116TH CONGRESS
1ST SESSION

S. 205

To amend title XIX of the Social Security Act to prevent the misclassification of drugs for purposes of the Medicaid drug rebate program.

IN THE SENATE OF THE UNITED STATES

JANUARY 24, 2019

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

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A BILL

To amend title XIX of the Social Security Act to prevent the misclassification of drugs for purposes of the Medicaid drug rebate program.

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 ''Right Rebate Act of 2019''.

SEC. 2. PREVENTING THE MISCLASSIFICATION OF DRUGS UNDER THE MEDICAID DRUG REBATE PROGRAM.

(a) APPLICATION OF CIVIL MONEY PENALTY FOR MISCLASSIFICATION OF COVERED OUTPATIENT DRUGS.—

(1) IN GENERAL.—Section 1927(b)(3) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)) is amended—

(A) in the paragraph heading, by inserting ''AND DRUG PRODUCT'' after ''PRICE'';

(B) in subparagraph (A)—

(i) in clause (ii), by striking ''; and'' at the end and inserting a semicolon;

(ii) in clause (iii), by striking the period at the end and inserting a semicolon;

(iii) in clause (iv), by striking the semicolon at the end and inserting ''; and''; and

(iv) by inserting after clause (iv) the following new clause:

''(v) not later than 30 days after the last day of each month of a rebate period under the agreement, such drug product information as the Secretary shall require

for each of the manufacturer's covered outpatient drugs.'';

(C) in subparagraph (C)—

(i) in clause (ii), by inserting '', including information related to drug pricing, drug product information, and data related to drug pricing or drug product information,'' after ''provides false information''; and

(ii) by adding at the end the following new clauses:

''(iii) MISCLASSIFIED OR MISREPORTED INFORMATION.—

''(I) IN GENERAL.—Any manufacturer with an agreement under this section that knowingly (as defined in section 1003.110 of title 42, Code of Federal Regulations (or any successor regulation)) misclassifies a covered outpatient drug, such as by knowingly submitting incorrect drug category information, is subject to a civil money penalty for each covered outpatient drug that is misclassified in an amount not to exceed 2 times the

amount of the difference, as determined by the Secretary, between—

"(aa) the total amount of rebates that the manufacturer paid with respect to the drug to all States for all rebate periods during which the drug was misclassified; and

"(bb) the total amount of rebates that the manufacturer would have been required to pay, as determined by the Secretary, with respect to the drug to all States for all rebate periods during which the drug was misclassified if the drug had been correctly classified.

"(II) OTHER PENALTIES AND RECOVERY OF UNDERPAID REBATES.—The civil money penalties described in subclause (I) are in addition to other penalties as may be prescribed by law and any other recovery of the underlying underpayment for rebates due under this section or the

terms of the rebate agreement as determined by the Secretary.

''(iv) INCREASING OVERSIGHT AND ENFORCEMENT.—Each year the Secretary shall retain, in addition to any amount retained by the Secretary to recoup investigation and litigation costs related to the enforcement of the civil money penalties under this subparagraph and subsection (c)(4)(B)(ii)(III), an amount equal to 25 percent of the total amount of civil money penalties collected under this subparagraph and subsection (c)(4)(B)(ii)(III) for the year, and such retained amount shall be available to the Secretary, without further appropriation and until expended, for activities related to the oversight and enforcement of this section and agreements under this section, including—

''(I) improving drug data reporting systems;

''(II) evaluating and ensuring manufacturer compliance with rebate obligations; and

"(III) oversight and enforcement related to ensuring that manufacturers accurately and fully report drug information, including data related to drug classification."; and

(iii) in subparagraph (D)—

(I) in clause (iv), by striking "; and" and inserting a comma;

(II) in clause (v), by striking the period and inserting "; and"; and

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

"(vi) in the case of categories of drug product or classification information that were not considered confidential by the Secretary on the day before the date of the enactment of the Right Rebate Act of 2019.".

(2) TECHNICAL AMENDMENTS.—

(A) Section 1903(i)(10) of the Social Security Act (42 U.S.C. 1396b(i)(10)) is amended—

(i) in subparagraph (C)—

(I) by adjusting the left margin so as to align with the left margin of subparagraph (B); and

(II) by striking ", and" and inserting a semicolon;

(ii) in subparagraph (D), by striking "; or" and inserting "; and"; and

(iii) by adding at the end the following new subparagraph:

"(E) with respect to any amount expended for a covered outpatient drug for which a suspension under section 1927(c)(4)(B)(ii)(II) is in effect; or".

(B) Section 1927(b)(3)(C)(ii) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(C)(ii)) is amended by striking "subsections (a) and (b)" and inserting "subsections (a), (b), (f)(3), and (f)(4)".

