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116TH CONGRESS
1ST SESSION

# H. R. 4178

To amend title XVIII of the Social Security Act to require manufacturers of certain single-dose vial drugs payable under part B of the Medicare program to provide rebates with respect to amounts of such drugs discarded, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

AUGUST 9, 2019

Mr. ENGEL 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 manufacturers of certain single-dose vial drugs payable under part B of the Medicare program to provide rebates with respect to amounts of such drugs discarded, 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 ''Recovering Excessive Funds for Unused and Needless Drugs Act of 2019'' or the ''REFUND Act of 2019''.

**SEC. 2. REQUIRING MANUFACTURERS OF CERTAIN SINGLE-DOSE VIAL DRUGS PAYABLE UNDER PART B OF THE MEDICARE PROGRAM TO PROVIDE REBATES WITH RESPECT TO DISCARDED AMOUNTS OF SUCH DRUGS.**

(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 FOR CERTAIN DISCARDED SINGLE-DOSE VIAL DRUGS.—

''(1) IN GENERAL.—The manufacturer (as defined in section 1847A(c)(6)(A)) of a rebatable single-dose vial drug furnished in a calendar quarter shall, not later than 30 days after the date of receipt of information described in paragraph (2)(A)(iii) with respect to such quarter, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such quarter.

''(2) SECRETARIAL DUTIES.—

''(A) IN GENERAL.—For each calendar quarter, the Secretary shall, with respect to a rebatable single-dose vial drug of a manufacturer furnished during such quarter—

''(i) require, through use of a modifier such as the JW modifier used as of the date of enactment of this subsection (or

any such successor code that includes such data as determined appropriate by the Secretary), an indication on a claim for such drug of the amount of such drug that was discarded after such drug was furnished, if any;

''(ii) determine the rebatable amount (as defined in subparagraph (B)) with respect to such drug; and

''(iii) not later than 60 days after the end of such quarter, provide to such manufacturer notice of—

''(I) the total number of units of such drug discarded during such quarter (as determined by the Secretary based on the aggregate rebatable amount (as so defined) with respect to such drug for such quarter), if any; and

''(II) the rebate amount specified in paragraph (3) for such drug and such quarter.

''(B) REBATABLE AMOUNT.—The term 'rebatable amount' means, with respect to a rebatable single-dose vial drug of a manufac-

turer furnished during a quarter, 90 percent of the amount (if any) of such drug that was discarded as indicated pursuant to subparagraph (A)(i).

''(3) REBATE AMOUNT.—The amount of the rebate specified in this paragraph is, with respect to a rebatable single-dose vial drug of a manufacturer furnished in a calendar quarter, an amount equal to the product of—

''(A) the total number of units of such drug discarded during such quarter as determined under paragraph (2)(A)(iii)(I); and

''(B) the lesser of—

''(i) the average sales price (as defined in section 1847A(c)(1)) for a unit of such drug for such quarter (or, in the case of a drug subject to an agreement with such manufacturer under section 340B of the Public Health Service Act, the price for a unit of such drug for such quarter under such agreement); or

''(ii) the wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) for a unit of such drug.

''(4) REBATE DEPOSITS.—Amounts paid as rebates pursuant to paragraph (1) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(5) ENFORCEMENT.—

''(A) AUDITS.—Each manufacturer of a rebatable single dose-vial drug that is required to provide a rebate under this subsection shall be subject to periodic audit with respect to such drug and such rebates by the Secretary.

''(B) CIVIL MONEY PENALTY.—

''(i) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer of a rebatable single dose-vial drug who has failed to comply with the requirement under paragraph (1) for such drug for a calendar quarter in an amount the Secretary determines is commensurate with the sum of—

''(I) the amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

''(II) 25 percent of such amount.

"(ii) APPLICATION.—The provisions of section 1128A (other than subsections (a) 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).

"(6) DEFINITIONS.—In this subsection:

"(A) REBATABLE SINGLE-DOSE VIAL DRUG.—The term 'rebatable single-dose vial drug' means a single source drug or biological (as defined in section 1847A(c)(6)(D)) paid for under this part and furnished on or after January 1, 2020, from a single-dose vial.

"(B) UNIT.—The term 'unit' has the meaning given such term in section 1847A(b)(2)(B).".

(b) COLLECTION OF COINSURANCE ONLY FOR PORTION OF REBATABLE SINGLE-DOSE VIAL DRUG ADMINISTERED.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—

(1) in subsection (a)(1)(S), by inserting "subject to subsection (cc)," before "with respect to"; and

(2) by adding at the end the following new subsection:

''(cc) COLLECTION OF COINSURANCE ONLY FOR PORTION OF REBATABLE SINGLE-DOSE VIAL DRUG ADMINISTERED.—When processing a claim for a rebatable single-dose vial drug (as defined in section 1834(w)(6)), the Secretary, acting through the relevant Medicare administrative contractor with respect to such claim, shall only collect coinsurance from a beneficiary, taking into account any coverage under a Medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage of the beneficiary, with respect to the portion of the drug administered (as indicated by the J-portion of the claim for the drug used as of the date of enactment of this subsection, or any successor code that includes such data as determined appropriate by the Secretary), in an amount equal to 20 percent of the amount of payment that would be made if payment for the claim was based only on the portion of the drug administered (as so indicated). Nothing in the preceding sentence shall affect the amount paid to the provider of services or supplier with respect to the drug under this part (as determined based on the total amount of the drug for which the claim was submitted, including the portion of the drug administered and the portion discarded, as indicated by

the J-portion of the claim and the JW modifier, respectively, used as of such date of enactment or any successor codes that include such data as determined appropriate by the Secretary).''.

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