

- The PBM regulatory landscape continues to evolve rapidly 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 July, August, and September 2023.

● Federal Legislative Activity and Oversight

Federal Legislative Activity

- **Ensuring Access to Lower-Cost Medicines for Seniors Act (S. 2129)/(H.R. 5461):** On June 22, 2023, Senators James Lankford (R-OK) and Bob Menendez (D-NJ) introduced the [Ensuring Access to Lower-Cost Medicines for Seniors Act](#) that would require prescription drug plan sponsors, including Medicare Advantage organizations offering Medicare Advantage-Prescription Drug (“MA-PD”) plans, (together referred to as “PDP Sponsors”) to include certain generic drugs and biosimilars on their formularies. In particular, the Act would require PDP Sponsors to (a) for brand products included on the formulary, include all generic drugs for which the wholesale acquisition cost is less than that of the brand drug, and (b) for brand biologics included on the formulary, include at least one biosimilar for which the wholesale acquisition cost is less than that of the brand biologic. Further, the PDP Sponsor would be prohibited from imposing limits on access to generics and biosimilars that are more restrictive than the limits imposed on the brand drugs (i.e., PDP Sponsors may not use prior authorization, utilization management or step therapy to effectively give a brand drug “preferred” status).

The Act would also require PDP Sponsors that apply tiered cost-sharing to have at least one cost-sharing tier that includes only generics and biosimilars, with either no cost-sharing or a cost-sharing requirement that is at least \$20 lower than that of the lowest brand tier. Similarly, if the PDP Sponsor has a specialty tier, it would also need to have a tier for certain specialty generics and biosimilars with a cost-sharing requirement that is lower than the specialty brand tier.

Finally, outside of specific circumstances, PDP Sponsors would not be able to apply a deductible specific to generic drugs/biosimilars unless such deductible, or a greater deductible, also applies to brand drugs.

On September 14, 2023, Representatives Kuster, Miller-Meeks, Matsui and Dunn introduced a similar [bill](#) in the House of Representatives. Some notable differences between the Senate and the House bills, include: (a) the Senate bill requirements would take effect with respect to plan years beginning after January 1, 2025, while the House bill would impact plan years beginning after January 1, 2024; (b) for brand biologics included on the formulary, the House bill requires that the PDP Sponsor include at least two covered biosimilars for which the wholesale acquisition cost is less than that of the brand biologic; and (c) the House bill does not include the specific cost-sharing tiering requirements for the generics and biosimilars that are found in the Senate bill.

Federal Legislative Activity and Oversight, cont'd.

- **Medicare PBM Accountability Act (S. 2254)/(H.R.5385):** On July 12, 2023, Senator Catherine Cortez Masto (D-NV), along with Senators Thom Tillis (R-NC), Ron Wyden (D-OR) and Mike Crapo (R-ID), introduced a bipartisan bill that would require PDP Sponsors to enter into agreements with PBMs that establish certain PBM reporting requirements designed to enhance transparency regarding pricing guarantees and evaluation of PBM's cost performance (e.g., rebates, discounts).

If enacted, the [Medicare PBM Accountability Act \(S. 2254\)](#) would require that, for plan years starting in January 1, 2026, contracts between a PDP Sponsor and their PBM require: (a) the PBM to provide transparency regarding guarantees and cost performance evaluations, this includes defining and applying terms consistently for calculating or otherwise evaluating PBM performance against pricing guarantees or similar cost performances measurements, disclosing excluded drugs from such calculations, and providing pricing benchmark equivalences; (b) the PBM to annually submit comprehensive standardized reports to the plan sponsor (and the HHS Secretary upon request) that include information about (i) drugs covered by the plan, their cost, out-of-pocket spending by plan enrollees, rebates and other relevant details, including total manufacturer-derived revenue and bona fide service fees, and benefit design explanations with respect to brand and generics, (ii) drugs covered by affiliate retail, mail order or specialty pharmacies, (iii) certain financial information including total spend on drugs by the plan and total amount retained by the PBM or an affiliate, and (iv) a list of brokers, consultants, and advisers that receive compensation from the PBM for the PBM services offered to the PDP Sponsor; and (c) to allow plan sponsors the right to audit PBM's compliance with the terms of the agreement. Plan sponsors would be required to submit an annual certification of compliance with these requirements.

