

117TH CONGRESS
1ST SESSION

H. R. 2139

To amend title XVIII of the Social Security Act to provide for the negotiation of lower covered part D drug prices on behalf of Medicare beneficiaries and the establishment and application of a formulary by the Secretary of Health and Human Services under Medicare part D, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 23, 2021

Mr. DOGGETT (for himself, Mr. WELCH, Ms. BUSH, Mr. KHANNA, Mr. POCAN, Ms. JAYAPAL, Mr. COHEN, Ms. DELAURO, Ms. TLAIB, Ms. WASSERMAN SCHULTZ, Mr. NEGUSE, Ms. OMAR, Ms. SCHAKOWSKY, and Mr. DEFAZIO) 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

A BILL

To amend title XVIII of the Social Security Act to provide for the negotiation of lower covered part D drug prices on behalf of Medicare beneficiaries and the establishment and application of a formulary by the Secretary of Health and Human Services under Medicare part D, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medicare Drug Price
3 Negotiation Act”.

4 **SEC. 2. NEGOTIATION OF LOWER COVERED PART D DRUG
5 PRICES ON BEHALF OF MEDICARE BENE-
6 FICIARIES; ESTABLISHMENT AND APPLICA-
7 TION OF FORMULARY BY THE SECRETARY OF
8 HEALTH AND HUMAN SERVICES UNDER
9 MEDICARE PART D.**

10 (a) IN GENERAL.—Section 1860D–11 of the Social
11 Security Act (42 U.S.C. 1395w–111) is amended by strik-
12 ing subsection (i) (relating to noninterference) and insert-
13 ing the following:

14 “(i) NEGOTIATION OF LOWER DRUG PRICES; ESTAB-
15 LISHMENT AND APPLICATION OF FORMULARY.—

16 “(1) NEGOTIATION.—

17 “(A) IN GENERAL.—Notwithstanding any
18 other provision of law, subject to subparagraph
19 (B), the Secretary shall, for plan years begin-
20 ning with plan year 2023—

21 “(i) negotiate with pharmaceutical
22 manufacturers the prices (including dis-
23 counts, rebates, and all other price conces-
24 sions) that may be charged to PDP spon-
25 sors and MA organizations for covered
26 part D drugs furnished to enrollees; and

1 “(ii) complete such negotiations for a
2 plan year not less than 30 days before the
3 first day of the application review process
4 for such plan year for new contracts or ex-
5 panding existing contracts with PDP spon-
6 sors and MA organizations to offer pre-
7 scription drug plans or MA–PD plans, re-
8 spectively.

9 “(B) USE OF FALLBACK IF NEGOTIATIONS
10 FAIL.—

11 “(i) IN GENERAL.—If, after negotia-
12 tions under subparagraph (A), the Sec-
13 retary is not successful in obtaining a rea-
14 sonable price for covered part D drugs in
15 accordance with clause (iii), the price that
16 may be charged to PDP sponsors and MA
17 organizations for such covered part D
18 drugs furnished to enrollees shall be the
19 lowest of the following:

20 “(I) The price applied pursuant
21 to section 8126 of title 38, United
22 States Code, for such drug for the
23 year.

24 “(II) The median price available,
25 during the most recent 12-month pe-

1 riod for which data is available from
2 the manufacturer to any wholesaler,
3 retailer, provider, health maintenance
4 organization, nonprofit entity, or gov-
5 ernmental entity in Canada, the
6 United Kingdom, Germany, France,
7 and Japan.

8 “(III) The average manufacturer
9 price (as defined in subsection (k) of
10 section 1927) for such drug for the
11 most recent rebate period (as defined
12 in such subsection) applicable to such
13 plan year, reduced by the sum of the
14 applicable rebate factors for the drug
15 and rebate period.

