

AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO COMMITTEE PRINT FOR SUBTITLE G RELATING TO MEDICAID OFFERED BY MR. GUTHRIE OF KENTUCKY

Add at the end of subtitle G the following new section:

**1 SEC. 30727. PRICE REPORTING CLARIFICATIONS FOR GENE
2 THERAPY OUTCOMES-BASED AGREEMENTS.**

3 (a) QUARTERLY PRICE REPORTING OBLIGATION.—
4 Section 1927(b)(3) of the Social Security Act (42 U.S.C.
5 1396r-8(b)(3)) is amended by adding at the end the fol-
6 lowing new subparagraph:

7 “(E) OUTCOMES-BASED AGREEMENTS.—
8 “(i) IN GENERAL.—Beginning Janu-
9 ary 1, 2022, in the case of a covered out-
10 patient drug that is a single course trans-
11 formative therapy (as defined in subsection
12 (k)(12)) and is sold under an outcomes-
13 based agreement (as defined in subsection
14 (k)(13)) during a rebate period, the manu-
15 facturer of such drug shall report (in addi-
16 tion to any other information required

1 under this paragraph) the pricing struc-
2 ture for such drug based on pre-defined
3 outcomes or measures specified in such
4 outcomes-based agreement.

5 “(ii) ACCESS TO OUTCOMES-BASED
6 AGREEMENTS FOR STATE PLANS.—As a
7 condition of excluding a refund, rebate, re-
8 imbursement, free item, withholding, or re-
9 payment made under an outcomes-based
10 agreement with respect to a covered out-
11 patient drug from the best price or average
12 manufacturer price of the drug for a re-
13 bate period (as described in subsection
14 (c)(1)(C)(i)(VII) or (k)(1)(B)(i)(VI), as
15 applicable), the manufacturer shall—

16 “(I) make available to each State
17 plan the opportunity to enter into an
18 outcomes-based agreement for such
19 drug and rebate period; and

20 “(II) certify to the Secretary that
21 the manufacturer has made such op-
22 portunity so available to each State
23 plan.

1 “(iii) RULES OF CONSTRUCTION.—
2 Nothing in this subparagraph shall be con-
3 strued as—

4 “(I) requiring a manufacturer to
5 execute an outcomes-based agreement
6 with a State for a covered outpatient
7 drug that is a single course trans-
8 formative therapy (as defined in sub-
9 section (k)(12)); ;

10 “(II) precluding the execution of
11 a rebate agreement under this section
12 for such a drug; or

13 “(III) limiting States’ ability to
14 join together for a multi-State con-
15 tract with a single manufacturer to
16 establish an outcomes-based agree-
17 ment for such a drug.”.

18 (b) DEFINITION OF BEST PRICE.—Section
19 1927(c)(1)(C) of the Social Security Act (42 U.S.C.
20 1396–8(c)(1)(C)) is amended—

21 (1) in clause (i)—

22 (A) in subclause (V), by striking “and”;

23 (B) in subclause (VI), by striking the pe-
24 riod at the end and inserting “; and”; and

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

3 “(VII) subject to subsection
4 (b)(3)(E)(ii), with respect to a covered
5 outpatient drug that is a single course
6 transformative therapy (as defined in
7 subsection (k)(12)) and is sold under
8 an outcomes-based agreement (as de-
9 fined in subsection (k)(13)) during
10 the rebate period, any prices resulting
11 from—

12 “(aa) a refund, rebate, reim-
13 bursement, or free goods from
14 the manufacturer or third party
15 on behalf of the manufacturer; or

16 “(bb) the withholding or re-
17 duction of a payment to the man-
18 ufacturer or third party on behalf
19 of the manufacturer;

20 that is triggered by a patient who
21 fails to achieve outcomes or measures
22 defined under the terms of such out-
23 comes-based agreement during the pe-
24 riod for which such agreement is ef-
25 fective.”; and

1 (2) in clause (ii)—

2 (A) in subclause (I), by striking the semi-
3 colon at the end and inserting “, except any
4 price adjustment described in clause (i)(VII);”;

5 (B) in subclause (III), by striking “and”;

6 (C) in subclause (IV)—

7 (i) by moving the left margin of such
8 subclause 2 ems to the right; and

9 (ii) by striking the period at the end
10 and inserting “; and”; and

11 (D) by adding at the end the following new
12 subclause:

13 “(V) in the case of a covered out-
14 patient drug that is a single course
15 transformative therapy (as defined in
16 subsection (k)(12)) and is sold under
17 an outcomes-based agreement (as de-
18 fined in subsection (k)(13)) that pro-
19 vides that payment for such drug is
20 made in installments over the course
21 of such agreement, shall be deter-
22 mined as if the aggregate price per
23 the terms of the agreement was paid
24 in full in the first installment during
25 the rebate period.”.