The Act also directs the GAO to conduct a study on federal and state reporting requirements related to prescription drug costs and prices and to submit a report within 2 years of the law's enactment. An equivalent bill was introduced in the House of Representatives ([H.R. 5385](#)) on September 12, 2023 and was referred to the Committee on Energy and Commerce and Committee on Ways and Means.

- **Neighborhood Options or Patients Buying Medicines (NO PBMs Act) (S. 2436):** On July 20, Senators Joe Manchin (D-WV) and Marsha Blackburn (R-TN) introduced [the Neighborhood Options for Patients Buying Medicines Act \(NO PBMs Act\)](#) that would assure pharmacy access and choice for Medicare beneficiaries. The NO PBMs Act would (a) require all PDP Sponsors or PBMs acting to develop a pharmacy network on behalf of a PDP Sponsor, to allow the participation of any pharmacy that meets standard contract terms to participate as a network pharmacy in such plans, and (b) require that all contract terms and conditions offered by such PDP Sponsor or PBM are "reasonable and relevant," as defined by the Secretary of HHS. The bill was introduced in the House of Representatives ([H.R. 5400](#)) on September 12, 2023 and was referred to the Committee on Energy and Commerce and Committee on Ways and Means.

Federal Legislative Activity and Oversight, cont'd.

- **Strengthening Pharmacy Access for Seniors Act (S. 2405):** On July 20, 2023, Senators John Thune (R-SD), Sherrod Brown (D-OH), Debbie Stabenow (D-MI) and John Barrasso (R-WY) introduced the bipartisan bill [Strengthening Pharmacy Access for Seniors Act](#). If enacted, the bill would increase beneficiary access to pharmacies and general transparency by, among other things, (a) requiring PDP Sponsors to annually submit to the Secretary certain information about its covered drugs designated as limited access drugs,¹ including: (i) the full list of drugs designated as limited access drugs, (ii) the written rationales for why a drug meets the definition of a limited access drug, (iii) requirements imposed on network pharmacies to ensure appropriate handling and dispensing the limited access drugs, (iv) the percentages of limited access drugs dispensed through retail, specialty, or mail order pharmacies or other dispensing channels, and (v) the annual percentage of limited access drugs dispensed through pharmacies wholly or partially owned, by or otherwise affiliated with, the PDP Sponsor or its PBM; and (b) preventing PDP Sponsors or their PBMs from restricting or limiting access to any covered drugs to a subset of their network pharmacies, other than with respect to a limited access drug. The Act would also require PDP Sponsors or their PBMs, upon the request of a network pharmacy, to provide such network pharmacies with information specific to such limited access drugs. Lastly, the bill states that the Secretary, on an annual basis, must submit a report to several House and Senate committees detailing, among other things, information the Secretary will receive from PBMs pursuant to this bill, if enacted.
- **Modernizing and Ensuring PBM Accountability Act (MEPA ACT) (S. 2973):** On July 26, 2023, Senators Ron Wyden (D-OR) and Mike Crapo (R-ID) in the Finance Committee held a markup of the [Modernizing and Ensuring PBM Accountability Act \(MEPA Act\)](#), legislation intended to bring additional transparency, accountability, and competition to the PBM industry. The bill was reported out of committee by a 26-1 vote and introduced to the Senate on September 28, 2023. The MEPA Act would, among other things, require that contracts between PDP Sponsors and a PBM meet the following requirements starting in plan year 2026: (a) set forth PBM fees that are flat, bona fide service fees based on fair market value in order to “delink” PBM income from prescription drug pricing; (b) define and apply drug pricing-related terms in a transparent and consistent manner to enable the evaluation of PBM performance; and (c) require PBM to annually report drug price and other information to PDP sponsors and the Secretary of HHS. Each such report must include specific information with respect to the previous plan year, including, without limitation: (i) lists of all drugs covered; (ii) information about dispensing of such drugs; (iii) information about enrollee cost-sharing; (iv) information on other financial relationships between the PBM and the drug manufacturers; (v) information related to net and gross prices and total drug spending; and (vi) information about the PBM’s affiliates. PBMs that are affiliated with a pharmacy must also report the following types of information: (A) information related to dispensing and costs by affiliate pharmacies; (B) information related to acquisition costs; and (C) information related to drugs subject to 340B arrangements.

