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Summer 2024

PBM

Policy and Legislative Update

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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 *PBM Policy and Legislative Update*. This update builds on prior issues and highlights federal and state activity from January 2024 through June 2024.

FEDERAL LEGISLATIVE ACTIVITY AND OVERSIGHT

Federal Legislative Activity

Prescription Drug Supply Chain Pricing Transparency Act (H.R. 7535). On March 5, 2024, Representatives Yadira Caraveo (D-CO) and Tracey Mann (R-KO) introduced a bipartisan bill to require the United States Comptroller General to study and report on price-related compensation and payment structures in the prescription drug supply chain. If enacted, the bill would amend the Social Security Act to include a new requirement for the Comptroller General to study the use of compensation and payment structures related to a prescription drug's price within the retail prescription drug supply chain and within two (2) years to provide a report containing an overview of, among other things, (i) the prevalence of compensation and payment structures related to a prescription drug's price between intermediaries in the prescription drug supply chain, including PBMs, pharmacies, manufacturers, part D plan sponsors, drug wholesalers, PSAOs, brokers, auditors, consultants and other service providers; (ii) variation in price-related compensation structures between affiliated entities and unaffiliated entities; and (iii) potential conflicts of interest among contracting entities related to the use of prescription drug pre-related compensation structures. The Comptroller General will also be required to provide recommendations for legislation and administrative action deemed appropriate in light of the study findings.

Amendment to Title XI of the Social Security Act to Enhance Pharmacy Benefit Manager Transparency Requirements (H.R. 7717). On March 19, 2024, Representative Ruben Gallego (D-AZ) introduced a bill to expand applicability of the transparency requirements for health plans and PBMs that provide prescription drug management services to PDP sponsors, MA-PD plans, or qualified health benefits plans, to PBM affiliates which act as price negotiators or group purchasers on behalf of the PBM, or a PDP sponsor, MA organization or qualified health benefits plan. As proposed, the bill will require health plans, PBMs and the PBMs' affiliates to disclose, among other things, information pertaining to (a) the percent of prescriptions provided through retail pharmacies compared to mail order pharmacies, (b) aggregate amount, percentage, and type of rebates, discounts or other price concessions that the PBM negotiates that are (i) attributable to patient utilization and (ii) passed through to the plan sponsor, (c) the aggregate amount of the difference between the amount health plan pays PBM and the amount PBM pays pharmacies, and (d) amount of fees PBM or an affiliate receives from manufacturers in connection with patient utilization and amount and percent of such fees passed through to the plan sponsor. If enacted, the bill would also require the Secretary to make publicly available on the CMS website an annual report summarizing trends observed from the data submitted.

Federal Spending Bills Leave Out Highly Anticipated PBM Reform (H.R. 4366; H.R. 2882). On March 9, 2024, and then on March 23, 2024, Congress passed spending bills to keep the government open through the end of the year. Absent from those bills were the much-discussed PBM reform efforts that had previously cleared two Senate Committees. Senate Finance Committee Chair Ron Wyden (D-OR) said in a statement that he was "extremely disappointed" that the final bills did not include "major reforms that would lower prescription drug costs," including the proposed PBM reforms.

PBM Reforms Included in the Preserving Telehealth, Hospital, and Ambulance Access Act (H.R. 8261). On May 8, 2024, the House Ways and Means Committee unanimously passed a bipartisan bill to extend for two years certain telehealth flexibilities adopted during the Covid-19 PHE for Medicare beneficiaries who receive services through Original Medicare; the bill also proposed significant PBM reform measures to offset the telehealth expenses. The proposed PBM reforms seek to consolidate proposals from the many House and Senate PBM-related bills currently making their way through the legislative process. Please see our article for an in-depth analysis of the proposed bill.

Updates to Previously Reported Federal Bills

The Delinking Revenue from Unfair Gouging (DRUG) Act (H.R.6283) was amended following a February 6, 2024 hearing, and the Committee passed the amended bipartisan bill, which bans PBMs from charging fees based on drug list prices under federal employee plans. The amendments to the DRUG Act include clerical changes and the addition of a new section to the Federal Employee Health Benefits (FEHB) Act that would require (i) PBMs to disclose certain information to the Office of Personnel Management (OPM) related to the PBMs' contract arrangements with manufacturers and/or pharmacies that relate to the FEHB program, and (ii) OPM to publish on its website certain information pertaining to, among other things, rebates and administrative fees received and retained by PBMs and/or health plans.

Senate Health, Education, Labor and Pensions (HELP) Committee Focus on Drug Pricing. On February 8, 2024, the Senate HELP Committee held a hearing to discuss "the outrageously high price of prescription drugs in the United States." As you know, the HELP Committee has been focused on examining ways to regulate PBM activities to lower the costs of drugs. The hearing held on February 8th brought in executives from drug manufacturers Bristol Myers Squibb, Co., Johnson & Johnson, and Merck. Committee Chair Bernie Sanders (I-VT) asked the CEOs of. to commit to lowering the list price of their top-selling drugs prior to the expiration of those drugs' patents. The request was denied by all three CEOs, who cited the pressure they face to invest in drug innovation and treatment access, as well as the role PBMs play in increased drug pricing.

In response, Sen. Mitt Romney suggested that PBM reform may provide a quicker route to reducing drug list prices. In fact, Merck's CEO Robert Davis urged Congress to require that revenue be "delinked" from a drug's list price, claiming that it would "remove incentives for the system to favor high list prices." Davis also advocated for Congress to require the rebates and discounts offered by pharmaceutical manufacturers to be passed through directly to patients. *See our PBM Policy and Legislative Update (Summer 2023) for a discussion on "delinking."*

The Pharmaceutical Care Management Association (PCMA) released a statement ahead of the Committee hearing urging the Committee to "reject false blame game" and "hold drug companies accountable" for high drug prices. PCMA urged

Congress to focus on legislation that would enhance competition between drug manufacturers in order to lower patient costs, citing Senate bill S. 3583, which proposes to target "patent thickets" — a practice whereby high numbers of overlapping patents are used to slow down or prevent new competition from entering the market without infringing upon some aspect of those patent rights.

Sanders continued to push for action regarding drug prices. In early June, the Committee called a vote to subpoena the CEO of Novo Nordisk to testify regarding the company's prices for its popular weight loss drugs Ozempic and Wegovy. In response to this, Novo Nordisk CEO Lars Jorgensen agreed to testify in September. Sanders previously employed similar tactics with regards to insulin products to some success; before appearing for a hearing called by Senator Sanders, manufacturing companies Eli Lilly, Novo Nordisk, and Sanofi announced voluntary changes to pricing for some of their insulin products, including lowered list prices and increased patient assistance programs. We will report back on Jorgensen's testimony in our next update.

Additional Senate Focus on Drug Prices

- **Insulin Price Caps.** There are two competing, bipartisan bills in the Senate currently targeting high insulin prices. The Affordable Insulin Now Act (S. 954), from Senators John Kennedy (R-LA) and Raphael Warnock (D-GA), proposes to cap monthly cost-sharing for insulin at the lesser of $35 or 25% of a plan's negotiated price, including for uninsured individuals. The INSULIN Act of 2023 (S. 1269), from Senators Susan Collins (R-ME) and Jeanne Shaheen (D-NH), proposes the same price caps, but does not cover uninsured individuals and contains additional provisions aimed at eliminating market incentives for high drug list prices by requiring pass-through pricing from PBMs. The four senators sponsoring these two bills are discussing a compromise, but it is unclear whether the resulting bill could garner the 60 votes necessary for passage.
- **Patient Access to Prostate Cancer Drugs.** On June 25, 2024, Senator Jacky Rosen (D-NV) wrote a letter to HHS asking for an investigation to identify 'market barriers' preventing widespread patient access to a low-cost oral prostate cancer drug. Abiraterone, a generic oral drug used in the treatment of prostate cancer, is sold for $160 by CivicaScript. CivicaScript is a nonprofit that partners with industry entities such as manufacturers, insurers, and PBMs to develop and sell drugs at a fraction of the typical cost to patients. Prior to the introduction of Civica's product, the medication cost the average patient $3,000 a month. Rosen seems to claim that patients are experiencing difficulties accessing the medication at the lower price point in part due to PBMs' lack of willingness to work with CivicaScript. Rosen asked HHS to investigate the cause of persistently high prices for abiraterone, "working with Civic to identify market barriers outside of [Civica's] control that have prevented widespread access to this drug." It is unclear what steps, if any, HHS will take in response to this letter.

