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116TH CONGRESS
1ST SESSION

H. R. 4619

To amend title XVIII of the Social Security Act to require drug manufacturers to pay a Medicare part D rebate for certain drugs if the price of such drugs increases faster than inflation.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 2019

Ms. SCHAKOWSKY (for herself, Mr. HIGGINS of New York, and Ms. WILD) 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 title XVIII of the Social Security Act to require drug manufacturers to pay a Medicare part D rebate for certain drugs if the price of such drugs increases faster than inflation.

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 ''Pharmaceutical Rebates for Excessive Pricing Above Inflation Act'' or the ''Pharmaceutical REPAI Act''.

SEC. 2. MEDICARE PART D PRESCRIPTION DRUG INFLATION REBATE BY MANUFACTURERS.

Part D of title XVIII of the Social Security Act is amended by inserting after section 1860D–14A (42 U.S.C. 1395w–114a) the following new section:

"SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.

''(a) IN GENERAL.—Subject to the provisions of this section, in order for coverage to be available under this part for a part D rebatable drug of a manufacturer dispensed during an applicable year, the manufacturer must have entered into and have in effect an agreement described in subsection (b). For purposes of this section the term 'applicable year' means a year beginning with 2022.

''(b) AGREEMENTS.—

''(1) TERMS OF AGREEMENT.—An agreement described in this subsection, with respect to a manufacturer of a part D rebatable drug, is an agreement under which the following applies:

''(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 9 months after the end of each applicable year with respect to which the agreement is in effect, the Secretary, for the part D rebatable drug of the manufac-

turer, reports to the manufacturer the following for such year:

"(i) Information on the total units (as defined in subsection (g)(2)) dispensed for each dosage form and strength with respect to such part D rebatable drug and year.

"(ii) Information on the amount (if any) of the excess average manufacturer price increase described in subsection (c)(1)(B) for each dosage form and strength with respect to such drug and year.

"(iii) The rebate amount specified under subsection (c) for each dosage form and strength with respect to such drug and year.

"(B) MANUFACTURER REQUIREMENTS.—For each applicable year with respect to which the agreement is in effect, the manufacturer of the part D rebatable drug, for each dosage form and strength with respect to such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such year, provides to

the Secretary a rebate that is equal to the amount specified in subsection (c) for such dosage form and strength with respect to such drug for such year.

''(2) LENGTH OF AGREEMENT.—

''(A) IN GENERAL.—An agreement under this section, with respect to a part D rebatable drug, shall be effective for an initial period of not less than one year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

''(B) TERMINATION.—

''(i) BY SECRETARY.—The Secretary may provide for termination of an agreement under this section for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

"(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall not be effective until the year beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

"(C) EFFECTIVENESS OF TERMINATION.—Any termination under this paragraph shall not affect rebates due under the agreement under this section before the effective date of its termination.

"(D) DELAY BEFORE REENTRY.—In the case of any agreement under this section with a manufacturer which is terminated in a plan year, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into before the subsequent plan year, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

"(3) INFORMATION.—For purposes of carrying out this section, the Secretary shall use information submitted by manufacturers under section 1927(b)(3).

"(c) REBATE AMOUNT.—

''(1) IN GENERAL.—For purposes of this section, the amount specified in this subsection for a dosage form and strength with respect to a part D rebatable drug and applicable year is, subject to subparagraphs (B) and (C) of paragraph (3), the amount equal to the product of—

''(A) the total average number of units weighted by, and dispensed for, such dosage form and strength with respect to such part D rebatable drug and year; and

''(B) the amount (if any) by which—

''(i) the average manufacturer price (as defined in subsection (g)) paid for such dosage form and strength with respect to such part D rebatable drug during the year; exceeds

''(ii) the inflation-adjusted payment amount determined under paragraph (2) for such dosage form and strength with respect to such part D rebatable drug during the year.

''(2) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this paragraph for a dosage form and strength with respect to a part D

rebatable drug for an applicable year, subject to subparagraphs (A) and (D) of paragraph (3), is—

"(A) the average manufacturer price paid for such dosage form and strength with respect to such drug in the payment amount benchmark year (as defined in subsection (g)(3)); increased by

"(B) the percentage by which the rebate period CPI–U (as defined in subsection (g)(5)) for the applicable year exceeds the benchmark period CPI–U (as defined in subsection (g)(4)).

