

118TH CONGRESS
1ST SESSION

H. R. 3134

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

IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2023

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

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 2023”.

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. 320C. 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 shall, not
6 later than 1 year after the date of enactment of this
7 section, make grants to States, Indian tribes, and
8 tribal organizations for the purpose of carrying out
9 programs to assist eligible individuals in obtaining
10 insulin in accordance with paragraph (4).

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

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

21 “(B) CERTAIN APPLICATIONS.—If a non-
22 profit private entity and a private entity that is
23 not a nonprofit entity both submit applications
24 to a State, Indian tribe, or tribal organization
25 to receive an award of a grant or contract
26 under subparagraph (A), the State, Indian

1 tribe, or tribal organization shall give priority to
2 the application submitted by the nonprofit pri-
3 vate entity in any case in which the State, In-
4 dian tribe, or tribal organization determines
5 that the quality of such application is equiva-
6 lent to the quality of the application submitted
7 by the other private entity.

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

13 “(A) a minimum amount determined by
14 the Secretary; and

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

22 “(4) PROGRAM COMPONENTS.—

23 “(A) IN GENERAL.—A State, Indian tribe,
24 or tribal organization carrying out a program
25 supported by a grant under this subsection—

1 “(i) shall use the grant funds to—

2 “(I) issue insulin cards to eligible
3 individuals in accordance with sub-
4 paragraph (B); and

5 “(II) enter into agreements with
6 pharmacies—

7 “(aa) for such pharmacies to
8 fill prescriptions for individuals
9 displaying valid insulin cards
10 that are issued in accordance
11 with subparagraph (B) at no cost
12 to such individuals; and

13 “(bb) for the State, Indian
14 tribe, or tribal organization to
15 pay such pharmacies for insulin
16 filled for a prescription described
17 in item (aa); and

18 “(ii) may use the grant funds to—

19 “(I) purchase insulin; or

20 “(II) assist individuals in seeking
21 eligibility for Federal or State-funded
22 programs which may provide coverage
23 for insulin or otherwise assist such in-
24 dividuals in obtaining insulin.

25 “(B) INSULIN CARDS.—

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

11 “(I) documentation indicating
12 proof of—

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

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

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

24 “(II) a prescription for insulin
25 that is prescribed to the individual;

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

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

11 “(ii) INITIAL CARD.—

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

21 “(II) TIMING.—A State, Indian
22 tribe, or tribal organization that re-
23 ceives an application under clause (i)
24 from an individual shall issue an ini-
25 tial insulin card to such individual not

1 later than 5 business days after re-
2 ceiving such application.

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

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

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

20 “(II) if the individual is an eligi-
21 ble individual, issue the individual an
22 insulin card that is valid for an ap-
23 proximate 90-day supply of insulin
24 that is appropriate for the individual
25 based on the prescription provided in

1 the application under clause (i) and
2 packaging and processing practices
3 for insulin.

4 “(iv) RENEWAL OF CARDS.—

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

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

19 “(b) REQUIREMENT OF MATCHING FUNDS.—

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

1 available non-Federal contributions (in cash or in
2 kind under paragraph (2)) toward such costs in an
3 amount equal to not less than \$1 for each \$3 of
4 Federal funds provided in the grant. Such contribu-
5 tions may be made directly or through donations
6 from public or private entities.

7 “(2) DETERMINATION OF AMOUNT OF NON-
8 FEDERAL CONTRIBUTION.—

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

18 “(B) MAINTENANCE OF EFFORT.—In
19 making a determination of the amount of non-
20 Federal contributions for purposes of paragraph
21 (1), the Secretary may include only non-Federal
22 contributions in excess of the average amount
23 of non-Federal contributions made by the State,
24 Indian tribe, or tribal organization involved to-
25 ward the purpose described in subsection (a)(1)

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

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

16 “(c) ADDITIONAL REQUIRED AGREEMENTS.—

17 “(1) STATEWIDE PROVISION OF SERVICES.—

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

1 “(B) WAIVER.—

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

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

22 “(2) RELATIONSHIP TO ITEMS AND SERVICES
23 UNDER OTHER PROGRAMS.—

24 “(A) IN GENERAL.—The Secretary may
25 not make a grant under subsection (a) unless

1 the State, Indian tribe, or tribal organization
2 involved agrees that the grant will not be ex-
3 pended to make payment for any item or serv-
4 ice to the extent that payment has been made,
5 or can reasonably be expected to be made, with
6 respect to such item or service—

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

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

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

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

24 “(4) RECORDS AND AUDITS.—The Secretary
25 may not make a grant under subsection (a) unless

