Policy Update

Pharmacy Benefit Manager Reform: What's on the Horizon? (December 2023 Update)

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 key stakeholders in the drug supply chain, functioning as intermediaries between insurance providers and pharmaceutical manufacturers. PBMs administer prescription drug benefits and seek discounts for insurers such as Medicare Part D standalone plans and commercial plans, including Medicare Advantage (MA), Medicaid Managed Care Organizations and employer-sponsored health plans. 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 cost of prescription drugs for patients and payers.

Congress has been pursuing prescription drug reform for 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.

Congress and other stakeholders are raising questions about PBMs' operations and their 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.

Because 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:

- House Committees: Energy and Commerce, Ways and Means, and Education and the Workforce
- Senate Committees: Finance; Health, Education, Labor and Pensions (HELP); and Commerce, Science, and Transportation.

All six committees have advanced PBM-related bills. Each bill was passed with significant bipartisan support except for the House Ways and Means Committee bill, which was approved along party lines. Democratic members of the Ways and Means Committee stated that the bill did not go far enough because it had fewer transparency requirements, particularly with respect to the role of private equity, compared to bills considered in other committees.

The House Energy and Commerce, Ways and Means, and Education and the Workforce Committees (with the exception of Ways and Means Democratic members) worked together to combine provisions from the various bills to introduce H.R. 5378, the Lower Costs, More Transparency

Act, which passed the House on December 11, 2023. The legislation's PBM provisions echo the provisions considered by each respective committee.

In the chart below, we review and compare policies in the Lower Costs, More Transparency Act and the PBM bills considered individually by the relevant House and Senate committees.

When forecasting the possible effects of these proposed changes, their potential cost is an important consideration. Changes to PBM operations could affect Part D or Affordable Care Act marketplace plan premiums, which would increase federal spending. The Congressional Budget Office (CBO) scored the PBM-related legislation advanced by the Senate Finance Committee and by the House Energy and Commerce Committee and determined that those broader bills are either budget neutral or would reduce spending. CBO has not released scores for the other bills. PBM provisions that 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.

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

The chart below compares policies in the following bills:

House Energy and Commerce, Ways and Means, and Education and the Workforce Committees

- H.R. 5378, the Lower Costs, More Transparency Act, passed by the House on December 11, 2023

House Energy and Commerce Committee

- H.R. 3560, the PATIENT Act of 2023, passed by the full committee on May 24, 2023
- H.R. 2880, Protecting Patients Against PBM Abuses Act, passed by the full committee on December 6, 2023
- H.R. 5385, Medicare PBM Accountability Act, passed by the full committee on December 6, 2023

House Ways and Means Committee

- H.R. 4822, the Health Care Price Transparency Act of 2023, passed by the full committee on July 26, 2023

House Education and the Workforce Committee

- H.R. 4507, the Transparency in Coverage Act, passed by the full committee on July 12, 2023

- H.R. 4508, the Hidden Fee Disclosure Act, passed by the full committee on July 12, 2023

Senate Finance Committee

- Modernizing and Ensuring PBM Accountability Act[1] (referred to below as the PBM Accountability Act), passed by the full committee on July 26, 2023
- Better Mental Health Care, Lower-Cost Drugs, and Extenders Act (referred to below as the Better Mental Health Act), passed by the full committee on November 8, 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

[1] Still awaiting official bill text.

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Transparency					
Ownership Disclosures	**Sec. 106:** Would require PBMs to semiannually provide group health plans and GAO with an explanation of any benefit design that encourages or requires prescriptions to be filled at a pharmacy under common ownership with the PBM and the total percentage of prescriptions dispensed by pharmacies under common ownership. **Sec. 108:** For plan year 2025 and every third year thereafter, would require MA organizations and Part D plan sponsors to 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.	**E&C H.R. 3560 Sec. 106:** For plan years beginning with 2026, would require MA organizations, Part D plan sponsors and PBMs to report to HHS certain information relating to their arrangements with entities with whom they share common ownership compared to those they do not. **E&C H.R. 5385:** PBMs would be required to 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 would also be required to provide information on the cost of those prescriptions compared to prescriptions filled at nonaffiliated pharmacies, and information related to drugs subject to 340B arrangements.	**PBM Accountability Act:** PBMs would be required to 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 would also be required to provide information on the cost of those prescriptions compared to those filled at nonaffiliated pharmacies, and information related to drugs subject to 340B arrangements.	**Sec. 2:** Would require PBMs to 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 would also have to note any differences in prices charged to enrollees when a drug is filled at a pharmacy where the PBM does not have an ownership stake.	**Sec. 4:** Would require PBMs to report to the Federal Trade Commission (FTC) on differences between reimbursement practices and direct and indirect remuneration (DIR) fees on pharmacies owned, controlled or affiliated with the PBM versus other pharmacies.
Reporting and Disclosures Related to Compensation, Fees, Rebates, Formularies	**Sec. 106:** Would require PBMs to semiannually provide group health plans and GAO with detailed data on prescription drug spending, including the acquisition cost of drugs, total out-of-pocket spending, formulary placement rationale and aggregate rebate information.	**E&C H.R. 5385:** Would require PBMs to provide prescription drug plan sponsors (PDPs) with information related to rebates, discounts and net prices paid for covered drugs. **E&C H.R. 5385:** Would permit PDPs to request an audit of a PBM at least once annually to ensure the	**PBM Accountability Act:** Would require PBMs to provide PDPs with information related to rebates, discounts and net prices paid for covered drugs. **PBM Accountability Act:** Would require PBMs to provide PDPs with a written explanation of any contract	**Sec. 2:** Would require PBMs to report to group health plan sponsors annually. PBMs would be required to disclose direct and indirect compensation to group health plans.	**Sec. 4:** Would require PBMs to report to the FTC amounts of generic effective rate fees, DIR fees charged to pharmacies, and payments rescinded or otherwise clawed back from pharmacies. **Sec. 4:** Would require PBMs to report to the FTC an explanation of changes to their formulary.

