

117TH CONGRESS
1ST SESSION

S. 908

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 SENATE OF THE UNITED STATES

MARCH 23, 2021

Mr. SANDERS (for himself, Mr. BLUMENTHAL, Mr. BOOKER, Mrs. GILLIBRAND, Mr. LEAHY, Mr. PADILLA, Mr. REED, Ms. SMITH, and Ms. WARREN) introduced the following bill; which was read twice and referred to the Committee on Finance

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Drug Price
5 Negotiation Act”.

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

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

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

13 “(1) NEGOTIATION.—

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

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

24 “(ii) complete such negotiations for a
 25 plan year not less than 30 days before the
 26 first day of the application review process

1 for such plan year for new contracts or ex-
2 panding existing contracts with PDP spon-
3 sors and MA organizations to offer pre-
4 scription drug plans or MA–PD plans, re-
5 spectively.

6 “(B) USE OF FALLBACK IF NEGOTIATIONS
7 FAIL.—

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

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

21 “(II) The median price available,
22 during the most recent 12-month pe-
23 riod for which data is available from
24 the manufacturer to any wholesaler,
25 retailer, provider, health maintenance

1 organization, nonprofit entity, or gov-
2 ernmental entity in Canada, the
3 United Kingdom, Germany, France,
4 and Japan.

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

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

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

24 “(II) paragraph (2)(A)(ii) of
25 such section;

1 “(III) paragraph (2)(B) of such
2 section;

3 “(IV) paragraph (2)(C) of such
4 section;

5 “(V) paragraph (3)(A)(i) of such
6 section; or

7 “(VI) paragraph (3)(C) of such
8 section.

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

18 “(I) The comparative clinical ef-
19 fectiveness and cost effectiveness, if
20 available, of such covered part D
21 drug.

22 “(II) The budgetary impact of
23 providing coverage under this part for
24 such covered part D drug.

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

5 “(IV) Associated unmet need or
6 severity of illness.

7 “(C) IDENTIFICATION OF COVERED PART
8 D DRUGS SUBJECT TO NEGOTIATION AND AP-
9 PLICATION OF NEGOTIATED PRICE.—

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

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

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

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

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

21 “(i) that are among—

22 “(I) the 40 covered part D drugs
23 that are utilized by at least 1,000
24 Medicare part D beneficiaries and
25 with respect to which there were the

1 highest total expenditures under this
2 part during the most recent 12-month
3 period for which data is available;

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

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

20 “(ii) with respect to which the cost of
21 such a drug to the part D eligible indi-
22 vidual involved would exceed the annual
23 out-of-pocket threshold applicable under
24 section 1860D-2(b)(4)(B) for such plan
25 year, if the drug were prescribed to the in-

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

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

11 “(E) ANNUAL REPORT TO CONGRESS.—

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

19 “(i) the number of covered part D
20 drug prices negotiated;

21 “(ii) the magnitude of savings
22 achieved as a result of such negotiations;

23 “(iii) the number of times price nego-
24 tiations failed (based on the criteria in-
25 cluded in the guidance issued pursuant to

1 clause (iii) of subparagraph (B)) and re-
2 sulted in the use of fallback prices under
3 clause (i) of such subparagraph, and the
4 rationale for any such decisions;

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

9 “(v) the barriers, if any, to achieving
10 savings through negotiations.

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

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

21 “(ii) the parties benefitting from such
22 lower prices, such as enrollees, the Federal
23 Government, States, prescription drug
24 plans and MA–PD plans, or other entities;

1 “(iii) how such price negotiations are
2 affecting—

3 “(I) the list price of covered part
4 D drugs; and

5 “(II) drug prices in the private
6 market; and

7 “(iv) recommendations for improving
8 price negotiations, if applicable.