1 the State, Indian tribe, or tribal organization in-
2 volved agrees that—

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

10 “(B) the State, Indian tribe, or tribal orga-
11 nization will keep such records as the Secretary
12 shall prescribe, including—

13 “(i) records that fully disclose—

14 “(I) the amount and disposition
15 by the State, Indian tribe, or tribal
16 organization of the proceeds of such
17 grant;

18 “(II) the total cost of the project
19 or undertaking intended to be carried
20 out through the grant; and

21 “(III) the amount of that portion
22 of the cost of the project or under-
23 taking supplied by sources other than
24 the grant; and

1 “(ii) such other records as the Sec-
2 retary determines appropriate for facili-
3 tating an effective audit of grants awarded
4 under this section; and

5 “(C) upon request, the State, Indian tribe,
6 or tribal organization will provide records main-
7 tained pursuant to subparagraphs (A) and (B)
8 to the Secretary or the Comptroller General of
9 the United States for purposes of auditing the
10 expenditures by the State, Indian tribe, or trib-
11 al organization of the grant.

12 “(5) REPORTS.—

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

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

24 “(ii) the number of insulin products
25 dispensed through such program and the

1 unit costs for those products during the
2 period covered by the report;

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

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

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

13 “(B) HIGH-DEDUCTIBLE HEALTH
14 PLANS.—The Secretary may not make a grant
15 under subsection (a) unless the State, Indian
16 tribe, or tribal organization involved agrees to,
17 as soon as practicable after each time the State,
18 Indian tribe, or tribal organization provides
19 payment to a pharmacy for insulin for an
20 underinsured individual, submit to the high-de-
21 ductible health plan in which the individual is
22 enrolled information on the amount of such
23 payment in order for such plan to comply with
24 the requirements under section 2710.

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

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

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

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

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

22 “(e) REQUIREMENT OF SUBMISSION OF APPLICA-
23 TION.—The Secretary may not make a grant under sub-
24 section (a) unless an application for the grant is submitted
25 to the Secretary, the application contains the description

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

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

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

15 “(2) PROVISION OF SUPPLIES AND SERVICES IN
16 LIEU OF GRANT FUNDS.—

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

1 officer or employee of the Department of
2 Health and Human Services.

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

16 “(g) EVALUATIONS AND REPORTS.—

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

22 “(A) the extent to which States, Indian
23 tribes, and tribal organizations carrying out
24 such programs are in compliance with sub-
25 section (a) and with subsection (c)(1); and

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

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

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

16 “(2) REPORTS TO CONGRESS.—The Secretary
17 shall, not later than 1 year after the date of enact-
18 ment of the Emergency Access to Insulin Act of
19 2023, and annually thereafter, submit to the Com-
20 mittee on Health, Education, Labor, and Pensions
21 of the Senate and the Committee on Energy and
22 Commerce of the House of Representatives a report
23 summarizing evaluations carried out under para-
24 graph (1) during the preceding fiscal year and mak-
25 ing such recommendations for administrative and

1 legislative initiatives with respect to this section as
2 the Secretary determines to be appropriate, includ-
3 ing recommendations regarding compliance by the
4 States, Indian tribes, and tribal organizations with
5 subsection (a) and with subsection (c)(1).

6 “(h) FUNDING FOR GENERAL PROGRAM.—

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

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

16 “(i) SUNSET.—The authority to award grants under
17 subsection (a) shall be effective beginning on the date of
18 enactment of the Emergency Access to Insulin Act of 2023
19 and ending on the date that is 5 years after such date.

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

21 “(1) ELIGIBLE INDIVIDUAL.—The term ‘eligible
22 individual’, with respect to a program supported by
23 a State, Indian tribe, or tribal organization receiving
24 a grant under this section, means an uninsured indi-
25 vidual or an underinsured individual—

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

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

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

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

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

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

22 “(4) INDIAN TRIBE.—The term ‘Indian tribe’
23 has the meaning given such term in section 4 of the
24 Indian Health Care Improvement Act (25 U.S.C.
25 1603).

