I

119TH CONGRESS
1ST SESSION

H. R. 6166

To expand the drug price negotiation program under title XI of the Social Security Act and repeal certain changes to the program made by Public Law 119–21, to apply prescription drug inflation rebates under the Medicare program to drugs furnished in the commercial market, and to establish out-of-pocket limits on expenditures for prescription drugs under private health insurance.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 20, 2025

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 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

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A BILL

To expand the drug price negotiation program under title XI of the Social Security Act and repeal certain changes to the program made by Public Law 119–21, to apply prescription drug inflation rebates under the Medicare program to drugs furnished in the commercial market, and to establish out-of-pocket limits on expenditures for prescription drugs under private health insurance.

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 ''Lowering Drug Costs for American Families Act''.

TITLE I—DRUG PRICE NEGOTIATION PROGRAM

SEC. 101. 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(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 selected 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 provided 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 Public 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. 1185 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 contents in section 1 of such Act is amended by inserting after the item relating to section 725 the following new item:

''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 enti-

tled 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 the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

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

SEC. 102. REQUIRING CONSIDERATION OF AVERAGE INTERNATIONAL MARKET PRICE UNDER DRUG PRICE NEGOTIATION PROGRAM.

(a) IN GENERAL.—Section 1194(e) of the Social Security Act (42 U.S.C. 1320f–3(e)) is amended by adding at the end the following new paragraph:

''(3) AVERAGE INTERNATIONAL MARKET PRICE.—

''(A) IN GENERAL.—The average price (which shall be the net average price, if practicable, and volume-weighted, if practicable) for

a unit (as defined in subparagraph (C)) of such drug for sales of such drug (calculated across different dosage forms and strengths of the drug and not based on the specific formulation or package size or package type), as computed (as of the date of publication of such drug as a selected drug under section 1192(a)) in all countries described in clause (ii) of subparagraph (B) that are applicable countries (as described in clause (i) of such subparagraph) with respect to such drug.

''(B) APPLICABLE COUNTRIES.—

''(i) IN GENERAL.—For purposes of subparagraph (A), a country described in clause (ii) is an applicable country described in this clause with respect to a drug if there is available an average price for any unit for the drug for sales of such drug in such country.

''(ii) COUNTRIES DESCRIBED.—For purposes of this paragraph, the following are countries described in this clause:

''(I) Australia.

''(II) Canada.

''(III) France.

''(IV) Germany.

''(V) Japan.

''(VI) The United Kingdom.

''(C) UNIT DEFINED.—For purposes of this paragraph, term 'unit' means, with respect to a drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug that is dispensed.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to negotiations under the Drug Price Negotiation Program under part E of title XI of the Social Security Act (42 U.S.C. 1320f et seq.) for initial price applicability years beginning on or after January 1, 2028, and renegotiations under such program for years beginning on or after such date.

SEC. 103. REPEALING CERTAIN CHANGES TO THE DRUG PRICE NEGOTIATION PROGRAM MADE BY PUBLIC LAW 119–21.

Section 71203 of the Act titled ''An Act to provide for reconciliation pursuant to title II of H. Con. Res. 14'' (Public Law 119–21) is repealed, and the provisions of law amended by such section are hereby restored as if such section had not been enacted into law.

TITLE II—PRESCRIPTION DRUG INFLATION REBATES

SEC. 201. 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 (c)(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 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 semicolon 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" 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 appli-

cable 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.

TITLE III—OUT-OF-POCKET LIMITS FOR PRESCRIPTION DRUGS

SEC. 301. ESTABLISHING AN OUT-OF-POCKET LIMIT ON EXPENDITURES FOR PRESCRIPTION DRUGS UNDER GROUP HEALTH PLANS AND GROUP AND INDIVIDUAL HEALTH INSURANCE COVERAGE.

(a) PHSA.—Title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.), as amended by section 101, is further amended—

(1) in section 2707, by adding at the end the following new subsection:

''(e) SUNSET.—The preceding provisions of this section shall not apply with respect to plan years beginning on or after January 1, 2027.''; and

(2) in part D, by adding at the end the following new section:

''SEC. 2799A–12. COMPREHENSIVE COVERAGE.

