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THE MODERNIZING AND ENSURING PBM ACCOUNTABILITY ACT

DECEMBER 7, 2023.—Ordered to be printed

Mr. WYDEN, from the Committee on Finance, submitted the following

R E P O R T

[To accompany S. 2973]

The Committee on Finance, to which was referred the bill (S. 2973) to amend titles XVIII and XIX of the Social Security Act to establish requirements relating to pharmacy benefit managers under Medicare and Medicaid programs, and for other purposes, reports favorably thereon with an amendment, in the nature of a substitute, and that the bill, as amended, do pass.

CONTENTS

I. LEGISLATIVE BACKGROUND

The Committee on Finance, having considered S. 2973, a bill to amend titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices and strengthen safeguards related to prescription drugs, and for other purposes, reported favorably thereon that the bill as modified by the Committee do pass.

General Background on Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) manage prescription drug benefits and pharmacy networks on behalf of health plans, employers, and other payers. PBMs may perform a variety of functions for their clients, including processing prescription drug claims, negotiating discounts with pharmaceutical manufacturers, developing formularies (covered drug lists), establishing pharmacy networks, and reimbursing pharmacies that dispense prescription drugs to patients.

PBMs emerged in the late 1960s and early 1970s as claims processors, as more and more health insurers began to offer prescription drug benefits. Up until the 1990s, PBMs primarily filled this limited administrative role. As the scope and cost of prescription drugs grew, claims processing became digitized, and programs like Medicare Part D expanded drug coverage in the U.S., plan sponsors began delegating additional functions to PBMs.[1]

Today, the PBM market is concentrated in three companies—CVS Caremark, Express Scripts, and OptumRx—which control approximately 80 percent of the U.S. prescription drug claims.[2] [3] This degree of concentration gives the dominant PBMs market power over data, drug coverage, and contracting. Many PBMs are also vertically integrated with other components of the prescription drug supply chain, such as health plans, pharmacies (retail, specialty, and mail-order), wholesalers, distributors, and provider services.[4] [5] While the extent and types of mergers vary, each of the three largest PBMs is integrated with a health plan and at least one pharmacy channel.[6]

PBM Compensation

PBMs operate in a multi-sided market—meaning they may earn revenue on both sides of a single transaction, from both their traditional clients (e.g. health plans, employers, and payers) and the vendors or contractors with whom they negotiate (e.g. pharmaceutical manufacturers, pharmacies). Any multi-sided market introduces the potential for conflicts of interest and perverse incentives.

PBMs often receive compensation from health plans in the form of fees per prescription dispensed (flat fees or percentage of drug price), flat per member per month (PMPM) fees, and retention of a portion of manufacturer rebates. PBMs also often guarantee

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[1] Motheral, Brenda. et al. "Changes in PBM Business Practices in 2019: True Innovation or More of the Same?" *Journal of Managed Care and Specialty Pharmacy*. October 2020. https://www.jmcp.org/doi/10.18553/jmcp.2020.20213?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed&.

[2] Mader, Josh. "Pharmacy Benefit Mangers: Market Landscape and Strategic Imperatives." *Health Industries Research.* https://www.hirc.com/PBM-market-landscape-and-imperatives.

[3] Myshko, Denise and Peter Wehrwein. "Beyond the Big Three PBMs." *Managed Healthcare Executive.* December 2022. https://www.managedhealthcareexecutive.com/view/beyond-the-big-three-pbms.

[4] Fein, Adam. "Drug Channels News Roundup, December 2022: Vertical Integration Updated, Walgreens vs. Pharmacy, Cash-Pay Rx, Curing 340B, and Deductible Season." *Drug Channels.* December 2022. https://www.drugchannels.net/2022/12/drug-channels-news-roundup-december.html.

[5] Dresser, Jesse. "Considerations for Maintaining Payer Network Access in the World of Vertical Integration—Part 1: The Pharmacy Benefits Landscape." *Pharmacy Times.* August 2022. https://www.pharmacytimes.com/view/considerations-for-maintaining-payer-network-access-in-the-world-of-vertical-integration-part-1-the-pharmacy-benefits-landscape.

[6] Fein, Adam. "Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers: A 2022 Update." *Drug Channels.* October 2022. https://www.drugchannels.net/2022/10/mapping-vertical-integration-of.html.

health plans a certain level of rebates. Client fees account for a substantial portion of PBM revenue, including in Part D.[7] [8]

PBMs also receive revenue from the pharmaceutical manufacturers. PBMs leverage the volume of covered lives they serve across all of their health plan clients to negotiate lower prices and secure larger discounts, rebates, and fees from manufacturers. PBMs may retain a portion of these discounts. Manufacturers also pay PBMs administrative fees for access to services and data.

Historically, a significant portion of PBM compensation came from retaining a percentage of the rebates they negotiate with drug manufacturers. In recent years, as critiques about the lack of transparency around rebate retention have grown, PBMs appear to be passing more rebates through to their clients. Between 2017 and 2019, PBM-retained rebates decreased from $4 billion to $1.6 billion in gross profits.[9] In 2016 the Government Accountability Office (GAO) found that PBMs passed through all or most rebates to plan sponsors within Part D.[10]

PBM compensation structures have evolved over the years. Administrative fees paid by manufacturers are a growing revenue source for PBMs. They appear to be replacing rebate retention as a key source of PBM revenue. These fees may be less likely than rebates to be passed through, or shared, by PBMs to health plans.[11] [12] A PEW survey found that administrative fees paid by manufacturers to PBMs have increased as rebate retention has declined, offsetting potentially over $2 billion in lost rebates to PBMs between 2014 and 2016.[13] Another report found that, from 2017 to 2019, PBM gross profits from administrative fees increased by 51 percent, from $3.8 billion to $5.7 billion.[14] In Part D, GAO found that non-rebate revenue paid to PBMs by manufacturers, including administrative fees, accounted for $516.5 million in 2016.[15]

Administrative fees paid to PBMs are often based on a percentage of Wholesale Acquisition Cost (WAC), or a drug's list price, and volume of utilization, mirroring the structure of post-sale re-

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[7] "Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization." U.S. Government Accountability Office. July 2019. https://www.gao.gov/assets/gao-19-498.pdf.

