118TH CONGRESS
1ST SESSION

S. 2254

To amend title XVIII of the Social Security Act to establish pharmacy benefit manager reporting requirements with respect to prescription drug plans and MA–PD plans under Medicare part D.

IN THE SENATE OF THE UNITED STATES

JULY 12, 2023

Ms. CORTEZ MASTO (for herself, Mr. TILLIS, Mr. WYDEN, and Mr. CRAPO) 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 establish pharmacy benefit manager reporting requirements with respect to prescription drug plans and MA–PD plans 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 ''Medicare PBM Accountability Act''.

SEC. 2. PHARMACY BENEFIT MANAGER REPORTING REQUIREMENTS WITH RESPECT TO PRESCRIPTION DRUG PLANS AND MA–PD PLANS.

(a) IN GENERAL.—

(1) PRESCRIPTION DRUG PLANS.—Section 1860D–12 of the Social Security Act (42 U.S.C. 1395w–112) is amended by adding at the end the following new subsection:

''(h) PHARMACY BENEFIT MANAGER REPORTING REQUIREMENTS.—For plan years beginning on or after January 1, 2026:

''(1) AGREEMENTS WITH PHARMACY BENEFIT MANAGERS.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that any pharmacy benefit manager acting on behalf of such sponsor has a written agreement with the PDP sponsor under which the pharmacy benefit manager agrees to meet the following requirements:

''(A) TRANSPARENCY REGARDING GUARANTEES AND COST PERFORMANCE EVALUATIONS.—The pharmacy benefit manager shall—

''(i) define, interpret, and apply terms (such as generic drug, brand name drug (consistent with the definition of those

terms under section 423.4 of title 42, Code of Federal Regulations, or a successor regulation), specialty drug, rebate, and discount) in a fully transparent and consistent manner for purposes of calculating or otherwise evaluating pharmacy benefit manager performance against pricing guarantees or similar cost performance measurements related to rebates, discounts, price concessions, or net costs;

''(ii) identify any drugs, claims, or price concessions excluded from any pricing guarantee or other cost performance calculation or evaluation in a clear and consistent manner; and

''(iii) where a pricing guarantee or other cost performance measure is based on a pricing benchmark other than the wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) of a drug, calculate and provide a wholesale acquisition cost-based equivalent to the pricing guarantee or other cost performance measure in the contract.

''(B) PROVISION OF INFORMATION.—

"(i) IN GENERAL.—Not later than July 1 of each year, the pharmacy benefit manager shall submit to the PDP sponsor, and to the Secretary upon request, a report, in accordance with this subparagraph, and shall make such report available to the sponsor at no cost to such sponsor in a machine-readable format and, as the Secretary may determine, other formats. Each such report shall include, with respect to such PDP sponsor and each plan offered by such sponsor, the following information with respect to the previous plan year:

"(I) A list of all drugs covered by the plan that were dispensed including, with respect to each such drug—

"(aa) the brand name, generic or non-proprietary name, and National Drug Code;

"(bb) the number of plan enrollees for whom the drug was dispensed, the total number of prescription claims for the drug (including original prescriptions

and refills, counted as separate claims), and the total number of dosage units of the drug dispensed;

"(cc) the number of claims described in item (bb) that were dispensed using each type of dispensing channel, including retail, mail order, specialty pharmacy, or other types of pharmacies or providers as defined by the pharmacy benefit manager;

"(dd) the average wholesale acquisition cost, listed as cost per day's supply, cost per dosage unit, and cost per typical course of treatment (as applicable);

"(ee) the average wholesale price for the drug, listed as cost per day's supply, cost per dosage unit, and cost per typical course of treatment (as applicable);

"(ff) the total out-of-pocket spending by plan enrollees on such drug after application of

any benefits under the plan, including plan enrollee spending through copayments, coinsurance, and deductibles;

''(gg) total rebates paid by the manufacturer on the drug as reported under the Detailed DIR Report (or any successor report) submitted by such sponsor to the Centers for Medicare & Medicaid Services;

''(hh) all other direct or indirect remuneration on the drug as reported under the Detailed DIR Report (or any successor report) submitted by such sponsor to the Centers for Medicare & Medicaid Services;

''(ii) the average pharmacy reimbursement amount charged to the plan for the drug by dispensing channel identified in item (cc);

''(jj) the average National Average Drug Acquisition Cost

(NADAC) for retail community pharmacies; and

''(kk) total manufacturer-derived revenue, inclusive of bona fide service fees, retained by the pharmacy benefit manager and any affiliate of such pharmacy benefit manager attributable to the drug.

