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116TH CONGRESS
1ST SESSION

H. R. 4663

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 11, 2019

Ms. PORTER (for herself, Ms. UNDERWOOD, Mr. CROW, and Mr. BLUMENAUER) 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 B 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 ''Freedom from Price Gouging Act''.

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

(a) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

''(x) REBATE BY MANUFACTURERS FOR SINGLE SOURCE DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.—

''(1) REQUIREMENTS.—

''(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 6 months after the end of each calendar quarter beginning on or after July 1, 2021, the Secretary shall, for each part B rebatable drug, report to each manufacturer of such part B rebatable drug the following for such calendar quarter:

''(i) Information on the total number of billing units described in subparagraph (A)(i) of paragraph (3) with respect to such drug and calendar quarter.

''(ii) Information on the amount (if any) of the excess average sales price increase described in subparagraph (A)(ii) of such paragraph for such drug and calendar quarter.

"(iii) The rebate amount specified under such paragraph for such part B rebatable drug and calendar quarter.

"(B) MANUFACTURER REQUIREMENT.—For each calendar quarter beginning on or after July 1, 2021, the manufacturer of a part B rebatable drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such calendar quarter, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such calendar quarter.

"(2) PART B REBATABLE DRUG DEFINED.—

"(A) IN GENERAL.—In this subsection, the term 'part B rebatable drug' means a single source drug or biological (as defined in subparagraph (D) of section 1847A(c)(6)), including a biosimilar biological product (as defined in subparagraph (H) of such section), paid for under this part, except such term shall not include such a drug or biological—

"(i) if the average total allowed charges for a year per individual that uses such a drug or biological, as determined by

the Secretary, are less than, subject to subparagraph (B), $100; or

''(ii) that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10).

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

''(i) for 2022, shall be the dollar amount specified under such subparagraph for 2021, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) as of the first quarter of the previous year; and

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

''(3) REBATE AMOUNT.—

"(A) IN GENERAL.—For purposes of paragraph (1)(B), the amount specified in this paragraph for a part B rebatable drug assigned to a billing and payment code for a calendar quarter is, subject to paragraph (4), the amount equal to the product of—

"(i) subject to subparagraph (B), the total number of billing units, as described in section 1847A(b)(6)(B), for such part B rebatable drug furnished under this part during the calendar quarter; and

"(ii) the amount (if any) by which—

"(I) the payment amount under subparagraph (B) or (C) of section 1847A(b)(1), as applicable, for such part B rebatable drug during the calendar quarter; exceeds

"(II) the inflation-adjusted payment amount determined under subparagraph (C) for such part B rebatable drug during the calendar quarter.

"(B) EXCLUDED UNITS.—For purposes of subparagraph (A)(i), the total number of billing

units for part B rebatable drugs furnished during a calendar quarter shall not include—

"(i) units packaged into the payment for a related procedure or service under section 1833(t) or under section 1833(i) (instead of separately payable under such respective section);

"(ii) units included under the single payment system for renal dialysis services under section 1881(b)(14); or

"(iii) units of a part B rebatable drug of a manufacturer that is furnished to an individual, if such manufacturer, with respect to the furnishing of such units of such drug, provides for discounts under section 340B of the Public Health Service Act or for rebates under section 1927.

"(C) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this subparagraph for a part B rebatable drug for a calendar quarter is—

"(i) the payment amount for the billing and payment code for such drug in the

payment amount benchmark quarter (as defined in subparagraph (D)); increased by

"(ii) the percentage by which the rebate period CPI–U (as defined in subparagraph (F)) for the calendar quarter exceeds the benchmark period CPI–U (as defined in subparagraph (E)).

"(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term 'payment amount benchmark quarter' means the calendar quarter beginning January 1, 2016.

"(E) BENCHMARK PERIOD CPI–U.—The term 'benchmark period CPI–U' means the consumer price index for all urban consumers (United States city average) for July 2015.

"(F) REBATE PERIOD CPI–U.—The term 'rebate period CPI–U' means, with respect to a calendar quarter described in subparagraph (C), the greater of the benchmark period CPI–U and the consumer price index for all urban consumers (United States city average) for the first month of the calendar quarter that is two calendar quarters prior to such described calendar quarter.

