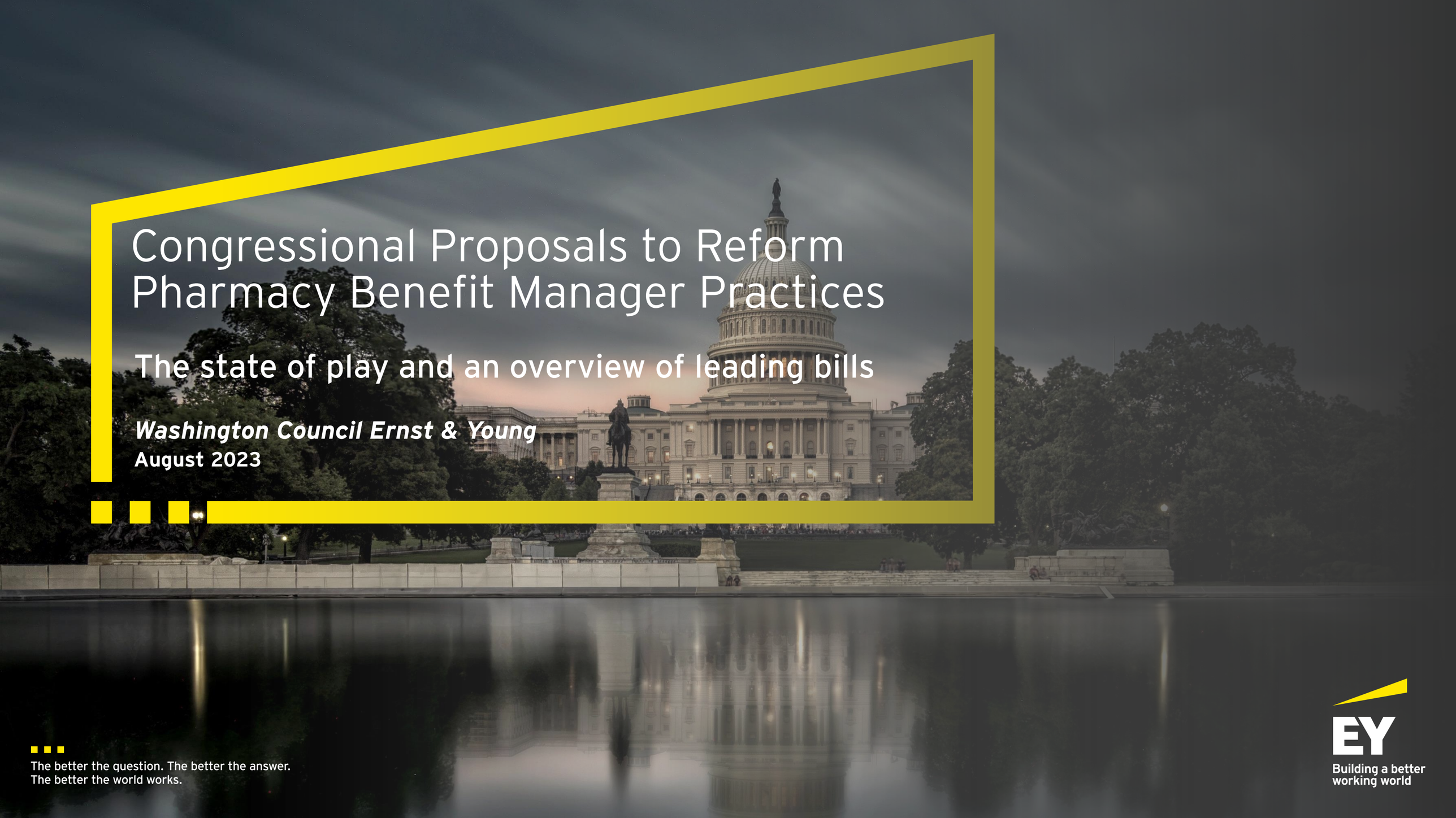

Congressional Proposals to Reform Pharmacy Benefit Manager Practices

The state of play and an overview of leading bills

Washington Council Ernst & Young

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The state of play

