

116TH CONGRESS
1ST SESSION

S. 2004

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

IN THE SENATE OF THE UNITED STATES

JUNE 27, 2019

Ms. SMITH (for herself and Mr. CRAMER) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Emergency Access to
5 Insulin Act of 2019”.

6 **SEC. 2. INSULIN ASSISTANCE PROGRAMS.**

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

1 **“SEC. 320B. INSULIN ASSISTANCE PROGRAMS.**

2 “(a) ESTABLISHMENT OF PROGRAM OF GRANTS TO
3 STATES, INDIAN TRIBES, AND TRIBAL ORGANIZA-
4 TIONS.—

5 “(1) IN GENERAL.—The Secretary, acting
6 through the Director of the Centers for Disease
7 Control and Prevention, shall, not later than 1 year
8 after the date of enactment of this section, make
9 grants to States, Indian tribes, and tribal organiza-
10 tions for the purpose of carrying out programs to as-
11 sist eligible individuals in obtaining insulin in ac-
12 cordance with paragraph (4).

13 “(2) GRANT AND CONTRACT AUTHORITY FOR
14 STATES, INDIAN TRIBES, AND TRIBAL ORGANIZA-
15 TIONS.—

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

23 “(B) CERTAIN APPLICATIONS.—If a non-
24 profit private entity and a private entity that is
25 not a nonprofit entity both submit applications
26 to a State, Indian tribe, or tribal organization

1 to receive an award of a grant or contract
2 under subparagraph (A), the State, Indian
3 tribe, or tribal organization may give priority to
4 the application submitted by the nonprofit pri-
5 vate entity in any case in which the State, In-
6 dian tribe, or tribal organization determines
7 that the quality of such application is equiva-
8 lent to the quality of the application submitted
9 by the other private entity.

10 “(3) ALLOTMENT.—Each State, Indian tribe,
11 or tribal organization that applies for a grant in ac-
12 cordance with subsection (e) shall receive a grant
13 under this section in an amount that is equal to the
14 sum of—

15 “(A) a minimum amount determined by
16 the Secretary; and

17 “(B) an additional amount based on cri-
18 teria established by the Secretary, which may
19 include the ability of the State, Indian tribe, or
20 tribal organization to successfully assist individ-
21 uals in seeking eligibility for Federal or State-
22 funded programs as described in paragraph
23 (4)(A)(iv).

24 “(4) PROGRAM COMPONENTS.—

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

5 “(i) purchase insulin;

6 “(ii) issue insulin cards to eligible in-
7 dividuals in accordance with subparagraph
8 (B);

9 “(iii) enter into agreements with phar-
10 macies—

11 “(I) for such pharmacies to fill
12 prescriptions for individuals displaying
13 valid insulin cards that are issued in
14 accordance with subparagraph (B) at
15 no cost to such individuals; and

16 “(II) for the State, Indian tribe,
17 or tribal organization to pay such
18 pharmacies for insulin filled for a pre-
19 scription described in subclause (I);
20 and

21 “(iv) assist individuals in seeking eli-
22 gibility for Federal or State-funded pro-
23 grams which may provide coverage for in-
24 sulin or otherwise assist such individuals in
25 obtaining insulin.

1 “(B) INSULIN CARDS.—

2 “(i) APPLICATION.—An eligible indi-
3 vidual seeking an insulin card through a
4 program supported by a grant under this
5 subsection shall submit an application to
6 the State, Indian tribe, or tribal organiza-
7 tion receiving the grant, at such time, in
8 such manner, and containing such infor-
9 mation as the State, Indian tribe, or tribal
10 organization may reasonably require for
11 purposes of this subsection, including—

12 “(I) documentation indicating
13 proof of—

14 “(aa) in the case of a grant
15 awarded to a State, residency in
16 the State;

17 “(bb) in the case of a grant
18 awarded to an Indian tribe, mem-
19 bership in the Indian tribe; or

20 “(cc) in the case of a grant
21 awarded to a tribal organization,
22 membership in the Indian tribe
23 or Indian community served by
24 the tribal organization;

1 “(II) a prescription for insulin
2 that is prescribed to the individual;

3 “(III) a statement that, to the
4 best of the individual’s knowledge, the
5 individual is an uninsured individual
6 or an underinsured individual; and

7 “(IV) if the individual is an
8 underinsured individual, the name of
9 the high-deductible health plan in
10 which the individual is enrolled and
11 any unique identifier of the plan, such
12 as a policy number.

13 “(ii) INITIAL CARD.—

14 “(I) IN GENERAL.—A State, In-
15 dian tribe, or tribal organization car-
16 rying out a program supported by a
17 grant under this subsection shall issue
18 an initial insulin card to each indi-
19 vidual that submits an application to
20 the State, Indian tribe, or tribal orga-
21 nization meeting the requirements
22 under clause (i).

23 “(II) TIMING.—A State, Indian
24 tribe, or tribal organization that re-
25 ceives an application under clause (i)

1 from an individual shall issue an ini-
2 tial insulin card to such individual not
3 later than 5 business days after re-
4 ceiving such application.

