

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.

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## 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.

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 “Generating Effective  
5 and Novel Evidence for Therapy Payment Act” or  
6 “GENE Therapy Payment Act”.

1 **SEC. 2. RISK-SHARING VALUE-BASED PAYMENT AGREE-**  
2 **MENTS FOR COVERED OUTPATIENT DRUGS**  
3 **UNDER MEDICAID.**

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

7 “(1) STATE OPTION TO PAY FOR COVERED OUT-  
8 PATIENT DRUGS THROUGH RISK-SHARING VALUE-BASED  
9 AGREEMENTS.—

10 “(1) IN GENERAL.—Beginning January 1,  
11 2022, a State shall have the option to pay (whether  
12 on a fee-for-service or managed care basis) for cov-  
13 ered outpatient drugs that are potentially curative  
14 treatments intended for one-time use that are ad-  
15 ministered to individuals under this title by entering  
16 into a risk-sharing value-based payment agreement  
17 with the manufacturer of the drug in accordance  
18 with the requirements of this subsection.

19 “(2) SECRETARIAL APPROVAL.—

20 “(A) IN GENERAL.—A State shall submit a  
21 request to the Secretary to enter into a risk-  
22 sharing value-based payment agreement, and  
23 the Secretary shall not approve a proposed risk-  
24 sharing value-based payment agreement be-  
25 tween a State and a manufacturer for payment

1 for a covered outpatient drug of the manufac-  
2 turer unless the following requirements are met:

3 “(i) MANUFACTURER HAS IN EFFECT  
4 A REBATE AGREEMENT AND IS IN COMPLI-  
5 ANCE WITH ALL APPLICABLE REQUIRE-  
6 MENTS.—The manufacturer has a rebate  
7 agreement in effect as required under sub-  
8 sections (a) and (b) of this section and is  
9 in compliance with all applicable require-  
10 ments under this title.

11 “(ii) NO INCREASE TO PROJECTED  
12 NET FEDERAL SPENDING.—

13 “(I) IN GENERAL.—The Chief  
14 Actuary certifies that the projected  
15 payments for each covered outpatient  
16 drug under a proposed risk-sharing  
17 value-based payment agreement is not  
18 expected to result in greater estimated  
19 Federal spending under this title than  
20 the net Federal spending that would  
21 result in the absence of such agree-  
22 ment.

23 “(II) NET FEDERAL SPENDING  
24 DEFINED.—For purposes of this sub-  
25 section, the term ‘net Federal spend-

1           ing’ means the amount of Federal  
2           payments the Chief Actuary estimates  
3           would be made under this title for ad-  
4           ministering a covered outpatient drug  
5           to an individual eligible for medical  
6           assistance under a State plan or a  
7           waiver of such plan, reduced by the  
8           amount of all rebates the Chief Actu-  
9           ary estimates would be paid with re-  
10          spect to the administering of such  
11          drug, including all rebates under this  
12          title and any supplemental or other  
13          additional rebates, in the absence of  
14          such an agreement.

15                 “(III) INFORMATION.—The Chief  
16          Actuary shall make the certifications  
17          required under this clause based on  
18          the most recently available and reli-  
19          able drug pricing and product infor-  
20          mation. The State and manufacturer  
21          shall provide the Secretary and the  
22          Chief Actuary with all necessary infor-  
23          mation required to make the estimates  
24          needed for such certifications.

1           “(iii) LAUNCH AND LIST PRICE JUS-  
2           TIFICATIONS.—The manufacturer submits  
3           all relevant information and supporting  
4           documentation necessary for pricing deci-  
5           sions as deemed appropriate by the Sec-  
6           retary, which shall be truthful and non-  
7           misleading, including manufacturer infor-  
8           mation and supporting documentation for  
9           launch price or list price increases, and  
10          any applicable justification required under  
11          section 1128L.