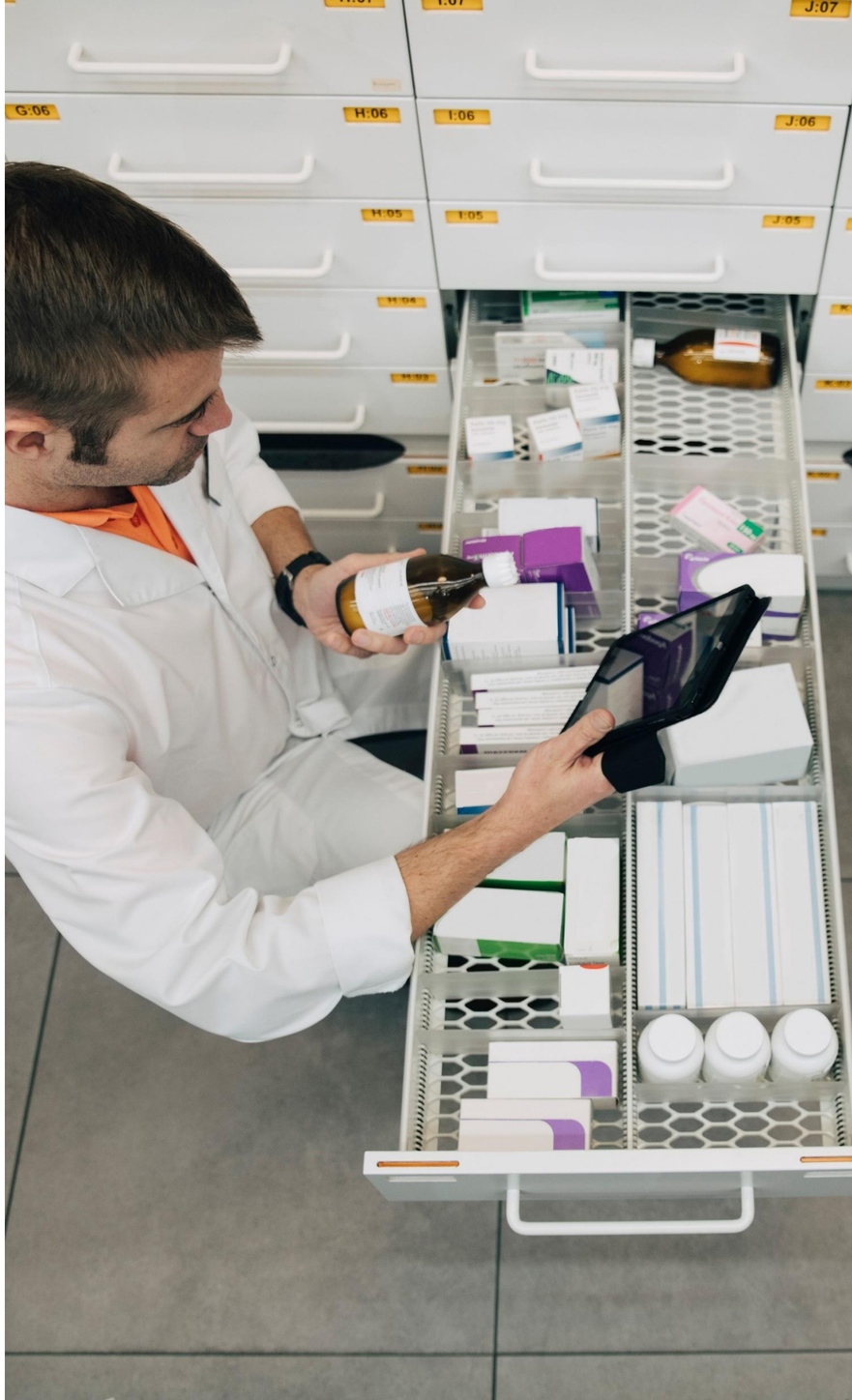
Pharmacy Benefit Managers (PBMs) have taken center stage in the latest bipartisan push to address drug costs, with lawmakers in both chambers considering a slew of proposals aimed at addressing current PBM business practices.

