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117TH CONGRESS
1ST SESSION

H. R. 4811

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate prices of drugs furnished under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2021

Mr. DOGGETT (for himself, Mr. BEYER, Mr. BLUMENAUER, Mr. BOWMAN, Ms. BUSH, Mr. CARTWRIGHT, Mr. CASTRO of Texas, Mr. CICILLINE, Mr. CLEAVER, Mr. COHEN, Mr. DEFAZIO, Ms. DELAURO, Mrs. DINGELL, Ms. ESCOBAR, Mr. ESPAILLAT, Mr. GARAMENDI, Mr. GARCÍA of Illinois, Mr. GREEN of Texas, Mr. GRIJALVA, Ms. JACKSON LEE, Ms. JAYAPAL, Mr. KAHELE, Ms. KAPTUR, Mr. KHANNA, Mr. KIM of New Jersey, Mr. KRISHNAMOORTHI, Mr. LANGEVIN, Ms. LEE of California, Mr. LEVIN of Michigan, Mr. LOWENTHAL, Mr. MCNERNEY, Mr. MFUME, Mr. NADLER, Mr. NEGUSE, Ms. NORTON, Ms. OCASIO-CORTEZ, Ms. OMAR, Mr. PERLMUTTER, Ms. PINGREE, Mr. POCAN, Ms. PORTER, Ms. PRESSLEY, Mr. RASKIN, Ms. SCHAKOWSKY, Mr. SHERMAN, Mr. TAKANO, Mr. THOMPSON of Mississippi, Ms. TITUS, Ms. TLAIB, Mr. TORRES of New York, Mr. VELA, Mr. YARMUTH, Ms. LEGER FERNANDEZ, Ms. MOORE of Wisconsin, Ms. WATERS, Ms. CHU, Ms. NEWMAN, and Ms. VELÁZQUEZ) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Oversight and Reform, Veterans' Affairs, and Armed Services, 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 amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate

prices of drugs furnished under the Medicare program, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare Negotiation and Competitive Licensing Act of 2021''.

SEC. 2. REQUIRING THE SECRETARY OF HEALTH AND HUMAN SERVICES TO NEGOTIATE PRICES OF DRUGS FURNISHED UNDER THE MEDICARE PROGRAM.

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

''(i) NEGOTIATION OF LOWER DRUG PRICES.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall, for plan years beginning on or after the date of the enactment of this subsection, negotiate with pharmaceutical manufacturers the negotiated prices (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and MA organizations during a negotiated price period (as specified by the Secretary) for specified covered part D drugs for such plan year for part D eligible individuals who

are enrolled under a prescription drug plan or under an MA–PD plan.

''(2) NEGOTIATION CONSIDERATIONS.—

''(A) FACTORS.—In negotiating such prices under paragraph (1), the Secretary shall take into account the following factors:

''(i) The comparative clinical effectiveness and cost effectiveness, when available from an impartial source, of such drug.

''(ii) The budgetary impact of providing coverage of such drug.

''(iii) The number of similarly effective drugs or alternative treatment regimens for each approved use of such drug.

''(iv) The associated financial burden on patients that utilize such drug.

''(v) The associated unmet patient need for such drug.

''(vi) The total revenues from global sales obtained by the manufacturer for such drug and the associated investment in research and development of such drug by the manufacturer.

''(B) ASSESSMENT OF FACTORS.—For purposes of assessing the factors described in sub-

paragraph (A) with respect to a covered part D drug, the Secretary shall, as soon as practicable, establish a value assessment process consisting of standardized measures for such factors. With respect to a negotiation that occurs before the Secretary establishes such a process, the Secretary may use such other assessments as the Secretary determines appropriate (such as assessments used with respect to ascertaining the value of drugs by the Secretary of Veterans Affairs, the Patient-Centered Outcomes Research Institute, the Institute for Clinical and Economic Review, and other countries).

''(3) SPECIFIED COVERED PART D DRUGS.—In this subsection, the term 'specified covered part D drug' means, with respect to a negotiated price period beginning during—

''(A) the first plan year beginning on or after the date of the enactment of this subsection, a covered part D drug that is a sole source drug (as defined in section 1833(t)(14)(F)(i))—

"(i) with respect to which gross revenues for the preceding plan year were $100,000,000 or greater; or

"(ii) that contains an active ingredient that was first approved by the Administrator for Food and Drugs not later than 10 years prior to the beginning of such first plan year;

"(B) the second plan year beginning on or after the date of the enactment of this subsection, a covered part D drug that is a sole source drug (as so defined) or a biosimilar biological product;

"(C) the third plan year beginning on or after the date of the enactment of this subsection, a covered part D drug—

"(i) that is described in subparagraph (B); or

"(ii) with respect to which, during the preceding plan year, fewer than 3 manufacturers (other than the manufacturer of such drug) marketed a generic version of such drug; and

"(D) the fourth plan year beginning on or after the date of the enactment of this sub-

section or a subsequent plan year, a covered part D drug.