PBM Executives Testified before the House Committee on Oversight and Accountability. Executives from Optum, CVS Caremark, and Express Scripts testified before the House Committee on Oversight and Accountability on July 23, 2024. The hearing was part of an ongoing investigation into PBMs' role in rising health care costs, spearheaded by Chairman James Comer (R-KY). Although it is unclear what impact the hearing will have on legislation, it is possible that the testimony could inform additional PBM reforms positioned to pass with other year-end legislation.

DOJ Drops Appeal in Copay Accumulator Programs Case

In a significant turn of events, on January 16, 2024, the US Department of Justice (DOJ) decided to drop its appeal of a September 2023 ruling by a US District Court for the District of Columbia regarding copay accumulator programs. The case, *HIV + Hepatitis Policy Institute et al. v. HHS,* centered on the legality of an HHS rule permitting health plans to implement copay accumulator programs. The September 2023 ruling struck down a federal rule that permitted health plans and PBMs to exclude drug manufacturer copay assistance from a patient's cost-sharing limits. However, the DOJ, on behalf of HHS, filed an appeal seeking to overturn the decision and reinstate the regulations permitting copay accumulator programs. The appeal set the stage for further legal proceedings and raised questions about the future of copay accumulator programs.

The DOJ's decision to drop its appeal indicates a shift in the government's stance on copay accumulator programs. Now, health plans and PBMs must follow the 2020 Notice of Benefit Payment Parameters, which requires copay assistance to count as patient cost-sharing for drugs and apply toward a patient's deductible, except for brand name drugs that have generic equivalents available. While this represents a victory for opponents of copay accumulator programs, the broader implications remain uncertain. It is still uncertain whether the government would take enforcement actions against health plans and PBMs for its copay accumulator programs. Further, the government had indicated that it would issue a new rule regarding copay assistance, and it is unclear what that new rule would include. Until then, there will be continued variation in state regulations and industry practices.

For additional background on copay accumulator programs and *HIV + Hepatitis Policy Institute et al. v. HHS*, please refer to the Fall 2023 *Update,* found here.

Other Federal Activity

National Association of Attorneys General Letter to Congress

On February 20, 2024, the National Association of Attorneys General, represented by the attorneys general from 39 states across the United States, sent a letter addressed to Representatives Mike Johnson and Hakeem Jeffries and Senators Chuck Schumer and Mitch McConnell in support of reforming PBM practices. The letter notes that many states have taken action to regulate PBMs through new and amended state laws that are often more stringent than current federal laws; however, these state laws are often challenged by PBMs based on federal jurisdiction and preemption issues that PBMs argue limit the states' authority to regulate PBMs. The letter urges the FTC and Congress to enact more fulsome regulation of PBMs nationwide, particularly as it relates to drug pricing and transparency. The attorneys general specifically supported three pieces of proposed legislation we have previously reported on: (i) the DRUG Act (S. 1542/H.R. 6283), (ii) the Protecting Patients Against PBM Abuses Act (H.R. 2880), and (iii) the Lower Costs, More Transparency Act (H.R. 5378).

White House Holds "Listening Session" on PBM Reform

On March 4, 2024, the White House held a listening session on PBM reform titled "Lowering Healthcare Costs and Bringing Transparency to Prescription Drug Middlemen." The roundtable, which did not include representatives from PBMs or PCMA, was described by the White House as an opportunity to highlight reforms that would "promote transparency and competition in pharmaceutical markets, support independent pharmacies, and

lower drug costs." Participants of the Roundtable included:

- Lina Khan, Chair, Federal Trade Commission
- Xavier Becerra, Secretary, Department of Health and Human Services
- Andy Beshear, Governor, Kentucky
- Mark Cuban, Co-Founder, Cost-Plus Drugs
- Other government officials and representatives of health systems and pharmacies.

The participants largely criticized the practices of PBMs. FTC Chair Lina Khan, whose agency is leading an inquiry into the business practices of PBMs, noted a potential lack of compliance with FTC document requests by certain PBMs. Khan stated that "FTC orders are not suggestions" and that the FTC "will not hesitate to use the full extent of [its] legal authorities to mandate compliance."

PCMA was highly critical of the listening session, noting that the listening session "serves to promote only one model and one perspective." An op-ed penned by former US Senator Pat Toomey (R-PA) similarly characterized the roundtable as "political theater," and stated that "PBMs have become one of the favorite scapegoats for the Biden administration and anti-corporate zealots in Washington."

Despite the tone of the roundtable, a White House fact sheet released on March 6, 2024, detailing President Biden's "New Steps to Lower Prescription Drug and Health Care Costs" did not mention any new proposed action against PBMs.

FTC 6(b) Interim Staff Report and Activity

On July 9, 2024, the Federal Trade Commission (FTC) Office of Policy Planning released an Interim Staff Report titled *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*. This is a preliminary report from the FTC's inquiry into the PBM industry, launched in June 2022 pursuant to the Commission's authority under Section 6(b) of the Federal Trade Commission Act to investigate markets. Please see our *Special Edition* of the *PBM Policy and Legislative Update* for key takeaways from the Interim Staff Report and a general summary of the FTC's activities related to the PBM industry.

CMS Dropped "Stacking" Provision Related to Medicaid Drug Rebate Program Best Price. On May 15, 2024, CMS announced that it would not finalize the "stacking" provision in its *Misclassification of Drugs, Program Administration and Program Integrity Updates under the Medicare Drug Rebate Program* proposed rule (Proposed Rule). Last year, CMS proposed revisions to the regulations at §447.505(d)(3) that would require manufacturers to "stack" cumulative discounts, rebates, or other arrangements "provided to different [best price-] eligible entities" for purposes of determining a final best price "*realized*" by the manufacturer, instead of identifying the Best Price "available" from the manufacturer. Some commenters argued that the proposal would have been a marked reversal pf CMS's prior guidance on the methodology for calculating Best Price. CMS indicated that it would continue to collect information from manufacturers regarding Best Price stacking methodologies to inform future rulemaking. Industry experts expect CMS to publish the MDRP Final Rule later this summer.

A quick note on the potential impact of *Chevron*. As a general matter, the Supreme Court's decision to overturn the *Chevron* doctrine opens the door for legal challenges to agency rules, policies, and guidance. In health care, particularly with respect to health plan benefits, pharmacy benefits, and drug pricing, Congress often defers to HHS and other agencies to set forth the technical, operative aspects of these complex laws. One lawsuit has already been filed to challenge CMS rules regarding Medicare reimbursement for hospital care. We expect to see additional challenges in the coming months and will be watching closely to see how the agencies' approach to rulemaking or reliance on other sub-regulatory guidance shifts.