PBMs are third-party service providers that manage prescription drug benefits and pharmacy networks on behalf of private health insurers, Medicare Part D drug plans, large employers, state Medicaid programs and other payers. PBMs are hired to work on behalf of the patient or the plan sponsor to drive down costs by negotiating discounts with drug manufacturers and determining which medications are covered by the health plan. However, pharmaceutical manufacturers argue that PBMs are driving high prescription drug prices in part due to their demand for high rebates, and some plan sponsors say opaque practices leave them in the dark about PBMs' true benefit.

Following last year's passage of the Inflation Reduction Act, which saw manufacturers take the brunt of the drug pricing policy changes, PBMs are now in the hot seat. They have been the focus of numerous congressional hearings and investigations, inquiries from the Federal Trade Commission (FTC), state legislative activity, and a flurry of advocacy action from others across the pharmaceutical supply chain.

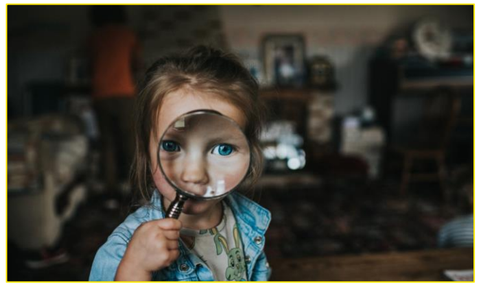
Over the past few weeks and months, at least six different congressional committees have unveiled major – mostly bipartisan – packages aimed in whole or in part at enhancing PBM transparency and addressing practices viewed by legislators as contributing to high costs or undesirable market manipulation. Others in Congress have unveiled their own stand-alone PBM bills, putting a stake in the ground with the goal of riding along with the final package or amalgamation of bills that ultimately rises to the top. Now that most of the committees of jurisdiction have acted, the goal will be for Congress to determine which provisions should move to the floor and into a final package. With the August recess now upon us, and a slate of September reauthorizations and budget priorities demanding attention when Congress returns, action may be pushed later into the year.

Even though activity may fall to later this year, one thing is clear: bipartisan, bicameral commitment to advance PBM legislation remains.



Emerging themes

Four key themes have emerged as top congressional priorities in addressing PBM practices



PBM transparency and reporting

Transparency is a common thread in PBM legislation as Congress tries to gain a better understanding of financial flows across the prescription drug supply chain and PBMs' impact on patients, payers and other stakeholders. Several bills focus on increasing transparency through mandated reporting to plan sponsors on information about prescription drugs covered and dispensed under the plan along with details on rebates, fees, alternative discounts, or other remuneration received from drug manufacturers. Some bills include additional transparency and reporting requirements around formulary and benefit design, such as the use of step therapy and other utilization management techniques; amounts paid to brokers, consultants, and other advisors; and relationships between PBMs, pharmacies and other entities in which PBMs may have an ownership or affiliation interest. Certain bills also enable plan fiduciaries to audit all de-identified claims and encounter data to ensure compliance with PBM contracts.

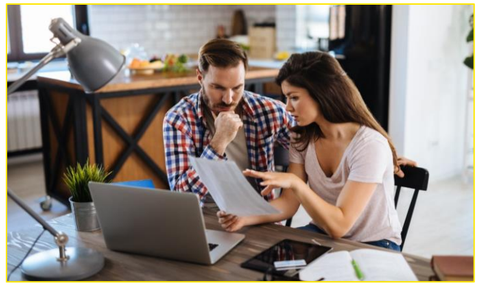
Regulatory authorities and congressional advisors are also tasked with publicly reporting certain information as well as developing reports on the role of PBMs in the supply chain including the impact of certain PBM practices on costs, vertical integration and anti-competitive behavior in the PBM market, and more to inform future policy.

