116TH CONGRESS
1ST SESSION

S. _____

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

Mr. SANDERS introduced the following bill; which was read twice and referred to the Committee on _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare Drug Price Negotiation Act''.

SEC. 2. NEGOTIATION OF LOWER COVERED PART D DRUG PRICES ON BEHALF OF MEDICARE BENEFICIARIES; ESTABLISHMENT AND APPLICATION OF FORMULARY BY THE SECRETARY OF HEALTH AND HUMAN SERVICES UNDER MEDICARE PART D.

(a) IN GENERAL.—Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended by striking subsection (i) (relating to noninterference) and inserting the following:

''(i) NEGOTIATION OF LOWER DRUG PRICES; ESTABLISHMENT AND APPLICATION OF FORMULARY.—

''(1) NEGOTIATION.—

''(A) IN GENERAL.—Notwithstanding any other provision of law, subject to subparagraph (B), the Secretary shall, with respect to an applicable period (as defined in subparagraph (H))—

''(i) during the negotiation year (as defined in such subparagraph) for such period, negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and all other price concessions) that may be charged to PDP sponsors and MA organizations for applicable covered 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,

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

''(II) The average of the prices available, during the most recent 12-month period for which data is available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in Canada, the United Kingdom, Germany, France, and Japan.

''(III) The best price determined under section 1927(c)(1)(C) for such drug for the most recent rebate period (as defined in section 1927(k)(8)) applicable to such first plan year of the applicable period.

''(ii) GUIDANCE.—Not later than 6 months before the Secretary begins negotiations under subparagraph (A) with respect to the first applicable period, the Secretary shall issue guidance on criteria to be considered for purposes of determining under clause (i) whether or not the

Secretary is successful in obtaining an appropriate price for an applicable covered part D drug. Such criteria shall include at least the following:

"(I) The comparative clinical effectiveness and cost effectiveness, if available, of such covered part D drug.

"(II) The budgetary impact of providing coverage under this part for such covered part D drug.

"(III) The number of similarly effective drug or alternative treatment regimens for each approved use of such covered part D drug.

"(IV) Associated unmet need or severity of illness.

"(C) IDENTIFICATION OF APPLICABLE COVERED PART D DRUGS.—

"(i) IN GENERAL.—The Secretary shall, for each applicable period, in accordance with the subsequent clauses of this subparagraph, and pursuant to rulemaking, identify applicable covered part D drugs for which negotiations under sub-

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

''(ii) IDENTIFICATION OF PRIORITIZED DRUGS.—In carrying out clause (i), except as provided under clause (iii), the Secretary may not identify a covered part D drug that is not a drug prioritized pursuant to subparagraph (D) as an applicable covered part D drug until all covered part D drugs that are so prioritized have been identified as an applicable covered part D drug for the applicable period or for a previous applicable period for which the negotiated price of such drug has not expired.

''(iii) DRUG INCLUSIONS FOR PRICE RENEGOTIATIONS.—In the case of a covered part D drug that is identified as an applicable covered part D drug for an applicable period, such covered part D drug 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

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

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

''(ii) with respect to which the cost of such a drug to the part D eligible individual involved would exceed the annual out-of-pocket threshold applicable under section 1860D–2(b)(4)(B) for such negotiation year, if the drug were prescribed to the individual for the period of the year or with respect to which a single treatment regimen is priced above such annual out-of-pocket threshold applicable under such section 1860D–2(b)(4)(B) for the year; or

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

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

"(i) the number of applicable covered part D drug prices negotiated;

"(ii) the magnitude of savings achieved as a result of such negotiations;

"(iii) the number of times price negotiations failed (based on the criteria included in the guidance issued pursuant to clause (ii) of subparagraph (B)) and resulted in the use of fallback prices under clause (i) of such subparagraph, and the rationale for any such decisions;

"(iv) the progress made toward negotiating the prices of covered part D drugs that are prioritized under subparagraph (D); and

"(v) the barriers, if any, to achieving savings through negotiations.

"(F) GAO REPORT.—Not later than December 31, 2024, the Comptroller General of the United States shall submit to Congress a report on the negotiations conducted by the Secretary under this paragraph, including a description and analysis of—

"(i) the extent to which such price negotiations are achieving lower prices for covered part D drugs for enrollees;

"(ii) the parties benefitting from such lower prices, such as enrollees, the Federal government, States, prescription drug plans and MA–PD plans, or other entities;

"(iii) how such price negotiations are affecting—

"(I) the list price of covered part D drugs; and

"(II) drug prices in the private market; and

"(iv) recommendations for improving price negotiations, if applicable.