[8] "Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers." PBM Accountability Project. December 2021. https://b11210f4-9a71-4e4c-a08f-cf43a83bc1df.usrfiles.com/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf.

[9] 3 Axis Advisors. "Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers." PBM Accountability Project. December 2021. https://b11210f4-9a71-4e4c-a08f-cf43a83bc1df.usrfiles.com/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf.

[10] "Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization." U.S. Government Accountability Office. July 2019. https://www.gao.gov/assets/gao-19-498.pdf.

[11] Feldman, Robin. "Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills." *Harvard Journal on Legislation.* 2020. https://repository.uchastings.edu/cgi/viewcontent.cgi?article=2773&context=faculty_scholarship.

[12] Part D plans are required to report bona fide service fees in excess of fair market value paid to PBMs as Direct and Indirect Remuneration (DIR), regardless of whether such amounts as passed onto the Part D plan.

[13] "The Prescription Drug Landscape Explored." Pew. March 2019. https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.

[14] 3 Axis Advisors. "Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers." PBM Accountability Project. December 2021. https://b11210f4-9a71-4e4c-a08f-cf43a83bc1df.usrfiles.com/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf.

[15] "Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization." U.S. Government Accountability Office. July 2019. https://www.gao.gov/assets/gao-19-498.pdf.

bates.[16] [17] For example, the Senate Finance Committee's landmark insulin investigation identified contracts between PBMs and manufacturers that required the manufacturer to pay the PBM an administrative fee of up to five percent of the drug's WAC per claim dispensed. The report also uncovered internal manufacturer correspondence suggesting that decreasing WAC prices would create business disadvantages with PBM partners as it would lead to reduced PBM fee revenue.[18]

Experts have noted that payments from manufacturers to PBMs may create conflicts of interest between PBMs and their health plan clients. Furthermore, linking PBM payment to a drug's list price could create incentives for PBMs to drive utilization of higher-priced drugs, rather than lower-priced, clinically equivalent alternatives, to achieve higher rebates and higher administrative fees.[19] [20] [21]

PBM Contracting with Pharmacies

PBMs create pharmacy networks and reimburse pharmacies on behalf of their health plan clients. Pharmacy networks may comprise retail, mail-order, and specialty pharmacies. Pharmacies contract with PBMs to determine drug dispensing reimbursement rates. In Medicare, the contractually set pharmacy reimbursement rate is known as the "negotiated price." This generally covers a drug's "ingredient cost" and a dispensing fee, as well as other costs, such as sales tax.[22] In Part D, beneficiary cost sharing for drugs dispensed by network pharmacies is based on a percentage of each plan sponsor's negotiated price, unless a flat copay applies.

Part D plan sponsors are required to establish pharmacy networks sufficient to ensure access to Medicare covered drugs for all enrollees. As part of the "Any Willing Pharmacy" requirements established by Congress, Part D plan sponsors must permit any pharmacy that is willing to accept the Part D sponsor's standard contracting terms and conditions to participate in the sponsor's network.[23] [24] [25]

PBMs recently began imposing retrospective, post-sale fees on pharmacies for not meeting contractually specified quality metrics

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[16] Feldman, Robin. "Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills." *Harvard Journal on Legislation.* 2020. https://repository.uchastings.edu/cgi/viewcontent.cgi?article=2773&context=faculty_scholarship.

[17] 3 Axis Advisors. "Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers." PBM Accountability Project. December 2021. https://b11210f4-9a71-4e4c-a08f-cf43a83bc1df.usrfiles.com/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf.

[18] Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug." U.S. Senate. January 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

[19] Feldman, Robin. "Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills." *Harvard Journal on Legislation.* 2020. https://repository.uchastings.edu/cgi/viewcontent.cgi?article=2773&context=faculty_scholarship.

[20] Shepherd, Joanna. "Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs." *The Yale Law and Policy Review.* January 2019. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3313828.

[21] Purchaser Business Group on Health. "Pharmacy Benefit Tactics Drive Up Drug Prices, Limit Access, Contribute to Health Risks." December 2022. https://www.pbgh.org/wp-content/uploads/2022/12/Pharmacy-Benefit-Tactics-Drive-Up-Drug-Prices-Limit-Access-Contribute-to-Health-Risks.pdf.

[22] 42 C.F.R. § 423.100.

[23] 42 U.S.C. § 1395w–104(b)(1)(A).

[24] 42 C.F.R. § 423.505(b)(18).

[25] CMS, "Medicare Program: Contract Year 2019 Policy and Technical Changes to Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, Medicare Prescription Drug Benefit Programs, and PACE Program," 83 Federal Register, April 16, 2018, p. 16589, https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf.

or as a condition of preferred network participation. These fees tend to substantially increase PBM revenue, ranging from 1.5 percent to 11 percent of a manufacturer list price, and are generally levied on pharmacies three to six months after dispensing.[26] These fees must be disclosed to the Centers for Medicare and Medicaid Services (CMS) as part of Direct and Indirect Remuneration (DIR) reporting. According to CMS, pharmacy DIR fees grew by 107,400 percent between 2010 and 2020.[27] In April 2022, CMS finalized rulemaking that requires Part D plan sponsors (and PBM contractors) to include such fees from network pharmacies in the negotiated price, with the goals of making PBM reimbursement to pharmacies more transparent, and lowering cost sharing for beneficiaries. This rule takes effect on January 1, 2024.[28]

Evidence suggests that some PBMs engage in a practice known as "spread pricing," which occurs when PBMs charge their health plan clients a higher amount than what the PBM actually reimburses the pharmacy for the same dispensed drug—with the PBM retaining the difference.[29] Across markets, PBM clients often lack line of sight into the extent of such spreads. Spread pricing has been widely documented in Medicaid. For example, a 2018 audit of Ohio's Medicaid program found that PBMs were charging the state an average nine percent spread across all drugs, with some spreads in excess of 30 percent for certain generics.[30] Similar behavior has been documented in other state Medicaid programs, prompting many state lawmakers and regulators to intervene.[31] Spread pricing is less common in Medicare Part D.[32]

Senate Finance Committee Engagement on PBM Issues

In 2015, then-Ranking Member Ron Wyden and senior Finance Committee member (and then-Chairman of the Judiciary Committee) Chuck Grassley conducted an 18-month investigation into the pricing of Sovaldi and Harvoni, Gilead's breakthrough hepatitis C drugs. The Senate Finance Committee has worked for many years to increase transparency throughout prescription drug pricing and hold actors across the supply chain accountable for predatory pricing practices. They uncovered that Gilead had set a high list price for the drug treatments to maximize revenue and profit,

[26] "Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers." Frier Levitt, LLC. February 2022. https://www.frierlevitt.com/articles/pharmacy-benefit-manager-expose-how-pbms-adversely-impact-cancer-care-while-profiting-at-the-expense-of-patients-providers-employers-and-taxpayers/.

