

112TH CONGRESS  
1ST SESSION

# H. R. 2190

To amend title XVIII of the Social Security Act to require drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals under the Medicare prescription drug benefit program.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 15, 2011

Mr. WAXMAN (for himself, Mr. LEVIN, Mr. STARK, Mr. DINGELL, Mr. GEORGE MILLER of California, and Mr. ANDREWS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title XVIII of the Social Security Act to require drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals under the Medicare prescription drug benefit 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 “Medicare Drug Savings  
5 Act of 2011”.

1 **SEC. 2. REQUIRING DRUG MANUFACTURERS TO PROVIDE**  
 2 **DRUG REBATES FOR DRUGS DISPENSED TO**  
 3 **LOW-INCOME INDIVIDUALS.**

4 (a) IN GENERAL.—Section 1860D–2 of the Social  
 5 Security Act (42 U.S.C. 1395w–102) is amended—

6 (1) in subsection (e)(1), in the matter preceding  
 7 subparagraph (A), by inserting “and subsection (f)”  
 8 after “this subsection”; and

9 (2) by adding at the end the following new sub-  
 10 section:

11 “(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR  
 12 REBATE ELIGIBLE INDIVIDUALS.—

13 “(1) REQUIREMENT.—

14 “(A) IN GENERAL.—For plan years begin-  
 15 ning on or after January 1, 2013, in this part,  
 16 the term ‘covered part D drug’ does not include  
 17 any drug or biological product that is manufac-  
 18 tured by a manufacturer that has not entered  
 19 into and have in effect a rebate agreement de-  
 20 scribed in paragraph (2).

21 “(B) 2012 PLAN YEAR REQUIREMENT.—

22 Any drug or biological product manufactured by  
 23 a manufacturer that declines to enter into a re-  
 24 bate agreement described in paragraph (2) for  
 25 the period beginning on January 1, 2012, and  
 26 ending on December 31, 2012, shall not be in-

1           cluded as a ‘covered part D drug’ for the subse-  
2           quent plan year.

3           “(2) REBATE AGREEMENT.—A rebate agree-  
4           ment under this subsection shall require the manu-  
5           facturer to provide to the Secretary a rebate for  
6           each rebate period (as defined in paragraph (6)(B))  
7           ending after December 31, 2011, in the amount  
8           specified in paragraph (3) for any covered part D  
9           drug of the manufacturer dispensed after December  
10          31, 2011, to any rebate eligible individual (as de-  
11          fined in paragraph (6)(A)) for which payment was  
12          made by a PDP sponsor or MA organization under  
13          this part for such period, including payments passed  
14          through the low-income and reinsurance subsidies  
15          under sections 1860D–14 and 1860D–15(b), respec-  
16          tively. Such rebate shall be paid by the manufac-  
17          turer to the Secretary not later than 30 days after  
18          the date of receipt of the information described in  
19          section 1860D–12(b)(7), including as such section is  
20          applied under section 1857(f)(3), or 30 days after  
21          the receipt of information under subparagraph (D)  
22          of paragraph (3), as determined by the Secretary.  
23          Insofar as not inconsistent with this subsection, the  
24          Secretary shall establish terms and conditions of  
25          such agreement relating to compliance, penalties,

1 and program evaluations, investigations, and audits  
2 that are similar to the terms and conditions for re-  
3 bate agreements under paragraphs (3) and (4) of  
4 section 1927(b).

5 “(3) REBATE FOR REBATE ELIGIBLE MEDICARE  
6 DRUG PLAN ENROLLEES.—

7 “(A) IN GENERAL.—The amount of the re-  
8 bate specified under this paragraph for a manu-  
9 facturer for a rebate period, with respect to  
10 each dosage form and strength of any covered  
11 part D drug provided by such manufacturer  
12 and dispensed to a rebate eligible individual,  
13 shall be equal to the product of—

14 “(i) the total number of units of such  
15 dosage form and strength of the drug so  
16 provided and dispensed for which payment  
17 was made by a PDP sponsor or an MA or-  
18 ganization under this part for the rebate  
19 period, including payments passed through  
20 the low-income and reinsurance subsidies  
21 under sections 1860D–14 and 1860D–  
22 15(b), respectively; and

23 “(ii) the amount (if any) by which—

24 “(I) the Medicaid rebate amount  
25 (as defined in subparagraph (B)) for

1 such form, strength, and period, ex-  
2 ceeds; and

3 “(II) the average Medicare drug  
4 program rebate eligible rebate amount  
5 (as defined in subparagraph (C)) for  
6 such form, strength, and period.

