Calendar No. 266

118TH CONGRESS
1ST SESSION

S. 2973

[Report No. 118–122]

To amend titles XVIII and XIX of the Social Security Act to establish requirements relating to pharmacy benefit managers under the Medicare and Medicaid programs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 28 (legislative day, SEPTEMBER 22), 2023

Mr. WYDEN introduced the following bill; which was read twice and referred to the Committee on Finance

DECEMBER 7, 2023

Reported by Mr. WYDEN, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend titles XVIII and XIX of the Social Security Act to establish requirements relating to pharmacy benefit managers under the Medicare and Medicaid programs, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Modernizing and Ensuring PBM Accountability Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. ARRANGEMENTS WITH PHARMACY BENEFIT MANAGERS 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) REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.—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) NO INCOME OTHER THAN BONA FIDE SERVICE FEES.—

''(i) IN GENERAL.—The pharmacy benefit manager and any affiliate of such pharmacy benefit manager shall not derive any remuneration with respect to any services provided in connection with the utilization of covered part D drugs from any entity or individual other than bona fide service fees, subject to clauses (ii) and (iii).

''(ii) INCENTIVE PAYMENTS.—For the purposes of this subsection, an incentive payment paid by a PDP sponsor to a phar-

macy benefit manager that is performing services on behalf of such sponsor shall be deemed a 'bona fide service fee' if such payment is a flat dollar amount, is consistent with fair market value, and is related to services actually performed by the pharmacy benefit manager or affiliate of such pharmacy benefit manager in connection with the utilization of covered part D drugs.

''(iii) CLARIFICATION ON REBATES AND DISCOUNTS USED TO LOWER COSTS FOR COVERED PART D DRUGS.—Rebates, discounts, and other price concessions received from manufacturers, even if such price concessions are calculated as a percentage of a drug's price, shall not be considered a violation of the requirements of clause (i) if they are fully passed through to a PDP sponsor and exclusively used to lower costs for prescription drugs under this part, including in cases where a PDP sponsor is acting as a pharmacy benefit manager on behalf of a prescription drug plan offered by such PDP sponsor.

"(iv) EVALUATION OF REMUNERATION ARRANGEMENTS.—Remuneration arrangements between pharmacy benefit managers or affiliates of such pharmacy benefit managers, as applicable, and other entities involved in the dispensing or utilization of covered part D drugs (including PDP sponsors, manufacturers, pharmacies, and other entities as determined appropriate by the Secretary) shall be subject to review by the Secretary and the Office of the Inspector General of the Department of Health and Human Services. The Secretary, in consultation with the Office of the Inspector General, shall evaluate whether remuneration under such arrangements is consistent with fair market value through reviews and assessments of such remuneration, as determined appropriate.

"(B) 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.

''(C) PROVISION OF INFORMATION.—

''(i) IN GENERAL.—Not later than July 1 of each year, beginning in 2026, 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 re-

port) 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 acquires 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 man-

agement 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 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) 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 bio-

logical 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 ben-

efit 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 de-

scription 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.

"(D) 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.

''(E) 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, 2025, 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 Of-

fice, 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'.''.

(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) REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.—For plan years be-

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

(3) FUNDING.—

(A) SECRETARY.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $20,000,000 for fiscal year 2026, to remain available until expended, to carry out the amendments made by this subsection.

(B) OIG.—In addition to amounts otherwise available, there is appropriated to the Inspector General of the Department of Health and Human Services, out of any money in the Treasury not otherwise appropriated, $5,000,000 for fiscal year 2026, to remain available until expended, to carry out the amendments made by this subsection.

(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) 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).~~

~~(c) 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.~~

~~SEC. 3. ENSURING FAIR ASSESSMENT OF PHARMACY PERFORMANCE AND QUALITY UNDER MEDICARE PART D.~~

~~(a) STANDARDIZED PHARMACY PERFORMANCE MEASURES.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended by adding at the end the following new subsection:~~

~~"(f) APPLICATION OF STANDARDIZED PHARMACY PERFORMANCE MEASURES.—~~

~~"(1) MEASURES.—For plan years beginning on or after January 1, 2025, a PDP sponsor offering a prescription drug plan and an MA organization offering an MA–PD plan shall, for purposes of incentive payments, price concessions, or any fees or other remuneration paid or charged to a pharmacy based on performance measures, only use measures that are—~~

"(A) established or adopted by the Secretary under paragraph (2) and included on the list described in subparagraph (B) of such paragraph; and

"(B) relevant to the performance of such pharmacy based on the type of pharmacy (including retail, mail order, specialty, long term care, and home infusion or other types of pharmacies), drugs dispensed by such pharmacy, and pharmacy services used to dispense and manage drugs by such pharmacy.

"(2) STANDARDIZED PHARMACY PERFORMANCE MEASURES.—

"(A) MEASURES.—

"(i) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall establish (or adopt pursuant to clause (iii)) standardized pharmacy performance measures that may be used by a PDP sponsor offering a prescription drug plan and an MA organization offering an MA–PD plan for the purpose of determining incentive payments, price concessions, or fees or other remuneration described in paragraph (1).

"(ii) REQUIREMENTS.—The measures under clause (i) shall focus on pharmacy performance and quality of care based on the type of pharmacy, as determined by the Secretary. Such measures shall be evidence-based, feasible, appropriate and reasonable.

"(iii) ADOPTION OF MEASURE.—In lieu of establishing some or all of the measures under this paragraph, the Secretary may adopt measures that are endorsed by one or more multi-stakeholder consensus organizations (such as the Pharmacy Quality Alliance), that has participation from pharmacies (including retail and specialty pharmacies not owned or affiliated with a plan, pharmacy benefit manager, or other pharmacy), health plans, pharmacy benefit managers, and the Centers for Medicare & Medicaid Services. Any measure adopted under this clause shall be deemed to meet the requirements under clause (ii).

"(B) MAINTENANCE OF LIST.—

"(i) IN GENERAL.—The Secretary shall maintain, and publish on a publicly available internet website, a list of measures established or adopted under this paragraph. Such list shall initially be published no later than June 1, 2024.

"(ii) UPDATE.—The Secretary shall periodically evaluate measures, and how measures are applied by type of pharmacy and update the measures on the list under clause (i) so that such measures meet the requirements under subparagraph (A)(ii).

"(3) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to any data collection undertaken by the Secretary under this subsection.".

(b) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $4,000,000 for fiscal year 2025, to remain available until expended, to carry out the amendment made by subsection (a).

SEC. 4. PROMOTING TRANSPARENCY FOR PHARMACIES UNDER MEDICARE PART D.

(a) TRANSPARENCY FOR PHARMACIES.—Section 1860D–2(f) of the Social Security Act (42 U.S.C. 1395w–102(f)), as added by section 3, is amended by adding at the end the following new paragraph:

"(4) TRANSPARENCY FOR PHARMACIES.—

"(A) IN GENERAL.—For plan years beginning on or after January 1, 2025, a PDP sponsor offering a prescription drug plan and an MA organization offering an MA–PD plan, with respect to payment made by such PDP sponsor or such MA organization to a pharmacy for a covered part D drug dispensed by such pharmacy during a plan year, shall promptly furnish, upon paying a claim for a covered part D drug from a pharmacy, to such pharmacy information related to such claim, such as the Network Reimbursement ID, fees, pharmacy price concessions, discounts, incentives, or any other forms of remuneration that affect payment and pricing of the claim.

"(B) STANDARDIZED FORMAT.—The PDP sponsor and the MA organization shall furnish the information described in subparagraph (A) in a standardized format (as specified by the

Secretary) that includes all fields needed to price the claim for a covered part D drug dispensed by such pharmacy.

"(C) AVAILABILITY OF INFORMATION TO THE SECRETARY.—A PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall make the information described in subparagraph (A) available to the Secretary upon request.

"(D) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary shall implement this paragraph by program instruction or otherwise.".

(b) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $2,000,000 for fiscal year 2025, to remain available until expended, to carry out the amendment made by subsection (a).

SEC. 5. PREVENTING THE USE OF ABUSIVE SPREAD PRICING IN MEDICAID.