16 “(ii) APPLICABLE REBATE FACTOR.—
17 For purposes of clause (i)(III), the term
18 ‘applicable rebate factor’ means, with re-
19 spect to a covered part D drug and a re-
20 bate period (as defined in section 1927(k)),
21 a dollar amount that applies for purposes
22 of determining the amount of a rebate that
23 is applicable to such drug for such rebate
24 period under—

1 “(I) paragraph (1)(A)(ii) of sec-
2 tion 1927(c);

3 “(II) paragraph (2)(A)(ii) of
4 such section;

5 “(III) paragraph (2)(B) of such
6 section;

7 “(IV) paragraph (2)(C) of such
8 section;

9 “(V) paragraph (3)(A)(i) of such
10 section; or

11 “(VI) paragraph (3)(C) of such
12 section.

13 “(iii) GUIDANCE.—Not later than 60
14 days after the date of enactment of this
15 subsection, the Secretary shall issue guid-
16 ance on criteria to be considered for pur-
17 poses of determining under clause (i)
18 whether or not the Secretary is successful
19 in obtaining a reasonable price for a cov-
20 ered part D drug. Such criteria shall in-
21 clude at least the following:

22 “(I) The comparative clinical ef-
23 fectiveness and cost effectiveness, if
24 available, of such covered part D
25 drug.

1 “(II) The budgetary impact of
2 providing coverage under this part for
3 such covered part D drug.

4 “(III) The number of similarly
5 effective drug or alternative treatment
6 regimens for each approved use of
7 such covered part D drug.

8 “(IV) Associated unmet need or
9 severity of illness.

10 “(C) IDENTIFICATION OF COVERED PART
11 D DRUGS SUBJECT TO NEGOTIATION AND AP-
12 PLICATION OF NEGOTIATED PRICE.—

13 “(i) IDENTIFICATION.—The Secretary
14 shall, for each plan year, in accordance
15 with the subsequent clauses of this sub-
16 paragraph, and pursuant to rulemaking,
17 identify covered part D drugs for which ne-
18 gotiations under subparagraph (A) shall be
19 conducted.

20 “(ii) APPLICATION OF NEGOTIATED
21 PRICE.—Except as provided in clause (iii),
22 the negotiated price of a covered Part D
23 drug shall be in effect for each subsequent
24 plan year, and may be adjusted for infla-
25 tion, as measured by the percentage in-

1 crease in the consumer price index for all
2 urban consumers over the preceding year.

3 “(iii) PROCESS FOR RENEGOTI-
4 ATION.—The Secretary may establish a
5 process whereby stakeholders may petition
6 for the negotiated price of a covered Part
7 D to be renegotiated after an appropriate
8 length of time and only if evidence justi-
9 fying the need for such renegotiation is
10 provided.

11 “(iv) REASONABLE NOTIFICATION.—
12 The Secretary shall carry out this subpara-
13 graph in such manner as to provide for
14 public notification of the covered part D
15 drugs subject to negotiations for a plan
16 year within a reasonable period before the
17 beginning of such negotiations.

18 “(D) PRIORITIZATION OF CERTAIN COV-
19 ERED PART D DRUGS.—For purposes of sub-
20 paragraph (C)(i), the Secretary shall prioritize
21 negotiating the prices of covered part D
22 drugs—

23 “(i) that are among—

24 “(I) the 40 covered part D drugs
25 that are utilized by at least 1,000

1 Medicare part D beneficiaries and
2 with respect to which there were the
3 highest total expenditures under this
4 part during the most recent 12-month
5 period for which data is available;

6 “(II) the 40 covered part D
7 drugs that are utilized by at least
8 1,000 Medicare part D beneficiaries
9 with respect to whom the total annual
10 spending per such a beneficiary under
11 this part for coverage of such a drug
12 is at least \$10,000; or

13 “(III) the 20 covered part D
14 drugs that are utilized by at least
15 1,000 Medicare part D beneficiaries
16 and with respect to which there are
17 unit cost increases at or above the
18 95th percentile of overall covered part
19 D drug unit cost increases during the
20 most recent 12-month period for
21 which data is available;

22 “(ii) with respect to which the cost of
23 such a drug to the part D eligible indi-
24 vidual involved would exceed the annual
25 out-of-pocket threshold applicable under

1 section 1860D–2(b)(4)(B) for such plan
2 year, if the drug were prescribed to the in-
3 dividual for the period of the year or with
4 respect to which a single treatment regi-
5 men is priced above such annual out-of-
6 pocket threshold applicable under such sec-
7 tion 1860D–2(b)(4)(B) for the year; or

8 “(iii) that are single-source drugs or
9 biologicals (as defined in section
10 1847A(c)(6)(D)) and that satisfy at least
11 one other criterion described in a previous
12 clause of this subparagraph.