''(a) COVERAGE FOR ESSENTIAL HEALTH BENEFITS PACKAGE.—A health insurance issuer that offers health

insurance coverage in the individual or small group market shall ensure that such coverage includes the essential health benefits package required under section 1302(a) of the Patient Protection and Affordable Care Act.

"(b) COST-SHARING LIMITATION.—

"(1) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall ensure that—

"(A) any annual cost-sharing imposed under the plan or coverage (including any such cost-sharing so imposed with respect to prescription drugs) does not exceed the dollar amounts specified in paragraph (2); and

"(B) any annual cost-sharing imposed under the plan or coverage with respect to prescription drugs does not exceed the dollar amounts specified in paragraph (3).

"(2) LIMITATION ON OVERALL OUT-OF-POCKET COST-SHARING.—For purposes of paragraph (1)(A), the dollar amounts specified in this paragraph are the following:

"(A) With respect to self-only coverage—

"(i) for plan years beginning in 2027, the dollar amount in effect under section 1302(c)(1) of the Patient Protection and

Affordable Care Act for such coverage for plan years beginning in 2014, increased by an amount equal to the product of that amount and the premium adjustment percentage specified in paragraph (4) of such section for the calendar year; and

''(ii) for plan years beginning in 2028 or a subsequent year, the dollar amount in effect under this subparagraph for plan years beginning in 2027, increased by an amount equal to the product of that amount the premium adjustment percentage specified in paragraph (4) for the calendar year.

''(B) With respect to coverage other than self-only coverage, for plan years beginning in 2027 or a subsequent year, twice the amount in effect under subparagraph (A) for such plan year.

If the amount of any increase under subparagraph (A) is not a multiple of $50, such increase shall be rounded to the next lowest multiple of $50.

''(3) LIMITATION ON PRESCRIPTION DRUG OUT-OF-POCKET COST-SHARING.—For purposes of para-

graph (1)(B), the dollar amounts specified in this paragraph are the following:

"(A) With respect to self-only coverage—

"(i) for plan years beginning in 2027, $2,000; and

"(ii) for plan years beginning in 2028 or a subsequent year, the dollar amount in effect under this subparagraph for plan years beginning in 2027, increased by an amount equal to the product of that amount and the premium adjustment percentage under paragraph (4) for the calendar year.

"(B) With respect to coverage other than self-only coverage, for plan years beginning in 2027 or a subsequent year, twice the amount in effect under subparagraph (A) for such plan year.

If the amount of any increase under subparagraph (A) is not a multiple of $50, such increase shall be rounded to the next lowest multiple of $50.

"(4) PREMIUM ADJUSTMENT PERCENTAGE.—For purposes of paragraphs (2)(A)(ii) and (3)(A)(ii), the premium adjustment percentage for any calendar year is the percentage (if any) by which the

average per capita premium for health insurance coverage in the United States for the preceding calendar year (as estimated by the Secretary no later than October 1 of such preceding calendar year) exceeds such average per capita premium for 2026 (as determined by the Secretary).

''(5) COST-SHARING.—In this section:

''(A) IN GENERAL.—The term 'cost-sharing' includes—

''(i) deductibles, coinsurance, copayments, or similar charges; and

''(ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of the Internal Revenue Code of 1986) with respect to essential health benefits covered under the plan or coverage.

''(B) EXCEPTIONS.—Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.

''(6) IMPLEMENTATION.—The Secretary may implement the provisions of this subsection by sub-regulatory guidance, interim final rule, or otherwise.

''(c) CHILD-ONLY PLANS.—If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 1302(d) of the Patient Protection and Affordable Care Act, the issuer shall also offer such coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

''(d) DENTAL ONLY.—This section shall not apply to a plan described in section 1311(d)(2)(B)(ii) of the Patient Protection and Affordable Care Act.''.

(b) ERISA.—

(1) 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. 1185 et seq.), as amended by section 101, is further amended by adding at the end the following new section:

''SEC. 727. COMPREHENSIVE COVERAGE.