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)
Arizona	S.B. 1165: Amends existing statutory law related to pharmacy benefits by, among other things, prohibiting auditing entities from retroactively reducing a claim payment after adjudication of such claim unless (i) the claim was fraudulent submitted as determined through an audit, (ii) the claim is a duplicate of a claim for which the pharmacy already received payment, or (iii) the original reimbursement was incorrect due to an error resulting in an overpayment by an insurer or a PBM.	03/29/2024	09/14/2024
Colorado	H.B. 1149: Requires PBMs that provide prior authorization services to a carrier to provide certain data to the carrier that shall be posted on the public-facing portion of the carrier's website. The bill also (i) requires PBMs and carriers to adopt prior authorization guidelines applicable to certain health care services and prescription drugs, which would be based on specified criteria, and (ii) prohibits PBMs from imposing prior authorization requirements more than once every three (3) years for FDA-approved chronic maintenance drugs that the carrier or PBM has previously approved for a covered person, except under specified conditions.	6/3/2024	08/07/2024
Connecticut	H.B. 5503 Requires PBMs to file a report with the commissioner no later than February 1, 2025, and annually thereafter, with information relating to rebates and drug formularies.	06/06/2024	01/01/2025
Idaho	H.B. 596: Amends the Idaho Code to include comprehensive PBM reform. Below is a brief summary. Please contact us for further details. The bill amends Idaho law to (i) prohibit a PBM from directly or indirectly charging a pharmacy benefits plan or program a different amount for a prescription drug's ingredient cost or dispensing fee than the amount the PBM reimburses a pharmacy for the ingredient cost/dispensing fee where the PBM retains the amount of any such difference; (ii) require a PBM to pass-through 100% of any manufacturer rebate to a pharmacy benefits plan/program; and (iii) require a PBM to provide full and complete disclosure of (1) the cost, price, and reimbursement of the prescription drug to each health	04/01/2024	01/01/2025

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
	plan, payer, and pharmacy with which the PBM has a contract, (2) each fee and markup it charges to each health plan, payer and pharmacy, and (3) the aggregate amount of all remuneration the PBM receives from a drug manufacturer for a prescription drug. The bill also establishes an annual reporting requirement for PBMs to the director of the Department of Insurance and requires certain terms and conditions to be included in contracts between PBMs and pharmacy benefit plans/programs. PBMs must also report annually to the director of the Department of Insurance certain information about pharmacy reimbursement and changes to its formulary design. The law also requires that certain provisions be included in a PBM's contractual arrangement with pharmacy benefit plans/programs and its network pharmacies. Additionally, the law prohibits PBMs from (i) restricting pharmacies or pharmacists from disclosing to any person certain information about the prescription drug, alternative treatments, and cost-sharing obligation, (ii) restricting pharmacies or pharmacists from disclosing information to the Department, law enforcement, or state and federal governmental officials, and (iii) communicating at the POS, or otherwise requiring a cost-sharing obligation for the covered person in an amount that exceeds the lesser of the applicable cost-sharing amount under the applicable benefit plan, or the amount that will be retained by the pharmacy.		
Illinois	S.B. 3268 Adds to the list of information PBMs are required to disclose to the Department to include: (i) the total number of prescriptions dispensed under each contract the PBM has with a managed care organization (MCO); (ii) the aggregate wholesale acquisition cost for drugs that were dispensed to enrollees in each MCO with which the PBM has a contract; (iii) the aggregate amount of administrative fees that the PBM received from all pharmaceutical manufacturers for prescriptions dispensed to MCO enrollees; (iv) the aggregate amount of payments received by the PBM and paid to contracting pharmacies for each MCO with which the PBM has a contract; and (v) any other information considered necessary by the Department. The bill also prohibits PBMs from discriminating against a pharmacy or a pharmacist with respect to participation referral, reimbursement of a covered service, or indemnification if a pharmacist is acting within the scope of the pharmacist's license and the pharmacy is operating in compliance with all applicable laws and rules.	06/07/2024	06/07/2024
Indiana	H.B. 1259: Prohibits PBMs from imposing fees for certain actions relating to an audit and to require PBMs to, among other things, (i) disclose to a contract holder, upon request, the actual amounts directly or indirectly paid by the PBM to the pharmacist or for the drug and for pharmacist services related to the drug; (ii) provide notice to a contract holder contracting with the PBM of any	3/13/2024	7/1/2024

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
	consideration that the PBM receives from a pharmaceutical manufacturer or group purchasing organization for any reason; and (iii) obtain information relating to rebates, drug claims and payments, and other revenue derived from pharmaceutical manufacturers that is requested in an audit under this section from a group purchasing organization or other partner entity of the PBM and confirm receipt of a request for an audit to the contract holder not later than ten (10) business days after the information is requested. "Contract holders" include entities that offer health insurance coverage to their employees or members through self-funded health benefit plans, health plans, or Medicaid or managed care organizations Additionally, the bill requires all PBM contracts entered into, issued, amended, or renewed after June 30, 2024 with plan sponsors or third-party administrators on behalf of plan sponsors to provide that the plan sponsor owns the claims data relating to the contract.		
Iowa	H.F. 2099: Adds a section prohibiting PBM retaliation against a pharmacy based on the pharmacy's exercise of rights or remedies against the PBM; expands the prohibition that PBMs cannot assess, charge, or collect any form of remuneration that passes from a pharmacy/pharmacist to the PBM to apply to all pharmacies/pharmacists, beyond those within a pharmacy network; and specifies that updates to the MAC list be made within seven (7) calendar days from the date of an increase of 10% or more in the NADAC of a prescription drug on the list.	05/01/2024	7/1/2024
Kentucky	H.B. 220: Amends existing law related to step therapy to clarify that PBMs and health plans may (i) require members to try AB-generic equivalents, interchangeable biological products, or biosimilar biological products, prior to providing members with coverage for a reference product, and (ii) require a pharmacist to substitute prescription drugs consistent with state law.	03/14/2024	07/15/2024
Louisiana	S.B. 281/H.B. 603: Adds language such that, as used in the Subpart of the law (relative to claims of pharmacies and pharmacists), a "health insurance issuer" shall now also include a pharmacy benefit manager and any person acting on behalf of a pharmacy benefit manager.	6/10/2024	8/1/2024
	S.B. 444: Prohibits PBMs, beginning January 1, 2025, from reimbursing certain pharmacies or pharmacists an amount less than the acquisition cost for the covered drug, device, or service.	6/19/2024	6/19/2024
	H.B. 172: Requires PBM to establish an administrative fee, or a calculation for an administrative fee, to be retained by the PBM and prohibits PBM from retaining revenues directly attributable to the contract other than the administrative fee. The bill also establishes an annual revenue reporting requirement for PBMs to report on revenues it receives outside its administrative fees and requires PBM to remit to the office all revenues that are directly attributable to its contract with the office.	6/10/2024	7/1/2024

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
Nebraska	L.B. 1073: Expands the Pharmacy Benefit Manager Licensure and Regulation Act to (i) update the definition of health plan to include a self-funded employee benefit plan, to the extent not preempted by federal law; (ii) require any contract or health benefit plan issued, renewed, recredentialed, amended, or extended on or after January 1, 2023, including any claims processing service or other prescription drug or device service performed through a third party to comply with the Act, and (iii) requires PBMs contracted with Medicaid MCOs to comply with the Act.	04/15/2024	07/18/2024
New Jersey	S. 3604: Amends existing (i) PBM regulations to restrict PBMs from prohibiting or applying any penalty or disincentive to a network pharmacy if a discounted price generated by a healthcare platform is applied to the payment of a covered person with an account or membership to the healthcare platform for a prescription drug, even if the covered person maintains health insurance coverage, and (ii) pharmacist-related provisions to define "healthcare platform" and to allow pharmacists in certain instances to provide discounts to healthcare platform account holders/members.	01/08/24	01/08/24
New Mexico	H.B. 33: Adds new sections to the New Mexico Insurance Code that, among other things, (i) define pharmacy benefit manager, pharmacy services administrative organization, and rebate, among other terms; (ii) require health insurers submit to the superintendent on an annual basis certain information pertaining to the top twenty-five (25) most frequently used and costly prescription drugs, among other information, and (iii) require PBMs submit to the superintendent on an annual basis information pertaining to the aggregate rebates and fees collected from manufacturers, including amounts that were passed on to health insurers and consumers at the point of sale, and amounts retained by the PBM.	03/01/2024	01/01/2025
Oklahoma	H.B. 1713: Prohibits PBMs and health benefit plans from (i) refusing to authorize, approve, or pay a participating provider for providing covered physician-administered drugs to covered persons; and (ii) requiring a covered patient to self-administer an injectable drug against a health care provider's recommendation in accordance with the manufacturer's approved guidelines. Also prohibits health benefit plans from requiring a covered patient to pay additional fees for "white bagged drugs" (as defined in the bill) beyond cost-sharing obligations as outlined in the individual's plan.	04/29/2024	04/29/2024

