary a drug for which the Director of the Agency for Healthcare Research and Quality or the advisory committee has not made a recommendation.

''(H) NOTICE OF CHANGES.—The President shall provide timely notice to beneficiaries and health professionals about changes to the formulary or formulary incentives.

''(f) INFORMING BENEFICIARIES.—The President shall take steps to inform beneficiaries about the availability of a Medicare operated drug plan or plans including providing information in the annual handbook distributed to all beneficiaries and adding information to the official public Medicare Web site related to prescription drug coverage available through this part.

''(g) APPLICATION OF ALL OTHER REQUIREMENTS FOR PRESCRIPTION DRUG PLANS.—Except as specifically provided in this section, any Medicare operated drug plan shall meet the same requirements as apply to any other prescription drug plan, including the requirements of sec-

tion 1860D–4(b)(1) relating to assuring pharmacy access.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1860D–3(a) of the Social Security Act (42 U.S.C. 1395w–103(a)) is amended by adding at the end the following new paragraph:

''(4) AVAILABILITY OF THE MEDICARE OPERATED PRESCRIPTION DRUG PLAN.—A Medicare operated prescription drug plan (as defined in section 1860D–11A(c)) shall be offered nationally in accordance with section 1860D–11A.''.

(2)(A) Section 1860D–3 of the Social Security Act (42 U.S.C. 1395w–103) is amended by adding at the end the following new subsection:

''(c) PROVISIONS ONLY APPLICABLE IN 2006 THROUGH 2017.—The provisions of this section shall only apply with respect to 2006 through 2017.''.

(B) Section 1860D–11(g) of such Act (42 U.S.C. 1395w–111(g)) is amended by adding at the end the following new paragraph:

''(8) NO AUTHORITY FOR FALLBACK PLANS AFTER 2017.—A fallback prescription drug plan shall not be available after December 31, 2017.''.

(3) Section 1860D–13(c)(3) of the Social Security Act (42 U.S.C. 1395w–113(c)(3)) is amended—

(A) in the heading, by inserting ''AND MEDICARE OPERATED PRESCRIPTION DRUG PLANS'' after ''FALLBACK PLANS''; and

(B) by inserting ''or a Medicare operated prescription drug plan'' after ''a fallback prescription drug plan''.

(4) Section 1860D–16(b)(1) of the Social Security Act (42 U.S.C. 1395w–116(b)(1)) is amended—

(A) in subparagraph (C), by striking ''and'' after the semicolon at the end;

(B) in subparagraph (D), by striking the period at the end and inserting ''; and''; and

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

''(E) payments for expenses incurred with respect to the operation of Medicare operated prescription drug plans under section 1860D–11A.''.

(5) Section 1860D–41(a) of the Social Security Act (42 U.S.C. 1395w–151(a)) is amended by adding at the end the following new paragraph:

''(19) MEDICARE OPERATED PRESCRIPTION DRUG PLAN.—The term 'Medicare operated prescrip-

tion drug plan' has the meaning given such term in section 1860D–11A(c).".

○