

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

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.

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 “Right Rebate Act of
5 2019”.

1 **SEC. 2. PREVENTING THE MISCLASSIFICATION OF DRUGS**
 2 **UNDER THE MEDICAID DRUG REBATE PRO-**
 3 **GRAM.**

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

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

10 (A) in the paragraph heading, by inserting
 11 “AND DRUG PRODUCT” after “PRICE”;

12 (B) in subparagraph (A)—

13 (i) in clause (ii), by striking “; and”
 14 at the end and inserting a semicolon;

15 (ii) in clause (iii), by striking the pe-
 16 riod at the end and inserting a semicolon;

17 (iii) in clause (iv), by striking the
 18 semicolon at the end and inserting “;
 19 and”; and

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

22 “(v) not later than 30 days after the
 23 last day of each month of a rebate period
 24 under the agreement, such drug product
 25 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

1 amount of the difference, as deter-
2 mined by the Secretary, between—

3 “(aa) the total amount of
4 rebates that the manufacturer
5 paid with respect to the drug to
6 all States for all rebate periods
7 during which the drug was
8 misclassified; and

9 “(bb) the total amount of
10 rebates that the manufacturer
11 would have been required to pay,
12 as determined by the Secretary,
13 with respect to the drug to all
14 States for all rebate periods dur-
15 ing which the drug was misclassi-
16 fied if the drug had been cor-
17 rectly classified.

18 “(II) OTHER PENALTIES AND
19 RECOVERY OF UNDERPAID RE-
20 BATES.—The civil money penalties de-
21 scribed in subclause (I) are in addi-
22 tion to other penalties as may be pre-
23 scribed by law and any other recovery
24 of the underlying underpayment for
25 rebates due under this section or the

1 terms of the rebate agreement as de-
2 termined by the Secretary.

3 “(iv) INCREASING OVERSIGHT AND
4 ENFORCEMENT.—Each year the Secretary
5 shall retain, in addition to any amount re-
6 tained by the Secretary to recoup inves-
7 tigation and litigation costs related to the
8 enforcement of the civil money penalties
9 under this subparagraph and subsection
10 (c)(4)(B)(ii)(III), an amount equal to 25
11 percent of the total amount of civil money
12 penalties collected under this subparagraph
13 and subsection (c)(4)(B)(ii)(III) for the
14 year, and such retained amount shall be
15 available to the Secretary, without further
16 appropriation and until expended, for ac-
17 tivities related to the oversight and en-
18 forcement of this section and agreements
19 under this section, including—

20 “(I) improving drug data report-
21 ing systems;

22 “(II) evaluating and ensuring
23 manufacturer compliance with rebate
24 obligations; and

1 “(III) oversight and enforcement
 2 related to ensuring that manufactur-
 3 ers accurately and fully report drug
 4 information, including data related to
 5 drug classification.”; and

6 (iii) in subparagraph (D)—

7 (I) in clause (iv), by striking “;
 8 and” and inserting a comma;

9 (II) in clause (v), by striking the
 10 period and inserting “; and”; and

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

13 “(vi) in the case of categories of drug
 14 product or classification information that
 15 were not considered confidential by the
 16 Secretary on the day before the date of the
 17 enactment of the Right Rebate Act of
 18 2019.”.

19 (2) TECHNICAL AMENDMENTS.—

20 (A) Section 1903(i)(10) of the Social Secu-
 21 rity Act (42 U.S.C. 1396b(i)(10)) is amended—

22 (i) in subparagraph (C)—

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

1 (II) by striking “, and” and in-
 2 serting a semicolon;

3 (ii) in subparagraph (D), by striking
 4 “; or” and inserting “; and”; and

5 (iii) by adding at the end the fol-
 6 lowing new subparagraph:

7 “(E) with respect to any amount expended
 8 for a covered outpatient drug for which a sus-
 9 pension under section 1927(c)(4)(B)(ii)(II) is in
 10 effect; or”.

11 (B) Section 1927(b)(3)(C)(ii) of the Social
 12 Security Act (42 U.S.C. 1396r-8(b)(3)(C)(ii))
 13 is amended by striking “subsections (a) and
 14 (b)” and inserting “subsections (a), (b), (f)(3),
 15 and (f)(4)”.

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

19 (1) IN GENERAL.—Section 1927(c) of the So-
 20 cial Security Act (42 U.S.C. 1396r-8(c)) is amended
 21 by adding at the end the following new paragraph:

22 “(4) RECOVERY OF UNPAID REBATE AMOUNTS
 23 DUE TO MISCLASSIFICATION OF COVERED OUT-
 24 PATIENT 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.

1 “(B) AUTHORITY TO CORRECT
2 MISCLASSIFICATIONS.—

3 “(i) IN GENERAL.—If the Secretary
4 determines that a manufacturer with an
5 agreement under this section has misclassi-
6 fied a covered outpatient drug (without re-
7 gard to whether the manufacturer know-
8 ingly made the misclassification or should
9 have known that the misclassification
10 would be made), the Secretary shall notify
11 the manufacturer of the misclassification
12 and require the manufacturer to correct
13 the misclassification in a timely manner.