''(II) In the case of a pharmacy benefit manager that has an affiliate that is a retail, mail order, or specialty pharmacy, with respect to drugs covered by such plan that were dispensed, the following information:

''(aa) The percentage of total prescriptions that were dispensed by pharmacies that are an affiliate of the pharmacy benefit manager for each drug.

''(bb) The interquartile range of the total combined costs paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply,

and per 90-day supply for each drug dispensed by pharmacies that are not with an affiliate of the pharmacy benefit manager and that are included in the pharmacy network of such plan.

''(cc) The interquartile range of the total combined costs paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply for each drug dispensed by pharmacies that are an affiliate of the pharmacy benefit manager that are included in the pharmacy network of such plan.

''(dd) The lowest total combined cost paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, for each drug that is available from any pharmacy included in the network of the plan.

''(ee) The difference between the average acquisition cost of the affiliate that initially acquires the drug and the amount reported under subclause (I)(jj) for each drug.

''(ff) A list of prescription drugs for which the pharmacy benefit manager or an affiliate of the pharmacy benefit manager had a contract or other arrangement with a covered entity under section 340B of the Public Health Service Act in the service area of such plan.

''(III) Where a drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (referred to in this subclause as the 'listed drug') is covered by the plan, the following information:

''(aa) A list of currently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic

Act pursuant to an application that references such listed drug that are not covered by the plan, are covered on a formulary tier typically associated with higher cost-sharing than the listed drug, or are subject to utilization management that the listed drug is not subject to.

''(bb) The estimated average beneficiary cost-sharing under the plan for a 30-day supply of the listed drug.

''(cc) The estimated average cost-sharing that a beneficiary would have paid for a 30-day supply of each of the generic drugs described in item (aa), had the plan provided coverage for such drugs on the same formulary tier as the listed drug.

''(dd) A written justification for providing more favorable coverage of the listed drug than the

generic drugs described in item (aa).

"(IV) Where a reference product (as defined in section 351(i) of the Public Health Service Act) is covered by the plan, the following information:

"(aa) a list of currently marketed biosimilar biological products licensed under section 351(k) of the Public Health Service Act pursuant to an application that refers to such reference product that are not covered by the plan, are covered on a formulary tier typically associated with higher cost-sharing than the reference product, or are subject to utilization management that the reference product is not subject to.

"(bb) The estimated average beneficiary cost-sharing under the plan for a 30-day supply of the reference product.

''(cc) The estimated average cost-sharing that a beneficiary would have paid for a 30-day supply of each of the biosimilar biological products described in item (aa), had the plan provided coverage for such products on the same formulary tier as the reference product.

''(dd) A written justification for providing more favorable coverage of the reference product than the biosimilar biological product described in item (aa).

''(V) Total gross spending on prescription drugs by the plan, not net of rebates, fees, discounts, or other direct or indirect remuneration.

''(VI) The total amount retained by the pharmacy benefit manager or an affiliate of such pharmacy benefit manager in revenue related to utilization of prescription drugs under that plan, inclusive of bona fide service fees.

''(VII) The total spending on prescription drugs net of rebates, fees, discounts, or other direct and indirect remuneration by the plan.

''(VIII) An explanation of any benefit design parameters under such plan that encourage plan enrollees to fill prescriptions at pharmacies that are an affiliate of such pharmacy benefit manager, such as mail and specialty home delivery programs, and retail and mail auto-refill programs.

''(IX) A list of all brokers, consultants, advisors, and auditors that receive compensation from the pharmacy benefit manager or an affiliate of such pharmacy benefit manager for referrals, consulting, auditing, or other services offered to PDP sponsors related to pharmacy benefit management services.

''(X) A list of all pharmacies, wholesalers, distributors, private labelers, providers, group purchasing organizations, health plans, or any other

entity that is an affiliate of the pharmacy benefit manager.

''(XI) A summary document submitted in a standardized template developed by the Secretary that includes such information described in subclauses (I) through (X).

''(ii) STANDARD FORMATS.—Not later than June 1, 2025, the Secretary shall specify standard formats for pharmacy benefit managers to submit annual reports required under clause (i).

''(iii) CONFIDENTIALITY.—

''(I) IN GENERAL.—Information disclosed by a pharmacy benefit manager or PDP sponsor under this subsection that is not otherwise publicly available shall not be disclosed by the Secretary or a PDP sponsor receiving the information, except that the Secretary may disclose the information for the following purposes:

''(aa) As the Secretary determines to be necessary to carry out this part.

"(bb) To permit the Comptroller General to review the information provided.

"(cc) To permit the Director of the Congressional Budget Office to review the information provided.

