

118TH CONGRESS
1ST SESSION

H. R. 4895

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”.

1 **SEC. 2. EXPANDING THE DRUG PRICE NEGOTIATION PRO-**
2 **GRAM.**

3 (a) INCREASING THE NUMBER OF DRUGS SUBJECT
4 TO NEGOTIATION.—Section 1192(a)(4) of the Social Se-
5 curity Act (42 U.S.C. 1320f–1(a)(4)) is amended by strik-
6 ing “20” each place it appears and inserting “50” in each
7 such place.

8 (b) EXPANSION OF DEFINITION OF MAXIMUM FAIR
9 PRICE ELIGIBLE INDIVIDUAL.—Section 1191(c)(2) of the
10 Social Security Act (42 U.S.C. 1320f–1(c)(2)) is amend-
11 ed—

12 (1) in subparagraph (A), by inserting “, or a
13 participant, beneficiary, or enrollee who is enrolled
14 under a group health plan or health insurance cov-
15 erage offered in the group or individual market (as
16 such terms are defined in section 2791 of the Public
17 Health Service Act) with respect to which there is in
18 effect an agreement with the Secretary under section
19 1197 with respect to such selected drug as so fur-
20 nished or dispensed” after “such selected drug”; and

21 (2) in subparagraph (B), by inserting “, or a
22 participant, beneficiary, or enrollee who is enrolled
23 under a group health plan or health insurance cov-
24 erage offered in the group or individual market (as
25 such terms are defined in section 2791 of the Public
26 Health Service Act) with respect to which there is in

1 effect an agreement with the Secretary under section
2 1197 with respect to such selected drug as so fur-
3 nished or administered” after “such selected drug”.

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

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

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

12 (3) by adding at the end the following new sub-
13 paragraph:

14 “(C) maximum fair price eligible individ-
15 uals not described in subparagraph (A) or
16 (B).”.

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

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

22 (2) by inserting after section 1196 the following
23 new section:

1 **“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER**
2 **HEALTH PLANS.**

3 “(a) AGREEMENT TO PARTICIPATE UNDER PRO-
4 GRAM.—

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

14 “(A) in the case such selected drug fur-
15 nished or dispensed at a pharmacy or by mail
16 order service if coverage is provided under such
17 plan or coverage during such period for such se-
18 lected drug as so furnished or dispensed; and

19 “(B) in the case such selected drug fur-
20 nished or administered by a hospital, physician,
21 or other provider of services or supplier if cov-
22 erage is provided under such plan or coverage
23 during such period for such selected drug as so
24 furnished or administered.

25 “(2) OPTING OUT OF AGREEMENT.—The Sec-
26 retary shall not be treated as having in effect an

1 agreement under the program under this part with
2 a group health plan or health insurance issuer offer-
3 ing group or individual health insurance coverage
4 with respect to a price applicability period and a se-
5 lected drug with respect to such period if such a
6 plan or issuer affirmatively elects, through a process
7 specified by the Secretary, not to participate under
8 the program with respect to such period and drug.

9 “(b) PUBLICATION OF ELECTION.—With respect to
10 each price applicability period and each selected drug with
11 respect to such period, the Secretary and the Secretary
12 of Labor and the Secretary of the Treasury, as applicable,
13 shall make public a list of each group health plan and each
14 health insurance issuer offering group or individual health
15 insurance coverage, with respect to which coverage is pro-
16 vided under such plan or coverage for such drug, that has
17 elected under subsection (a) not to participate under the
18 program with respect to such period and drug.”.

19 (e) APPLICATION TO GROUP HEALTH PLANS AND
20 HEALTH INSURANCE COVERAGE.—

21 (1) PHSA.—Part D of title XXVII of the Pub-
22 lic Health Service Act (42 U.S.C. 300gg–111 et
23 seq.) is amended by adding at the end the following
24 new section:

1 **“SEC. 2799A-11. DRUG PRICE NEGOTIATION PROGRAM AND**
2 **APPLICATION OF MAXIMUM FAIR PRICES.**

3 “(a) IN GENERAL.—In the case of a group health
4 plan or health insurance issuer offering group or indi-
5 vidual health insurance coverage that is treated under sec-
6 tion 1197 of the Social Security Act as having in effect
7 an agreement with the Secretary under the Drug Price
8 Negotiation Program under part E of title XI of such Act,
9 with respect to a price applicability period (as defined in
10 section 1191(b) of such Act) and a selected drug (as de-
11 fined in section 1192(c) of such Act) with respect to such
12 period for which coverage is provided under such plan or
13 coverage—

