

115TH CONGRESS  
1ST SESSION

# S. 2011

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.

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IN THE SENATE OF THE UNITED STATES

OCTOBER 25, 2017

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

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## 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 AND ESTABLISHMENT AND APPLI-**  
4 **CATION OF FORMULARY BY THE SECRETARY**  
5 **OF 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 during a negotiation  
17 year and with respect to the negotiation drug  
18 grouping identified under subparagraph (C)  
19 with respect to such negotiation year—

20 “(i) negotiate with pharmaceutical  
21 manufacturers the prices (including dis-  
22 counts, rebates, and all other price conces-  
23 sions) that may be charged for each plan  
24 year during the negotiated price period,  
25 with respect to such negotiation year, to  
26 PDP sponsors and MA organizations for

1 covered part D drugs identified as included  
2 within such negotiation drug grouping for  
3 part D eligible individuals who are enrolled  
4 under a prescription drug plan or under an  
5 MA–PD plan; and

6 “(ii) complete such negotiations 30  
7 days before the first day of the application  
8 review process for the first plan year dur-  
9 ing such negotiated price period for new  
10 contracts or expanding existing contracts  
11 with PDP sponsors and MA organizations  
12 to offer prescription drug plans or MA–PD  
13 plans, respectively.

14 “(B) USE OF FALLBACK IF NEGOTIATIONS  
15 FAIL.—If, after attempting to negotiate the  
16 price during a negotiation year for a covered  
17 part D drug that is identified as included with-  
18 in the negotiation drug grouping for such nego-  
19 tiation year, the Secretary is not successful in  
20 obtaining an appropriate price (as determined  
21 by the Secretary in accordance with guidance  
22 described in subparagraph (E)), the price that  
23 may be charged during each plan year during  
24 the negotiated price period, with respect to such  
25 negotiation year, to PDP sponsors and MA or-

1 organizations for such covered part D drugs for  
2 part D eligible individuals who are enrolled  
3 under a prescription drug plan or under an  
4 MA–PD plan shall be the lowest of—

5 “(i) the contract price applied pursu-  
6 ant to section 8126 of title 38, United  
7 States Code, for such drug for the contract  
8 year (as defined in such section 8126) be-  
9 ginning during the first plan year of such  
10 negotiated price period;

11 “(ii) the average of the prices avail-  
12 able, during the most recent 12-month pe-  
13 riod for which data is available prior to the  
14 beginning of such negotiated price period,  
15 from the manufacturer to any wholesaler,  
16 retailer, provider, health maintenance orga-  
17 nization, nonprofit entity, or governmental  
18 entity in the ten OECD (Organization for  
19 Economic Cooperation and Development)  
20 countries that have the largest gross do-  
21 mestic product with a per capita income  
22 that is not less than half the per capita in-  
23 come of the United States, as reported by  
24 the manufacturer to the Secretary; and

1           “(iii) the best price determined under  
2           section 1927(c)(1)(C) for such drug for the  
3           most recent rebate period (as defined in  
4           section 1927(k)(8)) applicable to such first  
5           plan year of such negotiated price period.

6           “(C) IDENTIFICATION OF NEGOTIATION  
7           DRUG GROUPINGS.—

8           “(i) IN GENERAL.—For each negotia-  
9           tion year, the Secretary shall, during the  
10          previous year, in accordance with the sub-  
11          sequent clauses of this subparagraph, and  
12          pursuant to rulemaking, identify covered  
13          part D drugs for which negotiations under  
14          subparagraph (A) shall be conducted dur-  
15          ing such negotiation year. In this sub-  
16          section, all such covered part D drugs so  
17          identified for a negotiation year are collec-  
18          tively referred to as the negotiation drug  
19          grouping, with respect to such year.

20          “(ii) IDENTIFICATION OF PRIORITIZED  
21          DRUGS.—In carrying out clause (i), except  
22          as provided under clause (iii), the Sec-  
23          retary may not identify for inclusion within  
24          the negotiation drug grouping with respect  
25          to a negotiation year, a covered part D

1 drug that is not a drug prioritized pursu-  
2 ant to subparagraph (D) before all covered  
3 part D drugs that are so prioritized have  
4 been identified for inclusion in such group-  
5 ing or in a negotiation drug grouping with  
6 respect to a previous negotiation year for  
7 which the negotiated price period has not  
8 expired.

9 “(iii) DRUG INCLUSIONS FOR PRICE  
10 RENEGOTIATIONS.—In the case of a cov-  
11 ered part D drug that is identified as in-  
12 cluded in a negotiation drug grouping  
13 under this subparagraph, with respect to a  
14 negotiation year, such covered part D drug  
15 shall be identified as included within the  
16 negotiation drug grouping for each subse-  
17 quent third negotiation year.

18 “(iv) REASONABLE NOTIFICATION.—  
19 The Secretary shall carry out this subpara-  
20 graph in such manner as to provide for  
21 public notification of the negotiation drug  
22 grouping identified with respect to a nego-  
23 tiation year within a reasonable period be-  
24 fore the beginning of such negotiation  
25 year.