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
	H.B. 3376: Adds language that includes a person or entity acting on behalf of PBM in the definition of a PBM and adds a definition of "pharmacy benefits management," defined as a service provided to covered entities to facilitate the provisions of prescription drug benefits to covered individuals within the State. Additionally, the law clarifies that the following entities are not PBMs: (i) an employer of its own self-funded health benefit plan (except when an employer performs PBM activities such as drug manufacturer negotiations, claims processing, and retail network of pharmacy management); and (ii) a pharmacy that provides a patient with a discount card or program that is for exclusive use at the pharmacy offering the discount.	5/15/2024	5/15/2024
	S.B. 1670: Amends the Pharmacy Audit Integrity Act to align the definition of PBM with Section 6960 of Title 36 of the Oklahoma Statutes (See H.B. 3376 above) and narrows the definition of "pharmacy benefits management" to remove certain patient compliance, therapeutic intervention and generic substitution programs, or disease management programs. Clarifies that employers are not PBMs of their own self-funded health benefit plan (except when an employer performs PBM activities such as drug manufacturer negotiations, claims processing, and retail network of pharmacy management) and adds new reimbursement appeal requirements for PBMs.	5/22/2024	5/22/2024
Oregon	H.B. 4113: Among other things, requires insurers that offer a health plan that provides pharmacy benefits and PBMs to include all amounts paid by an enrollee or paid by another person on behalf of an enrollee toward the cost of a covered prescription drug when calculating the enrollee's contribution to an out-of-pocket maximum, deductible, copayment, coinsurance or other cost-sharing requirement applied to the drug if (a) the drug does not have a generic equivalent; or (b) the drug has a generic equivalent, and the enrollee has met certain requirements.	03/28/2024	01/01/2025

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
	H.B. 4149: Amends definitions to (i) spread pricing, (ii) pharmacy services administrative organization, (iii) pharmacy services, (iv) administrative fee, (v) 340B drug, and (vi) pharmacy benefit manager. The law prohibits PBMs from penalizing network pharmacies for filing appeals, complaints, or challenging the PBMs practices or agreements, and from charging a fee to a pharmacy for submitting claims or for the adjudication of claims. Additionally, the law requires PBMs to be licensed (renewed annually) by the Department of Consumer and Business Services to operate in the State as a PBM, and requires PBMs to file a report to the Department containing, among other things, (i) the total dispensing fees paid to the PBM and pharmacies; (ii) the total administrative fees obtained and retained from manufacturers and carriers; and (iii) moneys obtained through spread pricing, pay-for-performance or similar means. Further, upon request, PBMs must submit contracts (and any amendments) with pharmacies/pharmacy services upon the request of the Department of Consumer and Business Services. Finally, the law prohibits health insurance policies from (i) discriminating in the reimbursement of a prescription for 340B drugs from other prescription drugs, (ii) assessing a fee, chargeback, clawback, or other adjustment for the dispensing of a 340B drug, (iii) or otherwise excluding or restricting a pharmacy from dispensing or delivering 340B drugs.	4/10/2024	1/1/2025
Rhode Island	S. 2086/H. 7365: Prohibits health insurers and PBMs from refusing to authorize, approve, or pay a provider for providing a covered clinician-administered drug that was administered and dispensed by any in-network hospital or clinic as long as dispensing, administration, and reimbursement are consistent with current policies and contracts.	6/24/2024	01/1/2025
South Carolina	H. 5235: Requires PBMs and other parties that are legally responsible for payment of a health care claim to (i) accept authorization provided by the State that the item or service is covered under the state Medicaid plan as if such authorization were the prior authorization made by the third party for such item or service; (ii) respond to inquiries from the State regarding a claim for payment within 60 days of receiving such inquiry; (iii) agree not to deny a claim submitted by the State solely on the basis of the date of submission of the claim, the type or format of the claim form, a failure to present proper documentation at the point-of-sale, or a failure to obtain prior authorization in the case of a responsible third party if certain criteria are met.	05/20/24	05/20/24

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
Vermont	H. 233: Adds a comprehensive law that includes many categories of state PBM reform efforts. Below is a brief summary, however, please contact us for further details. The law establishes a detailed regulatory framework for the licensure and regulation of PBMs. The law also prohibits PBMs from, among other things, (i) penalizing a pharmacy or pharmacist in any way from disclosing to any covered person health care information that the pharmacy or pharmacist deems appropriate, (ii) limiting disclosure of information to the Commissioner, law enforcement, or government officials under its contracts, (iii) terminating a contract with or penalizing a pharmacist or pharmacy due to the pharmacist or pharmacy disclosing certain PBM information; (iv) requiring a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of (A) the cost-sharing amount under the terms of the health benefit plan; (B) the maximum allowable cost (MAC) for the drug; or (C) the amount the covered person would pay for the drug, after application of any known discounts, if the covered person were paying the cash price; or (iv) conducting or participating in spread pricing in the State. The law establishes that PBMs have fiduciary duties to health insurer clients and imposes several disclosure requirements by PBMs to health insurer clients. Additionally, the law establishes certain PBM practices with respect to pharmacies, including, without limitation, (i) requiring PBMs to either reimburse or contest a pharmacy claim within 14 calendar days following receipt of the claim, (ii) prohibiting PBMs from requiring pharmacies to pass through potions of insured's cost-sharing responsibilities to the PBM, (iii) requiring PBMs to take certain actions when the PBM establishes a MAC for a drug in order to determine the reimbursement rate, (e) prohibiting PBMs from reimbursing a pharmacy/pharmacist in the State an amount less than the amount the PBM reimburses a PBM affiliate, (f) restricting, limiting, or imposing requirements on a licensed pharmacy in excess of those set forth by the Vermont Board of Pharmacy or applicable law, and (g) prohibiting PBMs from reimbursing 340B covered entities at lower rates than other entities or otherwise restrict 340B drug dispensing. At least annually through 2029, the law also requires a PBM that uses spread pricing to disclose to the Department the aggregate amount the PBM retained on all claims charged to the health insurer for prescriptions filled during the preceding calendar year in excess of the amount the PBM reimbursed pharmacies. Additionally, the law mandates that PBMs attribute any amount paid by or on behalf of a covered person toward the out-of-pocket limits for prescription drug costs, the covered person's deductible, and the annual out-of-pocket maximums applicable.	5/30/2024	7/1/2024

