

116TH CONGRESS  
1ST SESSION

# S. 99

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

JANUARY 10, 2019

Mr. SANDERS (for himself, Mr. BOOKER, Mrs. GILLIBRAND, Ms. HARRIS, Mr. LEAHY, Mr. REED, Ms. SMITH, 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; 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, with respect to an ap-  
 17 plicable period (as defined in subparagraph  
 18 (H))—

19 “(i) during the negotiation year (as  
 20 defined in such subparagraph) for such pe-  
 21 riod, negotiate with pharmaceutical manu-  
 22 facturers the prices (including discounts,  
 23 rebates, and all other price concessions)  
 24 that may be charged to PDP sponsors and  
 25 MA organizations for applicable covered  
 26 part D drugs (as defined in such subpara-

graph) furnished to enrollees during such period; and

“(ii) complete such negotiations not less than 30 days before the first day of the application review process for the first plan year during the applicable period for new contracts or expanding existing contracts with PDP sponsors and MA organizations to offer prescription drug plans or MA–PD plans, respectively.

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

“(i) IN GENERAL.—If, after negotiations under subparagraph (A) with respect to an applicable period, the Secretary is not successful in obtaining an appropriate price for applicable covered part D drugs in accordance with clause (ii), the price that may be charged to PDP sponsors and MA organizations for applicable covered part D drugs furnished to enrollees during such period shall be the lowest of the following:

“(I) The contract price applied pursuant to section 8126 of title 38,

1 United States Code, for such drug for  
2 the contract year (as defined in such  
3 section 8126).

4 “(II) The average of the prices  
5 available, during the most recent 12-  
6 month period for which data is avail-  
7 able from the manufacturer to any  
8 wholesaler, retailer, provider, health  
9 maintenance organization, nonprofit  
10 entity, or governmental entity in Can-  
11 ada, the United Kingdom, Germany,  
12 France, and Japan.

13 “(III) The best price determined  
14 under section 1927(c)(1)(C) for such  
15 drug for the most recent rebate period  
16 (as defined in section 1927(k)(8)) ap-  
17 plicable to such first plan year of the  
18 applicable period.

19 “(ii) GUIDANCE.—Not later than 6  
20 months before the Secretary begins nego-  
21 tiations under subparagraph (A) with re-  
22 spect to the first applicable period, the  
23 Secretary shall issue guidance on criteria  
24 to be considered for purposes of deter-  
25 mining under clause (i) whether or not the

1 Secretary is successful in obtaining an ap-  
2 propriate price for an applicable covered  
3 part D drug. Such criteria shall include at  
4 least the following:

5 “(I) The comparative clinical ef-  
6 fectiveness and cost effectiveness, if  
7 available, of such covered part D  
8 drug.

9 “(II) The budgetary impact of  
10 providing coverage under this part for  
11 such covered part D drug.

12 “(III) The number of similarly  
13 effective drug or alternative treatment  
14 regimens for each approved use of  
15 such covered part D drug.

16 “(IV) Associated unmet need or  
17 severity of illness.

18 “(C) IDENTIFICATION OF APPLICABLE  
19 COVERED PART D DRUGS.—

20 “(i) IN GENERAL.—The Secretary  
21 shall, for each applicable period, in accord-  
22 ance with the subsequent clauses of this  
23 subparagraph, and pursuant to rule-  
24 making, identify applicable covered part D  
25 drugs for which negotiations under sub-

1 paragraph (A) shall be conducted during  
2 the negotiation year for such period. In  
3 this paragraph, all such covered part D  
4 drugs so identified for an applicable period  
5 are collectively referred to as applicable  
6 covered part D drugs with respect to such  
7 period.

8 “(ii) IDENTIFICATION OF PRIORITIZED  
9 DRUGS.—In carrying out clause (i), except  
10 as provided under clause (iii), the Sec-  
11 retary may not identify a covered part D  
12 drug that is not a drug prioritized pursu-  
13 ant to subparagraph (D) as an applicable  
14 covered part D drug until all covered part  
15 D drugs that are so prioritized have been  
16 identified as an applicable covered part D  
17 drug for the applicable period or for a pre-  
18 vious applicable period for which the nego-  
19 tiated price of such drug has not expired.

20 “(iii) DRUG INCLUSIONS FOR PRICE  
21 RENEGOTIATIONS.—In the case of a cov-  
22 ered part D drug that is identified as an  
23 applicable covered part D drug for an ap-  
24 plicable period, such covered part D drug  
25 shall be identified as an applicable covered

part D drug for each subsequent third negotiation year.

“(iv) REASONABLE NOTIFICATION.—

The Secretary shall carry out this subparagraph in such manner as to provide for public notification of applicable covered part D drugs for the applicable period within a reasonable period before the beginning of the negotiation year for such period.