1           “(D) PRIORITIZATION.—For purposes of  
2           subparagraph (C)(ii), for a negotiation drug  
3           grouping, with respect to a negotiation year, the  
4           Secretary shall prioritize covered part D  
5           drugs—

6                   “(i) with respect to which the cost of  
7                   such a drug to the part D eligible indi-  
8                   vidual involved would exceed the annual  
9                   out-of-pocket threshold applicable under  
10                  section 1860D–2(b)(4)(B) for such nego-  
11                  tiation year, if the drug were prescribed to  
12                  the individual for the period of the year or  
13                  with respect to which a single treatment  
14                  regimen is priced above such annual out-  
15                  of-pocket threshold applicable under such  
16                  section 1860D–2(b)(4)(B) for the year;

17                   “(ii) that are among—

18                           “(I) the 40 covered part D drugs  
19                           that are utilized by at least 1,000  
20                           Medicare part D beneficiaries and  
21                           with respect to which there were the  
22                           highest total expenditures under this  
23                           part during the most recent 12-month  
24                           period prior to the beginning of such

1 negotiation year for which data is  
2 available;

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

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

20 “(iii) that are single-source drugs or  
21 biologicals (as defined in section  
22 1847A(c)(6)(D)) and that satisfy at least  
23 one other criterion described in a previous  
24 clause of this subparagraph.



1           “(E) GUIDANCE.—Not later than 6  
2 months before the Secretary begins negotiations  
3 under subparagraph (A) for the first negotia-  
4 tion year, the Secretary shall issue guidance on  
5 criteria to be considered for purposes of deter-  
6 mining under subparagraph (B) whether or not  
7 the Secretary is successful in obtaining an ap-  
8 propriate price for a covered part D drug. Such  
9 criteria shall include at least the following:

10           “(i) The comparative clinical effective-  
11 ness and cost effectiveness, if available, of  
12 such covered part D drug.

13           “(ii) The budgetary impact of pro-  
14 viding coverage under this part for such  
15 covered part D drug.

16           “(iii) The number of similarly effec-  
17 tive drug or alternative treatment regimens  
18 for each approved use of such covered part  
19 D drug.

20           “(iv) Associated unmet need or sever-  
21 ity of illness.

22           “(F) PUBLIC EXPLANATION ON NEGOTIA-  
23 TIONS OUTCOMES.—Not later than 30 days  
24 after the date on which the Secretary completes  
25 negotiations under this section during a nego-

1           tiation year with a pharmaceutical manufac-  
2           turer, with respect to the price for a covered  
3           part D drug for a negotiated price period, with  
4           respect to such year, the Secretary shall make  
5           publicly available an explanation of the outcome  
6           of such negotiations, based on the criteria in-  
7           cluded in the guidance issued pursuant to sub-  
8           paragraph (E).

9           “(G) MEDPAC REPORT.—

10           “(i) STUDY.—The Medicare Payment  
11           Advisory Commission shall conduct a study  
12           on the price negotiations conducted by the  
13           Secretary under this paragraph, including  
14           an analysis of—

15           “(I) the extent to which such  
16           price negotiations are achieving lower  
17           prices for covered part D drugs for  
18           part D eligible individuals who are en-  
19           rolled under a prescription drug plan  
20           or under an MA–PD plan;

21           “(II) the parties benefitting from  
22           such lower prices, such as part D eli-  
23           gible individuals described in sub-  
24           clause (I), the Federal government,

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

3 “(III) how such price negotia-  
4 tions are affecting drug prices in the  
5 private market; and

6 “(IV) how such price negotiations  
7 are affecting the list price of covered  
8 part D drugs.

9 “(ii) REPORT.—Not later than Janu-  
10 ary 1, 2022, the Medicare Payment Advi-  
11 sory Commission shall submit to Congress  
12 a report on the study conducted under  
13 clause (i), including recommendations for  
14 improving price negotiations described in  
15 clause (i).

16 “(H) DEFINITIONS.—For purposes of this  
17 paragraph:

18 “(i) NEGOTIATION YEAR.—The term  
19 ‘negotiation year’ means a year beginning  
20 with 2019.

21 “(ii) NEGOTIATED PRICE PERIOD.—  
22 The term ‘negotiated price period’ means,  
23 with respect to a negotiation year and ne-  
24 gotiation drug grouping, the 3-plan year  
25 period beginning with the first plan year

1 beginning after the negotiation year for  
2 such grouping.

