MINTZ

Winter 2025

PBM

Policy and Legislative Update

TABLE OF CONTENTS

The PBM regulatory landscape is rapidly evolving at both federal and state levels, making it critical for our clients involved in the PBM space to stay apprised of developments in the industry as they happen. Our team actively monitors these developments to provide you with this quarterly *PBM Policy and Legislative Update*. This update builds on prior issues and highlights federal and state activity from October, November, and December 2024.

FEDERAL LEGISLATIVE ACTIVITY AND OVERSIGHT

Federal Legislative Activity

Four more bills were introduced during the last quarter of 2024, for a total of nine federal legislative initiatives directly targeting the PBM industry and PBM-related practices introduced in 2024. Of course, the big news from 2024 relates to the proposed continuing resolution that included most of the federal PBM reform initiatives that have been introduced during the last Congress. Please see our summary on page 5 for more details.

Bipartisan Patients Before Monopolies Act (PBM Act). On December 11, 2024, Senators Elizabeth Warren (D-MA) and Josh Hawley (R-MO) introduced the Patients Before Monopolies Act (PBM Act), while Representatives Diana Harshbarger (R-TN) and Jake Auchincloss (D-MA) introduced a companion bill in the House. The proposed legislation would prohibit joint ownership of PBMs and pharmacies — which Rep. Harshbarger (a former practicing pharmacist) called "a gross conflict of interest" that "enables these companies to enrich themselves at the expense of patients and independent pharmacies."

The legislation proposes to address this conflict of interest by (i) prohibiting a parent company of a PBM or a health insurer from owning a pharmacy business, and (ii) requiring that a parent company in violation of the PBM Act *divest its pharmacy business within three years*. Practically, if passed as currently written, the Act would require major insurers to divest of any pharmacy business, often seen as a key component of the vertically integrated pharmaceutical supply chain. The proposed legislation delegates most enforcement authority to the Federal Trade Commission (FTC), requiring impacted companies to submit mandatory reporting to the FTC, among other requirements. The legislation would also give the FTC the authority to "review all divestitures and subsequent acquisitions to protect competition, financial viability, and the public interest." Alongside the FTC, the US Department of Health and Human Services (HHS), the Department of Justice (DOJ), and state attorney generals would also provide enforcement oversight of the PBM Act requiring violators to not only divest their pharmacy business but also disgorge any revenue received during the period of such violation.

The proposed legislation is currently pending before the respective House and Senate committees. Initial market reactions were mixed — shares dipped among major investors in vertically integrated health insurance and pharmacy benefit management companies in reaction to the news, although some suggest low odds of the legislation passing in its current form.

Study on PBM Audit Practices (H.R. 10050). On October 25, 2024, Representative Celeste Maloy (R-UT) introduced H.R. 10050, which would require the Secretary of HHS to conduct a study with input from independent pharmacists, PBMs, health care providers, and appropriate agencies and submit a

report to Congress on PBM audit practices related to drugs dispensed under Medicare, Medicaid, group health plans, and group or individual health insurance coverage. The report would assess the financial and operational impacts of current PBM audit requirements on pharmacies and the transparency of current and historic PBM audit requirements. It would also provide recommendations on how to make PBM audit requirements for pharmacies more transparent and less burdensome on pharmacists and best practices for PBM audit processes that ensure fairness and ease burdens on pharmacists without compromising audit integrity. On December 17, 2024, the bill was referred to the Subcommittee on Health.

Lowest Price for Patients Act of 2024 (H.R. 8987). On July 10, 2024, Representative Katie Porter (D-CA) introduced the Lowest Price for Patients Act of 2024, which would require that a group health plan not impose cost-sharing (including deductibles, coinsurance, and copayments) on a plan-covered outpatient drug dispensed by an in-network pharmacy in an amount that exceeds the nationwide average of consumer purchase prices for such drug for the one-year period ending on the first day of the plan year (as determined using information from the survey described in section 1927(f)(1)(A)(i) of the Social Security Act). A group health plan would be responsible for ensuring that any PBM providing services under the plan complies with the requirement. On December 17, 2024, the bill was referred to the Subcommittee on Health.

House Investigates CVS Caremark for Alleged Anti-Competitive Behavior Regarding Patient Support Hubs. The House Judiciary Committee is investigating whether CVS Caremark violated federal antitrust laws by limiting independent pharmacies' access to pharmaceutical hubs. On December 12, 2024, Representative Jim Jordan (R-OH), Chairman of the House Judiciary Committee, and Representative Thomas Massie (R-KY), Chairman of the Subcommittee on the Administrative State, Regulatory Reform, and Antitrust, sent a letter to CVS Health President and CEO David Joyner requesting documents and information related to CVS Caremark's practices that limit the ability of patients to access services through some independent pharmacies (the December 12, 2024 Letter). Reps. Jordan and Massie are particularly focused on independent pharmacy access to pharmaceutical hubs, which are a therapy management tool for patients. The Representatives focus follows expert testimony during the House Judiciary's September 2024 hearing regarding the role of PBMs in the health care industry, in which it was noted that one way PBMs could "choke off" potential competitors in the pharmaceutical marketplace is by limiting access to the hubs.

