

116TH CONGRESS
2D SESSION

H. R. 5749

To amend title XI of the Social Security Act to establish the American Insulin Program to provide for lower prices for insulin drugs, to maintain effort throughout the insulin supply chain, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 4, 2020

Mr. CRIST 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 title XI of the Social Security Act to establish the American Insulin Program to provide for lower prices for insulin drugs, to maintain effort throughout the insulin supply chain, 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 “Affordable Insulin for
5 All Act”.

1 **SEC. 2. PROVIDING FOR LOWER PRICES FOR INSULIN**
2 **DRUGS.**

3 Part A of title XI of the Social Security Act (42
4 U.S.C. 1301) is amended by adding at the end the fol-
5 lowing new section:

6 **“SEC. 1150C. ESTABLISHMENT OF PROGRAM.**

7 “(a) IN GENERAL.—The Secretary shall establish an
8 American Insulin Program (in this section referred to as
9 the ‘program’) by not later than 30 days after the date
10 of the enactment of this section. Under the program, the
11 Secretary shall enter into agreements described in sub-
12 section (b) with manufacturers and provide for the per-
13 formance of duties described in subsection (c). The Sec-
14 retary shall establish a model agreement for use under the
15 program by not later than 20 days after the date of the
16 enactment of this section, in consultation with manufac-
17 turers, and allow for comment on such model agreement.

18 “(b) TERMS OF AGREEMENT.—

19 “(1) IN GENERAL.—

20 “(A) AGREEMENT.—An agreement under
21 this section shall require the manufacturer to
22 provide applicable individuals access to Med-
23 icaid prices for insulin drugs of the manufac-
24 turer.

25 “(B) PROVISION OF DISCOUNTED PRICES
26 AS THE POINT-OF-SALE.—

1 “(i) IN GENERAL.—Subject to clause
2 (ii), such Medicaid prices shall be provided
3 to the applicable beneficiary at the phar-
4 macy or by the mail order service at the
5 point-of-sale of an insulin drug.

6 “(ii) CERTIFICATION OF
7 UNSUSTAINABLE REVENUES.—

8 “(I) IN GENERAL.—In the case
9 the Secretary submits to Congress a
10 certification that net revenues from
11 the sale of insulin drugs by manufac-
12 turers with an agreement under this
13 section is unsustainable because such
14 manufactures will be unable to meet
15 the demand for insulin drugs in the
16 United States, subject to subclause
17 (II), the Secretary may increase the
18 Medicaid price by 5 percent.

19 “(II) LIMITATION.—The Sec-
20 retary may not increase the Medicaid
21 price in accordance with subclause (I)
22 more than 3 times.

23 “(III) APPLICABILITY OF PRICE
24 INCREASE.—An increase to the Med-
25 icaid price of insulin drugs described

1 in subclause (I) shall apply to the sale
2 of insulin drugs 90 days after the
3 date of a certification described in
4 such subclause.

5 “(C) TIMING OF AGREEMENT.—

6 “(i) SPECIAL RULE FOR 2021.—In
7 order for an agreement with a manufac-
8 turer to be in effect under this section with
9 respect to the period beginning on January
10 1, 2021, and ending on December 31,
11 2021, the manufacturer shall enter into
12 such agreement not later than 30 days
13 after the date of the establishment of a
14 model agreement under subsection (a).

15 “(ii) 2022 AND SUBSEQUENT
16 YEARS.—In order for an agreement with a
17 manufacturer to be in effect under this
18 section with respect to plan year 2022 or
19 a subsequent plan year, the manufacturer
20 shall enter into such agreement (or such
21 agreement shall be renewed under para-
22 graph (4)(A)) not later than January 30 of
23 the preceding year.

24 “(2) PROVISION OF APPROPRIATE DATA.—Each
25 manufacturer with an agreement in effect under this

1 section shall collect and have available appropriate
2 data, as determined by the Secretary, to ensure that
3 it can demonstrate to the Secretary compliance with
4 the requirements under the program.

5 “(3) COMPLIANCE WITH REQUIREMENTS FOR
6 ADMINISTRATION OF PROGRAM.—Each manufac-
7 turer with an agreement in effect under this section
8 shall comply with requirements imposed by the Sec-
9 retary or a third party with a contract under sub-
10 section (d)(3), as applicable, for purposes of admin-
11 istering the program, including any determination
12 under clause (i) of subsection (c)(1)(A) or proce-
13 dures established under such subsection (c)(1)(A).

14 “(4) LENGTH OF AGREEMENT.—

15 “(A) IN GENERAL.—An agreement under
16 this section shall be effective for an initial pe-
17 riod of not less than 18 months and shall be
18 automatically renewed for a period of not less
19 than 1 year unless terminated under subpara-
20 graph (B).

