AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 5385

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare PBM Accountability Act''.

SEC. 2. ARRANGEMENTS WITH PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRESCRIPTION DRUG PLANS AND MA–PD PLANS.

(a) 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) REQUIREMENTS ON PHARMACY BENEFIT MANAGERS.—For plan years beginning on or after January 1, 2027:

''(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, 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, terms such as—

''(I) 'generic drug', in a manner consistent with the definition of the term under section 423.4 of title 42, Code of Federal Regulations, or a successor regulation;

''(II) 'brand name drug', in a manner consistent with the definition of the term under section 423.4 of title 42, Code of Federal Regulations, or a successor regulation;

"(III) 'specialty drug';

"(IV) 'rebate'; and

"(V) 'discount';

"(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 written agreement.

"(B) PROVISION OF INFORMATION.—

"(i) IN GENERAL.—Not later than July 1 of each year, beginning in 2027, the pharmacy benefit manager shall submit to the PDP sponsor, and to the Secretary, a report, in accordance with this subparagraph, and shall make such report available to such sponsor at no cost to such

sponsor in a format specified by the Secretary under paragraph (4). 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 prescription claims described in item (bb) by each type of dispensing channel through which the drug

was dispensed, including retail, mail order, specialty pharmacy, long term care pharmacy, home infusion pharmacy, or other types of pharmacies or providers;

''(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 paid by the plan for the drug in the aggregate and disaggregated 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 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 and 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 pharmacy network of such plan.

''(ee) The difference between the average acquisition cost of the affiliate, such as a pharmacy or other entity that acquires prescription drugs, that initially ac-

quires the drug and the amount reported under subclause (I)(jj) for each drug.

''(ff) A list of covered part D drugs subject to an agreement with a covered entity under section 340B of the Public Health Service Act for which the pharmacy benefit manager or an affiliate of the pharmacy benefit manager had a contract or other arrangement with such a covered entity 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 the same formulary tier or 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) Where a generic drug listed under item (aa) is on a formulary tier typically associated with higher cost-sharing than the listed drug, 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).

''(ee) The number 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.

''(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 the same formulary tier or a for-

mulary 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) Where a biosimilar biological product listed under item (aa) is on a formulary tier typically associated with higher cost-sharing than the listed drug, 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).

''(ee) The number 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.

''(V) Total gross spending on covered part D 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 covered part D 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 affiliates 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) WRITTEN EXPLANATION OF CONTRACTS OR AGREEMENTS WITH DRUG MANUFACTURERS.—

''(I) IN GENERAL.—The pharmacy benefit manager shall, not later than 30 days after the finalization of any contract or agreement between such pharmacy benefit manager or an affiliate of such pharmacy benefit manager and a drug manufacturer (or subsidiary, agent, or entity affiliated with such drug manufacturer) that makes rebates, discounts, payments, or other financial incentives related to one or more prescription drugs of the manufacturer directly or indirectly contingent upon coverage, formulary placement, or utilization management conditions on any other prescription drugs, submit to the PDP sponsor a written explanation of such contract or agreement.

"(II) REQUIREMENTS.—A written explanation under subclause (I) shall—

"(aa) include the manufacturer subject to the contract or agreement, all prescription drugs subject to the contract or agreement and the manufacturers of such drugs, and a high-level description of the terms of such contract or agreement and how such terms apply to such drugs; and

"(bb) be certified by the Chief Executive Officer, Chief Financial Officer, or General Counsel of such pharmacy benefit manager, affiliate of such pharmacy benefit manager, or an individual delegated with the authority to sign on behalf of one of these officers, who reports directly to the officer.

"(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 written agreement and the accuracy of information reported under subparagraph (C).

''(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 (C), subject to reasonable restrictions on how such information must be reported 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 (C) that is owned or held by an affiliate of such pharmacy benefit manager.