12          “(iv) CONFIDENTIALITY OF INFORMA-  
13          TION; PENALTIES.—The provisions of sub-  
14          paragraphs (C) and (D) of subsection  
15          (b)(3) shall apply to a manufacturer that  
16          fails to submit the information and docu-  
17          mentation required under clauses (ii) and  
18          (iii) on a timely basis, or that knowingly  
19          provides false or misleading information, in  
20          the same manner as such provisions apply  
21          to a manufacturer with a rebate agreement  
22          under this section.

23          “(B) CONSIDERATION OF STATE REQUEST  
24          FOR APPROVAL.—

1           “(i) IN GENERAL.—The Secretary  
2 shall treat a State request for approval of  
3 a risk-sharing value-based payment agree-  
4 ment in the same manner that the Sec-  
5 retary treats a State plan amendment, and  
6 subpart B of part 430 of title 42, Code of  
7 Federal Regulations, including, subject to  
8 clause (ii), the timing requirements of sec-  
9 tion 430.16 of such title (as in effect on  
10 the date of enactment of this subsection),  
11 shall apply to a request for approval of a  
12 risk-sharing value-based payment agree-  
13 ment in the same manner as such subpart  
14 applies to a State plan amendment.

15           “(ii) TIMING.—The Secretary shall  
16 consult with the Commissioner of Food  
17 and Drugs as required under subpara-  
18 graph (C) and make a determination on  
19 whether to approve a request from a State  
20 for approval of a proposed risk-sharing  
21 value-based payment agreement (or request  
22 additional information necessary to allow  
23 the Secretary to make a determination  
24 with respect to such request for approval)  
25 within the time period, to the extent prac-

1            ticable, specified in section 430.16 of title  
2            42, Code of Federal Regulations (as in ef-  
3            fect on the date of enactment of this sub-  
4            section), but in no case shall the Secretary  
5            take more than 180 days after the receipt  
6            of such request for approval or response to  
7            such request for additional information to  
8            make such a determination (or request ad-  
9            ditional information).

10            “(C) CONSULTATION WITH THE COMMIS-  
11            SIONER OF FOOD AND DRUGS.—In considering  
12            whether to approve a risk-sharing value-based  
13            payment agreement, the Secretary, to the ex-  
14            tent necessary, shall consult with the Commis-  
15            sioner of Food and Drugs to determine whether  
16            the relevant clinical parameters specified in  
17            such agreement are appropriate.

18            “(3) INSTALLMENT-BASED PAYMENT STRUC-  
19            TURE.—

20            “(A) IN GENERAL.—A risk-sharing value-  
21            based payment agreement shall provide for a  
22            payment structure under which, for every in-  
23            stallment year of the agreement (subject to sub-  
24            paragraph (B)), the State shall pay the total in-  
25            stallment year amount in equal installments to

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

3 “(B) REQUIREMENTS FOR INSTALLMENT  
4 PAYMENTS.—

5 “(i) TIMING OF FIRST PAYMENT.—

6 The State shall make the first of the in-  
7 stallment payments described in subpara-  
8 graph (A) for an installment year not later  
9 than 30 days after the end of such year.

10 “(ii) LENGTH OF INSTALLMENT PE-  
11 RIOD.—The period of time over which the  
12 State shall make the installment payments  
13 described in subparagraph (A) for an in-  
14 stallment year shall not be longer than 5  
15 years.

16 “(iii) NONPAYMENT OR REDUCED  
17 PAYMENT OF INSTALLMENTS FOLLOWING  
18 A FAILURE TO MEET CLINICAL PARAM-  
19 ETER.—If, prior to the payment date (as  
20 specified in the agreement) of any install-  
21 ment payment described in subparagraph  
22 (A) or any other alternative date or time  
23 frame (as otherwise specified in the agree-  
24 ment), the covered outpatient drug which  
25 is subject to the agreement fails to meet a



1 relevant clinical parameter of the agree-  
2 ment, the agreement shall provide that—

3 “(I) the installment payment  
4 shall not be made; or

5 “(II) the installment payment  
6 shall be reduced by a percentage spec-  
7 ified in the agreement that is based  
8 on the outcome achieved by the drug  
9 relative to the relevant clinical param-  
10 eter.

