118TH CONGRESS
1ST SESSION

S. 2406

To amend title XVIII of the Social Security Act to improve oversight of formulary development and management under Medicare part D.

IN THE SENATE OF THE UNITED STATES

JULY 20, 2023

Mr. CARPER (for himself and Mr. GRASSLEY) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act to improve oversight of formulary development and management under Medicare part D.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''PBM Oversight Act of 2023''.

SEC. 2. RESOLVING CONFLICTS OF INTEREST AND IMPROVING OVERSIGHT OF P&T COMMITTEE OVERRIDES.

(a) IN GENERAL.—Section 1860D–4(b)(3) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)) is amended—

(1) in subparagraph (A)(ii)(I), by inserting the following before the semicolon: ''(and, for 2025 and each subsequent year, any pharmacy benefit manager)''; and

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

''(J) REPORTING ON ADDITIONAL COMMITTEES WITH FORMULARY DECISION MAKING AUTHORITY.—

''(i) IN GENERAL.—For 2026 and each subsequent plan year, a PDP sponsor shall submit to the Secretary the following information, if applicable, with respect to each prescription drug plan offered by the PDP sponsor:

''(I) The name and a description of the role and composition of any committee, entity, or individual within or affiliated with the PDP sponsor (or a pharmacy benefit manager, acting

under contract with such sponsor) that has the authority to make a coverage, formulary placement, or utilization management decision (as defined in clause (ii)(I)), other than the pharmacy and therapeutic committee described in subparagraph (A).

''(II) A list of drugs for which a committee, entity, or individual described in subclause (I) made a coverage, formulary placement, or utilization management decision (as so defined) and the corresponding initial recommendation (as defined in clause (ii)(II)) made by the pharmacy and therapeutic committee.

''(III) A brief justification for each decision described in subclause (II).

''(ii) DEFINITIONS.—In this subparagraph:

''(I) COVERAGE, FORMULARY PLACEMENT, OR UTILIZATION MANAGEMENT DECISION.—The term 'coverage, formulary placement, or utiliza-

tion management decision' means a decision by a committee, entity, or individual described in clause (i)(I) that modifies, adjusts, reverses, or otherwise alters (such as by substituting the formulary inclusion of one covered part D drug for another or by substituting a more general initial recommendation for a more specific decision) an initial recommendation by the pharmacy and therapeutic committee.

''(II) INITIAL RECOMMENDATION.—The term 'initial recommendation' means a coverage, formulary placement, or utilization management decision recommended by the pharmacy and therapeutic committee prior to the review, adoption, or modification of such a recommendation by a committee, entity, or individual described in clause (i)(I). For purposes of this subparagraph, such initial recommendation shall be considered to be separate and distinct from the final

review and approval of the formulary design and components by such pharmacy and therapeutic committee, as required under section 423.120 of title 42, Code of Federal Regulations (or any successor regulation).

''(iii) NON-APPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this subparagraph.''.

(b) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by subsection (a) by program instruction or otherwise.

(c) GAO STUDY AND REPORT.—

(1) STUDY.—The Comptroller General shall conduct a study on the use of committees, entities, or individuals described in clause (i)(I) of section 1860D–4(b)(3)(J) of the Social Security Act, as added by subsection (a), in the development and review of formularies under part D of title XVIII of the Social Security Act. Such study shall include an analysis of the following:

(A) The prevalence of such committees, entities, or individuals.

(B) The number, type, and characteristics of drugs for which a committee, entity, or individual described in such clause (i)(I) made a coverage, formulary placement, or utilization management decision (as defined in clause (ii)(I) of such section 1860D–4(b)(3)(J)).

(C) Trends in the justifications provided under clause (i)(III) of such section 1860D–4(b)(3)(J).

(D) Trends in the application of utilization management tools (such as prior authorization, step therapy, and quantity limits) and formulary exclusions under prescription drug plans and MA–PD plans and the impact such tools and exclusions have on beneficiary access to covered part D drugs.

(2) REPORT.—Not later than January 1, 2029, the Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with any recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(3) DEFINITIONS.—In this subsection:

(A) COMPTROLLER GENERAL.—The term ''Comptroller General'' means the Comptroller General of the United States.

(B) OTHER TERMS.—The terms ''covered part D drug'', ''MA–PD plan'', and ''prescription drug plan'' have the meaning given those terms in section 1860D–41 of the Social Security Act (42 U.S.C. 1395w–151).

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