(a) IN GENERAL.—Section 1927(e) of the Social Security Act (42 U.S.C. 1396r–8(e)) is amended by adding at the end the following:

"(6) TRANSPARENT PRESCRIPTION DRUG PASS-THROUGH PRICING REQUIRED.—A contract between the State and a pharmacy benefit manager (referred to in this paragraph as a 'PBM'), or a contract between the State and a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D) and collectively referred to in this paragraph as the 'entity') that includes provisions making the entity responsible for coverage of covered outpatient drugs dispensed to individuals enrolled with the entity, shall require that payment for such drugs and related administrative services (as applicable), including payments made by a PBM on behalf of the State or entity, is based on a transparent prescription drug pass-through pricing model under which—

"(A) any payment made by the entity or the PBM (as applicable) for such a drug—

"(i) is limited to—

"(I) ingredient cost; and

"(II) a professional dispensing fee that is not less than the professional dispensing fee that the State plan or waiver would pay if the plan

or waiver was making the payment directly;

''(ii) is passed through in its entirety by the entity or PBM to the pharmacy or provider that dispenses the drug (and shall not be reduced or denied retroactively under post-adjudication processes); and

''(iii) is made in a manner that is consistent with sections 447.502, 447.512, 447.514, and 447.518 of title 42, Code of Federal Regulations (or any successor regulation) as if such requirements applied directly to the entity or the PBM, except that any payment by the entity or the PBM for the ingredient cost of such drug purchased by a covered entity (as defined in subsection (a)(5)(B)) may exceed the actual acquisition cost (as defined in 447.502 of title 42, Code of Federal Regulations, or any successor regulation) for such drug if—

''(I) such drug was subject to an agreement under section 340B of the Public Health Service Act;

"(II) such payment for the ingredient cost of such drug does not exceed the maximum payment that would have been made by the entity or the PBM for the ingredient cost of such drug if such drug had not been purchased by such covered entity; and

"(III) such covered entity reports to the Secretary (in a form and manner specified by the Secretary), on an annual basis and with respect to payments for the ingredient costs of such drugs so purchased by such covered entity that are in excess of the actual acquisition costs for such drugs, the aggregate amount of such excess;

"(B) payment to the entity or the PBM (as applicable) for administrative services performed by the entity or PBM is limited to the fair market value of such services;

"(C) the entity or the PBM (as applicable) shall make available to the State, and the Secretary upon request, all costs and payments related to covered outpatient drugs and accompanying administrative services incurred, re-

ceived, or made by the entity or the PBM, including ingredient costs, professional dispensing fees, administrative fees, post-sale and post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees, and any and all other remuneration; and

''(D) any form of spread pricing whereby any amount charged or claimed by the entity or the PBM (as applicable) that exceeds the amount paid to the pharmacies or providers on behalf of the State or entity, including any post-sale or post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees or assessments (after allowing for an administrative fee as described in subparagraph (B)) is not allowable for purposes of claiming Federal matching payments under this title.''.

(b) DEFINITION OF PHARMACY BENEFIT MANAGER.—Section 1927(k) of the Social Security Act (42 U.S.C. 1396r–8(k)) is amended by adding at the end the following new paragraph:

''(12) PHARMACY BENEFIT MANAGER.—The term 'pharmacy benefit manager' means any person or entity that, either directly or through an inter-

mediary, acts as a price negotiator or group purchaser on behalf of a State, managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)), or manages the prescription drug benefits provided by such State, managed care entity, or other specified entity, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the managing of appeals or grievances related to the prescription drug benefits, contracting with pharmacies, controlling the cost of covered outpatient drugs, or the provision of services related thereto. Such term includes any person or entity that carries out 1 or more of the activities described in the preceding sentence, irrespective of whether such person or entity calls itself a 'pharmacy benefit manager'.''.

(c) CONFORMING AMENDMENTS.—Section 1903(m) of such Act (42 U.S.C. 1396b(m)) is amended—

(1) in paragraph (2)(A)(xiii)—

(A) by striking ''and (III)'' and inserting ''(III)'';

(B) by inserting before the period at the end the following: '', and (IV) if the entity, or a pharmacy benefit manager acting on behalf of

the entity under a contract or other arrangement between the entity and the pharmacy benefit manager, performs any of the activities described in section 1927(k)(12), such activities shall comply with the requirements of section 1927(e)(6)''; and

(C) by moving the left margin 2 ems to the left; and

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

''(10) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by an other specified entity (as defined in paragraph (9)(D)(iii)) unless such services are provided in accordance with a contract between the State and such entity which satisfies the requirements of paragraph (2)(A)(xiii).''.

(d) EFFECTIVE DATE.—The amendments made by this section apply to contracts between States and managed care entities, other specified entities, or pharmacy benefit managers that have an effective date beginning on or after the date that is 18 months after the date of enactment of this Act.

SEC. 6. ENSURING ACCURATE PAYMENTS TO PHARMACIES UNDER MEDICAID.

(a) IN GENERAL.—Section 1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)) is amended—

(1) by striking "and" after the semicolon at the end of paragraph (1)(A)(i) and all that precedes it through "(1)" and inserting the following:

"(1) DETERMINING PHARMACY ACTUAL ACQUISITION COSTS.—The Secretary shall conduct a survey of retail community pharmacy drug prices to determine the national average drug acquisition cost as follows:

"(A) USE OF VENDOR.—The Secretary may contract services for—

"(i) with respect to retail community pharmacies, the determination of retail survey prices of the national average drug acquisition cost for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available) based on a monthly survey of such pharmacies; and";

(2) by adding at the end of paragraph (1) the following:

"(F) SURVEY REPORTING.—In order to meet the requirement of section 1902(a)(54), a State shall require that any retail community pharmacy in the State that receives any payment, reimbursement, administrative fee, discount, or rebate related to the dispensing of covered outpatient drugs to individuals receiving benefits under this title, regardless of whether such payment, reimbursement, administrative fee, discount, or rebate is received from the State or a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)) directly or from a pharmacy benefit manager or another entity that has a contract with the State or a managed care entity or other specified entity (as so defined), shall respond to surveys of retail prices conducted under this paragraph.

"(G) SURVEY INFORMATION.—Information on national drug acquisition prices obtained under this paragraph shall be made publicly available and shall include at least the following:

''(i) The monthly response rate to the survey including a list of pharmacies not in compliance with subparagraph (F).

''(ii) The sampling frame and number of pharmacies sampled monthly.

''(iii) Information on price concessions to the pharmacy, including discounts, rebates, and other price concessions, to the extent that such information may be publicly released and has been collected by the Secretary as part of the survey.

''(H) PENALTIES.—The Secretary may enforce non-compliance with this paragraph by a pharmacy through the establishment of penalties or the suspension of payments under this title, in full or in part, until compliance with this paragraph has been completed.'';

(3) in paragraph (2)—

(A) in subparagraph (A), by inserting '', including payment rates under Medicaid managed care entities or other specified entities (as such terms are defined in section 1903(m)(9)(D)),'' after ''under this title''; and

(B) in subparagraph (B), by inserting "and the basis for such dispensing fees" before the semicolon; and

(4) in paragraph (4), by inserting ", and $5,000,000 for fiscal year 2024 and each fiscal year thereafter," after "2010".

(b) EFFECTIVE DATE.—The amendments made by this section take effect on the first day of the first quarter that begins on or after the date that is 18 months after the date of enactment of this Act.

SEC. 7. OIG STUDY AND REPORT ON DRUG PRICE MARK-UPS IN MEDICARE PART D.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152) is amended by adding at the end the following new subsection:

"(e) OIG STUDY AND REPORT ON DRUG PRICE MARK-UPS UNDER THIS PART.—

"(1) STUDY.—The Inspector General of the Department of Health and Human Services (in this subsection referred to as the 'Inspector General') shall conduct a study on the impact of related party transactions within select vertically integrated entities on the negotiated price (as defined in section 1860D–2(d)(1)(B)) paid by part D plan sponsors

for covered part D drugs. Such study may include an analysis of the following:

"(A) Acquisition costs by the affiliate within such vertically integrated entities that initially acquires the prescription drug for a sample of covered part D drugs, including at least 5 generic drugs, brand drugs, specialty brand drugs, and specialty generic drugs.

"(B) The methodologies and negotiation processes used to calculate transfer prices or other transactions between related parties with respect to such covered part D drugs.

"(C) The impact of the transactions described in subparagraph (B) on the negotiated price, net of direct and indirect remuneration, for such covered part D drugs.

"(D) The margin captured by different affiliates within such vertically integrated entities through the transactions described in subparagraph (B).

"(E) An assessment of the impact of the transactions described in subparagraph (B) on costs to individuals enrolled in a prescription drug plan or an MA–PD plan and program spending on prescription drugs under this part.

"(F) Other issues determined to be relevant and appropriate by the Inspector General.

"(2) REPORT.—Not later than 3 years after the date of enactment of this subsection, the Inspector General shall submit to the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Inspector General determines appropriate.

"(3) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Inspector General, out of any money in the Treasury not otherwise appropriated, $5,200,000 for fiscal year 2024, to remain available until expended, to carry out this subsection.".