"(G) DEFINITIONS.—For purposes of this paragraph:

"(i) APPLICABLE COVERED PART D DRUGS.—The term 'applicable covered part D drugs' means, for an applicable period, covered part D drugs identified by the Secretary under subparagraph (C) for such period.

"(ii) APPLICABLE PERIOD.—The term 'applicable period' means, with respect to a negotiation year and applicable covered part D drugs, the 3-plan year period beginning with the first plan year beginning after the negotiation year for such covered part D drugs.

"(iii) NEGOTIATION YEAR.—The term 'negotiation year' means, with respect to an applicable period, a plan year, beginning with 2020, prior to the first plan year of the applicable period.

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

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

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

"(ii) require changes, as necessary, in the covered part D drugs included on formularies of PDP sponsors of prescription drug plans (including changes, as necessary, in the preferred or tiered cost-sharing status of such a drug) to take into account negotiations carried out by the Secretary pursuant to paragraph (1), regardless of whether such a covered part D drug is the subject of such negotiations.

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

''(C) APPLICATION OF DEVELOPMENT AND REVISION REQUIREMENTS AND REQUIRED INCLUSION OF ALL DRUGS IN CERTAIN CATEGORIES AND CLASSES.—The requirements described in subparagraphs (A) and (B) of section 1860D–4(b)(3) (relating to development and revision requirements of the formulary) and subparagraph (G) of such section (relating to required inclusion of all drugs in certain categories and classes) shall apply to a formulary established and applied under subparagraph (A)(i) of this paragraph.

''(3) PLAN FLEXIBILITY TO NEGOTIATE GREATER DISCOUNTS.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan, or an organization offering an MA–PD plan, from obtaining a discount or reduction of the price for a covered part D drug below the price negotiated under paragraph (1), if applicable, including through the use of preferred or tiered cost-sharing status.

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

place a process under which an enrollee in the plan may request coverage under the plan for a covered part D drug that is not on the formulary, or is subject to utilization management controls, such as tiered pricing, prior authorization, or step therapy.''.

(b) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is amended—

(A) in subsection (b)(3), in the matter preceding subparagraph (A), by striking ''If a PDP'' and inserting ''Subject to section 1860D–11(i)(2), if a PDP'';

(B) in subsection (g)—

(i) in paragraph (1), by inserting before the period at the end the following: '', except that the PDP sponsor of a prescription drug plan shall treat the presentation of a prescription to a participating pharmacy, which is transmitted to the plan by the pharmacy, as a request for a coverage determination (including with respect to prior authorization, step therapy, or quantity limits) and, in applying such paragraphs of section 1852(g), the response to

such transmittal shall be treated as a determination by the sponsor''; and

(ii) in paragraph (2), in the first sentence, 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 January 1, 2020.

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

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

(1) in subsection (e)(1), in the matter preceding subparagraph (A), by inserting ''and subsection (f)'' after ''this subsection''; and

(2) by adding at the end the following new subsection:

''(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR REBATE ELIGIBLE INDIVIDUALS.—

''(1) REQUIREMENT.—

''(A) IN GENERAL.—For plan years beginning on or after January 1, 2020, in this part, the term 'covered part D drug' does not include any drug or biological product that is manufactured by a manufacturer that has not entered into and have in effect a rebate agreement described in paragraph (2).

''(B) 2020 PLAN YEAR REQUIREMENT.—Any drug or biological product manufactured by a manufacturer that declines to enter into a rebate agreement described in paragraph (2) for the period beginning on January 1, 2020, and ending on December 31, 2020, shall not be in-

cluded as a 'covered part D drug' for the subsequent plan year.

''(2) REBATE AGREEMENT.—A rebate agreement under this subsection shall require the manufacturer to provide to the Secretary a rebate for each rebate period (as defined in paragraph (6)(B)) ending after December 31, 2019, in the amount specified in paragraph (3) for any covered part D drug of the manufacturer dispensed after December 31, 2019, to any rebate eligible individual (as defined in paragraph (6)(A)) for which payment was made by a PDP sponsor or MA organization under this part for such period, including payments passed through the low-income and reinsurance subsidies under sections 1860D–14 and 1860D–15(b), respectively. Such rebate shall be paid by the manufacturer to the Secretary not later than 30 days after the date of receipt of the information described in section 1860D–12(b)(8), including as such section is applied under section 1857(f)(3), or 30 days after the receipt of information under subparagraph (D) of paragraph (3), as determined by the Secretary. Insofar as not inconsistent with this subsection, the Secretary shall establish terms and conditions of such agreement relating to compliance, penalties,

and program evaluations, investigations, and audits that are similar to the terms and conditions for rebate agreements under paragraphs (3) and (4) of section 1927(b).

