

117TH CONGRESS
1ST SESSION

S. 1287

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 refunds with respect to amounts of such drugs discarded, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 21, 2021

Mr. DURBIN (for himself and Mr. PORTMAN) introduced the following bill;
which was read twice and referred to the Committee on Finance

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 refunds 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 2021” or
6 the “REFUND Act of 2021”.

1 **SEC. 2. REQUIRING MANUFACTURERS OF CERTAIN SINGLE-**
 2 **DOSE CONTAINER OR SINGLE-USE PACKAGE**
 3 **DRUGS PAYABLE UNDER PART B OF THE**
 4 **MEDICARE PROGRAM TO PROVIDE REFUNDS**
 5 **WITH RESPECT TO DISCARDED AMOUNTS OF**
 6 **SUCH DRUGS.**

7 Section 1847A of the Social Security Act (42 U.S.C.
 8 1395–3a), as amended by section 405 of division CC of
 9 the Consolidated Appropriations Act, 2021, is amended—

10 (1) by redesignating subsection (h) as sub-
 11 section (i); and

12 (2) inserting after subsection (g) the following:

13 “(h) REFUND FOR CERTAIN DISCARDED SINGLE-
 14 DOSE CONTAINER OR SINGLE-USE PACKAGE DRUGS.—

15 “(1) SECRETARIAL PROVISION OF INFORMA-
 16 TION.—

17 “(A) IN GENERAL.—For each calendar
 18 quarter beginning on or after January 1, 2022,
 19 the Secretary shall, with respect to a refundable
 20 single-dose container or single-use package drug
 21 (as defined in paragraph (8)), report to each
 22 manufacturer (as defined in subsection
 23 (c)(6)(A)) of such refundable single-dose con-
 24 tainer or single-use package drug the following
 25 for the calendar quarter:

1 “(i) Subject to subparagraph (C), in-
2 formation on the total number of units of
3 the billing and payment code of such drug,
4 if any, that were discarded during such
5 quarter, as determined using a mechanism
6 such as the JW modifier used as of the
7 date of enactment of this subsection (or
8 any such successor modifier that includes
9 such data as determined appropriate by
10 the Secretary).

11 “(ii) The refund amount that the
12 manufacturer is liable for pursuant to
13 paragraph (3).

14 “(B) DETERMINATION OF DISCARDED
15 AMOUNTS.—For purposes of subparagraph
16 (A)(i), with respect to a refundable single-dose
17 container or single-use package drug furnished
18 during a quarter, the amount of such drug that
19 was discarded shall be determined based on the
20 amount of such drug that was unused and dis-
21 carded for each drug on the date of service.

22 “(C) EXCLUSION OF UNITS OF PACKAGED
23 DRUGS.—The total number of units of the bill-
24 ing and payment code of a refundable single-
25 dose container or single-use package drug of a

1 manufacturer furnished during a calendar quar-
2 ter for purposes of subparagraph (A)(i) shall
3 not include such units that are packaged into
4 the payment amount for an item or service and
5 are not separately payable.

6 “(2) MANUFACTURER REQUIREMENT.—For
7 each calendar quarter beginning on or after January
8 1, 2022, the manufacturer of a refundable single-
9 dose container or single-use package drug shall, for
10 such drug, provide to the Secretary a refund that is
11 equal to the amount specified in paragraph (3) for
12 such drug for such quarter.

13 “(3) REFUND AMOUNT.—

14 “(A) IN GENERAL.—The amount of the re-
15 fund specified in this paragraph is, with respect
16 to a refundable single-dose container or single-
17 use package drug of a manufacturer assigned to
18 a billing and payment code for a calendar quar-
19 ter beginning on or after January 1, 2022, an
20 amount equal to 90 percent (or, in the case of
21 a refundable single-dose container or single-use
22 package drug described in subclause (I) or (II)
23 of subparagraph (B)(ii), the percent determined
24 for such drug under subparagraph (B)(i)) of
25 the product of—

1 “(i) the total number of units of the
2 billing and payment code for such drug
3 that were discarded during such quarter
4 (as determined under paragraph (1)); and

5 “(ii)(I) in the case of a refundable
6 single-dose container or single-use package
7 drug that is a single source drug or bio-
8 logical, the amount determined for such
9 drug under subsection (b)(4); or

10 “(II) in the case of a refundable sin-
11 gle-dose container or single-use package
12 drug that is a biosimilar biological product,
13 the average sales price determined under
14 subsection (b)(8)(A).