''(4) NEGOTIATED PRICE LIMITATIONS AND FINALIZATION.—The negotiated price of each specified covered part D drug for a negotiated price period—

''(A) may not be less than an amount necessary to allow such manufacturer to recoup such manufacturer's research and development costs associated with such drug;

''(B) subject to subparagraph (A), may not exceed 110 percent of the median price of such drug for the preceding plan year in the 10 countries of the Organisation for Economic Co-operation and Development with the highest gross domestic product and with a per capita income that is not less than half the per capita income of the United States for such preceding plan year; and

''(C) shall be finalized not later than 30 days before a PDP sponsor is required to submit information described in subsection (b)(2) for the first plan year in such negotiated price period.

''(5) COMPETITIVE LICENSING AUTHORITY.—

"(A) IN GENERAL.—Notwithstanding any exclusivity under clause (iii) or (iv) of section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act, clause (iii) or (iv) of section 505(c)(3)(E) of such Act, section 351(k)(7)(A) of the Public Health Service Act, or section 527(a) of the Federal Food, Drug, and Cosmetic Act, or by an extension of such exclusivity under section 505A of such Act or section 505E of such Act, and any other provision of law that provides for market exclusivity (or extension of market exclusivity) with respect to a drug, in the case that the Secretary is unable to successfully negotiate an appropriate price for a specified covered part D drug for a negotiated price period, the Secretary shall authorize the use of any patent, clinical trial data, or other exclusivity granted by the Federal government with respect to such drug as the Secretary determines appropriate for purposes of manufacturing such drug for sale under a Federal health care program, the insurance program under chapter 89 of title 5, United States Code, or a group health plan or health insurance coverage offered by a health insurance issuer. Any

entity making use of a competitive license to use patent, clinical trial data, or other exclusivity under this section shall provide to the manufacturer holding such exclusivity reasonable compensation, as determined by the Secretary based on the following factors:

''(i) The risk-adjusted value of any Federal government subsidies and investments in research and development used to support the development of such drug.

''(ii) The risk-adjusted value of any investment made by such manufacturer in the research and development of such drug.

''(iii) The impact of the price, including license compensation payments, on meeting the medical need of all patients.

''(iv) The relationship between the price of such drug, including compensation payments, and the health benefits of such drug.

''(v) Other relevant factors determined appropriate by the Secretary to provide reasonable compensation.

''(B) REASONABLE COMPENSATION.—

"(i) LIMITATIONS.—Reasonable compensation described in subparagraph (A) with respect to a specified covered outpatient drug and a plan year may not be made in an amount—

"(I) less than an amount necessary to allow such manufacturer to recoup such manufacturer's research and development costs associated with such drug; and

"(II) subject to subclause (I), greater than 12 percent of the negotiated price set by the Secretary for such drug and such plan year.

"(ii) RECOVERY.—The manufacturer described in subparagraph (A) may seek recovery against the United States in the United States Court of Federal Claims.

"(C) INTERIM PERIOD.—Until 1 year after a drug described in subparagraph (A) is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act or section 351(k) of the Public Health Service Act and is provided under license issued by the Secretary under such subparagraph, PDP plans and MA–

PD plans shall not pay more for such drug than 110 percent of the median of the prices available, during the most recent 12-month period for which data is available prior to the beginning of such negotiated price period, from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the ten Organisation for Economic Cooperation and Development countries that have the largest gross domestic product with a per capita income that is not less than half the per capita income of the United States.

''(D) AUTHORIZATION FOR SECRETARY TO PROCURE DRUGS DIRECTLY.—

''(i) IN GENERAL.—The Secretary may procure a drug manufactured pursuant to a competitive license under subparagraph (A) for purposes of this part or pursuant to a Federal program license under subparagraph (C)(ii) for purposes of a Federal program directly from the entity manufacturing the drug pursuant to such a license.

''(ii) CLARIFICATION REGARDING APPLICATION OF BUY AMERICAN ACT.—In the case where the Secretary procures a drug under this subparagraph, the provisions of chapter 83 of title 41, United States Code (commonly referred to as the 'Buy American Act') shall apply.

''(E) PRIORITY FOR U.S. MANUFACTURERS IN AUTHORIZING COMPETITIVE LICENSES.—In authorizing a competitive license under this paragraph, the Secretary—

''(i) shall give preference to entities that the Secretary determines have the highest safety and security standards; and

''(ii) may give priority to entities that will manufacture such drug in the United States.

''(6) FDA REVIEW OF LICENSED DRUG APPLICATIONS.—The Secretary shall prioritize review of applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act for drugs licensed under paragraph (3)(A).

''(7) PROHIBITION OF ANTICOMPETITIVE BEHAVIOR.—No drug manufacturer may engage in anticompetitive behavior with another manufacturer

that may interfere with the issuance and implementation of a competitive license or run contrary to public policy.

''(8) REQUIRED REPORTING.—The Secretary may require pharmaceutical manufacturers or any other entity to disclose to the Secretary such information that the Secretary determines necessary for purposes of carrying out this subsection.

''(9) CLARIFICATION.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan or an organization offering an MA–PD plan from obtaining a discount or reduction of the price for a covered part D drug below the price negotiated by the Secretary.

''(10) PUBLICATION OF NEGOTIATED PRICES AND CONTRACT TERMS.—The Secretary shall make available on a public website the price negotiated under this subsection, and any contract terms associated with such price, with respect to each specified covered part D drug.''.