''(a) COVERAGE FOR ESSENTIAL HEALTH BENEFITS PACKAGE.—A health insurance issuer that offers health insurance coverage in the small group market shall ensure that such coverage includes the essential health benefits package required under section 1302(a) of the Patient Protection and Affordable Care Act.

''(b) COST-SHARING LIMITATION.—

''(1) IN GENERAL.—A group health plan and a health insurance issuer offering group health insurance coverage shall ensure that—

''(A) any annual cost-sharing imposed under the plan or coverage (including any such cost-sharing so imposed with respect to prescription drugs) does not exceed the dollar amounts specified in paragraph (2); and

''(B) any annual cost-sharing imposed under the plan or coverage with respect to prescription drugs does not exceed the dollar amounts specified in paragraph (3).

''(2) LIMITATION ON OVERALL OUT-OF-POCKET COST-SHARING.—For purposes of paragraph (1)(A), the dollar amounts specified in this paragraph are the following:

''(A) With respect to self-only coverage—

''(i) for plan years beginning in 2027, the dollar amount in effect under section 1302(c)(1) of the Patient Protection and Affordable Care Act for such coverage for plan years beginning in 2014, increased by an amount equal to the product of that amount and the premium adjustment per-

centage specified in paragraph (4) of such section for the calendar year; and

''(ii) for plan years beginning in 2028 or a subsequent year, the dollar amount in effect under this subparagraph for plan years beginning in 2027, increased by an amount equal to the product of that amount the premium adjustment percentage specified in paragraph (4) for the calendar year.

''(B) With respect to coverage other than self-only coverage, for plan years beginning in 2027 or a subsequent year, twice the amount in effect under subparagraph (A) for such plan year.

If the amount of any increase under subparagraph (A) is not a multiple of $50, such increase shall be rounded to the next lowest multiple of $50.

''(3) LIMITATION ON PRESCRIPTION DRUG OUT-OF-POCKET COST-SHARING.—For purposes of paragraph (1)(B), the dollar amounts specified in this paragraph are the following:

''(A) With respect to self-only coverage—

''(i) for plan years beginning in 2027, $2,000; and

"(ii) for plan years beginning in 2028 or a subsequent year, the dollar amount in effect under this subparagraph for plan years beginning in 2027, increased by an amount equal to the product of that amount and the premium adjustment percentage under paragraph (4) for the calendar year.

"(B) With respect to coverage other than self-only coverage, for plan years beginning in 2027 or a subsequent year, twice the amount in effect under subparagraph (A) for such plan year.

If the amount of any increase under subparagraph (A) is not a multiple of $50, such increase shall be rounded to the next lowest multiple of $50.

"(4) PREMIUM ADJUSTMENT PERCENTAGE.—For purposes of paragraphs (2)(A)(ii) and (3)(A)(ii), the premium adjustment percentage for any calendar year is the percentage (if any) by which the average per capita premium for health insurance coverage in the United States for the preceding calendar year (as estimated by the Secretary no later than October 1 of such preceding calendar year) ex-

ceeds such average per capita premium for 2026 (as determined by the Secretary).

''(5) COST-SHARING.—In this section:

''(A) IN GENERAL.—The term 'cost-sharing' includes—

''(i) deductibles, coinsurance, copayments, or similar charges; and

''(ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of the Internal Revenue Code of 1986) with respect to essential health benefits covered under the plan or coverage.

''(B) EXCEPTIONS.—Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.

''(6) IMPLEMENTATION.—The Secretary may implement the provisions of this subsection by sub-regulatory guidance, interim final rule, or otherwise.

''(c) CHILD-ONLY PLANS.—If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 1302(d) of the Patient Protection and Affordable Care Act, the issuer shall also offer

such coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

''(d) DENTAL ONLY.—This section shall not apply to a plan described in section 1311(d)(2)(B)(ii) of the Patient Protection and Affordable Care Act.''.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of such Act is amended by inserting after the item relating to section 726 (as inserted by section 101) the following new item:

''Sec. 727. Comprehensive coverage.''.