¹ A limited access drug means a covered Part D drug that meets one or both of the following: (1) the FDA has restricted distribution of such covered Part D drug to certain facilities or physicians, or (2) dispensing such Part D drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy.

Federal Legislative Activity and Oversight, cont'd.

If enacted, the MEPA Act would also, among other things, (i) require the HHS Secretary to institute standard Part D measures for assessing network pharmacy performance; (ii) ban PBM spread pricing in the Medicaid program; and (iii) require the HHS OIG to investigate the impact of vertical integration between PDP Sponsor, PBMs, and pharmacies on beneficiary out-of-pocket costs and Medicare spending under the Part D program.

- **The Health Care Price Transparency Act of 2023 (HR 4822)** – On July 24, 2023, Representative Jason Smith (R-MO) introduced the [Health Care Price Transparency Act of 2023](#) to improve price transparency for certain health care services, including PBM transparency in reporting. If enacted, the Act would, among other things, require PBMs to annually submit to plan sponsors and employers information relating to copayment assistance programs, dispensed drugs, each therapeutic category or class of drugs dispensed, gross spend on prescription drugs before rebates and other manufacturer fees or remuneration, total amount received or expected in rebates, discounts, and any other manufacturer remunerations, net payments, costs of covered drugs, and any amounts paid to brokers, consultants, and advisors for the referral of the plan's business to the PBM. On July 26, a mark-up session was held by the Ways and Means Committee, and the Act was ordered to be reported to the House of Representatives as amended by a vote of 25-16.
- **Lowering Drug Costs for American Families Act (HR 4895)** – On July 26, 2023, House democratic leaders in the Energy and Commerce Committee, Ways and Means Committee, and Education and the Workforce Committee leaders introduced the [Lowering Drug Costs for American Families Act](#) to expand the drug pricing provisions included in the Inflation Reduction Act ("IRA") to the commercial market. Specifically, the Act would: (a) increase the number of drugs subject to negotiation from 20 to 50 starting in 2029 and each subsequent year thereafter; (b) extend the drug price negotiation program to the commercial market by expanding the definition of Maximum Fair Price (MFP) Eligible Individual to include an individual enrolled under a group health plan or health insurance covered offered in the group or individual market; and (c) require manufacturers to offer the negotiated prices and Part B and Part D inflation rebates to drugs furnished in the commercial market. The Act establishes that a group health plan or health insurance issuer shall be treated as having in effect an agreement for the purposes of applicability of the drug price negotiation program unless a plan or issuer affirmatively elects not to participate under the program for such price applicability period and selected drug through a process specified by the Secretary. The Secretary would make public the list of health plans and insurance issuers that elect not to participate in the program.

Federal Legislative Activity and Oversight, cont'd.

- **Lower Costs, More Transparency Act (H.B. 5378):** On September 8, 2023, members of the House Energy and Commerce, Ways and Means, and Education and the Workforce Committees introduced the bipartisan bill [Lower Costs, More Transparency Act](#). If enacted, the bill would, among other things, increase oversight and transparency of the PBM industry by setting specific reporting requirements for group health plans and PBMs, and prohibiting group health plans and PBMs from entering into agreements with third parties (i.e., drug manufacturers, rebate aggregators, and other subcontractors) that include “gag clauses” which would prevent the group health plans or PBMs from meeting their reporting requirements. Reports under this bill would be prepared at least biannually and would include information related to, among other things, drug cost, prescriptions filled, rationale for formulary placement, payment of direct or indirect rebates, fees, or any other type of compensation, benefit design, and information pertaining to drugs dispensed at pharmacies under common ownership with group health plans or PBMs. This bill would also specifically require contracts between State Medicaid programs and PBMs to, among other things, (i) include a pharmacy reimbursement model whereby there is total pass through of payment to the pharmacy or provider dispensing the drug, with no reductions unless otherwise permitted by law, (ii) prohibit any form of spread pricing in the reimbursements, and (iii) require that administrative fees paid to PBMs reflect fair market value.