5 “(III) SUPPLY.—An initial insu-
6 lin card issued to an individual under
7 this clause shall be valid for an ap-
8 proximate 7-day supply of insulin that
9 is appropriate for the individual based
10 on the prescription for the individual
11 provided in the application under
12 clause (i) and packaging and proc-
13 essing practices for insulin.

14 “(iii) 3-MONTH CARDS.—Not later
15 than 12 business days after an individual
16 submits an application under clause (i) to
17 a State, Indian tribe, or tribal organiza-
18 tion, the State, Indian tribe, or tribal orga-
19 nization shall—

20 “(I) determine whether the indi-
21 vidual is an eligible individual; and

22 “(II) if the individual is an eligi-
23 ble individual, issue the individual an
24 insulin card that is valid for an ap-
25 proximate 90-day supply of insulin

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

6 “(iv) RENEWAL OF CARDS.—

7 “(I) 3-MONTH CARDS.—An eligi-
8 ble individual that is issued an insulin
9 card under clause (iii) may apply to
10 renew such card in accordance with a
11 process established by the State, In-
12 dian tribe, or tribal organization.

13 “(II) LIMITATION.—An indi-
14 vidual that submits an application
15 under clause (i) and is denied an insu-
16 lin card under clause (ii) or (iii) may
17 not submit another application under
18 clause (i) for the 1-year period begin-
19 ning on the date on which the indi-
20 vidual is denied such card.

21 “(b) REQUIREMENT OF MATCHING FUNDS.—

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

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

9 “(2) DETERMINATION OF AMOUNT OF NON-
10 FEDERAL CONTRIBUTION.—

11 “(A) IN GENERAL.—Non-Federal contribu-
12 tions required in paragraph (1) may be in cash
13 or in kind, fairly evaluated, including equipment
14 or services (and excluding indirect or overhead
15 costs). Amounts provided by the Federal Gov-
16 ernment, or services assisted or subsidized to
17 any significant extent by the Federal Govern-
18 ment, may not be included in determining the
19 amount of such non-Federal contributions.

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

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

7 “(C) INCLUSION OF RELEVANT NON-FED-
8 ERAL CONTRIBUTIONS FOR MEDICAID.—In
9 making a determination of the amount of non-
10 Federal contributions for purposes of paragraph
11 (1), the Secretary shall, subject to subpara-
12 graphs (A) and (B) of this paragraph, include
13 any non-Federal amounts expended pursuant to
14 title XIX of the Social Security Act by the
15 State, Indian tribe, or tribal organization re-
16 lated to insulin dispensed to individuals eligible
17 for medical assistance under such title.

18 “(c) ADDITIONAL REQUIRED AGREEMENTS.—

19 “(1) STATEWIDE PROVISION OF SERVICES.—

20 “(A) IN GENERAL.—The Secretary may
21 not make a grant under subsection (a) unless
22 the State, Indian tribe, or tribal organization
23 involved agrees that services and activities
24 under the grant will be made available through-
25 out the State (including availability to members

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

3 “(B) WAIVER.—

4 “(i) IN GENERAL.—The Secretary
5 may waive the requirement established in
6 subparagraph (A) for a State, Indian tribe,
7 or tribal organization if the Secretary de-
8 termines that compliance by the State, In-
9 dian tribe, or tribal organization with the
10 requirement would result in an inefficient
11 allocation of resources with respect to car-
12 rying out the purpose described in sub-
13 section (a)(1).

14 “(ii) INDIAN TRIBES AND TRIBAL OR-
15 GANIZATIONS.—If an Indian tribe or tribal
16 organization is receiving a grant under
17 subsection (a) and the State in which the
18 tribe or organization is located is receiving
19 a grant under subsection (a), the require-
20 ment under subparagraph (A) for the
21 State regarding availability to the tribe or
22 organization is deemed to have been
23 waived under this subparagraph.

24 “(2) RELATIONSHIP TO ITEMS AND SERVICES
25 UNDER OTHER PROGRAMS.—

1 “(A) IN GENERAL.—The Secretary may
2 not make a grant under subsection (a) unless
3 the State, Indian tribe, or tribal organization
4 involved agrees that the grant will not be ex-
5 pended to make payment for any item or serv-
6 ice to the extent that payment has been made,
7 or can reasonably be expected to be made, with
8 respect to such item or service—

9 “(i) except as provided in subpara-
10 graph (B), under any State compensation
11 program, under an insurance policy, or
12 under any Federal or State health benefits
13 program; or

14 “(ii) by an entity that provides health
15 services on a prepaid basis.

16 “(B) EXCEPTION.—The requirement under
17 subparagraph (A)(i) shall not apply with re-
18 spect to coverage under a high-deductible health
19 plan.

20 “(3) LIMITATION ON ADMINISTRATIVE EX-
21 PENSES.—The Secretary may not make a grant
22 under subsection (a) unless the State, Indian tribe,
23 or tribal organization involved agrees that not more
24 than 10 percent of the grant will be expended for
25 administrative expenses with respect to the grant.