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

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

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

19 “(ii) require changes, as necessary, in
20 the covered part D drugs included on
21 formularies of PDP sponsors of prescrip-
22 tion drug plans (including changes, as nec-
23 essary, in the preferred or tiered cost-shar-
24 ing status of such a drug) to take into ac-
25 count negotiations carried out by the Sec-

1 retary pursuant to paragraph (1), regard-
2 less of whether such a covered part D drug
3 is the subject of such negotiations.

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

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

24 “(3) PLAN FLEXIBILITY TO NEGOTIATE GREAT-
25 ER DISCOUNTS.—Nothing in this subsection shall be

1 construed as preventing the sponsor of a prescrip-
2 tion drug plan, or an organization offering an MA-
3 PD plan, from obtaining a discount or reduction of
4 the price for a covered part D drug below the price
5 negotiated under paragraph (1), if applicable, in-
6 cluding through the use of preferred or tiered cost-
7 sharing status.

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

17 (b) CONFORMING AMENDMENTS.—

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

21 (A) in subsection (b)(3), in the matter pre-
22 ceding subparagraph (A), by striking “If a
23 PDP” and inserting “Subject to section
24 1860D–11(i)(2), if a PDP”;

25 (B) in subsection (g)—

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

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

21 (C) in subsection (h)—

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

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

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

10 **SEC. 3. REQUIRING DRUG MANUFACTURERS TO PROVIDE**
 11 **DRUG REBATES FOR DRUGS DISPENSED TO**
 12 **LOW-INCOME INDIVIDUALS.**

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

15 (1) in subsection (e)(1), in the matter preceding
 16 subparagraph (A), by inserting “and subsection (f)”
 17 after “this subsection”; and

18 (2) by adding at the end the following new sub-
 19 section:

20 “(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR
 21 REBATE ELIGIBLE INDIVIDUALS.—

22 “(1) REQUIREMENT.—

23 “(A) IN GENERAL.—For plan years begin-
 24 ning on or after January 1, 2023, in this part,
 25 the term ‘covered part D drug’ does not include

1 any drug or biological product that is manufac-
2 tured by a manufacturer that has not entered
3 into and have in effect a rebate agreement de-
4 scribed in paragraph (2).

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

13 “(2) REBATE AGREEMENT.—A rebate agree-
14 ment under this subsection shall require the manu-
15 facturer to provide to the Secretary a rebate for
16 each rebate period (as defined in paragraph (6)(B))
17 ending after December 31, 2022, in the amount
18 specified in paragraph (3) for any covered part D
19 drug of the manufacturer dispensed after December
20 31, 2022, to any rebate eligible individual (as de-
21 fined in paragraph (6)(A)) for which payment was
22 made by a PDP sponsor or MA organization under
23 this part for such period, including payments passed
24 through the low-income and reinsurance subsidies
25 under sections 1860D–14 and 1860D–15(b), respec-

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

15 “(3) REBATE FOR REBATE ELIGIBLE MEDICARE
16 DRUG PLAN ENROLLEES.—

17 “(A) IN GENERAL.—The amount of the re-
18 bate specified under this paragraph for a manu-
19 facturer for a rebate period, with respect to
20 each dosage form and strength of any covered
21 part D drug provided by such manufacturer
22 and dispensed to a rebate eligible individual,
23 shall be equal to the product of—

24 “(i) the total number of units of such
25 dosage form and strength of the drug so

1 provided and dispensed for which payment
2 was made by a PDP sponsor or an MA or-
3 ganization under this part for the rebate
4 period, including payments passed through
5 the low-income and reinsurance subsidies
6 under sections 1860D-14 and 1860D-
7 15(b), respectively; and

8 “(ii) the amount (if any) by which—

9 “(I) the Medicaid rebate amount
10 (as defined in subparagraph (B)) for
11 such form, strength, and period, ex-
12 ceeds

13 “(II) the average Medicare drug
14 program rebate eligible rebate amount
15 (as defined in subparagraph (C)) for
16 such form, strength, and period.