11 “(4) NOTICE OF INTENT.—

12 “(A) IN GENERAL.—Subject to subpara-  
13 graph (B), a manufacturer of a covered out-  
14 patient drug shall not be eligible to enter into  
15 a risk-sharing value-based payment agreement  
16 under this subsection with respect to such drug  
17 unless the manufacturer notifies the Secretary  
18 that the manufacturer is interested in entering  
19 into such an agreement with respect to such  
20 drug. The decision to submit and timing of a  
21 request to enter into a proposed risk-sharing  
22 value-based payment agreement shall remain  
23 solely within the discretion of the State and  
24 shall only be effective upon Secretarial approval  
25 as required under this subsection.

1                   “(B) TREATMENT OF SUBSEQUENTLY AP-  
2                   PROVED DRUGS.—

3                   “(i) IN GENERAL.—In the case of a  
4                   manufacturer of a covered outpatient drug  
5                   approved under section 505 of the Federal  
6                   Food, Drug, and Cosmetic Act or licensed  
7                   under section 351 of the Public Health  
8                   Service Act after the date of enactment of  
9                   this subsection, not more than 90 days  
10                  after meeting with the Food and Drug Ad-  
11                  ministration following phase II clinical  
12                  trials for such drug (or, in the case of a  
13                  drug described in clause (ii), not later than  
14                  March 31, 2022), the manufacturer must  
15                  notify the Secretary of the manufacturer’s  
16                  intent to enter into a risk-sharing value-  
17                  based payment agreement under this sub-  
18                  section with respect to such drug. If no  
19                  such meeting has occurred, the Secretary  
20                  may use discretion as to whether a poten-  
21                  tially curative treatment intended for one-  
22                  time use may qualify for a risk-sharing  
23                  value-based payment agreement under this  
24                  section. A manufacturer notification of in-  
25                  terest shall not have any influence on a de-

1 cision for drug approval by the Food and  
2 Drug Administration.

3 “(ii) APPLICATION TO CERTAIN SUB-  
4 SEQUENTLY APPROVED DRUGS.—A drug  
5 described in this clause is a covered out-  
6 patient drug of a manufacturer—

7 “(I) that is approved under sec-  
8 tion 505 of the Federal Food, Drug,  
9 and Cosmetic Act or licensed under  
10 section 351 of the Public Health Serv-  
11 ice Act after the date of enactment of  
12 this subsection; and

13 “(II) with respect to which, as of  
14 January 1, 2022, more than 90 days  
15 have passed after the manufacturer’s  
16 meeting with the Food and Drug Ad-  
17 ministration following phase II clinical  
18 trials for such drug.

19 “(iii) PARALLEL APPROVAL.—The  
20 Secretary, in coordination with the Admin-  
21 istrator of the Centers for Medicare &  
22 Medicaid Services and the Commissioner of  
23 Food and Drugs, shall, to the extent prac-  
24 ticable, approve a State’s request to enter  
25 into a proposed risk-sharing value-based

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

10 “(iv) RULE OF CONSTRUCTION.—

11 Nothing in this paragraph shall be applied  
12 or construed to modify or affect the time-  
13 frames or factors involved in the Sec-  
14 retary’s determination of whether to ap-  
15 prove or license a drug under section 505  
16 of the Federal Food, Drug, and Cosmetic  
17 Act or section 351 of the Public Health  
18 Service Act.

19 “(5) SPECIAL PAYMENT RULES.—

20 “(A) IN GENERAL.—Except as otherwise  
21 provided in this paragraph, with respect to an  
22 individual who is administered a unit of a cov-  
23 ered outpatient drug that is reimbursed under  
24 a State plan by a State Medicaid agency under  
25 a risk-sharing value-based payment agreement

1 in an installment year, the State shall remain  
2 liable to the manufacturer of such drug for pay-  
3 ment for such unit without regard to whether  
4 the individual remains enrolled in the State  
5 plan under this title (or a waiver of such plan)  
6 for each installment year for which the State is  
7 to make installment payments for covered out-  
8 patient drugs purchased under the agreement  
9 in such year.