1 “(4) RECORDS AND AUDITS.—The Secretary
2 may not make a grant under subsection (a) unless
3 the State, Indian tribe, or tribal organization in-
4 volved agrees that—

5 “(A) the State, Indian tribe, or tribal orga-
6 nization will establish such fiscal control and
7 fund accounting procedures as may be nec-
8 essary to ensure the proper disbursal of, and
9 accounting for, amounts received by the State,
10 Indian tribe, or tribal organization under such
11 subsection;

12 “(B) upon request, the State, Indian tribe,
13 or tribal organization will provide records main-
14 tained pursuant to subparagraph (A) to the
15 Secretary or the Comptroller General of the
16 United States for purposes of auditing the ex-
17 penditures by the State, Indian tribe, or tribal
18 organization of the grant; and

19 “(C) the State, Indian tribe, or tribal orga-
20 nization will keep such records as the Secretary
21 shall prescribe, including—

22 “(i) records that fully disclose—

23 “(I) the amount and disposition
24 by the State, Indian tribe, or tribal

1 organization of the proceeds of such
2 grant;

3 “(II) the total cost of the project
4 or undertaking intended to be carried
5 out through the grant; and

6 “(III) the amount of that portion
7 of the cost of the project or under-
8 taking supplied by sources other than
9 the grant; and

10 “(ii) such other records as the Sec-
11 retary determines appropriate for facili-
12 tating an effective audit of grants awarded
13 under this section.

14 “(5) REPORTS.—

15 “(A) REPORTS TO THE SECRETARY.—The
16 Secretary may not make a grant under sub-
17 section (a) unless the State, Indian tribe, or
18 tribal organization involved agrees to submit to
19 the Secretary such reports as the Secretary
20 may require with respect to the grant, including
21 a report on—

22 “(i) the types of problems and inquir-
23 ies encountered by individuals applying for
24 or receiving insulin through a program
25 supported by such grant;

1 “(ii) the number of insulin products
2 dispensed and the unit costs for those
3 products during the period covered by the
4 report;

5 “(iii) the number of pharmacies par-
6 ticipating in the program during the period
7 covered by the report;

8 “(iv) summary data on the individuals
9 applying for or receiving insulin through
10 the program; and

11 “(v) any other information the Sec-
12 retary shall determine necessary to provide
13 oversight of the grants made under this
14 section.

15 “(B) HIGH-DEDUCTIBLE HEALTH
16 PLANS.—The Secretary may not make a grant
17 under subsection (a) unless the State, Indian
18 tribe, or tribal organization involved agrees to,
19 as soon as practicable after each time the State,
20 Indian tribe, or tribal organization provides
21 payment to a pharmacy for insulin for an
22 underinsured individual, submit to the high-de-
23 ductible health plan in which the individual is
24 enrolled information on the amount of such

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

3 “(d) DESCRIPTION OF INTENDED USES OF
4 GRANT.—The Secretary may not make a grant under sub-
5 section (a) unless—

6 “(1) the State, Indian tribe, or tribal organiza-
7 tion involved submits to the Secretary a description
8 of the purposes for which the State, Indian tribe, or
9 tribal organization intends to expend the grant;

10 “(2) the description identifies the populations,
11 areas, and localities in the State, or under the juris-
12 diction of the Indian tribe or tribal organization,
13 with a need for a program to assist individuals in
14 obtaining insulin in accordance with subsection (a);

15 “(3) the description provides information relat-
16 ing to the services and activities to be provided, in-
17 cluding a description of the manner in which the
18 services and activities will be coordinated with any
19 similar services or activities of public or private enti-
20 ties; and

21 “(4) the description provides assurances that
22 the grant funds will be used in the most cost-effec-
23 tive manner.

24 “(e) REQUIREMENT OF SUBMISSION OF APPLICA-
25 TION.—The Secretary may not make a grant under sub-

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

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

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

17 “(2) PROVISION OF SUPPLIES AND SERVICES IN
18 LIEU OF GRANT FUNDS.—

19 “(A) IN GENERAL.—Upon the request of a
20 State, Indian tribe, or tribal organization re-
21 ceiving a grant under subsection (a), the Sec-
22 retary may, subject to subparagraph (B), pro-
23 vide supplies, equipment, and services for the
24 purpose of aiding the State, Indian tribe, or
25 tribal organization in carrying out such sub-

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

5 “(B) CORRESPONDING REDUCTION IN PAY-
6 MENTS.—With respect to a request described in
7 subparagraph (A), the Secretary shall reduce
8 the amount of payments under the grant under
9 subsection (a) to the State, Indian tribe, or
10 tribal organization involved by an amount equal
11 to the costs of detailing personnel (including
12 pay, allowances, and travel expenses) and the
13 fair market value of any supplies, equipment, or
14 services provided by the Secretary. The Sec-
15 retary shall, for the payment of expenses in-
16 curred in complying with such request, expend
17 the amounts withheld.