1 (c) DEFINITION OF AVERAGE MANUFACTURER

2 PRICE.—Section 1927(k)(1) of the Social Security Act (42

3 U.S.C. 1396r–8(k)(1)) is amended—

4 (1) in subparagraph (B)(i)—

5 (A) in subclause (IV), by striking at the
6 end “and”;

7 (B) in subclause (V), by striking the period
8 at the end and inserting “; and”; and

9 (C) by adding at the end the following new
10 subclause:

11 “(VI) subject to subsection
12 (b)(3)(E)(ii), with respect to a covered
13 outpatient drug that is a single course
14 transformative therapy (as defined in
15 paragraph (12)) and is sold under an
16 outcomes-based agreement (as defined
17 in paragraph (13)) during the rebate
18 period—

19 “(aa) a refund, rebate, reim-
20 bursment, or free goods from
21 the manufacturer or third party
22 on behalf of the manufacturer; or

23 “(bb) the withholding or re-
24 duction of a payment to the man-

1 ufacturer or third party on behalf
2 of the manufacturer;
3 that is triggered by a patient who
4 fails to achieve outcomes or measures
5 defined under the terms of such out-
6 comes-based agreement during the pe-
7 riod for which such agreement is ef-
8 fective.”; and

9 (2) by adding at the end the following new sub-
10 paragraph:

11 “(D) SPECIAL RULE FOR CERTAIN OUT-
12 COMES-BASED AGREEMENTS.—For the purpose
13 of subparagraph (A), in determining the aver-
14 age price paid to the manufacturer for a cov-
15 ered outpatient drug that is a single course
16 transformative therapy (as defined in para-
17 graph (12)) and is sold under an outcomes-
18 based agreement (as defined in paragraph (13))
19 that provides that payment for such drug is
20 made in installments over the course of such
21 agreement, such price shall be determined as if
22 the aggregate price per the terms of the agree-
23 ment was paid in full in the first installment
24 during the rebate period.”.

1 (d) OTHER DEFINITIONS.—Section 1927(k) of the
2 Social Security Act (42 U.S.C. 1396r–8(k)) is amended
3 by adding at the end the following paragraphs:

4 “(12) SINGLE COURSE TRANSFORMATIVE THER-
5 APY.—The term ‘single course transformative ther-
6 apy’ means a treatment that consists of the adminis-
7 tration of a covered outpatient drug that—

8 “(A) is a form of gene therapy, as defined
9 by the Commissioner of Food and Drugs, that
10 is—

11 “(i) designated under section 526 of
12 the Federal Food, Drug, and Cosmetics
13 Act; and

14 “(ii) licensed under subsection (a) or
15 (k) of section 351 of the Public Health
16 Service Act for a serious or life-threatening
17 rare disease or condition;

18 “(B) if administered in accordance with
19 the ‘Indications and Usage’ section of its label,
20 is expected to result in—

21 “(i) the cure of such disease or condi-
22 tion;

23 “(ii) a reduction in the symptoms of
24 such disease or condition to the extent that
25 it is expected to—

1 “(I) extend life expectancy for
2 those individuals with such disease or
3 condition;

4 “(II) prevent, eliminate, or halt
5 progression of comorbidities related to
6 such disease or condition in such indi-
7 viduals; or

8 “(III) allow such individuals to
9 achieve or maintain maximum func-
10 tional capacity in performing daily ac-
11 tivities; or

12 “(iii) prevention or elimination of epi-
13 sodes, illnesses, injuries, or disabilities re-
14 lated to such disease or condition; and

15 “(C) is expected to achieve a result de-
16 scribed in subparagraph (B), which may be
17 achieved over an extended period of time, fol-
18 lowing a single prescribed course of treatment.