13 “(E) ANNUAL REPORT TO CONGRESS.—
14 Not later than 30 days after the date on which
15 the Secretary completes negotiations under this
16 paragraph for the first plan year and each sub-
17 sequent plan year, the Secretary shall submit to
18 Congress and make available to the public a re-
19 port describing the negotiations during the pre-
20 ceding year, including—

21 “(i) the number of covered part D
22 drug prices negotiated;

23 “(ii) the magnitude of savings
24 achieved as a result of such negotiations;

1 “(iii) the number of times price nego-
2 tiations failed (based on the criteria in-
3 cluded in the guidance issued pursuant to
4 clause (iii) of subparagraph (B)) and re-
5 sulted in the use of fallback prices under
6 clause (i) of such subparagraph, and the
7 rationale for any such decisions;

8 “(iv) the progress made toward nego-
9 tiating the prices of covered part D drugs
10 that are prioritized under subparagraph
11 (D); and

12 “(v) the barriers, if any, to achieving
13 savings through negotiations.

14 “(F) EVALUATION.—Not later than De-
15 cember 31, 2026, the Inspector General of the
16 Department of Health and Human Services
17 shall submit to Congress a report evaluating the
18 negotiations conducted by the Secretary under
19 this paragraph, including a description and
20 analysis of—

21 “(i) the extent to which such price ne-
22 gotiations are achieving lower prices for
23 covered part D drugs for enrollees;

24 “(ii) the parties benefitting from such
25 lower prices, such as enrollees, the Federal

1 Government, States, prescription drug
2 plans and MA–PD plans, or other entities;

3 “(iii) how such price negotiations are
4 affecting—

5 “(I) the list price of covered part
6 D drugs; and

7 “(II) drug prices in the private
8 market; and

9 “(iv) recommendations for improving
10 price negotiations, if applicable.

11 “(2) ESTABLISHMENT AND APPLICATION OF
12 FORMULARY BY THE SECRETARY OR CHANGES IN
13 FORMULARIES TO BE REQUIRED BY SECRETARY.—

14 “(A) IN GENERAL.—The Secretary shall,
15 for plan years beginning with plan year 2023—

16 “(i) subject to subparagraphs (B) and
17 (C), establish and apply a formulary for
18 required use by sponsors of prescription
19 drug plans and organizations offering MA–
20 PD plans under this part; or

21 “(ii) require changes, as necessary, in
22 the covered part D drugs included on
23 formularies of PDP sponsors of prescrip-
24 tion drug plans (including changes, as nec-
25 essary, in the preferred or tiered cost-shar-

1 ing status of such a drug) to take into ac-
2 count negotiations carried out by the Sec-
3 retary pursuant to paragraph (1), regard-
4 less of whether such a covered part D drug
5 is the subject of such negotiations.

6 “(B) REQUIRED INCLUSION OF DRUGS IN
7 ALL THERAPEUTIC CATEGORIES.—A formulary
8 established and applied under subparagraph
9 (A)(i) shall include at least two covered part D
10 drugs in each category and class of covered part
11 D drugs as described in section
12 423.120(b)(2)(i) of title 42, Code of Federal
13 Regulations (as in effect on January 1, 2019).

14 “(C) APPLICATION OF DEVELOPMENT AND
15 REVISION REQUIREMENTS AND REQUIRED IN-
16 CLUSION OF ALL DRUGS IN CERTAIN CAT-
17 EGORIES AND CLASSES.—The requirements de-
18 scribed in subparagraphs (A) and (B) of section
19 1860D–4(b)(3) (relating to development and re-
20 vision requirements of the formulary) and sub-
21 paragraph (G) of such section (relating to re-
22 quired inclusion of all drugs in certain cat-
23 egories and classes) shall apply to a formulary
24 established and applied under subparagraph
25 (A)(i) of this paragraph.

