To amend title XI of the Social Security Act to expand the drug price negotiation program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 26, 2023

Mr. PALLONE (for himself, Mr. NEAL, and Mr. SCOTT of Virginia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XI of the Social Security Act to expand the drug price negotiation program, 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 “Lowering Drug Costs
5 for American Families Act”.


SEC. 2. EXPANDING THE DRUG PRICE NEGOTIATION PROGRAM.

(a) Increasing the Number of Drugs Subject to Negotiation.—Section 1192(a)(4) of the Social Security Act (42 U.S.C. 1320f–1(a)(4)) is amended by striking “20” each place it appears and inserting “50” in each such place.

(b) Expansion of Definition of Maximum Fair Price Eligible Individual.—Section 1191(c)(2) of the Social Security Act (42 U.S.C. 1320f–1(c)(2)) is amended—

(1) in subparagraph (A), by inserting “, or a participant, beneficiary, or enrollee who is enrolled under a group health plan or health insurance coverage offered in the group or individual market (as such terms are defined in section 2791 of the Public Health Service Act) with respect to which there is in effect an agreement with the Secretary under section 1197 with respect to such selected drug as so furnished or dispensed” after “such selected drug”; and

(2) in subparagraph (B), by inserting “, or a participant, beneficiary, or enrollee who is enrolled under a group health plan or health insurance coverage offered in the group or individual market (as such terms are defined in section 2791 of the Public Health Service Act) with respect to which there is in
effect an agreement with the Secretary under section 1197 with respect to such selected drug as so furnished or administered” after “such selected drug”.

(c) APPLICATION OF ADMINISTRATIVE PROCEDURES TO NEW MAXIMUM FAIR PRICE ELIGIBLE INDIVIDUALS.—Section 1196(a)(3) of the Social Security Act (42 U.S.C. 1320f–5(a)(3)) is amended—

(1) in subparagraph (A), by striking “and” at the end;

(2) in subparagraph (B), by striking the period and inserting “; and”; and

(3) by adding at the end the following new subparagraph:

“(C) maximum fair price eligible individuals not described in subparagraph (A) or (B).”.

(d) HEALTH INSURER AGREEMENTS.—Part E of title XI of the Social Security Act (42 U.S.C. 1320f et seq.) is amended—

(1) by redesignating sections 1197 and 1198 as sections 1198 and 1199, respectively; and

(2) by inserting after section 1196 the following new section:
“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER HEALTH PLANS.

“(a) Agreement To Participate Under Program.—

“(1) IN GENERAL.—Subject to paragraph (2), under the program under this part the Secretary shall be treated as having in effect an agreement with a group health plan or health insurance issuer offering group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), with respect to a price applicability period and a selected drug with respect to such period—

“(A) in the case such selected drug furnished or dispensed at a pharmacy or by mail order service if coverage is provided under such plan or coverage during such period for such selected drug as so furnished or dispensed; and

“(B) in the case such selected drug furnished or administered by a hospital, physician, or other provider of services or supplier if coverage is provided under such plan or coverage during such period for such selected drug as so furnished or administered.

“(2) Opting Out of Agreement.—The Secretary shall not be treated as having in effect an
agreement under the program under this part with
a group health plan or health insurance issuer offering
group or individual health insurance coverage
with respect to a price applicability period and a se-
lected drug with respect to such period if such a
plan or issuer affirmatively elects, through a process
specified by the Secretary, not to participate under
the program with respect to such period and drug.

“(b) Publication of Election.—With respect to
each price applicability period and each selected drug with
respect to such period, the Secretary and the Secretary
of Labor and the Secretary of the Treasury, as applicable,
shall make public a list of each group health plan and each
health insurance issuer offering group or individual health
insurance coverage, with respect to which coverage is pro-
vided under such plan or coverage for such drug, that has
elected under subsection (a) not to participate under the
program with respect to such period and drug.”.

(e) Application to Group Health Plans and
Health Insurance Coverage.—

(1) PHSA.—Part D of title XXVII of the Pub-
lic Health Service Act (42 U.S.C. 300gg–111 et
seq.) is amended by adding at the end the following
new section:
“SEC. 2799A–11. DRUG PRICE NEGOTIATION PROGRAM AND
APPLICATION OF MAXIMUM FAIR PRICES.

