I

116TH CONGRESS
1ST SESSION

H. R. 4010

To amend the Public Health Service Act to establish insulin assistance programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 25, 2019

Ms. CRAIG (for herself and Mr. PHILLIPS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 the Public Health Service Act to establish insulin assistance programs, 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 ''Emergency Access to Insulin Act of 2019''.

SEC. 2. INSULIN ASSISTANCE PROGRAMS.

(a) IN GENERAL.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by adding at the end the following:

"SEC. 320B. INSULIN ASSISTANCE PROGRAMS.

"(a) ESTABLISHMENT OF PROGRAM OF GRANTS TO STATES, INDIAN TRIBES, AND TRIBAL ORGANIZATIONS.—

"(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, not later than 1 year after the date of enactment of this section, make grants to States, Indian tribes, and tribal organizations for the purpose of carrying out programs to assist eligible individuals in obtaining insulin in accordance with paragraph (4).

"(2) GRANT AND CONTRACT AUTHORITY FOR STATES, INDIAN TRIBES, AND TRIBAL ORGANIZATIONS.—

"(A) IN GENERAL.—A State, Indian tribe, or tribal organization receiving a grant under paragraph (1) may, subject to subparagraph (B), expend the grant to carry out the purpose described in such paragraph through grants or contracts to public or private entities, including local governments.

"(B) CERTAIN APPLICATIONS.—If a nonprofit private entity and a private entity that is not a nonprofit entity both submit applications to a State, Indian tribe, or tribal organization

to receive an award of a grant or contract under subparagraph (A), the State, Indian tribe, or tribal organization may give priority to the application submitted by the nonprofit private entity in any case in which the State, Indian tribe, or tribal organization determines that the quality of such application is equivalent to the quality of the application submitted by the other private entity.

''(3) ALLOTMENT.—Each State, Indian tribe, or tribal organization that applies for a grant in accordance with subsection (e) shall receive a grant under this section in an amount that is equal to the sum of—

''(A) a minimum amount determined by the Secretary; and

''(B) an additional amount based on criteria established by the Secretary, which may include the ability of the State, Indian tribe, or tribal organization to successfully assist individuals in seeking eligibility for Federal or State-funded programs as described in paragraph (4)(A)(iv).

''(4) PROGRAM COMPONENTS.—

"(A) IN GENERAL.—A State, Indian tribe, or tribal organization carrying out a program supported by a grant under this subsection shall use the grant funds to—

"(i) purchase insulin;

"(ii) issue insulin cards to eligible individuals in accordance with subparagraph (B);

"(iii) enter into agreements with pharmacies—

"(I) for such pharmacies to fill prescriptions for individuals displaying valid insulin cards that are issued in accordance with subparagraph (B) at no cost to such individuals; and

"(II) for the State, Indian tribe, or tribal organization to pay such pharmacies for insulin filled for a prescription described in subclause (I); and

"(iv) assist individuals in seeking eligibility for Federal or State-funded programs which may provide coverage for insulin or otherwise assist such individuals in obtaining insulin.

"(B) INSULIN CARDS.—

"(i) APPLICATION.—An eligible individual seeking an insulin card through a program supported by a grant under this subsection shall submit an application to the State, Indian tribe, or tribal organization receiving the grant, at such time, in such manner, and containing such information as the State, Indian tribe, or tribal organization may reasonably require for purposes of this subsection, including—

"(I) documentation indicating proof of—

"(aa) in the case of a grant awarded to a State, residency in the State;

"(bb) in the case of a grant awarded to an Indian tribe, membership in the Indian tribe; or

"(cc) in the case of a grant awarded to a tribal organization, membership in the Indian tribe or Indian community served by the tribal organization;

"(II) a prescription for insulin that is prescribed to the individual;

"(III) a statement that, to the best of the individual's knowledge, the individual is an uninsured individual or an underinsured individual; and

"(IV) if the individual is an underinsured individual, the name of the high-deductible health plan in which the individual is enrolled and any unique identifier of the plan, such as a policy number.

"(ii) INITIAL CARD.—

"(I) IN GENERAL.—A State, Indian tribe, or tribal organization carrying out a program supported by a grant under this subsection shall issue an initial insulin card to each individual that submits an application to the State, Indian tribe, or tribal organization meeting the requirements under clause (i).

"(II) TIMING.—A State, Indian tribe, or tribal organization that receives an application under clause (i)

from an individual shall issue an initial insulin card to such individual not later than 5 business days after receiving such application.