18 “(g) EVALUATIONS AND REPORTS.—

19 “(1) EVALUATIONS.—The Secretary shall, di-
20 rectly or through contracts with public or private en-
21 tities, provide for annual evaluations of programs
22 carried out pursuant to subsection (a). Such evalua-
23 tions shall include evaluations of—

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

1 such programs are in compliance with sub-
2 section (a) and with subsection (c)(1); and

3 “(B) the extent to which each State, In-
4 dian tribe, or tribal organization receiving a
5 grant under this section is in compliance with
6 subsection (b), including identification of—

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

12 “(ii) the proportion of such amount of
13 non-Federal contributions relative to the
14 amount of Federal funds provided through
15 the grant to the State, Indian tribe, or
16 tribal organization for the preceding fiscal
17 year.

18 “(2) REPORTS TO CONGRESS.—The Secretary
19 shall, not later than 1 year after the date of the en-
20 actment of the Emergency Access to Insulin Act of
21 2019, and annually thereafter, submit to the Com-
22 mittee on Health, Education, Labor, and Pensions
23 of the Senate and the Committee on Energy and
24 Commerce of the House of Representatives a report
25 summarizing evaluations carried out under para-

1 graph (1) during the preceding fiscal year and mak-
2 ing such recommendations for administrative and
3 legislative initiatives with respect to this section as
4 the Secretary determines to be appropriate, includ-
5 ing recommendations regarding compliance by the
6 States, Indian tribes, and tribal organizations with
7 subsection (a) and with subsection (c)(1).

8 “(h) FUNDING FOR GENERAL PROGRAM.—

9 “(1) AUTHORIZATION OF APPROPRIATIONS.—

10 For the purpose of carrying out this section, there
11 are authorized to be appropriated such sums as may
12 be necessary.

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

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

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

23 “(1) ELIGIBLE INDIVIDUAL.—The term ‘eligible
24 individual’, with respect to a program supported by
25 a State, Indian tribe, or tribal organization receiving

1 a grant under this section, means an uninsured indi-
 2 vidual or an underinsured individual—

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

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

7 “(iii) in the case of a grant to a tribal or-
 8 ganization, who is a member of the Indian tribe
 9 or Indian community served by the tribal orga-
 10 nization; and

11 “(B) who has a valid prescription for insu-
 12 lin that is prescribed to such individual.

13 “(2) GROUP HEALTH INSURANCE COVERAGE;
 14 GROUP HEALTH PLAN; HEALTH INSURANCE
 15 ISSUER.—The terms ‘group health insurance cov-
 16 erage’, ‘group health plan’, and ‘health insurance
 17 issuer’ have the meanings given such terms in sec-
 18 tion 2791.

19 “(3) HIGH-DEDUCTIBLE HEALTH PLAN.—The
 20 term ‘high-deductible health plan’ means a group
 21 health plan or group or individual health insurance
 22 coverage (offered by a health insurance issuer) that
 23 meets criteria established by the Secretary.

24 “(4) INDIAN TRIBE.—The term ‘Indian tribe’
 25 has the meaning given such term in section 4 of the

1 Indian Health Care Improvement Act (25 U.S.C.
2 1603).

3 “(5) INDIVIDUAL HEALTH INSURANCE COV-
4 ERAGE.—The term ‘individual health insurance cov-
5 erage’ has the meaning given such term in section
6 2791.

7 “(6) TRIBAL ORGANIZATION.—The term ‘tribal
8 organization’ has the meaning given such term in
9 section 4 of the Indian Health Care Improvement
10 Act (25 U.S.C. 1603).

11 “(7) UNDERINSURED INDIVIDUAL.—The term
12 ‘underinsured individual’ means an individual who is
13 enrolled in a high-deductible health plan.

14 “(8) UNINSURED INDIVIDUAL.—The term ‘un-
15 insured individual’ means an individual who does not
16 have minimum essential coverage as defined in sec-
17 tion 5000A(f)(1) of the Internal Revenue Code of
18 1986 or coverage under a medical care program of
19 the Indian Health Service or of a tribal organization
20 or urban Indian organization.

21 “(9) URBAN INDIAN ORGANIZATION.—The term
22 ‘urban Indian organization’ has the meaning given
23 such term in section 4 of the Indian Health Care
24 Improvement Act.”.

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

6 (1) in subsection (c)(1)(C)(i)(III), by inserting
7 “or under an insulin assistance program supported
8 under section 320B of the Public Health Service
9 Act” after “State pharmaceutical assistance pro-
10 gram”; and

11 (2) in subsection (k)(1)(B)(i)—

12 (A) in subclause (IV), by striking “; and”
13 and inserting a semicolon;

14 (B) in subclause (V), by striking the period
15 at the end and inserting “; and”; and

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

18 “(VI) any prices used under an
19 insulin assistance program supported
20 under section 320B of the Public
21 Health Service Act.”.

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

1 Service Act (42 U.S.C. 300gg et seq.) is amended by add-
 2 ing at the end the following:

3 **“SEC. 2710. DEDUCTIBLES FOR UNDERINSURED INDIVID-**
 4 **UALS PARTICIPATING IN INSULIN ASSIST-**
 5 **ANCE PROGRAMS.**

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

18 “(b) HIGH-DEDUCTIBLE HEALTH PLAN.—For pur-
 19 poses of this section, the term ‘high-deductible health plan’
 20 has the meaning given such term in section 320B(j).”.

