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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R. _____

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.

IN THE HOUSE OF REPRESENTATIVES

Mr. WAXMAN (for himself, Mr. LEVIN, Mr. STARK, Mr. DINGELL, Mr. GEORGE MILLER of California, Mr. ANDREWS, and [see ATTACHED LIST of additional cosponsors]) introduced the following bill; which was referred to the Committee on _____

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

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).”.