PBM pricing practices

Many bills also take aim at two key practices heavily scrutinized throughout the hearing and investigatory process. This includes "spread pricing" – when PBMs charge a plan for a drug more than they reimburse the pharmacy for dispensing it – and retaining rebates that are negotiated from manufacturers instead of passing them along to plan sponsors. Certain bills would ban spread pricing outright and require 100% of rebates along with other price concessions and discounts to be passed on to the sponsor or patient, while others target one or the other or focus on enhanced reporting and transparency on how these practices are leveraged in each contract and/or across contractual relationships. Other bills aim to "delink" PBM compensation from list prices by prohibiting PBM compensation based on the price of a drug, requiring service fees to be in no way connected to the price of a drug, discounts, rebates, or other fees.

PBM pharmacy practices

Some bills focus on the way in which PBM contracting practices impact pharmacy compensation and access for patients and consumers. One bill aims to restrict PBMs from steering patients to PBM-owned or affiliated pharmacies while another restricts PBMs from reimbursing pharmacies that are not affiliated at a lower amount. Bills also aim to clarify ambiguities in Medicare's "Any Willing Pharmacy" rules to ensure that any pharmacy willing to meet a Part D Plan sponsor's (PDP's) terms and conditions is allowed to participate in their network, or to mandate that PBMs use standardized pharmacy performance measures, as some pharmacies find it difficult to gain access or maintain inclusion. Some bills prohibit "arbitrary, unfair or deceptive" clawbacks from pharmacies – a practice in which PBMs retroactively collect portions of payments made to the pharmacy – however others simply aim to shine a light and mandate reporting on such practices.



Consumer-focused provisions

While this brief focuses specifically on PBM-focused provisions and does not include a number of other proposals aimed at more directly addressing patient out-of-pocket costs (for example, limiting costs for insulin products), some provisions aim to enhance consumer understanding of their cost obligations by prohibiting PBM contacts that restrict or prevent a patient's access to drug pricing information through consumer decision-support tools or at the pharmacy counter. Other consumer-focused provisions aim to mitigate PBM steering of patients, including mandating an exceptions process for step therapy protocols – in which patients must try less expensive options before "stepping up" to drugs that cost more, in addition to enabling greater transparency of utilization management tactics. A couple of bills would more specifically address cost-sharing by setting a limit on what are deemed to be "highly rebated drugs," aimed at shielding consumers from the cost-burden of these practices.

Comparison of leading PBM bills (non-comprehensive): Key provisions and enforcement

