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116TH CONGRESS
2D SESSION

H. R. 5882

To amend title XIX of the Social Security Act to provide States with the option under the Medicaid program to pay for covered outpatient drugs through risk-sharing value-based agreements, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 12, 2020

Mr. SCHRADER (for himself, Mr. MARSHALL, Mr. CROW, Mr. MULLIN, Mr. BERA, Mr. KELLY of Pennsylvania, and Mr. SCHWEIKERT) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title XIX of the Social Security Act to provide States with the option under the Medicaid program to pay for covered outpatient drugs through risk-sharing value-based agreements, 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 ''Generating Effective and Novel Evidence for Therapy Payment Act'' or ''GENE Therapy Payment Act''.

SEC. 2. RISK-SHARING VALUE-BASED PAYMENT AGREEMENTS FOR COVERED OUTPATIENT DRUGS UNDER MEDICAID.

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

''(l) STATE OPTION TO PAY FOR COVERED OUTPATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED AGREEMENTS.—

''(1) IN GENERAL.—Beginning January 1, 2022, a State shall have the option to pay (whether on a fee-for-service or managed care basis) for covered outpatient drugs that are potentially curative treatments intended for one-time use that are administered to individuals under this title by entering into a risk-sharing value-based payment agreement with the manufacturer of the drug in accordance with the requirements of this subsection.

''(2) SECRETARIAL APPROVAL.—

''(A) IN GENERAL.—A State shall submit a request to the Secretary to enter into a risk-sharing value-based payment agreement, and the Secretary shall not approve a proposed risk-sharing value-based payment agreement between a State and a manufacturer for payment

for a covered outpatient drug of the manufacturer unless the following requirements are met:

"(i) MANUFACTURER HAS IN EFFECT A REBATE AGREEMENT AND IS IN COMPLIANCE WITH ALL APPLICABLE REQUIREMENTS.—The manufacturer has a rebate agreement in effect as required under subsections (a) and (b) of this section and is in compliance with all applicable requirements under this title.

"(ii) NO INCREASE TO PROJECTED NET FEDERAL SPENDING.—

"(I) IN GENERAL.—The Chief Actuary certifies that the projected payments for each covered outpatient drug under a proposed risk-sharing value-based payment agreement is not expected to result in greater estimated Federal spending under this title than the net Federal spending that would result in the absence of such agreement.

"(II) NET FEDERAL SPENDING DEFINED.—For purposes of this subsection, the term 'net Federal spend-

ing' means the amount of Federal payments the Chief Actuary estimates would be made under this title for administering a covered outpatient drug to an individual eligible for medical assistance under a State plan or a waiver of such plan, reduced by the amount of all rebates the Chief Actuary estimates would be paid with respect to the administering of such drug, including all rebates under this title and any supplemental or other additional rebates, in the absence of such an agreement.

''(III) INFORMATION.—The Chief Actuary shall make the certifications required under this clause based on the most recently available and reliable drug pricing and product information. The State and manufacturer shall provide the Secretary and the Chief Actuary with all necessary information required to make the estimates needed for such certifications.

"(iii) LAUNCH AND LIST PRICE JUSTIFICATIONS.—The manufacturer submits all relevant information and supporting documentation necessary for pricing decisions as deemed appropriate by the Secretary, which shall be truthful and nonmisleading, including manufacturer information and supporting documentation for launch price or list price increases, and any applicable justification required under section 1128L.

"(iv) CONFIDENTIALITY OF INFORMATION; PENALTIES.—The provisions of subparagraphs (C) and (D) of subsection (b)(3) shall apply to a manufacturer that fails to submit the information and documentation required under clauses (ii) and (iii) on a timely basis, or that knowingly provides false or misleading information, in the same manner as such provisions apply to a manufacturer with a rebate agreement under this section.

"(B) CONSIDERATION OF STATE REQUEST FOR APPROVAL.—

"(i) IN GENERAL.—The Secretary shall treat a State request for approval of a risk-sharing value-based payment agreement in the same manner that the Secretary treats a State plan amendment, and subpart B of part 430 of title 42, Code of Federal Regulations, including, subject to clause (ii), the timing requirements of section 430.16 of such title (as in effect on the date of enactment of this subsection), shall apply to a request for approval of a risk-sharing value-based payment agreement in the same manner as such subpart applies to a State plan amendment.