SEC. 8. RESOLVING P&T COMMITTEE CONFLICTS OF INTEREST.

Section 1860D–4(b)(3)(A)(ii)(I) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)(A)(ii)(I)) is amended by inserting the following before the semicolon: "(and, for 2025 and each subsequent year, any pharmacy benefit

manager acting under contract with such sponsor offering such plan)''.

SEC. 9. ENHANCING PBM TRANSPARENCY REQUIREMENTS.

(a) IN GENERAL.—Section 1150A of the Social Security Act (42 U.S.C. 1320b–23) is amended—

(1) by striking subsection (a) and inserting the following:

''(a) PROVISION OF INFORMATION.—

''(1) IN GENERAL.—The following entities shall provide the information described in subsection (b) to the Secretary and, in the case of an entity described in subparagraph (B) or an affiliate of such entity described in subparagraph (C), to the health benefits plan with which the entity is under contract, at such times, and in such form and manner, as the Secretary shall specify:

''(A) A health benefits plan.

''(B) Any entity that provides pharmacy benefits management services on behalf of a health benefits plan (in this section referred to as a 'PBM') that manages prescription drug coverage under a contract with—

''(i) a PDP sponsor of a prescription drug plan or an MA organization offering

an MA–PD plan under part D of title XVIII; or

''(ii) a qualified health benefits plan offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act.

''(C) Any affiliate of an entity described in subparagraph (B) that acts as a price negotiator or group purchaser on behalf of such PBM, PDP sponsor, MA organization, or qualified health benefits plan.

''(2) AFFILIATE DEFINED.—In this section, the term 'affiliate' means any entity that is owned by, controlled by, or related under a common ownership structure with a PBM (including an entity owned or controlled by the PDP sponsor of a prescription drug plan, MA organization offering an MA–PD plan, or qualified health benefits plan for which such entity is acting as a price negotiator or group purchaser).'';

(2) in subsection (b)—

(A) in paragraph (2), by inserting ''and percentage'' after ''and the aggregate amount''; and

(B) by adding at the end the following new paragraph:

''(4) The amount (in the aggregate and disaggregated by type) of all fees the PBM or an affiliate of the PBM receives from all pharmaceutical manufacturers in connection with patient utilization under the plan, and the amount and percentage (in the aggregate and disaggregated by type) of such fees that are passed through to the plan sponsor or issuer.''; and

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

''(c) ANNUAL REPORT.—The Secretary shall make publicly available on the internet website of the Centers for Medicare & Medicaid Services an annual report that summarizes the trends observed with respect to data reported under subsection (b).''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to plan or contract years beginning on or after January 1, 2027.

(c) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement the amendments made by this section by program instruction or otherwise.

(d) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the ''Paperwork Reduction Act of 1995''), shall not apply to the implementation of the amendments made by this section.

SEC. 10. FACILITATING MIDYEAR FORMULARY CHANGES FOR BIOSIMILARS.

(a) IN GENERAL.—Section 1860D–4(b) of the Social Security Act (42 U.S.C. 1395w–104(b)) is amended by adding at the end the following new paragraph:

''(5) MID-YEAR CHANGES IN FORMULARIES PERMITTED FOR CERTAIN BIOSIMILAR BIOLOGICAL PRODUCTS AND THE REFERENCE PRODUCT OF SUCH BIOSIMILARS.—If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following shall apply:

''(A) IN GENERAL.—For plan year 2025, and subsequent plan years, in the case of a covered part D drug that is the reference biological product (as defined in section 351(i) of the Public Health Service Act) with respect to a biosimilar biological product (defined as a biological product licensed under section 351(k) of such Act), the PDP sponsor may, with respect to a formulary, at any time after the first 60

days of the plan year, subject to paragraph (3)(E), change the preferred or tiered cost-sharing status of such reference biological product if such PDP sponsor adds, before or at the same time, to such formulary such biosimilar biological product at the same or a higher preferred status, or to the same or lower cost-sharing tier, as that of such reference biological product immediately prior to such change.

"(B) REQUEST FOR APPROVAL OF CHANGE.—Prior to making a change described in subparagraph (A), the PDP sponsor shall submit to the Secretary a request to make such change. If the Secretary approves the request or has not provided a decision to the PDP sponsor regarding such request within 30 days of receiving such request, such PDP sponsor may make such change.".

(b) ADMINISTRATION.—

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

(2) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the ''Paperwork Reduction Act of 1995''), shall not apply to the implementation of the amendment made by subsection (a).

SEC. 11. STRENGTHENING PHARMACY ACCESS FOR SENIORS.

Section 1860D–4(b)(1) of the Social Security Act (42 U.S.C. 1395w–104(b)(1)) is amended by adding at the end the following new subparagraph:

''(F) LIMITED ACCESS DRUGS.—

''(i) LIMITATION ON RESTRICTIONS OR LIMITS ON ACCESS.—For each plan year (beginning with plan year 2026), a PDP sponsor offering a prescription drug plan—

''(I) may not restrict or limit access to any covered part D drug to a subset of their network pharmacies, other than with respect to a limited access drug, as defined in clause (v); and

''(II) shall document the rationale for why a covered part D drug meets the definition of a limited ac-

cess drug under clause (v), if such plan restricts or limits access to a limited access drug to a subset of network pharmacies.

"(ii) ANNUAL SUBMISSION OF INFORMATION TO THE SECRETARY ON LIMITED ACCESS DRUGS.—For each plan year (beginning with plan year 2026), each PDP sponsor offering a prescription drug plan shall submit to the Secretary, at a time and in a manner specified by the Secretary, with respect to each prescription drug plan offered by the sponsor during such plan year—

"(I) a list of all covered part D drugs that the PDP sponsor designated as a limited access drug;

"(II) for each covered part D drug included in the list described in subclause (I), a written rationale for why such drug meets the definition of a limited access drug;

"(III) a summary of the requirements imposed on network pharmacies (including all accreditation require-

ments, if any) to ensure appropriate handling and dispensing of each covered part D drug included in the list described in subclause (I);

"(IV) the percentages of each covered part D drug included in the list described in subclause (I) that is dispensed through retail pharmacies, specialty pharmacies, mail order pharmacies, or other dispensing channels as defined by the PDP sponsor, respectively;

"(V) the annual percentage of each covered part D drug included in the list described in subclause (I) that is dispensed through a pharmacy that is affiliated with the plan or is an affiliate (as defined in section 1860D–12(h)(4)(A)) of a pharmacy benefit manager acting on behalf of such sponsor or such plan; and

"(VI) any other information determined appropriate by the Secretary.

"(iii) PHARMACY ACCESS TO LIMITED ACCESS DRUG INFORMATION.—For plan years beginning with plan year 2026, upon the request of a network pharmacy, a PDP sponsor of a prescription drug plan shall provide such pharmacy, not later than 14 days after receiving such request, with the information described in subclauses (I), (II), and (III) of clause (ii).

"(iv) HHS ANNUAL REPORT ON LIMITED ACCESS DRUGS.—Not later than December 31, 2028, and annually thereafter, the Secretary shall submit to the Committee on Finance of the Senate, and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report on compliance by PDP sponsors with the requirements under this subparagraph. Each such report shall include—

"(I) a description of the patterns, trends, variations, and rationales for the designation by PDP sponsors of certain covered part D drugs as limited access drugs, and the implications

of such designations on beneficiary access to such covered part D drugs;

"(II) a description of the information submitted to the Secretary under clause (ii) (in a manner that does not disclose the identity of a pharmacy, a PDP sponsor, a prescription drug plan, or pharmacy benefit manager, or any proprietary pricing information); and

"(III) any other information determined appropriate by the Secretary.

"(v) LIMITED ACCESS DRUG DEFINED.—In this subparagraph, the term 'limited access drug' means a covered part D drug that meets at least one of the following:

"(I) The Food and Drug Administration has restricted distribution of such covered part D drug to certain facilities or physicians.

"(II) The dispensing of such covered part D drug requires extraordinary special handling, provider co-

ordination, or patient education that cannot be met by a network pharmacy.''.

''(vii) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary shall implement this subparagraph by program instruction or otherwise.

''(viii) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to any data collection undertaken by the Secretary under this subparagraph.''.

SEC. 12. BENEFICIARY-FOCUSED LISTENING SESSIONS TO IMPROVE PRESCRIPTION DRUG PLAN TRANSPARENCY, ACCESS, AND CHOICE.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 7, is amended by adding at the end the following new subsection:

''(f) BENEFICIARY-FOCUSED LISTENING SESSIONS TO IMPROVE PRESCRIPTION DRUG PLAN TRANSPARENCY, ACCESS, AND CHOICE.—

''(1) IN GENERAL.—Not later than December 31, 2024, the Secretary shall hold at least one beneficiary-focused listening session to receive input on potential improvements to the experience with, and

transparency of, prescription drug plans under this part, as described in paragraph (2).