[27] "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency." Centers for Medicare and Medicaid Services. https://public-inspection.federalregister.gov/2022-09375.pdf.

[28] "CY 2023 Medicare Advantage and Part D Final Rule (CMS–4192–F)." Centers for Medicare and Medicaid Services. April 2022. https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-advantage-and-part-d-final-rule-cms-4192-f.

[29] Garfield, Rachel, Rachel Dolan, and Elizabeth Williams. "Costs and Savings under Federal Policy Approaches to Address Medicaid Prescription Drug Spending." June 2021. KFF. https://www.kff.org/medicaid/issue-brief/costs-and-savings-under-federal-policy-approaches-to-address-medicaid-prescription-drug-spending/.

[30] Meltzer, Rose. "Ohio Cracks Down on PBM Contracts After Audit Shows Egregious Spread Pricing in Medicaid." *Fierce Healthcare.* August 2018. https://www.fiercehealthcare.com/regulatory/ohio-takes-action-after-finding-pbms-engaged-egregious-spread-pricing-medicaid.

[31] Arkansas, Delaware, Georgia, Kentucky, Louisiana, Maine, Michigan, Minnesota, New York, Oklahoma, and Virginia have all passed laws seeking to curb spread pricing.

[32] "Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization." GAO. July 2019. https://www.gao.gov/assets/gao-19-498.pdf.

even though Gilead's internal analysis showed a lower price would enable more patients to access the treatment. In 2018, Finance Committee Ranking Member Ron Wyden released "A Tangled Web: Examination of the Drug Supply and Payment Chains," a report which examined how financial arrangements between different entities in the pharmaceutical delivery system have continually pushed drug prices higher. In 2021, then-Chairman Grassley and Ranking Member Wyden released "Insulin: Examining the Factors Behind the Rising Cost of a Century Old Drug," a report based on an investigation into how contracts and financial transactions between insulin manufacturers and PBMs influence prescription drug prices and drug spending.

In addition to producing written work products on drug pricing issues, the Finance Committee has held a series of hearing on these matters. In 2019, the Finance Committee held three hearings on drug pricing, including a hearing in which executives from the nation's five largest PBMs testified. Building on the Finance Committee's long-standing consideration of practices across the prescription drug supply chain that may raise drug prices, patient out-of-pocket costs, and total drug spending across Finance Committee jurisdiction programs, including in Medicare Part D and Medicaid, on March 30, 2023, Finance Committee Chairman Ron Wyden and Ranking Member Mike Crapo convened a hearing entitled "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers."

On April 20, 2023, Chairman Wyden and Ranking Member Crapo released the "Bipartisan Framework for Reducing Prescription Drug Costs by Modernizing the Supply Chain and Ensuring Meaningful Relief at the Pharmacy Counter." The framework outlined four key challenges facing federal prescription drug programs, including: (1) misaligned incentives that drive up drug prices and costs; (2) insufficient transparency that distorts the market; (3) hurdles to pharmacy access; and (4) behind-the-scenes practices that impede market competition and increase costs throughout the pharmaceutical supply chain. The framework also identified potential legislative solutions to modernize and enhance federal prescription drug programs and to help address these concerns.

On July 24, 2023, Chairman Wyden released a Chairman's Mark entitled the "Modernizing and Ensuring PBM Accountability Act" that contained bipartisan Finance Committee member policies. These policies, in addition to further proposals and modifications contained in the July 26, 2023, Modification to the Chairman's Mark, comprise the reported bill described below.

II. EXPLANATION OF THE BILL

SECTION 1. SHORT TITLE; TABLE OF CONTENTS

This section sets out the name of the bill—the "Modernizing and Ensuring PBM Accountability Act"—and lists the Table of Contents of the legislation.

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

Current Law

Medicare Part D is a voluntary outpatient prescription drug benefit, enacted in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; Pub. L. 108–173), effective January 1, 2006. Congress designed Part D as a market-based program. Private insurers submit annual contract bids to CMS to provide outpatient prescription coverage to Medicare beneficiaries. Medicare beneficiaries can choose a stand-alone Part D plan (PDP) or obtain drug coverage through a Medicare Advantage (Part C) plan with a Part D component (MA–PD plan). All Part D plans must provide coverage that meets or exceeds the minimum standard benefit that defines the range of drugs covered by Medicare Part D and maximum enrollee cost sharing, including deductibles and prescription co-insurance or copayments. Enrollee premiums are based on each plan's annual cost for offering Part D benefits. Part D plan sponsors may augment plan benefits as long as their plans meet the standard benefit specified at SSA 1860D–2(b).

Part D plan sponsors often contract with PBMs to design and administer Part D benefits. Since the program inception, Congress expected that PBMs, already in use in the commercial insurance market, would play a role in Part D to help control prices and costs. PBMs also perform a variety of other core functions for Part D plan sponsors, including developing formularies (covered drug lists), contracting with pharmacies to establish networks, negotiating price concessions from pharmaceutical manufacturers, operating mail order and specialty drug pharmacies, and administering electronic payment for prescription drug claims. Initially, most plans contracted with independent PBMs, however, recently, many insurers that offer Part D plans have merged or affiliated with PBMs.

Federal statutes and regulations govern annual CMS contracting with Part D plan sponsors.[33] PBM contract terms and service agreements with Part D plan sponsors vary from sponsor to sponsor, including with regard to the level and type of compensation (i.e., flat fees or retention of volume-based rebates), whether a contract includes PBM performance incentives, whether a contract includes Part D plan drug price guarantees and the specifications of such guarantees, and definitional terms. Neither statute or regulation govern the forms of compensation PBMs can generate from plan sponsors and entities in the supply chain related to prescription drugs dispensed under Part D. Further, PBM revenue streams have evolved considerably since 2003, when the MMA was enacted.