21 “(B) TERMINATION.—

22 “(i) BY THE SECRETARY.—The Sec-
23 retary may provide for termination of an
24 agreement under this section for a knowing
25 and willful violation of the requirements of

1 the agreement or other good cause shown.
2 Such termination shall not be effective ear-
3 lier than 30 days after the date of notice
4 to the manufacturer of such termination.
5 The Secretary shall provide, upon request,
6 a manufacturer with a hearing concerning
7 such a termination, and such hearing shall
8 take place prior to the effective date of the
9 termination with sufficient time for such
10 effective date to be repealed if the Sec-
11 retary determines appropriate.

12 “(ii) BY A MANUFACTURER.—A man-
13 ufacturer may terminate an agreement
14 under this section for any reason. Any
15 such termination shall be effective, with re-
16 spect to a plan year—

17 “(I) if the termination occurs be-
18 fore January 30 of a plan year, as of
19 the day after the end of the plan year;
20 and

21 “(II) if the termination occurs on
22 or after January 30 of a plan year, as
23 of the day after the end of the suc-
24 ceeding plan year.

1 “(iii) EFFECTIVENESS OF TERMI-
2 NATION.—Any termination under this sub-
3 paragraph shall not affect discounts for in-
4 sulin drugs of the manufacturer that are
5 due under the agreement before the effec-
6 tive date of its termination.

7 “(iv) NOTICE TO THIRD PARTY.—The
8 Secretary shall provide notice of such ter-
9 mination to a third party with a contract
10 under subsection (d)(3) within not less
11 than 30 days before the effective date of
12 such termination.

13 “(c) DUTIES DESCRIBED.—The duties described in
14 this subsection are the following:

15 “(1) ADMINISTRATION OF PROGRAM.—Admin-
16 istering the program, including—

17 “(A) the determination of the amount of
18 the Medicaid price of an insulin drug of a man-
19 ufacturer for applicable individuals in each
20 State;

21 “(B) except as provided in subparagraph
22 (C), the establishment of procedures under
23 which Medicaid prices are provided to applica-
24 ble individuals at pharmacies or by mail order
25 service at the point-of-sale of an insulin drug;

“(C) in the case where, during the period beginning on January 1, 2022, and ending on December 31, 2022, it is not practicable to provide such Medicaid prices at the point-of-sale (as described in subparagraph (B)), the establishment of procedures to provide such Medicaid prices as soon as practicable after the point-of-sale;

“(D) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an insulin drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

“(i) the negotiated price of the insulin drug; and

“(ii) the Medicaid price of the insulin drug; and

“(E) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable individuals, and the third party with a contract under subsection (d)(3).

“(2) MONITORING COMPLIANCE.—

1 “(A) IN GENERAL.—The Secretary shall
2 monitor compliance by a manufacturer with the
3 terms of an agreement under this section.

4 “(B) NOTIFICATION.—If a third party
5 with a contract under subsection (d)(3) deter-
6 mines that the manufacturer is not in compli-
7 ance with such agreement, the third party shall
8 notify the Secretary of such noncompliance for
9 appropriate enforcement under subsection (e).

10 “(3) COLLECTION OF DATA FROM STATE MED-
11 ICAID PROGRAMS.—The Secretary may collect appro-
12 priate data from each State Medicaid program under
13 title XIX in a timeframe that allows for Medicaid
14 prices to be provided for applicable drugs under this
15 section.

16 “(d) ADMINISTRATION.—

17 “(1) IN GENERAL.—Subject to paragraph (2),
18 the Secretary shall provide for the implementation of
19 this section, including the performance of the duties
20 described in subsection (c).

21 “(2) LIMITATION.—

22 “(A) IN GENERAL.—Subject to subpara-
23 graph (B), in providing for such implementa-
24 tion, the Secretary shall not receive or dis-

1 tribute any funds of a manufacturer under the
2 program.

3 “(B) EXCEPTION.—The limitation under
4 subparagraph (A) shall not apply to the Sec-
5 retary with respect to insulin drugs dispensed
6 during the period beginning on January 1,
7 2022, and ending on December 31, 2022, but
8 only if the Secretary determines that the excep-
9 tion to such limitation under this subparagraph
10 is necessary in order for the Secretary to begin
11 implementation of this section and provide ap-
12 plicable beneficiaries timely access to Medicaid
13 prices during such period.

