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:

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

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

''(E) OUTCOMES-BASED AGREEMENTS.—

''(i) IN GENERAL.—Beginning January 1, 2022, in the case of a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)) and is sold under an outcomes-based agreement (as defined in subsection (k)(13)) during a rebate period, the manufacturer of such drug shall report (in addition to any other information required

under this paragraph) the pricing structure for such drug based on pre-defined outcomes or measures specified in such outcomes-based agreement.

''(ii) ACCESS TO OUTCOMES-BASED AGREEMENTS FOR STATE PLANS.—As a condition of excluding a refund, rebate, reimbursement, free item, withholding, or repayment made under an outcomes-based agreement with respect to a covered outpatient drug from the best price or average manufacturer price of the drug for a rebate period (as described in subsection (c)(1)(C)(i)(VII) or (k)(1)(B)(i)(VI), as applicable), the manufacturer shall—

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

''(II) certify to the Secretary that the manufacturer has made such opportunity so available to each State plan.

''(iii) RULES OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as—

''(I) requiring a manufacturer to execute an outcomes-based agreement with a State for a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)); ;

''(II) precluding the execution of a rebate agreement under this section for such a drug; or

''(III) limiting States' ability to join together for a multi-State contract with a single manufacturer to establish an outcomes-based agreement for such a drug.''.

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

(1) in clause (i)—

(A) in subclause (V), by striking ''and'';

(B) in subclause (VI), by striking the period at the end and inserting ''; and''; and

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

''(VII) subject to subsection (b)(3)(E)(ii), with respect to a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)) and is sold under an outcomes-based agreement (as defined in subsection (k)(13)) during the rebate period, any prices resulting from—

''(aa) a refund, rebate, reimbursement, or free goods from the manufacturer or third party on behalf of the manufacturer; or

''(bb) the withholding or reduction of a payment to the manufacturer or third party on behalf of the manufacturer;

that is triggered by a patient who fails to achieve outcomes or measures defined under the terms of such outcomes-based agreement during the period for which such agreement is effective.''; and

(2) in clause (ii)—

(A) in subclause (I), by striking the semicolon at the end and inserting ‘‘, except any price adjustment described in clause (i)(VII);’’;

(B) in subclause (III), by striking ‘‘and’’;

(C) in subclause (IV)—

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

(ii) by striking the period at the end and inserting ‘‘; and’’; and

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

‘‘(V) in the case of a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)) and is sold under an outcomes-based agreement (as defined in subsection (k)(13)) that provides that payment for such drug is made in installments over the course of such agreement, shall be determined as if the aggregate price per the terms of the agreement was paid in full in the first installment during the rebate period.’’.

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

(1) in subparagraph (B)(i)—

(A) in subclause (IV), by striking at the end ''and'';

(B) in subclause (V), by striking the period at the end and inserting ''; and''; and

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

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

''(aa) a refund, rebate, reimbursement, or free goods from the manufacturer or third party on behalf of the manufacturer; or

''(bb) the withholding or reduction of a payment to the man-

ufacturer or third party on behalf of the manufacturer;

that is triggered by a patient who fails to achieve outcomes or measures defined under the terms of such outcomes-based agreement during the period for which such agreement is effective.''; and

(2) by adding at the end the following new subparagraph:

''(D) SPECIAL RULE FOR CERTAIN OUTCOMES-BASED AGREEMENTS.—For the purpose of subparagraph (A), in determining the average price paid to the manufacturer for a covered outpatient drug that is a single course transformative therapy (as defined in paragraph (12)) and is sold under an outcomes-based agreement (as defined in paragraph (13)) that provides that payment for such drug is made in installments over the course of such agreement, such price shall be determined as if the aggregate price per the terms of the agreement was paid in full in the first installment during the rebate period.''.

