

AMENDMENT

OFFERED BY MR. MULLIN OF OKLAHOMA

Add at the end of the bill the following (and conform the table of contents accordingly):

1 **TITLE VI—MISCELLANEOUS**

2 **SEC. 601. RISK-SHARING VALUE-BASED PAYMENT AGREE-**
3 **MENTS FOR COVERED OUTPATIENT DRUGS**
4 **UNDER MEDICAID.**

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

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

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

1 “(2) SECRETARIAL APPROVAL.—

2 “(A) IN GENERAL.—A State shall submit a
3 request to the Secretary to enter into a risk-
4 sharing value based payment agreement, and
5 the Secretary shall not approve a proposed risk-
6 sharing value-based payment agreement be-
7 tween a State and a manufacturer for payment
8 for a covered outpatient drug of the manufac-
9 turer unless the following requirements are met:

10 “(i) MANUFACTURER IS PARTY TO RE-
11 BATE AGREEMENT AND IN COMPLIANCE
12 WITH REQUIREMENTS.—The manufacturer
13 has a rebate agreement in effect as re-
14 quired under subsection (a) and (b) of this
15 section and is in compliance with all appli-
16 cable requirements under this title.

17 “(ii) NO INCREASE TO PROJECTED
18 NET FEDERAL SPENDING.—

19 “(I) IN GENERAL.—The Chief
20 Actuary certifies that the projected
21 payments for each covered outpatient
22 drug under such proposed agreement
23 would not result in greater estimated
24 Federal spending under this title than
25 the net Federal spending that would

1 result in the absence of the agree-
2 ment.

3 “(II) NET FEDERAL SPENDING
4 DEFINED.—For purposes of this sub-
5 section, the term ‘net Federal spend-
6 ing’ means the amount of Federal
7 payments the Chief Actuary estimates
8 would be made under this title for ad-
9 ministering a covered outpatient drug
10 to an individual eligible for medical
11 assistance under a State plan or a
12 waiver of such plan, reduced by the
13 amount of all rebates the Chief Actu-
14 ary estimates would be paid with re-
15 spect to the administering of such
16 drug, including all rebates under this
17 title and any supplemental or other
18 additional rebates, in the absence of
19 such an agreement.

20 “(III) INFORMATION.—The Chief
21 Actuary shall make the certifications
22 required under this clause based on
23 the most recently available and reli-
24 able drug pricing and product infor-
25 mation. The State and manufacturer

1 shall provide the Secretary and the
2 Chief Actuary with all necessary infor-
3 mation required to make the estimates
4 needed for such certifications.

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

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

1 to a manufacturer with a rebate agreement
2 under this section.

3 “(B) CONSIDERATION OF STATE REQUEST
4 FOR APPROVAL.—

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

19 “(ii) TIMING.—The Secretary shall
20 consult with the Commissioner of Food
21 and Drugs as required under subpara-
22 graph (C) and make a determination on
23 whether to approve a request from a State
24 for approval of a proposed risk-sharing
25 value-based payment agreement (or request

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

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

22 “(3) INSTALLMENT-BASED PAYMENT STRUC-
23 TURE.—

24 “(A) IN GENERAL.—A risk-sharing value-
25 based payment agreement shall provide for a

1 payment structure under which, for every in-
2 stallment year of the agreement (subject to sub-
3 paragraph (B)), the State shall pay the total in-
4 stallment year amount in equal installments to
5 be paid at regular intervals over a period of
6 time that shall be specified in the agreement.

7 “(B) REQUIREMENTS FOR INSTALLMENT
8 PAYMENTS.—

9 “(i) TIMING OF FIRST PAYMENT.—

10 The State shall make the first of the in-
11 stallment payments described in subpara-
12 graph (A) for an installment year not later
13 than 30 days after the end of such year.

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

20 “(iii) NONPAYMENT OR REDUCED
21 PAYMENT OF INSTALLMENTS FOLLOWING
22 A FAILURE TO MEET CLINICAL PARAM-
23 ETER.—If, prior to the payment date (as
24 specified in the agreement) of any install-
25 ment payment described in subparagraph

1 (A) or any other alternative date or time
2 frame (as otherwise specified in the agree-
3 ment), the covered outpatient drug which
4 is subject to the agreement fails to meet a
5 relevant clinical parameter of the agree-
6 ment, the agreement shall provide that—

7 “(I) the installment payment
8 shall not be made; or

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

15 “(4) NOTICE OF INTENT.—

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

1 value-based payment agreement shall remain
2 solely within the discretion of the State and
3 shall only be effective upon Secretarial approval
4 as required under this subsection.