The December 12, 2024 Letter clarifies that the Committee seeks information to investigate whether "CVS Caremark is engaged in activities that harm competition, stifle innovation, and may violate the antitrust laws" and seeks information regarding CVS Caremark's pharmaceutical hub practices. The Committee further states that it will use this information to "conduct oversight of this issue to inform potential legislative reforms."

Senate Field Hearing Considers Pharma Pricing. In October 2024, The Senate Judiciary Committee held a field hearing in Chicago regarding reducing the cost of prescription drugs. Led by Committee Chair Senator Dick Durbin (D-IL), who was joined by Illinois lawmakers, including Illinois Attorney General Kwame Raoul, the two-part Committee hearing addressed alleged patent "schemes," including a "patent thicket," in which a company obtains the intellectual property rights to a series of (often duplicative) patents around one drug. Sen. Durbin stated that patent thickets "block competition and create windfall profits" for manufacturers. Illinois AG Raoul highlighted state-level efforts to curb drug pricing, stating that his bureau is working "with nearly all other states on litigation against the generic drug industry for engaging in price-fixing conspiracies involving hundreds of generic drugs." Illinois Attorney General Raoul also highlighted PBMs' role in increasing drug costs, stating: "PBMs have made the pharmaceutical market more opaque and have driven up prescription drug pricing."

Senate Finance Committee to Continue its Focus on PBMs. Senator Mike Crapo (R-ID) will prioritize PBM reform, among other issues, as the Chairman of the Senate Finance Committee. On January 7, 2025, following his official appointment as Chairman of the Committee, the Committee released a statement outlining Sen. Crapo's priorities, including "efforts to enact much-needed PBM reform [...], as certain problematic practices jeopardize the viability and financial stability of pharmacies, driving up costs for consumers." In light of his previous bipartisan efforts to enact a PBM reform package, policy analysts suggest that Sen. Crapo may follow through on his commitment to enact PBM reforms.

PhRMA Lobbying Efforts Point to PBMs in New Ad Campaign. In November 2024, Pharmaceutical Research and Manufacturers of America (PhRMA) launched a targeted advertising campaign "urging Congress to make sure savings on medicines go to patients, not middlemen." The advertising campaign builds on PhRMA'S previous advertisement, casting PBMs as the pharmaceutical supply chain "middlemen," driving up patient health care costs while providing little clinical value to overall patient wellness and care. PhRMA notes that its campaign "adds to the growing chorus of voices, including pharmacies, providers, employers, AARP and others, calling on policymakers to help patients by pushing these critical PBM reforms over the finish line."

FTC Oversight

FTC Asks Court to Dismiss ESI's Defamation Suit. As we have discussed, Express Scripts, Inc. (ESI) sued the FTC for its publication of an interim report, alleging that, in addition to factual errors and misrepresentations, the report is defamatory, unlawful, and violates ESI's statutory and constitutional rights. The FTC responded by requesting the Missouri federal court dismiss the lawsuit, arguing that the FTC's interim report presented only "qualified conclusions" about the practices of the PBMs involved. The FTC countered that ESI's defamation claims lack merit both procedurally and substantively, arguing further that ESI failed to prove the report deprived it of "life, liberty, or property." The FTC contended that the agency has the authority to publish its findings from industry studies when the findings are "in the public interest." ESI continues to challenge the FTC's actions, maintaining that the FTC fundamentally misunderstands the PBM industry and overlooks PBMs' efforts to lower drug costs.

PBMs Issue Industry Report in Response to FTC's Interim Report. CVS Caremark, ESI, and OptumRx released a report challenging the FTC's findings that PBM practices inflate drug prices. This report, commissioned and funded by the PBMs, explains that PBMs operate within thin margins, largely pass rebates to plan sponsors, do not restrict access to generics, and do not drive independent pharmacies out of business.

FTC Likely to Continue PBM Scrutiny Under Trump Administration. The incoming Trump administration is expected to continue antitrust enforcement efforts related to PBMs, as concern over rising prescription drug prices and PBM practices remains a bipartisan issue. The new administration's antitrust team, including leadership changes at the DOJ and FTC, will inherit the ongoing cases against PBMs. Antitrust experts predict that the administration will focus on traditional legal frameworks and consumer welfare standards when approaching health care competition rules.