19 “(13) OUTCOMES-BASED AGREEMENT.—The
20 term ‘outcomes-based agreement’ means a written
21 contract between a manufacturer and purchaser in
22 which the aggregate price over the course of the con-
23 tract of the covered outpatient drug is based on the
24 achievement of pre-defined outcomes or measures
25 and adjusted accordingly.”.

1 (e) EFFECTIVE DATE.—The amendments made by
2 this section shall take effect on January 1, 2022.

3 **SEC. 30728. ANTI-KICKBACK STATUTE AND PHYSICIAN**
4 **SELF-REFERRAL SAFE HARBORS.**

5 (a) EXCLUSION FROM ANTIKICKBACK PROHIBI-
6 TION.—Section 1128B(b)(3) of the Social Security Act
7 (42 U.S.C. 1320a–7b(b)(3)) is amended—

8 (1) in subclause (J)—

9 (A) by moving the left margin of such sub-
10 paragraph 2 ems to the left; and

11 (B) by striking “and” after the semicolon
12 at the end;

13 (2) in subclause (K)—

14 (A) by moving the left margin of such sub-
15 paragraph 2 ems to the left; and

16 (B) by striking the period at the end and
17 inserting “; and”; and

18 (3) by adding at the end the following new sub-
19 paragraph:

20 “(L) any remuneration provided by a manufac-
21 turer or third party on behalf of a manufacturer to
22 a plan under an outcomes-based agreement (as de-
23 fined in section 1927(k)(13)) in the event a patient
24 fails to achieve outcomes or measures defined in
25 such agreement following the administration of a

1 covered outpatient drug that is a single course
2 transformative therapy (as defined in section
3 1927(k)(12)).”.

4 (b) EXCLUSION FROM PHYSICIAN SELF-REFERRAL
5 PROHIBITION.—Section 1877(h)(1)(C) of the Social Secu-
6 rity Act (42 U.S.C. 1395nn(h)(1)(C)) is amended by add-
7 ing at the end the following new clause:

8 “(iv) Any amounts paid under an out-
9 comes-based agreement (as defined in section
10 1927(k)(13)).”.

11 (c) EFFECTIVE DATE.—The amendments made by
12 this section shall take effect on January 1, 2022.

13 **SEC. 30729. GAO STUDY AND REPORT ON USE OF OUT-**
14 **COMES-BASED AGREEMENTS.**

15 (a) STUDY.—The Comptroller General of the United
16 States shall conduct a study on the extent to which out-
17 comes-based agreements (as defined in section
18 1927(k)(13) of the Social Security Act (42 U.S.C. 1396r-
19 8(k)(13)) for rare disease gene therapies facilitate patient
20 access to such therapies, improve patient outcomes, lower
21 overall health system costs, and lower costs for patients
22 in Federal health care programs. In conducting such
23 study, the Comptroller General shall—

24 (1) study the impact of this subtitle on—

1 (A) mitigating socioeconomic disparities in
2 accessing rare disease gene therapies through
3 its requirement that State Medicaid programs
4 have access to the same outcomes-based agree-
5 ment remedy terms that are available in the
6 commercial market for the gene therapy; and

7 (B) the Medicaid Drug Rebate Program,
8 the 340B Drug Pricing Program, and the Medi-
9 care Part B program, including compliance with
10 such programs; and

11 (2) with respect to rare disease gene therapies
12 sold under an outcomes-based agreement (as so de-
13 fined), conduct an audit of manufacturers offering
14 State Medicaid programs the same remedy terms for
15 non-responding patients as offered to commercial in-
16 surance plans during a particular rebate period, as
17 described in subsections (c)(1)(C)(i)(VII) and
18 (k)(1)(B)(i)(VI) of section 1927 of the Social Secu-
19 rity Act (42 U.S.C. 1396r–8), as added by this sub-
20 title.

21 (b) REPORT.—Not later than June 30, 2027, the
22 Comptroller General of the United States shall submit to
23 Congress a report containing the results of the study con-
24 ducted under subsection (a).