(b) RECOVERY OF UNPAID REBATE AMOUNTS DUE TO MISCLASSIFICATION OF COVERED OUTPATIENT DRUGS.—

(1) IN GENERAL.—Section 1927(c) of the Social Security Act (42 U.S.C. 1396r–8(c)) is amended by adding at the end the following new paragraph:

"(4) RECOVERY OF UNPAID REBATE AMOUNTS DUE TO MISCLASSIFICATION OF COVERED OUTPATIENT DRUGS.—

''(A) IN GENERAL.—If the Secretary determines that a manufacturer with an agreement under this section paid a lower per-unit rebate amount to a State for a rebate period as a result of the misclassification by the manufacturer of a covered outpatient drug (without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made) than the per-unit rebate amount that the manufacturer would have paid to the State if the drug had been correctly classified, the manufacturer shall pay to the State an amount equal to the product of—

''(i) the difference between—

''(I) the per-unit rebate amount paid to the State for the period; and

''(II) the per-unit rebate amount that the manufacturer would have paid to the State for the period, as determined by the Secretary, if the drug had been correctly classified; and

''(ii) the total units of the drug paid for under the State plan in the period.

''(B) AUTHORITY TO CORRECT MISCLASSIFICATIONS.—

''(i) IN GENERAL.—If the Secretary determines that a manufacturer with an agreement under this section has misclassified a covered outpatient drug (without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made), the Secretary shall notify the manufacturer of the misclassification and require the manufacturer to correct the misclassification in a timely manner.

''(ii) ENFORCEMENT.—If, after receiving notice of a misclassification from the Secretary under clause (i), a manufacturer fails to correct the misclassification by such time as the Secretary shall require, until the manufacturer makes such correction, the Secretary may—

''(I) correct the misclassification on behalf of the manufacturer;

''(II) suspend the misclassified drug and the drug's status as a covered outpatient drug under the manu-

facturer's national rebate agreement; or

"(III) impose a civil money penalty (which shall be in addition to any other recovery or penalty which may be available under this section or any other provision of law) for each rebate period during which the drug is misclassified not to exceed an amount equal to the product of—

"(aa) the total number of units of each dosage form and strength of such misclassified drug paid for under any State plan during such a rebate period; and

"(bb) 23.1 percent of the average manufacturer price for the dosage form and strength of such misclassified drug.

"(C) REPORTING AND TRANSPARENCY.—

"(i) IN GENERAL.—The Secretary shall submit a report to Congress on at least an annual basis that includes information on the covered outpatient drugs

that have been identified as misclassified, the steps taken to reclassify such drugs, the actions the Secretary has taken to ensure the payment of any rebate amounts which were unpaid as a result of such misclassification, and a disclosure of expenditures from the fund created in subsection (b)(3)(C)(iv), including an accounting of how such funds have been allocated and spent in accordance with such subsection.

''(ii) PUBLIC ACCESS.—The Secretary shall make the information contained in the report required under clause (i) available to the public on a timely basis.

''(D) OTHER PENALTIES AND ACTIONS.—Actions taken and penalties imposed under this clause shall be in addition to other remedies available to the Secretary including terminating the manufacturer's rebate agreement for noncompliance with the terms of such agreement and shall not exempt a manufacturer from, or preclude the Secretary from pursuing, any civil money penalty under this title or title XI, or

any other penalty or action as may be prescribed by law.''.

(2) OFFSET OF RECOVERED AMOUNTS AGAINST MEDICAL ASSISTANCE.—Section 1927(b)(1)(B) of the Social Security Act (42 U.S.C. 1396r–8(b)(1)(B)) is amended by inserting '', including amounts received by a State under subsection (c)(4),'' after ''in any quarter''.

(c) CLARIFYING DEFINITIONS.—Section 1927(k)(7)(A) of the Social Security Act (42 U.S.C. 1396r–8(k)(7)(A)) is amended—

(1) by striking ''an original new drug application'' and inserting ''a new drug application'' each place it appears;

(2) in clause (i), by inserting ''but including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4)'' after ''drug described in paragraph (5)'';

(3) in clause (ii), by striking ''was originally marketed'' and inserting ''is marketed''; and

(4) in clause (iv)—

(A) by inserting '', including a drug product approved for marketing as a non-prescription drug that is regarded as a covered out-

patient drug under paragraph (4),'' after ''covered outpatient drug''; and

(B) by adding at the end the following new sentence: ''Such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the Food and Drug Administration.''.

(d) EXCLUSION OF MANUFACTURERS FOR KNOWING MISCLASSIFICATION OF COVERED OUTPATIENT DRUGS.—Section 1128(b) of the Social Security Act (42 U.S.C. 1320a–7(b)) is amended by adding at the end the following new paragraph:

''(17) KNOWINGLY MISCLASSIFYING COVERED OUTPATIENT DRUGS.—Any manufacturer or officer, director, agent, or managing employee of such manufacturer that knowingly misclassifies a covered outpatient drug under an agreement under section 1927, knowingly fails to correct such misclassification, or knowingly provides false information related to drug pricing, drug product information, or data related to drug pricing or drug product information.''.

(e) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment

of this Act, and shall apply to covered outpatient drugs supplied by manufacturers under agreements under section 1927 of the Social Security Act (42 U.S.C. 1396r–8) on or after such date.

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