2024 Federal Legislative Activity

Bill Name	Requires Pass-Through Pricing/Prohibits Spread Pricing	Prohibits Patient Steering	Requires PBMs to Make Disclosures/Reports Related to Rebates, Fees, and/or Drug Cost, etc.	Impacts Medicare and/or Medicaid Plan Sponsor Contracts with PBMs	Authorized Govt. Agency to Investigate, Regulate, Study, and/or Publish Information about PBMs
Pharmacists Fight Back Act (H.R. 9096)	X	X	X	X	X
Preserving Telehealth, Hospital, and Ambulance Access Act (H.R. 8261)	X		X	X	X
To amend title XI of the Social Security Act to enhance pharmacy benefit manager transparency requirements (H.R. 7717)			X		X
Prescription Drug Supply Chain Pricing Transparency Act (H.R. 7535)				X	X
Patients Before Monopolies Act (H.R. 10632 / S. 5503)					X
Further Continuing Appropriations and Disaster Relief Supplemental Appropriations Act, 2025 (H.R. 10445)	X		X	X	X
To require the Secretary of Health and Human Services to conduct a study on pharmacy benefit manager audit practices (H.R. 10050)					X
Prescription Drug Affordability and Access Act (S. 4845)					X
Lowest Price for Patients Act of 2024 (H.R. 8987)				X	

SPECIAL FEATURE: Continuing Resolution

On December 17, 2024, Congress formally introduced a continuing resolution (CR) in an effort to stave off the impending government shutdown. This CR included many long-percolating initiatives seeking to regulate PBM activities. The proposed CR text included a broad definition of PBM, defining the targeted entities to include those that act as a price negotiator, a group purchaser, or manager of prescription drug benefits, regardless of whether the entity calls itself a PBM.

Upon introduction, the CR received swift pushback from PBM industry groups, including the Pharmaceutical Care Management Association (PCMA), which stated that the reforms included in the CR would risk "increasing costs for health plan sponsors," "undermine the role that PBMs play in lowering costs and providing choices for employers in the prescription drug marketplace," and, among other things, increase Part D premiums. Following public criticism from then-President-elect Trump and allies, the version of the CR introduced on December 17, 2024, was scrapped entirely. The funding proposal passed by Congress on December 20, 2024, did not include any PBM-related provisions.

Summary of PBM Reform Proposals

The original CR sought to regulate PBMs through a variety of mechanisms: prohibiting spread pricing in Medicaid; reducing PBM service fees and de-linking PBM compensation and size of negotiated discounts for Medicare Part D Plans; requiring PBMs to pass through rebates to group health plans and health plan sponsors; and requiring PBMs to provide detailed reporting to plan sponsors and government entities. Among other requirements, the CR included the following provisions of note for PBMs and health plans:

Medicare

PBMs contracting with prescription drug plan (PDP) Sponsors would be required to, among other things, agree to the following requirements:

- ***PBMs may not receive any income other than bona fide service fees***. The CR defines a bona fide service fee (BFSF) as a (i) flat fee, (ii) consistent with fair market value ("FMV"), (iii) for services actually performed by the PBM or its affiliate on behalf of the PDP Sponsor that the PDP Sponsor would otherwise perform itself if not for the arrangement with the PBM, (iv) not based or contingent upon drug price, remuneration (such as rebates, discounts, and other fees), coverage decisions, formulary placement, the volume or value of referrals or business generated between the PBM and PDP Sponsor, or other criteria prohibited by the Secretary, and (v) not passed on to a client or customer (regardless of who takes title to the drug). This definition of BFSF differs from the definition used in Medicare Part D and Medicaid and creates immediate tension by requiring that the fee be flat while at the same time being fair market value when the volume of services to be provided is often unknown. Further, the CR indicates that "incentive payments" paid by PDP Sponsors to PBMs will be deemed BFSF so long as they meet the relevant BFSF requirements. Rebates, discounts, and other price concessions received by a PBM from manufacturers, even if calculated as a percentage of a drug's price, would not be in violation of this provision if such amounts are fully passed through to the PDP Sponsor and reported in accordance with applicable DIR requirements. PBMs would be required to pass through to the PDP Sponsor any remuneration in violation of the BFSF requirements; and further, PBMs would be required to enter into written agreements with their affiliates to require such affiliates to identify and pass through to the PDP Sponsor any remuneration beyond payments as described above (e.g., BFSF, permitted incentive payments and rebates, discounts, and price concessions). Finally, agreements between PBMs and PDP Sponsors would be subject to review by the Secretary of HHS for determination of FMV of remuneration.

- ***Transparency Requirements.*** PBMs would be required to consistently and transparently define, interpret, and apply terms related to their performance of pricing guarantees or similar cost-performance measurements related to rebates, discounts, price concessions, or net costs set forth in agreements between PDP Sponsors and PBMs. Additionally, PBMs would be required to annually report to HHS and the PDP Sponsor detailed information related to dispensed drugs, including, but not limited to, rebates received by manufacturers, and total manufacturer-derived revenue (including BFSF retained by PBM and PBM affiliates).

Medicaid

Contracts between the state and (i) a PBM, or (ii) a Medicaid managed care entity (MCO) that includes drug coverage, would be based on a pass-through pricing model prohibiting spread pricing, under which:

- Payments to pharmacies for drugs must be:
  - limited to the ingredient cost of the drug and a professional dispensing fee that is not less than the professional dispensing fee a state would pay if the state were making the payment directly in accordance with the state Medicaid plan;
  - equivalent to the amounts that the PBM charges the state or MCO for the drug such that the full amount of the payment to the PBM is "passed through" to the pharmacy dispensing the drug (with exceptions for state laws and regulations in response to FWA); and
  - in a manner consistent with federal regulations specifying upper payment limits CMS will pay for drugs under the state Medicaid program.
- Payment for administrative services is limited to an administrative fee that reflects FMV.
- Upon request, the PBM or MCO reports to the state on a drug-level basis all costs and payments related to the covered outpatient drug and the accompanying administrative service fees.