''(III) SUPPLY.—An initial insulin card issued to an individual under this clause shall be valid for an approximate 7-day supply of insulin that is appropriate for the individual based on the prescription for the individual provided in the application under clause (i) and packaging and processing practices for insulin.

''(iii) 3-MONTH CARDS.—Not later than 12 business days after an individual submits an application under clause (i) to a State, Indian tribe, or tribal organization, the State, Indian tribe, or tribal organization shall—

''(I) determine whether the individual is an eligible individual; and

''(II) if the individual is an eligible individual, issue the individual an insulin card that is valid for an approximate 90-day supply of insulin

that is appropriate for the individual based on the prescription provided in the application under clause (i) and packaging and processing practices for insulin.

''(iv) RENEWAL OF CARDS.—

''(I) 3-MONTH CARDS.—An eligible individual that is issued an insulin card under clause (iii) may apply to renew such card in accordance with a process established by the State, Indian tribe, or tribal organization.

''(II) LIMITATION.—An individual that submits an application under clause (i) and is denied an insulin card under clause (ii) or (iii) may not submit another application under clause (i) for the 1-year period beginning on the date on which the individual is denied such card.

''(b) REQUIREMENT OF MATCHING FUNDS.—

''(1) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the State, Indian tribe, or tribal organization involved agrees, with respect to the costs to be incurred by the State,

Indian tribe, or tribal organization in carrying out the purpose described in subsection (a)(1), to make available non-Federal contributions (in cash or in-kind under paragraph (2)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

''(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—

''(A) IN GENERAL.—Non-Federal contributions required in paragraph (1) may be in cash or in-kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

''(B) MAINTENANCE OF EFFORT.—In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the State,

Indian tribe, or tribal organization involved toward the purpose described in subsection (a)(1) for the 2-year period preceding the first fiscal year for which the State, Indian tribe, or tribal organization is applying to receive a grant under subsection (a).

''(C) INCLUSION OF RELEVANT NON-FEDERAL CONTRIBUTIONS FOR MEDICAID.—In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary shall, subject to subparagraphs (A) and (B) of this paragraph, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act by the State, Indian tribe, or tribal organization related to insulin dispensed to individuals eligible for medical assistance under such title.

''(c) ADDITIONAL REQUIRED AGREEMENTS.—

''(1) STATEWIDE PROVISION OF SERVICES.—

''(A) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the State, Indian tribe, or tribal organization involved agrees that services and activities under the grant will be made available throughout the State (including availability to members

of any Indian tribe or tribal organization in the State), Indian tribe, or tribal organization.

''(B) WAIVER.—

''(i) IN GENERAL.—The Secretary may waive the requirement established in subparagraph (A) for a State, Indian tribe, or tribal organization if the Secretary determines that compliance by the State, Indian tribe, or tribal organization with the requirement would result in an inefficient allocation of resources with respect to carrying out the purpose described in subsection (a)(1).

''(ii) INDIAN TRIBES AND TRIBAL ORGANIZATIONS.—If an Indian tribe or tribal organization is receiving a grant under subsection (a) and the State in which the tribe or organization is located is receiving a grant under subsection (a), the requirement under subparagraph (A) for the State regarding availability to the tribe or organization is deemed to have been waived under this subparagraph.

''(2) RELATIONSHIP TO ITEMS AND SERVICES UNDER OTHER PROGRAMS.—

"(A) IN GENERAL.—The Secretary may not make a grant under subsection (a) unless the State, Indian tribe, or tribal organization involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

"(i) except as provided in subparagraph (B), under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

"(ii) by an entity that provides health services on a prepaid basis.

"(B) EXCEPTION.—The requirement under subparagraph (A)(i) shall not apply with respect to coverage under a high-deductible health plan.

"(3) LIMITATION ON ADMINISTRATIVE EXPENSES.—The Secretary may not make a grant under subsection (a) unless the State, Indian tribe, or tribal organization involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

''(4) RECORDS AND AUDITS.—The Secretary may not make a grant under subsection (a) unless the State, Indian tribe, or tribal organization involved agrees that—

''(A) the State, Indian tribe, or tribal organization will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State, Indian tribe, or tribal organization under such subsection;

''(B) upon request, the State, Indian tribe, or tribal organization will provide records maintained pursuant to subparagraph (A) to the Secretary or the Comptroller General of the United States for purposes of auditing the expenditures by the State, Indian tribe, or tribal organization of the grant; and

''(C) the State, Indian tribe, or tribal organization will keep such records as the Secretary shall prescribe, including—

''(i) records that fully disclose—

''(I) the amount and disposition by the State, Indian tribe, or tribal

organization of the proceeds of such grant;

''(II) the total cost of the project or undertaking intended to be carried out through the grant; and

''(III) the amount of that portion of the cost of the project or undertaking supplied by sources other than the grant; and

''(ii) such other records as the Secretary determines appropriate for facilitating an effective audit of grants awarded under this section.