14 “(3) CONTRACT WITH THIRD PARTIES.—The
15 Secretary shall enter into a contract with 1 or more
16 third parties to administer the requirements estab-
17 lished by the Secretary in order to carry out this
18 section. At a minimum, the contract with a third
19 party under the preceding sentence shall require
20 that the third party—

21 “(A) receive and transmit information be-
22 tween the Secretary, manufacturers, and other
23 individuals or entities the Secretary determines
24 appropriate;

1 “(B) receive, distribute, or facilitate the
2 distribution of funds of manufacturers to ap-
3 propriate individuals or entities in order to
4 meet the obligations of manufacturers under
5 agreements under this section;

6 “(C) provide adequate and timely informa-
7 tion to manufacturers, consistent with the
8 agreement with the manufacturer under this
9 section, as necessary for the manufacturer to
10 fulfill its obligations under this section; and

11 “(D) permit manufacturers to conduct
12 periodic audits, directly or through contracts, of
13 the data and information used by the third
14 party to determine discounts for insulin drugs
15 of the manufacturer under the program.

16 “(4) PERFORMANCE REQUIREMENTS.—The
17 Secretary shall establish performance requirements
18 for a third party with a contract under paragraph
19 (3) and safeguards to protect the independence and
20 integrity of the activities carried out by the third
21 party under the program under this section.

22 “(5) IMPLEMENTATION.—The Secretary may
23 implement the program under this section by pro-
24 gram instruction or otherwise.

1 “(6) ADMINISTRATION.—Chapter 35 of title 44,
2 United States Code, shall not apply to the program
3 under this section.

4 “(e) ENFORCEMENT.—

5 “(1) AUDITS.—Each manufacturer with an
6 agreement in effect under this section shall be sub-
7 ject to periodic audit by the Secretary.

8 “(2) CIVIL MONETARY PENALTY.—

9 “(A) IN GENERAL.—The Secretary shall
10 impose a civil money penalty on a manufacturer
11 that fails to provide individuals Medicaid prices
12 for insulin drugs of the manufacturer in accord-
13 ance with such agreement for each such failure
14 in an amount the Secretary determines is com-
15 mensurate with the sum of—

16 “(i) the amount that the manufac-
17 turer would have paid with respect to such
18 discounts under the agreement, which will
19 then be used to pay the discounts which
20 the manufacturer had failed to provide;
21 and

22 “(ii) 25 percent of such amount.

23 “(B) APPLICATION.—The provisions of
24 section 1128A (other than subsections (a) and
25 (b)) shall apply to a civil money penalty under

1 this paragraph in the same manner as such
2 provisions apply to a penalty or proceeding
3 under section 1128A(a).

4 “(f) DEFINITIONS.—In this section:

5 “(1) APPLICABLE INDIVIDUAL.—The term ‘ap-
6 plicable individual’ means an individual who has re-
7 ceived a diagnosis of diabetes.

8 “(2) APPLICABLE NUMBER OF CALENDAR
9 DAYS.—The term ‘applicable number of calendar
10 days’ means—

11 “(A) with respect to claims for reimburse-
12 ment submitted electronically, 14 days; and

13 “(B) with respect to claims for reimburse-
14 ment submitted otherwise, 30 days.

15 “(3) INSULIN DRUG.—The term ‘insulin drug’
16 means a medication approved by the Food and Drug
17 Administration to treat high blood glucose.

18 “(4) MANUFACTURER.—The term ‘manufac-
19 turer’ means, with respect to insulin drugs, any enti-
20 ty which is engaged in the production, preparation,
21 propagation, compounding, conversion, or processing
22 of prescription drug products, either directly or indi-
23 rectly by extraction from substances of natural ori-
24 gin, or independently by means of chemical syn-
25 thesis, or by a combination of extraction and chem-

1 ical synthesis. Such term does not include a whole-
2 sale distributor of insulin drugs or a retail pharmacy
3 licensed under State law.

4 “(5) MEDICAID PRICE.—

5 “(A) IN GENERAL.—The term ‘Medicaid
6 price’ means, with respect to an individual enti-
7 tled to medical assistance under title XIX, the
8 net receipt specified in subparagraph (B) for
9 the dosage form and strength of an insulin drug
10 and any increase due to a certification de-
11 scribed in subsection (b)(1)(B)(ii)(I).

12 “(B) NET RECEIPT SPECIFIED.—For pur-
13 poses of subparagraph (A), the net receipt spec-
14 ified in this subparagraph shall be equal to the
15 product of—

16 “(i) the total number of units of each
17 dosage form and strength purchased under
18 the program in the rebate period (as deter-
19 mined by the Secretary), and

20 “(ii) the amount that is the list price
21 of such drug during such rebate period,
22 less, the total amount of rebates that the manu-
23 facturer paid with respect to such drug during
24 such rebate period.

