117TH CONGRESS
1ST SESSION

S. _____

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

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

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.

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 2021'' or the ''REFUND Act of 2021''.

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

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

(1) by redesignating subsection (h) as subsection (i); and

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

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

''(1) SECRETARIAL PROVISION OF INFORMATION.—

''(A) IN GENERAL.—For each calendar quarter beginning on or after January 1, 2022, the Secretary shall, with respect to a refundable single-dose container or single-use package drug (as defined in paragraph (8)), report to each manufacturer (as defined in subsection (c)(6)(A)) of such refundable single-dose container or single-use package drug the following for the calendar quarter:

"(i) Subject to subparagraph (C), information on the total number of units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined using a mechanism such as the JW modifier used as of the date of enactment of this subsection (or any such successor modifier that includes such data as determined appropriate by the Secretary).

"(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (3).

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

"(C) EXCLUSION OF UNITS OF PACKAGED DRUGS.—The total number of units of the billing and payment code of a refundable single-dose container or single-use package drug of a

manufacturer furnished during a calendar quarter for purposes of subparagraph (A)(i) shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

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

''(3) REFUND AMOUNT.—

''(A) IN GENERAL.—The amount of the refund specified in this paragraph is, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2022, an amount equal to 90 percent (or, in the case of a refundable single-dose container or single-use package drug described in subclause (I) or (II) of subparagraph (B)(ii), the percent determined for such drug under subparagraph (B)(i)) of the product of—

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

"(ii)(I) in the case of a refundable single-dose container or single-use package drug that is a single source drug or biological, the amount determined for such drug under subsection (b)(4); or

"(II) in the case of a refundable single-dose container or single-use package drug that is a biosimilar biological product, the average sales price determined under subsection (b)(8)(A).

"(B) TREATMENT OF DRUGS THAT REQUIRE FILTRATION OR OTHER UNIQUE CIRCUMSTANCES.—

"(i) IN GENERAL.—The Secretary, through notice and comment rulemaking—

"(I) in the case of a refundable single-dose container or single-use package drug described in subclause (I) of clause (ii), shall adjust the percentage otherwise applicable for purposes of determining the refund

amount with respect to such drug under subparagraph (A) as determined appropriate by the Secretary; and

''(II) in the case of a refundable single-dose container or single-use package drug described in subclause (II) of clause (ii), may adjust the percentage otherwise applicable for purposes of determining the refund amount with respect to such drug under subparagraph (A) as determined appropriate by the Secretary.

''(ii) DRUG DESCRIBED.—For purposes of clause (i), a refundable single-dose container or single-use package drug described in this clause is either of the following:

''(I) A refundable single-dose container or single-use package drug for which preparation instructions required and approved by the Commissioner of the Food and Drug Administration include filtration during the drug preparation process, prior to di-

lution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

''(II) Any other refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product.

''(4) FREQUENCY.—Amounts required to be refunded pursuant to paragraph (2) shall be paid in regular intervals (as determined appropriate by the Secretary).

''(5) REFUND DEPOSITS.—Amounts paid as refunds pursuant to paragraph (2) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(6) ENFORCEMENT.—

''(A) AUDITS.—

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

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

''(ii) PROVIDER AUDITS.—The Secretary shall conduct periodic audits of claims submitted under this part with respect to refundable single-dose container or single-use package drugs in accordance with the authority under section 1833(e) to ensure compliance with the requirements applicable under this subsection.

''(B) CIVIL MONEY PENALTY.—

''(i) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (2) for such drug for a calendar quarter in an amount equal to 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).

"(7) IMPLEMENTATION.—The Secretary shall implement this subsection through notice and comment rulemaking.

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

"(A) IN GENERAL.—Except as provided in subparagraph (B), in this subsection, the term 'refundable single-dose container or single-use package drug' means a single source drug or biological (as defined in section 1847A(c)(6)(D)) or a biosimilar biological product (as defined in section 1847A(c)(6)(H)) for which payment is established under this part and that is furnished from a single-dose container or single-use package.

"(B) EXCLUSIONS.—The term 'refundable single-dose container or single-use package drug' does not include a drug or biological that

is either a radiopharmaceutical or an imaging agent.

''(9) REPORT TO CONGRESS.—

''(A) IN GENERAL.—Not later than 3 years after the date of enactment of this subsection, the Office of the Inspector General of the Department of Health and Human Services, in consultation with the Centers for Medicare & Medicaid Services and the Food and Drug Administration, shall submit to the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate, a report on any impact this subsection is demonstrated to have on—

''(i) the licensure, market entry, market retention, or marketing of biosimilar biological products; and

''(ii) vial size changes, label adjustments, or technological developments.

''(B) UPDATES.—At the direction of the Committees referred to in subparagraph (A), the Office of the Inspector General of the Department of Health and Human Services, in consultation with the Centers for Medicare &

Medicaid Services and the Food and Drug Administration, shall periodically update the report under such subparagraph.''.