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

''(i) disgorge to a PDP sponsor (or, in a case where the PDP sponsor is an affiliate of such pharmacy benefit manager, to the Secretary) any payment, remuneration, or other amount received by the pharmacy benefit manager or an affiliate of such pharmacy benefit manager in violation of subparagraph (A) or the written agreement entered into with such sponsor under this

part with respect to a prescription drug plan;

''(ii) 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

''(iii) 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) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as prohibiting payments related to reimbursement for ingredient costs to any entity that acquires prescription drugs, such as a pharmacy or wholesaler.

''(4) STANDARD FORMATS.—Not later than June 1, 2026, the Secretary shall specify standard, machine-readable formats for pharmacy benefit managers to submit annual reports required under paragraph (1)(C)(i).

''(5) CONFIDENTIALITY.—

''(A) IN GENERAL.—Information disclosed by a pharmacy benefit manager or PDP sponsor under this subsection that is not otherwise publicly available or available for purchase 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:

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

''(ii) To permit the Comptroller General to review the information provided.

''(iii) To permit the Director of the Congressional Budget Office to review the information provided.

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

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

"(vi) To the Inspector General of the Department of Health and Human Services in accordance with its authorities under the Inspector General Act of 1978 (section 406 of title 5, United States Code), and other applicable statutes.

"(B) 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 subparagraph (A) to the public in a manner that would identify a specific pharmacy benefit manager, affiliate, manufacturer or wholesaler, PDP sponsor, or plan, or contract prices, rebates, discounts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties.

"(6) 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 or PDP sponsor, or that acts as a contractor or agent to such pharmacy benefit manager or PDP sponsor, insofar as such contractor or agent performs any of the functions described under subparagraph (C).

"(B) BONA FIDE SERVICE FEE.—The term 'bona fide service fee' means a fee that is reflective of the fair market value for a bona fide, itemized service actually performed on behalf of an entity, that the entity would otherwise perform (or contract for) in the absence of the service arrangement and that are not passed on in whole or in part to a client or customer, whether or not the entity takes title to the drug. Such fee must be a flat dollar amount and shall not be directly or indirectly based on, or contingent upon—

"(i) drug price, such as wholesale acquisition cost or drug benchmark price (such as average wholesale price);

''(ii) discounts, rebates, fees, or other direct or indirect remuneration amounts with respect to covered part D drugs dispensed to enrollees in a prescription drug plan, except as permitted pursuant to paragraph (1)(A)(ii);

''(iii) coverage or formulary placement decisions or the volume or value of any referrals or business generated between the parties to the arrangement; or

''(iv) any other amounts or methodologies prohibited by the Secretary.

''(C) 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 related services. 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'.''.

(b) 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) REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.—For plan years beginning on or after January 1, 2027, section 1860D–12(h).''.

(c) 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 phar-

macy benefit managers related to prescription drug costs and prices.

(B) Selected States' 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 subparagraphs (A) and (B) overlap and conflict.

(D) The resources required by health plans and pharmacy benefit managers to comply with the reporting requirements described in subparagraphs (A) and (B).

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

(2) REPORT.—Not later than 2 years after the date on which information is first required to be reported under section 1860D–12(h)(1)(C) of the Social Security Act, as added by subsection (a)(1), 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).

(d) MEDPAC REPORTS ON AGREEMENTS WITH PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRESCRIPTION DRUG PLANS AND MA-PD PLANS.—The Medicare Payment Advisory Commission shall submit to Congress the following reports:

(1) Not later than March 31, 2027, a report regarding agreements with pharmacy benefit managers with respect to prescription drug plans and MA-PD plans. Such report shall include—

(A) a description of trends and patterns, including relevant averages, totals, and other figures for each of the types of information submitted;

(B) an analysis of any differences in agreements and their effects on plan enrollee out-of-pocket spending and average pharmacy reimbursement, and any other impacts; and

(C) any recommendations the Commission determines appropriate.

(2) Not later than March 31, 2029, a report describing any changes with respect to the information described in paragraph (1) over time, together with

any recommendations the Commission determines appropriate.

(e) FUNDING.—There are appropriated, out of any monies in the Treasury not otherwise obligated, $55,000,000 for fiscal year 2024, to remain available until expended, to the Secretary of Health and Human Services for purposes of carrying out the amendments made by subsections (a) and (b).

☒