1 “(6) NEGOTIATED PRICE.—The term ‘nego-
 2 tiated price’ has the meaning given such term in sec-
 3 tion 423.100 of title 42, Code of Federal Regula-
 4 tions (as in effect on the date of enactment of this
 5 section), except that such negotiated price shall not
 6 include any dispensing fee for the applicable drug.”.

7 **SEC. 3. MAINTENANCE OF EFFORT THROUGHOUT THE IN-**
 8 **SULIN SUPPLY CHAIN.**

9 (a) ELIMINATION OF PBM REBATES.—Section
 10 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a–
 11 7b(b)(3)) is amended—

12 (1) in subparagraph (E), by inserting “(except
 13 for a payment practice that permits rebates, dis-
 14 counts, or price concessions for insulin drugs (as de-
 15 fined in section 1150C(f)(3)) to be paid by a manu-
 16 facturer to a PBM (as defined in section 1150A(a))”
 17 before the semicolon at the end; and

18 (2) in subparagraph (J)—

19 (A) by moving the margin two ems to the
 20 left; and

21 (B) by inserting “(except for an insulin
 22 drug)” after “section 1860D–14A(g)”.

23 (b) EXCLUSION OF INSULIN PAYMENTS FROM
 24 MLR.—Not later than 90 days after the date of the enact-
 25 ment of this Act, the Secretary of Health and Human

1 Services shall exclude, beginning with plan years begin-
 2 ning on or after January 1, 2021, from the denominator
 3 (as defined in section 158.221(c) of title 45, Code of Fed-
 4 eral Regulations) section of a medical loss ratio (as cal-
 5 culated under section 158.221(a) of such title) of a health
 6 insurance issuer (as defined in section 144.103 of such
 7 title) the amount of payments that such issuer paid during
 8 a MLR reporting year (as defined in section 144.103 of
 9 such title) for insulin drugs through the promulgation of
 10 a regulation.

11 (c) MAXIMUM COST SHARING AND COINSURANCE
 12 FOR INSULIN DRUGS IN CERTAIN PRIVATE PLANS AND
 13 MEDICARE.—

14 (1) PHSA AMENDMENT.—Subpart II of part A
 15 of title XXVII of the Public Health Service Act (42
 16 U.S.C. 300gg–11 et seq.) is amended by inserting
 17 after section 2713 the following new section:

18 **“SEC. 2713A. COVERAGE OF INSULIN DRUGS.**

19 “(a) IN GENERAL.—Beginning with plan years begin-
 20 ning 90 days after the date of the enactment of this sec-
 21 tion, a group health plan and a health insurance issuer
 22 offering group or individual health insurance coverage
 23 shall, at a minimum provide coverage and may impose cost
 24 sharing for an insulin drug in accordance with subsection

1 (b) for an individual that is provided a prescription for
2 such drug.

3 “(b) COST SHARING.—Beginning with plan years be-
4 ginning 90 days after the date of the enactment of this
5 section, the cost sharing incurred under a plan or coverage
6 described in subsection (a) for an insulin drug may not
7 exceed \$10 for each 1-month period of coverage.

8 “(c) INSULIN DRUG DEFINED.—In this section, the
9 term ‘insulin drug’ has the meaning given such term in
10 section 1150C(f)(3) of the Social Security Act.”.

11 (2) MEDICARE AMENDMENTS.—

12 (A) COINSURANCE LIMITATION.—Section
13 1860D–2(b)(2) of the Social Security Act (42
14 U.S.C. 1395w–102(b)(2)) is amended—

15 (i) in subparagraph (A), by striking
16 “Subject to subparagraphs (C) and (D)”
17 and inserting “Subject to subparagraphs
18 (C), (D), and (E)”; and

19 (ii) by adding at the end, the fol-
20 lowing new subparagraph:

21 “(E) COVERAGE FOR INSULIN DRUGS.—
22 Beginning with plan years beginning 90 days
23 after the date of the enactment of this subpara-
24 graph, the coverage has coinsurance (for costs
25 above the annual deductible specified in para-

1 graph (1) and up to the initial coverage limit
 2 under paragraph (3)) for an insulin drug (as
 3 defined in section 1861(kkk)) is not more than
 4 \$10 for each 1-month period of coverage.”.

5 (B) INSULIN DRUG DEFINED.—Section
 6 1861 of the Social Security Act (42 U.S.C.
 7 1395x) is amended by adding at the end the
 8 following new subsection:

9 “(kkk) INSULIN DRUG.—The term ‘insulin drug’ has
 10 the meaning given such term in section 1150C(f)(3) fur-
 11 nished on or after 90 days after the date of the enactment
 12 of this subsection.”.