Federal matching Medicaid funds would be conditioned on the prohibition of "spread pricing," in which the amount paid to the pharmacy is less than the amount the PBM or MCO is paid for the covered drug.

Commercial

PBMs would be required to pass through to the group health plan or health insurance issuer offering group health insurance coverage 100% of rebates, fees, alternative discounts, and other remuneration received from any applicable entity. In addition, under certain circumstances, PBMs would be required to make their contracts with rebate aggregators and/or group purchasing organizations (GPOs) available for audit to group health plans or health insurance issuers and/or any associated third-party administrators.

Further, contracts between the group health plan or health insurance issuers and PBMs would require PBMs to provide all information necessary to enable the plan to submit to the Secretary a report containing information that helps identify spread pricing, including the contracted amount paid by the group health plan or health insurance issuer to PBMs and the contracted compensation paid to pharmacies.

The final CR enacted in December will keep the government open through March 14, 2025. Unless Congress chooses to pass a standalone PBM reform bill in the interim, it appears that the next opportunity for Congress to reintroduce the proposed PBM reform package will be this spring when the legislative body convenes to address the impending fiscal cliff. The March deadline opens the possibility for lawmakers and the Trump administration to pursue a different path for potential PBM reform, if not scrap the provisions altogether.

Where Have We Seen the Continuing Resolution Proposals Before?

This is not the first time we have seen the reform measures included in the CR. The chart below demonstrates that many of the concepts included in the CR were from previously introduced federal legislation.

Bill Name	Pass-Through and Spread Pricing Requirements	PBM Disclosure and Reporting Requirements	PBM Contracts with Medicare and/or Medicaid Plan Sponsors	Authorized Govt. Agency to Investigate, Regulate, Study, and/or Publish Information about PBMs
Accelerating Kids' Access to Care Act (H.R. 4758)	X	X	X	X
Pharmacists Fight Back Act (H.R. 9096)	X	X	X	X
Preserving Telehealth, Hospital, and Ambulance Access Act (H.R. 8261)	X	X	X	X
To amend title XI of the Social Security Act to enhance pharmacy benefit manager transparency requirements (H.R. 7717)		X		X
Prescription Drug Supply Chain Pricing Transparency Act (H.R. 7535)			X	X
Medicare PBM Accountability Act (H.R. 5385)		X	X	X
Delinking Revenue from Unfair Gouging Act (H.R. 6283)	X			
To amend title XVIII of the Social Security Act to ensure fair assessment of pharmacy performance and quality under Medicare part D, and for other purposes (H.R. 5393)				X
Protecting Patients Against PBM Abuses Act (H.R. 2880)	X	X		
Medicare Common Ownership Transparency Act of 2023 (H.R. 4883)				X
Transparency in Coverage Act of 2023 (H.R. 4507)		X		X
PBM Sunshine and Accountability Act (H.R. 2816)		X		
Pharmacy Benefit Manager Accountability Act (H.R. 2679)		X		X

PBM Reform under the Trump Administration

From the desk of…

ML STRATEGIES

With the Trump Administration and the 119th Congress now in place, PBM reform remains an issue that has significant bipartisan support and is a priority for key committee leaders. Our expectation continues to be that some PBM reform measures are likely to be signed into law this year, but the process and legislative pathways are unclear. Stakeholders should first look to the upcoming government funding bill, set to expire on March 14, as a potential to carry the provisions that were included in the first version of the appropriations continuing resolution (CR) in December. As a reminder, the PBM reform provisions that were ultimately dropped out of the CR version that was signed into law included:

- Banning "spread pricing" in Medicaid;
- Requiring PBMs to pass along all rebates to health plan sponsors;
- Limiting PBM service fees and de-coupling PBM compensation and size of negotiated discounts (for Medicare Part D plans); and
- Requiring PBMs to provide employers detailed reports on wholesale prices, discounts, and patient out-of-pocket costs for each covered drug

The prospects for PBM reform action as part of the upcoming CR—which must be passed by March 14th absent a final budget agreement—remains murky. It is unclear whether the CR will be a vehicle to carry legislative priorities with bipartisan support (like PBM reform), particularly as the specter of budget reconciliation(s), an extremely partisan activity, looms and threatens possibilities for bipartisan collaboration.

In addition to the CR, Stakeholders should also look to the GOP majorities in both Chambers to attempt to move PBM reform bills through the "regular order" – i.e., bill introductions, hearings and mark-ups in Committees. Passage of measures in the House would seem likely but most of these measures could be subject to a 60-vote threshold in the Senate. Despite the widespread bipartisan support for PBM reform, it's possible that politics could get in the way of easy passage.