14 “(ii) ENFORCEMENT.—If, after receiv-
15 ing notice of a misclassification from the
16 Secretary under clause (i), a manufacturer
17 fails to correct the misclassification by
18 such time as the Secretary shall require,
19 until the manufacturer makes such correc-
20 tion, the Secretary may—

21 “(I) correct the misclassification
22 on behalf of the manufacturer;

23 “(II) suspend the misclassified
24 drug and the drug’s status as a cov-
25 ered outpatient drug under the manu-

1 factorer’s national rebate agreement;
2 or

3 “(III) impose a civil money pen-
4 alty (which shall be in addition to any
5 other recovery or penalty which may
6 be available under this section or any
7 other provision of law) for each rebate
8 period during which the drug is
9 misclassified not to exceed an amount
10 equal to the product of—

11 “(aa) the total number of
12 units of each dosage form and
13 strength of such misclassified
14 drug paid for under any State
15 plan during such a rebate period;
16 and

17 “(bb) 23.1 percent of the av-
18 erage manufacturer price for the
19 dosage form and strength of such
20 misclassified drug.

21 “(C) REPORTING AND TRANSPARENCY.—

22 “(i) IN GENERAL.—The Secretary
23 shall submit a report to Congress on at
24 least an annual basis that includes infor-
25 mation on the covered outpatient drugs

1 that have been identified as misclassified,
2 the steps taken to reclassify such drugs,
3 the actions the Secretary has taken to en-
4 sure the payment of any rebate amounts
5 which were unpaid as a result of such
6 misclassification, and a disclosure of ex-
7 penditures from the fund created in sub-
8 section (b)(3)(C)(iv), including an account-
9 ing of how such funds have been allocated
10 and spent in accordance with such sub-
11 section.

12 “(ii) PUBLIC ACCESS.—The Secretary
13 shall make the information contained in
14 the report required under clause (i) avail-
15 able to the public on a timely basis.

16 “(D) OTHER PENALTIES AND ACTIONS.—
17 Actions taken and penalties imposed under this
18 clause shall be in addition to other remedies
19 available to the Secretary including terminating
20 the manufacturer’s rebate agreement for non-
21 compliance with the terms of such agreement
22 and shall not exempt a manufacturer from, or
23 preclude the Secretary from pursuing, any civil
24 money penalty under this title or title XI, or

1 any other penalty or action as may be pre-
2 scribed by law.”.

3 (2) OFFSET OF RECOVERED AMOUNTS AGAINST
4 MEDICAL ASSISTANCE.—Section 1927(b)(1)(B) of
5 the Social Security Act (42 U.S.C. 1396r–
6 8(b)(1)(B)) is amended by inserting “, including
7 amounts received by a State under subsection
8 (c)(4),” after “in any quarter”.

9 (c) CLARIFYING DEFINITIONS.—Section
10 1927(k)(7)(A) of the Social Security Act (42 U.S.C.
11 1396r–8(k)(7)(A)) is amended—

12 (1) by striking “an original new drug applica-
13 tion” and inserting “a new drug application” each
14 place it appears;

15 (2) in clause (i), by inserting “but including a
16 drug product approved for marketing as a non-pre-
17 scription drug that is regarded as a covered out-
18 patient drug under paragraph (4)” after “drug de-
19 scribed in paragraph (5)”;

20 (3) in clause (ii), by striking “was originally
21 marketed” and inserting “is marketed”; and

22 (4) in clause (iv)—

23 (A) by inserting “, including a drug prod-
24 uct approved for marketing as a non-prescrip-
25 tion drug that is regarded as a covered out-

1 patient drug under paragraph (4),” after “cov-
 2 ered outpatient drug”; and

3 (B) by adding at the end the following new
 4 sentence: “Such term also includes a covered
 5 outpatient drug that is a biological product li-
 6 censed, produced, or distributed under a bio-
 7 logics license application approved by the Food
 8 and Drug Administration.”.

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

14 “(17) KNOWINGLY MISCLASSIFYING COVERED
 15 OUTPATIENT DRUGS.—Any manufacturer or officer,
 16 director, agent, or managing employee of such man-
 17 ufacturer that knowingly misclassifies a covered out-
 18 patient drug under an agreement under section
 19 1927, knowingly fails to correct such misclassifica-
 20 tion, or knowingly provides false information related
 21 to drug pricing, drug product information, or data
 22 related to drug pricing or drug product informa-
 23 tion.”.

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

1 of this Act, and shall apply to covered outpatient drugs
2 supplied by manufacturers under agreements under sec-
3 tion 1927 of the Social Security Act (42 U.S.C. 1396r-
4 8) on or after such date.

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