"(ii) TIMING.—The Secretary shall consult with the Commissioner of Food and Drugs as required under subparagraph (C) and make a determination on whether to approve a request from a State for approval of a proposed risk-sharing value-based payment agreement (or request additional information necessary to allow the Secretary to make a determination with respect to such request for approval) within the time period, to the extent prac-

ticable, specified in section 430.16 of title 42, Code of Federal Regulations (as in effect on the date of enactment of this subsection), but in no case shall the Secretary take more than 180 days after the receipt of such request for approval or response to such request for additional information to make such a determination (or request additional information).

''(C) CONSULTATION WITH THE COMMISSIONER OF FOOD AND DRUGS.—In considering whether to approve a risk-sharing value-based payment agreement, the Secretary, to the extent necessary, shall consult with the Commissioner of Food and Drugs to determine whether the relevant clinical parameters specified in such agreement are appropriate.

''(3) INSTALLMENT-BASED PAYMENT STRUCTURE.—

''(A) IN GENERAL.—A risk-sharing value-based payment agreement shall provide for a payment structure under which, for every installment year of the agreement (subject to subparagraph (B)), the State shall pay the total installment year amount in equal installments to

be paid at regular intervals over a period of time that shall be specified in the agreement.

''(B) REQUIREMENTS FOR INSTALLMENT PAYMENTS.—

''(i) TIMING OF FIRST PAYMENT.—The State shall make the first of the installment payments described in subparagraph (A) for an installment year not later than 30 days after the end of such year.

''(ii) LENGTH OF INSTALLMENT PERIOD.—The period of time over which the State shall make the installment payments described in subparagraph (A) for an installment year shall not be longer than 5 years.

''(iii) NONPAYMENT OR REDUCED PAYMENT OF INSTALLMENTS FOLLOWING A FAILURE TO MEET CLINICAL PARAMETER.—If, prior to the payment date (as specified in the agreement) of any installment payment described in subparagraph (A) or any other alternative date or time frame (as otherwise specified in the agreement), the covered outpatient drug which is subject to the agreement fails to meet a

relevant clinical parameter of the agreement, the agreement shall provide that—

"(I) the installment payment shall not be made; or

"(II) the installment payment shall be reduced by a percentage specified in the agreement that is based on the outcome achieved by the drug relative to the relevant clinical parameter.

"(4) NOTICE OF INTENT.—

"(A) IN GENERAL.—Subject to subparagraph (B), a manufacturer of a covered outpatient drug shall not be eligible to enter into a risk-sharing value-based payment agreement under this subsection with respect to such drug unless the manufacturer notifies the Secretary that the manufacturer is interested in entering into such an agreement with respect to such drug. The decision to submit and timing of a request to enter into a proposed risk-sharing value-based payment agreement shall remain solely within the discretion of the State and shall only be effective upon Secretarial approval as required under this subsection.

"(B) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—

"(i) IN GENERAL.—In the case of a manufacturer of a covered outpatient drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act after the date of enactment of this subsection, not more than 90 days after meeting with the Food and Drug Administration following phase II clinical trials for such drug (or, in the case of a drug described in clause (ii), not later than March 31, 2022), the manufacturer must notify the Secretary of the manufacturer's intent to enter into a risk-sharing value-based payment agreement under this subsection with respect to such drug. If no such meeting has occurred, the Secretary may use discretion as to whether a potentially curative treatment intended for one-time use may qualify for a risk-sharing value-based payment agreement under this section. A manufacturer notification of interest shall not have any influence on a de-

cision for drug approval by the Food and Drug Administration.

''(ii) APPLICATION TO CERTAIN SUBSEQUENTLY APPROVED DRUGS.—A drug described in this clause is a covered outpatient drug of a manufacturer—

''(I) that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act after the date of enactment of this subsection; and

''(II) with respect to which, as of January 1, 2022, more than 90 days have passed after the manufacturer's meeting with the Food and Drug Administration following phase II clinical trials for such drug.

''(iii) PARALLEL APPROVAL.—The Secretary, in coordination with the Administrator of the Centers for Medicare & Medicaid Services and the Commissioner of Food and Drugs, shall, to the extent practicable, approve a State's request to enter into a proposed risk-sharing value-based

payment agreement that otherwise meets the requirements of this subsection at the time that such a drug is approved by the Food and Drug Administration to help provide that no State that wishes to enter into such an agreement is required to pay for the drug in full at one time if the State is seeking to pay over a period of time as outlined in the proposed agreement.