(b) PART B.—

(1) IN GENERAL.—Section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o)) is amended by adding at the end the following new paragraph:

''(8)(A) Notwithstanding any preceding provision of this subsection, in the case of a drug or biological described in paragraph (1) furnished during a negotiated price period beginning on or after January 1 of the first year beginning on or after the date of the enactment of this paragraph, the amount payable under this part for such drug or biological shall be equal to the negotiated price for such drug or biological and period, as established pursuant to subparagraph (B).

''(B) The provisions of section 1860D–11(i) shall be applied to the negotiation of a negotiated price for a drug or biological described in subparagraph (A) and a negotiated price period in a similar manner (as determined by the Secretary) as such provisions apply with respect to the negotiation of a negotiated price for a specified part D drug for a negotiated price period under such section.''.

(2) APPLICATION TO MA.—Section 1852 of the Social Security Act (42 U.S.C. 1395w–22) is amended by adding at the end the following new subsection:

''(o) LIMITATION ON REIMBURSEMENT FOR CERTAIN DRUGS.—In the case of a drug or biological furnished during a negotiated price period (as defined for purposes of section 1842(o)(8)) for which payment may be made under such section, the total reimbursement for such drug

or biological made by an Medicare Advantage plan may not exceed the negotiated price for such drug or biological and period established pursuant to such section.''.

SEC. 3. IDENTIFICATION OF PRESCRIPTION DRUG PRICE SPIKES.

(a) DEFINITIONS.—In this section:

(1) APPLICABLE ENTITY.—The term ''applicable entity'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or of a license issued under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a drug described in paragraph (5)(A).

(2) AVERAGE MANUFACTURER PRICE.—The term ''average manufacturer price''—

(A) has the same meaning given such term under section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)); or

(B) with respect to a drug for which there is no average manufacturer price as so defined, such term shall mean the wholesale acquisition cost of the drug.

(3) COMMERCE.—The term ''commerce'' has the meaning given such term in section 4 of the Federal Trade Commission Act (15 U.S.C. 44).

(4) INSPECTOR GENERAL.—The term ''Inspector General'' means the Inspector General of the Department of Health and Human Services.

(5) PRESCRIPTION DRUG.—

(A) IN GENERAL.—The term ''prescription drug'' means any drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))), including a combination product whose primary mode of action is determined under section 503(g) of such Act (21 U.S.C. 353(g)) to be that of a drug, and that—

(i) is subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

(ii) is covered by a Federal health care program (as defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(f))).

(B) TREATMENT OF REFORMULATED DRUGS.—For purposes of this section, a prescription drug with respect to which the Sec-

retary of Health and Human Services has approved any minor reformulation that does not produce a meaningful therapeutic benefit, the drug that was approved prior to any such reformulation and the drug with any such reformulation shall be considered one prescription drug.

(6) PRICE SPIKE.—

(A) IN GENERAL.—The term ''price spike'' means an increase in the average manufacturer price in commerce of a prescription drug for which the price spike percentage is equal to or greater than applicable price increase allowance.

(B) PRICE SPIKE PERCENTAGE.—The price spike percentage is the percentage (if any) by which—

(i) the average manufacturer price of a prescription drug in commerce for the calendar year; exceeds

(ii) the average manufacturer price of such prescription drug in commerce for the calendar year preceding such year.

(C) APPLICABLE PRICE INCREASE ALLOWANCE.—The applicable price increase allowance for any calendar year is the percentage (rounded to the nearest one-tenth of 1 percent) by

which the C–CPI–U (as defined in section 1(f)(6) of the Internal Revenue Code of 1986) for that year exceeds the C–CPI–U for the preceding calendar year.

(7) PRICE SPIKE REVENUE.—

(A) IN GENERAL.—The price spike revenue for any calendar year is an amount equal to—

(i) the gross price spike revenue, minus

(ii) the adjustment amount.

(B) GROSS PRICE SPIKE REVENUE.—The gross price spike revenue for any calendar year is an amount equal to the product of—

(i) an amount equal to the difference between clause (i) of paragraph (6)(B) and clause (ii) of such paragraph; and

(ii) the total number of units of the prescription drug which were sold in commerce in such calendar year.

(C) ADJUSTMENT AMOUNT.—The adjustment amount is the amount, if any, of the gross price spike revenue which the Inspector General has determined is due solely to an increase in the cost of the inputs necessary to manufacture the prescription drug subject to the price spike.

(b) SUBMISSION BY PHARMACEUTICAL COMPANIES OF INFORMATION TO INSPECTOR GENERAL.—

(1) IN GENERAL.—For each prescription drug, the applicable entity shall submit to the Inspector General a quarterly report that includes the following:

(A) For each prescription drug of the applicable entity—

(i) the total number of units of the prescription drug which were sold in commerce in the preceding calendar quarter;

(ii) the average and median price per unit of such prescription drug in commerce in the preceding calendar quarter, disaggregated by month; and

(iii) the gross revenues from sales of such prescription drug in commerce in the preceding calendar quarter.

(B) Such information related to increased input costs or public health considerations as the applicable entity may wish the Inspector General to consider in making a determination under clause (ii) of subsection (c)(2)(B) or an assessment in clause (iii) of such subsection for the preceding calendar quarter.

(C) Such information related to any anticipated increased input costs for the subsequent calendar quarter as the applicable entity may wish the Inspector General to consider in making a determination under clause (ii) of subsection (c)(2)(B) or an assessment in clause (iii) of such subsection for such calendar quarter.