''(5) REPORTS.—

''(A) REPORTS TO THE SECRETARY.—The Secretary may not make a grant under subsection (a) unless the State, Indian tribe, or tribal organization involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant, including a report on—

''(i) the types of problems and inquiries encountered by individuals applying for or receiving insulin through a program supported by such grant;

"(ii) the number of insulin products dispensed and the unit costs for those products during the period covered by the report;

"(iii) the number of pharmacies participating in the program during the period covered by the report;

"(iv) summary data on the individuals applying for or receiving insulin through the program; and

"(v) any other information the Secretary shall determine necessary to provide oversight of the grants made under this section.

"(B) HIGH-DEDUCTIBLE HEALTH PLANS.—The Secretary may not make a grant under subsection (a) unless the State, Indian tribe, or tribal organization involved agrees to, as soon as practicable after each time the State, Indian tribe, or tribal organization provides payment to a pharmacy for insulin for an underinsured individual, submit to the high-deductible health plan in which the individual is enrolled information on the amount of such

payment in order for such plan to comply with the requirements under section 2710.

''(d) DESCRIPTION OF INTENDED USES OF GRANT.—The Secretary may not make a grant under subsection (a) unless—

''(1) the State, Indian tribe, or tribal organization involved submits to the Secretary a description of the purposes for which the State, Indian tribe, or tribal organization intends to expend the grant;

''(2) the description identifies the populations, areas, and localities in the State, or under the jurisdiction of the Indian tribe or tribal organization, with a need for a program to assist individuals in obtaining insulin in accordance with subsection (a);

''(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or private entities; and

''(4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

''(e) REQUIREMENT OF SUBMISSION OF APPLICATION.—The Secretary may not make a grant under sub-

section (a) unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required under subsection (d), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(f) TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

''(1) TECHNICAL ASSISTANCE.—The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to subsection (a). The Secretary may provide such technical assistance directly or through grants to, or contracts with, public or private entities.

''(2) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF GRANT FUNDS.—

''(A) IN GENERAL.—Upon the request of a State, Indian tribe, or tribal organization receiving a grant under subsection (a), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the State, Indian tribe, or tribal organization in carrying out such sub-

section and, for such purpose, may detail to the State, Indian tribe, or tribal organization any officer or employee of the Department of Health and Human Services.

''(B) CORRESPONDING REDUCTION IN PAYMENTS.—With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the grant under subsection (a) to the State, Indian tribe, or tribal organization involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

''(g) EVALUATIONS AND REPORTS.—

''(1) EVALUATIONS.—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to subsection (a). Such evaluations shall include evaluations of—

''(A) the extent to which States, Indian tribes, and tribal organizations carrying out

such programs are in compliance with subsection (a) and with subsection (c)(1); and

"(B) the extent to which each State, Indian tribe, or tribal organization receiving a grant under this section is in compliance with subsection (b), including identification of—

"(i) the amount of the non-Federal contributions by the State, Indian tribe, or tribal organization for the preceding fiscal year, disaggregated according to the source of the contributions; and

"(ii) the proportion of such amount of non-Federal contributions relative to the amount of Federal funds provided through the grant to the State, Indian tribe, or tribal organization for the preceding fiscal year.

"(2) REPORTS TO CONGRESS.—The Secretary shall, not later than 1 year after the date of the enactment of the Emergency Access to Insulin Act of 2019, and annually thereafter, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report summarizing evaluations carried out under para-

graph (1) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this section as the Secretary determines to be appropriate, including recommendations regarding compliance by the States, Indian tribes, and tribal organizations with subsection (a) and with subsection (c)(1).

''(h) FUNDING FOR GENERAL PROGRAM.—

''(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

''(2) SET-ASIDE FOR TECHNICAL ASSISTANCE AND PROVISION OF SUPPLIES AND SERVICES.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out subsection (f).