	Market	Transparency and reporting provisions	Prohibitions on PBM compensation and practices	Pharmacy- and consumer-focused provisions	Enforcement and penalties
SENATE: COMMITTEE-APPROVED BILLS					
Pharmacy Benefit Manager Transparency Act (S. 127) Approved by Senate Commerce, Science, & Transportation Committee (3/22/2023)	All	**Beginning no later than 1 year after enactment and annually thereafter, PBMs must report to the FTC information about payments received from health plans and fees charged to pharmacies** including: spread pricing; aggregate fees, remuneration, price concessions and clawbacks from pharmacies; formulary tier reassignments and explanations when it results in higher costs to consumers or lower reimbursement to pharmacies; and differential pricing based on ownership or affiliation to pharmacy.	**Prohibits PBMs** managing prescription drug benefits for a health plan **from engaging in spread pricing** and "arbitrary, unfair or deceptive" **clawbacks** from pharmacies. PBMs are not subject to prohibitions if they both 1) **pass along 100% of price concessions and discounts** to the health plan and 2) **disclose all costs, prices, reimbursements, fees, markups, discounts, and aggregate payments** with respect to their PBM services to the plan.		**FTC enforcement** and penalties under existing authorities for an "unfair or deceptive act or practice" as well as up to $1M in civil penalties per day. **State attorneys general authorized to enforce**, including under ERISA plans. Also contains **whistleblower protections**.
Pharmacy Benefit Manager Reform Act (S. 1339) Approved by the Senate Health, Education, Labor, and Pensions (HELP) Committee (6/22/2023)	Group and individual health plans	For plan years beginning on or after 30 months after the date of enactment, an entity providing PBM services on behalf of a covered group health plan or group health insurance coverage **at least once a year must report to the plan sponsor specified information about the PBM's services**, including the amount of prescription drug copayment assistance funded by drug manufacturers; a list of covered drugs billed under the plan during the reporting period; gross spending and amounts received in rebates, fees, discounts and other remuneration; amounts paid to brokers, consultants, and advisors related to PBM services; explanation of benefit design parameters, including dispensing limitations and ownership overlap; summary documents and more.	For plan years beginning on or after 30 months after the date of enactment**, prohibits PBMs** from engaging in **spread pricing** and **requires 100% of rebates, fees, alternative discounts and other remuneration to be passed on** to the group health plan or health insurance issuer offering group or individual health insurance coverage. **Prohibits** group health plans and health insurance issuers offering group or individual health insurance coverage from entering into **contracts with PBMs that would prevent or restrict patient access to drug pricing information** otherwise available through consumer decision-support tools. Require self-insured group health plans, or health insurance coverage offered in connection with such a plan, to provide an **exception process for any medication step therapy** protocol.		**Civil monetary penalties** of $10,000 for each day of a **reporting violation**; **Civil monetary penalties** of up to $100,000 for each item of false information; waivers for good-faith effort.
Modernizing and Ensuring PBM Accountability (S. _) *Approved by the Senate Finance Committee (7/26/2023)*	Medicare Part D and Medicaid	Beginning in plan years on or after 2026**, requires PBMs to annually report to the PDP sponsor, and secretary upon request,** a report including information on covered drugs dispensed and those at a PBM affiliate pharmacy; available generics and biosimilars, cost-sharing, and formulary tier placement; total spending and the amount retained by the PBM or affiliate; PBM affiliates including dispensing and costs; contracts or arrangements with drug manufacturer or affiliate that provides price concessions or financial incentives contingent on coverage, formulary placement, or utilization management conditions; and more. Not less than once a year, or at the request of the PDP sponsor, **the PBM must allow for an audit to ensure compliance** with all terms and conditions of the contract and should make all records, data, contracts and other information available.	Beginning in plan years on or after 2026, **prohibits PBM compensation based on the price of a drug** or other such benchmarks as a condition of contracting with a Part D plan. No income must be derived other than bona fide service fees, which must be a flat dollar amount that cannot be passed on to another entity. Beginning 18 months after enactment, **bans the use of spread pricing** in the Medicaid program; limits payment for PBM services to the ingredient cost for the drug and a professional dispensing fee, passed through in its entirety from the PBM to the pharmacy. For plan years on or after 2026, each contract entered into with a PDP sponsor with respect to a prescription drug plan and PBM acting on its behalf has a written agreement under which the PBM agrees to **apply contract terms (such as generic, brand, specialty drug, rebate and discount) in a transparent and consistent manner** for the purposes of calculating of evaluating PBM performance and identify drugs, claims or price concessions excluded. Requires that at least one practicing physician and one practicing pharmacist **on the pharmacy and therapeutic (P&T) committee is independent and free of conflict** with respect to any PBM.	Beginning in plan years on or after 2025, require MA and Part D plans to use **standardized pharmacy performance measures** established or adopted by the HHS secretary that are evidence-based, focused on patient health outcomes and other areas. Beginning in plan year 2026, **restrict PBMs from steering patients** to PBM-owned pharmacies for medicines that do not qualify as "limited access drugs" and increase transparency for these drugs. Beginning in plan year 2025, **allow PDP sponsors to change the preferred or tiered cost-sharing status mid-year** of a reference biological product if adding a biosimilar to the formulary.	**Require PBMs to disgorge remuneration** received by the PBM or an affiliate **in violation of the bona fide service** fee requirements; **reimburse the PDP sponsor for any civil monetary penalty** imposed on the sponsor due to the failure of the PBM to meet the bill's provisions; and be **subject to punitive remedies for breach of contract** for failing to comply. Require each PDP sponsor to **provide the HHS secretary an annual certification of compliance** with the provisions.