''(3) REBATE FOR REBATE ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

''(A) IN GENERAL.—The amount of the rebate specified under this paragraph for a manufacturer for a rebate period, with respect to each dosage form and strength of any covered part D drug provided by such manufacturer and dispensed to a rebate eligible individual, shall be equal to the product of—

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

''(ii) the amount (if any) by which—

''(I) the Medicaid rebate amount (as defined in subparagraph (B)) for

such form, strength, and period, exceeds

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

"(B) MEDICAID REBATE AMOUNT.—For purposes of this paragraph, the term 'Medicaid rebate amount' means, with respect to each dosage form and strength of a covered part D drug provided by the manufacturer for a rebate period—

"(i) in the case of a single source drug or an innovator multiple source drug, the amount specified in paragraph (1)(A)(ii)(II) or (2)(C) of section 1927(c) plus the amount, if any, specified in subparagraph (A)(ii) of paragraph (2) of such section, for such form, strength, and period; or

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

"(C) AVERAGE MEDICARE DRUG PROGRAM REBATE ELIGIBLE REBATE AMOUNT.—For purposes of this subsection, the term 'average Medicare drug program rebate eligible rebate amount' means, with respect to each dosage form and strength of a covered part D drug provided by a manufacturer for a rebate period, the sum, for all PDP sponsors under part D and MA organizations administering an MA–PD plan under part C, of—

"(i) the product, for each such sponsor or organization, of—

"(I) the sum of all rebates, discounts, or other price concessions (not taking into account any rebate provided under paragraph (2) or any discounts under the program under section 1860D–14A) for such dosage form and strength of the drug dispensed, calculated on a per-unit basis, but only to the extent that any such rebate, discount, or other price concession applies equally to drugs dispensed to rebate eligible Medicare drug plan enrollees and drugs dis-

pensed to PDP and MA–PD enrollees who are not rebate eligible individuals; and

''(II) the number of the units of such dosage and strength of the drug dispensed during the rebate period to rebate eligible individuals enrolled in the prescription drug plans administered by the PDP sponsor or the MA–PD plans administered by the MA organization; divided by

''(ii) the total number of units of such dosage and strength of the drug dispensed during the rebate period to rebate eligible individuals enrolled in all prescription drug plans administered by PDP sponsors and all MA–PD plans administered by MA organizations.

''(D) USE OF ESTIMATES.—The Secretary may establish a methodology for estimating the average Medicare drug program rebate eligible rebate amounts for each rebate period based on bid and utilization information under this part and may use these estimates as the basis for 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));

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

"(iii) any part D eligible individual not described in clause (i) or (ii) who is determined for purposes of the State plan under title XIX to be eligible for medical assistance under clause (i), (iii), or (iv) of section 1902(a)(10)(E).

"(B) REBATE PERIOD.—The term 'rebate period' has the meaning given such term in section 1927(k)(8).".

(b) REPORTING REQUIREMENT FOR THE DETERMINATION AND PAYMENT OF REBATES BY MANUFACTURERS RELATED TO REBATE FOR REBATE ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

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

"(8) REPORTING REQUIREMENT FOR THE DETERMINATION AND PAYMENT OF REBATES BY MANUFACTURERS RELATED TO REBATE FOR REBATE ELIGIBLE 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

by PDP sponsors under this paragraph in the same manner that such provisions apply to information disclosed by manufacturers or wholesalers under such section, except—

"(i) that any reference to 'this section' in clause (i) of such subparagraph shall be treated as being a reference to this section;

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

"(iii) clause (iv) of such subparagraph shall not apply.

"(E) OVERSIGHT.—Information reported under this paragraph may be used by the Inspector General of the Department of Health and Human Services for the statutorily authorized purposes of audit, investigation, and evaluations.

"(F) PENALTIES FOR FAILURE TO PROVIDE TIMELY INFORMATION AND PROVISION OF FALSE INFORMATION.—In the case of a PDP 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

DRUG PLAN ENROLLEES.—Section 1860D–12(b)(8).''.

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

''(6) REBATE FOR REBATE ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—Amounts paid under a rebate agreement under section 1860D–2(f) shall be deposited into the Account.''.

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

(1) EXCLUSION FROM BEST PRICE DETERMINATION.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by inserting ''and amounts paid under a rebate agreement under section 1860D–2(f)'' after ''this section''.

(2) EXCLUSION FROM AVERAGE MANUFACTURER PRICE DETERMINATION.—Section 1927(k)(1)(B)(i) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)(B)(i)) is amended—

(A) in subclause (IV), by striking ''and'' after the semicolon;

(B) in subclause (V), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(VI) amounts paid under a rebate agreement under section 1860D–2(f).''.