''(i) SUNSET.—The authority to award grants under subsection (a) shall be effective beginning on the date of enactment of the Emergency Access to Insulin Act of 2019 and ending on the date that is 5 years after such date.

''(j) DEFINITIONS.—For purposes of this section:

''(1) ELIGIBLE INDIVIDUAL.—The term 'eligible individual', with respect to a program supported by a State, Indian tribe, or tribal organization receiving

a grant under this section, means an uninsured individual or an underinsured individual—

"(A)(i) in the case of a grant to a State, who is a resident of the State;

"(ii) in the case of a grant to an Indian tribe, who is a member of such tribe; or

"(iii) in the case of a grant to a tribal organization, who is a member of the Indian tribe or Indian community served by the tribal organization; and

"(B) who has a valid prescription for insulin that is prescribed to such individual.

"(2) GROUP HEALTH INSURANCE COVERAGE; GROUP HEALTH PLAN; HEALTH INSURANCE ISSUER.—The terms 'group health insurance coverage', 'group health plan', and 'health insurance issuer' have the meanings given such terms in section 2791.

"(3) HIGH-DEDUCTIBLE HEALTH PLAN.—The term 'high-deductible health plan' means a group health plan or group or individual health insurance coverage (offered by a health insurance issuer) that meets criteria established by the Secretary.

"(4) INDIAN TRIBE.—The term 'Indian tribe' has the meaning given such term in section 4 of the

Indian Health Care Improvement Act (25 U.S.C. 1603).

''(5) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The term 'individual health insurance coverage' has the meaning given such term in section 2791.

''(6) TRIBAL ORGANIZATION.—The term 'tribal organization' has the meaning given such term in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

''(7) UNDERINSURED INDIVIDUAL.—The term 'underinsured individual' means an individual who is enrolled in a high-deductible health plan.

''(8) UNINSURED INDIVIDUAL.—The term 'uninsured individual' means an individual who does not have minimum essential coverage as defined in section 5000A(f)(1) of the Internal Revenue Code of 1986 or coverage under a medical care program of the Indian Health Service or of a tribal organization or urban Indian organization.

''(9) URBAN INDIAN ORGANIZATION.—The term 'urban Indian organization' has the meaning given such term in section 4 of the Indian Health Care Improvement Act.''.

(b) EXEMPTING PRICES USED UNDER AN INSULIN ASSISTANCE PROGRAM FROM BEST PRICE AND AVERAGE MANUFACTURER PRICE UNDER THE MEDICAID DRUG REBATE PROGRAM.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(1) in subsection (c)(1)(C)(i)(III), by inserting ''or under an insulin assistance program supported under section 320B of the Public Health Service Act'' after ''State pharmaceutical assistance program''; and

(2) in subsection (k)(1)(B)(i)—

(A) in subclause (IV), by striking ''; and'' and inserting a semicolon;

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

(C) by adding at the end the following new subclause:

''(VI) any prices used under an insulin assistance program supported under section 320B of the Public Health Service Act.''.

(c) DEDUCTIBLES FOR UNDERINSURED INDIVIDUALS PARTICIPATING IN INSULIN ASSISTANCE PROGRAMS.—Subpart I of part A of title XXVII of the Public Health

Service Act (42 U.S.C. 300gg et seq.) is amended by adding at the end the following:

"SEC. 2710. DEDUCTIBLES FOR UNDERINSURED INDIVIDUALS PARTICIPATING IN INSULIN ASSISTANCE PROGRAMS.

"(a) IN GENERAL.—A group health plan that is a high-deductible health plan and a health insurance issuer offering a high-deductible health plan shall, with respect to any individual who is enrolled in such plan and obtains insulin during a plan year through an insulin card issued to the individual by a State, Indian tribe, or tribal organization carrying out an insulin assistance program under section 320B, count the amount the State, Indian tribe, or tribal organization pays a pharmacy for insulin for such individual for such plan year towards any deductible or other out-of-pocket expenses required to be paid under the plan.

"(b) HIGH-DEDUCTIBLE HEALTH PLAN.—For purposes of this section, the term 'high-deductible health plan' has the meaning given such term in section 320B(j).".

SEC. 3. ANNUAL FEES APPLICABLE TO INSULIN MANUFACTURERS.

(a) DEFINITIONS.—For purposes of this section:

(1) ANNUAL PAYMENT DATE.—The term "annual payment" date means, with respect to a cal-

endar year, the date determined by the Secretary, but in no event later than September 30 of such calendar year.