''(4) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

''(A) SUBSEQUENTLY APPROVED DRUGS.—Subject to subparagraph (B), in the case of a part B rebatable drug first approved by the Food and Drug Administration after July 1, 2015, clause (i) of paragraph (3)(C) shall be applied as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the third full calendar quarter after the day on which the drug was first marketed and clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (3)(E) as if the reference to 'July 2015' under such paragraph were a reference to 'the first month of the first full calendar quarter after the day on which the drug was first marketed'.

''(B) TIMELINE FOR PROVISION OF REBATES FOR NEW DRUGS.—In the case of a part B rebatable drug first approved by the Food and Drug Administration after July 1, 2015, clause (i) of paragraph (1)(B) shall be applied as if the reference to 'July 1, 2021' under such paragraph were a reference to the later of the

6th full calendar quarter after the day on which the drug was first marketed or July 1, 2021.

''(C) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate under paragraph (1)(B) with respect to a part B rebatable drug that appears on the drug shortage list in effect under section 506(e) of the Federal Food, Drug, and Cosmetic Act or in the case of other exigent circumstances, as determined by the Secretary.

''(5) APPLICATION TO BENEFICIARY COINSURANCE.—In the case of a part B rebatable drug for which a rebate is payable under this subsection—

''(A) in computing the amount of any coinsurance applicable under this title to an individual with respect to such drug, the computation of such coinsurance shall be based on the inflation-adjusted payment amount determined under paragraph (3)(C) for such part B rebatable drug; and

''(B) the amount of such coinsurance is equal to 20 percent of such inflation-adjusted payment amount so determined.

''(6) REBATE DEPOSITS.—Amounts paid as rebates under paragraph (1)(B) shall be deposited into

the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(7) CIVIL MONEY PENALTY.—If a manufacturer of a part B rebatable drug has failed to comply with the requirements under paragraph (1)(B) for such drug for a calendar quarter, the manufacturer shall be subject to, in accordance with a process established by the Secretary pursuant to regulations, a civil money penalty in an amount equal to at least 125 percent of the amount specified in paragraph (3) for such drug for such calendar quarter. 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 paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(8) STUDY AND REPORT.—

''(A) STUDY.—The Secretary shall conduct a study of the feasibility of and operational issues involved with the following:

''(i) Including multiple source drugs (as defined in section 1847A(c)(6)(C)) in the rebate system under this subsection.

''(ii) Including drugs and biologicals paid for under MA plans under part C in the rebate system under this subsection.

''(iii) Including drugs excluded under paragraph (2)(A) and billing units of drugs excluded under paragraph (3)(B) in the rebate system under this subsection.

''(B) REPORT.—Not later than 3 years after the date of the enactment of this subsection, the Secretary shall submit to Congress a report on the study conducted under subparagraph (A).

''(9) APPLICATION TO MULTIPLE SOURCE DRUGS.—The Secretary may, based on the report submitted under paragraph (8) and pursuant to rulemaking, apply the provisions of this subsection to multiple source drugs (as defined in section 1847A(c)(6)(C)), including, for purposes of determining the rebate amount under paragraph (3), by calculating manufacturer-specific average sales prices for the benchmark period and the rebate period.''.

(b) AMOUNTS PAYABLE; COST-SHARING.—Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (S), by striking ''with respect to'' and inserting ''subject to subparagraph (DD), with respect to'';

(B) by striking ''and (CC)'' and inserting ''(CC)''; and

(C) by inserting before the semicolon at the end the following: '', and (DD) with respect to a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) for which a rebate is payable under such section, the amounts paid shall be the difference between (i) the payment amount under paragraph (3)(A)(ii)(I) of such section for such drug, and (ii) 20 percent of the inflation-adjusted payment amount under paragraph (3)(A)(ii)(II) of such section for such drug''; and

(2) by adding at the end of the flush left matter following paragraph (9), the following:

''For purposes of applying paragraph (1)(DD) and section 1834(x)(5), the Secretary shall make such estimates and use such data as the Secretary determines appropriate.''.

(c) CONFORMING AMENDMENT TO PART B ASP CALCULATION.—Section 1847A(c)(3) of the Social Security

Act (42 U.S.C. 1395w–3a(c)(3)) is amended by inserting ''or section 1834(x)'' after ''section 1927''.

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