

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.

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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.

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

1 for each of the manufacturer’s covered out-  
2 patient drugs.”;

3 (C) in subparagraph (C)—

4 (i) in clause (ii), by inserting “, in-  
5 cluding information related to drug pric-  
6 ing, drug product information, and data  
7 related to drug pricing or drug product in-  
8 formation,” after “provides false informa-  
9 tion”; and

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

12 “(iii) MISCLASSIFIED OR  
13 MISREPORTED INFORMATION.—

14 “(I) IN GENERAL.—Any manu-  
15 facturer with an agreement under this  
16 section that knowingly (as defined in  
17 section 1003.110 of title 42, Code of  
18 Federal Regulations (or any successor  
19 regulation)) misclassifies a covered  
20 outpatient drug, such as by knowingly  
21 submitting incorrect drug category in-  
22 formation, is subject to a civil money  
23 penalty for each covered outpatient  
24 drug that is misclassified in an  
25 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.—

1           “(A) IN GENERAL.—If the Secretary deter-  
2 mines that a manufacturer with an agreement  
3 under this section paid a lower per-unit rebate  
4 amount to a State for a rebate period as a re-  
5 sult of the misclassification by the manufac-  
6 turer of a covered outpatient drug (without re-  
7 gard to whether the manufacturer knowingly  
8 made the misclassification or should have  
9 known that the misclassification would be  
10 made) than the per-unit rebate amount that the  
11 manufacturer would have paid to the State if  
12 the drug had been correctly classified, the man-  
13 ufacturer shall pay to the State an amount  
14 equal to the product of—

15           “(i) the difference between—

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

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

23           “(ii) the total units of the drug paid  
24 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            facturer’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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