Currently no PBM legislation has been introduced in the new Congress. Rep. Buddy Carter (R-Ga), who chairs the House E&C Subcommittee on Health, said in early January that he hopes to "rush through" the PBM reform package outlined in the proposed (but not passed) December CR, that was dropped from the stopgap funding bill. The prospects of PBM reform on reconciliation could be limited by strict parliamentary rules on what may and may not be included.

Senator Bill Cassidy (R-La), who chairs the Senate HELP Committee, vowed to try to pass this Congressional session the bipartisan PBM Reform Act, which was passed out of committee last Congressional session and which would require 100 percent pass through of rebates and ban spread pricing. Cassidy had also tried to pass other legislation last December aimed at reducing drug prices. "Unfortunately," Chair Cassidy remarked, "these did not pass last Congress, but we will continue to advance them this Congress." Following confirmation hearings for HHS and CMS nominees, drug pricing and PBM reform would seem to remain at the top of the HELP Committee priority list to tackle.

During his January 29th confirmation hearing, President Trump's pick to lead HHS, RFK Jr., expressed support for PBM reform. "Trump is absolutely committed to fixing the PBMs," RFK said. "I think that we need to reform the PBMs. I think we need to get rid of all of these vested interests that are draining money from the system …. I support the efforts of this committee to come up with bipartisan legislation. President Trump wants to get the excess profits away from the PBMs and send it back to primary care, to patients in this country, to high quality health care." When pressed by Senator Cantwell (D-Wa) over whether he would allow PBMs to regulate themselves, RFK said he would meet with PBMs, but that "doesn't mean I would let the PBMs write their own ticket." During his first administration, President Trump signed an Executive Order that aimed to pass rebates on prescription drugs to patients instead of allowing them to be kept by PBMs. Although President Trump has vowed to "knock out" PBMs, it remains to be seen what executive action he will take to reform PBMs.

For questions or additional information, please reach out to Alexander Hecht or visit www.mlstrategies.com.

STATE LEGISLATION AND LITIGATION

Recently Enacted State Legislation

States enacted the following initiatives during the first quarter of 2024. The initiatives listed below impact (i) PBM contracts with pharmacies and providers, (ii) pharmacy pricing and reimbursement requirements, (iii) pharmacy network requirements, and/or (iv) PBM licensure and registration requirements.

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
Massachusetts	S.B. 3012 – Among other things, the law (i) establishes a licensing program for PBMs; (ii) requires PBMs to submit detailed financial and operational data to state agencies; (iii) requires all licensed PBMs to pay, based on the individual PBM's market share in the Commonwealth, between 5% to 10% of the amount appropriated by the legislature for the Health Policy Commission (HPC) and Center for Health Information and Analysis (CHIA), to help fund the HPC's and CHIA's oversight and monitoring activities; (iv) requires PBMs to provide notice of conflicts of interest with health carriers; and (v) mandates that certain health plans offer limited or no patient cost-sharing for specific generic and brand drugs for chronic illnesses. The law also prohibits certain payments from PBMs to consultants and brokers involved in the bidding or contracting process for pharmacy benefits, if the payment constitutes a conflict of interest as determined by the commissioner.	1/9/205	7/1/2025 (for the PBM licensure program only, 1/1/2026)
New York	S.B. 9040: Amends existing law pertaining to required contract provisions between PBMs and pharmacies to require the inclusion of specific language prohibiting pharmacy benefit managers from penalizing pharmacies for providing individuals with information pertaining to a pharmacy's cost of and reimbursement for prescription medications and services.	09/27/2024	09/27/2024
Ohio	S.B. 95 – Among other things, prohibits health plans, PBMs, and other administrators from preventing pharmacies from mailing or delivering drugs to patients as an ancillary service.	1/8/2025	04/09/2025

New York Department of Financial Services PBM Regulations

On November 27, 2024, the New York Department of Financial Services (DFS) issued new regulations that establish additional obligations for PBMs providing services in the state. The regulations include (i) changes to PBMs' management of pharmacy networks, (ii) guidelines for PBMs' audits of pharmacies, and (iii) a requirement to obtain state approval for any acquisition of a PBM. The regulations also include requirements around consumer protection, registration of trade names, and disclosure of PBMs' cost of compliance with the DFS regulations. As it relates to the management of pharmacy networks, PBMs will be subject to specific requirements related to how and when contracts with pharmacies may be terminated. Notably, these regulations also make New York among the handful of states that require state approval for transactions involving the acquisition of a PBM. In considering whether an acquisition of control of a licensed PBM can take place, the Superintendent of the DFS will evaluate, among other things, (i) the source of funds for the acquisition, (ii) the contribution of the acquisition to potential excessive concentration or vertical integration, and (iii) the potential hazardous impact on health plans, patients, pharmacies, and other stakeholders in the pharmaceutical supply chain.

Pending State Legislation

The following state initiatives affecting (i) PBM contract terms with pharmacies and providers, (ii) pharmacy pricing and reimbursement requirements, (iii) pharmacy network requirements, and/or (iv) PBM licensure and registration requirements were introduced in the last quarter of 2024.