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

''(12) SINGLE COURSE TRANSFORMATIVE THERAPY.—The term 'single course transformative therapy' means a treatment that consists of the administration of a covered outpatient drug that—

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

''(i) designated under section 526 of the Federal Food, Drug, and Cosmetics Act; and

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

''(B) if administered in accordance with the 'Indications and Usage' section of its label, is expected to result in—

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

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

''(I) extend life expectancy for those individuals with such disease or condition;

''(II) prevent, eliminate, or halt progression of comorbidities related to such disease or condition in such individuals; or

''(III) allow such individuals to achieve or maintain maximum functional capacity in performing daily activities; or

''(iii) prevention or elimination of episodes, illnesses, injuries, or disabilities related to such disease or condition; and

''(C) is expected to achieve a result described in subparagraph (B), which may be achieved over an extended period of time, following a single prescribed course of treatment.

''(13) OUTCOMES-BASED AGREEMENT.—The term 'outcomes-based agreement' means a written contract between a manufacturer and purchaser in which the aggregate price over the course of the contract of the covered outpatient drug is based on the achievement of pre-defined outcomes or measures and adjusted accordingly.''.

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

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

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

(1) in subclause (J)—

(A) by moving the left margin of such subparagraph 2 ems to the left; and

(B) by striking ''and'' after the semicolon at the end;

(2) in subclause (K)—

(A) by moving the left margin of such subparagraph 2 ems to the left; and

(B) by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(L) any remuneration provided by a manufacturer or third party on behalf of a manufacturer to a plan under an outcomes-based agreement (as defined in section 1927(k)(13)) in the event a patient fails to achieve outcomes or measures defined in such agreement following the administration of a

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

(b) EXCLUSION FROM PHYSICIAN SELF-REFERRAL PROHIBITION.—Section 1877(h)(1)(C) of the Social Security Act (42 U.S.C. 1395nn(h)(1)(C)) is amended by adding at the end the following new clause:

''(iv) Any amounts paid under an outcomes-based agreement (as defined in section 1927(k)(13)).''.

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

SEC. 30729. GAO STUDY AND REPORT ON USE OF OUTCOMES-BASED AGREEMENTS.

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

(1) study the impact of this subtitle on–

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

(B) the Medicaid Drug Rebate Program, the 340B Drug Pricing Program, and the Medicare Part B program, including compliance with such programs; and

(2) with respect to rare disease gene therapies sold under an outcomes-based agreement (as so defined), conduct an audit of manufacturers offering State Medicaid programs the same remedy terms for non-responding patients as offered to commercial insurance plans during a particular rebate period, as described in subsections (c)(1)(C)(i)(VII) and (k)(1)(B)(i)(VI) of section 1927 of the Social Security Act (42 U.S.C. 1396r–8), as added by this subtitle.

(b) REPORT.—Not later than June 30, 2027, the Comptroller General of the United States shall submit to Congress a report containing the results of the study conducted under subsection (a).

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

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

''(E) OUTCOMES-BASED AGREEMENTS.—

''(i) IN GENERAL.—Beginning January 1, 2022, in the case of a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)) and is sold under an outcomes-based agreement (as defined in subsection (k)(13)) during a rebate period, the manufacturer of such drug shall report (in addition to any other information required under this paragraph) the pricing structure for such drug based on pre-defined outcomes or measures specified in such outcomes-based agreement.

''(ii) ACCESS TO OUTCOMES-BASED AGREEMENTS FOR STATE PLANS.—As a condition of excluding a refund, rebate, reimbursement, free item, withholding, or repayment made under an outcomes-based agreement with respect to a covered out-

patient drug from the best price or average manufacturer price of the drug for a rebate period (as described in subsection (c)(1)(C)(i)(VII) or (k)(1)(B)(i)(VI), as applicable), the manufacturer shall—

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

''(II) certify to the Secretary that the manufacturer has made such opportunity so available to each State plan.