Other Federal Activity

- **FTC withdrawing its prior guidance regarding PBMs.** As previously reported, on July 18, 2023, the FTC voted to withdraw all prior PBM-related letters and reports until “its current PBM study is complete and earlier materials can be revaluated in light of current market conditions.” The FTC letters and reports, issued between 2004 and 2014, contended that state and federal proposals advocating for increased PBM transparency could undermine competitive processes. The FTC has noted that the goal of the ongoing study is to shed light on the emerging trends and changes in the industry and the market power of PBMs.
- **Transparency in Coverage FAQs.** The Departments of Labor, Health and Human Services, and the Treasury (collectively, the “Departments”) jointly released a new enforcement-related FAQ document regarding implementation of plan requirements under the Transparency in Coverage Final Rules (“TiC Final Rules”). By way of background, the TiC Final Rules require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage to make certain cost-sharing information available to participants, beneficiaries, and enrollees. On August 20, 2021, the Departments released FAQs (FAQs Part 49) announcing the deferral of enforcement regarding certain TiC requirements, among other things, and on April 19, 2022, the Departments issued FAQs Part 53, announcing an enforcement safe harbor for satisfying the reporting requirements for plan and issuers that were unable to comply with those requirements for specified reasons.

Federal Legislative Activity and Oversight, cont'd.

In the new FAQs, the Departments rescind portions of the guidance previously provided. Specifically, the Departments rescinded Q1 of FAQs Part 49 and stated that they no longer intend to engage in future rulemaking on enforcement of the TiC Final Rules. Enforcement will now be handled on “a case-by-case basis, as the facts and circumstances warrant.”

The Departments also rescinded a portion of FAQs Part 53 clarifying that there is no “enforcement safe harbor” and that health plan compliance with certain rate disclosure requirements will be viewed with a fact-specific determination. The Departments intend to exercise enforcement discretion with respect to the disclosure requirements on a case-by-case basis. The Departments note, however, that they will not pursue enforcement action “if a plan or issuer can demonstrate that compliance with the relevant provisions of the TiC Final Rules would have been extremely difficult or impossible, including, but not limited to, for the reasons stated in FAQs Part 53.

Understanding Copay Assistance Programs

Pharmaceutical manufacturers have long offered coupons and copay assistance programs for certain high-priced drugs to reduce the patient cost-sharing obligations (i.e. copayments, coinsurance or deductibles) under a patient's health plan. However, from the health plan's perspective, cost-sharing obligations are an important benefit strategy meant to incentivize members to use lower cost products and prevent overutilization and manufacturer coupons are used to keep patients on higher cost drugs when lower cost drugs are available. These competing interests contributed to the development of programs known as **copay accumulators** and **copay maximizers**, which enable health plans to use the value from manufacturer copay assistance dollars offered to patients with commercial insurance to reduce the cost of the drugs paid for by the plan.

- **Copay Accumulators** apply the manufacturer's coupons or copay assistance to the cost of the prescription drug until the annual benefit is exhausted. The amount that the manufacturer pays does not “accumulate” towards the patient's deductible or out-of-pocket maximum (“OOP”), so if the manufacturer payments are exhausted before the end of the year, the patient is then responsible for their cost-sharing obligations, consistent with their plan design. This can result in a sudden high-cost to patients who may not have understood that using manufacturer coupons did not result in them satisfying their applicable deductible. This means that, depending on benefit design and value of the manufacturer coupons, a health plan would use the value of the manufacturer coupons to bring down plan's costs, and then the patient's deductible (if applicable) before covering the cost of the drug. This practice has received significant scrutiny from patient advocacy groups. Additionally, because some manufacturers offer copay assistance programs are dependent on patients not having adequate coverage for the applicable drug, some plans have designed their benefits in order to exclude coverage for the applicable drug until a manufacturer's copay assistance program is exhausted for the year.
- **Copay Maximizers**, largely a response to the initial backlash against accumulators, evenly apply the manufacturer's copay assistance throughout the benefit year. Typically, the patient's cost-sharing obligations are set to equal the maximum value of the copay assistance and as such, patients will not face significant OOP costs. Though not required to count the manufacturer payment towards the patient's deductible and OOP max, many plans choose to do so.