1 **SEC. 30730. PRICE REPORTING CLARIFICATIONS FOR GENE**
2 **THERAPY OUTCOMES-BASED AGREEMENTS.**

3 (a) QUARTERLY PRICE REPORTING OBLIGATION.—
4 Section 1927(b)(3) of the Social Security Act (42 U.S.C.
5 1396r-8(b)(3)) is amended by adding at the end the fol-
6 lowing new subparagraph:

7 “(E) OUTCOMES-BASED AGREEMENTS.—

8 “(i) IN GENERAL.—Beginning Janu-
9 ary 1, 2022, in the case of a covered out-
10 patient drug that is a single course trans-
11 formative therapy (as defined in subsection
12 (k)(12)) and is sold under an outcomes-
13 based agreement (as defined in subsection
14 (k)(13)) during a rebate period, the manu-
15 facturer of such drug shall report (in addi-
16 tion to any other information required
17 under this paragraph) the pricing struc-
18 ture for such drug based on pre-defined
19 outcomes or measures specified in such
20 outcomes-based agreement.

21 “(ii) ACCESS TO OUTCOMES-BASED
22 AGREEMENTS FOR STATE PLANS.—As a
23 condition of excluding a refund, rebate, re-
24 imbursement, free item, withholding, or re-
25 payment made under an outcomes-based
26 agreement with respect to a covered out-

1 patient drug from the best price or average
2 manufacturer price of the drug for a re-
3 bate period (as described in subsection
4 (c)(1)(C)(i)(VII) or (k)(1)(B)(i)(VI), as
5 applicable), the manufacturer shall—

6 “(I) make available to each State
7 plan the opportunity to enter into an
8 outcomes-based agreement for such
9 drug and rebate period; and

10 “(II) certify to the Secretary that
11 the manufacturer has made such op-
12 portunity so available to each State
13 plan.

14 “(iii) RULES OF CONSTRUCTION.—
15 Nothing in this subparagraph shall be con-
16 strued as—

17 “(I) requiring a manufacturer to
18 execute an outcomes-based agreement
19 with a State for a covered outpatient
20 drug that is a single course trans-
21 formative therapy (as defined in sub-
22 section (k)(12)); ;

23 “(II) precluding the execution of
24 a rebate agreement under this section
25 for such a drug; or

1 “(III) limiting States’ ability to
2 join together for a multi-State con-
3 tract with a single manufacturer to
4 establish an outcomes-based agree-
5 ment for such a drug.”.

6 (b) DEFINITION OF BEST PRICE.—Section
7 1927(c)(1)(C) of the Social Security Act (42 U.S.C.
8 1396–8(c)(1)(C)) is amended—

9 (1) in clause (i)—

10 (A) in subclause (V), by striking “and”;

11 (B) in subclause (VI), by striking the pe-
12 riod at the end and inserting “; and”; and

13 (C) by adding at the end the following new
14 subclause:

15 “(VII) subject to subsection
16 (b)(3)(E)(ii), with respect to a covered
17 outpatient drug that is a single course
18 transformative therapy (as defined in
19 subsection (k)(12)) and is sold under
20 an outcomes-based agreement (as de-
21 fined in subsection (k)(13)) during
22 the rebate period, any prices resulting
23 from—

24 “(aa) a refund, rebate, reim-
25 bursement, or free goods from

1 the manufacturer or third party
2 on behalf of the manufacturer; or

3 “(bb) the withholding or re-
4 duction of a payment to the man-
5 ufacturer or third party on behalf
6 of the manufacturer;

7 that is triggered by a patient who
8 fails to achieve outcomes or measures
9 defined under the terms of such out-
10 comes-based agreement during the pe-
11 riod for which such agreement is ef-
12 fective.”; and

13 (2) in clause (ii)—

14 (A) in subclause (I), by striking the semi-
15 colon at the end and inserting “, except any
16 price adjustment described in clause (i)(VII);”;

17 (B) in subclause (III), by striking “and”;

18 (C) in subclause (IV)—

19 (i) by moving the left margin of such
20 subclause 2 ems to the right; and

21 (ii) by striking the period at the end
22 and inserting “; and”; and

23 (D) by adding at the end the following new
24 subclause:

1 “(V) in the case of a covered out-
2 patient drug that is a single course
3 transformative therapy (as defined in
4 subsection (k)(12)) and is sold under
5 an outcomes-based agreement (as de-
6 fined in subsection (k)(13)) that pro-
7 vides that payment for such drug is
8 made in installments over the course
9 of such agreement, shall be deter-
10 mined as if the aggregate price per
11 the terms of the agreement was paid
12 in full in the first installment during
13 the rebate period.”.