October – December 2024

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology or Restrictions on PBM Fees (e.g., Requires Pass-Through Pricing/ Prohibits Spread Pricing)	Regulates PBM Payments to Pharmacies	Regulates PBM Contracts with Pharmacies	Regulates Patient Cost-Sharing	Prohibits Patient Steering and Other Related Activities	Requires PBMs to Make Disclosures or Reports	Regulates Health Insurers Contracts and Arrangements with PBMs	Establishes PBM License/ Registration Requirements	Regulates Coverage of Prescription Drug Benefits (Health Insurers and PBMs)
California	S.B. 41	Introduced on 12/3/24	X	X	X	X	X	X	X	X	
Illinois	H.B. 5917	Introduced and referred to the Rules Committee on 11/21/24						X			
New Jersey	S.B. 3703	Introduced in Senate and referred to Senate Commerce Committee on 9/30/24				X					
	A.B. 4953	Introduced on 10/17/24, amended but not reported on 12/9/24	X	X				X			
	S.B. 3818	Referred to Senate Budget and Appropriations Committee on 12/12/24				X		X			X

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology or Restrictions on PBM Fees (e.g., Requires Pass-Through Pricing/ Prohibits Spread Pricing)	Regulates PBM Payments to Pharmacies	Regulates PBM Contracts with Pharmacies	Regulates Patient Cost-Sharing	Prohibits Patient Steering and Other Related Activities	Requires PBMs to Make Disclosures or Reports	Regulates Health Insurers Contracts and Arrangements with PBMs	Establishes PBM License/ Registration Requirements	Regulates Coverage of Prescription Drug Benefits (Health Insurers and PBMs)
	S.B.3842	Introduced in the Senate, Referred to Senate Commerce Committee on 1028/24	X	X	X		X				
South Carolina	S.B. 99	Referred to Senate Judiciary Committee on 12/11/24				X					X
	H.B. 3575	Referred to Committee on Labor, Commerce and Industry on 12/12/24				X					X
Tennessee	H.B. 37	Filed for Introduction on 12/16/4							X		
Texas	H.B. 970	Filed on 11/12/24	X	X		X					
	S.B. 493	Filed on 11/22/24			X						
Virginia	H.B.1041	Left in Labor and Commerce Committee on 11/18/24; Continued to 2025 in Labor and Commerce by voice vote	X			X			X		
	S.B. 758	Referred to Committee on Education and Health on 12/10/24	X						X		

State Law Challenges

Employer Groups Challenge State PBM Laws. In December 2024, The ERISA Industry Committee (ERIC) — alongside the National Labor Alliance of Health Care Coalitions and Cigna — filed its first lawsuit against a state regulator challenging a PBM-targeted state law under ERISA preemption. ERIC's lawsuit against the Minnesota Department of Commerce signals a shift in the status quo for litigation between state regulators and industry groups, which have often been spearheaded by PBM trade associations rather than employer group representatives or other trade groups. In its complaint, ERIC alleges that two provisions of the Minnesota Pharmacy Benefit Manager Licensure and Regulation Act, which set forth certain requirements and prohibitions for PBM-established mail-order and specialty pharmacy networks, "dictate[] the design and structure of the pharmacy networks that plan sponsors are permitted to use," and are "plainly preempted" by ERISA.

In early January 2025, ERIC also filed an amicus brief in the US District Court for the Eastern District of Tennessee, urging the court to grant summary judgment in *McKee Foods Corporation v. BFP, Inc.* and affirm that ERISA preempts the "any willing pharmacy" provision included in Tennessee's comprehensive PBM reform law. We will continue to track how ERIC's entrance into the ongoing volley between state regulators and PBMs regarding the permissibility of certain state initiatives affects the current state of affairs.

MN Prescription Drug Advisory Board Suit. In our Summer 2024 edition, we discussed the US District Court for the District of Minnesota's granting of a preliminary injunction against the state's generic drug anti–price gouging law on the grounds that the plaintiff, the Association for Accessible Medicines (AAM), was likely to succeed on its claim that the law violates the US Constitution's dormant commerce clause. The decision, which has halted implementation of the law since late 2023, was appealed to the Eighth Circuit and heard by a three-judge panel in October 2024. Although a decision has not yet been published, the Eighth Circuit's ruling is likely to cause waves — whether by creating a potential circuit split with the Seventh Circuit or potentially limiting the ability of states (e.g., Colorado and Maryland) and their prescription drug affordability boards' from regulating the prices of prescription drugs in their respective states.