21 **SEC. 3. ANNUAL FEES APPLICABLE TO INSULIN MANUFAC-**
 22 **TURERS.**

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

24 (1) ANNUAL PAYMENT DATE.—The term “an-
 25 nual payment date” means, with respect to a cal-

1 endar year, the date determined by the Secretary,
2 but in no event later than September 30 of such cal-
3 endar year.

4 (2) COVERED ENTITY.—The term “covered en-
5 tity”, with respect to a calendar year, means an en-
6 tity that—

7 (A) is the holder of an application ap-
8 proved under subsection (c) of section 505 of
9 the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 355), or of a license issued under sub-
11 section (a) of section 351 of the Public Health
12 Service Act (42 U.S.C. 262), for an insulin
13 product; and

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

19 (3) INSPECTOR GENERAL.—The term “Inspec-
20 tor General” means the Inspector General of the De-
21 partment of Health and Human Services.

22 (4) SECRETARY.—The term “Secretary” means
23 the Secretary of Health and Human Services.

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

1 shall pay to the Secretary not later than the annual pay-
2 ment date of such calendar year a fee in an amount deter-
3 mined under subsection (c).

4 (c) AMOUNT OF FEES.—

5 (1) TOTAL AMOUNT.—The Secretary shall en-
6 sure that the total amount in fees assessed under
7 subsection (b)—

8 (A) for calendar year 2020, equals the
9 total amount the Secretary estimates as the
10 total expenditures for carrying out section
11 320B of the Public Health Service Act for such
12 calendar year; and

13 (B) for each of calendar years 2021
14 through 2024, equals the total amount of ex-
15 penditures the Secretary determines for car-
16 rying out such section for the preceding cal-
17 endar year.

18 (2) DETERMINATION OF FEES FOR EACH MAN-
19 UFACTURER.—

20 (A) FORMULA.—With respect to each cov-
21 ered entity, the fee under this section for a cal-
22 endar year shall be equal to an amount that
23 bears the same ratio to the total amount as-
24 sessed under subsection (b) for such year as the
25 covered entity's sales of insulin products taken

1 into account during the preceding calendar
2 year, bears to the aggregate sales of insulin
3 products of all covered entities taken into ac-
4 count during such preceding calendar year.

5 (B) SALES OF INSULIN PRODUCTS.—

6 (i) IN GENERAL.—For purposes of
7 this paragraph, the sales of insulin prod-
8 ucts taken into account during any cal-
9 endar year with respect to any covered en-
10 tity shall be determined based on the total
11 number of units of the insulin product
12 which were sold in commerce in the pre-
13 ceding calendar year based on—

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

17 (II) for a fee assessed for each of
18 calendar years 2021 through 2024,
19 the information provided in the an-
20 nual reports issued by the Inspector
21 General and made public under sec-
22 tion 4(e)(1).

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

1 entity to submit to the Secretary informa-
2 tion on the total number of units of the in-
3 sulin product manufactured by the entity
4 that were sold in commerce in calendar
5 year 2019.

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

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

14 **SEC. 4. IDENTIFICATION OF INSULIN PRICE SPIKES; APPLI-**
15 **CATION OF EXCISE TAX.**

16 (a) DEFINITIONS.—In this section:

17 (1) APPLICABLE ENTITY.—The term “applica-
18 ble entity” means the holder of an application ap-
19 proved under subsection (c) or (j) of section 505 of
20 the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 355), or of a license issued under subsection
22 (a) or (k) of section 351 of the Public Health Serv-
23 ice Act (42 U.S.C. 262), for an insulin product.

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

4 (3) INSPECTOR GENERAL.—The term “Inspec-
5 tor General” means the Inspector General of the De-
6 partment of Health and Human Services.

7 (4) PRICE SPIKE.—

8 (A) IN GENERAL.—The term “price spike”
9 means an increase in the wholesale acquisition
10 cost in commerce of an insulin product for
11 which the price spike percentage is equal to or
12 greater than the applicable price increase allow-
13 ance.

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

17 (i) the wholesale acquisition cost of an
18 insulin product in commerce for the cal-
19 endar year; exceeds

20 (ii) the wholesale acquisition cost of
21 such insulin product in commerce for the
22 calendar year preceding such year.

23 (C) APPLICABLE PRICE INCREASE ALLOW-
24 ANCE.—The applicable price increase allowance
25 for any calendar year is the percentage (round-

1 ed to the nearest one-tenth of 1 percent) by
2 which the C-CPI-U (as defined in section
3 1(f)(6) of the Internal Revenue Code of 1986)
4 for that year exceeds the C-CPI-U for the pre-
5 ceding calendar year.

6 (5) PRICE SPIKE REVENUE.—

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

9 (i) the gross price spike revenue,
10 minus

11 (ii) the adjustment amount.