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

15 “(A) in the case the drug is furnished or
16 dispensed at a pharmacy or by a mail order
17 service, to such plan or coverage, and to the
18 participants, beneficiaries, and enrollees en-
19 rolled under such plan or coverage, during such
20 period, with respect to such selected drug, in
21 the same manner as such provisions apply to
22 prescription drug plans and MA–PD plans, and
23 to participants, beneficiaries, and enrollees en-
24 rolled under such prescription drug plans and
25 MA–PD plans during such period; and

1 “(B) in the case the drug is furnished or
2 administered by a hospital, physician, or other
3 provider of services or supplier, to such plan or
4 coverage, and to the participants, beneficiaries,
5 and enrollees enrolled under such plan or cov-
6 erage, and to hospitals, physicians, and other
7 providers of services and suppliers during such
8 period, with respect to such drug in the same
9 manner as such provisions apply to the Sec-
10 retary, to participants, beneficiaries, and enroll-
11 ees entitled to benefits under part A of title
12 XVIII or enrolled under part B of such title,
13 and to hospitals, physicians, and other pro-
14 viders and suppliers participating under title
15 XVIII during such period;

16 “(2) the plan or issuer shall apply any cost-
17 sharing responsibilities under such plan or coverage,
18 with respect to such selected drug, by substituting
19 an amount not more than the maximum fair price
20 negotiated under such part E of title XI for such
21 drug in lieu of the drug price upon which the cost-
22 sharing would have otherwise applied, and such cost-
23 sharing responsibilities with respect to such selected
24 drug may not exceed such maximum fair price; and

1 “(3) the Secretary shall apply the provisions of
2 such part E to such plan, issuer, and coverage, such
3 participants, beneficiaries, and enrollees so enrolled
4 in such plans and coverage, and such hospitals, phy-
5 sicians, and other providers and suppliers partici-
6 pating in such plans and coverage.

7 “(b) NOTIFICATION REGARDING NONPARTICIPATION
8 IN DRUG PRICE NEGOTIATION PROGRAM.—A group
9 health plan or a health insurance issuer offering group or
10 individual health insurance coverage shall publicly dis-
11 close, in a manner and in accordance with a process speci-
12 fied by the Secretary, any election made under section
13 1197 of the Social Security Act by such plan or issuer
14 to not participate in the Drug Price Negotiation Program
15 under part E of title XI of such Act with respect to a
16 selected drug (as defined in section 1192(c) of such Act)
17 for which coverage is provided under such plan or coverage
18 before the beginning of the plan year for which such elec-
19 tion was made.”.

20 (2) ERISA.—

21 (A) IN GENERAL.—Subpart B of part 7 of
22 subtitle B of title I of the Employee Retirement
23 Income Security Act of 1974 (29 U.S.C. 1181
24 et seq.) is amended by adding at the end the
25 following new section:

1 **“SEC. 726. DRUG PRICE NEGOTIATION PROGRAM AND AP-**
2 **PLICATION OF MAXIMUM FAIR PRICES.**

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

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

16 “(A) in the case the drug is furnished or
17 dispensed at a pharmacy or by a mail order
18 service, to such plan or coverage, and to the
19 participants and beneficiaries enrolled under
20 such plan or coverage, during such period, with
21 respect to such selected drug, in the same man-
22 ner as such provisions apply to prescription
23 drug plans and MA–PD plans, and to partici-
24 pants and beneficiaries enrolled under such pre-
25 scription drug plans and MA–PD plans during
26 such period; and

1 “(B) in the case the drug is furnished or
2 administered by a hospital, physician, or other
3 provider of services or supplier, to the group
4 health plan or coverage offered by an issuer, to
5 the participants and beneficiaries enrolled
6 under such plans or coverage, and to hospitals,
7 physicians, and other providers of services and
8 suppliers during such period, with respect to
9 such drug in the same manner as such provi-
10 sions apply to the Secretary of Health and
11 Human Services, to participants and bene-
12 ficiaries entitled to benefits under part A of
13 title XVIII or enrolled under part B of such
14 title, and to hospitals, physicians, and other
15 providers and suppliers participating under title
16 XVIII during such period;

17 “(2) the plan or issuer shall apply any cost-
18 sharing responsibilities under such plan or coverage,
19 with respect to such selected drug, by substituting
20 an amount not more than the maximum fair price
21 negotiated under such part E of title XI for such
22 drug in lieu of the drug price upon which the cost-
23 sharing would have otherwise applied, and such cost-
24 sharing responsibilities with respect to such selected
25 drug may not exceed such maximum fair price; and

1 “(3) the Secretary shall apply the provisions of
2 such part E to such plan, issuer, and coverage, and
3 such participants and beneficiaries so enrolled in
4 such plans.

