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115TH CONGRESS
2D SESSION

H. R. 5150

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

MARCH 1, 2018

Mr. LEVIN 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 ''Protecting Medicare from Excessive Price Increases Act of 2018''.

SEC. 2. MEDICARE PART B REBATE BY MANUFACTURERS FOR CERTAIN DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.

(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:

''(w) NO PAYMENT WITHOUT REBATE BY MANUFACTURERS FOR SINGLE SOURCE DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.—

''(1) NO PAYMENT FOR NONCOMPLIANT MANUFACTURERS.—Subject to the subsequent paragraphs of this subsection, no payment shall be available under this part for a unit of a rebatable drug of a manufacturer (as defined in section 1847A(c)(6)(A)) for each calendar quarter beginning on or after July 1, 2019, if such manufacturer has failed to comply with the requirement under paragraph (2)(B)(i) for the rebate period with respect to such calendar quarter.

''(2) REQUIREMENTS.—

''(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 6 months after the end of each rebate period with respect to a calendar quarter beginning on or after July 1, 2019, the Secretary shall, for each rebatable

drug, report to each manufacturer of such rebatable drug—

"(i) information on the total number of units described in subparagraph (A)(i) of paragraph (4) with respect to such drug and rebate period;

"(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 period; and

"(iii) the rebate amount specified under such paragraph for such rebatable drug and period.

"(B) MANUFACTURER REQUIREMENTS.—The manufacturer of a rebatable drug, for such drug, shall meet each of the following requirements for each rebate period with respect to a calendar quarter beginning on or after July 1, 2019:

"(i) REBATE PAYMENT.—The manufacturer shall, not later than 30 days after the date of receipt of the information described in subparagraph (A) from the Secretary, provide to the Secretary a rebate

that is equal to the amount specified in paragraph (4) for such drug for such rebate period.

''(ii) REPORT OF ASP.—The manufacturer shall report to the Secretary the information described in section 1927(b)(3)(A)(iii) in a time and manner consistent with the reporting under such section, unless such information is already reported in accordance with section 1927(b)(3)(C).

''(3) REBATABLE DRUG DEFINED.—In this subsection, the term 'rebatable drug' means a drug or biological (as defined in section 1847A(c)(6)(D)) paid for under this part, except such term shall not include such a drug or biological—

''(A) to the extent the units of such drug or biological are furnished as part of a grouping of items and services and paid for as such a grouping in an ambulatory payment classification under section 1833(t) or in a single payment under section 1833(i) (instead of separately payable under such respective section);

''(B) to the extent payment for the units of such drug or biological is included under the

single payment system for renal dialysis services under section 1881(b)(14);

''(C) to the extent the average total allowed charges per year per individual that uses such drug or biological are less than $100; or

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

''(4) REBATE AMOUNT.—

''(A) IN GENERAL.—For purposes of paragraph (2)(B)(i), the amount specified in this paragraph for a rebatable drug assigned to a billing and payment code for a rebate period is, subject to paragraph (5), the amount equal to the product of—

''(i) the total number of units for which payment was made under this part for such rebatable drug during the rebate period; and

''(ii) the amount (if any) by which—

''(I) the applicable manufacturer's average sales price (as determined under subparagraph (B)) for such rebatable drug for sales that occurred two quarters prior to the rebate period; exceeds

"(II) the inflation-adjusted ASP determined under subparagraph (C) for such rebatable drug for sales that occurred two quarters prior to the rebate period.

"(B) DETERMINATION OF APPLICABLE MANUFACTURER'S ASP.—The applicable manufacturer's average sales price, with respect to a manufacturer, determined under this subparagraph for a billing and payment code is the weighted average of the average sales prices of all of the rebatable drugs of the manufacturer identified by a national drug code assigned to such billing and payment code for sales that occurred two quarters prior to the rebate period.