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

15 (i) an amount equal to the difference
16 between clause (i) of paragraph (4)(B) and
17 clause (ii) of such paragraph; and

18 (ii) the total number of units of the
19 insulin product which were sold in com-
20 merce in such calendar year.

21 (C) ADJUSTMENT AMOUNT.—The adjust-
22 ment amount is the amount, if any, of the gross
23 price spike revenue which the Inspector General
24 has determined is due solely to an increase in

1 the cost of the inputs necessary to manufacture
2 the insulin product subject to the price spike.

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

5 (1) IN GENERAL.—For each insulin product,
6 the applicable entity shall submit to the Inspector
7 General a quarterly report that includes the fol-
8 lowing:

9 (A) For each insulin product of the appli-
10 cable entity—

11 (i) the total number of units of the in-
12 sulin product which were sold in commerce
13 in the preceding calendar quarter;

14 (ii) the average and median wholesale
15 acquisition cost per unit of such insulin
16 product in commerce in the preceding cal-
17 endar quarter, disaggregated by month;
18 and

19 (iii) the gross revenues from sales of
20 such insulin product in commerce in the
21 preceding calendar quarter.

22 (B) Such information related to increased
23 input costs or public health considerations as
24 the applicable entity may wish the Inspector
25 General to consider in making a determination

1 under clause (ii) of subsection (c)(2)(B) or an
2 assessment in clause (iii) of such subsection for
3 the preceding calendar quarter.

4 (C) Such information related to any antici-
5 pated increased input costs for the subsequent
6 calendar quarter as the applicable entity may
7 wish the Inspector General to consider in mak-
8 ing a determination under clause (ii) of sub-
9 section (c)(2)(B) or an assessment in clause
10 (iii) of such subsection for such calendar quar-
11 ter.

12 (2) PENALTY FOR FAILURE TO SUBMIT.—

13 (A) IN GENERAL.—An applicable entity de-
14 scribed in paragraph (1) that fails to submit in-
15 formation to the Inspector General regarding
16 an insulin product, as required by such para-
17 graph, before the date specified in paragraph
18 (3) shall be liable for a civil penalty, as deter-
19 mined under subparagraph (B).

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

23 (i) an amount, as determined appro-
24 priate by the Inspector General, which is—

1 (I) not less than 0.5 percent of
2 the gross revenues from sales of the
3 insulin product described in subpara-
4 graph (A) for the preceding calendar
5 year; and

6 (II) not greater than 1 percent of
7 the gross revenues from sales of such
8 insulin product for the preceding cal-
9 endar year; and

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

12 (I) the applicable date specified
13 in paragraph (3); and

14 (II) the date on which the In-
15 spector General receives the informa-
16 tion described in paragraph (1) from
17 the applicable entity.

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

22 (c) ASSESSMENT BY INSPECTOR GENERAL.—

23 (1) IN GENERAL.—Not later than the last day
24 in February of each year, the Inspector General, in

1 consultation with other relevant Federal agencies
2 (including the Federal Trade Commission), shall—

3 (A) complete an assessment of the infor-
4 mation the Inspector General received pursuant
5 to subsection (b)(1) with respect to sales of in-
6 sulin products in the preceding calendar year;
7 and

8 (B) in the case of any insulin product
9 which satisfies the conditions described in para-
10 graph (1) or (2) of subsection (d), submit a rec-
11 ommendation to the Secretary of Health and
12 Human Services that such insulin product be
13 exempted from application of the tax imposed
14 under section 4192 of the Internal Revenue
15 Code of 1986 (as added by subsection (g)) for
16 such year.

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

19 (A) Identification of each price spike relat-
20 ing to an insulin product in the preceding cal-
21 endar year.

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

24 (i) a determination of the price spike
25 revenue;

1 (ii) a determination regarding the ac-
2 curacy of the information submitted by the
3 applicable entity regarding increased input
4 costs; and

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

7 (d) EXEMPTION OF CERTAIN INSULIN PRODUCTS.—

8 (1) IN GENERAL.—The Secretary of Health and
9 Human Services, upon recommendation of the In-
10 spector General pursuant to subsection (c)(1)(B),
11 may exempt any insulin product which has been sub-
12 ject to a price spike during the preceding calendar
13 year from application of the tax imposed under sec-
14 tion 4192 of the Internal Revenue Code of 1986 for
15 such year, if the Secretary determines that, based on
16 information submitted pursuant to subsection
17 (b)(1)(B), a for-cause price increase exemption
18 should apply.

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

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

1 (B) shall exclude from such consideration
2 any information submitted by the applicable en-
3 tity threatening to curtail or limit production of
4 the insulin product if the Secretary does not
5 grant an exemption from the application of the
6 tax under section 4192 of the Internal Revenue
7 Code of 1986.

8 (e) REPORTS BY INSPECTOR GENERAL.—

9 (1) PUBLIC REPORT.—

10 (A) IN GENERAL.—Not later than the last
11 day in February of each year, subject to sub-
12 paragraph (C), the Inspector General shall
13 issue a report containing the information de-
14 scribed in subparagraph (B) to be made avail-
15 able to the public, including on the Internet
16 website of the Inspector General.