"(2) BENEFICIARY-FOCUSED LISTENING SESSIONS.—Any beneficiary-focused listening session held under paragraph (1) shall be open to the public, including beneficiaries, caregivers of beneficiaries, consumer and patient advocacy organizations, health care providers, and other interested parties. Any such listening sessions may include an opportunity for the public to provide input to the Secretary on potential improvements to—

"(A) the information made available by prescription drug plans to individuals;

"(B) tools and mechanisms to assist enrollees of prescription drug plans in navigating plan complaint systems, as well as the efficiency and effectiveness of such systems;

"(C) tools and mechanisms to assist beneficiaries in selecting a prescription drug plan;

"(D) tools and mechanisms to assist enrollees of prescription drug plans in navigating utilization management requirements of such plans, such as step therapy and prior authorization;

"(E) access to, and effectiveness and utilization of, electronic real-time benefit tools (as described in section 423.160(b)(7) of title 42, Code of Federal Regulations, or any successor regulation) and beneficiary real-time benefit tools (as described in section 423.128(d)(4) of title 42, Code of Federal Regulations, or any successor regulation);

"(F) formulary management and oversight by prescription drug plans; and

"(G) other subjects, as determined appropriate by the Secretary.".

SEC. 13. REPORTING ON ENFORCEMENT AND OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 12, is amended by adding at the end the following new subsection:

"(g) BIENNIAL REPORT ON ENFORCEMENT AND OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of this subsection, and at least once every 2 years thereafter, the Secretary shall publish a report on enforcement and oversight actions and activities undertaken by the Secretary

with respect to the requirements under section 1860D–4(b)(1).

''(2) LIMITATION.—A report under paragraph (1) shall not disclose—

''(A) identifiable information about individuals or entities unless such information is otherwise publicly available; or

''(B) trade secrets with respect to any entities.''.

SEC. 14. GAO STUDY ON PRICE-RELATED COMPENSATION ACROSS THE SUPPLY CHAIN.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 13, is amended by adding at the end the following new subsection:

''(h) GAO STUDY AND REPORT ON PRICE-RELATED COMPENSATION AND PAYMENT STRUCTURES IN THE PRESCRIPTION DRUG SUPPLY CHAIN.—

''(1) STUDY.—The Comptroller General of the United States (in this subsection referred to as the 'Comptroller General') shall conduct a study describing the use of compensation and payment structures related to a prescription drug's price within the retail prescription drug supply chain in this part. Such study shall summarize information from Federal

agencies and industry experts, to the extent available, with respect to the following:

''(A) The type, magnitude, other features (such as the pricing benchmarks used), and prevalence of compensation and payment structures related to a prescription drug's price, such as calculating fee amounts as a percentage of a prescription drug's price, between intermediaries in the prescription drug supply chain, including—

''(i) pharmacy benefit managers;

''(ii) part D plan sponsors;

''(iii) drug wholesalers;

''(iv) pharmacies;

''(v) manufacturers;

''(vi) pharmacy services administrative organizations;

''(vii) brokers, auditors, consultants, and other entities that advise part D plan sponsors about pharmacy benefits or review part D plan sponsor contracts with pharmacy benefit managers; and

''(viii) other service providers that contract with any of the entities described in clauses (i) through (vii) that may use

price-related compensation and payment structures, such as rebate aggregators (or other entities that negotiate or process price concessions on behalf of pharmacy benefit managers, plan sponsors, or pharmacies).

"(B) The primary business models and compensation structures for each category of intermediary described in subparagraph (A).

"(C) Variation in price-related compensation structures between affiliated entities (such as entities with common ownership, either full or partial, and subsidiary relationships) and unaffiliated entities.

"(D) Potential conflicts of interest among contracting entities related to the use of prescription drug price-related compensation structures, such as the potential for fees or other payments set as a percentage of a prescription drug's price to advantage formulary selection, distribution, or purchasing of prescription drugs with higher prices.

"(E) Notable differences, if any, in the use and level of price-based compensation structures over time and between different market

segments, such as under this part and the Medicaid program under title XIX.

''(F) The effects of drug price-related compensation structures and alternative compensation structures on Federal health care programs and program beneficiaries, including with respect to cost-sharing, premiums, Federal outlays, biosimilar and generic drug adoption and utilization, drug shortage risks, and the potential for fees set as a percentage of a drug's price to advantage the formulary selection, distribution, or purchasing of drugs with higher prices.

''(G) Other issues determined to be relevant and appropriate by the Comptroller General.

''(2) REPORT.—Not later than 2 years after the date of enactment of this subsection, the Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.''.

SEC. 15. REPORTS ON INAPPROPRIATE PHARMACY REJECTIONS.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 14, is amended by adding at the end the following new subsection:

"(i) BIENNIAL REPORT ON EFFORTS TO ADDRESS INAPPROPRIATE PHARMACY REJECTIONS AND INAPPROPRIATE COVERAGE DENIALS UNDER MEDICARE PART D.—

"(1) IN GENERAL.—Not later than January 1, 2026, and at least once every 4 years thereafter, the Secretary, in consultation with the Office of the Inspector General of the Department of Health and Human Services, shall post, on a publicly available website, a report related to preventing, identifying, or addressing inappropriate pharmacy rejections (as defined in paragraph (2)(B)) and inappropriate coverage denials (as defined in paragraph (2)(A)) under this part. Such reports shall include—

"(A) a description of programs, reviews, or initiatives underway to prevent, identify, or address such rejections and denials, in accordance with existing authorities;

"(B) a summary of data collected or other information available with respect to such rejections and denials, including—

"(i) standards (if any such standards have been adopted) used by the Secretary for identifying PDP sponsors and MA organizations with relatively high rates of such rejections or denials; and

"(ii) notable longitudinal trends or other patterns, as determined appropriate by the Secretary;

"(C) an overview of corrective actions taken and technical assistance provided by the Secretary in response to violations of existing requirements with respect to such rejections and denials; and

"(D) a description of barriers, if any, preventing the Secretary from taking administrative actions sufficient to identify and address such rejections and denials.

"(2) DEFINITIONS.—For purposes of this subsection:

"(A) INAPPROPRIATE COVERAGE DENIAL.—The term 'inappropriate coverage denial' means a denial of coverage of a covered part D drug claim that violates the requirements of this part.

"(B) INAPPROPRIATE PHARMACY REJECTIONS.—The term 'inappropriate pharmacy rejection' means a rejection of a covered part D drug claim that violates the requirements of this part, such as through the application of utilization management requirements that the Secretary has not approved.".

SEC. 16. GAO STUDY ON DRUG SHORTAGES.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 15, is amended by adding at the end the following new subsection:

"(j) GAO STUDY AND REPORT ON DRUG SHORTAGES.—

"(1) STUDY.—The Comptroller General of the United States (in this subsection referred to as the 'Comptroller General') shall conduct a study on factors contributing to shortages of covered part D drugs across the outpatient prescription drug supply chain. Such study shall include analysis of—

"(A) common features of and trends in covered part D drugs that have experienced at least 1 shortage (as defined under section 506C of the Federal Food, Drug, and Cosmetic Act);

"(B) patterns, trends, and variations in the duration of shortages experienced by covered part D drugs;

"(C) patterns, trends, and variations in the proximate causes and other potential causes of shortages experienced by covered part D drugs;

"(D) effects of such shortages on beneficiaries enrolled in prescription drug plans under this part, including with respect to access to covered part D drugs and out-of-pocket costs; and

"(E) other issues determined appropriate by the Comptroller General.

"(2) REPORT.—Not later than 2 years after the date of enactment of this subsection, the Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.".

SEC. 17. REPORT ON BIOSIMILAR AND GENERIC ACCESS UNDER MEDICARE PART D.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 16, is amended by adding at the end the following new subsection:

''(k) OIG REPORT ON BIOSIMILAR AND GENERIC ACCESS UNDER PART D.—

''(1) STUDY.—The Office of the Inspector General of the Department of Health and Human Services (referred to in this subsection as the 'Office of the Inspector General') shall conduct a study on biosimilar and generic drug access and adoption under prescription drug plans offered under this part, including with respect to barriers to increased adoption and utilization of lower-priced biosimilar and generic utilization, plan features that discourage or encourage the utilization of these products, and the gross and net spending effects of policies that increased adoption of these products under this part.

''(2) REPORT.—Not later than 1 year after the date of enactment of this subsection, the Office of the Inspector General shall publish a report on the study conducted under paragraph (1).''.