''(iv) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be applied or construed to modify or affect the timeframes or factors involved in the Secretary's determination of whether to approve or license a drug under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

''(5) SPECIAL PAYMENT RULES.—

''(A) IN GENERAL.—Except as otherwise provided in this paragraph, with respect to an individual who is administered a unit of a covered outpatient drug that is reimbursed under a State plan by a State Medicaid agency under a risk-sharing value-based payment agreement

in an installment year, the State shall remain liable to the manufacturer of such drug for payment for such unit without regard to whether the individual remains enrolled in the State plan under this title (or a waiver of such plan) for each installment year for which the State is to make installment payments for covered outpatient drugs purchased under the agreement in such year.

''(B) DEATH.—In the case of an individual described in subparagraph (A) who dies during the period described in such subparagraph, the State plan shall not be liable for any remaining payment for the unit of the covered outpatient drug administered to the individual which is owed under the agreement described in such subparagraph.

''(C) WITHDRAWAL OF APPROVAL.—In the case of a covered outpatient drug that is the subject of a risk-sharing value-based payment agreement between a State and a manufacturer under this subsection, including a drug approved in accordance with section 506(c) of the Federal Food, Drug, and Cosmetic Act, and such drug is the subject of an application that

has been withdrawn by the Secretary, the State plan shall not be liable for any remaining payment that is owed under the agreement.

"(D) ALTERNATIVE ARRANGEMENT UNDER AGREEMENT.—Subject to approval by the Secretary, the terms of a proposed risk-sharing value-based payment agreement submitted for approval by a State may provide that subparagraph (A) shall not apply.

"(E) GUIDANCE.—Not later than January 1, 2022, the Secretary shall issue guidance to States establishing a process for States to notify the Secretary when an individual who is administered a unit of a covered outpatient drug that is purchased by a State plan under a risk-sharing value-based payment agreement ceases to be enrolled under the State plan under this title (or a waiver of such plan) or dies before the end of the installment period applicable to such unit under the agreement.

"(6) TREATMENT OF PAYMENTS UNDER RISK-SHARING VALUE-BASED AGREEMENTS FOR PURPOSES OF AVERAGE MANUFACTURER PRICE; BEST PRICE.—The Secretary shall treat any payments made to the manufacturer of a covered outpatient

drug under a risk-sharing value-based payment agreement under this subsection during a rebate period in the same manner that the Secretary treats payments made under a State supplemental rebate agreement under sections 447.504(c)(19) and 447.505(c)(7) of title 42, Code of Federal Regulations (or any successor regulations) for purposes of determining average manufacturer price and best price under this section with respect to the covered outpatient drug and a rebate period and for purposes of offsets required under subsection (b)(1)(B).

"(7) ASSESSMENTS AND REPORT TO CONGRESS.—

"(A) ASSESSMENTS.—

"(i) IN GENERAL.—Not later than 180 days after the end of each assessment period of any risk-sharing value-based payment agreement for a State approved under this subsection, the Secretary shall conduct an evaluation of such agreement which shall include an evaluation by the Chief Actuary to determine whether program spending under the risk-sharing value-based payment agreement aligned with the projections for the agreement

made under paragraph (2)(A)(ii), including an assessment of whether actual Federal spending under this title under the agreement was less or more than net Federal spending would have been in the absence of the agreement.

''(ii) ASSESSMENT PERIOD.—For purposes of clause (i)—

''(I) the first assessment period for a risk-sharing value-based payment agreement shall be the period of time over which payments are scheduled to be made under the agreement for the first 10 individuals who are administered covered outpatient drugs under the agreement except that such period shall not exceed the 5-year period after the date on which the Secretary approves the agreement; and

''(II) each subsequent assessment period for a risk-sharing value-based payment agreement shall be the 5-year period following the end of the previous assessment period.

''(B) RESULTS OF ASSESSMENTS.—

"(i) TERMINATION OPTION.—If the Secretary determines as a result of the assessment by the Chief Actuary under subparagraph (A) that the actual Federal spending under this title for any covered outpatient drug that was the subject of the State's risk-sharing value-based payment agreement was greater than the net Federal spending that would have resulted in the absence of the agreement, the Secretary may terminate approval of such agreement and shall immediately conduct an assessment under this paragraph of any other ongoing risk-sharing value-based payment agreement to which the same manufacturer is a party.

"(ii) REPAYMENT REQUIRED.—

"(I) IN GENERAL.—If the Secretary determines as a result of the assessment by the Chief Actuary under subparagraph (A) that the Federal spending under the risk-sharing value-based agreement for a covered outpatient drug that was subject to such agreement was greater than the

net Federal spending that would have resulted in the absence of the agreement, the manufacturer shall repay the difference to the State and Federal Governments in a timely manner as determined by the Secretary.