Under current law, Part D plans and their PBMs must report all price concessions that affect the price of Part D drugs to CMS via two main mechanisms:

(i) Prescription Drug Event (PDE): A PDE report is generated each time a beneficiary fills a prescription at a network pharmacy. The PDE includes information on the negotiated price, including the amount paid to the pharmacy for the drug, the quantity dispensed, the out-of-pocket spending by the bene-

[33] Part D contract regulations are at 42 CFR § 423.505.

ficiary, and any coverage by qualified third parties, such as other insurers.

(ii) Direct and Indirect Remuneration (DIR): DIR reporting applies to price concessions that are not passed on to enrollees at the point of sale. DIR includes discounts, rebates, pharmacy fees, and other price concessions or similar benefits from manufacturers, pharmacies, or similar entities that are obtained by an intermediary organization, such as a PBM, with which the Part D plan sponsor has contracted.[34]

Provisions

These provisions would require that, beginning in plan year 2026, each Part D plan sponsor must have a written agreement with any PBM acting on its behalf under which the PBM agrees to meet the requirements outlined below. All of these requirements would apply to MA–PD plans, as well as PDPs.

These provisions also would define "pharmacy benefit manager" as any entity that acts as a price negotiator or group purchaser, manages prescription drug benefits, processes and pays prescription drug claims, performs drug utilization reviews, processes prior authorization requests, adjudicates drug plan appeals or grievances, contracts with network pharmacies, controls the cost of covered Part D drugs, or provides related services on behalf of a Part D plan. These provisions would define an "affiliate" as any entity owned by, controlled by, or related under a common ownership structure with a PBM.

I. Bona Fide Service Fees

This provision would require that a PBM and any affiliate of a PBM may not derive remuneration for services provided in connection with the use of Part D covered drugs, except in the form of bona fide service fees. The provision would define a "bona fide service fee" as a fee that reflects the fair market value for a bona fide, itemized service. A bona fide service fee would be required to be a flat dollar amount not based on the drug's price or other related drug price benchmarks and factors. Remuneration would be subject to audit, including by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG), to ensure compliance with these requirements.

Part D plan sponsors could continue to collect rebates, discounts, or price concessions that lower net costs for covered part D drugs. Nothing in this provision would be construed as prohibiting a PBM from reimbursing entities that acquire prescription drugs for the ingredient cost of the products.[35]

II. Transparency Regarding Guarantees and Cost Performance Evaluations

This provision would institute transparency standards for written agreements between Part D plan sponsors and PBMs. Specifically, the provision would require PBMs to define and apply drug and drug pricing terms in written agreements with plan sponsors in a transparent and consistent manner for the purposes of calcu-

[34] 42 CFR § 423.308.

[35] In general, the ingredient cost is the amount paid by the pharmacy or wholesaler for the drug. It does not include pharmacy dispensing fees.

lating or evaluating PBM performance against pricing guarantees or similar cost performance measurements. PBMs would also have to identify any exceptions to such guarantees and provide a calculation of such guarantees using either the WAC or an equivalent, in addition to any other benchmarks used.

III. PBM Data Reporting Requirements

This provision would set out new requirements for PBMs to annually report drug price and other information to Part D plans and to HHS. PBMs would be required to include several categories of information in their reports, including the following:

- Lists of all drugs covered;
- Information about dispensing of such drugs;
- Information about enrollee cost sharing and access to generics and biosimilars, including the relative formulary tier placement of such generics and biosimilars, if a plan covers the brand-name drugs or biologic reference products;
- Information on financial relationships between the PBM and other entities in the drug pricing supply chain;
- Information related to net and gross prices and total drug spending; and
- Information about the PBM's affiliates.

PBMs that are affiliated with a pharmacy must also report the following categories of information:

- Information related to dispensing and drug costs by affiliate pharmacies;
- Information related to drug acquisition costs; and
- Information related to drugs subject to 340B arrangements.

This provision would also require PBMs or their affiliates to provide Part D plans with a written explanation of contracts or arrangements with a drug manufacturer (or affiliate) that makes rebates, discounts, payments, or other financial incentives related the drug manufacturer's drug(s) contingent upon coverage, formulary placement, or utilization management conditions on other prescription drugs. The PBM would be required to provide this information shortly after the contract or arrangement with the drug manufacturer is finalized. The written agreement must be certified and would include information about the manufacturers and drugs subject to such arrangement.

IV. Confidentiality

This provision would bar the HHS Secretary from publicly disclosing information obtained from a Part D sponsor or PBM under the required agreements and reports that is not otherwise publicly available, except in limited circumstances, including:

- By the HHS Secretary to carry out this part;
- To the GAO, the Congressional Budget Office (CBO), the HHS OIG, and the Medicare Payment Advisory Commission (MedPAC); and
- To permit oversight and enforcement by government agencies.

These agencies would not be permitted to report on or disclose the information in a way that would identify a specific supply chain stakeholder or prices for specific drugs.

V. Audit Rights

This provision would permit audits, by an auditor of the Part D plan sponsor's choice, of a PBM, no less than once a year, if requested by a Part D sponsor, including to ensure the accuracy of drug price information reported under these provisions. The PBM would be required to provide information to the auditor necessary to perform the audit and confirm the accuracy of PBM reporting, including information owned or held by a PBM's affiliate, in a timely manner. The HHS Secretary would be allowed to include reasonable restrictions on how the information is reported to prevent redisclosure.

VI. Enforcement

This provision would require a PBM to:

- Disgorge remuneration received by the PBM, or an affiliate of such PBM, in violation of the bona fide service fee requirements;
- Reimburse the Part D sponsor for any civil money penalty imposed on the sponsor due to the failure of the PBM to meet the requirements of these provisions; and
- Be subject to punitive remedies for breach of contract for failing to comply with the requirements of these provisions.

This provision would also require each Part D sponsor to provide the HHS Secretary an annual certification of compliance with the provisions outlined above, as well as such additional information as the Secretary determines necessary to carry out this subsection.