5 “(B) TREATMENT OF SUBSEQUENTLY AP-
6 PROVED DRUGS.—

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

1 time use may qualify for a risk-sharing
2 value-based payment agreement under this
3 section. A manufacturer notification of in-
4 terest shall not have any influence on a de-
5 cision for approval by the Food and Drug
6 Administration.

7 “(ii) APPLICATION TO CERTAIN SUB-
8 SEQUENTLY APPROVED DRUGS.—A drug
9 described in this clause is a covered out-
10 patient drug of a manufacturer—

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

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

23 “(iii) PARALLEL APPROVAL.—The
24 Secretary, in coordination with the Admin-
25 istrator of the Centers for Medicare &

1 Medicaid Services and the Commissioner of
2 Food and Drugs, shall, to the extent prac-
3 ticable, approve a State’s request to enter
4 into a proposed risk-sharing value-based
5 payment agreement that otherwise meets
6 the requirements of this subsection at the
7 time that such a drug is approved by the
8 Food and Drug Administration to help
9 provide that no State that wishes to enter
10 into such an agreement is required to pay
11 for the drug in full at one time if the State
12 is seeking to pay over a period of time as
13 outlined in the proposed agreement.

14 “(iv) RULE OF CONSTRUCTION.—
15 Nothing in this paragraph shall be applied
16 or construed to modify or affect the time-
17 frames or factors involved in the Sec-
18 retary’s determination of whether to ap-
19 prove or license a drug under section 505
20 of the Federal Food, Drug, and Cosmetic
21 Act or section 351 of the Public Health
22 Service Act.

23 “(5) SPECIAL PAYMENT RULES.—

24 “(A) IN GENERAL.—Except as otherwise
25 provided in this paragraph, with respect to an

1 individual who is administered a unit of a cov-
2 ered outpatient drug that is purchased under a
3 State plan by a State Medicaid agency under a
4 risk-sharing value-based payment agreement in
5 an installment year, the State shall remain lia-
6 ble to the manufacturer of such drug for pay-
7 ment for such unit without regard to whether
8 the individual remains enrolled in the State
9 plan under this title (or a waiver of such plan)
10 for each installment year for which the State is
11 to make installment payments for covered out-
12 patient drugs purchased under the agreement
13 in such year.

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

22 “(C) WITHDRAWAL OF APPROVAL.—In the
23 case of a covered outpatient drug that is the
24 subject of a risk-sharing value-based agreement
25 between a State and a manufacturer under this

1 subsection, including a drug approved in ac-
2 cordance with section 506(c) of the Federal
3 Food, Drug, and Cosmetic Act, and such drug
4 is the subject of an application that has been
5 withdrawn by the Secretary, the State plan
6 shall not be liable for any remaining payment
7 that is owed under the agreement.

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

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

1 “(6) TREATMENT OF PAYMENTS UNDER RISK-
2 SHARING VALUE-BASED AGREEMENTS FOR PUR-
3 POSES OF AVERAGE MANUFACTURER PRICE; BEST
4 PRICE.—The Secretary shall treat any payments
5 made to the manufacturer of a covered outpatient
6 drug under a risk-sharing value-based payment
7 agreement under this subsection during a rebate pe-
8 riod in the same manner that the Secretary treats
9 payments made under a State supplemental rebate
10 agreement under sections 447.504(c)(19) and
11 447.505(e)(7) of title 42, Code of Federal Regula-
12 tions (or any successor regulations) for purposes of
13 determining best price under this section with re-
14 spect to the covered outpatient drug and a rebate
15 period and for purposes of offsets required under
16 subsection (b)(1)(B).

17 “(7) ASSESSMENTS AND REPORT TO CON-
18 GRESS.—

19 “(A) ASSESSMENTS.—

20 “(i) IN GENERAL.—Not later than
21 180 days after the end of each assessment
22 period of any risk-sharing value-based pay-
23 ment agreement for a State approved
24 under this subsection, the Secretary shall
25 conduct an evaluation of such agreement

1 which shall include an evaluation by the
2 Chief Actuary to determine whether pro-
3 gram spending under the risk-sharing
4 value-based payment agreement aligned
5 with the projections for the agreement
6 made under paragraph (2)(A)(ii), including
7 an assessment of whether actual Federal
8 spending under this title under the agree-
9 ment was less or more than net Federal
10 spending would have been in the absence
11 of the agreement.