7 “(B) MEDICAID REBATE AMOUNT.—For  
8 purposes of this paragraph, the term ‘Medicaid  
9 rebate amount’ means, with respect to each  
10 dosage form and strength of a covered part D  
11 drug provided by the manufacturer for a rebate  
12 period—

13 “(i) in the case of a single source  
14 drug or an innovator multiple source drug,  
15 the amount specified in paragraph  
16 (1)(A)(ii)(II) or (2)(C) of section 1927(c)  
17 plus the amount, if any, specified in sub-  
18 paragraph (A)(ii) of paragraph (2) of such  
19 section, for such form, strength, and pe-  
20 riod; or

21 “(ii) in the case of any other covered  
22 outpatient drug, the amount specified in  
23 paragraph (3)(A)(i) of such section for  
24 such form, strength, and period.

1                   “(C) AVERAGE MEDICARE DRUG PROGRAM  
2 REBATE ELIGIBLE REBATE AMOUNT.—For pur-  
3 poses of this subsection, the term ‘average  
4 Medicare drug program rebate eligible rebate  
5 amount’ means, with respect to each dosage  
6 form and strength of a covered part D drug  
7 provided by a manufacturer for a rebate period,  
8 the sum, for all PDP sponsors under part D  
9 and MA organizations administering an MA-  
10 PD plan under part C, of—

11                   “(i) the product, for each such spon-  
12 sor or organization, of—

13                   “(I) the sum of all rebates, dis-  
14 counts, or other price concessions (not  
15 taking into account any rebate pro-  
16 vided under paragraph (2) or any dis-  
17 counts under the program under sec-  
18 tion 1860D–14A) for such dosage  
19 form and strength of the drug dis-  
20 pensed, calculated on a per-unit basis,  
21 but only to the extent that any such  
22 rebate, discount, or other price con-  
23 cession applies equally to drugs dis-  
24 pensed to rebate eligible Medicare  
25 drug plan enrollees and drugs dis-

1                   pensed to PDP and MA–PD enrollees  
2                   who are not rebate eligible individuals;  
3                   and

4                   “(II) the number of the units of  
5                   such dosage and strength of the drug  
6                   dispensed during the rebate period to  
7                   rebate eligible individuals enrolled in  
8                   the prescription drug plans adminis-  
9                   tered by the PDP sponsor or the MA–  
10                  PD plans administered by the MA or-  
11                  ganization; divided by

12                  “(ii) the total number of units of such  
13                  dosage and strength of the drug dispensed  
14                  during the rebate period to rebate eligible  
15                  individuals enrolled in all prescription drug  
16                  plans administered by PDP sponsors and  
17                  all MA–PD plans administered by MA or-  
18                  ganizations.

19                  “(D) USE OF ESTIMATES.—The Secretary  
20                  may establish a methodology for estimating the  
21                  average Medicare drug program rebate eligible  
22                  rebate amounts for each rebate period based on  
23                  bid and utilization information under this part  
24                  and may use these estimates as the basis for  
25                  determining the rebates under this section. If

1 the Secretary elects to estimate the average  
2 Medicare drug program rebate eligible rebate  
3 amounts, the Secretary shall establish a rec-  
4 onciliation process for adjusting manufacturer  
5 rebate payments not later than 3 months after  
6 the date that manufacturers receive the infor-  
7 mation collected under section 1860D-  
8 12(b)(7)(B).

9 “(4) LENGTH OF AGREEMENT.—The provisions  
10 of paragraph (4) of section 1927(b) (other than  
11 clauses (iv) and (v) of subparagraph (B)) shall apply  
12 to rebate agreements under this subsection in the  
13 same manner as such paragraph applies to a rebate  
14 agreement under such section.

