AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO COMMITTEE PRINT FOR SUBTITLE E RELATING TO DRUG PRICING

OFFERED BY M__. _____

Add at the end the following:

PART 5—CODIFYING VALUE-BASE PURCHASING ARRANGEMENTS UNDER MEDICAID AND REFORMS RELATING TO PRICES UNDER SUCH ARRANGEMENTS

SEC. 30541. CODIFYING VALUE-BASE PURCHASING ARRANGEMENTS UNDER MEDICAID AND REFORMS RELATING TO PRICES UNDER SUCH ARRANGEMENTS.

(a) CODIFICATION OF VBP RULE.—The text of part 447 of the final rule (85 Federal Register 87101 - 87104) published on December 31, 2020, by the Secretary of Health and Human Services (relating to Supporting Value-Based Purchasing under State Medicaid plans) shall have the force and effect of law.

(b) REQUIREMENT TO UPDATE AMP REPORTING.—Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(A)) is amended by adding at the

end of the flush left matter at the end the following new sentence: ''Information reported under clause (i)(I) relating to average manufacturer price shall be updated for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the average price paid to the manufacturer for covered outpatient drugs of the manufacturer.''

(c) ENSURING COVERAGE OF CERTAIN DRUGS UNDER MEDICAID.—

(1) MANUFACTURERS WHICH HAVE ONLY ENTERED INTO A VALUE-BASED ARRANGEMENT.—

(A) IN GENERAL.—Beginning 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall require manufacturers of Medicaid drugs to report the average non-value based purchasing arrangement, commercial price of such drugs on semi annual basis.

(B) ENFORCEMENT.—In the case a manufacturer does not comply with subparagraph (A), the manufacturer may not participate in any value-based purchasing arrangement under Medicaid.

(2) FORGIVENESS OF AMOUNTS FOR CERTAIN DRUGS.—Notwithstanding any other provision of

law, the forgiveness of the amount of a drug that would have otherwise been required to be paid for a drug subject to value-based purchasing arrangement shall not be considered remuneration.

(d) GAO STUDY AND REPORT.—

(1) STUDY.—The Comptroller General shall conduct a study on facilitating patient access to therapies, improving patient outcomes, lowering overall health system costs, and lowering costs for patients in Federal health care programs. In conducting such study, the Comptroller General shall also include information on, or details of—

(A) the impact of the provisions of this Act and the amendments made by this Act on—

(i) 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

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

(B) with respect to a drug sold under an outcomes-based agreement, 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.

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

(e) CERTIFICATION OF MULTIPLE BEST PRICES FOR VALUE-BASED PURCHASING ARRANGEMENTS.—Section 1927(b)(3) of the Social Security Act is amended by adding at the end the following new clauses:

''(A) CERTIFICATION OF MULTIPLE BEST PRICES FOR VALUE-BASED PURCHASING ARRANGEMENTS.—

''(i) MANUFACTURER CERTIFICATION OF STATE MEDICAID ACCESS TO LOWEST AVAILABLE PRICE UNDER A VALUE-BASED PURCHASING ARRANGEMENT.—As part of its submission in subparagraph (A)(i), the manufacturer shall certify that they offer the value-based payment arrangement pricing structure reported, to each State with

which it negotiates a value-based purchasing arrangement for such covered outpatient drug during the rebate period in which the drug is sold.

''(ii) ANNUAL AUDIT.—The Inspector General of the Department of Health and Human Services shall annually audit the manufacturer certification described in clause (i).

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

''(I) requiring—

''(aa) a State to enter into a value-based purchasing arrangement with a manufacturer for a covered outpatient drug; or

''(bb) a manufacturer to enter into a value-based purchasing arrangement with a State for a covered outpatient drug;

''(II) prohibiting a manufacturer from treating events described in

items (aa) or (bb) in subsection (c)(1)(C)(i)(VII) as a bundled sale; or

''(III) precluding the execution of a supplemental rebate agreement, as provided in subsection (a)(1), for a covered outpatient drug sold under a value-based purchasing arrangement.''.

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