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

19 (i) The information received under
20 subsection (b)(1) with respect to the pre-
21 ceding calendar year.

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

1 (iii) The price spike revenue deter-
2 minations made under subparagraph (B)(i)
3 of such subsection.

4 (iv) The determinations and assess-
5 ments made under clauses (ii) and (iii) of
6 subparagraph (B) of such subsection.

7 (C) PROPRIETARY INFORMATION.—The In-
8 spector General shall ensure that any informa-
9 tion made public in accordance with subpara-
10 graph (A) excludes trade secrets and confiden-
11 tial commercial information.

12 (2) REPORT TO INTERNAL REVENUE SERV-
13 ICE.—

14 (A) IN GENERAL.—Subject to subpara-
15 graph (C), not later than the last day in Feb-
16 ruary of each year, the Inspector General shall
17 transmit to the Internal Revenue Service a re-
18 port on the findings of the Inspector General
19 with respect to the information the Inspector
20 General received under subsection (b)(1) with
21 respect to the preceding calendar year and the
22 assessment carried out by the Inspector General
23 under subsection (e)(1)(A) with respect to such
24 information.

1 (B) CONTENTS.—The report transmitted
2 under subparagraph (A) shall include the infor-
3 mation described in paragraph (1)(B).

4 (C) NOTICE AND OPPORTUNITY FOR HEAR-
5 ING.—

6 (i) IN GENERAL.—No report shall be
7 transmitted to the Internal Revenue Serv-
8 ice under subparagraph (A) with respect to
9 an insulin product unless the Inspector
10 General has provided the applicable entity
11 with—

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

15 (II) notice of their right to a
16 hearing in regards to such assess-
17 ment.

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

23 (iii) REQUEST FOR HEARING.—Sub-
24 ject to clause (v), an applicable entity may
25 request a hearing before the Secretary of

1 Health and Human Services not later than
2 30 days after the date on which the notice
3 under clause (ii) is received.

4 (iv) COMPLETION OF HEARING.—In
5 the case of an applicable entity which re-
6 quests a hearing pursuant to clause (iii),
7 the Secretary of Health and Human Serv-
8 ices shall, not later than 12 months after
9 the date on which the assessment under
10 subsection (c)(1)(A) was completed by the
11 Inspector General—

12 (I) make a final determination in
13 regards to the accuracy of such as-
14 sessment; and

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

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

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

1 mined to have been subject to a price spike during the
 2 preceding calendar year and the amount of the tax im-
 3 posed on such applicable entity pursuant to section 4192
 4 of the Internal Revenue Code of 1986.

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

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

10 **“SEC. 4192. INSULIN PRODUCTS SUBJECT TO PRICE SPIKES.**

11 **“(a) IMPOSITION OF TAX.—**

12 **“(1) IN GENERAL.—**Subject to paragraph (3),
 13 for each taxable insulin product sold by an applica-
 14 ble entity during the calendar year, there is hereby
 15 imposed on such entity a tax equal to the greater
 16 of—

17 **“(A)** the annual price spike tax for such
 18 insulin product, or

19 **“(B)** subject to paragraph (2), the cumu-
 20 lative price spike tax for such insulin product.

21 **“(2) LIMITATION.—**In the case of a taxable in-
 22 sulin product for which the applicable period (as de-
 23 termined under subsection (c)(2)(E)(i)) is less than
 24 2 calendar years, the cumulative price spike tax shall
 25 not apply.

1 “(3) EXEMPTION.—For any calendar year in
2 which the Secretary of Health and Human Services
3 has provided an exemption for a taxable insulin
4 product pursuant to section 4(d) of the Emergency
5 Access to Insulin Act of 2019, the amount of the tax
6 determined under paragraph (1) for such insulin
7 product for such calendar year shall be reduced to
8 zero.

9 “(b) ANNUAL PRICE SPIKE TAX.—

10 “(1) IN GENERAL.—The amount of the annual
11 price spike tax shall be equal to the applicable per-
12 centage of the price spike revenue received by the
13 applicable entity on the sale of the taxable insulin
14 product during the calendar year.

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

18 “(A) in the case of a taxable insulin prod-
19 uct which has been subject to a price spike per-
20 centage greater than the applicable price in-
21 crease allowance (as defined in section
22 4(a)(4)(C) of the Emergency Access to Insulin
23 Act of 2019) but less than 15 percent, 50 per-
24 cent,

1 “(B) in the case of a taxable insulin prod-
2 uct which has been subject to a price spike per-
3 centage equal to or greater than 15 percent but
4 less than 20 percent, 75 percent, and

5 “(C) in the case of a taxable insulin prod-
6 uct which has been subject to a price spike per-
7 centage equal to or greater than 20 percent,
8 100 percent.

9 “(c) CUMULATIVE PRICE SPIKE TAX.—

10 “(1) IN GENERAL.—The amount of the cumu-
11 lative price spike tax shall be equal to the applicable
12 percentage of the cumulative price spike revenue re-
13 ceived by the applicable entity on the sale of the tax-
14 able insulin product during the calendar year.