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

18 “(C) WITHDRAWAL OF APPROVAL.—In the  
19 case of a covered outpatient drug that is the  
20 subject of a risk-sharing value-based payment  
21 agreement between a State and a manufacturer  
22 under this subsection, including a drug ap-  
23 proved in accordance with section 506(c) of the  
24 Federal Food, Drug, and Cosmetic Act, and  
25 such drug is the subject of an application that

1 has been withdrawn by the Secretary, the State  
2 plan shall not be liable for any remaining pay-  
3 ment that is owed under the agreement.

4 “(D) ALTERNATIVE ARRANGEMENT UNDER  
5 AGREEMENT.—Subject to approval by the Sec-  
6 retary, the terms of a proposed risk-sharing  
7 value-based payment agreement submitted for  
8 approval by a State may provide that subpara-  
9 graph (A) shall not apply.

10 “(E) GUIDANCE.—Not later than January  
11 1, 2022, the Secretary shall issue guidance to  
12 States establishing a process for States to no-  
13 tify the Secretary when an individual who is ad-  
14 ministered a unit of a covered outpatient drug  
15 that is purchased by a State plan under a risk-  
16 sharing value-based payment agreement ceases  
17 to be enrolled under the State plan under this  
18 title (or a waiver of such plan) or dies before  
19 the end of the installment period applicable to  
20 such unit under the agreement.

21 “(6) TREATMENT OF PAYMENTS UNDER RISK-  
22 SHARING VALUE-BASED AGREEMENTS FOR PUR-  
23 POSES OF AVERAGE MANUFACTURER PRICE; BEST  
24 PRICE.—The Secretary shall treat any payments  
25 made to the manufacturer of a covered outpatient

1 drug under a risk-sharing value-based payment  
2 agreement under this subsection during a rebate pe-  
3 riod in the same manner that the Secretary treats  
4 payments made under a State supplemental rebate  
5 agreement under sections 447.504(c)(19) and  
6 447.505(c)(7) of title 42, Code of Federal Regula-  
7 tions (or any successor regulations) for purposes of  
8 determining average manufacturer price and best  
9 price under this section with respect to the covered  
10 outpatient drug and a rebate period and for pur-  
11 poses of offsets required under subsection (b)(1)(B).

12 “(7) ASSESSMENTS AND REPORT TO CON-  
13 GRESS.—

14 “(A) ASSESSMENTS.—

15 “(i) IN GENERAL.—Not later than  
16 180 days after the end of each assessment  
17 period of any risk-sharing value-based pay-  
18 ment agreement for a State approved  
19 under this subsection, the Secretary shall  
20 conduct an evaluation of such agreement  
21 which shall include an evaluation by the  
22 Chief Actuary to determine whether pro-  
23 gram spending under the risk-sharing  
24 value-based payment agreement aligned  
25 with the projections for the agreement

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

7 “(ii) ASSESSMENT PERIOD.—For pur-  
8 poses of clause (i)—

9 “(I) the first assessment period  
10 for a risk-sharing value-based pay-  
11 ment agreement shall be the period of  
12 time over which payments are sched-  
13 uled to be made under the agreement  
14 for the first 10 individuals who are  
15 administered covered outpatient drugs  
16 under the agreement except that such  
17 period shall not exceed the 5-year pe-  
18 riod after the date on which the Sec-  
19 retary approves the agreement; and

20 “(II) each subsequent assessment  
21 period for a risk-sharing value-based  
22 payment agreement shall be the 5-  
23 year period following the end of the  
24 previous assessment period.