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

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

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

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

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

23 (b) EXEMPTING PRICES USED UNDER AN INSULIN
24 ASSISTANCE PROGRAM FROM BEST PRICE AND AVERAGE
25 MANUFACTURER PRICE UNDER THE MEDICAID DRUG

1 REBATE PROGRAM.—Section 1927 of the Social Security
2 Act (42 U.S.C. 1396r–8) is amended—

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

8 (2) in subsection (k)(1)(B)(i)—

9 (A) in subclause (IV), by inserting a semi-
10 colon at the end;

11 (B) in subclause (VII), by striking “; and”
12 and inserting a semicolon;

13 (C) in subclause (VIII), by striking the pe-
14 riod at the end and inserting “; and”; and

15 (D) by adding at the end the following new
16 subclause:

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

21 (c) DEDUCTIBLES FOR UNDERINSURED INDIVIDUALS

22 PARTICIPATING IN INSULIN ASSISTANCE PROGRAMS.—

23 Subpart I of part A of title XXVII of the Public Health
24 Service Act (42 U.S.C. 300gg et seq.) is amended by add-
25 ing at the end the following:

1 **“SEC. 2710. DEDUCTIBLES AND OTHER OUT-OF-POCKET EX-**
2 **PENSES FOR UNDERINSURED INDIVIDUALS**
3 **PARTICIPATING IN INSULIN ASSISTANCE**
4 **PROGRAMS.**

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

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

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

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

23 (1) ANNUAL PAYMENT DATE.—The term “an-
24 nual payment date” means, with respect to a cal-
25 endar year, the date determined by the Secretary,

1 but in no event later than September 30 of such cal-
2 endar year.

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

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

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

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

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

23 (b) IMPOSITION OF FEE.—Each covered entity for a
24 calendar year, beginning in 2024 and ending in 2028,
25 shall pay to the Secretary not later than the annual pay-

1 ment date of such calendar year a fee in an amount deter-
2 mined under subsection (c).

3 (c) AMOUNT OF FEES.—

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

7 (A) for calendar year 2024, equals the
8 total amount the Secretary estimates as the
9 total expenditures for carrying out section 320C
10 of the Public Health Service Act for such cal-
11 endar year; and

12 (B) for each of calendar years 2025
13 through 2028, equals the total amount of ex-
14 penditures the Secretary determines for car-
15 rying out such section for the preceding cal-
16 endar year.

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

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

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

4 (B) SALES OF INSULIN PRODUCTS.—

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

13 (I) for a fee assessed for calendar
14 year 2024, information obtained by
15 the Secretary under clause (ii); and

16 (II) for a fee assessed for each of
17 calendar years 2025 through 2028,
18 the information provided in the an-
19 nual reports issued by the Inspector
20 General and made public under sec-
21 tion 4(e)(1).

22 (ii) FEES ASSESSED FOR CALENDAR
23 YEAR 2024.—For purposes of clause (i)(I),
24 the Secretary shall require each covered
25 entity to submit to the Secretary informa-

1 tion on the total number of units of the in-
2 sulin product manufactured by the entity
3 that were sold in commerce in calendar
4 year 2023.

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

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

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

15 (a) DEFINITIONS.—In this section:

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

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

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

4 (4) PRICE SPIKE.—

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

11 (B) PRICE SPIKE PERCENTAGE.—The term
12 “price spike percentage” means the percentage
13 (if any) by which—

14 (i) the wholesale acquisition cost of an
15 insulin product in commerce for the cal-
16 endar year; exceeds

17 (ii) the wholesale acquisition cost of
18 such insulin product in commerce for the
19 calendar year preceding such year.

20 (C) APPLICABLE PRICE INCREASE ALLOW-
21 ANCE.—The term “applicable price increase al-
22 lowance”, with respect to a calendar year,
23 means the percentage (rounded to the nearest
24 one-tenth of 1 percent) by which the C-CPI-U
25 (as defined in section 1(f)(6) of the Internal

1 Revenue Code of 1986) for that year exceeds
2 the C-CPI-U (as so defined) for the preceding
3 calendar year.

4 (5) PRICE SPIKE REVENUE.—

5 (A) IN GENERAL.—The term “price spike
6 revenue”, with respect to a calendar year,
7 means an amount equal to—

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

10 (ii) the adjustment amount.

11 (B) GROSS PRICE SPIKE REVENUE.—The
12 term “gross price spike revenue”, with respect
13 to a calendar year, means an amount equal to
14 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 term
22 “adjustment amount” means the amount, if
23 any, of the gross price spike revenue which the
24 Inspector General has determined is due solely
25 to an increase in the cost of the inputs nec-

1 essary to manufacture the insulin product sub-
2 ject 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 each of the
8 following:

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 4191 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 each of 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 4191 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), information submitted pursuant to
21 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 4191 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 each of the fol-
19 lowing:

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

23 (ii) The price spikes identified under
24 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 4191
4 of the Internal Revenue Code of 1986.

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

7 (1) IN GENERAL.—Chapter 32 of the Internal
8 Revenue Code of 1986 is amended by inserting after
9 subchapter D the following new subchapter:

10 **“Subchapter E—Certain Insulin Products**

“Sec. 4191. Insulin products subject to price spikes.