''(II) TERMINATION FOR FAILURE TO PAY.—The failure of a manufacturer to make repayments required under subclause (I) in a timely manner shall result in immediate termination of all risk-sharing value-based agreements to which the manufacturer is a party.

''(III) ADDITIONAL PENALTIES.—In the case of a manufacturer that fails to make repayments required under subclause (I), the Secretary may treat such manufacturer in the same manner as a manufacturer that fails to pay required rebates under this section, and the Secretary may—

"(aa) suspend or terminate the manufacturer's rebate agreement under this section; and

"(bb) pursue any other remedy that would be available if the manufacturer had failed to pay required rebates under this section.

"(C) REPORT TO CONGRESS.—Not later than 5 years after the first risk-sharing value-based payment agreement is approved under this subsection, the Secretary shall submit to Congress and make available to the public a report that includes—

"(i) an assessment of the impact of risk-sharing value-based payment agreements on access for individuals who are eligible for benefits under a State plan or waiver under this title to medically necessary covered outpatient drugs and related treatments;

"(ii) an analysis of the impact of such agreements on overall State and Federal spending under this title;

"(iii) an assessment of the impact of such agreements on drug prices, including launch price and price increases; and

"(iv) such recommendations to Congress as the Secretary deems appropriate.

"(8) GUIDANCE AND REGULATIONS.—

"(A) IN GENERAL.—Not later than January 1, 2022, the Secretary shall issue guidance to States seeking to enter into risk-sharing value-based payment agreements under this subsection that includes a model template for such agreements. The Secretary may issue any additional guidance or promulgate regulations as necessary to implement and enforce the provisions of this subsection.

"(B) MODEL AGREEMENTS.—

"(i) IN GENERAL.—If a State expresses an interest in pursuing a risk-sharing value-based payment agreement under this subsection with a manufacturer for the purchase of a covered outpatient drug, the Secretary may share with such State any risk-sharing value-based agreement between a State and the manufacturer for the purchase of such drug that has been

approved under this subsection. While such shared agreement may serve as a template for a State that wishes to propose, the use of a previously approved agreement shall not affect the submission and approval process for approval of a proposed risk-sharing value-based payment agreement under this subsection, including the requirements under paragraph (2)(A).

''(ii) CONFIDENTIALITY.—In the case of a risk-sharing value-based payment agreement that is disclosed to a State by the Secretary under this subparagraph and that is only in effect with respect to a single State, the confidentiality of information provisions described in subsection (b)(3)(D) shall apply to such information.

''(C) OIG CONSULTATION.—

''(i) IN GENERAL.—The Secretary shall consult with the Office of the Inspector General of the Department of Health and Human Services to determine whether there are potential program integrity concerns (including issues related to compliance with sections 1128B and 1877) with

agreement approvals or templates and address accordingly.

''(ii) OIG POLICY UPDATES AS NECESSARY.—The Inspector General of the Department of Health and Human Services shall review and update, as necessary, any policies or guidelines of the Office of the Inspector General of the Department of Health and Human Services (including policies related to the enforcement of section 1128B) to accommodate the use of risk-sharing value-based payment agreements in accordance with this section.

''(9) RULES OF CONSTRUCTION.—

''(A) MODIFICATIONS.—Nothing in this subsection or any regulations promulgated under this subsection shall prohibit a State from requesting a modification from the Secretary to the terms of a risk-sharing value-based payment agreement. A modification that is expected to result in any increase to projected net State or Federal spending under the agreement shall be subject to recertification by the Chief Actuary as described in paragraph

(2)(A)(ii) before the modification may be approved.

''(B) REBATE AGREEMENTS.—Nothing in this subsection shall be construed as requiring a State to enter into a risk-sharing value-based payment agreement or as limiting or superseding the ability of a State to enter into a supplemental rebate agreement for a covered outpatient drug.

''(C) FFP FOR PAYMENTS UNDER RISK-SHARING VALUE-BASED PAYMENT AGREEMENTS.—Federal financial participation shall be available under this title for any payment made by a State to a manufacturer for a covered outpatient drug under a risk-sharing value-based payment agreement in accordance with this subsection, except that no Federal financial participation shall be available for any payment made by a State to a manufacturer under such an agreement on and after the effective date of a disapproval of such agreement by the Secretary.