State Enforcement

Hawaii's Suit Against PBMs Continues. In late October 2024, the US District Court for the District of Hawaii dismissed the State of Hawaii's lawsuit against the nation's three largest PBMs — CVS Caremark, ESI, and OptumRx — without prejudice, granting the State leave to file a second amended complaint by no later than December 16, 2024. Judge Leslie Kobayashi's order dismissing the State's first amended complaint noted that the State had failed to adequately meet the court's standards in its pleadings, which claim that the PBMs violated Hawaii's prohibitions against deceptive commercial acts and practices and unfair methods of competition, but that such defects could possibly be cured through amendment. In compliance with the court's decision, the State filed its second amended complaint on November 27, 2024, to which the PBMs renewed their motion to dismiss for failure to state a claim upon which relief can be granted. A hearing on the merits has not yet been scheduled, and no further order has been filed by the court at this time.

OTHER TOPICS OF INTEREST

OPIOID SUITS

We continue to track the ongoing litigation governments at the federal, state, and municipal levels have brought against PBMs for their alleged contribution to the national opioid crisis. Here we summarize a few case updates from the last quarter.

West Virginia

In West Virginia, the state alleged that ESI failed to adequately monitor prescriptions, which allowed controlled substances to be distributed without sufficient safeguards. On December 18, 2024, the court dismissed the state's negligence and Racketeer Influenced and Corrupt Organizations (RICO) claims, holding that West Virginia law did not support such causes of action under the circumstances. However, the court allowed the public nuisance claims to proceed, finding that ESI failed to monitor and report suspicious prescription activity, which substantially interfered with public health and safety. Specifically, the court held that the PBM's inaction contributed to widespread opioid misuse and addiction, creating a public health crisis with far-reaching consequences for communities across West Virginia. *See State of W. Va. v. Express Scripts*, No. 23-C-789 (W. Va. Cir. Ct. Dec. 18, 2024).

Michigan

On October 24, 2024, Michigan's Attorney General filed a lawsuit against ESI and OptumRx, alleging that the PBMs failed to enforce adequate safeguards in monitoring prescriptions. The lawsuit includes claims of public nuisance, negligence, and violations under the Drug Dealer Liability Act. The complaint asserts that this failure contributed to excessive prescribing and widespread opioid misuse in Michigan. Additionally, it emphasized that PBMs play a critical role in ensuring compliance with state and federal regulations governing controlled substances. *See State of Mich. v. Express Scripts & OptumRx*, No. 24-001-CZ (Mich. Cir. Ct. Jan. 8, 2025).

LA County

On December 17, 2024, a California Superior Court allowed Los Angeles County's lawsuit against ESI and OptumRx to proceed, rejecting the PBMs' motions to dismiss. The county alleges that the PBMs' insufficient oversight of prescription practices exacerbated the opioid crisis in the county. The public nuisance claim contends that the PBMs' failure to enforce robust monitoring and reporting mechanisms created substantial and ongoing interference with public health and safety. The court also noted allegations that the PBMs accepted substantial rebates from pharmaceutical companies, including Purdue Pharma LP, as kickbacks for giving OxyContin and other opioids preferred formulary status with minimal restrictions on their approval. The county argues that these practices incentivized the overprescription of opioids. Additionally, the negligence claim asserts that the PBMs breached their duty to implement adequate controls over the distribution of high-risk prescriptions. *See County of Los Angeles v. Express Scripts*, No. BC763456 (Cal. Super. Ct. Dec. 20, 2024).

Multidistrict Litigation

On January 12, 2025, in the ongoing multidistrict opioid litigation (MDL), the federal court overseeing the proceedings criticized several defendants, including PBMs as well as manufacturers, distributors, and pharmacies, for procedural delays during the discovery process. The MDL, which includes thousands of cases filed by state and local governments, states that these entities contributed to the opioid crisis by enabling the overprescription and overdistribution of opioids. The claims against PBMs are that they failed to ensure proper oversight of prescription practices, prioritized profit over safety, and neglected their responsibility to prevent the misuse of controlled substances. The court also

criticized the PBMs' excessive motion practice and repeated objections during document production as "stall tactics." *See In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-02804 (N.D. Ohio Jan. 12, 2025).

Medicare Part D Beneficiaries' Drug Pricing Class Action against CVS Continues

In *Jones v. CVS Health Corp.*, a class action lawsuit brought by Medicare Part D beneficiaries, the plaintiffs allege that CVS and brand-name drug manufacturers worked together to push brand-name drugs over cheaper generics, thereby driving up out-of-pocket costs for Medicare beneficiaries. The lawsuit alleges violations of the RICO Act, common-law fraud, and state consumer protection laws.

In ruling on CVS's Motion to Dismiss, Judge John Milton Younge, US District Court for the Eastern District of Pennsylvania, dismissed the plaintiffs' claims related to unjust enrichment and violations of Idaho consumer protection law but permitted the rest of the plaintiffs' the allegations to proceed. Specifically, Judge Younge ruled that the plaintiffs provided enough evidence to allege both a direct violation of RICO and a conspiracy under RICO, rejecting CVS's argument that the plaintiffs had failed to demonstrate the companies' involvement in racketeering activities. The court found that the defendants' actions, which included concealing information through communications, were sufficient to sustain the fraud claims.