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
	H. 766: Requires health insurance or other health benefit plan offered by a health insurer or by a PBM on behalf of a health insurer that provides coverage for prescription drugs and uses step-therapy protocols to (i) not require the failure, including discontinuation due to lack of efficacy or effectiveness, diminished effect, or an adverse event, on the same medication on more than one occasion for insureds who are continuously enrolled in a plan offered by the insurer or its PBM; and (ii) grant an exception to its step-therapy protocols upon request of an insured or the insured's treating health care professional if certain conditions apply. The bill also requires the health insurance or other health benefit plans to cover, without requiring prior authorization, at least one readily available asthma controller medication from each class of medication and mode of administration.	5/20/2024	1/1/2025
Virginia	H.B. 1402/S.B. 660: Amends existing statutory PBM laws to (i) define "aggregate retained rebate percentage," "retained rebate," and "retained rebate percentage," (ii) impose a $5,000-per-day civil monetary penalty on entities that provide pharmacy benefit management services without a license, and (iii) expand a carrier's reporting obligations to include, for each health benefit plan, the aggregate amount of the pharmacy benefit manager's retained rebates, the pharmacy benefit manager's aggregate retained rebate percentage, and the aggregate amount of administrative fees received by the pharmacy benefits manager, among other things, which shall be reported to the Commissioner on a yearly basis.	H.B. 1402: 4/2/2024 S.B. 660: 4/8/2024	7/1/2024
Washington	S.B. 5213: Amends existing statutory PBM law by, among other things, adding provisions that prohibit PBMs from (i) conditioning or linking restrictions on fees to a pharmacy's credentialing, participation, certification, or enrollment in the PBM's pharmacy network, and (ii) excluding pharmacies from participating in a PBM's pharmacy network based solely on the length of time the pharmacy has been open, or because of a pharmacy's license or location transfer, except in certain circumstances.	03/25/2024	06/06/2024 *Certain sections of the law take effect 1/1/2026.*
West Virginia	S.B. 453: Amends and reenacts a portion of the West Virginia Public Employees Insurance Act related to state contracts with PBMs, to require, among other things, for requests for proposals and contracts with PBMs that the PBMs (i) disclose all information and data related to contracting, reimbursement, rebates, fees, and other information as requested by the Public Employees Insurance Agency, the legislature, and vendors, and (ii) reimburse pharmacies in the State no less than the national average drug acquisition cost plus a dispensing fee at least equal to the dispensing fee paid by West Virginia Medicaid for outpatient drugs.	04/23/2024	6/7/2024 *Certain sections of the law took effect 7/1/2024.*

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 first quarter of 2024.

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
Alaska	H.B. 226	Awaiting transmittal to governor / Manifest Error(s) On 06/05/24						X		X	
	S.B. 121	Referred to Labor and Commerce and Finance Committees on 02/08/2024	X		X		X	X	X		
Arizona	S.B. 1164:	House APROP Committee Action: Do Pass Amended, on 03/25/24						X			X
	S.B. 1533	Senate read second time on 02/06/24	X					X			
California	S.B. 966	Read second time and amended. Re-referred to Assembly Appropriations Committee on 07/03/24	X		X	X	X	X	X	X	
	A.B. 2180	In committee; Held under submission on 05/16/24				X					
Georgia	S.B. 455	House Passed /Adopted by Substitute on 03/20/24						X			X

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
	H.B. 1363	Senate Read and Referred to Health and Human Services Committee on 03/04/24		X							
Idaho	S. 1389	Retained on Calendar on 04/03/24	X		X		X		X		X
Illinois	S.B. 3225	Rule 3-9 / Re-referred to Senate Assignments Committee on 03/15/24			X		X				
	H.B. 4548	Rule 19(a) / Re-referred to Rules Committee; Added co-sponsor on 05/02/24	X	X			X		X		X
	S.B. 2790	Referred to Assignments Committee on 01/17/2024; Multiple senator co-sponsors added as of 05/02/24	X	X				X	X		
Indiana	S.B. 257	First reading: Referred to Committee of Health and Provider Services on 01/16/24							X		
	H.B. 1327	First Reading: Referred to Committee on Health and Provider Services on 02/12/24						X	X		
	H.B. 1377	First reading: Referred to Committee on Insurance on 01/10/24				X					

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
Iowa	H.F. 2401	Placed on calendar under unfinished business on 03/21/24; Fiscal note filed on 04/18/24	X	X	X				X		
	H.F. 2473	Introduced and referred to Commerce Committee on 2/13/24				X	X				
Kentucky	S.B. 149	Referred to Banking & Insurance Committee on 02/01/24.				X		X			
Louisiana	S.B. 347	Read by title and returned to the Calendar, subject to call on 04/30/24				X			X		
	H.B. 704	Read second time by title and referred to the Committee on Insurance on 04/29/24						X	X		
	S.B. 241	Introduced in the Senate; Referred to the Committee on Insurance on 03/11/24			X						
	H.B. 509	Read by title: Referred to the Committee on Insurance on 03/11/24									X
Maryland	S.B. 595 H.B. 879	S.B. 595: House refuses to Recede on 04/05/24 H.B. 879: referred to Finance on 3/14/24				X					X

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
	S.B. 526	Hearing scheduled for 2/14/24					X				
	H.B. 876	Referred to Finance Committee on 3/18/24		X			X				X
	S.B. 754	Hearing scheduled for the Finance Committee on 02/28/24		X	X		X				X
	S.B. 1019	Hearing scheduled for the Senate Finance Committee on 03/13/24				X					
	H.B. 880 S.B. 1021	H.B. 880: Hearing scheduled for 02/29/24 S.B. 1021: Hearing scheduled for Senate Finance Committee on 03/13/24		X					X		
Massachusetts	H. 934	Accompanied a study order, see H4634 on 05/09/24	X					X	X		
	S. 2637	Accompanied a study order, see H4634 on 05/09/24						X			
	H. 1155	Reported favorably by committee and referred to the Joint Committee on Health Care Financing on 4/4/24							X		

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
	H. 1055	Introduced on 2/16/2023; Accompanied a study order, see H4691 on 5/30/24			X	X					
Minnesota	H.F. 4332 S.F. 3879	H.F. 4332: Introduced and referred to Taxes Committee on 02/28/24 S.F. 3879: Introduced and referred to Health and Human Services Committee on 02/19/24								X	
	S.F. 5329	Referred to Health and Human Services Committee on 04/04/24						X			
	H.F. 5470	Introduction and first reading, referred to Health Finance and Policy Committee on 05/13/24	X	X	X						
	H.F. 5469	Introduction and first reading; Referred to Health Finance and Policy Committee on 05/13/24									X
Missouri	H.B. 2267	Second read and referred to Senate Insurance and Banking Committee on 04/22/24			X						

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
	H.B. 2425	Referred to House General Laws Committee on 05/17/24		X							
	S.B. 1105	Hearing Conducted Senate Insurance and Banking Committee on 3/26/24		X	X		X		X		
New Hampshire	S.B. 354	Conference Committee Report: Not Filed House Journal 15, on 06/07/24				X					
	S.B. 555:	Enrolled Adopted in the Senate on 07/11/24; Enrolled in the House on 07/15/24						X	X		
	H.B. 1380	Enrolled Adopted in the Senate on 07/18/24				X		X	X		
New Jersey	A. 1646	(Carry over from previous session) Introduced and Referred to Assembly Financial Institutions and Insurance Committee on 01/09/24							X		
	A. 1440	A. 1440: (Carry over from previous session) Introduced; Referred to Assembly Financial Institutions and Insurance Committee on 01/09/24					X				

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
	S. 1020	S. 1020: (Carry over from previous session) Introduced in the Senate and Referred to Senate Commerce Committee on 01/09/24									
	S. 1008	(Carry over from previous session) Introduced in the Senate and Referred to Senate Commerce Committee on 01/09/24			X						
	S. 2257	(Carry over from previous session) Introduced in the Senate and Referred to Senate Commerce Committee on 01/09/24									X
	S. 796	(Carry over from previous session) Introduced in the Senate; Referred to Senate Commerce Committee on 01/09/24									X
	S. 1047	(Carry over from previous session) Introduced in the Senate; Referred to Senate Commerce Committee on 01/09/24	X	X	X	X	X	X	X		

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
New York	S. 6738 A. 7304	S. 6738: Referred to insurance on 01/30/24 A. 7304: Referred to Codes on 01/03/24								X	
	S. 7110 A. 10107	S. 7110: Referred to Health on 01/03/24 A. 10107: Referred to Health on 05/03/24		X	X						
	A. 6352 S. 1888	A. 6352: Referred to Insurance on 01/03/24 S. 1888: Referred to Insurance on 01/03/24	X					X			
	A. 5911 S. 5136	A. 5911: Referred to Health on 01/03/24 S. 5136: Referred to Health on 01/03/24	X	X	X						
	S. 950	Referred to Health on 01/03/24		X	X					X	X
	S. 9040	Passed Assembly, returned to Senate on 06/06/24			X						
	S. 9570 A. 10327	S. 9570: Referred to Senate Health Committee on 05/16/24 A. 10327: Referred to Assembly Health Committee on 05/17/24		X							