5 “(b) NOTIFICATION REGARDING NONPARTICIPATION
6 IN DRUG PRICE NEGOTIATION PROGRAM.—A group
7 health plan or a health insurance issuer offering group
8 health insurance coverage shall publicly disclose in a man-
9 ner and in accordance with a process specified by the Sec-
10 retary any election made under section 1197 of the Social
11 Security Act by the plan or issuer to not participate in
12 the Drug Price Negotiation Program under part E of title
13 XI of such Act with respect to a selected drug (as defined
14 in section 1192(c) of such Act) for which coverage is pro-
15 vided under such plan or coverage before the beginning
16 of the plan year for which such election was made.”.

17 (B) APPLICATION TO RETIREE AND CER-
18 TAIN SMALL GROUP HEALTH PLANS.—Section
19 732(a) of the Employee Retirement Income Se-
20 curity Act of 1974 (29 U.S.C. 1191a(a)) is
21 amended by striking “section 711” and insert-
22 ing “sections 711 and 726”.

23 (C) CLERICAL AMENDMENT.—The table of
24 sections for subpart B of part 7 of subtitle B
25 of title I of the Employee Retirement Income

1 Security Act of 1974 is amended by adding at
2 the end the following:

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

3 (3) IRC.—

4 (A) IN GENERAL.—Subchapter B of chap-
5 ter 100 of the Internal Revenue Code of 1986
6 is amended by adding at the end the following
7 new section:

8 **“SEC. 9826. DRUG PRICE NEGOTIATION PROGRAM AND AP-
9 PPLICATION OF MAXIMUM FAIR PRICES.**

10 “(a) IN GENERAL.—In the case of a group health
11 plan that is treated under section 1197 of the Social Secu-
12 rity Act as having in effect an agreement with the Sec-
13 retary of Health and Human Services under the Drug
14 Price Negotiation Program under part E of title XI of
15 such Act, with respect to a price applicability period (as
16 defined in section 1191(b) of such Act) and a selected
17 drug (as defined in section 1192(c) of such Act) with re-
18 spect to such period for which coverage is provided under
19 such plan—

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

22 “(A) if coverage of such selected drug is
23 provided under such plan if the drug is fur-
24 nished or dispensed at a pharmacy or by a mail

1 order service, to the plan, and to the partici-
2 pants and beneficiaries enrolled under such
3 plan during such period, with respect to such
4 selected drug, in the same manner as such pro-
5 visions apply to prescription drug plans and
6 MA-PD plans, and to participants and bene-
7 ficiaries enrolled under such prescription drug
8 plans and MA-PD plans during such period;
9 and

10 “(B) if coverage of such selected drug is
11 provided under such plan if the drug is fur-
12 nished or administered by a hospital, physician,
13 or other provider of services or supplier, to the
14 plan, to the participants and beneficiaries en-
15 rolled under such plan, and to hospitals, physi-
16 cians, and other providers of services and sup-
17 pliers during such period, with respect to such
18 drug in the same manner as such provisions
19 apply to the Secretary of Health and Human
20 Services, to participants and beneficiaries enti-
21 tled to benefits under part A of title XVIII or
22 enrolled under part B of such title, and to hos-
23 pitals, physicians, and other providers and sup-
24 pliers participating under title XVIII during
25 such period;

1 “(2) the plan shall apply any cost-sharing re-
2 sponsibilities under such plan, with respect to such
3 selected drug, by substituting an amount not more
4 than the maximum fair price negotiated under such
5 part E of title XI for such drug in lieu of the drug
6 price upon which the cost-sharing would have other-
7 wise applied, and such cost-sharing responsibilities
8 with respect to such selected drug may not exceed
9 such maximum fair price; and

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

13 “(b) NOTIFICATION REGARDING NONPARTICIPATION
14 IN DRUG PRICE NEGOTIATION PROGRAM.—A group
15 health plan shall publicly disclose in a manner and in ac-
16 cordance with a process specified by the Secretary any
17 election made under section 1197 of the Social Security
18 Act by the plan to not participate in the Drug Price Nego-
19 tiation Program under part E of title XI of such Act with
20 respect to a selected drug (as defined in section 1192(c)
21 of such Act) for which coverage is provided under such
22 plan before the beginning of the plan year for which such
23 election was made.”.

24 (B) APPLICATION TO RETIREE AND CER-
25 TAIN SMALL GROUP HEALTH PLANS.—Section

1 9831(a)(2) of the Internal Revenue Code of
 2 1986 is amended by inserting “other than with
 3 respect to section 9826,” before “any group
 4 health plan”.