12 “(ii) ASSESSMENT PERIOD.—For pur-
13 poses of clause (i)—

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

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

6 “(B) RESULTS OF ASSESSMENTS.—

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

23 “(ii) REPAYMENT REQUIRED.—

24 “(I) IN GENERAL.—If the Sec-
25 retary determines as a result of the

1 assessment by the Chief Actuary
2 under subparagraph (A) that the Fed-
3 eral spending under the risk-sharing
4 value-based agreement for a covered
5 outpatient drug that was subject to
6 such agreement was greater than the
7 net Federal spending that would have
8 resulted in the absence of the agree-
9 ment, the manufacturer shall repay
10 the difference to the State and Fed-
11 eral governments in a timely manner
12 as determined by the Secretary.

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

21 “(III) ADDITIONAL PEN-
22 ALTIES.—In the case of a manufac-
23 turer that fails to make repayments
24 required under subclause (I), the Sec-
25 retary may treat such manufacturer

1 in the same manner as a manufac-
2 turer that fails to pay required re-
3 bates under this section, and the Sec-
4 retary may—

5 “(aa) suspend or terminate
6 the manufacturer’s rebate agree-
7 ment under this section; and

8 “(bb) pursue any other rem-
9 edy that would be available if the
10 manufacturer had failed to pay
11 required rebates under this sec-
12 tion.

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

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

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

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

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

9 “(8) GUIDANCE AND REGULATIONS.—

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

19 “(B) MODEL AGREEMENTS.—

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

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

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

21 “(C) OIG CONSULTATION.—

22 “(i) IN GENERAL.—The Secretary
23 shall consult with the Office of the Inspec-
24 tor General of the Department of Health
25 and Human Services to determine whether

1 there are potential program integrity con-
2 cerns with agreement approvals or tem-
3 plates and address accordingly.

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

15 “(9) RULES OF CONSTRUCTION.—

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

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 “(ex-
4 cept for drugs for which payment is made by a
5 State under a risk-sharing value-based payment
6 agreement under subsection (l))” after “under
7 the State plan for such period”; 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”.

16 **SEC. 602. DEFINITIONS OF BEST PRICE AND AVERAGE MAN-**
17 **UFACTURER PRICE; EXCLUSION OF CERTAIN**
18 **VALUE-BASED ARRANGEMENTS FROM ANTI-**
19 **KICKBACK AND PHYSICIAN SELF-REFERRAL**
20 **PROHIBITIONS.**

21 (a) **DEFINITION OF BEST PRICE.**—Section
22 1927(c)(1)(C) of the Social Security Act (42 U.S.C.
23 1396r–8(c)(1)(C)) is amended—

24 (1) in clause (i), by striking “The term” and
25 inserting “Subject to clause (iv), the term”; and

1 (2) by adding at the end the following new
2 clauses:

3 “(iv) TREATMENT OF PAYMENTS
4 MADE UNDER VALUE-BASED PAYMENT AR-
5 RANGEMENTS.—In the case of a covered
6 outpatient drug that is a potentially cura-
7 tive treatment intended for one-time use
8 (as defined in subsection (l)(11)) and is
9 sold under a value-based payment arrange-
10 ment (as defined in clause (vi)) during a
11 rebate period, the lowest price available for
12 such drug during such rebate period shall
13 be deemed to be the lesser of—

14 “(I) the lowest price available for
15 the drug during the rebate period
16 from the manufacturer other than
17 under a value-based payment arrange-
18 ment; or

19 “(II) the lowest adjusted price
20 available for the drug during the re-
21 bate period from the manufacturer
22 under a value-based payment arrange-
23 ment.

24 “(v) ADJUSTED PRICE.—

1 “(I) IN GENERAL.—For purposes
2 of this subparagraph, the term ‘ad-
3 justed price’ means, with respect to a
4 covered outpatient drug, a value-based
5 payment arrangement, and a rebate
6 period, the average of all prices (sub-
7 ject to subclause (II)) charged for the
8 drug under the arrangement during
9 the period.

10 “(II) EXCLUSIONS.—In deter-
11 mining the adjusted price for a cov-
12 ered outpatient drug under a value-
13 based payment arrangement for a re-
14 bate period, the following prices
15 charged for the drug under the ar-
16 rangement during the period shall be
17 excluded:

18 “(aa) Any price that would
19 be excluded from the best price
20 as determined under clause (i).

