Policy Update

Pharmacy Benefit Manager Reform: What's on the Horizon?

Introduction

The price of prescription drugs has brought scrutiny to the entire drug supply chain. Congress and other policymakers continue to seek opportunities to lower costs for patients and the federal government.

Pharmacy benefit managers (PBMs) are a key stakeholder in the drug supply chain, functioning as intermediaries between insurance providers and pharmaceutical manufacturers. PBMs administer prescription drug benefits and seek discounts for insurers as standalone plans, such as Medicare Part D plans, or as entities embedded in commercial insurance products, including Medicare Advantage (MA), Medicaid Managed Care Organizations and employer-sponsored coverage. PBMs often create formularies, negotiate rebates with drug manufacturers, process claims, create pharmacy networks, review drug utilization, and manage mail-order specialty pharmacies. PBMs most often play a behind-the-scenes role in determining the total costs of prescription drugs.

PBMs are under increased scrutiny from policymakers due to the perceived opaqueness of their operations and their perceived role in increasing drug costs.

As part of this scrutiny, Congress and other stakeholders are raising questions about PBMs' impact on drug prices and out-of-pocket costs for patients. In the 118th Congress, several key committees have advanced legislation that would increase PBM transparency and reporting obligations and modify other business practices.

Congress has been pursuing prescription drug reform for the last several years. Congress's most recent notable action was passage of the Inflation Reduction Act, which largely focused on drug manufacturers and their impact on drug prices in the Medicare program. Now, legislators are turning to PBM reform as a potential next step in addressing the cost of prescription drugs.

Since PBMs touch a variety of insurance programs and have many roles in the healthcare system, at least six congressional committees have jurisdiction over some aspect of PBMs: the US House of Representatives Energy and Commerce Committee; the House Ways and Means Committee; the House Education and the Workforce Committee; the US Senate Finance Committee; the Senate Health, Education, Labor and Pensions (HELP) Committee; and the Senate Commerce, Science, and Transportation Committee. All six committees have advanced PBM-related legislation, and the table below compares the key provisions in these bills.

Each bill was passed with significant bipartisan support except for the Ways and Means Committee bill, which was approved along party lines. Democratic committee members stated that the bill did not go far enough because it had fewer transparency requirements compared to bills considered in other committees. Apart from the Ways and Means Committee, the high level of bipartisan engagement around this issue suggests that this Congress is likely to enact some form of PBM legislation.

Side-by-Side Comparison of House and Senate PBM Bills

ISSUE/PROVISION	House Energy and Commerce Committee H.R. 3561 – PATIENT Act of 2023 *Passed by the full committee on May 24, 2023*	House Ways and Means Committee **H.R. 4822 – Health Care Price Transparency Act** ***Passed by the full committee on July 26, 2023 (along party lines)***	House Education and Workforce Committee H.R. 4507 – Transparency in Coverage Act H.R. 4508 – Hidden Fee Disclosure Act *Both passed by the full committee on July 12, 2023*	Senate Finance Committee Modernizing and Ensuring PBM Accountability Act (still awaiting official bill text) *Passed by the full committee on July 26, 2023*	Senate HELP Committee S.1339 – Pharmacy Benefit Manager Reform Act *Passed by the full committee on May 11, 2023*	Senate Commerce, Science, and Transportation Committee S. 127 – Pharmacy Benefit Manager Transparency Act of 2023 *Passed by the full committee on March 22, 2023*
Transparency						
Ownership Disclosures	For plan years beginning in 2026, Part D plan sponsors (PDPs) must disclose pharmacies in which they have an ownership stake. For plan years beginning in 2026, PBMs must disclose whether they are owned by a PDP.	Provisions are similar but less robust than the Energy and Commerce bill's provisions. MA plans and PDPs must report to the US Department of Health and Human Services (HHS) certain information relating to healthcare providers, PBMs and pharmacies with which they share common ownership.		PBMs must disclose to plan sponsors and HHS any ownership or affiliation with pharmacies used to dispense prescriptions and the percentage of total prescriptions filled at those pharmacies. They must also provide information on the cost of those prescriptions compared to those filled at non-affiliated pharmacies. They must also provide information	PBMs must report to plan sponsors any ownership of in-network pharmacies and any design benefits or parameters that encourage or require the use of those pharmacies. They must also report the percentage of total prescriptions and a list of all drugs dispensed from pharmacies in which they have an ownership stake. The report must also note	PBMs must report to the Federal Trade Commission (FTC) on differences between reimbursement practices, direct and indirect remuneration (DIR) fees and clawbacks on pharmacies owned, controlled or affiliated with the PBM versus other pharmacies.