“(D) PRIORITIZATION OF CERTAIN COVERED PART D DRUGS.—For purposes of subparagraph (C)(ii), the Secretary shall prioritize covered part D drugs—

“(i) that are among—

“(I) the 40 covered part D drugs that are utilized by at least 1,000 Medicare part D beneficiaries and with respect to which there were the highest total expenditures under this part during the most recent 12-month period for which data is available;

“(II) the 40 covered part D drugs that are utilized by at least 1,000 Medicare part D beneficiaries

1 with respect to whom the total annual  
2 spending per such a beneficiary under  
3 this part for coverage of such a drug  
4 is at least \$10,000; or

5 “(III) the 20 covered part D  
6 drugs that are utilized by at least  
7 1,000 Medicare part D beneficiaries  
8 and with respect to which there are  
9 unit cost increases at or above the  
10 95th percentile of overall covered part  
11 D drug unit cost increases during the  
12 most recent 12-month period prior to  
13 the beginning of such negotiation year  
14 for which data is available;

15 “(ii) with respect to which the cost of  
16 such a drug to the part D eligible indi-  
17 vidual involved would exceed the annual  
18 out-of-pocket threshold applicable under  
19 section 1860D–2(b)(4)(B) for such nego-  
20 tiation year, if the drug were prescribed to  
21 the individual for the period of the year or  
22 with respect to which a single treatment  
23 regimen is priced above such annual out-  
24 of-pocket threshold applicable under such  
25 section 1860D–2(b)(4)(B) for the year; or



1 “(iii) that are single-source drugs or  
2 biologicals (as defined in section  
3 1847A(c)(6)(D)) and that satisfy at least  
4 one other criterion described in a previous  
5 clause of this subparagraph.

6 “(E) ANNUAL REPORT TO CONGRESS.—  
7 Not later than 30 days after the date on which  
8 the Secretary completes negotiations under this  
9 paragraph for the first negotiation year and  
10 each year thereafter, the Secretary shall submit  
11 to Congress and make available to the public a  
12 report describing the negotiations during the  
13 preceding negotiation year, including—

14 “(i) the number of applicable covered  
15 part D drug prices negotiated;

16 “(ii) the magnitude of savings  
17 achieved as a result of such negotiations;

18 “(iii) the number of times price nego-  
19 tiations failed (based on the criteria in-  
20 cluded in the guidance issued pursuant to  
21 clause (ii) of subparagraph (B)) and re-  
22 sulted in the use of fallback prices under  
23 clause (i) of such subparagraph, and the  
24 rationale for any such decisions;

1 “(iv) the progress made toward nego-  
2 tiating the prices of covered part D drugs  
3 that are prioritized under subparagraph  
4 (D); and

5 “(v) the barriers, if any, to achieving  
6 savings through negotiations.

7 “(F) GAO REPORT.—Not later than De-  
8 cember 31, 2024, the Comptroller General of  
9 the United States shall submit to Congress a  
10 report on the negotiations conducted by the  
11 Secretary under this paragraph, including a de-  
12 scription and analysis of—

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

16 “(ii) the parties benefitting from such  
17 lower prices, such as enrollees, the Federal  
18 Government, States, prescription drug  
19 plans and MA–PD plans, or other entities;

20 “(iii) how such price negotiations are  
21 affecting—

22 “(I) the list price of covered part  
23 D drugs; and

24 “(II) drug prices in the private  
25 market; and

1 “(iv) recommendations for improving  
2 price negotiations, if applicable.

3 “(G) DEFINITIONS.—For purposes of this  
4 paragraph:

5 “(i) APPLICABLE COVERED PART D  
6 DRUGS.—The term ‘applicable covered part  
7 D drugs’ means, for an applicable period,  
8 covered part D drugs identified by the Sec-  
9 retary under subparagraph (C) for such  
10 period.

11 “(ii) APPLICABLE PERIOD.—The term  
12 ‘applicable period’ means, with respect to a  
13 negotiation year and applicable covered  
14 part D drugs, the 3-plan year period be-  
15 ginning with the first plan year beginning  
16 after the negotiation year for such covered  
17 part D drugs.

18 “(iii) NEGOTIATION YEAR.—The term  
19 ‘negotiation year’ means, with respect to  
20 an applicable period, a plan year, begin-  
21 ning with 2020, prior to the first plan year  
22 of the applicable period.

23 “(2) ESTABLISHMENT AND APPLICATION OF  
24 FORMULARY BY THE SECRETARY OR CHANGES IN  
25 FORMULARIES TO BE REQUIRED BY SECRETARY.—

1           “(A) IN GENERAL.—The Secretary shall,  
2           for plan years beginning with plan year 2020—

3                   “(i) subject to subparagraphs (B) and  
4                   (C), establish and apply a formulary for  
5                   required use by sponsors of prescription  
6                   drug plans and organizations offering MA-  
7                   PD plans under this part; or

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

18           “(B) REQUIRED INCLUSION OF DRUGS IN  
19           ALL THERAPEUTIC CATEGORIES.—A formulary  
20           established and applied under subparagraph  
21           (A)(i) shall include at least two covered part D  
22           drugs in each category and class of covered part  
23           D drugs as described in section  
24           423.120(b)(2)(i) of title 42, Code of Federal  
25           Regulations (as in effect on January 1, 2017).