15 “(5) OTHER TERMS AND CONDITIONS.—The  
16 Secretary shall establish other terms and conditions  
17 of the rebate agreement under this subsection, in-  
18 cluding terms and conditions related to compliance,  
19 that are consistent with this subsection.

20 “(6) DEFINITIONS.—In this subsection and sec-  
21 tion 1860D-12(b)(7):

22 “(A) REBATE ELIGIBLE INDIVIDUAL.—The  
23 term ‘rebate eligible individual’ means—

24 “(i) a subsidy eligible individual (as  
25 defined in section 1860D-14(a)(3)(A));



1 “(ii) a Medicaid beneficiary treated as  
 2 a subsidy eligible individual under clause  
 3 (v) of section 1860D–14(a)(3)(B); and

4 “(iii) any part D eligible individual  
 5 not described in clause (i) or (ii) who is de-  
 6 termined for purposes of the State plan  
 7 under title XIX to be eligible for medical  
 8 assistance under clause (i), (iii), or (iv) of  
 9 section 1902(a)(10)(E).

10 “(B) REBATE PERIOD.—The term ‘rebate  
 11 period’ has the meaning given such term in sec-  
 12 tion 1927(k)(8).”.

13 (b) REPORTING REQUIREMENT FOR THE DETER-  
 14 MINATION AND PAYMENT OF REBATES BY MANUFAC-  
 15 TURES RELATED TO REBATE FOR REBATE ELIGIBLE  
 16 MEDICARE DRUG PLAN ENROLLEES.—

17 (1) REQUIREMENTS FOR PDP SPONSORS.—Sec-  
 18 tion 1860D–12(b) of the Social Security Act (42  
 19 U.S.C. 1395w–112(b)) is amended by adding at the  
 20 end the following new paragraph:

21 “(7) REPORTING REQUIREMENT FOR THE DE-  
 22 TERMINATION AND PAYMENT OF REBATES BY MANU-  
 23 FACTURERS RELATED TO REBATE FOR REBATE ELI-  
 24 GIBLE MEDICARE DRUG PLAN ENROLLEES.—

1           “(A) IN GENERAL.—For purposes of the  
2           rebate under section 1860D–2(f) for contract  
3           years beginning on or after January 1, 2013,  
4           each contract entered into with a PDP sponsor  
5           under this part with respect to a prescription  
6           drug plan shall require that the sponsor comply  
7           with subparagraphs (B) and (C).

8           “(B) REPORT FORM AND CONTENTS.—Not  
9           later than a date specified by the Secretary, a  
10          PDP sponsor of a prescription drug plan under  
11          this part shall report to each manufacturer—

12               “(i) information (by National Drug  
13               Code number) on the total number of units  
14               of each dosage, form, and strength of each  
15               drug of such manufacturer dispensed to re-  
16               bate eligible Medicare drug plan enrollees  
17               under any prescription drug plan operated  
18               by the PDP sponsor during the rebate pe-  
19               riod;

20               “(ii) information on the price dis-  
21               counts, price concessions, and rebates for  
22               such drugs for such form, strength, and  
23               period;

24               “(iii) information on the extent to  
25               which such price discounts, price conces-

1           sions, and rebates apply equally to rebate  
2           eligible Medicare drug plan enrollees and  
3           PDP enrollees who are not rebate eligible  
4           Medicare drug plan enrollees; and

5           “(iv) any additional information that  
6           the Secretary determines is necessary to  
7           enable the Secretary to calculate the aver-  
8           age Medicare drug program rebate eligible  
9           rebate amount (as defined in paragraph  
10          (3)(C) of such section), and to determine  
11          the amount of the rebate required under  
12          this section, for such form, strength, and  
13          period.

14       Such report shall be in a form consistent with  
15       a standard reporting format established by the  
16       Secretary.

17           “(C) SUBMISSION TO SECRETARY.—Each  
18       PDP sponsor shall promptly transmit a copy of  
19       the information reported under subparagraph  
20       (B) to the Secretary for the purpose of audit  
21       oversight and evaluation.