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
	A. 10479	Referred to Assembly Health Committee on 05/29/24						X			
	A. 10575	Referred to Assembly Governmental Operations Committee on 06/20/24							X		
Ohio	H.B. 505	Referred to House Insurance Committee on 04/30/24		X	X			X	X		
	S.B. 95	Senate Passed on 05/22/24; Referred to House Health Provider Services Committee on 6/11/24			X						
Oklahoma	S.B. 1567	Second Reading referred to Retirement and Insurance on 02/06/24								X	
	S.B. 1581	Reported Do Pass Retirement and Insurance Committee; CR filed on 02/13/24							X		
	H.B. 3368	CR; Do Pass Insurance Committee on 02/22/24				X					X
	S.B. 1916	Second reading and referred to Retirement and Insurance Committee on 02/06/24			X						

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
Pennsylvania	S.B. 1000	Re-referred to Senate Rules and Executive Nominations Committee	X	X	X		X	X			
Rhode Island	H. 7139	Committee recommended measure to be held for further study on 01/30/24	X	X	X	X	X	X	X		X
	S. 2385	Senate Health and Human Services Committee recommended measure be held for further study on 03/05/24	X		X			X	X		X
	S. 2387 H. 7898	S. 2387: Senate Health and Human Services Committee recommended measure be held for further study on 03/05/2024 H. 7898: House Finance Committee recommended measure be held for further study on 05/01/24	X		X			X			X
	S. 2395	S. 2395: Senate Health and Human Services Committee recommended measure be held for further study on 03/05/24		X							

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
	H. 7720	H. 7720: House Corporations Committee recommended measure be held for further study on 04/11/24									
	H. 8041 S. 2720	H. 8041: House Corporations Committee recommended measure be held for further study on 04/11/24 S. 2720: Engrossed on 03/28/24 and referred to House Corporation Committee on 03/29/24				X				X	
South Carolina	S. 1024	Introduced and referred to Senate Committee on Banking and Insurance on 02/06/24				X				X	X
Tennessee	H.B. 2170 S.B. 2008	H.B. 2170: Taken off notice for cal. in Calendar & Rules Committee on 03/28/24 S.B. 2008: Assigned to General Subcommittee of Senate Commerce and Labor Committee on 03/27/24				X					X

State	Bill	Most Recent Status(es)	Regulates Pricing Methodology and/or 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 Decisions/Prior Auth Activities (Health Insurers and PBMs)
Virginia	H.B. 1041	Continued to 2025 in Labor and Commerce by voice vote on 02/08/24	X	X	X	X	X		X	X	
	H.B. 104	Left in Labor and Commerce on 02/13/24			X						
	H.B. 1006	Left in Labor and Commerce on 02/13/24					X				
West Virginia	H.B. 4174	Introduced to House Health and Human Resources on 01/10/24		X		X	X				
	H.B. 5379 S.B. 831	Passed in the House on 02/28/2024. Introduced and referred to the Senate Health and Human Resources Committee on 02/29/24 S.B. 831: Introduced and referred to Health and Human Resources Committee on 02/16/24				X					X

State Law Challenges

PCMA v. Mulready. On May 10, 2024, the State of Oklahoma filed a certiorari petition with the Supreme Court seeking a reversal of the Tenth Circuit's August 2023 decision in *PCMA v. Mulready*, which found that certain provisions of Oklahoma's Patient's Right to Pharmacy Choice Act were preempted by ERISA or Medicare Part D. In its petition, the State argues that the Tenth Circuit's decision contravenes the standards articulated by the Supreme Court in its 2020 *Rutledge v. PCMA* decision, and further, splits from the Eighth Circuit's 2021 decision in *PCMA v. Webhi* regarding ERISA and Medicare Part D preemption of a similar North Dakota law. A handful of amicus briefs in support of the State's petition have been filed, most notably being an amicus brief filed by a bipartisan group of 32 attorneys general (representing 31 states and DC). Although the Supreme Court has not yet announced whether it will hear the case, its decision to do so could allow the Court a much-needed opportunity to refine and more clearly define the legal standards that should be applied when considering ERISA and Part D preemption challenges (which, as we discussed in March 2022, were crucially missing in *Rutledge*).

Advocacy Group Urges NY to Update PBM Regulations. The ERISA Industry Committee (ERIC), a lobbying organization that represents large employers providing benefit plans governed by ERISA On May 28, 2024, ERIC sent a comment letter to the NY Department of Financial Services in response to the agency's proposed rules implementing the NY law governing PBMs. ERIC raised concerns that, as drafted, the rules could be applied to self-insured benefit plans governed by ERISA and thereby "threaten ERISA preemption and the national, uniform benefits that self-insured, large employer health plans offer to their nationwide employees." Ultimately, Dillon Clair, Director of State Advocacy at ERIC, stated, "Even though significant improvements have been made to the Proposed Rules, they still allow room for application to ERISA self-funded health benefit plans and could trigger ERISA preemption concerns. To prevent this conflict and likely litigation on preemption grounds, ERIC urges the Department to amend the Proposed Rules to include an explicit exemption for ERISA self-insured health benefit plans." It will be interesting to see whether the state considers the potential for ERISA preemption and litigation as it finalizes the rules.

State Activities re Drug Pricing

Prescription Drug Advisory Boards

Colorado and Maryland PDABs Continue Analysis of Drug Prices

The Colorado PDAB continued to move forward with its review of additional "unaffordable" drugs in its June and July meetings. Most recently, the PDAB designated the Novartis arthritis drug Cosentyx as unaffordable. The PDAB will decide at a later date whether to pursue an upper payment limit (UPL) on the drug.

Similarly, on March 25, 2024, Maryland's PDAB held its 2024 Annual Board Meeting. At the meeting, the PDAB presented key information and considered public comments received on whether to refer any of the eight (8) previously selected drugs to a "cost review" by the PDAB's Stakeholder Council. The list of drugs put forth by the PDAB included Novo Nordisk A/S's Ozempic, Eli Lilly & Co.'s Trulicity, Boehringer Ingelheim's Jardiance, AstraZeneca PLC's Farxiga, AbbVie Inc.'s Skyrizi, Regeneron Pharmaceutical Inc.'s Dupixent, Gilead Sciences Inc.'s Biktarvy, and Takeda Pharmaceuticals' Vyvanse.

At its May 20, 2024, hearing, the five-member board ultimately decided against including Biktarvy and

Vyvanse in its month-long cost review process after receiving stakeholder feedback that raised numerous concerns about including both drugs in its cost review. The PDAB was expected to meet on July 22, 2024 to further discuss its upcoming cost review and, among other things, discuss how it may implement future upper payment limits on prescription drugs.

Despite being the first PDAB established in the nation, Maryland has yet to move forward with implementing a UPL for any prescription drug. Under Maryland law, the PDAB will have to first finalize a plan for implementation of UPLs and have that plan approved by the Legislative Policy Committee of the General Assembly or, separately, by the Governor and the Attorney General.

As Colorado and Maryland continue to lead the way among the 11 state PDABs, it will be interesting to see what effect the pending legal challenges in Colorado will have on activity in the other nine states that have established PDABs and the numerous other states that are currently considering legislation to establish their own state PDAB.