(2) PENALTY FOR FAILURE TO SUBMIT.—

(A) IN GENERAL.—An applicable entity described in paragraph (1) that fails to submit information to the Inspector General regarding a prescription drug, as required by such paragraph, before the date specified in paragraph (3) shall be liable for a civil penalty, as determined under subparagraph (B).

(B) AMOUNT OF PENALTY.—The amount of the civil penalty shall be equal to the product of—

(i) an amount, as determined appropriate by the Inspector General, which is—

(I) not less than 0.5 percent of the gross revenues from sales of the prescription drug described in sub-

paragraph (A) for the preceding calendar year, and

(II) not greater than 1 percent of the gross revenues from sales of such prescription drug for the preceding calendar year, and

(ii) the number of days in the period between—

(I) the applicable date specified in paragraph (3), and

(II) the date on which the Inspector General receives the information described in paragraph (1) from the applicable entity.

(3) SUBMISSION DEADLINE.—An applicable entity shall submit each quarterly report described in paragraph (1) not later than January 17, April 18, June 15, and September 15 of each calendar year.

(c) ASSESSMENT BY INSPECTOR GENERAL.—

(1) IN GENERAL.—Not later than the last day in February of each year, the Inspector General, in consultation with other relevant Federal agencies (including the Federal Trade Commission), shall—

(A) complete an assessment of the information the Inspector General received pursuant

to subsection (b)(1) with respect to sales of prescription drugs in the preceding calendar year; and

(B) in the case of any prescription drug which satisfies the conditions described in paragraph (1) or (2) of subsection (d), submit a recommendation to the Secretary of Health and Human Services that such drug be exempted from application of the tax imposed under section 4192 of the Internal Revenue Code of 1986 (as added by section 3 of this Act) for such year.

(2) ELEMENTS.—The assessment required by paragraph (1)(A) shall include the following:

(A) Identification of each price spike relating to a prescription drug in the preceding calendar year.

(B) For each price spike identified under subparagraph (A)—

(i) a determination of the price spike revenue;

(ii) a determination regarding the accuracy of the information submitted by the applicable entity regarding increased input costs; and

(iii) an assessment of the rationale of the applicable entity for the price spike.

(d) EXEMPTION OF CERTAIN DRUGS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, upon recommendation of the Inspector General pursuant to subsection (c)(1)(B), may exempt any prescription drug which has been subject to a price spike during the preceding calendar year from application of the tax imposed under section 4192 of the Internal Revenue Code of 1986 for such year, if the Secretary determines that—

(A) based on information submitted pursuant to subsection (b)(1)(B), a for-cause price increase exemption should apply; or

(B)(i) the prescription drug which has been subject to a price spike has an average manufacturer price of not greater than $10 for a 30 day supply; and

(ii) such drug is marketed by not less than 3 other holders of applications approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), where such applications approved under

such subsection (j) use as a reference drug the drug so approved under such subsection (c).

(2) CLARIFICATION.—In considering, under paragraph (1)(A), information submitted pursuant to subsection (b)(1)(B), the Secretary—

(A) has the discretion to determine that such information does not warrant a for-cause price increase exemption; and

(B) shall exclude from such consideration any information submitted by the applicable entity threatening to curtail or limit production of the prescription drug if the Secretary does not grant an exemption from the application of the tax under section 4192 of the Internal Revenue Code of 1986.

(e) INSPECTOR GENERAL REPORT TO INTERNAL REVENUE SERVICE.—

(1) IN GENERAL.—Subject to paragraph (3), not later than the last day in February of each year, the Inspector General shall transmit to the Internal Revenue Service a report on the findings of the Inspector General with respect to the information the Inspector General received under subsection (b)(1) with respect to the preceding calendar year and the assessment carried out by the Inspector General

under subsection (c)(1)(A) with respect to such information.

(2) CONTENTS.—The report transmitted under paragraph (1) shall include the following:

(A) The information received under subsection (b)(1) with respect to the preceding calendar year.

(B) The price spikes identified under subparagraph (A) of subsection (c)(2).

(C) The price spike revenue determinations made under subparagraph (B)(i) of such subsection.

(D) The determinations and assessments made under clauses (ii) and (iii) of subparagraph (B) of such subsection.

(3) NOTICE AND OPPORTUNITY FOR HEARING.—

(A) IN GENERAL.—No report shall be transmitted to the Internal Revenue Service under paragraph (1) in regards to a prescription drug unless the Inspector General has provided the applicable entity with—

(i) the assessment of such drug under subsection (c)(1)(A); and

(ii) notice of their right to a hearing in regards to such assessment.

(B) NOTICE.—The notice required under subparagraph (A) shall be provided to the applicable entity not later than 30 days after completion of the assessment under subsection (c)(1)(A).

(C) REQUEST FOR HEARING.—Subject to subparagraph (E), an applicable entity may request a hearing before the Secretary of Health and Human Services not later than 30 days after the date on which the notice under subparagraph (B) is received.

(D) COMPLETION OF HEARING.—In the case of an applicable entity which requests a hearing pursuant to subparagraph (C), the Secretary of Health and Human Services shall, not later than 12 months after the date on which the assessment under subsection (c)(1)(A) was completed by the Inspector General—

(i) make a final determination in regards to the accuracy of such assessment; and

(ii) provide the report described in paragraph (2) to the Internal Revenue Service.