13 (d) FREEZING OF SUPPLEMENTAL REBATES IN
 14 MEDICAID.—Section 1902(a) of the Social Security Act
 15 (42 U.S.C. 1396a(a)) is amended—

16 (1) in paragraph (85), by striking at the end
 17 “and”;

18 (2) in paragraph (86), by striking the period at
 19 the end and inserting “; and”; and

20 (3) by inserting after paragraph (86), the fol-
 21 lowing new paragraph:

22 “(87) provide that the State may not—

23 “(A) secure from the manufacturer of a
 24 drug payable under this title a supplemental re-
 25 bate that is not a rebate under section 1927

1 that exceeds the amount of the supplemental re-
 2 bate on the date of the enactment of this para-
 3 graph; or

4 “(B) secure any other supplemental re-
 5 bates.”.

6 (e) ELIMINATION OF SPREAD PRICING AND RE-
 7 LATED PRACTICES IN MEDICAID.—

8 (1) IN GENERAL.—Section 1927(e) of the So-
 9 cial Security Act (42 U.S.C. 1396r–8(e)) is amended
 10 by adding at the end the following:

11 “(6) PASS-THROUGH PRICING REQUIRED.—A
 12 contract between the State and a pharmacy benefit
 13 manager (referred to in this paragraph as a ‘PBM’),
 14 or a contract between the State and a managed care
 15 entity or other specified entity (as such terms are
 16 defined in section 1903(m)(9)(D)) that includes pro-
 17 visions making the entity responsible for coverage of
 18 covered outpatient drugs dispensed to individuals en-
 19 rolled with the entity, shall require that payment for
 20 such drugs and related administrative services (as
 21 applicable), including payments made by a PBM on
 22 behalf of the State or entity, is based on a pass-
 23 through pricing model under which—

24 “(A) any payment made by the entity or
 25 the PBM (as applicable) for such a drug—

1 “(i) is limited to—

2 “(I) ingredient cost; and

3 “(II) a professional dispensing
4 fee that is not less than the profes-
5 sional dispensing fee that the State
6 plan or waiver would pay if the plan
7 or waiver was making the payment di-
8 rectly;

9 “(ii) is passed through in its entirety
10 by the entity or PBM to the pharmacy
11 that dispenses the drug; and

12 “(iii) is made in a manner that is con-
13 sistent with section 1902(a)(30)(A) and
14 sections 447.512, 447.514, and 447.518 of
15 title 42, Code of Federal Regulations (or
16 any successor regulation) as if such re-
17 quirements applied directly to the entity or
18 the PBM;

19 “(B) payment to the entity or the PBM
20 (as applicable) for administrative services per-
21 formed by the entity or PBM is limited to a
22 reasonable administrative fee that covers the
23 reasonable cost of providing such services;

24 “(C) the entity or the PBM (as applicable)
25 shall make available to the State, and the Sec-

retary upon request, all costs and payments related to covered outpatient drugs and accompanying administrative services incurred, received, or made by the entity or the PBM, including ingredient costs, professional dispensing fees, administrative fees, post-sale and post-invoice fees. Discounts, or related adjustments such as direct and indirect remuneration fees, and any and all remuneration; and

“(D) any form of spread pricing whereby any amount charged or claimed by the entity or the PBM (as applicable) that is in excess of the amount paid to the pharmacies on behalf of the entity, including any post-sale or post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees or assessments (after allowing for a reasonable administrative fee as described in subparagraph (B)), is not allowable for purposes of claiming Federal matching payments under this title.”.

(2) CONFORMING AMENDMENT.—Clause (xiii) of section 1903(m)(2)(A) of such Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

(A) by striking “and (III)” and inserting “(III)”; and

1 (B) by inserting before the period at the
2 end the following: “, and (IV) pharmacy benefit
3 management services provided by the entity, or
4 provided by a pharmacy benefit manager on be-
5 half of the entity under a contract or other ar-
6 rangement between the entity and the phar-
7 macy benefit manager, shall comply with the re-
8 quirements of section 1927(e)(6)”.

9 (3) EFFECTIVE DATE.—The amendments made
10 by this subsection apply to contracts between States
11 and managed care entities, other specified entities,
12 or pharmacy benefits managers that are entered into
13 or renewed on or after the date that is 90 days after
14 the date of enactment of this Act.

15 **SEC. 4. GAO REPORT.**

16 Not later than 180 days after the date of the enact-
17 ment of this Act, the Comptroller General of the United
18 States shall submit to Congress a report on the feasibility
19 and affordability of direct manufacturing by the Federal
20 Government.

○