25 “(B) RESULTS OF ASSESSMENTS.—



1           “(i) TERMINATION OPTION.—If the  
2           Secretary determines as a result of the as-  
3           sessment by the Chief Actuary under sub-  
4           paragraph (A) that the actual Federal  
5           spending under this title for any covered  
6           outpatient drug that was the subject of the  
7           State’s risk-sharing value-based payment  
8           agreement was greater than the net Fed-  
9           eral spending that would have resulted in  
10          the absence of the agreement, the Sec-  
11          retary may terminate approval of such  
12          agreement and shall immediately conduct  
13          an assessment under this paragraph of any  
14          other ongoing risk-sharing value-based  
15          payment agreement to which the same  
16          manufacturer is a party.

17           “(ii) REPAYMENT REQUIRED.—

18           “(I) IN GENERAL.—If the Sec-  
19           retary determines as a result of the  
20           assessment by the Chief Actuary  
21           under subparagraph (A) that the Fed-  
22           eral spending under the risk-sharing  
23           value-based agreement for a covered  
24           outpatient drug that was subject to  
25           such agreement was greater than the

1 net Federal spending that would have  
2 resulted in the absence of the agree-  
3 ment, the manufacturer shall repay  
4 the difference to the State and Fed-  
5 eral Governments in a timely manner  
6 as determined by the Secretary.

7 “(II) TERMINATION FOR FAIL-  
8 URE TO PAY.—The failure of a manu-  
9 facturer to make repayments required  
10 under subclause (I) in a timely man-  
11 ner shall result in immediate termi-  
12 nation of all risk-sharing value-based  
13 agreements to which the manufacturer  
14 is a party.

15 “(III) ADDITIONAL PEN-  
16 ALTIES.—In the case of a manufac-  
17 turer that fails to make repayments  
18 required under subclause (I), the Sec-  
19 retary may treat such manufacturer  
20 in the same manner as a manufac-  
21 turer that fails to pay required re-  
22 bates under this section, and the Sec-  
23 retary may—

1                   “(aa) suspend or terminate  
2                   the manufacturer’s rebate agree-  
3                   ment under this section; and

4                   “(bb) pursue any other rem-  
5                   edy that would be available if the  
6                   manufacturer had failed to pay  
7                   required rebates under this sec-  
8                   tion.

9                   “(C) REPORT TO CONGRESS.—Not later  
10                  than 5 years after the first risk-sharing value-  
11                  based payment agreement is approved under  
12                  this subsection, the Secretary shall submit to  
13                  Congress and make available to the public a re-  
14                  port that includes—

15                  “(i) an assessment of the impact of  
16                  risk-sharing value-based payment agree-  
17                  ments on access for individuals who are eli-  
18                  gible for benefits under a State plan or  
19                  waiver under this title to medically nec-  
20                  essary covered outpatient drugs and re-  
21                  lated treatments;

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

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

4                   “(iv) such recommendations to Con-  
5                   gress as the Secretary deems appropriate.

6                   “(8) GUIDANCE AND REGULATIONS.—

7                   “(A) IN GENERAL.—Not later than Janu-  
8                   ary 1, 2022, the Secretary shall issue guidance  
9                   to States seeking to enter into risk-sharing  
10                  value-based payment agreements under this  
11                  subsection that includes a model template for  
12                  such agreements. The Secretary may issue any  
13                  additional guidance or promulgate regulations  
14                  as necessary to implement and enforce the pro-  
15                  visions of this subsection.

16                  “(B) MODEL AGREEMENTS.—

17                  “(i) IN GENERAL.—If a State ex-  
18                  presses an interest in pursuing a risk-shar-  
19                  ing value-based payment agreement under  
20                  this subsection with a manufacturer for  
21                  the purchase of a covered outpatient drug,  
22                  the Secretary may share with such State  
23                  any risk-sharing value-based agreement be-  
24                  tween a State and the manufacturer for  
25                  the purchase of such drug that has been

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

10 “(ii) CONFIDENTIALITY.—In the case  
11 of a risk-sharing value-based payment  
12 agreement that is disclosed to a State by  
13 the Secretary under this subparagraph and  
14 that is only in effect with respect to a sin-  
15 gle State, the confidentiality of information  
16 provisions described in subsection  
17 (b)(3)(D) shall apply to such information.