“(a) In General.—In the case of a group health plan or health insurance issuer offering group or individual health insurance coverage that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary under the Drug Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period for which coverage is provided under such plan or coverage—

“(1) the provisions of such part shall apply—

“(A) in the case the drug is furnished or dispensed at a pharmacy or by a mail order service, to such plan or coverage, and to the participants, beneficiaries, and enrollees enrolled under such plan or coverage, during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to participants, beneficiaries, and enrollees enrolled under such prescription drug plans and MA–PD plans during such period; and
“(B) in the case the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to such plan or coverage, and to the participants, beneficiaries, and enrollees enrolled under such plan or coverage, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to participants, beneficiaries, and enrollees entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

“(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and
“(3) the Secretary shall apply the provisions of such part E to such plan, issuer, and coverage, such participants, beneficiaries, and enrollees so enrolled in such plans and coverage, and such hospitals, physicians, and other providers and suppliers participating in such plans and coverage.

“(b) NOTIFICATION REGARDING NONPARTICIPATION IN DRUG PRICE NEGOTIATION PROGRAM.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall publicly disclose, in a manner and in accordance with a process specified by the Secretary, any election made under section 1197 of the Social Security Act by such plan or issuer to not participate in the Drug Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan or coverage before the beginning of the plan year for which such election was made.”.

(2) ERISA.—

(A) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181 et seq.) is amended by adding at the end the following new section:
SEC. 726. DRUG PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering group health insurance coverage that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary of Health and Human Services under the Drug Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period for which coverage is provided under such plan or coverage—

(1) the provisions of such part shall apply, as applicable—

(A) in the case the drug is furnished or dispensed at a pharmacy or by a mail order service, to such plan or coverage, and to the participants and beneficiaries enrolled under such plan or coverage, during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to participants and beneficiaries enrolled under such prescription drug plans and MA–PD plans during such period; and
“(B) in the case the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the group health plan or coverage offered by an issuer, to the participants and beneficiaries enrolled under such plans or coverage, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary of Health and Human Services, to participants and beneficiaries entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;

“(2) the plan or issuer shall apply any cost-sharing responsibilities under such plan or coverage, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and
“(3) the Secretary shall apply the provisions of such part E to such plan, issuer, and coverage, and such participants and beneficiaries so enrolled in such plans.

“(b) Notification Regarding Nonparticipation in Drug Price Negotiation Program.—A group health plan or a health insurance issuer offering group health insurance coverage shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan or issuer to not participate in the Drug Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan or coverage before the beginning of the plan year for which such election was made.”.

(B) Application to Retiree and Certain Small Group Health Plans.—Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking “section 711” and inserting “sections 711 and 726”.

(C) Clerical Amendment.—The table of sections for subpart B of part 7 of subtitle B of title I of the Employee Retirement Income
Security Act of 1974 is amended by adding at the end the following:

“Sec. 726. Drug Price Negotiation Program and application of maximum fair prices.”

(3) IRC.—

(A) In general.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

“SEC. 9826. DRUG PRICE NEGOTIATION PROGRAM AND APPLICATION OF MAXIMUM FAIR PRICES.

“(a) In general.—In the case of a group health plan that is treated under section 1197 of the Social Security Act as having in effect an agreement with the Secretary of Health and Human Services under the Drug Price Negotiation Program under part E of title XI of such Act, with respect to a price applicability period (as defined in section 1191(b) of such Act) and a selected drug (as defined in section 1192(c) of such Act) with respect to such period for which coverage is provided under such plan—

“(1) the provisions of such part shall apply, as applicable—

“(A) if coverage of such selected drug is provided under such plan if the drug is furnished or dispensed at a pharmacy or by a mail
order service, to the plan, and to the participants and beneficiaries enrolled under such plan during such period, with respect to such selected drug, in the same manner as such provisions apply to prescription drug plans and MA–PD plans, and to participants and beneficiaries enrolled under such prescription drug plans and MA–PD plans during such period; and

“(B) if coverage of such selected drug is provided under such plan if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plan, to the participants and beneficiaries enrolled under such plan, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary of Health and Human Services, to participants and beneficiaries entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period;
“(2) the plan shall apply any cost-sharing responsibilities under such plan, with respect to such selected drug, by substituting an amount not more than the maximum fair price negotiated under such part E of title XI for such drug in lieu of the drug price upon which the cost-sharing would have otherwise applied, and such cost-sharing responsibilities with respect to such selected drug may not exceed such maximum fair price; and

“(3) the Secretary shall apply the provisions of such part E to such plan and such participants and beneficiaries so enrolled in such plan.

“(b) Notification Regarding Nonparticipation in Drug Price Negotiation Program.—A group health plan shall publicly disclose in a manner and in accordance with a process specified by the Secretary any election made under section 1197 of the Social Security Act by the plan to not participate in the Drug Price Negotiation Program under part E of title XI of such Act with respect to a selected drug (as defined in section 1192(c) of such Act) for which coverage is provided under such plan before the beginning of the plan year for which such election was made.”.