SEC. 18. MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking ''during and after fiscal year 2022, $180,000,000'' and inserting the following: ''during and after—

''(A) fiscal year 2022, $180,000,000; and

''(B) fiscal year 2028, $1,947,000,000''.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Modernizing and Ensuring PBM Accountability Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. ARRANGEMENTS WITH PHARMACY BENEFIT MANAGERS 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) REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.—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) NO INCOME OTHER THAN BONA FIDE SERVICE FEES.—

"(i) IN GENERAL.—The pharmacy benefit manager and any affiliate of such pharmacy benefit manager shall not derive any remuneration with respect to any services provided in connection with the utilization of covered part D drugs from any entity or individual other than bona fide service fees, subject to clauses (ii) and (iii).

"(ii) INCENTIVE PAYMENTS.—For the purposes of this subsection, an incentive payment paid by a PDP sponsor to a pharmacy benefit manager that is performing

services on behalf of such sponsor shall be deemed a 'bona fide service fee' if such payment is a flat dollar amount, is consistent with fair market value, and is related to services actually performed by the pharmacy benefit manager or affiliate of such pharmacy benefit manager in connection with the utilization of covered part D drugs.

"(iii) CLARIFICATION ON REBATES AND DISCOUNTS USED TO LOWER COSTS FOR COVERED PART D DRUGS.—Rebates, discounts, and other price concessions received from manufacturers, even if such price concessions are calculated as a percentage of a drug's price, shall not be considered a violation of the requirements of clause (i) if they are fully passed through to a PDP sponsor and exclusively used to lower costs for prescription drugs under this part, including in cases where a PDP sponsor is acting as a pharmacy benefit manager on behalf of a prescription drug plan offered by such PDP sponsor.

"(iv) EVALUATION OF REMUNERATION ARRANGEMENTS.—Remuneration arrange-

ments between pharmacy benefit managers or affiliates of such pharmacy benefit managers, as applicable, and other entities involved in the dispensing or utilization of covered part D drugs (including PDP sponsors, manufacturers, pharmacies, and other entities as determined appropriate by the Secretary) shall be subject to review by the Secretary and the Office of the Inspector General of the Department of Health and Human Services. The Secretary, in consultation with the Office of the Inspector General, shall evaluate whether remuneration under such arrangements is consistent with fair market value through reviews and assessments of such remuneration, as determined appropriate.

"(B) 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.

"(C) PROVISION OF INFORMATION.—

"(i) IN GENERAL.—Not later than July 1 of each year, beginning in 2026, 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 co-payments, 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 acquires 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 ar-

rangement 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 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) Where a biosimilar biological product listed under item (aa) is on a formulary tier typi-

cally 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 re-

ferrals, 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.

"(D) 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 infor-

mation 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.

"(E) 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 ben-

efit 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, 2025, 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'.".

(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) REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.—For plan years beginning on or after January 1, 2026, section 1860D–12(h).".

(3) FUNDING.—

(A) SECRETARY.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $20,000,000 for fiscal year 2026, to remain

available until expended, to carry out the amendments made by this subsection.

(B) OIG.—In addition to amounts otherwise available, there is appropriated to the Inspector General of the Department of Health and Human Services, out of any money in the Treasury not otherwise appropriated, $5,000,000 for fiscal year 2026, to remain available until expended, to carry out the amendments made by this subsection.

(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) 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).

(c) 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.

SEC. 3. ENSURING FAIR ASSESSMENT OF PHARMACY PERFORMANCE AND QUALITY UNDER MEDICARE PART D.

(a) STANDARDIZED PHARMACY PERFORMANCE MEASURES.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended by adding at the end the following new subsection:

"(f) APPLICATION OF STANDARDIZED PHARMACY PERFORMANCE MEASURES.—

"(1) MEASURES.—For plan years beginning on or after January 1, 2025, a PDP sponsor offering a prescription drug plan and an MA organization offering an MA–PD plan shall, for purposes of incentive payments, price concessions, or any fees or other remuneration paid or charged to a pharmacy based on performance measures, only use measures that are—

"(A) established or adopted by the Secretary under paragraph (2) and included on the list described in subparagraph (B) of such paragraph; and

"(B) relevant to the performance of such pharmacy based on the type of pharmacy (including retail, mail order, specialty, long term care, and home infusion or other types of pharmacies), drugs dispensed by such pharmacy, and

pharmacy services used to dispense and manage drugs by such pharmacy.

"(2) STANDARDIZED PHARMACY PERFORMANCE MEASURES.—

"(A) MEASURES.—

"(i) IN GENERAL .—Notwithstanding any other provision of law, the Secretary shall establish (or adopt pursuant to clause (iii)) standardized pharmacy performance measures that may be used by a PDP sponsor offering a prescription drug plan and an MA organization offering an MA–PD plan for the purpose of determining incentive payments, price concessions, or fees or other remuneration described in paragraph (1).

"(ii) REQUIREMENTS.—The measures under clause (i) shall focus on pharmacy performance and quality of care based on the type of pharmacy, as determined by the Secretary. Such measures shall be evidence-based, feasible, appropriate and reasonable.

"(iii) ADOPTION OF MEASURE.—In lieu of establishing some or all of the measures under this paragraph, the Secretary

may adopt measures that are endorsed by one or more multi-stakeholder consensus organizations (such as the Pharmacy Quality Alliance), that has participation from pharmacies (including retail and specialty pharmacies not owned or affiliated with a plan, pharmacy benefit manager, or other pharmacy), health plans, pharmacy benefit managers, and the Centers for Medicare & Medicaid Services. Any measure adopted under this clause shall be deemed to meet the requirements under clause (ii).

"(B) MAINTENANCE OF LIST.—

"(i) IN GENERAL.—The Secretary shall maintain, and publish on a publicly available internet website, a list of measures established or adopted under this paragraph. Such list shall initially be published no later than June 1, 2024.

"(ii) UPDATE.—The Secretary shall periodically evaluate measures, and how measures are applied by type of pharmacy and update the measures on the list under clause (i) so that such measures meet the requirements under subparagraph (A)(ii).

"(3) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to any data collection undertaken by the Secretary under this subsection.".

(b) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $4,000,000 for fiscal year 2025, to remain available until expended, to carry out the amendment made by subsection (a).

SEC. 4. PROMOTING TRANSPARENCY FOR PHARMACIES UNDER MEDICARE PART D.

(a) TRANSPARENCY FOR PHARMACIES.—Section 1860D–2(f) of the Social Security Act (42 U.S.C. 1395w–102(f)), as added by section 3, is amended by adding at the end the following new paragraph:

"(4) TRANSPARENCY FOR PHARMACIES.—

"(A) IN GENERAL.—For plan years beginning on or after January 1, 2025, a PDP sponsor offering a prescription drug plan and an MA organization offering an MA–PD plan, with respect to payment made by such PDP sponsor or such MA organization to a pharmacy for a covered part D drug dispensed by such pharmacy

during a plan year, shall promptly furnish, upon paying a claim for a covered part D drug from a pharmacy, to such pharmacy information related to such claim, such as the Network Reimbursement ID, fees, pharmacy price concessions, discounts, incentives, or any other forms of remuneration that affect payment and pricing of the claim.

"(B) STANDARDIZED FORMAT.—The PDP sponsor and the MA organization shall furnish the information described in subparagraph (A) in a standardized format (as specified by the Secretary) that includes all fields needed to price the claim for a covered part D drug dispensed by such pharmacy.

"(C) AVAILABILITY OF INFORMATION TO THE SECRETARY.—A PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan shall make the information described in subparagraph (A) available to the Secretary upon request.

"(D) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary shall implement this paragraph by program instruction or otherwise.".

(b) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $2,000,000 for fiscal year 2025, to remain available until expended, to carry out the amendment made by subsection (a).

SEC. 5. PREVENTING THE USE OF ABUSIVE SPREAD PRICING IN MEDICAID.