18 “(C) OIG CONSULTATION.—

19 “(i) IN GENERAL.—The Secretary  
20 shall consult with the Office of the Inspec-  
21 tor General of the Department of Health  
22 and Human Services to determine whether  
23 there are potential program integrity con-  
24 cerns (including issues related to compli-  
25 ance with sections 1128B and 1877) with

1 agreement approvals or templates and ad-  
2 dress accordingly.

3 “(ii) **OIG POLICY UPDATES AS NEC-**  
4 **CESSARY.**—The Inspector General of the  
5 Department of Health and Human Serv-  
6 ices shall review and update, as necessary,  
7 any policies or guidelines of the Office of  
8 the Inspector General of the Department  
9 of Health and Human Services (including  
10 policies related to the enforcement of sec-  
11 tion 1128B) to accommodate the use of  
12 risk-sharing value-based payment agree-  
13 ments in accordance with this section.

14 “(9) **RULES OF CONSTRUCTION.**—

15 “(A) **MODIFICATIONS.**—Nothing in this  
16 subsection or any regulations promulgated  
17 under this subsection shall prohibit a State  
18 from requesting a modification from the Sec-  
19 retary to the terms of a risk-sharing value-  
20 based payment agreement. A modification that  
21 is expected to result in any increase to pro-  
22 jected net State or Federal spending under the  
23 agreement shall be subject to recertification by  
24 the Chief Actuary as described in paragraph

1 (2)(A)(ii) before the modification may be ap-  
2 proved.

3 “(B) REBATE AGREEMENTS.—Nothing in  
4 this subsection shall be construed as requiring  
5 a State to enter into a risk-sharing value-based  
6 payment agreement or as limiting or super-  
7 seding the ability of a State to enter into a sup-  
8 plemental rebate agreement for a covered out-  
9 patient drug.

10 “(C) FFP FOR PAYMENTS UNDER RISK-  
11 SHARING VALUE-BASED PAYMENT AGREE-  
12 MENTS.—Federal financial participation shall  
13 be available under this title for any payment  
14 made by a State to a manufacturer for a cov-  
15 ered outpatient drug under a risk-sharing  
16 value-based payment agreement in accordance  
17 with this subsection, except that no Federal fi-  
18 nancial participation shall be available for any  
19 payment made by a State to a manufacturer  
20 under such an agreement on and after the ef-  
21 fective date of a disapproval of such agreement  
22 by the Secretary.

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

1 any regulations promulgated under this sub-  
2 section shall affect the application of any other  
3 provision of this Act.

4 “(10) APPROPRIATIONS.—For fiscal year 2020  
5 and each fiscal year thereafter, there are appro-  
6 priated to the Secretary \$5,000,000 for the purpose  
7 of carrying out this subsection.

8 “(11) DEFINITIONS.—In this subsection:

9 “(A) CHIEF ACTUARY.—The term ‘Chief  
10 Actuary’ means the Chief Actuary of the Cen-  
11 ters for Medicare & Medicaid Services.

12 “(B) INSTALLMENT YEAR.—The term ‘in-  
13 stallment year’ means, with respect to a risk-  
14 sharing value-based payment agreement, a 12-  
15 month period during which a covered outpatient  
16 drug is administered under the agreement.

17 “(C) POTENTIALLY CURATIVE TREATMENT  
18 INTENDED FOR ONE-TIME USE.—The term ‘po-  
19 tentially curative treatment intended for one-  
20 time use’ means a treatment that consists of  
21 the administration of a covered outpatient drug  
22 that—

23 “(i) is a form of gene therapy for a  
24 rare disease, as defined by the Commis-  
25 sioner of Food and Drugs, designated



1 under section 526 of the Federal Food,  
2 Drug, and Cosmetic Act, and approved  
3 under section 505 of such Act or licensed  
4 under subsection (a) or (k) of section 351  
5 of the Public Health Service Act to treat  
6 a serious or life-threatening disease or con-  
7 dition;