VII. Funding

This provision would provide $20 million to CMS for FY 2026 and $5 million to the HHS OIG to carry out the provision. The funds would remain available until expended.

VIII. GAO Report on Certain Pricing Requirements

This provision would require GAO to conduct a study of federal and state reporting requirements for health plans and PBMs regarding the transparency of prescription drug costs and prices. Study results would be required to include recommendations for legislation and administrative actions to streamline and reduce burden with respect to the reporting requirements for health plans and PBMs.

IX. MedPAC Reports on PBM Reported Information

This provision would require MedPAC to issue two reports and related recommendations to Congress on the information being reported by PBMs under this section, including: (1) an initial analysis of information reported by PBMs during the early years of implementation; and (2) a second analysis several years later analyzing changes in trends revealed in the information reported over time.

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

Current Law

Part D plan sponsors and PBMs create contracted networks of retail pharmacies that dispense covered drugs at negotiated reimbursement rates. Part D regulations[36] require plan sponsors to have standard pharmacy contracts with reasonable and relevant terms and conditions of participation, and to allow any willing pharmacy to participate in their basic pharmacy network. Actual contract terms vary across Part D plans, however, meaning that retail pharmacies, which often contract with multiple Part D plans, may have to navigate differing plan contracts, payment rates, and other terms.

Many plans and PBMs use quality measures to evaluate pharmacy performance in various areas, such as medication adherence and generic dispensing. In recent years, however, pharmacies have reported that the quality measures imposed by plans and PBMs are unpredictable, assessing items outside the scope of the pharmacy practice, and/or measuring outcomes over which pharmacies have limited control.[37]

Provision

This provision would require the HHS Secretary to institute standard Part D measures for assessing network pharmacy performance, beginning in 2025. Under the provision, a Part D sponsor that wanted to institute fees, price concessions, or incentive payments based on network pharmacy performance would only be able to do so if the plan sponsor/PBM used performance measures that were: (1) established or adopted by the HHS Secretary; and (2) relevant to the pharmacy, as determined by pharmacy type.

The HHS Secretary would be required to establish or adopt standardized pharmacy performance measures that were: (1) evidence-based and reasonable; and (2) focused on pharmacy performance related to patient health outcomes and other areas that pharmacies can reasonably impact, as determined by the Secretary. The Secretary's determination may be based on data and information from relevant stakeholders.

Rather than establishing some or all of the required performance measures, the Secretary may adopt measures endorsed by a multi-stakeholder consensus organization (such as the Pharmacy Quality Alliance), that has participation from pharmacies, health plans, PBMs, and CMS. The performance measure list would be subject to periodic evaluation and revision by the Secretary.

This provision would provide $4 million to CMS in FY 2025 to carry out the provision. The funds would remain available until expended.

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[36] 42 CFR § 423.505.

[37] Frier Levitt and the National Association of Specialty Pharmacy. "'Performance' Based DIR Fees: A Rigged System with Disparate Effect on Specialty Pharmacies, Medicare Part D Beneficiaries and the U.S. Healthcare System." March 20, 2017. https://communityoncology.org/research-publications/studies/performance-based-dir-fees-a-rigged-system-with-disparate-effect-on-specialty-pharmacies-medicare-part-d-beneficiaries-and-the-us-healthcare-system/.

SECTION 4. PROMOTING TRANSPARENCY FOR PHARMACIES UNDER MEDICARE PART D

Current Law

Just as drug pricing and formulary coverage vary among Part D plans, Part D plan reimbursements to pharmacies also differ according to formulary requirements, plan specifications, and a plan's negotiated price for a covered drug. Pharmacies dispense billions of Part D drugs each year, and payments from Part D plan sponsors are processed in real time at the point of sale through electronic systems that aggregate plan-specific data, including the drug ingredient cost, dispensing fees, cost-sharing requirements, and other third-party sources of payment.

In recent years, CMS has noted a sharp rise in pharmacy fees and other price concessions that plan sponsors and PBMs extracted from retail pharmacies after the point of sale and reported as DIR. Part D pharmacy DIR includes administrative fees, network access fees, and fees for not meeting plan quality metrics. Part D plan sponsors may provide incentive payments to pharmacies for meeting specified goals, but CMS data indicate that extracted fees, or penalties, far outpace additional compensation to pharmacies. According to CMS, pharmacy fees are the fastest-growing category of DIR, accounting for nearly 5 percent of gross Part D drug costs ($9.5 billion) in 2020, compared to 0.01 percent ($8.9 million) in 2010. The increase in fees, as well as their post-point of sale nature, have made it difficult for pharmacies to accurately predict their total reimbursement for dispensing a covered drug.[38] Differences in reporting of negotiated prices among Part D plans can also affect beneficiary cost sharing, CMS payments to plans, and, according to CMS, can even diminish competition between Part D plans.

In May 2022, CMS issued a final rule, effective in 2024, to help address the uncertainties in pharmacy reimbursement caused by PBM fees. The rule changes the definition of "negotiated price" to include the lowest possible reimbursement that a network pharmacy will receive in total for dispensing a drug.[39] Part D plan sponsors are required to take the rule change into account when submitting 2024 contract bids.

Provision

This provision would establish a process by which Part D plan sponsors provide their network pharmacies with comprehensive information about the pricing of prescription drug claims. The new system would be required to take effect in 2025.

This provision would provide $2 million for FY 2025 to CMS to carry out the provision. The funds would remain available until expended.

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[38] CMS, "Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs," 87 Federal Register, May 2022, p. 1413, https://www.federalregister.gov/d/2022-09375/p-1413.

[39] CMS, "Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs," 87 Federal Register, May 2022.

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

Current Law

State Medicaid programs reimburse statutorily defined retail community pharmacies for covered outpatient drugs (CODs) dispensed to Medicaid beneficiaries. The payment to retail community pharmacies has two components: (1) an amount to cover the cost of acquiring the drug (ingredient cost); and (2) an amount for the pharmacist's professional services in filling a prescription (dispensing fee).