(2) COVERED ENTITY.—The term ''covered entity'', with respect to a calendar year, means an entity that—

(A) is the holder of an application approved under subsection (c) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or of a license issued under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262), for an insulin product; and

(B) during the preceding calendar year, manufactured any insulin product that was sold in commerce and covered by a Federal health program at least once during such preceding calendar year.

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

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(b) IMPOSITION OF FEE.—Each covered entity for a calendar year, beginning in 2020 and ending in 2024,

shall pay to the Secretary not later than the annual payment date of such calendar year a fee in an amount determined under subsection (c).

(c) AMOUNT OF FEES.—

(1) TOTAL AMOUNT.—The Secretary shall ensure that the total amount in fees assessed under subsection (b)—

(A) for calendar year 2020, equals the total amount the Secretary estimates as the total expenditures for carrying out section 320B of the Public Health Service Act for such calendar year; and

(B) for each of calendar years 2021 through 2024, equals the total amount of expenditures the Secretary determines for carrying out such section for the preceding calendar year.

(2) DETERMINATION OF FEES FOR EACH MANUFACTURER.—

(A) FORMULA.—With respect to each covered entity, the fee under this section for a calendar year shall be equal to an amount that bears the same ratio to the total amount assessed under subsection (b) for such year as the covered entity's sales of insulin products taken

into account during the preceding calendar year, bears to the aggregate sales of insulin products of all covered entities taken into account during such preceding calendar year.

(B) SALES OF INSULIN PRODUCTS.—

(i) IN GENERAL.—For purposes of this paragraph, the sales of insulin products taken into account during any calendar year with respect to any covered entity shall be determined based on the total number of units of the insulin product which were sold in commerce in the preceding calendar year based on—

(I) for a fee assessed for calendar year 2020, information obtained by the Secretary under clause (ii); and

(II) for a fee assessed for each of calendar years 2021 through 2024, the information provided in the annual reports issued by the Inspector General and made public under section 4(e)(1).

(ii) FEES ASSESSED FOR CALENDAR YEAR 2020.—For purposes of clause (i)(I), the Secretary shall require each covered

entity to submit to the Secretary information on the total number of units of the insulin product manufactured by the entity that were sold in commerce in calendar year 2019.

(d) DEPOSIT.—The Secretary shall deposit amounts received through fees assessed under subsection (b) into the general fund of the Treasury.

(e) ENFORCEMENT.—The Secretary may bring an action in any court of competent jurisdiction to recover the amount of any fee that is assessed under subsection (b) for a calendar year and not paid by the annual payment date.

SEC. 4. IDENTIFICATION OF INSULIN PRICE SPIKES; APPLICATION OF EXCISE TAX.

(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 an insulin product.

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

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

(4) PRICE SPIKE.—

(A) IN GENERAL.—The term ''price spike'' means an increase in the wholesale acquisition cost in commerce of an insulin product for which the price spike percentage is equal to or greater than the applicable price increase allowance.

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

(i) the wholesale acquisition cost of an insulin product in commerce for the calendar year; exceeds

(ii) the wholesale acquisition cost of such insulin product 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 (round-

ed 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.

(5) 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 (4)(B) and clause (ii) of such paragraph; and

(ii) the total number of units of the insulin product 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 insulin product subject to the price spike.

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

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

(A) For each insulin product of the applicable entity—

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

(ii) the average and median wholesale acquisition cost per unit of such insulin product in commerce in the preceding calendar quarter, disaggregated by month; and

(iii) the gross revenues from sales of such insulin product 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 an insulin product, 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 insulin product described in subparagraph (A) for the preceding calendar year; and

(II) not greater than 1 percent of the gross revenues from sales of such insulin product 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 insulin products in the preceding calendar year; and

(B) in the case of any insulin product 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 insulin product be exempted from application of the tax imposed under section 4192 of the Internal Revenue Code of 1986 (as added by subsection (g)) for such year.

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

(A) Identification of each price spike relating to an insulin product 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 INSULIN PRODUCTS.—

(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 insulin product 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, based on information submitted pursuant to subsection (b)(1)(B), a for-cause price increase exemption should apply.

(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 insulin product 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) REPORTS BY INSPECTOR GENERAL.—

(1) PUBLIC REPORT.—

(A) IN GENERAL.—Not later than the last day in February of each year, subject to subparagraph (C), the Inspector General shall issue a report containing the information described in subparagraph (B) to be made available to the public, including on the Internet website of the Inspector General.