"(3) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

"(A) SUBSEQUENTLY APPROVED DRUGS.—In the case of a part D rebatable drug first approved by the Food and Drug Administration after January 1, 2016, subparagraph (A) of paragraph (2) shall be applied as if the term 'payment amount benchmark year' were defined under subsection (g)(3) as the first year beginning after the day on which the drug was first marketed and subparagraph (B) of paragraph (2) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (g)(4) as if the reference to 'January 2016'

under such subsection were a reference to 'January of the first year beginning after the date on which the drug was first marketed by any manufacturer'.

''(B) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate under paragraph (1) with respect to a part D rebatable drug in the case of a shortage of such drug or other exigent circumstances, as determined by the Secretary.

''(C) TREATMENT OF NEW FORMULATIONS.—

''(i) IN GENERAL.—In the case of a part D rebatable drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the Secretary shall establish a formula for determining the amount specified in this subsection with respect to such part D rebatable drug and an applicable year with consideration of the single source drug or an innovator multiple source drug.

''(ii) LINE EXTENSION DEFINED.—In this subparagraph, the term 'line exten-

sion' means, with respect to a part D rebatable drug, a new formulation of the drug (as determined by the Secretary), such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.

''(d) REBATE DEPOSITS.—Amounts paid as rebates under subsection (c) shall be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(e) CIVIL MONEY PENALTY.—In the case of a manufacturer of a part D rebatable drug with an agreement in effect under this section who has failed to comply with the terms of the agreement under subsection (b)(1)(B) with respect to such drug for an applicable year, the Secretary may impose a civil money penalty on such manufacturer in an amount equal to 125 percent of the amount specified in subsection (c) for such drug for such year. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty

under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(f) JUDICIAL REVIEW.—There shall be no judicial review of the following:

''(1) The determination of units under this section.

''(2) The determination of whether a drug is a part D rebatable drug under this section.

''(3) The calculation of the rebate amount under this section.

''(g) DEFINITIONS.—In this section:

''(1) PART D REBATABLE DRUG DEFINED.—

''(A) IN GENERAL.—The term 'part D rebatable drug' means a drug or biological that would (without application of this section) be a covered part D drug, except such term shall, with respect to an applicable year, not include such a drug or biological if the average total cost under a prescription drug plan under this part or MA–PD plan under part C for such year per individual who uses such a drug or biological, as determined by the Secretary, are less than, subject to subparagraph (B), $100, as determined by the Secretary using the most

recent data available or, if data is not available, as estimated by the Secretary.

''(B) INCREASE.—The dollar amount applied under subparagraph (A)—

''(i) for 2023, shall be the dollar amount specified under such subparagraph for 2022, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) as of January of 2022; and

''(ii) for a subsequent year, shall be the dollar amount specified in this subparagraph (or subparagraph (A)) for the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) as of January of the previous year.

Any dollar amount specified under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(2) UNIT DEFINED.—The term 'unit' means, with respect to a part D rebatable drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the part D rebatable drug that is dispensed to individuals en-

rolled under a prescription drug plan under this part or an MA–PD plan under part C.

''(3) PAYMENT AMOUNT BENCHMARK YEAR.—The term 'payment amount benchmark year' means the year beginning January 1, 2016.

''(4) BENCHMARK PERIOD CPI–U.—The term 'benchmark period CPI–U' means the consumer price index for all urban consumers (United States city average) for January 2016.

''(5) REBATE PERIOD CPI–U.—The term 'rebate period CPI–U' means, with respect to an applicable year, the consumer price index for all urban consumers (United States city average) for January of such year.

''(6) AVERAGE MANUFACTURER PRICE.—The term 'average manufacturer price' has the meaning, with respect to a part D rebatable drug of a manufacturer for an applicable year, given such term in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927. For purposes of applying the previous sentence, with respect to a part D rebatable drug of a manufacturer and an applicable year, the Secretary shall use the information with respect to the average manufacturer price for such drug re-

ported by the manufacturer under section 1927(b)(3) with respect to each of the quarters in the applicable year and calculate an annual average manufacturer price for such applicable year as the average of such average manufacturer prices for each such quarter, weighted by units of such drug sold or dispensed with respect to such applicable year.''.

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