

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.

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Recovering Excessive
5 Funds for Unused and Needless Drugs Act of 2019” or
6 the “REFUND Act of 2019”.

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

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

9 “(x) REBATE FOR CERTAIN DISCARDED SINGLE-
10 DOSE VIAL DRUGS.—

11 “(1) IN GENERAL.—The manufacturer (as de-
12 fined in section 1847A(c)(6)(A)) of a rebatable sin-
13 gle-dose vial drug furnished in a calendar quarter
14 shall, not later than 30 days after the date of receipt
15 of information described in paragraph (2)(A)(iii)
16 with respect to such quarter, provide to the Sec-
17 retary a rebate that is equal to the amount specified
18 in paragraph (3) for such drug for such quarter.

19 “(2) SECRETARIAL DUTIES.—

20 “(A) IN GENERAL.—For each calendar
21 quarter, the Secretary shall, with respect to a
22 rebatable single-dose vial drug of a manufac-
23 turer furnished during such quarter—

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

1 any such successor code that includes such
2 data as determined appropriate by the Sec-
3 retary), an indication on a claim for such
4 drug of the amount of such drug that was
5 discarded after such drug was furnished, if
6 any;

7 “(ii) determine the rebatable amount
8 (as defined in subparagraph (B)) with re-
9 spect to such drug; and

10 “(iii) not later than 60 days after the
11 end of such quarter, provide to such manu-
12 facturer notice of—

13 “(I) the total number of units of
14 such drug discarded during such
15 quarter (as determined by the Sec-
16 retary based on the aggregate rebata-
17 ble amount (as so defined) with re-
18 spect to such drug for such quarter),
19 if any; and

20 “(II) the rebate amount specified
21 in paragraph (3) for such drug and
22 such quarter.

23 “(B) REBATABLE AMOUNT.—The term
24 ‘rebatable amount’ means, with respect to a
25 rebatable single-dose vial drug of a manufac-

1 turer furnished during a quarter, 90 percent of
2 the amount (if any) of such drug that was dis-
3 carded as indicated pursuant to subparagraph
4 (A)(i).

5 “(3) REBATE AMOUNT.—The amount of the re-
6 bate specified in this paragraph is, with respect to
7 a rebatable single-dose vial drug of a manufacturer
8 furnished in a calendar quarter, an amount equal to
9 the product of—

10 “(A) the total number of units of such
11 drug discarded during such quarter as deter-
12 mined under paragraph (2)(A)(iii)(I); and

13 “(B) the lesser of—

14 “(i) the average sales price (as de-
15 fined in section 1847A(c)(1)) for a unit of
16 such drug for such quarter (or, in the case
17 of a drug subject to an agreement with
18 such manufacturer under section 340B of
19 the Public Health Service Act, the price
20 for a unit of such drug for such quarter
21 under such agreement); or

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

1 “(4) REBATE DEPOSITS.—Amounts paid as re-
2 bates pursuant to paragraph (1) shall be deposited
3 into the Federal Supplementary Medical Insurance
4 Trust Fund established under section 1841.

5 “(5) ENFORCEMENT.—

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

11 “(B) CIVIL MONEY PENALTY.—

12 “(i) IN GENERAL.—The Secretary
13 shall impose a civil money penalty on a
14 manufacturer of a rebateable single dose-
15 vial drug who has failed to comply with the
16 requirement under paragraph (1) for such
17 drug for a calendar quarter in an amount
18 the Secretary determines is commensurate
19 with the sum of—

20 “(I) the amount that the manu-
21 facturer would have paid under such
22 paragraph with respect to such drug
23 for such quarter; and

24 “(II) 25 percent of such amount.

1 “(ii) APPLICATION.—The provisions
2 of section 1128A (other than subsections
3 (a) and (b)) shall apply to a civil money
4 penalty under this subparagraph in the
5 same manner as such provisions apply to a
6 penalty or proceeding under section
7 1128A(a).

8 “(6) DEFINITIONS.—In this subsection:

9 “(A) REBATABLE SINGLE-DOSE VIAL
10 DRUG.—The term ‘rebatable single-dose vial
11 drug’ means a single source drug or biological
12 (as defined in section 1847A(c)(6)(D)) paid for
13 under this part and furnished on or after Janu-
14 ary 1, 2020, from a single-dose vial.

15 “(B) UNIT.—The term ‘unit’ has the
16 meaning given such term in section
17 1847A(b)(2)(B).”.

18 (b) COLLECTION OF COINSURANCE ONLY FOR POR-
19 TION OF REBATABLE SINGLE-DOSE VIAL DRUG ADMINIS-
20 TERED.—Section 1833 of the Social Security Act (42
21 U.S.C. 1395l) is amended—

22 (1) in subsection (a)(1)(S), by inserting “sub-
23 ject to subsection (cc),” before “with respect to”;
24 and

1 (2) by adding at the end the following new sub-
2 section:

3 “(cc) COLLECTION OF COINSURANCE ONLY FOR
4 PORTION OF REBATABLE SINGLE-DOSE VIAL DRUG AD-
5 MINISTERED.—When processing a claim for a rebatable
6 single-dose vial drug (as defined in section 1834(w)(6)),
7 the Secretary, acting through the relevant Medicare ad-
8 ministrative contractor with respect to such claim, shall
9 only collect coinsurance from a beneficiary, taking into ac-
10 count any coverage under a Medicare supplemental policy
11 certified under section 1882 or any other supplemental in-
12 surance coverage of the beneficiary, with respect to the
13 portion of the drug administered (as indicated by the J-
14 portion of the claim for the drug used as of the date of
15 enactment of this subsection, or any successor code that
16 includes such data as determined appropriate by the Sec-
17 retary), in an amount equal to 20 percent of the amount
18 of payment that would be made if payment for the claim
19 was based only on the portion of the drug administered
20 (as so indicated). Nothing in the preceding sentence shall
21 affect the amount paid to the provider of services or sup-
22 plier with respect to the drug under this part (as deter-
23 mined based on the total amount of the drug for which
24 the claim was submitted, including the portion of the drug
25 administered and the portion discarded, as indicated by

1 the J-portion of the claim and the JW modifier, respec-
2 tively, used as of such date of enactment or any successor
3 codes that include such data as determined appropriate
4 by the Secretary).”.

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