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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

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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.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Affordable Insulin for All Act''.

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

Part A of title XI of the Social Security Act (42 U.S.C. 1301) is amended by adding at the end the following new section:

"SEC. 1150C. ESTABLISHMENT OF PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish an American Insulin Program (in this section referred to as the 'program') by not later than 30 days after the date of the enactment of this section. Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of duties described in subsection (c). The Secretary shall establish a model agreement for use under the program by not later than 20 days after the date of the enactment of this section, in consultation with manufacturers, and allow for comment on such model agreement.

''(b) TERMS OF AGREEMENT.—

''(1) IN GENERAL.—

''(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide applicable individuals access to Medicaid prices for insulin drugs of the manufacturer.

''(B) PROVISION OF DISCOUNTED PRICES AS THE POINT-OF-SALE.—

"(i) IN GENERAL.—Subject to clause (ii), such Medicaid prices shall be provided to the applicable beneficiary at the pharmacy or by the mail order service at the point-of-sale of an insulin drug.

"(ii) CERTIFICATION OF UNSUSTAINABLE REVENUES.—

"(I) IN GENERAL.—In the case the Secretary submits to Congress a certification that net revenues from the sale of insulin drugs by manufacturers with an agreement under this section is unsustainable because such manufactures will be unable to meet the demand for insulin drugs in the United States, subject to subclause (II), the Secretary may increase the Medicaid price by 5 percent.

"(II) LIMITATION.—The Secretary may not increase the Medicaid price in accordance with subclause (I) more than 3 times.

"(III) APPLICABILITY OF PRICE INCREASE.—An increase to the Medicaid price of insulin drugs described

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

''(C) TIMING OF AGREEMENT.—

''(i) SPECIAL RULE FOR 2021.—In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2021, and ending on December 31, 2021, the manufacturer shall enter into such agreement not later than 30 days after the date of the establishment of a model agreement under subsection (a).

''(ii) 2022 AND SUBSEQUENT YEARS.—In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2022 or a subsequent plan year, the manufacturer shall enter into such agreement (or such agreement shall be renewed under paragraph (4)(A)) not later than January 30 of the preceding year.

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

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

''(3) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under clause (i) of subsection (c)(1)(A) or procedures established under such subsection (c)(1)(A).

''(4) LENGTH OF AGREEMENT.—

''(A) IN GENERAL.—An agreement under this section shall be effective for an initial period of not less than 18 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

''(B) TERMINATION.—

''(i) BY THE SECRETARY.—The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of

the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

''(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

''(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and

''(II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.

''(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect discounts for insulin drugs of the manufacturer that are due under the agreement before the effective date of its termination.

''(iv) NOTICE TO THIRD PARTY.—The Secretary shall provide notice of such termination to a third party with a contract under subsection (d)(3) within not less than 30 days before the effective date of such termination.

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

''(1) ADMINISTRATION OF PROGRAM.—Administering the program, including—

''(A) the determination of the amount of the Medicaid price of an insulin drug of a manufacturer for applicable individuals in each State;

''(B) except as provided in subparagraph (C), the establishment of procedures under which Medicaid prices are provided to applicable individuals at pharmacies or by mail order 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.—

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

''(B) NOTIFICATION.—If a third party with a contract under subsection (d)(3) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under subsection (e).

''(3) COLLECTION OF DATA FROM STATE MEDICAID PROGRAMS.—The Secretary may collect appropriate data from each State Medicaid program under title XIX in a timeframe that allows for Medicaid prices to be provided for applicable drugs under this section.

''(d) ADMINISTRATION.—

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

''(2) LIMITATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), in providing for such implementation, the Secretary shall not receive or dis-

tribute any funds of a manufacturer under the program.

''(B) EXCEPTION.—The limitation under subparagraph (A) shall not apply to the Secretary with respect to insulin drugs dispensed during the period beginning on January 1, 2022, and ending on December 31, 2022, but only if the Secretary determines that the exception to such limitation under this subparagraph is necessary in order for the Secretary to begin implementation of this section and provide applicable beneficiaries timely access to Medicaid prices during such period.

''(3) CONTRACT WITH THIRD PARTIES.—The Secretary shall enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this section. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—

''(A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

"(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this section;

"(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this section, as necessary for the manufacturer to fulfill its obligations under this section; and

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

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

"(5) IMPLEMENTATION.—The Secretary may implement the program under this section by program instruction or otherwise.

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

''(e) ENFORCEMENT.—

''(1) AUDITS.—Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

''(2) CIVIL MONETARY PENALTY.—

''(A) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer that fails to provide individuals Medicaid prices for insulin drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is commensurate with the sum of—

''(i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

''(ii) 25 percent of such amount.

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

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

''(f) DEFINITIONS.—In this section:

''(1) APPLICABLE INDIVIDUAL.—The term 'applicable individual' means an individual who has received a diagnosis of diabetes.

''(2) APPLICABLE NUMBER OF CALENDAR DAYS.—The term 'applicable number of calendar days' means—

''(A) with respect to claims for reimbursement submitted electronically, 14 days; and

''(B) with respect to claims for reimbursement submitted otherwise, 30 days.

''(3) INSULIN DRUG.—The term 'insulin drug' means a medication approved by the Food and Drug Administration to treat high blood glucose.