21 “(bb) Any price that is in
22 the bottom 25 percent of all
23 prices charged for the drug under
24 the arrangement during the pe-
25 riod.

1 “(cc) Any price that is in
2 the top 25 percent of all prices
3 charged for the drug under the
4 arrangement during the period.

5 “(vi) VALUE-BASED PAYMENT AR-
6 RANGEMENT.—The term ‘value-based pay-
7 ment arrangement’ means an agreement
8 between a manufacturer of a covered out-
9 patient drug that is a potentially curative
10 treatment intended for one-time use (as
11 defined in subsection (l)(11)) and a pur-
12 chaser of such drug under which—

13 “(I) the manufacturer is required
14 to provide a rebate to the purchaser
15 based on the occurrence or nonoccur-
16 rence of 1 or more outcomes specified
17 in the agreement; or

18 “(II) full payment for the drug is
19 conditioned on the occurrence or non-
20 occurrence of 1 or more outcomes
21 specified in the agreement.”.

22 (b) DEFINITION OF AVERAGE MANUFACTURER
23 PRICE.—Section 1927(k)(1)(B)(i) of the Social Security
24 Act (42 U.S.C. 1396r–8(k)(1)(B)(i)) is amended—

1 (1) in subclause (IV), by striking “; and” and
2 inserting a semicolon;

3 (2) in subclause (V), by striking the period at
4 the end and inserting “; and”; and

5 (3) by adding at the end the following new sub-
6 clause:

7 “(VI) payments made to, or re-
8 bates provided by, manufacturers for
9 covered outpatient drugs that are po-
10 tentially curative treatments intended
11 for one-time use (as defined in sub-
12 section (l)(11)) under a risk-sharing
13 value-based payment agreement under
14 subsection (l) or under a value-based
15 payment arrangement (as defined in
16 subsection (c)(1)(C)(vi)).”.

17 (c) EXCLUSION OF CERTAIN VALUE-BASED AR-
18 RANGEMENTS FROM ANTI-KICKBACK AND PHYSICIAN
19 SELF-REFERRAL PROHIBITIONS.—

20 (1) ANTI-KICKBACK.—Section 1128B(b)(3) of
21 the Social Security Act (42 U.S.C. 1320a–7b(b)(3))
22 is amended—

23 (A) in subparagraph (J)—

24 (i) by moving such subparagraph 2
25 ems to the left; and

1 (ii) by striking “and” at the end;

2 (B) in subparagraph (K)—

3 (i) by moving such subparagraph 2
4 ems to the left; and

5 (ii) by striking the period at the end
6 and inserting a semicolon; and

7 (C) by adding at the end the following new
8 subparagraph:

9 “(L) a risk-sharing value-based payment
10 arrangement between a State plan and a manu-
11 facturer—

12 “(i) for the purchase of a covered out-
13 patient drug of the manufacturer that is a
14 potentially curative treatment intended for
15 one-time use (as defined in paragraph
16 (11)(C) of section 1927(l));

17 “(ii) under which payment for such
18 drug shall be made pursuant to an install-
19 ment-based payment structure that meets
20 the requirements of paragraph (3) of such
21 section;

22 “(iii) which conditions payment on the
23 achievement of at least 2 relevant clinical
24 parameters (as defined in paragraph
25 (11)(D) of such section);

1 “(iv) which provides that—

2 “(I) the State plan will directly
3 reimburse the manufacturer for the
4 drug; or

5 “(II) a third party will reimburse
6 the manufacture in a manner ap-
7 proved by the Secretary; and

8 “(v) is approved by the Secretary in
9 accordance with paragraph (2) of such sec-
10 tion.”.

11 (2) PHYSICIAN SELF-REFERRAL.—Section
12 1877(h)(1)(C) of the Social Security Act (42 U.S.C.
13 1395nn(h)(1)(C)) is amended by adding at the end
14 the following new clause:

15 “(iv) Any amounts determined under a
16 risk-sharing value-based payment arrangement
17 described in section 1128(b)(3)(L).”.

18 (d) EFFECTIVE DATE.—The amendments made by
19 this section shall take effect on January 1, 2022, and the
20 amendments made by subsections (a) and (b) shall apply
21 with respect to determinations of best price or average
22 manufacturer price made under section 1927 of the Social
23 Security Act (42 U.S.C. 1396r–8) on or after such date.