The Patient Protection and Affordable Care Act (ACA, Pub. L. 111–148) required drug manufacturers that participate in the Medicaid Drug Rebate Program to provide rebates on CODs that are dispensed to beneficiaries covered under a managed care organization (MCO) that contracts with the state Medicaid program. Most MCOs and other entities that provide Medicaid prescription drug benefits contract with PBMs to manage and administer their drug benefits. Generally, MCOs pay PBMs for drugs supplied to Medicaid beneficiaries based on a published price, such as a percentage of the average wholesale price (AWP), while PBMs separately determine pharmacy reimbursement. Although the difference (spread) between the MCO payments to PBMs and the PBM payments to pharmacies may be small for each individual drug, it can be substantial when aggregated across all drugs dispensed by an MCO.

Contracts between Medicaid MCOs and PBMs are sometimes based on the margin (spread) between the amount charged to the MCO for a COD and the amount paid by a PBM to the pharmacy provider.[40] Effective April 2017, the Centers for Medicare and Medicaid Services required prescription drug benefits under fee-for-service (FFS) Medicaid programs to use a drug pass-through pricing model, but this requirement does not apply to Medicaid MCOs. Under pass-through pricing PBMs charge their MCO clients the actual amount it reimburses the pharmacy for CODs, then passes back all the rebates from manufacturers, and only collects explicit administrative fees as income. Although CMS has issued spread pricing guidance,[41] federal statute does not prohibit the use of spread pricing in contracts between Medicaid MCOs and PBM or other entities.[42]

Provision

The provision requires a pass-through pricing model for CODs reimbursed under Medicaid, including when services are provided under contract with MCOs. This section would require payment for PBM services to be limited to the ingredient cost and a professional dispensing fee equivalent to no less than the professional dispensing fee paid under FFS through a state plan or waiver and passed through in its entirety to the dispensing pharmacy. The pro-

[40] Centers for Medicare and Medicaid Services (CMS), Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 88 Federal Register 34249, May 26, 2023.

[41] CMS, Center for Medicaid and CHIP Services Informational Bulletin, Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors, May 19, 2019.

[42] CMS, Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 88 Federal Register 34250, May 26, 2023.

vision would allow an exception to the pass-through payment requirement for drugs purchased by 340B covered entities.

Payments to PBMs for administrative services would be limited to the fair market value of those services. PBMs and other entities would be required to make available to state Medicaid programs, and the Secretary upon request, all specified costs and payments related to CODs and accompanying administrative services.

This provision would also prohibit any form of spread pricing that exceeds the amount paid to pharmacies or providers on behalf of the state for purpose of claiming federal Medicaid matching payments. State Medicaid programs would be prohibited from making payments to certain specified health plans unless the contract between the state and the entity met the Medicaid Drug Rebate Program and other prescription drug requirements.

This provision would apply to state Medicaid program contracts between MCOs, other specified entities, and PBMs with an effective date that begins 18 months after this law's enactment date.

SECTION 6. ENSURING ACCURATE PAYMENTS TO PHARMACIES UNDER MEDICAID

Current Law

State Medicaid programs reimburse statutorily defined retail community pharmacies for CODs dispensed to Medicaid beneficiaries based on two components: (1) the cost of the medicine, the ingredient cost; and (2) a payment for the cost to the pharmacy of administering and filling a prescription (i.e., the professional dispensing fee). State Medicaid programs, subject to CMS approval, determine pharmacy ingredient payment rates, as well as professional dispensing fees.

For multiple source drugs with generic equivalent products, state Medicaid programs are subject to annual aggregate upper limits on payments. Prices available for multiple source drugs can vary widely, so upper payment limits ensure states pay competitive prices. State Medicaid programs are required to have a CMS-approved methodology to determine multiple source drug payments, including addressing the ingredient costs and pharmacy dispensing fees. Medicaid regulations require states to base the ingredient cost component for multiple source drugs on each product's actual acquisition cost (AAC). State Medicaid programs have discretion in determining AAC, such as using a state administered pharmacy survey to determine a drug's average cost or using the results of a national drug acquisition cost survey of retail community pharmacies authorized in Medicaid statute.

The Deficit Reduction Act of 2005 (DRA, Pub. L. 109–171) amended SSA Section 1927 by adding a new subsection (f) that required the Department of Health and Human Services Secretary (the Secretary) to retain a contractor to survey retail community pharmacies. To implement the survey, CMS contracted for the National Average Drug Acquisition Cost (NADAC) survey. NADAC is a monthly survey of acquisition costs paid for most CODs, including multiple source and single source (brand name) drugs and biological products. CMS, through a contractor, surveys a national random sample of retail community pharmacies monthly and has been publishing NADAC data since November 2013. Pharmacy par-

ticipation in NADAC is voluntary, but to provide a national estimate of average acquisition costs, it is important that the sample is representative of all geographic areas and different pharmacy types such as independent and chain pharmacies.

Provision

This provision would require the Secretary to survey retail community pharmacies drug prices in the 50 states and the District of Columbia to determine national average drug acquisition costs. Retail community pharmacies that receive payment related to the dispensing of CODs to individuals receiving benefits under Medicaid would be required to respond to the survey. The Secretary would be authorized to use a vendor to conduct the NADAC survey of Medicaid CODs. Information on national drug acquisition prices obtained through the NADAC survey would be publicly available, as would other specified information on the NADAC survey. The NADAC survey also would identify information on price concessions to the pharmacy.

The HHS Secretary may enforce noncompliance with the NADAC survey through monetary penalties or by fully or partially suspending Medicaid payments until the pharmacy complies. State Medicaid programs would be required to report additional information including the basis for setting drug dispensing fees as well as payment rates under Medicaid managed care plans.

This provision would be effective 18 months after this law's enactment date. The Secretary would receive a $5 million appropriation in FY 2024 and each fiscal year thereafter to conduct the NADAC survey.

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

Current Law

The past several decades have seen rapid consolidation in the health care sector, including among PBMs. The early 2000s saw horizontal integration as freestanding PBMs merged. More recently, there has been vertical integration, with major PBMs now owned by, or affiliated with, retail pharmacy chains, insurers, and health care providers such as hospitals. As a result of the consolidation, the three largest PBMs were expected to account for nearly 80 percent of prescription claims processed in 2022.[43] In addition, some PBMs have entered into strategic agreements with insurers and retail pharmacies to provide certain services to insurers and retail pharmacies.