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				related to drugs subject to 340B arrangements.	any differences in prices charged to enrollees when a drug is filled at a pharmacy where the PBM does not have an ownership stake.	
Annual Reporting and Disclosures Related to Compensation, Fees, Rebates, Formularies	For plan years beginning in 2025, PBMs must provide an annual report to the group health plan sponsors they serve detailing the amount of drug manufacturer-funded copayment assistance, cost, formulary placement and other information on each drug that was covered and dispensed; information on manufacturer rebates; and amounts paid in DIR. PBMs that serve state Medicaid plans must report to the State, and	For plan years beginning three years after enactment, PBMs must provide an annual report to the group health plan sponsors they serve detailing the amount of drug manufacturer-funded copayment assistance, cost, formulary placement and other information on each drug that was covered and dispensed; information on manufacturer rebates; and amounts paid in DIR.	**H.R. 4507** – For plan years beginning in 2025, PBMs must provide an annual report to the plan administrators they serve detailing the amount of drug manufacturer-funded copayment assistance, cost, formulary placement and other information on each drug that was covered and dispensed; information on manufacturer rebates; and amounts paid in DIR. **H.R. 4508** – PBMs must disclose a variety	PBMs must provide PDPs with information related to rebates, discounts and net prices paid for covered drugs. PBMs must provide PDPs with a written explanation of any contract with a drug manufacturer that provides a rebate or discount for a drug contingent upon formulary placement or utilization management conditions. PBMs must provide information on which drugs are placed on which formularies,	Similar to the Energy and Commerce bill and the Ways and Means bill, PBMs are required to report to group health plan sponsors annually. PBM must disclose direct and indirect compensation to group health plans.	PBMs must report to the FTC amounts of generic effective rate fees, DIR fees charged to pharmacies, and payments rescinded or otherwise clawed back from pharmacies. PBMs must report to the FTC an explanation of changes to their formulary.

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	to the HHS Secretary upon request, information on costs and payments for covered outpatient drugs and administrative services, including any DIR. For plan years beginning in 2026, PDPs must submit an annual report to HHS detailing the average negotiated price for each covered Part D drug at each in-network pharmacy, specify which in-network pharmacies share an ownership stake with the PDP, and report the average per-drug amount of DIR dispensed. For plan years beginning in 2026, PBMs must submit an		of information related to compensation and fees, including compensation from all sources, the rebates received from drug manufacturers, and the amount of rebates and price concessions passed through to the plan sponsor or plan enrollees. PBMs must disclose to plan sponsors any compensation received as a result of paying a lower amount for the drug than the amount charged as a copayment, coinsurance amount or deductible. PBMs must disclose to plan sponsors any payments received from drug manufacturers that are	especially generic drugs and biosimilars. PDPs are permitted to request an audit of a PBM at least once annually to ensure the accuracy of reported drug information. PBMs must provide their network pharmacies with comprehensive information about pricing of prescription drug claims to help increase predictability in pharmacy reimbursement. PBMs are to report annually to PDPs and HHS a list of all drugs covered by the PBM, information related to how the drugs are dispensed by the PDP, enrollee cost-sharing, enrollee access to		