(a) IN GENERAL.—Section 1927(e) of the Social Security Act (42 U.S.C. 1396r–8(e)) is amended by adding at the end the following:

"(6) TRANSPARENT PRESCRIPTION DRUG PASS-THROUGH PRICING REQUIRED.—A contract between the State and a pharmacy benefit manager (referred to in this paragraph as a 'PBM'), or a contract between the State and a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D) and collectively referred to in this paragraph as the 'entity') that includes provisions making the entity responsible for coverage of covered outpatient drugs dispensed to individuals enrolled with the entity, shall require that payment for such drugs and related administrative services (as applicable), including payments made by a PBM on behalf

of the State or entity, is based on a transparent prescription drug pass-through pricing model under which—

"(A) any payment made by the entity or the PBM (as applicable) for such a drug—

"(i) is limited to—

"(I) ingredient cost; and

"(II) a professional dispensing fee that is not less than the professional dispensing fee that the State plan or waiver would pay if the plan or waiver was making the payment directly;

"(ii) is passed through in its entirety by the entity or PBM to the pharmacy or provider that dispenses the drug (and shall not be reduced or denied retroactively under post-adjudication processes); and

"(iii) is made in a manner that is consistent with sections 447.502, 447.512, 447.514, and 447.518 of title 42, Code of Federal Regulations (or any successor regulation) as if such requirements applied directly to the entity or the PBM, except that any payment by the entity or the PBM for the ingredient cost of such drug purchased

by a covered entity (as defined in subsection (a)(5)(B)) may exceed the actual acquisition cost (as defined in 447.502 of title 42, Code of Federal Regulations, or any successor regulation) for such drug if—

"(I) such drug was subject to an agreement under section 340B of the Public Health Service Act;

"(II) such payment for the ingredient cost of such drug does not exceed the maximum payment that would have been made by the entity or the PBM for the ingredient cost of such drug if such drug had not been purchased by such covered entity; and

"(III) such covered entity reports to the Secretary (in a form and manner specified by the Secretary), on an annual basis and with respect to payments for the ingredient costs of such drugs so purchased by such covered entity that are in excess of the actual acquisition costs for such drugs, the aggregate amount of such excess;

"(B) payment to the entity or the PBM (as applicable) for administrative services performed by the entity or PBM is limited to the fair market value of such services;

"(C) the entity or the PBM (as applicable) shall make available to the State, and the Secretary upon request, all costs and payments related to covered outpatient drugs and accompanying administrative services incurred, received, or made by the entity or the PBM, including ingredient costs, professional dispensing fees, administrative fees, post-sale and post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees, and any and all other remuneration; and

"(D) any form of spread pricing whereby any amount charged or claimed by the entity or the PBM (as applicable) that exceeds the amount paid to the pharmacies or providers on behalf of the State or entity, including any post-sale or post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees or assessments (after allowing for an administrative fee as described in subparagraph (B)) is

not allowable for purposes of claiming Federal matching payments under this title.".

(b) DEFINITION OF PHARMACY BENEFIT MANAGER.—Section 1927(k) of the Social Security Act (42 U.S.C. 1396r–8(k)) is amended by adding at the end the following new paragraph:

"(12) 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 State, managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)), or manages the prescription drug benefits provided by such State, managed care entity, or other specified entity, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the managing of appeals or grievances related to the prescription drug benefits, contracting with pharmacies, controlling the cost of covered outpatient drugs, or the provision of services related thereto. Such term includes any person or entity that carries out 1 or more of the activities described in the preceding sentence, irrespective of

whether such person or entity calls itself a 'pharmacy benefit manager'.".

(c) CONFORMING AMENDMENTS.—Section 1903(m) of such Act (42 U.S.C. 1396b(m)) is amended—

(1) in paragraph (2)(A)(xiii)—

(A) by striking "and (III)" and inserting "(III)";

(B) by inserting before the period at the end the following: ", and (IV) if the entity, or a pharmacy benefit manager acting on behalf of the entity under a contract or other arrangement between the entity and the pharmacy benefit manager, performs any of the activities described in section 1927(k)(12), such activities shall comply with the requirements of section 1927(e)(6)"; and

(C) by moving the left margin 2 ems to the left; and

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

"(10) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by an other specified entity (as defined in paragraph (9)(D)(iii)) unless such services are provided in accordance with a contract between the

State and such entity which satisfies the requirements of paragraph (2)(A)(xiii).".

(d) EFFECTIVE DATE.—The amendments made by this section apply to contracts between States and managed care entities, other specified entities, or pharmacy benefit managers that have an effective date beginning on or after the date that is 18 months after the date of enactment of this Act.

SEC. 6. ENSURING ACCURATE PAYMENTS TO PHARMACIES UNDER MEDICAID.

(a) IN GENERAL.—Section 1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)) is amended—

(1) by striking "and" after the semicolon at the end of paragraph (1)(A)(i) and all that precedes it through "(1)" and inserting the following:

"(1) DETERMINING PHARMACY ACTUAL ACQUISITION COSTS.—The Secretary shall conduct a survey of retail community pharmacy drug prices to determine the national average drug acquisition cost as follows:

"(A) USE OF VENDOR.—The Secretary may contract services for—

"(i) with respect to retail community pharmacies, the determination of retail survey prices of the national average drug acquisition cost for covered outpatient drugs

that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available) based on a monthly survey of such pharmacies; and'';

(2) by adding at the end of paragraph (1) the following:

''(F) SURVEY REPORTING.—In order to meet the requirement of section 1902(a)(54), a State shall require that any retail community pharmacy in the State that receives any payment, reimbursement, administrative fee, discount, or rebate related to the dispensing of covered outpatient drugs to individuals receiving benefits under this title, regardless of whether such payment, reimbursement, administrative fee, discount, or rebate is received from the State or a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)) directly or from a pharmacy benefit manager or another entity that has a contract with the State or a managed care entity or other specified entity (as so defined), shall re-

spond to surveys of retail prices conducted under this paragraph.

"(G) SURVEY INFORMATION.—Information on national drug acquisition prices obtained under this paragraph shall be made publicly available and shall include at least the following:

"(i) The monthly response rate to the survey including a list of pharmacies not in compliance with subparagraph (F).

"(ii) The sampling frame and number of pharmacies sampled monthly.

"(iii) Information on price concessions to the pharmacy, including discounts, rebates, and other price concessions, to the extent that such information may be publicly released and has been collected by the Secretary as part of the survey.

"(H) PENALTIES.—The Secretary may enforce non-compliance with this paragraph by a pharmacy through the establishment of penalties or the suspension of payments under this title, in full or in part, until compliance with this paragraph has been completed.";

(3) in paragraph (2)—

(A) in subparagraph (A), by inserting ", including payment rates under Medicaid managed care entities or other specified entities (as such terms are defined in section 1903(m)(9)(D))," after "under this title"; and

(B) in subparagraph (B), by inserting "and the basis for such dispensing fees" before the semicolon; and

(4) in paragraph (4), by inserting ", and $5,000,000 for fiscal year 2024 and each fiscal year thereafter," after "2010".

(b) EFFECTIVE DATE.—The amendments made by this section take effect on the first day of the first quarter that begins on or after the date that is 18 months after the date of enactment of this Act.

SEC. 7. OIG STUDY AND REPORT ON DRUG PRICE MARK-UPS IN MEDICARE PART D.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152) is amended by adding at the end the following new subsection:

"(e) OIG STUDY AND REPORT ON DRUG PRICE MARK-UPS UNDER THIS PART.—

"(1) STUDY.—The Inspector General of the Department of Health and Human Services (in this subsection referred to as the 'Inspector General') shall

conduct a study on the impact of related party transactions within select vertically integrated entities on the negotiated price (as defined in section 1860D–2(d)(1)(B)) paid by part D plan sponsors for covered part D drugs. Such study may include an analysis of the following:

"(A) Acquisition costs by the affiliate within such vertically integrated entities that initially acquires the prescription drug for a sample of covered part D drugs, including at least 5 generic drugs, brand drugs, specialty brand drugs, and specialty generic drugs.

"(B) The methodologies and negotiation processes used to calculate transfer prices or other transactions between related parties with respect to such covered part D drugs.

"(C) The impact of the transactions described in subparagraph (B) on the negotiated price, net of direct and indirect remuneration, for such covered part D drugs.

"(D) The margin captured by different affiliates within such vertically integrated entities through the transactions described in subparagraph (B).

"(E) An assessment of the impact of the transactions described in subparagraph (B) on costs to individuals enrolled in a prescription drug plan or an MA–PD plan and program spending on prescription drugs under this part.

"(F) Other issues determined to be relevant and appropriate by the Inspector General.

"(2) REPORT.—Not later than 3 years after the date of enactment of this subsection, the Inspector General shall submit to the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Inspector General determines appropriate.

"(3) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Inspector General, out of any money in the Treasury not otherwise appropriated, $5,200,000 for fiscal year 2024, to remain available until expended, to carry out this subsection.".

SEC. 8. RESOLVING P&T COMMITTEE CONFLICTS OF INTEREST.

Section 1860D–4(b)(3)(A)(ii)(I) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)(A)(ii)(I)) is amended by inserting the following before the semicolon: "(and, for 2025 and each subsequent year, any pharmacy benefit manager acting under contract with such sponsor offering such plan)".

SEC. 9. ENHANCING PBM TRANSPARENCY REQUIREMENTS.