	Market	Transparency and reporting provisions	Prohibitions on PBM compensation and practices	Pharmacy- and consumer-focused provisions	Enforcement and penalties
HOUSE: COMMITTEE-APPROVED BILLS					
PATIENT Act of 2023 (H.R. 3561)* *Approved by House Committee on Energy and Commerce (5/24/2023)* *Part of a larger package including other non-PBM provisions	Group health plans, Medicare Part D, Medicaid	For plan years beginning on or after 2025 no less **frequently than annually**, requires an entity providing PBM services on behalf of a covered group health plan or group health insurance coverage to **report to the plan sponsor specified information about the PBM's services** including the amount of prescription drug copayment assistance funded by drug manufacturers; a list of covered drugs dispensed under the plan during the reporting period; gross and net spending and amounts received in rebates, fees, discounts and other remuneration; amounts paid to brokers, consultants, and advisors related to PBM services; and more. For plan years beginning on or after 2026, **PBMs** performing services **under a PDP contract for Part B drugs must report to the secretary information** including the total amount of direct and indirect remuneration, including what is passed through and retained; total amount paid to pharmacies and payment from the plan sponsor; administrative costs and information on whether they have an ownership or control interest.	Effective 18 months after enactment, requires **pass-through pricing models**, and **prohibits spread-pricing**, for payment arrangements with PBMs under Medicaid. Limits payments made by a state or designated entity (i.e. managed care entity) to a PBM for pharmacy price reimbursement to ingredient cost and professional dispensing fee. Payment for administrative services must be fair market value. **Entity or PBM must make available to the state and the secretary upon request all cost and payments** related to covered outpatient drugs and administrative services.	For plan years that begin on or after 2027, a group health plan or issuer offering group or individual coverage or a PBM that provides services on their behalf shall **not impose cost sharing in excess of the average net price of a drug deemed "highly rebated"** and imposes other restrictions.	**Civil monetary penalties** of $10,000 for each day of a violation of plan sponsor reporting; up to $100,000 for each item of false information; waivers for good-faith effort.
Transparency in Coverage Act of 2023 (H.R. 4507)* *Approved by House Education and Workforce Committee (7/12/2023)* *Part of a larger package including other non-PBM provisions	Group health plans	For plan years beginning on or after 2025 not less than **quarterly and upon request**, requires an entity providing PBM services **on behalf of a covered group health plan or group health insurance coverage** to report to the plan administrator specified information about the PBM's services, including the amount of prescription drug copayment assistance funded by drug manufacturers; a list of covered drugs billed under the plan during the reporting period; gross and net spending and amounts received in rebates, fees, discounts and other remuneration; acquisition costs on date of dispensing; amounts paid to brokers, consultants, and advisors related to PBM services; explanation of benefit design parameters including dispensing limitations and ownership overlap; summary documents; and more.	**Bars group health plans, health insurance issuers offering group health insurance** or entities providing PBM services under contract **from restricting**, directly or indirectly, **any pharmacy** that dispenses a prescription drug to a participant from **informing them of any difference between out-of-pocket cost with or without utilizing insurance.**		**Civil monetary penalties** of $10,000 for each day of a violation of plan sponsor reporting; up to $100,000 for each item of false information; waivers for good-faith effort.
Health Data Access, Transparency, and Affordability Act or the "Health DATA Act" (H.R. 4527) *Approved by House Education and Workforce Committee (7/12/2023)*	Self-funded employer plans	Prohibits contracts or service arrangements between a group health plan and any other entity including a PBM unless the contract or agreement allows the **plan fiduciary to audit all de-identified claims and encounter information.**			The secretary may impose **a civil monetary penalty** in the amount of $10,000 for each day of a violation.