5 (C) CLERICAL AMENDMENT.—The table of
 6 sections for subchapter B of chapter 100 of
 7 such Code is amended by adding at the end the
 8 following new item:

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

9 **SEC. 3. APPLICATION OF PRESCRIPTION DRUG INFLATION**

10 **REBATES TO DRUGS FURNISHED IN THE**
 11 **COMMERCIAL MARKET.**

12 (a) PART B DRUGS.—

13 (1) APPLICATION OF PRESCRIPTION DRUG IN-
 14 FLATION REBATES TO DRUGS FURNISHED IN THE
 15 COMMERCIAL MARKET.—Section 1847A(i) of the So-
 16 cial Security Act (42 U.S.C. 1395w–3a(i)) is amend-
 17 ed—

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

20 (B) in paragraph (2)(A), by striking “for
 21 which payment is made under this part” and
 22 inserting “that would be payable under this
 23 part if such drug were furnished to an indi-
 24 vidual enrolled under this part”; and

1 (C) in paragraph (3)—

2 (i) in subparagraph (A)(i), by striking

3 “units” and inserting “billing units”; and

4 (ii) by striking subparagraph (B) and

5 inserting the following:

6 “(B) TOTAL NUMBER OF BILLING

7 UNITS.—For purposes of subparagraph (A)(i),

8 the total number of billing units with respect to

9 a part B rebatable drug is determined as fol-

10 lows:

11 “(i) Determine the total number of

12 units equal to—

13 “(I) the total number of units, as

14 reported under subsection (c)(1)(B)

15 for each National Drug Code of such

16 drug during the calendar quarter that

17 is two calendar quarters prior to the

18 calendar quarter as described in sub-

19 paragraph (A), minus

20 “(II) the total number of units

21 with respect to each National Drug

22 Code of such drug for which payment

23 was made under a State plan under

24 title XIX (or waiver of such plan), as

25 reported by States under section

1 1927(b)(2)(A) for the rebate period
2 that is the same calendar quarter as
3 described in subclause (I).

4 “(ii) Convert the units determined
5 under clause (i) to billing units for the bill-
6 ing and payment code of such drug, using
7 a methodology similar to the methodology
8 used under this section, by dividing the
9 units determined under clause (i) for each
10 National Drug Code of such drug by the
11 billing unit for the billing and payment
12 code of such drug.

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

16 (2) EFFECTIVE DATE.—The amendments made
17 by this subsection shall apply with respect to cal-
18 endar quarters beginning after the date of the enact-
19 ment of this Act.

20 (b) COVERED PART D DRUGS.—

21 (1) APPLICATION OF PRESCRIPTION DRUG IN-
22 FLATION REBATES TO DRUGS FURNISHED IN THE
23 COMMERCIAL MARKET.—Section 1860D–14B of the
24 Social Security Act (42 U.S.C. 1395w–114b) is
25 amended—

1 (A) in subsection (b)—

2 (i) in paragraph (1)—

3 (I) in subparagraph (A)(i), by
4 striking “the total number of units”
5 and all that follows through the semi-
6 colon and inserting the following: “the
7 total number of units that are used to
8 calculate the average manufacturer
9 price of such dosage form and
10 strength with respect to such part D
11 rebatable drug, as reported by the
12 manufacturer of such drug under sec-
13 tion 1927 for each month, with re-
14 spect to such period;” and

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

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

23 “(i) Units of each dosage form and
24 strength of such part D rebatable drug for
25 which payment was made under a State

1 plan under title XIX (or waiver of such
2 plan), as reported by States under section
3 1927(b)(2)(A).

4 “(ii) Units of each dosage form and
5 strength of such part D rebatable drug for
6 which a rebate is paid under section
7 1847A(i).

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

14 (ii) in paragraph (6), by striking “IN-
15 FORMATION.—The Secretary” and all that
16 follows through “rebatable covered part D
17 drug dispensed” and inserting the fol-
18 lowing: “AMP REPORTS.—The Secretary
19 shall provide for a method and process
20 under which, in the case of a manufacturer
21 of a part D rebatable drug that submits
22 revisions to information submitted under
23 section 1927 by the manufacturer with re-
24 spect to such drug”; and

1 (B) by striking subsection (d) and insert-
2 ing the following:

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

7 (2) EFFECTIVE DATE.—The amendments made
8 by this subsection shall apply with respect to appli-
9 cable periods (as defined in section 1860D-
10 14B(g)(7) of the Social Security Act (42 U.S.C.
11 1395w-114b(g)(7))) beginning after the date of the
12 enactment of this Act.

○