1 “(3) PLAN FLEXIBILITY TO NEGOTIATE GREAT-
2 ER DISCOUNTS.—Nothing in this subsection shall be
3 construed as preventing the sponsor of a prescrip-
4 tion drug plan, or an organization offering an MA-
5 PD plan, from obtaining a discount or reduction of
6 the price for a covered part D drug below the price
7 negotiated under paragraph (1), if applicable, in-
8 cluding through the use of preferred or tiered cost-
9 sharing status.

10 “(4) ENSURING BENEFICIARY ACCESS TO
11 NEEDED DRUGS.—Beginning with plan year 2023,
12 each PDP sponsor of a prescription drug plan and
13 organization offering an MA–PD plan shall have in
14 place a process under which an enrollee in the plan
15 may request coverage under the plan for a covered
16 part D drug that is not on the formulary, or is sub-
17 ject to utilization management controls, such as
18 tiered pricing, prior authorization, or step therapy.”.

19 (b) CONFORMING AMENDMENTS.—

20 (1) IN GENERAL.—Section 1860D–4 of the So-
21 cial Security Act (42 U.S.C. 1395w–104) is amend-
22 ed—

23 (A) in subsection (b)(3), in the matter pre-
24 ceding subparagraph (A), by striking “If a

1 PDP” and inserting “Subject to section
2 1860D–11(i)(2), if a PDP”;

3 (B) in subsection (g)—

4 (i) in paragraph (1), by inserting be-
5 fore the period at the end the following: “,
6 except that the PDP sponsor of a prescrip-
7 tion drug plan shall treat the presentation
8 of a prescription to a participating phar-
9 macy, which is transmitted to the plan by
10 the pharmacy, as a request for a coverage
11 determination (including with respect to
12 prior authorization, step therapy, or quan-
13 tity limits) and, in applying such para-
14 graphs of section 1852(g), the response to
15 such transmittal shall be treated as a de-
16 termination by the sponsor”; and

17 (ii) in paragraph (2), in the first sen-
18 tence, by inserting “(or a participating
19 pharmacy, on behalf of such individual,
20 through transmission of a prescription as
21 described in paragraph (1))” after “a part
22 D eligible individual who is enrolled in the
23 plan”; and

24 (C) in subsection (h)—

1 (i) in paragraph (1), in the second
2 sentence, by inserting “(or a participating
3 pharmacy, on behalf of such individual)”
4 after “the part D eligible individual”; and

5 (ii) in paragraph (2), by inserting
6 “(or a participating pharmacy, on behalf of
7 such individual)” after “A part D eligible
8 individual who is enrolled in a prescription
9 drug plan offered by a PDP sponsor”.

10 (2) EFFECTIVE DATE.—The amendments made
11 by subparagraphs (B) and (C) of paragraph (1)
12 shall apply to plan years beginning on or after Janu-
13 ary 1, 2023.

14 **SEC. 3. REQUIRING DRUG MANUFACTURERS TO PROVIDE**
15 **DRUG REBATES FOR DRUGS DISPENSED TO**
16 **LOW-INCOME INDIVIDUALS.**

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

19 (1) in subsection (e)(1), in the matter preceding
20 subparagraph (A), by inserting “and subsection (f)”
21 after “this subsection”; and

22 (2) by adding at the end the following new sub-
23 section:

24 “(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR
25 REBATE ELIGIBLE INDIVIDUALS.—

1 “(1) REQUIREMENT.—

2 “(A) IN GENERAL.—For plan years begin-
3 ning on or after January 1, 2023, in this part,
4 the term ‘covered part D drug’ does not include
5 any drug or biological product that is manufac-
6 tured by a manufacturer that has not entered
7 into and have in effect a rebate agreement de-
8 scribed in paragraph (2).