(a) IN GENERAL.—Section 1150A of the Social Security Act (42 U.S.C. 1320b–23) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) PROVISION OF INFORMATION.—

"(1) IN GENERAL.—The following entities shall provide the information described in subsection (b) to the Secretary and, in the case of an entity described in subparagraph (B) or an affiliate of such entity described in subparagraph (C), to the health benefits plan with which the entity is under contract, at such times, and in such form and manner, as the Secretary shall specify:

"(A) A health benefits plan.

"(B) Any entity that provides pharmacy benefits management services on behalf of a health benefits plan (in this section referred to as

a 'PBM') that manages prescription drug coverage under a contract with—

"(i) a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan under part D of title XVIII; or

"(ii) a qualified health benefits plan offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act.

"(C) Any affiliate of an entity described in subparagraph (B) that acts as a price negotiator or group purchaser on behalf of such PBM, PDP sponsor, MA organization, or qualified health benefits plan.

"(2) AFFILIATE DEFINED.—In this section, the term 'affiliate' means any entity that is owned by, controlled by, or related under a common ownership structure with a PBM (including an entity owned or controlled by the PDP sponsor of a prescription drug plan, MA organization offering an MA–PD plan, or qualified health benefits plan for which such entity is acting as a price negotiator or group purchaser).";

(2) in subsection (b)—

(A) in paragraph (2), by inserting "and percentage" after "and the aggregate amount"; and

(B) by adding at the end the following new paragraph:

"(4) The amount (in the aggregate and disaggregated by type) of all fees the PBM or an affiliate of the PBM receives from all pharmaceutical manufacturers in connection with patient utilization under the plan, and the amount and percentage (in the aggregate and disaggregated by type) of such fees that are passed through to the plan sponsor or issuer."; and

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

"(e) ANNUAL REPORT.—The Secretary shall make publicly available on the Internet website of the Centers for Medicare & Medicaid Services an annual report that summarizes the trends observed with respect to data reported under subsection (b).".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to plan or contract years beginning on or after January 1, 2027.

(c) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement the amend-

ments made by this section by program instruction or otherwise.

(d) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the "Paperwork Reduction Act of 1995"), shall not apply to the implementation of the amendments made by this section.

SEC. 10. FACILITATING MIDYEAR FORMULARY CHANGES FOR BIOSIMILARS.

(a) IN GENERAL.—Section 1860D–4(b) of the Social Security Act (42 U.S.C. 1395w–104(b)) is amended by adding at the end the following new paragraph:

"(5) MID-YEAR CHANGES IN FORMULARIES PERMITTED FOR CERTAIN BIOSIMILAR BIOLOGICAL PRODUCTS AND THE REFERENCE PRODUCT OF SUCH BIOSIMILARS.—If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following shall apply:

"(A) IN GENERAL.—For plan year 2025, and subsequent plan years, in the case of a covered part D drug that is the reference biological product (as defined in section 351(i) of the Public Health Service Act) with respect to a biosimilar biological product (defined as a biological product licensed under section 351(k) of such

Act), the PDP sponsor may, with respect to a formulary, at any time after the first 60 days of the plan year, subject to paragraph (3)(E), change the preferred or tiered cost-sharing status of such reference biological product if such PDP sponsor adds, before or at the same time, to such formulary such biosimilar biological product at the same or a higher preferred status, or to the same or lower cost-sharing tier, as that of such reference biological product immediately prior to such change.

"(B) REQUEST FOR APPROVAL OF CHANGE.—Prior to making a change described in subparagraph (A), the PDP sponsor shall submit to the Secretary a request to make such change. If the Secretary approves the request or has not provided a decision to the PDP sponsor regarding such request within 30 days of receiving such request, such PDP sponsor may make such change.".

(b) ADMINISTRATION.—

(1) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendment

made by subsection (a) by program instruction or otherwise.

(2) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the "Paperwork Reduction Act of 1995"), shall not apply to the implementation of the amendment made by subsection (a).

SEC. 11. STRENGTHENING PHARMACY ACCESS FOR SENIORS.

Section 1860D–4(b)(1) of the Social Security Act (42 U.S.C. 1395w–104(b)(1)) is amended by adding at the end the following new subparagraph:

"(F) LIMITED ACCESS DRUGS.—

"(i) LIMITATION ON RESTRICTIONS OR LIMITS ON ACCESS.—For each plan year (beginning with plan year 2026), a PDP sponsor offering a prescription drug plan—

"(I) may not restrict or limit access to any covered part D drug to a subset of their network pharmacies, other than with respect to a limited access drug, as defined in clause (v); and

"(II) shall document the rationale for why a covered part D drug meets the definition of a limited access drug

under clause (v), if such plan restricts or limits access to a limited access drug to a subset of network pharmacies.

"(ii) ANNUAL SUBMISSION OF INFORMATION TO THE SECRETARY ON LIMITED ACCESS DRUGS.—For each plan year (beginning with plan year 2026), each PDP sponsor offering a prescription drug plan shall submit to the Secretary, at a time and in a manner specified by the Secretary, with respect to each prescription drug plan offered by the sponsor during such plan year—

"(I) a list of all covered part D drugs that the PDP sponsor designated as a limited access drug;

"(II) for each covered part D drug included in the list described in subclause (I), a written rationale for why such drug meets the definition of a limited access drug;

"(III) a summary of the requirements imposed on network pharmacies (including all accreditation require-

ments, if any) to ensure appropriate handling and dispensing of each covered part D drug included in the list described in subclause (I);

"(IV) the percentages of each covered part D drug included in the list described in subclause (I) that is dispensed through retail pharmacies, specialty pharmacies, mail order pharmacies, or other dispensing channels as defined by the PDP sponsor, respectively;

"(V) the annual percentage of each covered part D drug included in the list described in subclause (I) that is dispensed through a pharmacy that is affiliated with the plan or is an affiliate (as defined in section 1860D–12(h)(4)(A)) of a pharmacy benefit manager acting on behalf of such sponsor or such plan; and

"(VI) any other information determined appropriate by the Secretary.

"(iii) PHARMACY ACCESS TO LIMITED ACCESS DRUG INFORMATION.—For plan

years beginning with plan year 2026, upon the request of a network pharmacy, a PDP sponsor of a prescription drug plan shall provide such pharmacy, not later than 14 days after receiving such request, with the information described in subclauses (I), (II), and (III) of clause (ii).

"(iv) HHS ANNUAL REPORT ON LIMITED ACCESS DRUGS.—Not later than December 31, 2028, and annually thereafter, the Secretary shall submit to the Committee on Finance of the Senate, and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report on compliance by PDP sponsors with the requirements under this subparagraph. Each such report shall include—

"(I) a description of the patterns, trends, variations, and rationales for the designation by PDP sponsors of certain covered part D drugs as limited access drugs, and the implications of such designations on beneficiary access to such covered part D drugs;

"(II) a description of the information submitted to the Secretary under clause (ii) (in a manner that does not disclose the identity of a pharmacy, a PDP sponsor, a prescription drug plan, or pharmacy benefit manager, or any proprietary pricing information); and

"(III) any other information determined appropriate by the Secretary.

"(v) LIMITED ACCESS DRUG DEFINED.—In this subparagraph, the term 'limited access drug' means a covered part D drug that meets at least one of the following:

"(I) The Food and Drug Administration has restricted distribution of such covered part D drug to certain facilities or physicians.

"(II) The dispensing of such covered part D drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy.".

"(vii) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary shall implement this subparagraph by program instruction or otherwise.

"(viii) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to any data collection undertaken by the Secretary under this subparagraph.".

SEC. 12. BENEFICIARY-FOCUSED LISTENING SESSIONS TO IMPROVE PRESCRIPTION DRUG PLAN TRANSPARENCY, ACCESS, AND CHOICE.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 7, is amended by adding at the end the following new subsection:

"(f) BENEFICIARY-FOCUSED LISTENING SESSIONS TO IMPROVE PRESCRIPTION DRUG PLAN TRANSPARENCY, ACCESS, AND CHOICE.—

"(1) IN GENERAL.—Not later than December 31, 2024, the Secretary shall hold at least one beneficiary-focused listening session to receive input on potential improvements to the experience with, and transparency of, prescription drug plans under this part, as described in paragraph (2).