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

13                  “(3) PLAN FLEXIBILITY TO NEGOTIATE GREAT-  
 14                  ER DISCOUNTS.—Nothing in this subsection shall be  
 15                  construed as preventing the sponsor of a prescrip-  
 16                  tion drug plan, or an organization offering an MA–  
 17                  PD plan, from obtaining a discount or reduction of  
 18                  the price for a covered part D drug below the price  
 19                  negotiated under paragraph (1), if applicable, in-  
 20                  cluding through the use of preferred or tiered cost-  
 21                  sharing status.

22                  “(4) ENSURING BENEFICIARY ACCESS TO  
 23                  NEEDED DRUGS.—Beginning with plan year 2020,  
 24                  each PDP sponsor of a prescription drug plan and  
 25                  organization offering an MA–PD plan shall have in

1 place a process under which an enrollee in the plan  
 2 may request coverage under the plan for a covered  
 3 part D drug that is not on the formulary, or is sub-  
 4 ject to utilization management controls, such as  
 5 tiered pricing, prior authorization, or step therapy.”.

6 (b) CONFORMING AMENDMENTS.—

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

10 (A) in subsection (b)(3), in the matter pre-  
 11 ceding subparagraph (A), by striking “If a  
 12 PDP” and inserting “Subject to section  
 13 1860D–11(i)(2), if a PDP”;

14 (B) in subsection (g)—

15 (i) in paragraph (1), by inserting be-  
 16 fore the period at the end the following: “,  
 17 except that the PDP sponsor of a prescrip-  
 18 tion drug plan shall treat the presentation  
 19 of a prescription to a participating phar-  
 20 macy, which is transmitted to the plan by  
 21 the pharmacy, as a request for a coverage  
 22 determination (including with respect to  
 23 prior authorization, step therapy, or quan-  
 24 tity limits) and, in applying such para-  
 25 graphs of section 1852(g), the response to

such transmittal shall be treated as a de-  
termination by the sponsor”; and

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

(C) in subsection (h)—

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

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

(2) EFFECTIVE DATE.—The amendments made  
by subparagraphs (B) and (C) of paragraph (1)  
shall apply to plans years beginning on or after Jan-  
uary 1, 2020.

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, 2020, 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) 2020 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, 2020, and  
 26 ending on December 31, 2020, 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, 2019, in the amount  
8           specified in paragraph (3) for any covered part D  
9           drug of the manufacturer dispensed after December  
10          31, 2019, 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)(8), 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

the Secretary elects to estimate the average Medicare drug program rebate eligible rebate amounts, the Secretary shall establish a reconciliation process for adjusting manufacturer rebate payments not later than 3 months after the date that manufacturers receive the information collected under section 1860D–12(b)(8)(B).

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

“(5) OTHER TERMS AND CONDITIONS.—The Secretary shall establish other terms and conditions of the rebate agreement under this subsection, including terms and conditions related to compliance, that are consistent with this subsection.

“(6) DEFINITIONS.—In this subsection and section 1860D–12(b)(8):

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

“(i) a subsidy eligible individual (as 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 “(8) 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.—

“(A) IN GENERAL.—For purposes of the rebate under section 1860D–2(f) for contract years beginning on or after January 1, 2020, each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan shall require that the sponsor comply with subparagraphs (B) and (C).

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

“(i) information (by National Drug Code number) on the total number of units of each dosage, form, and strength of each drug of such manufacturer dispensed to rebate eligible Medicare drug plan enrollees under any prescription drug plan operated by the PDP sponsor during the rebate period;

“(ii) information on the price discounts, price concessions, and rebates for such drugs for such form, strength, and period;

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



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

“(iv) any additional information that the Secretary determines is necessary to enable the Secretary to calculate the average Medicare drug program rebate eligible rebate amount (as defined in paragraph (3)(C) of such section), and to determine the amount of the rebate required under this section, for such form, strength, and period.

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

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

“(D) CONFIDENTIALITY OF INFORMATION.—The provisions of subparagraph (D) of section 1927(b)(3), relating to confidentiality of 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—

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

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

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

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

“(E) REPORTING REQUIREMENT RELATED TO REBATE FOR REBATE ELIGIBLE MEDICARE

1           DRUG PLAN ENROLLEES.—Section 1860D–  
2           12(b)(8).”.

3           (c) DEPOSIT OF REBATES INTO MEDICARE PRE-  
4           SCRIPTION 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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