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		accuracy of reported drug information. **E&C H.R. 2880:** Would require that PBMs report to the HHS Secretary and Medicare Part D plan sponsors the administrative fees, rebates, and direct and indirect remuneration with respect to drugs furnished under the Part D plan. **W&M H.R. 4822 Sec. 103:** Would require PBMs to annually provide group health plans and GAO with detailed data on prescription drug spending, including the acquisition cost of drugs, total out-of-pocket spending, formulary placement rationale and aggregate rebate information. **Ed&W H.R. 4507:** For plan years beginning in 2025, would require PBMs to 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 **Ed&W H.R. 4508:** Would require PBMs to disclose a variety 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	with a drug manufacturer that provides a rebate or discount for a drug contingent upon formulary placement or utilization management conditions. **PBM Accountability Act:** Would require PBMs to provide information on which drugs are placed on which formularies, especially generic drugs and biosimilars. **PBM Accountability Act:** Would permit PDPs to request an audit of a PBM at least once annually to ensure the accuracy of reported drug information. **PBM Accountability Act:** Would require PBMs to provide their network pharmacies with comprehensive information about pricing of prescription drug claims to help increase predictability in pharmacy reimbursement. **PBM Accountability Act:** Would require PBMs 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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		plan sponsor or plan enrollees. PBMs would be required to 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 would also have to disclose to plan sponsors any payments received from drug manufacturers that are 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 **A practice found in Medicaid where a PBM retains all or some of the rebate dollars collected from a drug company rather than passing the savings along to the Managed Care Organization**					
	Sec. 202: Would ban 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.	**E&C H.R. 3560 Sec. 303:** Would ban 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.	**PBM Accountability Act:** Would ban 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. **PBM Accountability Act:** Would prohibit any form of spread pricing that exceeds the amount paid to a pharmacy or provider and is meant to claim the federal Medicaid matching payments.	**Sec. 2:** Would prohibit group health plans and PBMs from charging prices for drugs in excess of prices paid to the pharmacy.	**Sec. 2:** Would prohibit 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 to a pharmacy to offset other payment changes.

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Beneficiary Out-of-Pocket Costs					
		W&M H.R. 4822 Sec. 201: Would prohibit PDPs and PBMs from charging patients more in cost-sharing than the net price of a drug. **Ed&W H.R. 4507:** Group health plans and PBMs would be 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.	**Better Mental Health Act:** Would require that, when a Medicare Part D plan includes a reference biologic and/or "low-discount" biosimilar on its formulary, it also includes at least one "high-discount" biosimilar on a tier with lower cost sharing.		
Rebate Pass-Through					
			Better Mental Health Act: Would requires post-deductible Medicare Part D enrollee co-insurance for "discount-eligible drugs" to be based on net prices inclusive of rebates rather than negotiated prices. Discount-eligible drugs include specific categories and classes of drugs and any drug where the manufacturer's price concessions are 50% or more of gross costs in Part D.	**Sec. 2:** Would require PBMs to pass on 100% of the rebates they get from drug manufacturers to group health plans.	
Delinking					