9 “(B) 2023 PLAN YEAR REQUIREMENT.—
10 Any drug or biological product manufactured by
11 a manufacturer that declines to enter into a re-
12 bate agreement described in paragraph (2) for
13 the period beginning on January 1, 2023, and
14 ending on December 31, 2023, shall not be in-
15 cluded as a ‘covered part D drug’ for the subse-
16 quent plan year.

17 “(2) REBATE AGREEMENT.—A rebate agree-
18 ment under this subsection shall require the manu-
19 facturer to provide to the Secretary a rebate for
20 each rebate period (as defined in paragraph (6)(B))
21 ending after December 31, 2022, in the amount
22 specified in paragraph (3) for any covered part D
23 drug of the manufacturer dispensed after December
24 31, 2022, to any rebate eligible individual (as de-
25 fined in paragraph (6)(A)) for which payment was

1 made by a PDP sponsor or MA organization under
2 this part for such period, including payments passed
3 through the low-income and reinsurance subsidies
4 under sections 1860D–14 and 1860D–15(b), respec-
5 tively. Such rebate shall be paid by the manufac-
6 turer to the Secretary not later than 30 days after
7 the date of receipt of the information described in
8 section 1860D–12(b)(8), including as such section is
9 applied under section 1857(f)(3), or 30 days after
10 the receipt of information under subparagraph (D)
11 of paragraph (3), as determined by the Secretary.
12 Insofar as not inconsistent with this subsection, the
13 Secretary shall establish terms and conditions of
14 such agreement relating to compliance, penalties,
15 and program evaluations, investigations, and audits
16 that are similar to the terms and conditions for re-
17 bate agreements under paragraphs (3) and (4) of
18 section 1927(b).

19 “(3) REBATE FOR REBATE ELIGIBLE MEDICARE
20 DRUG PLAN ENROLLEES.—

21 “(A) IN GENERAL.—The amount of the re-
22 bate specified under this paragraph for a manu-
23 facturer for a rebate period, with respect to
24 each dosage form and strength of any covered
25 part D drug provided by such manufacturer

1 and dispensed to a rebate eligible individual,
2 shall be equal to the product of—

3 “(i) the total number of units of such
4 dosage form and strength of the drug so
5 provided and dispensed for which payment
6 was made by a PDP sponsor or an MA or-
7 ganization under this part for the rebate
8 period, including payments passed through
9 the low-income and reinsurance subsidies
10 under sections 1860D–14 and 1860D–
11 15(b), respectively; and

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

13 “(I) the Medicaid rebate amount
14 (as defined in subparagraph (B)) for
15 such form, strength, and period, ex-
16 ceeds

17 “(II) the average Medicare drug
18 program rebate eligible rebate amount
19 (as defined in subparagraph (C)) for
20 such form, strength, and period.

21 “(B) MEDICAID REBATE AMOUNT.—For
22 purposes of this paragraph, the term ‘Medicaid
23 rebate amount’ means, with respect to each
24 dosage form and strength of a covered part D

1 drug provided by the manufacturer for a rebate
2 period—

3 “(i) in the case of a single source
4 drug or an innovator multiple source drug,
5 the amount specified in paragraph
6 (1)(A)(ii)(II) or (2)(C) of section 1927(c)
7 plus the amount, if any, specified in sub-
8 paragraph (A)(ii) of paragraph (2) of such
9 section, for such form, strength, and pe-
10 riod; or

11 “(ii) in the case of any other covered
12 outpatient drug, the amount specified in
13 paragraph (3)(A)(i) of such section for
14 such form, strength, and period.