(E) LIMITATION.—An applicable entity may request a hearing under subparagraph (C) with respect to a particular prescription drug only once within a 5-year period.

(4) PUBLICATION.—

(A) IN GENERAL.—Not later than the last day in February of each year, subject to subparagraph (B), the Inspector General shall make the report transmitted under paragraph (1) available to the public, including on the Internet website of the Inspector General, subject to subparagraph (B).

(B) PROPRIETARY INFORMATION.—The Inspector General shall ensure that any information made public in accordance with subparagraph (A) excludes trade secrets and confidential commercial information.

(f) NOTIFICATION.—The Secretary of the Treasury, in conjunction with the Inspector General, shall notify, at such time and in such manner as the Secretary of the Treasury shall provide, each applicable entity in regard to any prescription drug which has been determined to

have been subject to a price spike during the preceding calendar year and the amount of the tax imposed on such applicable entity pursuant to section 4192 of the Internal Revenue Code of 1986.

SEC. 4. EXCISE TAX ON PRESCRIPTION DRUGS SUBJECT TO PRICE SPIKES.

(a) IN GENERAL.—Subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

"SEC. 4192. PRESCRIPTION DRUGS SUBJECT TO PRICE SPIKES.

''(a) IMPOSITION OF TAX.—

''(1) IN GENERAL.—Subject to paragraph (3), for each taxable prescription drug sold by an applicable entity during the calendar year, there is hereby imposed on such entity a tax equal to the greater of—

''(A) the annual price spike tax for such prescription drug, or

''(B) subject to paragraph (2), the cumulative price spike tax for such prescription drug.

''(2) LIMITATION.—In the case of a taxable prescription drug for which the applicable period (as determined under subsection (c)(2)(E)(i)) is less

than 2 calendar years, the cumulative price spike tax shall not apply.

''(3) EXEMPTION.—For any calendar year in which the Secretary of Health and Human Services has provided an exemption for a taxable prescription drug pursuant to section 3(d) of the Medicare Negotiation and Competitive Licensing Act of 2021, the amount of the tax determined under paragraph (1) for such drug or device for such calendar year shall be reduced to zero.

''(b) ANNUAL PRICE SPIKE TAX.—

''(1) IN GENERAL.—The amount of the annual price spike tax shall be equal to the applicable percentage of the price spike revenue received by the applicable entity on the sale of the taxable prescription drug during the calendar year.

''(2) APPLICABLE PERCENTAGE.—For purposes of paragraph (1), the applicable percentage shall be equal to—

''(A) in the case of a taxable prescription drug which has been subject to a price spike percentage greater than the applicable price increase allowance (as defined in section 3(a)(6)(C) of the Medicare Negotiation and

Competitive Licensing Act of 2021) but less than 15 percent, 50 percent,

"(B) in the case of a taxable prescription drug which has been subject to a price spike percentage equal to or greater than 15 percent but less than 20 percent, 75 percent, and

"(C) in the case of a taxable prescription drug which has been subject to a price spike percentage equal to or greater than 20 percent, 100 percent.

"(c) CUMULATIVE PRICE SPIKE TAX.—

"(1) IN GENERAL.—The amount of the cumulative price spike tax shall be equal to the applicable percentage of the cumulative price spike revenue received by the applicable entity on the sale of the taxable prescription drug during the calendar year.

"(2) APPLICABLE PERCENTAGE.—

"(A) IN GENERAL.—For purposes of paragraph (1), the applicable percentage shall be equal to—

"(i) in the case of a taxable prescription drug which has been subject to a cumulative price spike percentage greater than the cumulative price increase allow-

ance but less than the first multi-year percentage, 50 percent,

"(ii) in the case of a taxable prescription drug which has been subject to a cumulative price spike percentage equal to or greater than the first multi-year percentage but less than the second multi-year percentage, 75 percent, and

"(iii) in the case of a taxable prescription drug which has been subject to a cumulative price spike percentage equal to or greater than the second multi-year percentage, 100 percent.

"(B) CUMULATIVE PRICE SPIKE PERCENTAGE.—The cumulative price spike percentage is the percentage (if any) by which—

"(i) the average manufacturer price of the taxable prescription drug in commerce for the preceding calendar year, exceeds

"(ii) the average manufacturer price of such prescription drug in commerce for the base year.

"(C) CUMULATIVE PRICE INCREASE ALLOWANCE.—For purposes of clause (i) of subparagraph (A), the cumulative price increase al-

lowance for any calendar year is the percentage (rounded to the nearest one-tenth of 1 percent) by which the C–CPI–U (as defined in section 1(f)(6)) for that year exceeds the C–CPI–U for the base year.

''(D) MULTI-YEAR PERCENTAGES.—For purposes of subparagraph (A), the first multi-year percentage and second multi-year percentage shall be determined in accordance with the following table:

''Number of years in applicable period	First multi-year percentage	Second multi-year percentage
2 years	17.5	22.5
3 years	20	25
4 years	22.5	27.5
5 years	25	30.

''(E) APPLICABLE PERIOD AND BASE YEAR.—

''(i) APPLICABLE PERIOD.—The applicable period shall be the lesser of—

''(I) the 5 preceding calendar years,

''(II) all calendar years beginning after the date of enactment of this section, or

''(III) all calendar years in which the taxable prescription drug was sold in commerce.