(c) IRC.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 101, is further amended by adding at the end the following new section:

''SEC. 9827. COMPREHENSIVE COVERAGE.

''(a) COST-SHARING LIMITATION.—

''(1) IN GENERAL.—A group health plan shall ensure that—

''(A) any annual cost-sharing imposed under the plan (including any such cost-sharing so imposed with respect to prescription drugs) does not exceed the dollar amounts specified in paragraph (2); and

"(B) any annual cost-sharing imposed under the plan with respect to prescription drugs does not exceed the dollar amounts specified in paragraph (3).

"(2) LIMITATION ON OVERALL OUT-OF-POCKET COST-SHARING.—For purposes of paragraph (1)(A), the dollar amounts specified in this paragraph are the following:

"(A) With respect to self-only coverage—

"(i) for plan years beginning in 2027, the dollar amount in effect under section 1302(c)(1) of the Patient Protection and Affordable Care Act for such coverage for plan years beginning in 2014, increased by an amount equal to the product of that amount and the premium adjustment percentage specified in paragraph (4) of such section for the calendar year; and

"(ii) for plan years beginning in 2028 or a subsequent year, the dollar amount in effect under this subparagraph for plan years beginning in 2027, increased by an amount equal to the product of that amount the premium adjustment percent-

age specified in paragraph (4) for the calendar year.

''(B) With respect to coverage other than self-only coverage, for plan years beginning in 2027 or a subsequent year, twice the amount in effect under subparagraph (A) for such plan year.

If the amount of any increase under subparagraph (A) is not a multiple of $50, such increase shall be rounded to the next lowest multiple of $50.

''(3) LIMITATION ON PRESCRIPTION DRUG OUT-OF-POCKET COST-SHARING.—For purposes of paragraph (1)(B), the dollar amounts specified in this paragraph are the following:

''(A) With respect to self-only coverage—

''(i) for plan years beginning in 2027, $2,000; and

''(ii) for plan years beginning in 2028 or a subsequent year, the dollar amount in effect under this subparagraph for plan years beginning in 2027, increased by an amount equal to the product of that amount and the premium adjustment percentage under paragraph (4) for the calendar year.

''(B) With respect to coverage other than self-only coverage, for plan years beginning in 2027 or a subsequent year, twice the amount in effect under subparagraph (A) for such plan year.

If the amount of any increase under subparagraph (A) is not a multiple of $50, such increase shall be rounded to the next lowest multiple of $50.

''(4) PREMIUM ADJUSTMENT PERCENTAGE.—For purposes of paragraphs (2)(A)(ii) and (3)(A)(ii), the premium adjustment percentage for any calendar year is the percentage (if any) by which the average per capita premium for health insurance coverage in the United States for the preceding calendar year (as estimated by the Secretary no later than October 1 of such preceding calendar year) exceeds such average per capita premium for 2026 (as determined by the Secretary).

''(5) COST-SHARING.—In this section:

''(A) IN GENERAL.—The term 'cost-sharing' includes—

''(i) deductibles, coinsurance, copayments, or similar charges; and

''(ii) any other expenditure required of an insured individual which is a qualified

medical expense (within the meaning of section 223(d)(2) of the Internal Revenue Code of 1986) with respect to essential health benefits covered under the plan.

''(B) EXCEPTIONS.—Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.

''(6) IMPLEMENTATION.—The Secretary may implement the provisions of this subsection by sub-regulatory guidance, interim final rule, or otherwise.

''(b) DENTAL ONLY.—This section shall not apply to a plan described in section 1311(d)(2)(B)(ii) of the Patient Protection and Affordable Care Act.''.

(2) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 101, is further amended by adding at the end the following new item:

''Sec. 9827. Comprehensive coverage.''.