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	annual report to HHS detailing the total amount of DIR collected for part D drugs, the total amount paid to pharmacies for drugs dispensed, the total payments made by PDPs to the PBM and administrative costs incurred.		based on the price or utilization of a drug.	generic drugs and biosimilars, net and gross prices for covered drugs, and total drug spending.		
Spread Pricing						
	The bill bans spread pricing in Medicaid by requiring that contracts between state Medicaid plans and PBMs be based on the drug cost and a professional dispensing fee. Spread pricing allows a PBM to determine how it uses the dollars collected through rebates and doesn't require it to			The bill bans spread pricing in Medicaid by requiring that contracts between state Medicaid plans and PBMs be based on the drug cost and a professional dispensing fee. The bill prohibits any form of spread pricing that exceeds the amount paid to a pharmacy or provider and is meant to	The bill prohibits group health plans and PBMs from charging prices for drugs in excess of prices paid to the pharmacy.	The bill prohibits PBMs from charging a health plan or payer prices for drugs in excess of prices paid to the pharmacy; reducing, rescinding or clawing back reimbursement payments to pharmacies; or increasing fees or lowering reimbursement

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	pass all savings on to the state.			claim the federal Medicaid matching payments.		to a pharmacy to offset other payment changes.
Beneficiary Out-of-Pocket Costs						
		PBMs are prohibited from charging enrollees more in cost-sharing than the net price of a drug.	**H.R. 4507** – Group health plans and PBMs are prohibited from restricting pharmacies that serve plan beneficiaries from informing beneficiaries of any difference in out-of-pocket costs under the plan and outside the plan's coverage.			
Rebate Pass-Through						
					PBMs must pass on 100% of the rebates they get from drug	

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					manufacturers to group health plans.	
Delinking						
				The bill prohibits PBM compensation based on the price of a drug as a condition of entering into a contract with a Medicare Part D plan. Service fees will not be connected to the price of a drug, discounts, rebates or other fees.		
Pharmacy Performance and Payment						
	Retail community pharmacies must participate in the National Average Drug Acquisition Cost (NADAC) survey, which measures pharmacy acquisition costs and is			The bill includes the same provision as the Energy and Commerce bill, requiring retail community pharmacies to participate in the NADAC survey.		

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	often used in the Medicaid program to help inform reimbursement to pharmacies.			The bill requires HHS to establish or adopt standardized pharmacy performance measures that are evidence based and reasonable. PBMs are required to use pharmacy performance measures that are both established or adopted by HHS and relevant to the specific pharmacy.		
Reports to Congress						
	The bill requires a MedPAC report on the effects of vertical integration in the healthcare sector on the Medicare program, by December 31, 2027, and every two years thereafter. The bill requires a US Government Accountability Office	The bill requires a MedPAC report on vertical integration in Medicare, including PBM ownership of in-network pharmacies, by June 15, 2029, and every three years thereafter. The bill requires a GAO report on PBM ownership of in-network		The bill requires a GAO report on state and federal reporting requirements related to transparency of drug prices and costs. The report must include recommendations for legislative and administrative action. The bill requires an HHS Office of Inspector	The bill requires a GAO report on PBM ownership of in-network pharmacies. The bill requires an Assistant Secretary for Planning and Evaluation study on how the US healthcare market would be impacted by potential regulatory changes disallowing	The bill requires an FTC report on enforcement actions related to reporting requirements and PBM formulary design. The bill requires a GAO report on the role of PBMs in the pharmaceutical supply chain, competition among PBMs, PBM use

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	(GAO) report on PBM ownership of in-network pharmacies, within three years of enactment.	pharmacies, within three years of enactment.		General investigation into the impact of vertical integration between Part D plans, PBMs and pharmacies, including effects on beneficiary out-of-pocket costs and Medicare spending under the Part D program.	drug manufacturer rebates. The bill requires a Secretary of Labor report on the impact of imposing fiduciary duties on PBMs.	of rebates and fees, whether PBMs structure formularies in favor of high-rebate drugs, prior authorization and step therapy use, the extent to which PBMs engage in spread pricing, and recommendations for legislative action.

When forecasting the possible effects of these proposed changes, the potential cost of some reforms is an important consideration. Changes to PBM operations could affect Part D or Affordable Care Act marketplace plan premiums, which would increase federal spending. No Congressional Budget Office (CBO) score has been released yet for any of the bills. However, PBM provisions that either save the federal government money or have a low or zero cost (or CBO score) are more likely to be top contenders for inclusion in a final package that advances through Congress.