	Market	Transparency and reporting provisions	Prohibitions on PBM compensation and practices	Pharmacy- and consumer-focused provisions	Enforcement and penalties
HOUSE: COMMITTEE-APPROVED BILLS, CONTINUED					
Hidden Fee Disclosure Act (H.R. 4508) *Approved by House Education and Workforce Committee (7/12/2023)*	**Self-funded employer plans**	Strengthens **disclosure requirements with respect to PBMs**, including mandating **annual disclosure to a responsible plan fiduciary** of all compensation including fees, rebates, alternative discounts, co-payment offsets and other remuneration received; the form of the compensation and amounts expected to be passed through; and specific detail around spread pricing, rebates spending, and clawbacks.			
The Heath Care Transparency Act of 2023 (H.R. 4822)* *Approved by House Ways and Means Committee (7/27/2023)* *Part of a larger package including other non-PBM provisions	**Group health plans, Medicare Part D**	For plan years beginning on or three years after enactment, not less **frequently than annually**, an entity providing PBM services on behalf of a covered group health plan or group health insurance coverage must **report to the plan sponsor specified information about the PBM's services** including the amount of prescription drug copayment assistance funded by drug manufacturers; a list of covered drugs dispensed under the plan during the reporting period; gross and net spending and amounts received in rebates, fees, discounts and other remuneration; for any drug for which gross spending exceeded $10,000 during the plan year, a list of therapeutic alternatives and rationale for formulary placement; detail on therapeutic category or class dispensing and spending; amounts paid to brokers, consultants, and advisors related to PBM services; and more.		For plan years beginning on or after 2027, **limits cost sharing** after the deductible and before the out-of-pocket max is reached **to the net price amount for Part D** drugs.	

	Market	Transparency and reporting provisions	Prohibitions on PBM compensation and practices	Pharmacy- and consumer-focused provisions	Enforcement and penalties
Other bills of interest (non-comprehensive) *Note: stand-alone bills contained in the above are not included*					
Patients Before Middlemen (PBM) Act (S. 1967) *Introduced and referred to Senate Finance Committee (6/14/2023)*	Medicare Part D	Clarifies that requirements to **disclose direct and indirect compensation for brokers and consultants** to employer-sponsored health plans apply to PBM services.	Prohibits **PBM compensation based on the price of a drug** as a condition of entering into a contract with a Part D plan. No income can be derived other **than bona fide service fees**, which must be a flat dollar amount that cannot be passed on to another entity or be directly or indirectly related to drug price, discounts, rebates, fees or other remuneration.		Creates an enforcement mechanism requiring PBMs to **pay any amount in excess of the designated service fees** to the secretary and requires **certification of compliance** from the PDP sponsor and PBM.
Protecting Patients Against PBM Abuses Act (H.R. 2880) *Introduced and referred to House Energy and Commerce Committee (4/26/2023)*	Medicare Part D	Updates **PBM reporting to PDP sponsor requirements to include** data related to PBM rebates and administrative fees, including rebates not passed through to the plan sponsor and other plans managed. The information reported will be published by the HHS secretary on a public website. Any PBM contracting with a PDP sponsor must **submit a report to the sponsor on formulary design** regarding therapeutic equivalent drugs not included.	Any PBM contracting with a PDP sponsor **cannot derive income** with respect to any services provided for covered Part D drugs furnished under such plan from an entity other **than flat dollar amount services**. Such fees may not be directly or indirectly based on or contingent upon the price; discounts, rebates, fees or other remuneration. With respect to a covered Part D drug, PBMs **may not engage in spread pricing**.	PBM **may not reimburse a network pharmacy** for a Part D drug at an **amount** less than the amount for an affiliated pharmacy.	Each PDP sponsor shall furnish to the secretary an **annual certification of compliance** with the contract provisions. A **PBM shall disgorge to the secretary** any payment, remuneration or other amount **received in violation**.
Pharmacy Benefit Manager Sunshine and Accountability Act (H.R. 2816) *Introduced and referred to House Energy and Commerce and Ways and Means Committees (4/25/2023)*	Group and individual health plans and Medicare Part D	Updates PBM reporting requirements **to include group health plans or health insurance issuers offering group or individual health insurance coverage** and **updates required reporting** to include the aggregate dollar amount of all rebates, administrative fees, clawbacks and which are passed through, as well as aggregate retained rebates under each contract and across all contractual relationships. The s**ecretary of HHS must publish** the information on a public website in accordance with confidentiality requirements.			
Neighborhood Options for Patients Buying Medicines (NO PBMs) Act (S. _) *Introduced by Sens. Manchin and Blackburn*	Medicare Part D			**Updates Medicare's "any willing pharmacy" rules** to clarify that a PDP sponsor offering a prescription drug plan or a PBM acting on their behalf must allow any pharmacy that meets standard contract terms and conditions (which must be "reasonable and relevant") to participate.	
PBM Oversight Act of 2023 (S__) *Introduced by Sens. Carper and Grassley*	Medicare Part D	For 2026 and each subsequent plan year, **a PDP sponsor or PBM shall submit to the secretary information with respect to each plan offered** information about any committee, entity or individual within or affiliated that has the authority to make coverage, formulary placement, or utilization management decisions other than the P&T committee, along with a list of drugs for which they made recommendations and the initial recommendation by the P&T committee.			