3 “(2) ESTABLISHMENT AND APPLICATION OF  
4 FORMULARY BY THE SECRETARY OR CHANGES IN  
5 FORMULARIES TO BE REQUIRED BY SECRETARY.—

6 “(A) IN GENERAL.—The Secretary shall,  
7 for plan years beginning with plan year 2019—

8 “(i) subject to subparagraphs (B) and  
9 (C), establish and apply a formulary for  
10 required use by sponsors of prescription  
11 drug plans and organizations offering MA-  
12 PD plans under this part; or

13 “(ii) require changes, as necessary, in  
14 the covered part D drugs included on  
15 formularies of PDP sponsors of prescrip-  
16 tion drug plans (including changes, as nec-  
17 essary, in the preferred or tiered cost-shar-  
18 ing status of such a drug) to take into ac-  
19 count negotiations carried out by the Sec-  
20 retary pursuant to paragraph (1), regard-  
21 less of whether such a covered part D drug  
22 is the subject of such negotiations.

23 “(B) REQUIRED INCLUSION OF DRUGS IN  
24 ALL THERAPEUTIC CATEGORIES.—A formulary  
25 established and applied under subparagraph

1 (A)(i) shall include at least two covered part D  
2 drugs in each category and class of covered part  
3 D drugs as described in section  
4 423.120(b)(2)(i) of title 42, Code of Federal  
5 Regulations (as in effect on January 1, 2017).

6 “(C) APPLICATION OF DEVELOPMENT AND  
7 REVISION REQUIREMENTS AND REQUIRED IN-  
8 CLUSION OF ALL DRUGS IN CERTAIN CAT-  
9 EGORIES AND CLASSES.—The requirements de-  
10 scribed in subparagraphs (A) and (B) of section  
11 1860D–4(b)(3) (relating to development and re-  
12 vision requirements of the formulary) and sub-  
13 paragraph (G) of such section (relating to re-  
14 quired inclusion of all drugs in certain cat-  
15 egories and classes) shall apply to a formulary  
16 established and applied under subparagraph  
17 (A)(i) of this paragraph.

18 “(3) PLAN FLEXIBILITY TO NEGOTIATE GREAT-  
19 ER DISCOUNTS.—Nothing in this subsection shall be  
20 construed as preventing the sponsor of a prescrip-  
21 tion drug plan, or an organization offering an MA-  
22 PD plan, from obtaining a discount or reduction of  
23 the price for a covered part D drug below the price  
24 negotiated under paragraph (1), if applicable, in-

1 cluding through the use of preferred or tiered cost-  
2 sharing status.

3 “(4) ENSURING BENEFICIARY ACCESS TO  
4 NEEDED DRUGS.—Beginning with plan year 2019,  
5 Each PDP sponsor of a prescription drug plan and  
6 organization offering an MA–PD plan shall have in  
7 place a process under which an enrollee in the plan  
8 may request coverage under the plan for a covered  
9 part D drug that is not on the formulary, or is sub-  
10 ject to utilization management controls, such as  
11 tiered pricing, prior authorization, or step therapy.”.

12 (b) CONFORMING AMENDMENTS.—Section 1860D–4  
13 of the Social Security Act (42 U.S.C. 1395w–104) is  
14 amended—

15 (1) in subsection (b)(3), in the matter pre-  
16 ceding subparagraph (A), by striking “If a PDP”  
17 and inserting “Subject to section 1860D–11(i)(2), if  
18 a PDP”;

19 (2) in subsection (g)—

20 (A) in paragraph (1), by inserting before  
21 the period at the end the following: “, except  
22 that the PDP sponsor of a prescription drug  
23 plan shall treat the presentation of a prescrip-  
24 tion to a participating pharmacy, which is  
25 transmitted to the plan by the pharmacy, as a

1 request for a coverage determination (including  
2 with respect to prior authorization, step ther-  
3 apy, or quantity limits) and, in applying such  
4 paragraphs of section 1852(g), the response to  
5 such transmittal shall be treated as a deter-  
6 mination by the sponsor”; and

7 (B) in paragraph (2), in the first sentence,  
8 by inserting “(or a participating pharmacy, on  
9 behalf of such individual, through transmission  
10 of a prescription as described in paragraph  
11 (1))” after “a part D eligible individual who is  
12 enrolled in the plan”; and

13 (3) in subsection (h)—

14 (A) in paragraph (1), in the second sen-  
15 tence, by inserting “(or a participating phar-  
16 macy, on behalf of such individual)” after “the  
17 part D eligible individual”; and

18 (B) in paragraph (2), by inserting “(or a  
19 participating pharmacy, on behalf of such indi-  
20 vidual)” after “A part D eligible individual who  
21 is enrolled in a prescription drug plan offered  
22 by a PDP sponsor”.

23 (4) EFFECTIVE DATE.—The amendments made  
24 by paragraphs (2) and (3) shall apply to plans years  
25 beginning on or after January 1, 2019.

1 **SEC. 3. 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, 2019, 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) 2019 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, 2019, and  
26 ending on December 31, 2019, 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, 2018, in the amount  
8           specified in paragraph (3) for any covered part D  
9           drug of the manufacturer dispensed after December  
10          31, 2018, 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 MANUFACTUR-  
15           ERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDI-  
16           CARE 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, 2019,  
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).”.

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