17 “(B) MEDICAID REBATE AMOUNT.—For
18 purposes of this paragraph, the term ‘Medicaid
19 rebate amount’ means, with respect to each
20 dosage form and strength of a covered part D
21 drug provided by the manufacturer for a rebate
22 period—

23 “(i) in the case of a single source
24 drug or an innovator multiple source drug,
25 the amount specified in paragraph

1 (1)(A)(ii)(II) or (2)(C) of section 1927(c)
2 plus the amount, if any, specified in sub-
3 paragraph (A)(ii) of paragraph (2) of such
4 section, for such form, strength, and pe-
5 riod; or

6 “(ii) in the case of any other covered
7 outpatient drug, the amount specified in
8 paragraph (3)(A)(i) of such section for
9 such form, strength, and period.

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

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

22 “(I) the sum of all rebates, dis-
23 counts, or other price concessions (not
24 taking into account any rebate pro-
25 vided under paragraph (2) or any dis-

1 counts under the program under sec-
2 tion 1860D–14A) for such dosage
3 form and strength of the drug dis-
4 pensed, calculated on a per-unit basis,
5 but only to the extent that any such
6 rebate, discount, or other price con-
7 cession applies equally to drugs dis-
8 pensed to rebate eligible Medicare
9 drug plan enrollees and drugs dis-
10 pensed to PDP and MA–PD enrollees
11 who are not rebate eligible individuals;
12 and

13 “(II) the number of the units of
14 such dosage and strength of the drug
15 dispensed during the rebate period to
16 rebate eligible individuals enrolled in
17 the prescription drug plans adminis-
18 tered by the PDP sponsor or the MA–
19 PD plans administered by the MA or-
20 ganization; divided by

21 “(ii) the total number of units of such
22 dosage and strength of the drug dispensed
23 during the rebate period to rebate eligible
24 individuals enrolled in all prescription drug
25 plans administered by PDP sponsors and

1 all MA–PD plans administered by MA or-
2 ganizations.

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

18 “(4) LENGTH OF AGREEMENT.—The provisions
19 of paragraph (4) of section 1927(b) (other than
20 clauses (iv) and (v) of subparagraph (B)) shall apply
21 to rebate agreements under this subsection in the
22 same manner as such paragraph applies to a rebate
23 agreement under such section.

24 “(5) OTHER TERMS AND CONDITIONS.—The
25 Secretary shall establish other terms and conditions

1 of the rebate agreement under this subsection, in-
 2 cluding terms and conditions related to compliance,
 3 that are consistent with this subsection.

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

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

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

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

13 “(iii) any part D eligible individual
 14 not described in clause (i) or (ii) who is de-
 15 termined for purposes of the State plan
 16 under title XIX to be eligible for medical
 17 assistance under clause (i), (iii), or (iv) of
 18 section 1902(a)(10)(E).

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

22 (b) REPORTING REQUIREMENT FOR THE DETER-
 23 MINATION AND PAYMENT OF REBATES BY MANUFACTUR-
 24 ERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDI-
 25 CARE DRUG PLAN ENROLLEES.—

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

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

9 “(A) IN GENERAL.—For purposes of the
10 rebate under section 1860D–2(f) for contract
11 years beginning on or after January 1, 2023,
12 each contract entered into with a PDP sponsor
13 under this part with respect to a prescription
14 drug plan shall require that the sponsor comply
15 with subparagraphs (B) and (C).

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

20 “(i) information (by National Drug
21 Code number) on the total number of units
22 of each dosage, form, and strength of each
23 drug of such manufacturer dispensed to re-
24 bate eligible Medicare drug plan enrollees
25 under any prescription drug plan operated

1 by the PDP sponsor during the rebate pe-
2 riod;

3 “(ii) information on the price dis-
4 counts, price concessions, and rebates for
5 such drugs for such form, strength, and
6 period;

7 “(iii) information on the extent to
8 which such price discounts, price conces-
9 sions, and rebates apply equally to rebate
10 eligible Medicare drug plan enrollees and
11 PDP enrollees who are not rebate eligible
12 Medicare drug plan enrollees; and

13 “(iv) any additional information that
14 the Secretary determines is necessary to
15 enable the Secretary to calculate the aver-
16 age Medicare drug program rebate eligible
17 rebate amount (as defined in paragraph
18 (3)(C) of such section), and to determine
19 the amount of the rebate required under
20 this section, for such form, strength, and
21 period.

