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115TH CONGRESS
2D SESSION

H. R. 6574

To amend part D of title XVIII of the Social Security Act to require the Secretary of Health and Human Services to determine, on behalf of Medicare beneficiaries, covered part D drug prices for certain covered part D drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 26, 2018

Ms. SCHAKOWSKY 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

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A BILL

To amend part D of title XVIII of the Social Security Act to require the Secretary of Health and Human Services to determine, on behalf of Medicare beneficiaries, covered part D drug prices for certain covered part D drugs, 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 ''Medicare Fair Drug Pricing Act of 2018''.

SEC. 2. REQUIREMENT TO DETERMINE LOWER COVERED PART D DRUG PRICES FOR CERTAIN COVERED PART D DRUGS.

(a) IN GENERAL.—Section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)) is amended—

(1) by striking ''(i) NONINTERFERENCE.—In'' and inserting the following:

''(i) NONINTERFERENCE.—

''(1) IN GENERAL.—In'';

(2) by inserting ''subject to paragraph (2),'' after ''part,''; and

(3) by adding at the end the following new paragraph:

''(2) EXCEPTION FOR SPECIFIED DRUGS.—

''(A) REQUIREMENT.—

''(i) IN GENERAL.—Notwithstanding paragraph (1), the part D price for specified drugs shall be determined in accordance with the process described in subparagraph (B).

''(ii) SPECIFIED DRUGS.—For purposes of this paragraph, the term 'specified drug' means a covered part D drug—

''(I) that is—

''(aa) a single source drug or biological;

''(bb) not a biological product licensed pursuant to an application under section 351(k) of the Public Health Service Act; and

''(cc) not both manufactured by more than two drug manufacturers and manufactured by at least one such manufacturer as a generic drug; or

''(II) that—

''(aa) is selected by the Secretary for purposes of this paragraph; and

''(bb) the Secretary determines is a covered part D drug with respect to which there is limited ability for PDP sponsors and MA organizations to negotiate manufacturer rebates, such that the Secretary determines that the failure to apply this paragraph will have a significant fiscal impact on the program under this title.

"(iii) PART D PRICE DEFINED.—For purposes of this paragraph, the term 'part D price' means, with respect to a covered part D drug, the price (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and MA organizations for such drug for part D eligible individuals who are enrolled under a prescription drug plan or under an MA–PD plan.

"(iv) REGULATIONS FOR IDENTIFICATION OF SPECIFIED DRUGS.—The Secretary, not later than one year after the date of the enactment of this paragraph, shall promulgate regulations regarding the identification of single source drugs and biologicals as specified drugs.

"(v) PROCESS TO PETITION THAT DRUG IS NO LONGER A SPECIFIED DRUG.—The Secretary shall establish a process under which a manufacturer for a specified drug may petition the Secretary for the rescinding of a previous identification of a drug as a specified drug under clause (ii)

based upon the drug involved no longer being a specified drug.

''(B) PRICE DETERMINATION PROCESS.—For purposes of subparagraph (A), the process described in this subparagraph, with respect to the part D price for a specified drug for a plan year, is the following:

''(i) LIMITED PERIOD FOR NEGOTIATION FOR FIRST PLAN YEAR.—

''(I) IN GENERAL.—The Secretary shall negotiate such price with the drug manufacturer involved for a period of not more than 90 days beginning on the date of identification of the drug as a specified drug for such plan year by the Secretary.

''(II) SUCCESSFUL NEGOTIATIONS.—In the case that such negotiation with respect to such 90-day period results in a price that is agreed to by both the Secretary and manufacturer, such price shall be the maximum part D price for such specified drug through the end of the plan year beginning after such period.

"(ii) SECRETARY SETS PRICE FOR FIRST PLAN YEAR IN CASE OF FAILURE TO NEGOTIATE PRICE.—In the case that negotiations under clause (i), with respect to a specified drug, do not result in a price for such specified drug that is so agreed to by the Secretary and drug manufacturer, the Secretary shall determine a price for such drug based on—

"(I) the information provided to the Secretary by the drug manufacturer during the 90-day period described in clause (i)(I) regarding costs associated with such drug that are applicable with respect to such drug manufacturer;

"(II) in the case that payment is made for such drug by the Department of Veterans Affairs or under title XIX, the net priced paid for such drug by such Department or under such title, as applicable;

"(III) ensuring affordability of such drug, and accessibility to such drug, for individuals entitled to bene-

fits under part A or enrolled under part B; and

"(IV) such other factors as the Secretary determines appropriate.