''(iii) RULES OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as—

''(I) requiring a manufacturer to execute an outcomes-based agreement with a State for a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)); ;

''(II) precluding the execution of a rebate agreement under this section for such a drug; or

"(III) limiting States' ability to join together for a multi-State contract with a single manufacturer to establish an outcomes-based agreement for such a drug.".

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

(1) in clause (i)—

(A) in subclause (V), by striking "and";

(B) in subclause (VI), by striking the period at the end and inserting "; and"; and

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

"(VII) subject to subsection (b)(3)(E)(ii), with respect to a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)) and is sold under an outcomes-based agreement (as defined in subsection (k)(13)) during the rebate period, any prices resulting from—

"(aa) a refund, rebate, reimbursement, or free goods from

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

''(bb) the withholding or reduction of a payment to the manufacturer or third party on behalf of the manufacturer;

that is triggered by a patient who fails to achieve outcomes or measures defined under the terms of such outcomes-based agreement during the period for which such agreement is effective.''; and

(2) in clause (ii)—

(A) in subclause (I), by striking the semicolon at the end and inserting '', except any price adjustment described in clause (i)(VII);'';

(B) in subclause (III), by striking ''and'';

(C) in subclause (IV)—

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

(ii) by striking the period at the end and inserting ''; and''; and

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

''(V) in the case of a covered outpatient drug that is a single course transformative therapy (as defined in subsection (k)(12)) and is sold under an outcomes-based agreement (as defined in subsection (k)(13)) that provides that payment for such drug is made in installments over the course of such agreement, shall be determined as if the aggregate price per the terms of the agreement was paid in full in the first installment during the rebate period.''.

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

(1) in subparagraph (B)(i)—

(A) in subclause (IV), by striking at the end ''and'';

(B) in subclause (V), by striking the period at the end and inserting ''; and''; and

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

''(VI) subject to subsection (b)(3)(E)(ii), with respect to a covered

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

''(aa) a refund, rebate, reimbursement, or free goods from the manufacturer or third party on behalf of the manufacturer; or

''(bb) the withholding or reduction of a payment to the manufacturer or third party on behalf of the manufacturer;

that is triggered by a patient who fails to achieve outcomes or measures defined under the terms of such outcomes-based agreement during the period for which such agreement is effective.''; and

(2) by adding at the end the following new subparagraph:

''(D) SPECIAL RULE FOR CERTAIN OUTCOMES-BASED AGREEMENTS.—For the purpose of subparagraph (A), in determining the aver-

age price paid to the manufacturer for a covered outpatient drug that is a single course transformative therapy (as defined in paragraph (12)) and is sold under an outcomes-based agreement (as defined in paragraph (13)) that provides that payment for such drug is made in installments over the course of such agreement, such price shall be determined as if the aggregate price per the terms of the agreement was paid in full in the first installment during the rebate period.''.

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

''(12) SINGLE COURSE TRANSFORMATIVE THERAPY.—The term 'single course transformative therapy' means a treatment that consists of the administration of a covered outpatient drug that—

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

''(i) designated under section 526 of the Federal Food, Drug, and Cosmetics Act; and

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

''(B) if administered in accordance with the 'Indications and Usage' section of its label, is expected to result in—

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

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

''(I) extend life expectancy for those individuals with such disease or condition;

''(II) prevent, eliminate, or halt progression of comorbidities related to such disease or condition in such individuals; or

''(III) allow such individuals to achieve or maintain maximum functional capacity in performing daily activities; or

"(iii) prevention or elimination of episodes, illnesses, injuries, or disabilities related to such disease or condition; and

"(C) is expected to achieve a result described in subparagraph (B), which may be achieved over an extended period of time, following a single prescribed course of treatment.

"(13) OUTCOMES-BASED AGREEMENT.—The term 'outcomes-based agreement' means a written contract between a manufacturer and purchaser in which the aggregate price over the course of the contract of the covered outpatient drug is based on the achievement of pre-defined outcomes or measures and adjusted accordingly.".

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