15 “(B) TREATMENT OF DRUGS THAT RE-
16 QUIRE FILTRATION OR OTHER UNIQUE CIR-
17 CUMSTANCES.—

18 “(i) IN GENERAL.—The Secretary,
19 through notice and comment rulemaking—

20 “(I) in the case of a refundable
21 single-dose container or single-use
22 package drug described in subclause
23 (I) of clause (ii), shall adjust the per-
24 centage otherwise applicable for pur-
25 poses of determining the refund

1 amount with respect to such drug
2 under subparagraph (A) as deter-
3 mined appropriate by the Secretary;
4 and

5 “(II) in the case of a refundable
6 single-dose container or single-use
7 package drug described in subclause
8 (II) of clause (ii), may adjust the per-
9 centage otherwise applicable for pur-
10 poses of determining the refund
11 amount with respect to such drug
12 under subparagraph (A) as deter-
13 mined appropriate by the Secretary.

14 “(ii) DRUG DESCRIBED.—For pur-
15 poses of clause (i), a refundable single-dose
16 container or single-use package drug de-
17 scribed in this clause is either of the fol-
18 lowing:

19 “(I) A refundable single-dose
20 container or single-use package drug
21 for which preparation instructions re-
22 quired and approved by the Commis-
23 sioner of the Food and Drug Adminis-
24 tration include filtration during the
25 drug preparation process, prior to di-

1 lution and administration, and require
2 that any unused portion of such drug
3 after the filtration process be dis-
4 carded after the completion of such
5 filtration process.

6 “(II) Any other refundable sin-
7 gle-dose container or single-use pack-
8 age drug that has unique cir-
9 cumstances involving similar loss of
10 product.

11 “(4) FREQUENCY.—Amounts required to be re-
12 funded pursuant to paragraph (2) shall be paid in
13 regular intervals (as determined appropriate by the
14 Secretary).

15 “(5) REFUND DEPOSITS.—Amounts paid as re-
16 funds pursuant to paragraph (2) shall be deposited
17 into the Federal Supplementary Medical Insurance
18 Trust Fund established under section 1841.

19 “(6) ENFORCEMENT.—

20 “(A) AUDITS.—

21 “(i) MANUFACTURER AUDITS.—Each
22 manufacturer of a refundable single-dose
23 container or single-use package drug that
24 is required to provide a refund under this
25 subsection shall be subject to periodic

1 audit with respect to such drug and such
2 refunds by the Secretary.

3 “(ii) PROVIDER AUDITS.—The Sec-
4 retary shall conduct periodic audits of
5 claims submitted under this part with re-
6 spect to refundable single-dose container or
7 single-use package drugs in accordance
8 with the authority under section 1833(e) to
9 ensure compliance with the requirements
10 applicable under this subsection.

11 “(B) CIVIL MONEY PENALTY.—

12 “(i) IN GENERAL.—The Secretary
13 shall impose a civil money penalty on a
14 manufacturer of a refundable single-dose
15 container or single-use package drug who
16 has failed to comply with the requirement
17 under paragraph (2) for such drug for a
18 calendar quarter in an amount equal to the
19 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 “(7) IMPLEMENTATION.—The Secretary shall
9 implement this subsection through notice and com-
10 ment rulemaking.

11 “(8) DEFINITION OF REFUNDABLE SINGLE-
12 DOSE CONTAINER OR SINGLE-USE PACKAGE DRUG.—

13 “(A) IN GENERAL.—Except as provided in
14 subparagraph (B), in this subsection, the term
15 ‘refundable single-dose container or single-use
16 package drug’ means a single source drug or bi-
17 ological (as defined in section 1847A(c)(6)(D))
18 or a biosimilar biological product (as defined in
19 section 1847A(c)(6)(H)) for which payment is
20 established under this part and that is fur-
21 nished from a single-dose container or single-
22 use package.

23 “(B) EXCLUSIONS.—The term ‘refundable
24 single-dose container or single-use package
25 drug’ does not include a drug or biological that

1 is either a radiopharmaceutical or an imaging
2 agent.

3 “(9) REPORT TO CONGRESS.—

4 “(A) IN GENERAL.—Not later than 3 years
5 after the date of enactment of this subsection,
6 the Office of the Inspector General of the De-
7 partment of Health and Human Services, in
8 consultation with the Centers for Medicare &
9 Medicaid Services and the Food and Drug Ad-
10 ministration, shall submit to the Committee on
11 Energy and Commerce and the Committee on
12 Ways and Means of the House of Representa-
13 tives and the Committee on Finance of the Sen-
14 ate, a report on any impact this subsection is
15 demonstrated to have on—

16 “(i) the licensure, market entry, mar-
17 ket retention, or marketing of biosimilar
18 biological products; and

19 “(ii) vial size changes, label adjust-
20 ments, or technological developments.

21 “(B) UPDATES.—At the direction of the
22 Committees referred to in subparagraph (A),
23 the Office of the Inspector General of the De-
24 partment of Health and Human Services, in
25 consultation with the Centers for Medicare &

1 Medicaid Services and the Food and Drug Ad-
2 ministration, shall periodically update the re-
3 port under such subparagraph.”.

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