US District Court Judge Dismisses Challenge Against Illinois' Generic Drug Pricing Law While Lawsuits in Other States Continue. On June 18, 2024, a US District Court judge for the Northern District of Illinois dismissed a lawsuit filed by the Association for Accessible Medicines (AAM) against the state of Illinois. AAM had sued Illinois, arguing that the state's "Pharmaceutical and Health Affordability: Restrictions on Manufacturers' Amoral Behavior through Reasonable Oversight Act," which prohibited certain price increases on generic prescription drugs, was unconstitutional. Specifically, AAM argued that the Illinois law was in violation of the Commerce Clause of the US Constitution because it purportedly regulates the price of generic drug transactions that take place outside of Illinois. At issue was language in the law that targeted price hikes related to generic drugs that are "ultimately sold in Illinois," which therefore incorporated out-of-state transactions occurring prior to the drugs eventual sale in Illinois.

In its decision, the court found that AAM lacked standing and would be unlikely to prevail on the merits of its dormant Commerce Clause argument. With respect to standing, the court argued that AAM failed to show imminent injury or any injury-in-fact with respect to enforcement of the law. The court further elaborated that the sweeping complaint and "fact-intensive theories" were best left to an as-applied challenge. With respect to the Commerce Clause argument, the court relied on recent Supreme Court precedent in the *National Pork Producers Council v. Ross* decision to determine that Illinois had not violated the dormant Commerce Clause because the state law does not discriminate against out-of-state companies. AAM has since filed an amendment to its original complaint.

The decision in Illinois contrasts with a US District of Minnesota court decision that granted AAM's preliminary injunction against a similar generic anti-price gouging law in Minnesota. This decision by the court to pause enforcement of the law is currently being appealed in the Eight Circuit in *Ass'n for Accessible Medicines v. Keith Ellison*, 8th Cir., No. 24-01019.

Minnesota Releases Drugs of Substantial Public Interest List, Starting Countdown on New PBM Drug Price Reporting Requirements. Like other states, Minnesota enacted a drug price transparency law that requires manufacturers to report to its state Department of Health (MDH) information on new drug introductions and price increases for prescription drugs sold in the state. However, in 2023, the state legislature amended the 2020 law to require drug manufacturers, as well as wholesalers, PBMs, and pharmacies, to report data on rebates, fees, and other transactions for drugs identified on the state's drugs "of substantial public interest" list. Once released, reporting entities must report all required information to the MDH within 60 days of notification by the MDH.

The law grants the MDH broad discretion in selecting drugs of substantial public interest. Specifically, the MDH commissioner is permitted by law to consider any information relevant to "providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the state." Further, the commissioner will also consider drugs that: met the initial transparency requirements of the originally enacted law, whose average claims paid amount is 125% greater than list price or wholesale acquisition cost (WAC) and have been identified by the public.

On June 26, 2024, the MDH released the list of selected drugs along with information on the commissioner's methodology behind selection. The list contains 364 drugs from 76 manufacturers, organized across 10 drug families. The MDH noted on its website that reporting entities will be notified within 30 days of the list releasing. Once notified, the entities will have 60 days to report required data to the state.

Insulin Pricing

- **State Laws to Cap Insulin Prices** Colorado enacted the Prescription Insulin Pricing and Access Act in 2021, which capped insulin prices at $100 for an entire month's supply of the drug for Colorado residents. A new bill, HB24-1438, is seeking to further reduce the cost of a one-month supply of insulin to just $35. The bill would also permit increased enforcement under the Colorado Consumer Protection Act by the Colorado Attorney General against manufacturers and pharmacies that fail to comply with the new pricing requirements. The bill would scrap the old $10,000 fine associated with non-compliance with the affordability program and allow prosecutors to pursue a more open-ended enforcement, where fines against violators would vary based on "the amount and frequency that is permitted under the Colorado Consumer Protection Act." In some instances, violations of the insulin cap could potentially result in as much as $50,000 in civil monetary penalties per violation and could lead to additional damage penalties.

  Iowa lawmakers similarly advanced a bill that would cap out-of-pocket costs for insulin at $75 month, joining a growing number of states that are considering, or already have passed into law, insulin price caps. The bill's requirements would extend to health insurance plans regulated by the state, including private health insurance and state-provided Medicaid. The bill has bipartisan support, and in February 2024, it advanced out of an Iowa State Senate subcommittee that recommended its passage.

As federal legislation to bring down insulin prices has stalled in Congress, many state and local governments have increasingly viewed lawsuits against PBMs and drug manufacturers as an alternative to legislation to cap the price of insulin. As we covered in December 2023, state and local authorities in 20 states have brought suits against PBMs, alleging that they have artificially inflated the price of insulin. However, the latest updates in these cases show just how complicated it will be for state and local governments to reduce insulin prices through litigation, as two recent decisions brought blows to states' efforts.

- **Hawaii Insulin Price Case Against PBMs Moved to Federal Court.** In July, a federal judge dismissed the Hawaii Attorney General's insulin price suit against the three largest PBMs — Express Scripts, CVS, and OptumRx — but gave the state 45 days to amend its complaint. While the court's written decision is pending, the judge said during a hearing, "If the state's allegations are right, then the state is a direct participant in and beneficiary of the alleged wrongdoing." The decision is a blow to the Hawaii AG, who, in October 2023, brought a complaint alleging that the three PBMs worked together to raise the list prices of prescription drugs, including insulin, harming consumers in violation of the Hawaii Unfair or Deceptive Acts or Practices (UDAP) law. The PBMs argued in their motion to dismiss that

the state failed to show any injury against consumers under the UDAP, as consumers "do not purchase or use the PBM's services." The suit's dismissal comes two months after the case was remanded from Hawaii state court to federal court in May 2024, after the PBMs cited the federal officer removal statute.

- **In California AG Insulin Price Lawsuit, Judge Gives Partial Win to PBMs and Drug Manufacturers.** In the California AG's case against the three largest PBMs and several drug manufacturers, who are alleged to have conspired together to artificially raise the price of insulin, the judge ruled that the alleged price gouging occurred outside of the statute of limitations under California's Unfair Competition Law (UCL). The AG was invited to amend the complaint, while the Judge also stated that the UCL's safe harbors do not shield the drug manufacturers from liability. The AG's original complaint alleged the three largest PBMs used their market power to raise the prices of rebates from drug manufacturers, who in turn increased the list prices of their drugs to make up for the higher rebates, ultimately resulting in higher insulin prices for consumers. Per the judge's request, the AG has until August to file an amendment complaint.

OTHER INDUSTRY NEWS

PBMs and the Opioid Crisis. We have been tracking litigation initiated by governments at the federal, state, and municipal levels regarding the PBM's role in the nationwide opioid crisis. Governments are now targeting PBMs for opioid dispensing practices and their relationships with opioid manufacturers. Most recently, in our *PBM Policy and Legislative Update (Winter 2024)*, we discussed state initiatives against PBMs for these practices and a case brought by the city of Boston against Express Scripts (ESI) and OptumRx. Since then, additional states have brought actions against PBMs, including Arkansas and Alaska:

- The Arkansas Attorney General sued Optum and ESI for "negotiating favorable deals" with opioid manufacturers and ignoring the "necessary safeguards" to diminish an oversupply of prescriptions and sales. In the complaint filed June 24, 2024, the state presented claims of public nuisance, negligence, and unjust enrichment against the PBMs for contributing to the public health crisis in Arkansas. These claims were based on allegations that ESI improperly increased opioid utilization, dispensed billions of opioid equivalents through their mail order pharmacies, and generally encouraged the over-dispensing of opioids to Arkansas residents.
- Alaska's lawsuit includes similar claims against ESI and is currently pending in federal court. In response to a motion to dismiss from ESI, the court recently found that some, but not all, of the state's claims against the PBM were viable. Specifically, the court found that the state adequately stated a claim for public nuisance, finding that under the state's public nuisance standard, a claim need not be property-based, can involve the use of a lawful product, and is a right common to the general public's health and safety. The court also allowed the state to amend its original complaint to contend that ESI violated the federal Consumer Protection Act. However, the court found that the state's claims as they related to Medicare Part D drugs were preempted by federal law, and thus, ESI are not

subjected to liability for their relationships with plans covered by Medicare Part D.