"(dd) To permit the Executive Director of the Medicare Payment Advisory Commission to review the information provided.

"(ee) To the Attorney General for the purposes of conducting oversight and enforcement under this title.

"(II) RESTRICTION ON USE OF INFORMATION.—The Secretary, the Comptroller General, the Director of the Congressional Budget Office, and the Executive Director of the Medicare Payment Advisory Commission shall not report on or disclose information disclosed pursuant to subclause (I) to the public in a manner that would identify a specific phar-

macy benefit manager, affiliate, PDP sponsor, or plan, or prices charged for specific drugs.

''(C) AUDIT RIGHTS.—

''(i) IN GENERAL.—Not less than once a year, at the request of the PDP sponsor, the pharmacy benefit manager shall allow for an audit of the pharmacy benefit manager to ensure compliance with all terms and conditions under the contract and the accuracy of information reported under subparagraph (B).

''(ii) AUDITOR.—The PDP sponsor shall have the right to select an auditor. The pharmacy benefit manager shall not impose any limitations on the selection of such auditor.

''(iii) PROVISION OF INFORMATION.—The pharmacy benefit manager shall make available to such auditor all records, data, contracts, and other information necessary to confirm the accuracy of information provided under subparagraph (B), subject to reasonable restrictions on how such information must be reported (as determined

by the Secretary) to prevent redisclosure of such information.

''(iv) TIMING.—The pharmacy benefit manager must provide information under clause (iii) and other information, data, and records relevant to the audit to such auditor within 6 months of the initiation of the audit and respond to requests for additional information from such auditor within 30 days after the request for additional information.

''(v) INFORMATION FROM AFFILIATES.—The pharmacy benefit manager shall be responsible for providing to such auditor information required to be reported under subparagraph (B) that is owned or held by an affiliate of such pharmacy benefit manager.

''(D) ENFORCEMENT.—The pharmacy benefit manager shall—

''(i) reimburse the PDP sponsor for any civil money penalty imposed on the PDP sponsor as a result of the failure of the pharmacy benefit manager to meet the requirements of this paragraph that are

applicable to the pharmacy benefit manager under the agreement; and

''(ii) be subject to punitive remedies for breach of contract for failure to comply with the requirements applicable under this paragraph.

''(2) CERTIFICATION OF COMPLIANCE.—Each PDP sponsor shall furnish to the Secretary (in a time and manner specified by the Secretary) an annual certification of compliance with this subsection, as well as such information as the Secretary determines necessary to carry out this subsection.

''(3) DEFINITIONS.—For purposes of this subsection:

''(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled by, or related under a common ownership structure with a pharmacy benefit manager (including an entity owned or controlled by the PDP sponsor) or that acts as a contractor or agent to such pharmacy benefit manager, insofar as such contractor or agent performs any of the functions described under subparagraph (B).

''(B) PHARMACY BENEFIT MANAGER.—The term 'pharmacy benefit manager' means any

person or entity that, either directly or through an intermediary, acts as a price negotiator or group purchaser on behalf of a PDP sponsor or prescription drug plan, or manages the prescription drug benefits provided by such sponsor or plan, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered part D drugs, or the provision of services related thereto. Such term includes any person or entity that carries out one or more of the activities described in the preceding sentence, irrespective of whether such person or entity calls itself a 'pharmacy benefit manager'.''.

(2) MA–PD PLANS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following new subparagraph:

''(F) PHARMACY BENEFIT MANAGER REPORTING REQUIREMENTS.—For plan years be-

ginning on or after January 1, 2026, section 1860D–12(h).''.

(b) GAO STUDY AND REPORT ON CERTAIN REPORTING REQUIREMENTS.—

(1) STUDY.—The Comptroller General of the United States (in this subsection referred to as the ''Comptroller General'') shall conduct a study on Federal and State reporting requirements for health plans and pharmacy benefit managers related to the transparency of prescription drug costs and prices. Such study shall include an analysis of the following:

(A) Federal statutory and regulatory reporting requirements for health plans and pharmacy benefit managers related to prescription drug costs and prices.

(B) State statutory and regulatory reporting requirements for health plans and pharmacy benefit managers related to prescription drug costs and prices.

(C) The extent to which the statutory and regulatory reporting requirements identified in clauses (i) and (ii) overlap and conflict.

(D) The resources required by health plans and pharmacy benefit managers to comply with

the reporting requirements described in clauses (i) and (ii).

(E) Other items determined appropriate by the Comptroller General.

(2) REPORT.—Not later than 2 years after enactment, the Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for legislation and administrative actions that would streamline and reduce the burden associated with the reporting requirements for health plans and pharmacy benefit managers described in paragraph (1).

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