''(ii) BASE YEAR.—The base year shall be the calendar year immediately preceding the applicable period.

''(3) CUMULATIVE PRICE SPIKE REVENUE.—For purposes of paragraph (1), the cumulative price spike revenue for any taxable prescription drug shall be an amount equal to—

''(A) an amount equal to the product of—

''(i) an amount (not less than zero) equal to—

''(I) the average manufacturer price of such prescription drug in commerce for the preceding calendar year, minus

''(II) the average manufacturer price of such prescription drug in commerce for the base year, and

''(ii) the total number of units of such prescription drug which were sold in commerce in the preceding calendar year, minus

''(B) an amount equal to the sum of the adjustment amounts, if any, determined under section 3(a)(7)(C) of the Medicare Negotiation and Competitive Licensing Act of 2021 for each calendar year during the applicable period.

''(d) DEFINITIONS.—For purposes of this section—

''(1) TAXABLE PRESCRIPTION DRUG.—The term 'taxable prescription drug' means a prescription drug which has been identified by the Inspector General of the Department of Health and Human Services as being subject to a price spike.

''(2) OTHER TERMS.—The terms 'applicable entity', 'average manufacturer price', 'price spike', 'price spike percentage', and 'price spike revenue' have the same meaning given such terms under section 3(a) of the Medicare Negotiation and Competitive Licensing Act of 2021.''.

(b) CLERICAL AMENDMENTS.—

(1) The heading of subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by striking ''**Medical Devices**'' and inserting ''**Certain Medical Devices and Prescription Drugs**''.

(2) The table of subchapters for chapter 32 of such Code is amended by striking the item relating

to subchapter E and inserting the following new item:

''SUBCHAPTER E. CERTAIN MEDICAL DEVICES AND PRESCRIPTION DRUGS''.

(3) The table of sections for subchapter E of chapter 32 of such Code is amended by adding at the end the following new item:

''Sec. 4192. Prescription drugs subject to price spikes.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after the date of the enactment of this Act.

SEC. 5. APPLICATION OF MEDICARE PRICES TO OTHER INSURERS AND THE UNINSURED.

(a) FEDERAL HEALTH CARE PROGRAMS.—Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new section:

''SEC. 1150C. APPLICATION OF MEDICARE NEGOTIATED PRICES.

''(a) IN GENERAL.—Notwithstanding any other provision of law, the price recognized under a Federal health care program (as defined in section 1128B) or the insurance program established under chapter 89 of title 5, United States Code, for a specified covered part D drug (as defined in section 1860D–11(i)), or a drug or biological for which payment may be made under section 1842(o), with respect to a year for which coverage is provided under such Federal health care program or such in-

surance program may not exceed the price for such drug established under such section 1860D–11(i) or 1842(o), as applicable.

''(b) APPLICATION OF OTHER PROVISIONS.—The provisions of section 1860D–11(i) shall apply with respect to a Federal health care program and the insurance program established under chapter 89 of title 5, United States Code, in the same manner as such provisions apply with respect to a prescription drug plan or an MA–PD plan under part D or C, respectively, of title XVIII.''.

(b) PRIVATE INSURER.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.) is amended by adding at the end the following new section:

''SEC. 2730. APPLICATION OF MEDICARE NEGOTIATED PRICES.

''(a) IN GENERAL.—Notwithstanding any other provision of law, the price recognized under a group health plan, or under individual or group health insurance coverage offered by a health insurance issuer, for a specified covered part D drug (as defined in section 1860D–11(i)), or a drug or biological for which payment may be made under section 1842(o), with respect to a year for which coverage is provided under such plan or such coverage may

not exceed the price for such drug established under such section 1860D–11(i) or 1842(o), as applicable.

''(b) APPLICATION OF OTHER PROVISIONS.—The provisions of section 1860D–11(i) shall apply with respect to a group health plan, or individual or group health insurance coverage offered by a health insurance issuer, in the same manner as such provisions apply with respect to a prescription drug plan or an MA–PD plan under part D or C, respectively, of title XVIII.''.

(c) UNINSURED.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the amount that a pharmacy furnishing a drug to a specified individual (as defined in paragraph (2)) may require as payment for such drug from such individual shall not exceed the price for such drug established under section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)) (or, if applicable, under section 1842(o)(8) of such Act).

(2) DEFINITION.—For purposes of paragraph (1), the term ''specified individual'' means, with respect to a drug, an individual who is not covered, or who has no coverage with respect to such drug, under a group health plan or group or individual health insurance coverage (as such terms are defined

in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91)) or under a Federal health care program (as defined in section 1128B of the Social Security Act, but including the insurance program established under chapter 89 of title 5, United States Code).

(3) ENFORCEMENT.—The Secretary of Health and Human Services may impose a civil monetary penalty of not more than $10,000 per day on a pharmacy for a violation of paragraph (1).

SEC. 6. MANUFACTURER PROVISION OF INFORMATION.