14 (c) DEFINITION OF AVERAGE MANUFACTURER
15 PRICE.—Section 1927(k)(1) of the Social Security Act (42
16 U.S.C. 1396r–8(k)(1)) is amended—

17 (1) in subparagraph (B)(i)—

18 (A) in subclause (IV), by striking at the
19 end “and”;

20 (B) in subclause (V), by striking the period
21 at the end and inserting “; and”; and

22 (C) by adding at the end the following new
23 subclause:

24 “(VI) subject to subsection
25 (b)(3)(E)(ii), with respect to a covered

1 outpatient drug that is a single course
2 transformative therapy (as defined in
3 paragraph (12)) and is sold under an
4 outcomes-based agreement (as defined
5 in paragraph (13)) during the rebate
6 period—

7 “(aa) a refund, rebate, reim-
8 bursement, or free goods from
9 the manufacturer or third party
10 on behalf of the manufacturer; or

11 “(bb) the withholding or re-
12 duction of a payment to the man-
13 ufacturer or third party on behalf
14 of the manufacturer;

15 that is triggered by a patient who
16 fails to achieve outcomes or measures
17 defined under the terms of such out-
18 comes-based agreement during the pe-
19 riod for which such agreement is ef-
20 fective.”; and

21 (2) by adding at the end the following new sub-
22 paragraph:

23 “(D) SPECIAL RULE FOR CERTAIN OUT-
24 COMES-BASED AGREEMENTS.—For the purpose
25 of subparagraph (A), in determining the aver-

1 age price paid to the manufacturer for a cov-
2 ered outpatient drug that is a single course
3 transformative therapy (as defined in para-
4 graph (12)) and is sold under an outcomes-
5 based agreement (as defined in paragraph (13))
6 that provides that payment for such drug is
7 made in installments over the course of such
8 agreement, such price shall be determined as if
9 the aggregate price per the terms of the agree-
10 ment was paid in full in the first installment
11 during the rebate period.”.

12 (d) OTHER DEFINITIONS.—Section 1927(k) of the
13 Social Security Act (42 U.S.C. 1396r–8(k)) is amended
14 by adding at the end the following paragraphs:

15 “(12) SINGLE COURSE TRANSFORMATIVE THER-
16 APY.—The term ‘single course transformative ther-
17 apy’ means a treatment that consists of the adminis-
18 tration of a covered outpatient drug that—

19 “(A) is a form of gene therapy, as defined
20 by the Commissioner of Food and Drugs, that
21 is—

22 “(i) designated under section 526 of
23 the Federal Food, Drug, and Cosmetics
24 Act; and

1 “(ii) licensed under subsection (a) or
2 (k) of section 351 of the Public Health
3 Service Act for a serious or life-threatening
4 rare disease or condition;

5 “(B) if administered in accordance with
6 the ‘Indications and Usage’ section of its label,
7 is expected to result in—

8 “(i) the cure of such disease or condi-
9 tion;

10 “(ii) a reduction in the symptoms of
11 such disease or condition to the extent that
12 it is expected to—

13 “(I) extend life expectancy for
14 those individuals with such disease or
15 condition;

16 “(II) prevent, eliminate, or halt
17 progression of comorbidities related to
18 such disease or condition in such indi-
19 viduals; or

20 “(III) allow such individuals to
21 achieve or maintain maximum func-
22 tional capacity in performing daily ac-
23 tivities; or

1 “(iii) prevention or elimination of epi-
2 sodes, illnesses, injuries, or disabilities re-
3 lated to such disease or condition; and

4 “(C) is expected to achieve a result de-
5 scribed in subparagraph (B), which may be
6 achieved over an extended period of time, fol-
7 lowing a single prescribed course of treatment.

8 “(13) OUTCOMES-BASED AGREEMENT.—The
9 term ‘outcomes-based agreement’ means a written
10 contract between a manufacturer and purchaser in
11 which the aggregate price over the course of the con-
12 tract of the covered outpatient drug is based on the
13 achievement of pre-defined outcomes or measures
14 and adjusted accordingly.”.

15 (e) EFFECTIVE DATE.—The amendments made by
16 this section shall take effect on January 1, 2022.