(d) CONFORMING AMENDMENTS.—The Patient Protection and Affordable Care Act (Public Law 111–148) is amended—

(1) in section 1302—

(A) in subsection (a)(2), by inserting ''with respect to plan years beginning before January 1, 2027,'' before ''limits cost-sharing''; and

(B) in subsection (e)(1)(B)(i)—

(i) by inserting ''(or, with respect to plan years beginning on or after January 1, 2027, in effect under section 2799A–12(b)(1)(A)) of the Public Health Service Act)'' after ''subsection (c)(1)''; and

(ii) by inserting ''and except, with respect to plan years beginning on or after January 1, 2027, in the case of an individual who has incurred cost-sharing expenses with respect to prescription drugs in an amount equal to the annual limitation in effect under section 2799A–12(b)(1)(B) of such Act, for benefits consisting of prescription drugs'' after ''section 2713''; and

(2) in section 1402(c)(1)(A), by inserting ''(or, with respect to plan years beginning on or after January 1, 2027, the applicable out-of-pocket limit under section 2799A–12(b)(1)(A) of the Public Health Service Act)'' after ''section 1302(c)(1)''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after January 1, 2027.

SEC. 302. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR INSULIN PRODUCTS.

(a) PHSA.—Part D of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–111 et seq.), as amended by sections 101 and 301, is further amended by adding at the end the following new section:

"SEC. 2799A–13. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2027, a group health plan or health insurance issuer offering group or individual health insurance coverage shall provide coverage of selected insulin products, and with respect to such products, shall not—

''(1) apply any deductible; or

''(2) impose any cost-sharing in excess of the lesser of, per 30-day supply—

''(A) $35; or

''(B) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan or coverage, including price concessions received by or on behalf of third-

party entities providing services to the plan or coverage, such as pharmacy benefit management services.

''(b) DEFINITIONS.—In this section:

''(1) SELECTED INSULIN PRODUCTS.—The term 'selected insulin products' means at least one of each dosage form (such as vial, pump, or inhaler dosage forms) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting, and premixed) of insulin (as defined below), when available, as selected by the group health plan or health insurance issuer.

''(2) INSULIN DEFINED.—The term 'insulin' means insulin that is licensed under subsection (a) or (k) of section 351 and continues to be marketed under such section, including any insulin product that has been deemed to be licensed under section 351(a) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) and continues to be marketed pursuant to such licensure.

''(c) OUT-OF-NETWORK PROVIDERS.—Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for selected insulin products described in this section that are delivered by an out-

of-network provider, or precludes a plan or issuer that has a network of providers from imposing higher cost-sharing than the levels specified in subsection (a) for selected insulin products described in this section that are delivered by an out-of-network provider.

''(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group health plan or health insurance coverage from imposing cost-sharing other than the levels specified in subsection (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law.

''(e) APPLICATION OF COST-SHARING TOWARDS DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any cost-sharing payments made pursuant to subsection (a)(2) shall be counted toward any deductible or out-of-pocket maximum that applies under the plan or coverage.''.

(b) ERISA.—

(1) 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. 1185 et seq.), as amended by sections 101 and 301, is further amended by adding at the end the following new section:

"SEC. 728. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

"(a) IN GENERAL.—For plan years beginning on or after January 1, 2027, a group health plan or health insurance issuer offering group health insurance coverage shall provide coverage of selected insulin products, and with respect to such products, shall not—

"(1) apply any deductible; or

"(2) impose any cost-sharing in excess of the lesser of, per 30-day supply—

"(A) $35; or

"(B) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan or coverage, including price concessions received by or on behalf of third-party entities providing services to the plan or coverage, such as pharmacy benefit management services.

"(b) DEFINITIONS.—In this section:

"(1) SELECTED INSULIN PRODUCTS.—The term 'selected insulin products' means at least one of each dosage form (such as vial, pump, or inhaler dosage forms) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting, and premixed) of insulin (as defined

below), when available, as selected by the group health plan or health insurance issuer.

''(2) INSULIN DEFINED.—The term 'insulin' means insulin that is licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) and continues to be marketed under such section, including any insulin product that has been deemed to be licensed under section 351(a) of such Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) and continues to be marketed pursuant to such licensure.

''(c) OUT-OF-NETWORK PROVIDERS.—Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for selected insulin products described in this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing higher cost-sharing than the levels specified in subsection (a) for selected insulin products described in this section that are delivered by an out-of-network provider.