These ongoing lawsuits between PBMs and municipal governments gained attention for the back-and-forth regarding both parties' alleged unwillingness to share, and at times, alleged destruction of discoverable materials related to the cases. In a multidistrict opioid case filed in Ohio federal court, PBMs contend that municipal government-plaintiffs failed to maintain, and at times deleted, emails that pertained to four bellwether cases. The municipal governments filed a similar motion, essentially arguing that PBMs also failed to provide evidence after receiving requests to provide materials. Both parties alleged that the opposition failed to comply with court rules requiring preservation of potentially discoverable material, typically in the form of emails. Destroying documents could be grounds for a judge to dismiss a plaintiff's case or lead to other less stringent sanctions.

Recent Settlements

In recent months, two settlements have been reached regarding PBMs and allegations of their contribution to the opioid crisis, namely, in violation of the Controlled Substances Act (CSA). In April 2024, an Illinois federal judge approved a settlement agreement between Walgreens and its shareholders in a shareholder derivative suit. The shareholder-plaintiffs alleged that Walgreens and its officers and directors failed to adequately limit their retail pharmacies from dispensing unreasonably high amounts of opioid drugs, exposing the company to liability under the CSA. Following negotiations, Walgreens agreed to create committees at the board and management levels to oversee compliance, safety, and quality risks of the company's opioid-related practices. Walgreens also added two new independent directors to its board.

In late June 2024, the Department of Justice (DOJ) and OptumRx settled a case for $20 million to resolve allegations that OptumRx (via its mail order pharmacy) violated the CSA by mixing opioid drugs and other substances, such as benzodiazepines and muscle relaxants, resulting in a potentially dangerous combination not intended for "legitimate medical use." DOJ's investigation found that OptumRx primarily filled these combined substances, called "trinity" prescriptions, via their mail order pharmacy.

Federal Courts Hear PBM Alternative Dispute Resolution Lawsuits. Federal courts across the US are considering whether to hear claims brought in class action lawsuits against some of the top PBMs or to enforce agreed upon alternative dispute resolution (ADR) methods, such as arbitration or mediation to resolve their disputes.

On May 30, 2024, a Rhode Island federal judge granted CaremarkPCS Health, L.L.C.'s (Caremark) motion to dismiss the claims brought against it in a class action alleging that CVS Pharmacy, Inc. (CVS), Caremark and others conspired to overcharge for prescription drugs. The court dismissed the claims against Caremark on the basis that the contracts between Caremark and the plaintiffs contained ***enforceable arbitration clauses*** requiring the parties to engage in arbitration prior to litigation. CVS, a non-party to the contracts, also motioned the court to dismiss the claims on the grounds of equitable estoppel. The court stayed the claims of some plaintiffs, ordered some plaintiffs to be excluded from the class, and ordered others to proceed based on the arbitration clauses in — and the state laws governing — the contracts.

California's Court of Appeal is considering whether it should enforce the limited arbitration clause in an OptumRx agreement affecting hundreds of pharmacies nationwide. While the parties initially contracted to resolve their disputes through ADR, the plaintiffs argue that the unusual and strict limitations imposed by the arbitration provisions in the Optum agreement would cause each pharmacy to pay $100,000 in arbitration expenses — a burden too costly for smaller, independent pharmacies.

While there is much precedent for courts to enforce arbitration clauses, the court may be enticed to "blue pencil" the clause to reduce its stringent requirements. With roughly $1 billion dollars in claims at stake affecting nearly a thousand pharmacies, the court's decision in this case will have a widespread impact on the PBM space, so our team will continue to monitor it closely.

Employers Still Struggle to Access Insurers' Health Cost Data. After the Consolidated Appropriations Act of 2021 (H.R. 133), part of which aimed to increase information-sharing about the cost and quality of medical services by health plans and health insurance companies, the "vast majority" of insurers complied with requirements to attest by 2023 that their plan agreements did not contain gag clauses limiting the plan's duty to provide such information. Despite these attestations, many plan sponsors are reporting that their insurers are refusing to turn over claims, pricing, and/or quality data. The Departments of HHS, Labor, and Treasury have received many complaints from employer plans about the lack of access to pricing and quality data despite the absence of gag clauses in agreements with health insurance issuers and third-party administrators, and the departments have noted they are investigating these complaints. However, it seems like employer plans and employees themselves are taking matters into their own hands by initiating lawsuits aimed at tackling the lack of access to information and the mismanagement of prescription drug benefits. On February 6, 2024, such an employee class action was filed against Johnson & Johnson, alleging Johnson and Johnson failed to provide employees with requested plan documents and breached its fiduciary duties by, among other things, overpaying for prescription drugs and failing to negotiate for rates that were near acquisition cost. Overall, access to claims data is highly important to plan sponsors, many of whom have seen success in reducing their health care spending when claims data is transparent by, among other things, entering into direct contracts with hospitals and other providers or switching from fully insured to self-funding models.

Drug Store Closings. Large national pharmacy chains continue to narrow their brick-and-mortar footprint across the country. Most recently, Walgreens stated it would close a "significant" number of its roughly 8,600 stores in the United States. Rite Aid also told the US Bankruptcy Court in New Jersey that it was closing 27 stores in Ohio and Michigan, but there are indications that it is planning to close more than 300 pharmacies in Ohio and Michigan, accounting for the vast majority of the stores in those states. CVS also stated earlier in the year that it expected to close about 300 stores.

Rite Aid Row with MedImpact Over Unpaid Elixir Reimbursement. Rite Aid has been organizing deals with creditors and bondholders to implement a restructuring plan after filing for bankruptcy in October of 2023. Among these deals was the sale of its PBM, Elixir, to MedImpact Healthcare Systems, which led to a $200 million dispute between Rite Aid and MedImpact over which entity is responsible for unpaid reimbursements to CVS Health Corp., Walgreens Boots Alliance Inc., and Walmart Inc. The case currently sits in US Bankruptcy Court for the District of New Jersey.

Amazon Expands Monthly Subscription Service to Medicare Patients. Amazon Pharmacy's $5 monthly prescription drug subscription service, RxPass, is now available to more than 50 million Medicare members in 46 states. Amazon Pharmacy has also partnered with four manufacturers to offer coupons on select brand-name drugs, including Trelegy, AUVI-Q, Wegovy, and the G6 and G7 continuous glucose monitoring systems.

FROM THE DESK OF THE IRA UPDATE…

- **June 26, 2024** – CMS published its quarterly list of Medicare Part B drugs with prices that increased faster than the rate of inflation. Manufacturers of these 64 drugs will be required to pay rebates to Medicare under the Medicare Inflation Rebate Program.

- **July 2, 2024** – Following publication of its Draft Guidance for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027 CMS issued an information collection request seeking stakeholder input and comment on the cost burden of collecting information from manufacturers as part of the price negotiation process (the Negotiation Data Elements) as well as the proposed revisions to the Drug Price Negotiation Process set forth in the Draft Guidance. Comments are due to CMS by September 3, 2024.

- **July 10, 2024** – CMS issued a proposed rule to codify policies establish in the revised guidance documents for the Part B Drug Inflation Rebate Program and the Part D Inflation Rebate Program. See the CMS Fact Sheet for additional information. Comments are due September 9, 2024.

- **July 16, 2024** – CMS released the final version of part two of its guidance regarding the Medicare Prescription Payment Plan (Final Part Two Guidance). See our blog post regarding the draft Part Two Guidance for additional details.

SINCE WE WENT TO PUBLICATION…

- The House Oversight and Accountability Committee released its scathing report regarding the PBM industry in advance of the July 23rd hearing. The report describes the Committee's findings "that PBMs inflate prescription drug costs and interfere with patient care for their own financial benefit."

- Executives from ESI, CVS, and OptumRx testified on July 23, 2024 before the House Oversight and Accountability Committee. The executives focused their testimony on the ways in which PBMs lower drug costs for patients despite the high list prices set by manufacturers.

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