"(2) BENEFICIARY-FOCUSED LISTENING SESSIONS.—Any beneficiary-focused listening session held under paragraph (1) shall be open to the public, including beneficiaries, caregivers of beneficiaries, consumer and patient advocacy organizations, health care providers, and other interested parties. Any such listening sessions may include an opportunity for the public to provide input to the Secretary on potential improvements to—

"(A) the information made available by prescription drug plans to individuals;

"(B) tools and mechanisms to assist enrollees of prescription drug plans in navigating plan complaint systems, as well as the efficiency and effectiveness of such systems;

"(C) tools and mechanisms to assist beneficiaries in selecting a prescription drug plan;

"(D) tools and mechanisms to assist enrollees of prescription drug plans in navigating utilization management requirements of such plans, such as step therapy and prior authorization;

"(E) access to, and effectiveness and utilization of, electronic real-time benefit tools (as described in section 423.160(b)(7) of title 42, Code of Federal Regulations, or any successor regula-

tion) and beneficiary real-time benefit tools (as described in section 423.128(d)(4) of title 42, Code of Federal Regulations, or any successor regulation);

"(F) formulary management and oversight by prescription drug plans; and

"(G) other subjects, as determined appropriate by the Secretary.".

SEC. 13. REPORTING ON ENFORCEMENT AND OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 12, is amended by adding at the end the following new subsection:

"(g) BIENNIAL REPORT ON ENFORCEMENT AND OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of this subsection, and at least once every 2 years thereafter, the Secretary shall publish a report on enforcement and oversight actions and activities undertaken by the Secretary with respect to the requirements under section 1860D–4(b)(1).

"(2) LIMITATION.—A report under paragraph (1) shall not disclose—

"(A) identifiable information about individuals or entities unless such information is otherwise publicly available; or

"(B) trade secrets with respect to any entities.".

SEC. 14. GAO STUDY ON PRICE-RELATED COMPENSATION ACROSS THE SUPPLY CHAIN.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 13, is amended by adding at the end the following new subsection:

"(h) GAO STUDY AND REPORT ON PRICE-RELATED COMPENSATION AND PAYMENT STRUCTURES IN THE PRESCRIPTION DRUG SUPPLY CHAIN.—

"(1) STUDY.—The Comptroller General of the United States (in this subsection referred to as the 'Comptroller General') shall conduct a study describing the use of compensation and payment structures related to a prescription drug's price within the retail prescription drug supply chain in this part. Such study shall summarize information from Federal agencies and industry experts, to the extent available, with respect to the following:

"(A) The type, magnitude, other features (such as the pricing benchmarks used), and prevalence of compensation and payment structures

related to a prescription drug's price, such as calculating fee amounts as a percentage of a prescription drug's price, between intermediaries in the prescription drug supply chain, including—

"(i) pharmacy benefit managers;

"(ii) part D plan sponsors;

"(iii) drug wholesalers;

"(iv) pharmacies;

"(v) manufacturers;

"(vi) pharmacy services administrative organizations;

"(vii) brokers, auditors, consultants, and other entities that advise part D plan sponsors about pharmacy benefits or review part D plan sponsor contracts with pharmacy benefit managers; and

"(viii) other service providers that contract with any of the entities described in clauses (i) through (vii) that may use price-related compensation and payment structures, such as rebate aggregators (or other entities that negotiate or process price concessions on behalf of pharmacy benefit managers, plan sponsors, or pharmacies).

"(B) The primary business models and compensation structures for each category of intermediary described in subparagraph (A).

"(C) Variation in price-related compensation structures between affiliated entities (such as entities with common ownership, either full or partial, and subsidiary relationships) and unaffiliated entities.

"(D) Potential conflicts of interest among contracting entities related to the use of prescription drug price-related compensation structures, such as the potential for fees or other payments set as a percentage of a prescription drug's price to advantage formulary selection, distribution, or purchasing of prescription drugs with higher prices.

"(E) Notable differences, if any, in the use and level of price-based compensation structures over time and between different market segments, such as under this part and the Medicaid program under title XIX.

"(F) The effects of drug price-related compensation structures and alternative compensation structures on Federal health care programs and program beneficiaries, including with re-

spect to cost-sharing, premiums, Federal outlays, biosimilar and generic drug adoption and utilization, drug shortage risks, and the potential for fees set as a percentage of a drug's price to advantage the formulary selection, distribution, or purchasing of drugs with higher prices.

"(G) Other issues determined to be relevant and appropriate by the Comptroller General.

"(2) REPORT.—Not later than 2 years after the date of enactment of this subsection, the Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.".

SEC. 15. REPORTS ON INAPPROPRIATE PHARMACY REJECTIONS.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 14, is amended by adding at the end the following new subsection:

"(i) BIENNIAL REPORT ON EFFORTS TO ADDRESS INAPPROPRIATE PHARMACY REJECTIONS AND INAPPROPRIATE COVERAGE DENIALS UNDER MEDICARE PART D.—

"(1) IN GENERAL.—Not later than January 1, 2026, and at least once every 4 years thereafter, the

Secretary, in consultation with the Office of the Inspector General of the Department of Health and Human Services, shall post, on a publicly available website, a report related to preventing, identifying, or addressing inappropriate pharmacy rejections (as defined in paragraph (2)(B)) and inappropriate coverage denials (as defined in paragraph (2)(A)) under this part. Such reports shall include—

"(A) a description of programs, reviews, or initiatives underway to prevent, identify, or address such rejections and denials, in accordance with existing authorities;

"(B) a summary of data collected or other information available with respect to such rejections and denials, including—

"(i) standards (if any such standards have been adopted) used by the Secretary for identifying PDP sponsors and MA organizations with relatively high rates of such rejections or denials; and

"(ii) notable longitudinal trends or other patterns, as determined appropriate by the Secretary;

"(C) an overview of corrective actions taken and technical assistance provided by the Sec-

retary in response to violations of existing requirements with respect to such rejections and denials; and

"(D) a description of barriers, if any, preventing the Secretary from taking administrative actions sufficient to identify and address such rejections and denials.

"(2) DEFINITIONS.—For purposes of this subsection:

"(A) INAPPROPRIATE COVERAGE DENIAL.—The term 'inappropriate coverage denial' means a denial of coverage of a covered part D drug claim that violates the requirements of this part.

"(B) INAPPROPRIATE PHARMACY REJECTIONS.—The term 'inappropriate pharmacy rejection' means a rejection of a covered part D drug claim that violates the requirements of this part, such as through the application of utilization management requirements that the Secretary has not approved.".

SEC. 16. GAO STUDY ON DRUG SHORTAGES.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 15, is amended by adding at the end the following new subsection:

"(j) GAO STUDY AND REPORT ON DRUG SHORTAGES.—

"(1) STUDY.—The Comptroller General of the United States (in this subsection referred to as the 'Comptroller General') shall conduct a study on factors contributing to shortages of covered part D drugs across the outpatient prescription drug supply chain. Such study shall include analysis of—

"(A) common features of and trends in covered part D drugs that have experienced at least 1 shortage (as defined under section 506C of the Federal Food, Drug, and Cosmetic Act);

"(B) patterns, trends, and variations in the duration of shortages experienced by covered part D drugs;

"(C) patterns, trends, and variations in the proximate causes and other potential causes of shortages experienced by covered part D drugs;

"(D) effects of such shortages on beneficiaries enrolled in prescription drug plans under this part, including with respect to access to covered part D drugs and out-of-pocket costs; and

"(E) other issues determined appropriate by the Comptroller General.

"(2) REPORT.—Not later than 2 years after the date of enactment of this subsection, the Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.".

SEC. 17. REPORT ON BIOSIMILAR AND GENERIC ACCESS UNDER MEDICARE PART D.

Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 16, is amended by adding at the end the following new subsection:

"(k) OIG REPORT ON BIOSIMILAR AND GENERIC ACCESS UNDER PART D.—

"(1) STUDY.—The Office of the Inspector General of the Department of Health and Human Services (referred to in this subsection as the 'Office of the Inspector General') shall conduct a study on biosimilar and generic drug access and adoption under prescription drug plans offered under this part, including with respect to barriers to increased adoption and utilization of lower-priced biosimilar and generic utilization, plan features that discourage or encourage the utilization of these products, and the gross and

net spending effects of policies that increased adoption of these products under this part.

"(2) REPORT.—Not later than 1 year after the date of enactment of this subsection, the Office of the Inspector General shall publish a report on the study conducted under paragraph (1).".

SEC. 18. MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking "during and after fiscal year 2022, $180,000,000" and inserting the following: "during and after—

"(A) fiscal year 2022, $180,000,000; and

"(B) fiscal year 2028, $1,947,000,000".

Calendar No. 266

118TH CONGRESS
1ST SESSION

S. 2973

[Report No. 118–122]

A BILL

To amend titles XVIII and XIX of the Social Security Act to establish requirements relating to pharmacy benefit managers under the Medicare and Medicaid programs, and for other purposes.

DECEMBER 7, 2023

Reported with an amendment