''(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group health plan or health insurance coverage from imposing cost-sharing other than the levels specified in subsection

(a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law.

''(e) APPLICATION OF COST-SHARING TOWARDS DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any cost-sharing payments made pursuant to subsection (a)(2) shall be counted toward any deductible or out-of-pocket maximum that applies under the plan or coverage.''.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of such Act is amended by inserting after the item relating to section 727 (as inserted by section 301) the following new item:

''Sec. 728. Requirements with respect to cost-sharing for certain insulin products.''.

(c) IRC.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by sections 101 and 301, is further amended by adding at the end the following new section:

''SEC. 9828. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2027, a group health plan shall provide coverage of selected insulin products, and with respect to such products, shall not—

''(1) apply any deductible; or

''(2) impose any cost-sharing in excess of the lesser of, per 30-day supply—

''(A) $35; or

''(B) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan, including price concessions received by or on behalf of third-party entities providing services to the plan, such as pharmacy benefit management services.

''(b) DEFINITIONS.—In this section:

''(1) SELECTED INSULIN PRODUCTS.—The term 'selected insulin products' means at least one of each dosage form (such as vial, pump, or inhaler dosage forms) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting, and premixed) of insulin (as defined below), when available, as selected by the group health plan.

''(2) INSULIN DEFINED.—The term 'insulin' means insulin that is licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) and continues to be marketed under such section, including any insulin product

that has been deemed to be licensed under section 351(a) of such Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) and continues to be marketed pursuant to such licensure.

''(c) OUT-OF-NETWORK PROVIDERS.—Nothing in this section requires a plan that has a network of providers to provide benefits for selected insulin products described in this section that are delivered by an out-of-network provider, or precludes a plan that has a network of providers from imposing higher cost-sharing than the levels specified in subsection (a) for selected insulin products described in this section that are delivered by an out-of-network provider.

''(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group health plan from imposing cost-sharing other than the levels specified in subsection (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law.

''(e) APPLICATION OF COST-SHARING TOWARDS DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any cost-sharing payments made pursuant to subsection (a)(2)

shall be counted toward any deductible or out-of-pocket maximum that applies under the plan.''.

(2) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by sections 101 and 301, is further amended by adding at the end the following new item:

''Sec. 9828. Requirements with respect to cost-sharing for certain insulin products.''.

(d) NO EFFECT ON OTHER COST-SHARING.—Section 1302(d)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(d)(2)) is amended by adding at the end the following new subparagraph:

''(D) SPECIAL RULE RELATING TO INSULIN COVERAGE.—The exemption of coverage of selected insulin products (as defined in section 2799A–13(b) of the Public Health Service Act) from the application of any deductible pursuant to section 2799A–13(a)(1) of such Act, section 728(a)(1) of the Employee Retirement Income Security Act of 1974, or section 9828(a)(1) of the Internal Revenue Code of 1986 shall not be considered when determining the actuarial value of a qualified health plan under this subsection.''.

(e) COVERAGE OF CERTAIN INSULIN PRODUCTS UNDER CATASTROPHIC PLANS.—Section 1302(e) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(e)) is amended by adding at the end the following new paragraph:

"(4) COVERAGE OF CERTAIN INSULIN PRODUCTS.—

"(A) IN GENERAL.—Notwithstanding paragraph (1)(B)(i), a health plan described in paragraph (1) shall provide coverage of selected insulin products, in accordance with section 2799A–13 of the Public Health Service Act, for a plan year before an enrolled individual has incurred cost-sharing expenses in an amount equal to the annual limitation in effect under subsection (c)(1) for the plan year.

"(B) TERMINOLOGY.—For purposes of subparagraph (A)—

"(i) the term 'selected insulin products' has the meaning given such term in section 2799A–13(b) of the Public Health Service Act; and

"(ii) the requirements of section 2799A–13 of such Act shall be applied by deeming each reference in such section to

'individual health insurance coverage' to be a reference to a plan described in paragraph (1).''.

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