Comparison of PBM bills (non-comprehensive): Study and reporting provisions

	Required studies and reports to Congress on PBMs and the pharmaceutical supply chain
Pharmacy Benefit Manager Transparency Act (S. 127)	• Annual FTC report to Congress on enforcement actions and investigations; analysis of the act on mergers; impact of formulary design on gross revenue and patient costs; and policy recommendations. • GAO report to Congress on the role of PBMs in the supply chain; state of competition; use of rebates and fees, formulary design, step therapy, prior authorization practices, and spread pricing; impact of PBM business practices on costs; and policy recommendations.
Pharmacy Benefit Manager Reform Act (S. 1339)	• Secretary of Labor study on the impact of a policy requiring a PBM to be considered a fiduciary with respect to group health plan or group health insurance coverage.
Modernizing and Ensuring PBM Accountability (S. _)	• GAO study on reporting requirements for health plans and PBMs related to the transparency of prescription drug costs and prices, along with policy recommendations. • GAO study on price-linked compensation across the supply chain. • GAO study on drug shortages and factors across outpatient prescription supply chain. • HHS OIG study and report investigating the impact of vertical integration between Part D plans, PBMs, and pharmacies including the effect on beneficiary costs and Medicare spending. • HHS OIG study on biosimilar and generic access under Part D. • MedPAC reports on the information being reported in this bill, analysis and policy recommendations. • HHS Secretary reports on enforcement actions and oversight with respect to pharmacy access requirements and on inappropriate pharmacy rejections.
Prescription Pricing for the People Act (S. 113)	• FTC to issue a report addressing alleged anti-competitive behaviors in the pharmaceutical supply chain including PBM ownership interests, legal or regulatory obstacles in enforcing antitrust and consumer protection laws, and policy recommendations.
PATIENT Act of 2023 (H.R. 3561)	• MedPAC report describing the state of vertical integration in the health care sector with respect to entitles participating in the Medicare program. • Health insurance issuer or entity providing PBM services shall submit the first four reports mandated under this bill directly to the GAO. • HHS Secretary report to Congress on specialty drug coverage and reimbursement in Medicaid.
Transparency in Coverage Act of 2023 (H.R. 4507)	• Health insurance issuer or entity providing PBM services must submit the first four reports mandated under the bill on PBM services for plan sponsors directly to the GAO.
Health DATA Act (H.R. 4527)	• Secretary of Labor study on the status of de-identified claims and encounter information or data including restrictions and violations; policy proposals to ensure compliance and appropriate data use.
The Heath Care Transparency Act of 2023 (H.R. 4822)	• Health insurance issuer or entity providing PBM services must submit the **first four reports mandated under the bill on PBM services for plan sponsors directly to the GAO**. • GAO study on pharmacy networks and pharmacies under common ownership and practices including design parameters and usage. • GAO report on compliance of Part D cost-sharing provisions.
PBM Oversight Act of 2023 (S__)	• GAO study and report on the use of P&T committees, entities or individuals in the development and review of formularies under Part D including prevalence, information on drugs addressed and trends in justifications, application of utilization management tools and more.
Pharmacy Benefit Manager Transparency Act (S. 127)	• Annual FTC report to Congress on enforcement actions and investigations; analysis of the act on mergers; impact of formulary design on gross revenue and patient costs; and policy recommendations. • GAO report to Congress on the role of PBMs in the supply chain; state of competition; use of rebates and fees, formulary design, step therapy, prior authorization practices, and spread pricing; impact of PBM business practices on costs; and policy recommendations.

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