It can be difficult to determine the pricing structure and flow of funds within these vertically integrated entities. MedPAC's June 2023 report, however, included an analysis that suggested vertically integrated organizations, such as pharmacy benefit managers affiliated with a health plan and at least one pharmacy channel, appear to be paying their affiliate pharmacies more than other pharmacies. Specifically, in comparing Part D payments between plan-sponsor-affiliated (vertically integrated) pharmacies and non-

[43] Adam J. Fein, "The Top Pharmacy Benefit Managers of 2022: Market Share and Trends for the Biggest Companies," *Drug Channels*, May 23, 2023, https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html.

affiliated (non-vertically integrated) pharmacies, MedPAC found that in 71 percent of cases, plans incurred the highest average net drug costs for transactions with their pharmacy affiliates.[44] Other recent studies have found that Part D may be overpaying for certain medicines relative to purchases made by entities such as Costco or the Mark Cuban Cost Plus Drug Company, potentially by billions of dollars.[45]

Provision

This provision would require the HHS OIG to study how vertical integration between Part D plans, PBMs, and pharmacies affects Part D plan negotiated prices (i.e., the prices Part D plans charge the Medicare program for drugs dispensed to Part D enrollees). The study would include an analysis of the following:

- Affiliate acquisition costs within vertically integrated entities;
- Transfer pricing and margin created between affiliates;
- The impact of such transactions on Part D; and
- Other issues determined to be relevant and appropriate by the Inspector General.

The Inspector General would submit the study under a specified timeframe to the Senate Finance and House Energy and Commerce and Ways and Means Committees. The provision would provide $5.2 million to the HHS OIG for FY 2024 to carry out the provision, to remain available until expended.

SECTION 8. MEDICARE IMPROVEMENT FUND

Current Law

The Medicare Improvements for Patient and Providers Act (MIPPA) established the Medicare Improvement Fund (MIF), available to the Secretary to make improvements under the original fee-for-service program under Parts A and B for Medicare beneficiaries. Under current law, $180 million is available for services furnished during and after FY 2022.

Provision

This provision would direct $1.726 billion in savings to the MIF.

SECTION 9. P&T COMMITTEE CONFLICTS OF INTEREST

Current Law

Under the Part D statute, pharmacy and therapeutic (P&T) committees must develop and review formularies of covered drugs for prescription drug plans. The statute stipulates that at least one practicing pharmacist and at least one practicing physician on every such P&T committee must be free of conflicts of interest with respect to the PDP sponsor, but neither statute nor regulations and guidance extend these limitations to PBMs explicitly, and a num-

[44] MedPAC June 2023 Report: https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf.

[45] Lalani, H. et al. (July 2022). "Potential Medicare Part D Savings on Generic Drugs From the Mark Cuban Cost Plus Drug Company." *Annals of Internal Medicine*. Available at: https://pubmed.ncbi.nlm.nih.gov/35724381/; Trish, E. et al. (July 2021), "Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members." *JAMA*. Available at: https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2781810?guestAccessKey=89d9de51-fc11-4451-97aa-90b352b7867b.

ber of oversight reports have indicated inconsistent or unclear enforcement and compliance with respect to conflict of interest provisions under Part D.

Provision

This provision would amend Section 1860D–4 of the Social Security Act (SSA) to require that at least one practicing physician and one practicing pharmacist is independent and free of conflict with respect to any pharmacy benefit manager.

SECTION 10. ENHANCING PBM TRANSPARENCY REQUIREMENTS

Current Law

The Social Security Act (SSA) includes a set of reporting requirements for pharmacy benefit managers, including with respect to generic dispensing rates (including by pharmacy dispensing channel), rebates and price concessions received from drug manufacturers (and the amount of such concessions passed along), and prescription volume, among other data elements. These reporting requirements currently exclude transparency regarding service fees collected and retained by PBMs. Additionally, the codification of these requirements largely predated the establishment and, in some cases, acquisition of certain downstream PBM affiliates that serve as rebate negotiators and aggregators for a growing share of the PBM market.

Provision

This provision would amend Section 1150A of the SSA to expand the type of entities that must report data to the HHS Secretary to include certain PBM affiliates, to add data elements that would be required to be reported (to include fees received from manufacturers), and to add a requirement for CMS to produce an annual report with confidentiality protections.

SECTION 11. FACILITATING MIDYEAR FORMULARY CHANGES FOR BIOSIMILARS

Current Law

In the case of small-molecule drugs, a Part D plan may generally make a negative formulary change (i.e., placement on a higher or otherwise less favorable tier) with respect to the reference product for a generic drug if said plan simultaneously (or prior to doing so) places the generic drug on the formulary, subject to a number of guidelines and beneficiary safeguards. With respect to biologics, however, CMS has not established regulatory or subregulatory guidelines along these lines. A number of reports from HHS OIG, MedPAC, and other entities suggest that greater biosimilar uptake and adoption under Part D would produce both gross and net savings for beneficiaries and the Medicare program.

Provision

This provision would allow PDP sponsors to change the preferred or tiered cost-sharing status of a reference biological product if such sponsor adds a biosimilar for such reference product to the formulary. The PDP sponsor would need to submit a request to the

Secretary in order to make such a change. This provision would take effect beginning in plan year 2025.

SECTION 12. STRENGTHENING PHARMACY ACCESS FOR SENIORS

Current Law

Current Part D statute, regulations, and guidance bar PDP sponsors from inappropriately steering beneficiaries towards affiliated pharmacies, including specialty pharmacies. Through guidance, for instance, CMS has established criteria for the limited circumstances under which a sponsor may subject the dispensing a covered part D drug to a subset of network pharmacies.

Provision

This provision would mitigate PBMs from steering patients to PBM-owned pharmacies for medicines that do not qualify as "limited access drugs" by codifying a portion of the Part D manual. The provision would also increase transparency of PBM practices in the prescription drug supply chain related to the dispensing of limited access drugs.

SECTION 13. INITIATING MEANINGFUL PATIENT REVIEW OF VARIOUS EXISTING PART D REGULATIONS

Current Law

The Part D statute includes a number of beneficiary protections with respect, for instance, to prescription drug plan disclosures, utilization management requirements, and appeals processes. Beneficiary experience, however, varies on these fronts, as well as on navigation of comparison tools and other resources provided by CMS or by PDP sponsors.