15 “(2) APPLICABLE PERCENTAGE.—

16 “(A) IN GENERAL.—For purposes of para-
17 graph (1), the applicable percentage shall be
18 equal to—

19 “(i) in the case of a taxable insulin
20 product which has been subject to a cumu-
21 lative price spike percentage greater than
22 the cumulative price increase allowance but
23 less than the first multi-year percentage,
24 50 percent,

1 “(ii) in the case of a taxable insulin
2 product which has been subject to a cumu-
3 lative price spike percentage equal to or
4 greater than the first multi-year percent-
5 age but less than the second multi-year
6 percentage, 75 percent, and

7 “(iii) in the case of a taxable insulin
8 product which has been subject to a cumu-
9 lative price spike percentage equal to or
10 greater than the second multi-year percent-
11 age, 100 percent.

12 “(B) CUMULATIVE PRICE SPIKE PERCENT-
13 AGE.—The cumulative price spike percentage is
14 the percentage (if any) by which—

15 “(i) the wholesale acquisition cost of
16 the taxable insulin product in commerce
17 for the preceding calendar year, exceeds

18 “(ii) the wholesale acquisition cost of
19 such insulin product in commerce for the
20 base year.

21 “(C) CUMULATIVE PRICE INCREASE AL-
22 LOWANCE.—For purposes of clause (i) of sub-
23 paragraph (A), the cumulative price increase al-
24 lowance for any calendar year is the percentage
25 (rounded to the nearest one-tenth of 1 percent)

1 by which the C–CPI–U (as defined in section
 2 1(f)(6)) for that year exceeds the C–CPI–U for
 3 the base year.

4 “(D) MULTI-YEAR PERCENTAGES.—For
 5 purposes of subparagraph (A), the first multi-
 6 year percentage and second multi-year percent-
 7 age shall be determined in accordance with the
 8 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.

9 “(E) APPLICABLE PERIOD AND BASE
 10 YEAR.—

11 “(i) APPLICABLE PERIOD.—The appli-
 12 cable period shall be the lesser of—

13 “(I) the 5 preceding calendar
 14 years,

15 “(II) all calendar years beginning
 16 after the date of enactment of this
 17 section, or

18 “(III) all calendar years in which
 19 the taxable insulin product was sold in
 20 commerce.

1 “(ii) BASE YEAR.—The base year
2 shall be the calendar year immediately pre-
3 ceding the applicable period.

4 “(3) CUMULATIVE PRICE SPIKE REVENUE.—
5 For purposes of paragraph (1), the cumulative price
6 spike revenue for any taxable insulin product shall
7 be an amount equal to—

8 “(A) an amount equal to the product of—

9 “(i) an amount (not less than zero)
10 equal to—

11 “(I) the wholesale acquisition
12 cost of such insulin product in com-
13 merce for the preceding calendar year,
14 minus

15 “(II) the wholesale acquisition
16 cost of such insulin product in com-
17 merce for the base year, and

18 “(ii) the total number of units of such
19 insulin product which were sold in com-
20 merce in the preceding calendar year,
21 minus

22 “(B) an amount equal to the sum of the
23 adjustment amounts, if any, determined under
24 section 4(a)(5)(C) of the Emergency Access to

1 Insulin Act of 2019 for each calendar year dur-
2 ing the applicable period.

3 “(d) DEFINITIONS.—For purposes of this section—

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

11 “(2) OTHER TERMS.—The terms ‘applicable en-
12 tity’, ‘price spike’, ‘price spike percentage’, and
13 ‘price spike revenue’ have the same meaning given
14 such terms under section 4(a) of the Emergency Ac-
15 cess to Insulin Act of 2019.”.

16 (2) CLERICAL AMENDMENTS.—

17 (A) The heading of subchapter E of chap-
18 ter 32 of the Internal Revenue Code of 1986 is
19 amended by striking “**Medical Devices**”
20 and inserting “**Certain Medical Devices**
21 **and Insulin Products**”.

22 (B) The table of subchapters for chapter
23 32 of such Code is amended by striking the
24 item relating to subchapter E and inserting the
25 following new item:

“SUBCHAPTER E. CERTAIN MEDICAL DEVICES AND INSULIN PRODUCTS”.

1 (C) The table of sections for subchapter E
2 of chapter 32 of such Code is amended by add-
3 ing at the end the following new item:

“Sec. 4192. Insulin products subject to price spikes.”.

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

7 **SEC. 5. BIOLOGICAL PRODUCT EXCLUSIVITY.**

8 (a) **IN GENERAL.**—Section 351(k)(7)(A) of the Pub-
9 lic Health Service Act (42 U.S.C. 262(k)(7)(A)) is amend-
10 ed by striking “12 years” and inserting “7 years”.

11 (b) **CONFORMING AMENDMENTS.**—Paragraphs
12 (2)(A) and (3)(A) of section 351(m) of the Public Health
13 Service Act (42 U.S.C. 262(m)) is amended by striking
14 “12 years” each place it appears and inserting “7 years”.

○