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

11 “(I) the cure of such disease or  
12 condition; or

13 “(II) a reduction in the symp-  
14 toms of such disease or condition to  
15 the extent that such disease or condi-  
16 tion is not expected to lead to early  
17 mortality; and

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

22 “(D) RELEVANT CLINICAL PARAMETER.—

23 The term ‘relevant clinical parameter’ means,  
24 with respect to a covered outpatient drug that

1 is the subject of a risk-sharing value-based pay-  
2 ment agreement—

3 “(i) a clinical endpoint specified in the  
4 drug’s labeling or supported by one or  
5 more of the compendia described in section  
6 1861(t)(2)(B)(ii)(I) that—

7 “(I) is able to be measured or  
8 evaluated on an annual basis for each  
9 year of the agreement on an inde-  
10 pendent basis by a provider or other  
11 entity; and

12 “(II) is required to be achieved  
13 (based on observed metrics in patient  
14 populations) under the terms of the  
15 agreement; or

16 “(ii) a surrogate endpoint (as defined  
17 in section 507(e)(9) of the Federal Food,  
18 Drug, and Cosmetic Act), including those  
19 developed by patient-focused drug develop-  
20 ment tools, that—

21 “(I) is able to be measured or  
22 evaluated on an annual basis for each  
23 year of the agreement on an inde-  
24 pendent basis by a provider or other  
25 entity; and

1                   “(II) has been qualified by the  
2                   Food and Drug Administration.

3                   “(E) RISK-SHARING VALUE-BASED PAY-  
4                   MENT AGREEMENT.—The term ‘risk-sharing  
5                   value-based payment agreement’ means an  
6                   agreement between a State plan and a manu-  
7                   facturer—

8                   “(i) for the purchase of a covered out-  
9                   patient drug of the manufacturer that is a  
10                  potentially curative treatment intended for  
11                  one-time use;

12                  “(ii) under which payment for such  
13                  drug shall be made pursuant to an install-  
14                  ment-based payment structure that meets  
15                  the requirements of paragraph (3);

16                  “(iii) which conditions payment on the  
17                  achievement of at least 2 relevant clinical  
18                  parameters (as defined in subparagraph  
19                  (C));

20                  “(iv) which provides that—

21                         “(I) the State plan will directly  
22                         reimburse the manufacturer for the  
23                         drug; or

1                   “(II) a third party will reimburse  
2                   the manufacture in a manner ap-  
3                   proved by the Secretary; and

4                   “(v) is approved by the Secretary in  
5                   accordance with paragraph (2).

6                   “(F)     TOTAL     INSTALLMENT     YEAR  
7                   AMOUNT.—The term ‘total installment year  
8                   amount’ means, with respect to a risk-sharing  
9                   value-based payment agreement for the pur-  
10                  chase of a covered outpatient drug and an in-  
11                  stallment year, an amount equal to the product  
12                  of—

13                  “(i) the unit price of the drug charged  
14                  under the agreement; and

15                  “(ii) the number of units of such drug  
16                  administered under the agreement during  
17                  such installment year.”.

18                  (b) CONFORMING AMENDMENTS.—

19                  (1) Section 1903(i)(10)(A) of the Social Secu-  
20                  rity Act (42 U.S.C. 1396b(i)(10)(A)) is amended by  
21                  striking “or unless section 1927(a)(3) applies” and  
22                  inserting “, section 1927(a)(3) applies with respect  
23                  to such drugs, or such drugs are the subject of a  
24                  risk-sharing value-based payment agreement under  
25                  section 1927(l)”.

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

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

8                   (B) in paragraph (3)—

9                           (i) in subparagraph (C)(i), by insert-  
10                           ing “or subsection (l)(2)(A)” after “sub-  
11                           paragraph (A)”; and

12                           (ii) in subparagraph (D), in the mat-  
13                           ter preceding clause (i), by inserting “,  
14                           under subsection (l)(2)(A),” after “under  
15                           this paragraph”.

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