22           “(D) CONFIDENTIALITY OF INFORMA-  
23       TION.—The provisions of subparagraph (D) of  
24       section 1927(b)(3), relating to confidentiality of  
25       information, shall apply to information reported

1 by PDP sponsors under this paragraph in the  
2 same manner that such provisions apply to in-  
3 formation disclosed by manufacturers or whole-  
4 salers under such section, except—

5 “(i) that any reference to ‘this sec-  
6 tion’ in clause (i) of such subparagraph  
7 shall be treated as being a reference to this  
8 section;

9 “(ii) the reference to the Director of  
10 the Congressional Budget Office in clause  
11 (iii) of such subparagraph shall be treated  
12 as including a reference to the Medicare  
13 Payment Advisory Commission; and

14 “(iii) clause (iv) of such subparagraph  
15 shall not apply.

16 “(E) OVERSIGHT.—Information reported  
17 under this paragraph may be used by the In-  
18 spector General of the Department of Health  
19 and Human Services for the statutorily author-  
20 ized purposes of audit, investigation, and eval-  
21 uations.

22 “(F) PENALTIES FOR FAILURE TO PRO-  
23 VIDE TIMELY INFORMATION AND PROVISION OF  
24 FALSE INFORMATION.—In the case of a PDP  
25 sponsor—

1 “(i) that fails to provide information  
2 required under subparagraph (B) on a  
3 timely basis, the sponsor is subject to a  
4 civil money penalty in the amount of  
5 \$10,000 for each day in which such infor-  
6 mation has not been provided; or

7 “(ii) that knowingly (as defined in  
8 section 1128A(i)) provides false informa-  
9 tion under such subparagraph, the sponsor  
10 is subject to a civil money penalty in an  
11 amount not to exceed \$100,000 for each  
12 item of false information.

13 Such civil money penalties are in addition to  
14 other penalties as may be prescribed by law.  
15 The provisions of section 1128A (other than  
16 subsections (a) and (b)) shall apply to a civil  
17 money penalty under this subparagraph in the  
18 same manner as such provisions apply to a pen-  
19 alty or proceeding under section 1128A(a).”.

20 (2) APPLICATION TO MA ORGANIZATIONS.—Sec-  
21 tion 1857(f)(3) of the Social Security Act (42  
22 U.S.C. 1395w–27(f)(3)) is amended by adding at  
23 the end the following:

24 “(D) REPORTING REQUIREMENT RELATED  
25 TO REBATE FOR REBATE ELIGIBLE MEDICARE

1 DRUG PLAN ENROLLEES.—Section 1860D–  
2 12(b)(7).”.

3 (c) DEPOSIT OF REBATES INTO MEDICARE PRE-  
4 SCRIPTON DRUG ACCOUNT.—Section 1860D–16(c) of the  
5 Social Security Act (42 U.S.C. 1395w–116(c)) is amended  
6 by adding at the end the following new paragraph:

7 “(6) REBATE FOR REBATE ELIGIBLE MEDICARE  
8 DRUG PLAN ENROLLEES.—Amounts paid under a re-  
9 bate agreement under section 1860D–2(f) shall be  
10 deposited into the Account.”.

11 (d) EXCLUSION FROM DETERMINATION OF BEST  
12 PRICE AND AVERAGE MANUFACTURER PRICE UNDER  
13 MEDICAID.—

14 (1) EXCLUSION FROM BEST PRICE DETERMINA-  
15 TION.—Section 1927(c)(1)(C)(ii)(I) of the Social Se-  
16 curity Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is  
17 amended by inserting “and amounts paid under a  
18 rebate agreement under section 1860D–2(f)” after  
19 “this section”.

20 (2) EXCLUSION FROM AVERAGE MANUFAC-  
21 Turer PRICE DETERMINATION.—Section  
22 1927(k)(1)(B)(i) of the Social Security Act (42  
23 U.S.C. 1396r–8(k)(1)(B)(i)) is amended—

24 (A) in subclause (IV), by striking “and”  
25 after the semicolon;

1 (B) in subclause (V), by striking the period  
2 at the end and inserting “; and”; and  
3 (C) by adding at the end the following:  
4 “(VI) amounts paid under a re-  
5 bate agreement under section 1860D–  
6 2(f).”.

○