"(C) DETERMINATION OF INFLATION-ADJUSTED ASP.—The inflation-adjusted ASP determined under this subparagraph for a rebatable drug for a rebate period is—

"(i) the average sales price for the billing and payment code for all units of such drug for sales that occurred in the ASP benchmark quarter (as defined in subparagraph (E)); increased by

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

"(D) REBATE PERIOD.—For purposes of this subsection, subject to paragraph (5)(E), the term 'rebate period' means, with respect to a calendar quarter, the period that is 2 calendar quarters prior to such calendar quarter.

"(E) ASP BENCHMARK QUARTER.—The term 'ASP benchmark quarter' means the calendar quarter beginning January 1, 2016.

"(F) 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.

"(G) REBATE PERIOD CPI–U.—The term 'rebate period CPI–U' means, with respect to a rebate period, 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 the rebate period.

''(5) SPECIAL TREATMENT OF CERTAIN DRUGS.—

''(A) SUBSEQUENTLY APPROVED DRUGS.—Subject to subparagraph (B), in the case of a single source rebatable drug first approved by the Food and Drug Administration after January 1, 2016, clause (i) of paragraph (4)(C) shall be applied as if the term 'ASP benchmark quarter' were defined under paragraph (4)(E) as the third full calendar quarter after the day on which the drug was first marketed and clause (ii) of paragraph (4)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (4)(F) as if the reference to 'January 2016' under such paragraph were a reference to 'the first month of the third full calendar quarter after the day on which the drug was first marketed'.

''(B) SPECIAL RULE FOR NEW DRUGS.—In applying this subsection in the case of a newly approved single source rebatable drug for which a payment and billing code has not previously been established the first calendar quarter to which this subsection shall apply shall be the

sixth full calendar quarter after the day on which the drug was first marketed.

''(6) ADJUSTMENT OF COINSURANCE.—With respect to coinsurance under this part with respect to a rebatable drug for which a rebate is paid under this subsection, the Secretary shall, on an annual basis, pay the individual an amount as if the coinsurance for a rebatable drug for which payment is made under this part for such individual were computed as if the payment amount incurred under this part for such drug were ratably reduced to reflect the rebate amount under this subsection for such drug.

''(7) REBATE DEPOSITS.—Amounts paid as rebates under paragraph (2)(B)(i) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(8) EXEMPTIONS.—

''(A) OTHER REBATES OR DISCOUNTS.—The Secretary shall waive the rebate under paragraph (2)(B)(i) with respect to the units of a 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.

''(B) SHORTAGES.—The Secretary may reduce or waive the rebate under paragraph (2)(B)(i) with respect to a rebatable drug in the case of a shortage of such drug or other exigent circumstances, as determined by the Secretary.

''(9) VERIFICATION SURVEYS.—The Secretary may survey wholesalers and manufacturers that directly distribute rebatable drugs, when necessary, to verify the manufacturer's average sales prices (including wholesale acquisition cost) reported under paragraph (2)(B)(ii). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler or manufacturer that refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. 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 subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(10) CIVIL MONETARY PENALTY.—In lieu of applying paragraph (1) for a calendar quarter, in the case of a manufacturer of a rebatable drug who has failed to comply with the requirements under paragraph (2)(B)(i) for such drug for the rebate period with respect to such calendar quarter, the Secretary may, pursuant to regulations, impose a civil monetary penalty on such manufacturer in an amount not to exceed 2 percent of the total expenditures under this part for such drug for such failure with respect to such drug and 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 subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(11) STUDY AND REPORT.—

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

''(i) Including multisource drugs (as defined in section 1847A(c)(3)(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 (3) 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).

"(12) APPLICATION TO MULTISOURCE DRUGS.—The Secretary may, based on the report submitted under paragraph (11) and pursuant to rulemaking, apply the provisions of this subsection to multisource drugs (as defined in section 1847A(c)(3)(C)).".

(b) PROVIDING MEDPAC ACCESS TO INFORMATION.—Section 1927(b)(3)(D) of the Social Security Act is amended—

(1) in clause (iv), by striking at the end "and";

(2) in clause (v), by striking at the end the period and inserting ", and"; and

(3) by inserting after clause (v) the following new clause:

"(vi) to permit the Medicare Payment Advisory Commission to review the information provided.".

(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(w)" after "section 1927".

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