''(D) CONTINUED APPLICATION OF OTHER PROVISIONS.—Except as expressly provided in this subsection, nothing in this subsection or in

any regulations promulgated under this subsection shall affect the application of any other provision of this Act.

''(10) APPROPRIATIONS.—For fiscal year 2020 and each fiscal year thereafter, there are appropriated to the Secretary $5,000,000 for the purpose of carrying out this subsection.

''(11) DEFINITIONS.—In this subsection:

''(A) CHIEF ACTUARY.—The term 'Chief Actuary' means the Chief Actuary of the Centers for Medicare & Medicaid Services.

''(B) INSTALLMENT YEAR.—The term 'installment year' means, with respect to a risk-sharing value-based payment agreement, a 12-month period during which a covered outpatient drug is administered under the agreement.

''(C) POTENTIALLY CURATIVE TREATMENT INTENDED FOR ONE-TIME USE.—The term 'potentially curative treatment intended for one-time use' means a treatment that consists of the administration of a covered outpatient drug that—

''(i) is a form of gene therapy for a rare disease, as defined by the Commissioner of Food and Drugs, designated

under section 526 of the Federal Food, Drug, and Cosmetic Act, and approved under section 505 of such Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act to treat a serious or life-threatening disease or condition;

''(ii) if administered in accordance with the labeling of such drug, is expected to result in either—

''(I) the cure of such disease or condition; or

''(II) a reduction in the symptoms of such disease or condition to the extent that such disease or condition is not expected to lead to early mortality; and

''(iii) is expected to achieve a result described in clause (ii), which may be achieved over an extended period of time, after not more than 3 administrations.

''(D) RELEVANT CLINICAL PARAMETER.—The term 'relevant clinical parameter' means, with respect to a covered outpatient drug that

is the subject of a risk-sharing value-based payment agreement—

"(i) a clinical endpoint specified in the drug's labeling or supported by one or more of the compendia described in section 1861(t)(2)(B)(ii)(I) that—

"(I) is able to be measured or evaluated on an annual basis for each year of the agreement on an independent basis by a provider or other entity; and

"(II) is required to be achieved (based on observed metrics in patient populations) under the terms of the agreement; or

"(ii) a surrogate endpoint (as defined in section 507(e)(9) of the Federal Food, Drug, and Cosmetic Act), including those developed by patient-focused drug development tools, that—

"(I) is able to be measured or evaluated on an annual basis for each year of the agreement on an independent basis by a provider or other entity; and

''(II) has been qualified by the Food and Drug Administration.

''(E) RISK-SHARING VALUE-BASED PAYMENT AGREEMENT.—The term 'risk-sharing value-based payment agreement' means an agreement between a State plan and a manufacturer—

''(i) for the purchase of a covered outpatient drug of the manufacturer that is a potentially curative treatment intended for one-time use;

''(ii) under which payment for such drug shall be made pursuant to an installment-based payment structure that meets the requirements of paragraph (3);

''(iii) which conditions payment on the achievement of at least 2 relevant clinical parameters (as defined in subparagraph (C));

''(iv) which provides that—

''(I) the State plan will directly reimburse the manufacturer for the drug; or

''(II) a third party will reimburse the manufacture in a manner approved by the Secretary; and

''(v) is approved by the Secretary in accordance with paragraph (2).

''(F) TOTAL INSTALLMENT YEAR AMOUNT.—The term 'total installment year amount' means, with respect to a risk-sharing value-based payment agreement for the purchase of a covered outpatient drug and an installment year, an amount equal to the product of—

''(i) the unit price of the drug charged under the agreement; and

''(ii) the number of units of such drug administered under the agreement during such installment year.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1903(i)(10)(A) of the Social Security Act (42 U.S.C. 1396b(i)(10)(A)) is amended by striking ''or unless section 1927(a)(3) applies'' and inserting '', section 1927(a)(3) applies with respect to such drugs, or such drugs are the subject of a risk-sharing value-based payment agreement under section 1927(l)''.

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

(A) in paragraph (1)(A), by inserting ''but excluding any drugs for which payment is made by a State under a risk-sharing value-based payment agreement under subsection (l))'' after ''for coverage of such drugs''; and

(B) in paragraph (3)—

(i) in subparagraph (C)(i), by inserting ''or subsection (l)(2)(A)'' after ''subparagraph (A)''; and

(ii) in subparagraph (D), in the matter preceding clause (i), by inserting '', under subsection (l)(2)(A),'' after ''under this paragraph''.

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