(B) Application to Retiree and Certain Small Group Health Plans.—Section
9831(a)(2) of the Internal Revenue Code of 1986 is amended by inserting “other than with respect to section 9826,” before “any group health plan”.

(C) Clerical Amendment.—The table of sections for subchapter B of chapter 100 of such Code is amended by adding at the end the following new item:

“Sec. 9826. Drug Price Negotiation Program and application of maximum fair prices.”.

SEC. 3. APPLICATION OF PRESCRIPTION DRUG INFLATION REBATES TO DRUGS FURNISHED IN THE COMMERCIAL MARKET.

(a) Part B Drugs.—

(1) Application of prescription drug inflation rebates to drugs furnished in the commercial market.—Section 1847A(i) of the Social Security Act (42 U.S.C. 1395w–3a(i)) is amended—

(A) in paragraph (1)(A)(i), by striking “units” and inserting “billing units”;  

(B) in paragraph (2)(A), by striking “for which payment is made under this part” and inserting “that would be payable under this part if such drug were furnished to an individual enrolled under this part”; and
(C) in paragraph (3)—

(i) in subparagraph (A)(i), by striking “units” and inserting “billing units”; and

(ii) by striking subparagraph (B) and inserting the following:

“(B) TOTAL NUMBER OF BILLING UNITS.—For purposes of subparagraph (A)(i), the total number of billing units with respect to a part B rebatable drug is determined as follows:

“(i) Determine the total number of units equal to—

“(I) the total number of units, as reported under subsection (e)(1)(B) for each National Drug Code of such drug during the calendar quarter that is two calendar quarters prior to the calendar quarter as described in subparagraph (A), minus

“(II) the total number of units with respect to each National Drug Code of such drug for which payment was made under a State plan under title XIX (or waiver of such plan), as reported by States under section
HR 4895 IH

1927(b)(2)(A) for the rebate period that is the same calendar quarter as described in subclause (I).

“(ii) Convert the units determined under clause (i) to billing units for the billing and payment code of such drug, using a methodology similar to the methodology used under this section, by dividing the units determined under clause (i) for each National Drug Code of such drug by the billing unit for the billing and payment code of such drug.

“(iii) Compute the sum of the billing units for each National Drug Code of such drug in clause (ii).”.

(2) Effective Date.—The amendments made by this subsection shall apply with respect to calendar quarters beginning after the date of the enactment of this Act.

(b) Covered Part D Drugs.—

(1) Application of prescription drug inflation rebates to drugs furnished in the commercial market.—Section 1860D–14B of the Social Security Act (42 U.S.C. 1395w–114b) is amended—
(A) in subsection (b)—

(i) in paragraph (1)—

(I) in subparagraph (A)(i), by striking “the total number of units” and all that follows through the semi-colon and inserting the following: “the total number of units that are used to calculate the average manufacturer price of such dosage form and strength with respect to such part D rebatable drug, as reported by the manufacturer of such drug under section 1927 for each month, with respect to such period;”; and

(II) by striking subparagraph (B) and inserting the following:

“(B) EXCLUDED UNITS.—For purposes of subparagraph (A)(i), the Secretary shall exclude from the total number of units for a dosage form and strength with respect to a part D rebatable drug, with respect to an applicable period, the following:

“(i) Units of each dosage form and strength of such part D rebatable drug for which payment was made under a State
plan under title XIX (or waiver of such plan), as reported by States under section 1927(b)(2)(A).

“(ii) Units of each dosage form and strength of such part D rebatable drug for which a rebate is paid under section 1847A(i).

“(iii) Beginning with plan year 2026, units of each dosage form and strength of such part D rebatable drug for which the manufacturer provides a discount under the program under section 340B of the Public Health Service Act.”; and

(ii) in paragraph (6), by striking “INFORMATION.—The Secretary” and all that follows through “rebatable covered part D drug dispensed” and inserting the following: “AMP REPORTS.—The Secretary shall provide for a method and process under which, in the case of a manufacturer of a part D rebatable drug that submits revisions to information submitted under section 1927 by the manufacturer with respect to such drug”; and
(B) by striking subsection (d) and inserting the following:

“(d) INFORMATION.—For purposes of carrying out this section, the Secretary shall use information submitted by manufacturers under section 1927(b)(3) and information submitted by States under section 1927(b)(2)(A).”.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to applicable periods (as defined in section 1860D–14B(g)(7) of the Social Security Act (42 U.S.C. 1395w–114b(g)(7))) beginning after the date of the enactment of this Act.