15 “(C) AVERAGE MEDICARE DRUG PROGRAM
16 REBATE ELIGIBLE REBATE AMOUNT.—For pur-
17 poses of this subsection, the term ‘average
18 Medicare drug program rebate eligible rebate
19 amount’ means, with respect to each dosage
20 form and strength of a covered part D drug
21 provided by a manufacturer for a rebate period,
22 the sum, for all PDP sponsors under part D
23 and MA organizations administering an MA-
24 PD plan under part C, of—

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

3 “(I) the sum of all rebates, dis-
4 counts, or other price concessions (not
5 taking into account any rebate pro-
6 vided under paragraph (2) or any dis-
7 counts under the program under sec-
8 tion 1860D-14A) for such dosage
9 form and strength of the drug dis-
10 pensed, calculated on a per-unit basis,
11 but only to the extent that any such
12 rebate, discount, or other price con-
13 cession applies equally to drugs dis-
14 pensed to rebate eligible Medicare
15 drug plan enrollees and drugs dis-
16 pensed to PDP and MA-PD enrollees
17 who are not rebate eligible individuals;
18 and

19 “(II) the number of the units of
20 such dosage and strength of the drug
21 dispensed during the rebate period to
22 rebate eligible individuals enrolled in
23 the prescription drug plans adminis-
24 tered by the PDP sponsor or the MA-

1 PD plans administered by the MA or-
2 ganization; divided by

3 “(ii) the total number of units of such
4 dosage and strength of the drug dispensed
5 during the rebate period to rebate eligible
6 individuals enrolled in all prescription drug
7 plans administered by PDP sponsors and
8 all MA–PD plans administered by MA or-
9 ganizations.

10 “(D) USE OF ESTIMATES.—The Secretary
11 may establish a methodology for estimating the
12 average Medicare drug program rebate eligible
13 rebate amounts for each rebate period based on
14 bid and utilization information under this part
15 and may use these estimates as the basis for
16 determining the rebates under this section. If
17 the Secretary elects to estimate the average
18 Medicare drug program rebate eligible rebate
19 amounts, the Secretary shall establish a rec-
20 onciliation process for adjusting manufacturer
21 rebate payments not later than 3 months after
22 the date that manufacturers receive the infor-
23 mation collected under section 1860D–
24 12(b)(8)(B).

1 “(4) LENGTH OF AGREEMENT.—The provisions
2 of paragraph (4) of section 1927(b) (other than
3 clauses (iv) and (v) of subparagraph (B)) shall apply
4 to rebate agreements under this subsection in the
5 same manner as such paragraph applies to a rebate
6 agreement under such section.

7 “(5) OTHER TERMS AND CONDITIONS.—The
8 Secretary shall establish other terms and conditions
9 of the rebate agreement under this subsection, in-
10 cluding terms and conditions related to compliance,
11 that are consistent with this subsection.

12 “(6) DEFINITIONS.—In this subsection and sec-
13 tion 1860D–12(b)(8):

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

16 “(i) a subsidy eligible individual (as
17 defined in section 1860D–14(a)(3)(A));

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

21 “(iii) any part D eligible individual
22 not described in clause (i) or (ii) who is de-
23 termined for purposes of the State plan
24 under title XIX to be eligible for medical

1 assistance under clause (i), (iii), or (iv) of
2 section 1902(a)(10)(E).

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

6 (b) REPORTING REQUIREMENT FOR THE DETER-
7 MINATION AND PAYMENT OF REBATES BY MANUFACTUR-
8 ERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDI-
9 CARE DRUG PLAN ENROLLEES.—

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

14 “(8) REPORTING REQUIREMENT FOR THE DE-
15 TERMINATION AND PAYMENT OF REBATES BY MANU-
16 FACTURERS RELATED TO REBATE FOR REBATE ELI-
17 GIBLE MEDICARE DRUG PLAN ENROLLEES.—

18 “(A) IN GENERAL.—For purposes of the
19 rebate under section 1860D–2(f) for contract
20 years beginning on or after January 1, 2023,
21 each contract entered into with a PDP sponsor
22 under this part with respect to a prescription
23 drug plan shall require that the sponsor comply
24 with subparagraphs (B) and (C).