22 Such report shall be in a form consistent with
23 a standard reporting format established by the
24 Secretary.

1 “(C) SUBMISSION TO SECRETARY.—Each
2 PDP sponsor shall promptly transmit a copy of
3 the information reported under subparagraph
4 (B) to the Secretary for the purpose of audit
5 oversight and evaluation.

6 “(D) CONFIDENTIALITY OF INFORMA-
7 TION.—The provisions of subparagraph (D) of
8 section 1927(b)(3), relating to confidentiality of
9 information, shall apply to information reported
10 by PDP sponsors under this paragraph in the
11 same manner that such provisions apply to in-
12 formation disclosed by manufacturers or whole-
13 salers under such section, except—

14 “(i) that any reference to ‘this sec-
15 tion’ in clause (i) of such subparagraph
16 shall be treated as being a reference to this
17 section;

18 “(ii) the reference to the Director of
19 the Congressional Budget Office in clause
20 (iii) of such subparagraph shall be treated
21 as including a reference to the Medicare
22 Payment Advisory Commission; and

23 “(iii) clause (iv) of such subparagraph
24 shall not apply.

1 “(E) OVERSIGHT.—Information reported
2 under this paragraph may be used by the In-
3 spector General of the Department of Health
4 and Human Services for the statutorily author-
5 ized purposes of audit, investigation, and eval-
6 uations.

7 “(F) PENALTIES FOR FAILURE TO PRO-
8 VIDE TIMELY INFORMATION AND PROVISION OF
9 FALSE INFORMATION.—In the case of a PDP
10 sponsor—

11 “(i) that fails to provide information
12 required under subparagraph (B) on a
13 timely basis, the sponsor is subject to a
14 civil money penalty in the amount of
15 \$10,000 for each day in which such infor-
16 mation has not been provided; or

17 “(ii) that knowingly (as defined in
18 section 1128A(i)) provides false informa-
19 tion under such subparagraph, the sponsor
20 is subject to a civil money penalty in an
21 amount not to exceed \$100,000 for each
22 item of false information.

23 Such civil money penalties are in addition to
24 other penalties as may be prescribed by law.
25 The provisions of section 1128A (other than

1 subsections (a) and (b)) shall apply to a civil
 2 money penalty under this subparagraph in the
 3 same manner as such provisions apply to a pen-
 4 alty or proceeding under section 1128A(a).”.

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

9 “(E) REPORTING REQUIREMENT RELATED
 10 TO REBATE FOR REBATE ELIGIBLE MEDICARE
 11 DRUG PLAN ENROLLEES.—Section 1860D–
 12 12(b)(8).”.

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

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

21 (d) EXCLUSION FROM DETERMINATION OF BEST
 22 PRICE AND AVERAGE MANUFACTURER PRICE UNDER
 23 MEDICAID.—

24 (1) EXCLUSION FROM BEST PRICE DETERMINA-
 25 TION.—Section 1927(c)(1)(C)(ii)(I) of the Social Se-

1 security Act (42 U.S.C. 1396r-8(c)(1)(C)(ii)(I)) is
2 amended by inserting “and amounts paid under a
3 rebate agreement under section 1860D-2(f)” after
4 “this section”.

5 (2) EXCLUSION FROM AVERAGE MANUFAC-
6 Turer PRICE DETERMINATION.—Section
7 1927(k)(1)(B)(i) of the Social Security Act (42
8 U.S.C. 1396r-8(k)(1)(B)(i)) is amended—

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

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

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

14 “(VI) amounts paid under a re-
15 bate agreement under section 1860D-
16 2(f).”.

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