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It is common practice for PBMs to base administrative fees paid by drug manufacturers on the price of a drug. Delinking prevents **drug price and utilization from being used as part of the administrative fee with the goal of better aligning incentives to lower prescription drug costs.**					
		E&C H.R. 2880: Would prohibit PBM compensation based on the price of a drug as a condition of entering into a contract with a PDP plan. Service fees would not be connected to the price of a drug, discounts, rebates or other fees. Would require PDPs and PBMs to certify compliance to the HHS Secretary. Would require PBMs to disgorge noncompliant payments to the HHS Secretary.	**PBM Accountability Act:** Would prohibit 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 would not be connected to the price of a drug, discounts, rebates or other fees.		
Pharmacy Performance and Payment					
	Sec. 202: Would require retail community pharmacies to participate in the National Average Drug Acquisition Cost (NADAC) survey, which measures pharmacy acquisition costs and is often used in the Medicaid program to help inform reimbursement to pharmacies.		**PBM Accountability Act:** Would require retail community pharmacies to participate in the NADAC survey, which measures pharmacy acquisition costs and is often used in the Medicaid program to help inform reimbursement to pharmacies. **PBM Accountability Act:** Would require HHS to establish or adopt standardized pharmacy performance measures that are evidence based and reasonable. **PBM Accountability Act:** Would require PDPs to use pharmacy performance		

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			measures that are established or adopted by HHS and relevant to the specific pharmacy. **Better Mental Health Act:** Would codify regulatory requirements that PDPs contract with any willing pharmacy. **Better Mental Health Act:** Would create a new designation for "essential retail pharmacies," defined as pharmacies not affiliated with a PBM or plan sponsor and located in a medically underserved area. Would sets network and reimbursement requirements for PDP contracts with such pharmacies. **Better Mental Health Act:** Would require the HHS Secretary to survey drug prices at non-retail pharmacies, including state-licensed non-retail community pharmacies (such as mail-order and specialty pharmacies), to determine NADAC-like benchmarks for such pharmacies. Pharmacies at clinics, hospitals and long-term care facilities would not be included.		

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Reports to Congress					
	Sec. 106: Would require a GAO report on the impact of PBM ownership of in-network pharmacies on formulary design and beneficiary access to pharmacies apart from those under common ownership. **Sec. 106:** Would require a GAO report on the role of copay assistance programs and their impact on commercial health insurance and drug prices. **Sec. 108:** Would require a MedPAC report on the effects of vertical integration in the healthcare sector on the Medicare program. PBMs, MA plans, pharmacies and providers would be included in the study.	**W&M H.R. 4822 Sec. 103:** Would require a GAO report on the impact of PBM ownership of in-network pharmacies on formulary design and beneficiary access to pharmacies apart from those under common ownership. **W&M H.R. 4822 Sec. 105:** Would require a MedPAC report on the effects of vertical integration in the healthcare sector on the Medicare program. PBMs, MA plans, pharmacies and providers would be included in the study. **E&C H.R. 5385:** Would require a GAO report on federal and state reporting requirements for health plans and PBMs related to the transparency of prescription drug costs and prices.	**Better Mental Health Act:** Would require that the Secretary issue a report to Congress on monitoring of changes to contract terms offered to pharmacies for network or preferred network participation; enforcement and oversight of Part D "any willing pharmacy" provisions; and plans, strategies or initiatives to address or mitigate concerns related to convenient pharmacy access. **Better Mental Health Act:** Would require a GAO report on the effects of the provisions on discount-eligible drugs with respect to enrollee cost-sharing, utilization and adherence, formulary coverage and placement, and utilization management; changes to pharmacy reimbursement methodologies and levels; changes in manufacturer rebating levels; and other behavioral responses by PDPs, enrollees, manufacturers, pharmacies or other entities.	**Sec. 2:** Would require a GAO report on PBM ownership of in-network pharmacies. **Sec. 2:** Would require an Assistant Secretary for Planning and Evaluation study on how the US healthcare market would be impacted by potential regulatory changes disallowing drug manufacturer rebates. **Sec. 4:** Would require a Secretary of Labor report on the impact of imposing fiduciary duties on PBMs.	**Sec. 4:** Would require an FTC report on enforcement actions related to reporting requirements and PBM formulary design. **Sec. 4:** Would require a GAO report on the role of PBMs in the pharmaceutical supply chain, competition among PBMs, PBM use 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.

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Advisory Committees					
	Sec. 109: Would establish a committee of nine members to advise the Secretary on how to standardize and make useable information collected through sections 105 and 106 of this bill and Section 204 of the Consolidated Appropriations Act of 2021, which require insurance companies and employer-based health plans to submit information about prescription drugs and healthcare spending to the Centers for Medicare & Medicaid Services. Would require this advisory committee to be established no later than January 1, 2025, and to sunset in 2028.				
Gag Clauses **Found in contracts between PBMs and pharmacies**, gag clauses **ban pharmacists from informing patients that their drug could have a lower out-of-pocket cost if purchased without insurance. Legislation to ban gag clauses was enacted in 2018, and the ban applies to Medicare and private insurance products.**					
	Sec. 403: Would confirm that the existing ban on gag clauses applies to all private health plans.				