11 **“SEC. 4191. INSULIN PRODUCTS SUBJECT TO PRICE SPIKES.**

12 “(a) IMPOSITION OF TAX.—

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

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

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

22 “(2) LIMITATION.—In the case of a taxable in-
23 sulin product for which the applicable period (as de-
24 termined under subsection (c)(2)(E)(i)) is less than

1 2 calendar years, the cumulative price spike tax shall
2 not apply.

3 “(3) EXEMPTION.—For any calendar year in
4 which the Secretary of Health and Human Services
5 has provided an exemption for a taxable insulin
6 product pursuant to section 4(d) of the Emergency
7 Access to Insulin Act of 2023, the amount of the tax
8 determined under paragraph (1) for such insulin
9 product for such calendar year shall be reduced to
10 zero.

11 “(b) ANNUAL PRICE SPIKE TAX.—

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

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

20 “(A) in the case of a taxable insulin prod-
21 uct which has been subject to a price spike per-
22 centage greater than the applicable price in-
23 crease allowance (as defined in section
24 4(a)(4)(C) of the Emergency Access to Insulin

1 Act of 2023) but less than 15 percent, 50 per-
2 cent,

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

7 “(C) in the case of a taxable insulin prod-
8 uct which has been subject to a price spike per-
9 centage equal to or greater than 20 percent,
10 100 percent.

11 “(c) CUMULATIVE PRICE SPIKE TAX.—

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

17 “(2) APPLICABLE PERCENTAGE.—

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

21 “(i) in the case of a taxable insulin
22 product which has been subject to a cumu-
23 lative price spike percentage greater than
24 the cumulative price increase allowance but

1 less than the first multi-year percentage,
2 50 percent,

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

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

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

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

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

23 “(C) CUMULATIVE PRICE INCREASE AL-
24 LOWANCE.—For purposes of clause (i) of sub-
25 paragraph (A), the cumulative price increase al-

1 lowance for any calendar year is the percentage
 2 (rounded to the nearest one-tenth of 1 percent)
 3 by which the C–CPI–U (as defined in section
 4 1(f)(6)) for that year exceeds the C–CPI–U for
 5 the base year.

6 “(D) MULTI-YEAR PERCENTAGES.—For
 7 purposes of subparagraph (A), the first multi-
 8 year percentage and second multi-year percent-
 9 age shall be determined in accordance with the
 10 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.

11 “(E) APPLICABLE PERIOD AND BASE
 12 YEAR.—

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

15 “(I) the 5 preceding calendar
 16 years,

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

1 “(III) all calendar years in which
2 the taxable insulin product was sold in
3 commerce.

4 “(ii) BASE YEAR.—The base year
5 shall be the calendar year immediately pre-
6 ceding the applicable period.

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

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

12 “(i) an amount (not less than zero)
13 equal to—

14 “(I) the wholesale acquisition
15 cost of such insulin product in com-
16 merce for the preceding calendar year,
17 minus

18 “(II) the wholesale acquisition
19 cost of such insulin product in com-
20 merce for the base year, and

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

1 “(B) an amount equal to the sum of the
2 adjustment amounts, if any, determined under
3 section 4(a)(5)(C) of the Emergency Access to
4 Insulin Act of 2023 for each calendar year dur-
5 ing the applicable period.

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

7 “(1) TAXABLE INSULIN PRODUCT.—The term
8 ‘taxable insulin product’ means an insulin product
9 which has been identified by the Inspector General
10 of the Department of Health and Human Services,
11 under section 4(c)(2)(A) of the Emergency Access to
12 Insulin Act of 2023, as being subject to a price
13 spike.

14 “(2) OTHER TERMS.—The terms ‘applicable en-
15 tity’, ‘price spike’, ‘price spike percentage’, and
16 ‘price spike revenue’ have the same meaning given
17 such terms under section 4(a) of the Emergency Ac-
18 cess to Insulin Act of 2023.”.

19 (2) CLERICAL AMENDMENT.—The table of sub-
20 chapters for chapter 32 of the Internal Revenue
21 Code of 1986 is amended by inserting after the item
22 relating to subchapter D the following new item:

 “SUBCHAPTER E—CERTAIN INSULIN PRODUCTS”.

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

1 **SEC. 5. BIOLOGICAL PRODUCT EXCLUSIVITY.**

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

5 (b) CONFORMING AMENDMENTS.—Paragraphs
6 (2)(A) and (3)(A) of section 351(m) of the Public Health
7 Service Act (42 U.S.C. 262(m)) is amended by striking
8 “12 years” each place it appears and inserting “7 years”.

○