''(4) MANUFACTURER.—The term 'manufacturer' means, with respect to insulin drugs, any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chem-

ical synthesis. Such term does not include a wholesale distributor of insulin drugs or a retail pharmacy licensed under State law.

"(5) MEDICAID PRICE.—

"(A) IN GENERAL.—The term 'Medicaid price' means, with respect to an individual entitled to medical assistance under title XIX, the net receipt specified in subparagraph (B) for the dosage form and strength of an insulin drug and any increase due to a certification described in subsection (b)(1)(B)(ii)(I).

"(B) NET RECEIPT SPECIFIED.—For purposes of subparagraph (A), the net receipt specified in this subparagraph shall be equal to the product of—

"(i) the total number of units of each dosage form and strength purchased under the program in the rebate period (as determined by the Secretary), and

"(ii) the amount that is the list price of such drug during such rebate period,

less, the total amount of rebates that the manufacturer paid with respect to such drug during such rebate period.

''(6) NEGOTIATED PRICE.—The term 'negotiated price' has the meaning given such term in section 423.100 of title 42, Code of Federal Regulations (as in effect on the date of enactment of this section), except that such negotiated price shall not include any dispensing fee for the applicable drug.''.

SEC. 3. MAINTENANCE OF EFFORT THROUGHOUT THE INSULIN SUPPLY CHAIN.

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

(1) in subparagraph (E), by inserting ''(except for a payment practice that permits rebates, discounts, or price concessions for insulin drugs (as defined in section 1150C(f)(3)) to be paid by a manufacturer to a PBM (as defined in section 1150A(a))'' before the semicolon at the end; and

(2) in subparagraph (J)—

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

(B) by inserting ''(except for an insulin drug)'' after ''section 1860D–14A(g)''.

(b) EXCLUSION OF INSULIN PAYMENTS FROM MLR.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human

Services shall exclude, beginning with plan years beginning on or after January 1, 2021, from the denominator (as defined in section 158.221(c) of title 45, Code of Federal Regulations) section of a medical loss ratio (as calculated under section 158.221(a) of such title) of a health insurance issuer (as defined in section 144.103 of such title) the amount of payments that such issuer paid during a MLR reporting year (as defined in section 144.103 of such title) for insulin drugs through the promulgation of a regulation.

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

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

"SEC. 2713A. COVERAGE OF INSULIN DRUGS.

''(a) IN GENERAL.—Beginning with plan years beginning 90 days after the date of the enactment of this section, a group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage and may impose cost sharing for an insulin drug in accordance with subsection

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

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

''(c) INSULIN DRUG DEFINED.—In this section, the term 'insulin drug' has the meaning given such term in section 1150C(f)(3) of the Social Security Act.''.

(2) MEDICARE AMENDMENTS.—

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

(i) in subparagraph (A), by striking ''Subject to subparagraphs (C) and (D)'' and inserting ''Subject to subparagraphs (C), (D), and (E)''; and

(ii) by adding at the end, the following new subparagraph:

''(E) COVERAGE FOR INSULIN DRUGS.—Beginning with plan years beginning 90 days after the date of the enactment of this subparagraph, the coverage has coinsurance (for costs above the annual deductible specified in para-

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

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

''(kkk) INSULIN DRUG.—The term 'insulin drug' has the meaning given such term in section 1150C(f)(3) furnished on or after 90 days after the date of the enactment of this subsection.''.

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

(1) in paragraph (85), by striking at the end ''and'';

(2) in paragraph (86), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (86), the following new paragraph:

''(87) provide that the State may not—

''(A) secure from the manufacturer of a drug payable under this title a supplemental rebate that is not a rebate under section 1927

that exceeds the amount of the supplemental rebate on the date of the enactment of this paragraph; or

"(B) secure any other supplemental rebates.".

(e) ELIMINATION OF SPREAD PRICING AND RELATED PRACTICES IN MEDICAID.—

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

"(6) PASS-THROUGH PRICING REQUIRED.—A contract between the State and a pharmacy benefit manager (referred to in this paragraph as a 'PBM'), or a contract between the State and a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)) that includes provisions making the entity responsible for coverage of covered outpatient drugs dispensed to individuals enrolled with the entity, shall require that payment for such drugs and related administrative services (as applicable), including payments made by a PBM on behalf of the State or entity, is based on a pass-through pricing model under which—

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

''(i) is limited to—

''(I) ingredient cost; and

''(II) a professional dispensing fee that is not less than the professional dispensing fee that the State plan or waiver would pay if the plan or waiver was making the payment directly;

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

''(iii) is made in a manner that is consistent with section 1902(a)(30)(A) and sections 447.512, 447.514, and 447.518 of title 42, Code of Federal Regulations (or any successor regulation) as if such requirements applied directly to the entity or the PBM;

''(B) payment to the entity or the PBM (as applicable) for administrative services performed by the entity or PBM is limited to a reasonable administrative fee that covers the reasonable cost of providing such services;

''(C) the entity or the PBM (as applicable) 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

(B) by inserting before the period at the end the following: ‘‘, and (IV) pharmacy benefit management services provided by the entity, or provided by a pharmacy benefit manager on behalf of the entity under a contract or other arrangement between the entity and the pharmacy benefit manager, shall comply with the requirements of section 1927(e)(6)’’.

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

SEC. 4. GAO REPORT.

Not later than 180 days after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the feasibility and affordability of direct manufacturing by the Federal Government.

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