The price determined under this clause shall be the maximum part D price for such specified drug through the end of the plan year beginning after such determination of such price.

"(iii) PRICE IN SUBSEQUENT PLAN YEARS.—For each plan year that is subsequent to the plan year for which a price is determined for a specified drug under clause (i) or (ii) and in which, on the first day of such subsequent plan year, the identification of such drug as a specified drug still applies, the maximum price for such drug shall be the maximum part D price for the previous year determined under clause (i) or (ii), as applicable, increased by the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the year before such subsequent plan year.

"(iv) CONSULTATION.—In determining a price for a specified drug under clause (ii), the Secretary may consult with the Comptroller General, the Medicare Payment Advisory Commission, the Medicaid and CHIP Payment and Access Commission, or other outside, independent experts.

"(C) NO CHANGE IN RULES FOR FORMULARIES.—

"(i) IN GENERAL.—Nothing in subparagraph (A) or (B) shall be construed to authorize the Secretary to establish or require a particular formulary.

"(ii) CONSTRUCTION.—Clause (i) shall not be construed as affecting the Secretary'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).

"(D) CONSTRUCTION.—Nothing in this paragraph shall be construed as—

''(i) 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 described in subparagraph (A) below the price negotiated under such subparagraph or determined under subparagraph (B); or

''(ii) permitting the Secretary to make proprietary data available to the public.

''(E) DEFINITIONS.—In this paragraph:

''(i) DRUG MANUFACTURER.—The term 'drug manufacturer' has the meaning given the term 'manufacturer' in section 1860D–14A(g)(5).

''(ii) SINGLE SOURCE DRUG OR BIOLOGICAL.—The term 'single source drug or biological' has the meaning given such term in section 1847A(c)(6)(D).''.

(b) REQUIRING PARTICIPATION IN NEGOTIATION PROCESS AS CONDITION OF PART D DRUG COVERAGE.—Section 1860D–14A(b) of the Social Security Act (42 U.S.C. 1395w–114a(b)) is amended by adding at the end the following new paragraph:

''(5) PARTICIPATION IN NEGOTIATION PROCESS.—Each agreement under this subsection shall include, with respect to plans years beginning with plan year 2019, an agreement by the manufacturer, with respect to each specified drug of such manufacturer under section 1860d–11(i)(2), to participate in the negotiation process under such section for such drug, including accepting the price resulting from the negotiation (or, in the case that such negotiation does not result in a price for such drug that is agreed to by the Secretary and the manufacturer, the price resulting from the application of subparagraph (B)(ii) of such section) as the maximum price for such drug for the period provided under such section.''.

SEC. 3. STUDY AND REPORT.

(a) STUDY.—The Secretary of Health and Human Services shall conduct a study examining—

(1) the impact of the amendments made by section 2 on—

(A) the cost of single source drugs and biologicals (as defined in section 1847A(c)(6)(D) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(D))) for which payment

is made under part B of title XVIII of such Act; and

(B) the accessibility of such drugs and biologicals for individuals entitled to benefits under part A of such title or enrolled under part B of such title; and

(2) options that would permit or require the Secretary to create and implement, not later than one year after the date of the report described in subsection (b)—

(A) a method to apply to such single source drugs and biologicals for which the Secretary determines appropriate—

(i) an authority similar to the authority granted to the Secretary under subparagraph (A) of section 1860D–11(i)(2) of such Act (relating to negotiating with drug manufacturers the part D prices for certain specified drugs); and

(ii) a negotiation process similar to the process under subparagraph (B) of such section; and

(B) a method, such as a rebate program, to incorporate the rate negotiated for such drugs and biologicals pursuant to the authority

described in subparagraph (A) into payments for such drugs and biologicals under part B of such Act.

(b) REPORT.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to Congress on the results of the study conducted under subsection (a). Such report shall include recommendations regarding the options examined pursuant to paragraph (2) of such subsection.

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