(B) CONTENTS.—The report issued under subparagraph (A) shall include the following:

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

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

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

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

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

(2) REPORT TO INTERNAL REVENUE SERVICE.—

(A) IN GENERAL.—Subject to subparagraph (C), 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.

(B) CONTENTS.—The report transmitted under subparagraph (A) shall include the information described in paragraph (1)(B).

(C) NOTICE AND OPPORTUNITY FOR HEARING.—

(i) IN GENERAL.—No report shall be transmitted to the Internal Revenue Service under subparagraph (A) with respect to an insulin product unless the Inspector General has provided the applicable entity with—

(I) the assessment of such insulin product under subsection (c)(1)(A); and

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

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

(iii) REQUEST FOR HEARING.—Subject to clause (v), 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 clause (ii) is received.

(iv) COMPLETION OF HEARING.—In the case of an applicable entity which requests a hearing pursuant to clause (iii), 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 the accuracy of such assessment; and

(II) provide the report described in subparagraph (B) to the Internal Revenue Service.

(v) LIMITATION.—An applicable entity may request a hearing under clause (iii) with respect to a particular insulin product only once within a 5-year period.

(f) NOTIFICATION.—The Secretary of the Treasury shall notify, at such time and in such manner as the Secretary of the Treasury shall provide, each applicable entity in regard to any insulin product which has been deter-

mined 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.

(g) EXCISE TAX ON INSULIN PRODUCTS SUBJECT TO PRICE SPIKES.—

(1) 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. INSULIN PRODUCTS SUBJECT TO PRICE SPIKES.

''(a) IMPOSITION OF TAX.—

''(1) IN GENERAL.—Subject to paragraph (3), for each taxable insulin product 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 insulin product, or

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

''(2) LIMITATION.—In the case of a taxable insulin product 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 insulin product pursuant to section 4(d) of the Emergency Access to Insulin Act of 2019, the amount of the tax determined under paragraph (1) for such insulin product 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 insulin product 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 insulin product which has been subject to a price spike percentage greater than the applicable price increase allowance (as defined in section 4(a)(4)(C) of the Emergency Access to Insulin Act of 2019) but less than 15 percent, 50 percent,

"(B) in the case of a taxable insulin product 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 insulin product 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 insulin product 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 insulin product which has been subject to a cumulative price spike percentage greater than the cumulative price increase allowance but less than the first multi-year percentage, 50 percent,

"(ii) in the case of a taxable insulin product 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 insulin product 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 wholesale acquisition cost of the taxable insulin product in commerce for the preceding calendar year, exceeds

"(ii) the wholesale acquisition cost of such insulin product in commerce for the base year.

"(C) CUMULATIVE PRICE INCREASE ALLOWANCE.—For purposes of clause (i) of subparagraph (A), the cumulative 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)) 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	20.0	25.0
4 years	22.5	27.5
5 years	25.0	30.0.

"(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 insulin product 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 insulin product 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 wholesale acquisition cost of such insulin product in commerce for the preceding calendar year, minus

"(II) the wholesale acquisition cost of such insulin product in commerce for the base year, and

"(ii) the total number of units of such insulin product 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 4(a)(5)(C) of the Emergency Access to

Insulin Act of 2019 for each calendar year during the applicable period.

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

''(1) TAXABLE INSULIN PRODUCT.—The term 'taxable insulin product' means an insulin product which has been identified by the Inspector General of the Department of Health and Human Services, under section 4(c)(2)(A) of the Emergency Access to Insulin Act of 2019, as being subject to a price spike.

''(2) OTHER TERMS.—The terms 'applicable entity', 'price spike', 'price spike percentage', and 'price spike revenue' have the same meaning given such terms under section 4(a) of the Emergency Access to Insulin Act of 2019.''.

(2) CLERICAL AMENDMENTS.—

(A) 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 Insulin Products**''.

(B) 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 INSULIN PRODUCTS''.

(C) 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. Insulin products subject to price spikes.".

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

SEC. 5. BIOLOGICAL PRODUCT EXCLUSIVITY.

(a) IN GENERAL.—Section 351(k)(7)(A) of the Public Health Service Act (42 U.S.C. 262(k)(7)(A)) is amended by striking "12 years" and inserting "7 years".

(b) CONFORMING AMENDMENTS.—Paragraphs (2)(A) and (3)(A) of section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) is amended by striking "12 years" each place it appears and inserting "7 years".

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