GoodRx, PBMs Face Allegations of Antitrust Violations for Reimbursement Price-Fixing Schemes

Independent Pharmacies' Allegations

On December 18, 2024, lead plaintiff CAAS LLC d/b/a Harbor Pharmacy, an independent pharmacy, filed a class action lawsuit against GoodRx, a drug coupon aggregator, and four PBMs — CVS Caremark, ESI, Medimpact, and Navitus — alleging antitrust violations for a "price-fixing" arrangement that suppresses drug reimbursements to independent pharmacies for generic prescription drugs.

Specifically, the plaintiffs allege that, as part of GoodRx's integrated savings programs (ISP), PBMs "agreed to supply competitively sensitive information to GoodRx and, using that competitively sensitive information, GoodRx works as a common decisionmaker to set the rates for reimbursement by PBMs to independent pharmacies for generic prescription medication." The plaintiffs further allege that PBMs agreed not to bid against each other for the prices that they will pay independent pharmacies for generic prescription medication, neutralizing GoodRx's natural price competition between itself, a discount services program, and the PBMs. The plaintiffs argue that the alleged price-fixing scheme "deprived Plaintiff of competitive rebate and generic prescription drug reimbursement rates."

The CAAS class action suit joins at least three other lawsuits filed in late 2024 by independent pharmacies regarding the alleged price-fixing scheme.

Independent Pharmacists Allegations

On December 4, 2024, in a separate legal action against GoodRx and the same four PBMs, lead plaintiff the Philadelphia Association of Retail Druggists filed a class action lawsuit alleging the defendants conspired to "fix prices to pharmacies for reimbursement of prescription drug claims." The lawsuit contains many of the same price-fixing allegations as the *CAAS LLC v. GoodRx Inc*. suit, including the role of GoodRx's ISP partnership with PBMs to increase the PBMs' and GoodRx's profits, resulting in lower paid claim reimbursements to independent pharmacies. Specifically, the plaintiffs allege the "partnership" between the PBMs and GoodRx are "price-fixing arrangements" to "dramatically increase the portion of prescriptions processed through discount cards, instead of

through regular insurance transactions, leading to greater losses for independent pharmacies." The plaintiffs argue that the alleged price-fixing scheme has contributed to the closure of hundreds of independent pharmacies, "lessening competition in the prescription drug dispensing market. And in the end, consumers will suffer as these restraints on competition lead to fewer pharmacy choices, lower quality services, and higher healthcare costs."

Insulin Case Updates

FTC denies PBM efforts to Halt Litigation in FTC Insulin Price Trial, and Private Company Joins Insulin MDL Against PBMs. The FTC's in-house administrative complaint filed in September 2024 alleges that the three largest PBMs — CVS Caremark, ESI, and OptumRx — have engaged in unfair insulin rebate schemes that violate the nation's competition laws. Since September, the FTC has faced new, unsuccessful challenges from the PBMs in an attempt to halt the FTC's case. Motions filed by the PBMs to remove the three Democratic FTC commissioners from the case were denied. Similarly, the FTC denied the PBMs' motions to separate the evidentiary hearings. And in November, the PBMs separately asked a federal court to halt the FTC's insulin case, arguing that the FTC's in-house case deals with claims that should be reviewed by a federal judge. While the FTC has argued that its administrative court has jurisdiction over claims involving public rights, the lawsuit represents the latest challenge to the FTC's case against the PBMs, which, for now, will continue to move forward.

Meanwhile, the first private company has joined the ongoing multidistrict litigation (MDL) against PBMs and drug manufacturers for allegedly fixing the prices of insulin. In the past year, over 100 state attorneys general, cities, and counties have filed lawsuits against PBMs for allegedly engaging in an insulin price-fixing scheme, all of which have been consolidated into multidistrict litigation. At the end of December, Braman Motors joined the multidistrict litigation as the first private company to do so when it filed a lawsuit against CVS Caremark, ESI, and OptumRx. The private company argues that the PBMs, along with drug manufacturers, conspired to raise insulin prices, ultimately harming companies like Braman that run a self-insured health plan. Eli Lilly has said the "copycat allegations are baseless," and the PBMs have reaffirmed their commitment to making insulin affordable.

Breaking News!

On January 14, 2025, the FTC Office of Policy Planning released a second **Interim Staff Report** titled *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers.* See our **Special Edition** of the PBM Policy and Legislative Update for a full discussion of the Second Report.

HEALTH LAW DIAGNOSED
A Mintz Podcast

Health Law Diagnosed

Host Bridgette Keller dives into potential health care policy changes following the November 2024 election. She is joined by Alex Hecht from ML Strategies to unpack the impact of an all-Republican government and what stakeholders can expect in 2025. They discuss potential PBM reform and what that might look like around minute 20 — give it a listen!

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MINTZ

Our team possesses unparalleled expertise within the intricate world of Pharmacy Benefit Management (PBM). Navigating the maze of federal and state laws and regulations can be daunting for PBMs and the entities with which PBMs do business. That's where we come in. With an in-depth understanding of the PBM industry, legal frameworks, and policy trends, we offer insightful and strategic guidance to help clients meet their business objectives.

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