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

5 “(i) information (by National Drug
6 Code number) on the total number of units
7 of each dosage, form, and strength of each
8 drug of such manufacturer dispensed to re-
9 bate eligible Medicare drug plan enrollees
10 under any prescription drug plan operated
11 by the PDP sponsor during the rebate pe-
12 riod;

13 “(ii) information on the price dis-
14 counts, price concessions, and rebates for
15 such drugs for such form, strength, and
16 period;

17 “(iii) information on the extent to
18 which such price discounts, price conces-
19 sions, and rebates apply equally to rebate
20 eligible Medicare drug plan enrollees and
21 PDP enrollees who are not rebate eligible
22 Medicare drug plan enrollees; and

23 “(iv) any additional information that
24 the Secretary determines is necessary to
25 enable the Secretary to calculate the aver-

1 age Medicare drug program rebate eligible
2 rebate amount (as defined in paragraph
3 (3)(C) of such section), and to determine
4 the amount of the rebate required under
5 this section, for such form, strength, and
6 period.

7 Such report shall be in a form consistent with
8 a standard reporting format established by the
9 Secretary.

10 “(C) SUBMISSION TO SECRETARY.—Each
11 PDP sponsor shall promptly transmit a copy of
12 the information reported under subparagraph
13 (B) to the Secretary for the purpose of audit
14 oversight and evaluation.

15 “(D) CONFIDENTIALITY OF INFORMA-
16 TION.—The provisions of subparagraph (D) of
17 section 1927(b)(3), relating to confidentiality of
18 information, shall apply to information reported
19 by PDP sponsors under this paragraph in the
20 same manner that such provisions apply to in-
21 formation disclosed by manufacturers or whole-
22 salers under such section, except—

23 “(i) that any reference to ‘this sec-
24 tion’ in clause (i) of such subparagraph

1 shall be treated as being a reference to this
2 section;

3 “(ii) the reference to the Director of
4 the Congressional Budget Office in clause
5 (iii) of such subparagraph shall be treated
6 as including a reference to the Medicare
7 Payment Advisory Commission; and

8 “(iii) clause (iv) of such subparagraph
9 shall not apply.

10 “(E) OVERSIGHT.—Information reported
11 under this paragraph may be used by the In-
12 spector General of the Department of Health
13 and Human Services for the statutorily author-
14 ized purposes of audit, investigation, and eval-
15 uations.

16 “(F) PENALTIES FOR FAILURE TO PRO-
17 VIDE TIMELY INFORMATION AND PROVISION OF
18 FALSE INFORMATION.—In the case of a PDP
19 sponsor—

20 “(i) that fails to provide information
21 required under subparagraph (B) on a
22 timely basis, the sponsor is subject to a
23 civil money penalty in the amount of
24 \$10,000 for each day in which such infor-
25 mation has not been provided; or

1 “(ii) that knowingly (as defined in
2 section 1128A(i)) provides false informa-
3 tion under such subparagraph, the sponsor
4 is subject to a civil money penalty in an
5 amount not to exceed \$100,000 for each
6 item of false information.

7 Such civil money penalties are in addition to
8 other penalties as may be prescribed by law.
9 The provisions of section 1128A (other than
10 subsections (a) and (b)) shall apply to a civil
11 money penalty under this subparagraph in the
12 same manner as such provisions apply to a pen-
13 alty or proceeding under section 1128A(a).”.

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

18 “(E) REPORTING REQUIREMENT RELATED
19 TO REBATE FOR REBATE ELIGIBLE MEDICARE
20 DRUG PLAN ENROLLEES.—Section 1860D–
21 12(b)(8).”.

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

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

5 (d) EXCLUSION FROM DETERMINATION OF BEST
6 PRICE AND AVERAGE MANUFACTURER PRICE UNDER
7 MEDICAID.—

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

14 (2) EXCLUSION FROM AVERAGE MANUFAC-
15 TURER PRICE DETERMINATION.—Section
16 1927(k)(1)(B)(i) of the Social Security Act (42
17 U.S.C. 1396r–8(k)(1)(B)(i)) is amended—

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

20 (B) in subclause (V), by striking the period
21 at the end and inserting “; and”; and

22 (C) by adding at the end the following:

1 “(VI) amounts paid under a re-
2 bate agreement under section 1860D-
3 2(f).”.

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