Provision

This provision would direct CMS to conduct beneficiary-focused listening sessions open to the public on potential Medicare Part D improvements.

SECTION 14. REPORTING ON ENFORCEMENT AND OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS

Current Law

The Part D statute includes a number of requirements related to ensuring pharmacy access for beneficiaries. The "any willing pharmacy" provision, for instance, specifies that a PDP sponsor must permit any pharmacy willing to meet its terms and conditions into its network, and regulations further stipulate that these terms must be reasonable and relevant, including with respect to reasonable reimbursement.

Provision

This provision would require the HHS Secretary to publish biennial reports on enforcement actions and oversight activities undertaken by the Department with respect to the pharmacy access requirements under section 1860D 4(b)(1) of the Social Security Act.

SECTION 15. STUDY ON PRICE LINKED COMPENSATION ACROSS THE SUPPLY CHAIN

Current Law

As numerous government oversight reports in the past have illustrated, a wide range of stakeholders included in the outpatient prescription drug supply chain engage in compensation arrangements tied to drug prices or other related benchmarks.

Provision

This provision would require GAO to complete a study of compensation and payment structures related to drug prices in the retail prescription drug supply chain.

SECTION 16. REPORTS ON INAPPROPRIATE PHARMACY REJECTIONS

Current Law

PDP sponsors employ a number of cost-containment measures, including utilization management tools (i.e., prior authorization, step therapy, quantity limits). Under current law, CMS must approve the use of these mechanisms. In practice, however, oversight agencies, including HHS OIG, have found that inappropriate pharmacy rejections and coverage denials sometimes prevent beneficiaries from accessing covered part D drugs, sometimes as a result of the use of unapproved utilization management tools, as well as other factors. Moreover, a number of data collection efforts and other initiatives intended to identify such practices have lapsed in recent years.

Provision

This provision would require the Secretary to publicly post a biennial report related to preventing, identifying, or addressing inappropriate pharmacy rejections and inappropriate coverage denials under Part D.

SECTION 17. STUDY ON DRUG SHORTAGES

Current Law According to the American Society of Health-System Pharmacists (ASHP), active drug shortages had risen to 301 at the end of the first quarter of 2023, up from 271 at the close of Q1 2021.[46] [47] ASHP reports that "[o]ngoing and active shortages are the highest since 2014."[48] A March 2023 majority staff report from the Senate Homeland Security and Government Affairs Committee (HSGAC) found that new medication shortages increased by close to 30 percent between 2021 and 2022.[49] While some shortages conclude fairly quickly, others persist for years. With some exceptions, federal health care programs generally do not include comprehensive provisions explicitly related to drug shortages, although a range of agencies and experts have cited economic dynamics and factors as playing a role in such shortages.

[46] https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics.
[47] Note: FDA also maintains a list of drug shortages, although the agency's criteria differ. https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.
[48] https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics.
[49] https://www.hsgac.senate.gov/wp-content/uploads/Drug-Shortages-HSGAC-Majority-Staff-Report-2023-03-22.pdf.

Provision

This provision would require GAO to complete a study of factors across the outpatient prescription drug supply chain that influence prescription drug shortages.

SECTION 18. REPORT ON BIOSIMILAR AND GENERIC ACCESS UNDER PART D

Current Law

Part D has generally offered high generic dispensing rates, while the retail outpatient biosimilar market has only begun to emerge in recent years. A number of agencies, including HHS OIG, have found that biosimilar uptake and adoption in Part D plans has remained relatively low, particularly with respect to low-wholesale acquisition cost (WAC) options that would translate into lower cost sharing for beneficiaries.

Provision

This provision would direct HHS OIG to conduct a study and generate a report on biosimilar and generic drug access under Part D, including with respect to Part D plan features that discourage or encourage low-priced biosimilar and generic drug adoption and utilization under the program, along with trends in such adoption and utilization.

III. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATES

In compliance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate and section 308(a)(1) of the Congressional Budget and Impoundment Control Act of 1974, as amended (the "Budget Act"), the following statement is made concerning the estimated budget effects of the revenue provisions of the Modernizing and Ensuring PBM Accountability Act, as reported. The spending effects of the bill will be included in the statement from the Congressional Budget Office that will be provided separately, as described in Part C below.

B. BUDGET AUTHORITY

In compliance with section 308(a)(1) of the Budget Act, the Committee states that the extent to which the provisions of the bill as reported involve new or increased budget authority or affect levels of tax expenditures will be included in the statement from the Congressional Budget Office that will be provided separately, as described in Part C below.

C. CONSULTATION WITH CONGRESSIONAL BUDGET OFFICE

In accordance with section 403 of the Budget Act, the Committee advises that the Congressional Budget Office has not submitted a statement on the bill. The statement from the Congressional Budget Office will be provided separately.

IV. VOTES OF THE COMMITTEE

In compliance with paragraph 7(b) of rule XXVI of the Standing Rules of the Senate, the Committee states that, with a majority present, the Modernizing and Ensuring PBM Accountability Act was ordered favorably reported by a roll call vote of 26 ayes and 1 nay on July 26, 2023.

V. REGULATORY IMPACT AND OTHER MATTERS

A. REGULATORY IMPACT

Pursuant to paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee makes the following statement concerning the regulatory impact that might be incurred in carrying out the provisions of the bill.

Impact on individuals and businesses, personal privacy and paperwork

In carrying out the provisions of the bill, individuals and businesses across the drug supply chain including drug manufacturers, PBMs, health plans, and pharmacies that provide prescription drugs to individuals with Medicare or Medicaid coverage will be subject to new reporting requirements. The requirements range from PBMs reporting drug cost and dispensing information to pharmacies reporting acquisition cost information. The new information will be reported to Part D plan sponsors and the HHS Secretary. In some cases, the Secretary will share certain reported information with other entities and the public.

The provisions of the bill do not impact personal privacy.

B. UNFUNDED MANDATES STATEMENT

The Committee adopts as its own the estimate of federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), which will be provided separately.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In the opinion of the Committee, it is necessary in order to expedite the business of the Senate, to dispense with the requirements of paragraph 12 of rule XXVI of the Standing Rules of the Senate (relating to the showing of changes in existing law made by the bill as reported by the Committee).