(a) IN GENERAL.—In the case of a manufacturer of a drug or biological subject to a competitive licensing agreement under section 1860D–11(i)(5) of the Social Security Act, as added by this Act, such manufacturer shall, upon request from an entity electing to manufacture such drug or biological, provide to such entity materials, data, and information relating to the manufacture or supply of such drug or biological, including—

(1) cellular clones and hybridoma stocks;

(2) plasmids, plasmid maps, and sequences of antibody complementarity determining regions;

(3) physicochemical and biophysical characterization;

(4) growth conditions and protocols;

(5) attenuation or inactivation protocols;

(6) extraction and purification protocols;

(7) synthetic work-up and schemes;

(8) sufficient quantities of the drug or biological for testing;

(9) the protocols and methods used for testing the drug or biological; and

(10) the expected outcomes from those protocols.

(b) ENFORCEMENT.—The Secretary of Health and Human Services may impose a civil monetary penalty on a manufacturer of not more than $10,000 per day for a violation of subsection (a).

SEC. 7. APPLICABILITY OF NEGOTIATED PRICE TO PRESCRIPTION DRUGS FURNISHED BY THE DEPARTMENT OF DEFENSE AND THE DEPARTMENT OF VETERANS AFFAIRS.

(a) IN GENERAL.—Section 8126(a) of title 38, United States Code, is amended—

(1) in paragraph (2), by inserting ", but may not exceed the amount of the price negotiated by the Secretary of Health and Human Services under section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)) (as amended by the Medicare Negotiation and Competitive Licensing Act of 2019)

for a specified covered part D drug (as defined in such section) (or, if applicable, may not exceed the amount of the price negotiated by the Secretary of Health and Human Services under section 1842(o)(8) of such Act for a drug or biological payable under such section) that is a covered drug of a manufacturer'' after ''best interests of the Department or such Federal agencies''; and

(2) in paragraph (3), by inserting ''or, for a covered drug of a manufacturer that is a specified covered part D drug (as defined in section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)) (as amended by the Medicare Negotiation and Competitive Licensing Act of 2019)) or a drug or biological for which payment may be made under section 1842(o)(8) of such Act, the price negotiated by the Secretary of Health and Human Services under such section 1806D–11(i) or 1842(o)(8) (as applicable) for the specified covered part D drug or the drug or biological'' after ''the price charged under the Federal Supply Schedule at the time the drug is procured''.

(b) DEPARTMENT OF DEFENSE ELEMENTS FOR PURPOSES OF PRICING STANDARDS.—Section 1074g(f) of title 10, United States Code, is amended—

(1) in the header, by inserting ''AND NATIONAL MAIL-ORDER PHARMACY PROGRAM'' after ''PHARMACY PROGRAM'';

(2) by striking ''the TRICARE retail pharmacy program shall be treated as an element of the Department of Defense'' and inserting ''the TRICARE retail pharmacy program and the national mail-order pharmacy program shall be treated as elements of the Department of Defense''; and

(3) by striking ''provided by pharmacies under the program'' and inserting ''provided under such programs''.

SEC. 8. SPECIFIED COVERED PART D DRUGS EXCISE TAX.

(a) IN GENERAL.—Subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

''SEC. 4193. SPECIFIED COVERED PART D DRUGS.

''(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any specified covered part D drug for a price in excess of the negotiated price in violation of section 1860D–11(i)(5)(C) of the Social Security Act during any period described in such section a tax equal to 100 percent of the price for which so sold.

''(b) DEFINITIONS.—The terms 'specified covered part D drug' and 'negotiated price' have the meaning such terms have under section 1860D–11 of the Social Security Act.''.

(b) CLERICAL AMENDMENTS.—

(1) The heading of subchapter E of chapter 32 of the Internal Revenue Code of 1986 is amended by striking ''**Medical Devices**'' and inserting ''**Other Medical Products**''.

(2) The table of subchapters for chapter 32 of such Code is amended by striking the item relating to subchapter E and inserting the following new item:

''SUBCHAPTER E. OTHER MEDICAL PRODUCTS''.

(3) The table of sections for subchapter E of chapter 32 of such Code is amended by adding at the end the following new item:

''Sec. 4193. Specified covered part D drugs.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to sales on or after the date that is 1 year after the date of the enactment of this Act.

SEC. 9. DRUG MANUFACTURER REPORTING.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–7. DRUG MANUFACTURER REPORTING.

"(a) MANDATORY REPORTING.—A drug manufacturer shall submit to the Secretary and to Congress an annual report specifying with respect to the previous calendar year (except as provided in subsection (d)(2))—

"(1) the total expenditures of the manufacturer on—

"(A) domestic and foreign drug research and development, including an itemized description of—

"(i) basic and preclinical research;

"(ii) clinical research, reported separately for each clinical trial;

"(iii) development of alternative dosage forms and strengths for the drug molecule or combinations, including the molecule;

"(iv) other drug development activities, such as nonclinical laboratory studies and record and report maintenance;

"(v) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act;

"(vi) carrying out postmarket requirements related to such drug, including under section 505(o)(3) of such Act;

"(vii) carrying out risk evaluation and mitigation strategies in accordance with section 505–1 of such Act; and

"(viii) marketing research;

"(B) the acquisition of drug components and packaging, in total and per unit sold, broken out by source and cost and identifying specific costs that reflect internal transfers within the manufacturer's company;

"(C) other acquisitions relating to drugs, including for the purchase of patents and licensing or the acquisition of any corporate entity owning any rights to a drug during or after development of the drug; and

"(D) marketing, advertising, and educating for the promotion of a drug, including a breakdown of amounts aimed at consumers, prescribers, managed care organizations, and others, irrespective of whether a particular drug is mentioned in the marketing, advertising, or educating;

''(2) the gross revenue, net revenue, gross profit, and net profit of the manufacturer with respect to drugs;

''(3) the total number of units of each type of drug that were sold in interstate commerce;

''(4) pricing information with respect to the sale of drugs, including—

''(A) wholesale acquisition cost;

''(B) net average price realized by prescription drug benefit managers for drugs provided to individuals in the United States, after accounting for any rebates or other payments from the manufacturer to the pharmacy benefit manager and from the pharmacy benefit manager to the manufacturer; and

''(C) the net price of each drug, after accounting for discounts, rebates, or other financial considerations, charged to purchasers in each applicable country of the Organisation for Economic Co-operation and Development;

''(5) any Federal benefits received by the manufacturer with respect to a drug, including the amounts and periods of impact for each such benefit, including tax credits; Federal grants, including from the National Institutes of Health, the Depart-

ment of Defense, the Department of Energy, the Centers for Disease Control and Prevention, or other Federal departments or agencies; patent applications that benefitted from such grants; patent extensions; exclusivity periods; and waivers of fees;

''(6) the percentage of research and development expenditures described in clauses (i) through (v) of paragraph (1)(A) that were derived from Federal funds;

''(7) executive compensation for the chief executive officer, chief financial officer, and the 3 other most highly compensated executive officers, including bonuses, paid by such manufacturer, and stock options affiliated with the manufacturer that were offered to or accrued by such officers; and

''(8) any other information as the Secretary may require.

''(b) VOLUNTARY SUPPLEMENTAL REPORTING.—A drug manufacturer may supplement a report under subsection (a) with any additional information the manufacturer chooses to provide related to drug pricing decisions, such as—

''(1) total expenditures on drug research, drug development, and clinical trials on drugs that failed

to receive approval by the Food and Drug Administration; and

''(2) a list of drugs and drug prices of other manufacturers for purposes of comparison with the manufacturer's own drugs and drug prices.

''(c) SPECIAL RULE.—A drug manufacturer shall—

''(1) to the extent possible, disaggregate the information required to be reported by this section by the particular drug involved; and

''(2) submit all information required to be reported by this section with respect to each applicable drug in a single annual report.

''(d) SUBMISSION OF REPORTS.—

''(1) IN GENERAL.—

''(A) SUBMISSION BY DRUG MANUFACTURERS.—Drug manufacturers shall submit the annual reports required under this section to the Secretary in a usable format, as the Secretary may require.

''(B) COLLATION BY THE SECRETARY.—The Secretary shall collate the reports received as described in subparagraph (A) and submit such collated reports to Congress, together with an analysis of the reports by the Secretary that includes—

"(i) a summary of data from the reports;

"(ii) consideration of factors such as trends on research and development costs, Federal benefits, and manufacturer patient assistance programs; and

"(iii) the relationship between the factors described in clause (ii) and prescription drug prices.

"(C) PUBLIC AVAILABILITY.—The Secretary shall make the reports submitted by manufacturers as described in subparagraph (A) and the collated reports together with the analysis of the Secretary described in subparagraph (B) publicly available, including by posting such reports to the internet website of the Department of Health and Human Services, in a searchable format.

"(2) INITIAL REPORT.—

"(A) IN GENERAL.—A drug manufacturer shall submit an initial report pursuant to this section not later than one year after the date of enactment of this subparagraph (except as provided in subparagraph (B)).

"(B) REPORTING PERIOD.—Notwithstanding the requirement in subsection (a) that each report under such subsection be for the previous calendar year, the initial report of a drug manufacturer under subsection (a) shall include, for each drug marketed by the manufacturer, the information described in paragraphs (1) through (6) of subsection (a) for the calendar year period beginning with the later of—

"(i) the calendar year in which the drug was approved under section 505 of the Federal Food, Drug, and Cosmetic Act, was licensed under section 351 of this Act, or received an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3) of this Act; and

"(ii) the calendar year in which the manufacturer acquired the drug so approved, licensed, or exempted.

"(C) SMALL BUSINESSES.—In the case of a drug manufacturer that has fewer than 500 employees, the initial report required by in sub-

paragraph (A) shall be submitted by a date determined by the Secretary, which shall be—

"(i) not earlier than the deadline described in subparagraph (A); and

"(ii) not later than the date that is 3 years after the date of enactment of this clause.

"(e) AUDIT BY THIRD PARTY.—The Secretary shall select a percentage (to be determined by the Secretary) of the reports submitted under subsection (a) for a fiscal year to be audited by an accredited third-party auditor (to be selected by the Secretary).

"(f) PENALTY FOR NONCOMPLIANCE.—The Secretary shall report to the Office of the Inspector General any manufacturer's failure to submit a complete report as required under this section. Any manufacturer that fails to submit a complete report required under this section shall be subject to a civil penalty of up to $200,000 for each day on which the violation continues. The Secretary shall collect the civil penalties under this subsection and, without further appropriation, shall use such funds to support research of the National Institutes of Health.

"(g) DEFINITION.—In this section, the term 'drug manufacturer' means the manufacturer of an approved drug (including a drug approved under subsection (c) or

(j) of section 505 of the Federal Food, Drug, and Cosmetic Act and a biological product licensed under subsection (a) or (k) of section 351 of this Act).''.

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