Prior to 2019, federal law was silent as to whether copay accumulators and maximizers were permitted. While the implementing regulations for the ACA defined “cost sharing,” they did not specify whether manufacturer coupons or assistance must apply towards the ACA's cost sharing limits.

In the 2020 Notice of Benefit and Payment Parameters (NBPP), CMS opined on the issue, stating that it would permit plans to exclude the value of manufacturer assistance from the ACA's annual out-of-pocket maximums “for specific prescription brand drugs that have an available and medically appropriate generic equivalent.” CMS also noted that if there was not a medically appropriate generic equivalent available, then the plan was required to apply the manufacturer coupon towards the member's OOP max. For many stakeholders, the language of the 2020 NBPP, and the particular focus on drugs with a generic equivalent, made it unclear whether CMS's intent was to “require plans and issuers to count the value of drug manufacturers' coupons toward the annual limitation on cost sharing, other than in circumstances in which there is a medically appropriate generic equivalent available.”

In the 2021 NBPP, CMS sought to clarify the issue through a proposal to “interpret the definition of cost sharing to exclude expenditures covered by drug manufacturer coupons.” In the 2021 NBPP Final Rule, however, CMS opted not to finalize this interpretation, instead writing that, to the extent consistent with state law, manufacturer assistance “may be, but [is] not required to be” applied towards the patient's annual cost sharing limits. In essence, the 2021 NBPP gave plans the discretion to either count, or not count, manufacturer payments “toward the annual limitation on cost sharing,” regardless of whether the drug has a generic equivalent.

Federal Legislative Activity and Oversight, cont'd.

Regulatory Challenges

HIV and Hepatitis Policy Institute et al v. United States Department of Health and Human Services et al.

On August 30, 2022, three patient-advocacy groups sued the Centers for Medicare & Medicaid Services (“CMS”) and the U.S. Department of Health and Human Services (“HHS”) to invalidate rulemaking from the 2021 Notice of Benefit and Payment Parameters (“NBPP”) that allowed health plans to operate copay accumulator and maximizer programs, arguing that the rule violated the Affordable Care Act (“ACA”). On February 23, 2023, the plaintiffs moved for summary judgement, arguing that the 2021 NBPP was unlawful and must be set aside because: (1) it conflicts with the ACA’s statutory definition of “cost sharing,” (2) it conflicts with preexisting regulatory agency definition of “cost sharing”, and (3) the 2021 NBPP is arbitrary and capricious.

On September 29, 2023, the Court granted plaintiffs’ motion for summary judgement and vacated the 2021 NBPP based on the rule’s contradictory reading of the same statutory and regulatory language from the 2020 NBPP and the fact that the agencies have yet to offer definitive interpretation of the term “cost sharing” that would support the rule.

The Court deemed the 2021 NBPP rule unlawful and mandated that insurers adhere to the 2020 NBPP federal rule. According to the 2020 rule, plans are permitted to exclude the value of manufacturer assistance from patient cost-sharing obligations for brand drugs that have an available generic. Given that most copay assistance programs are for brand name drugs without a generic equivalent, some in the industry have interpreted the court’s ruling as no longer “allowing” health plans to use copay accumulators.

As a result, health plans and PBMs will need to adjust operations related to copay assistance programs to align with the reinstated federal rule. Importantly, health plans and PBMs should ensure that any changes are clearly communicated to ensure members understand their cost-sharing responsibilities. Additionally, health plans and PBMs may need to reevaluate their formulary and benefit design to accommodate the new regulatory landscape while continuing to provide cost-effective and quality care to patients. Industry there is also the possibility the CMS will step in to provide additional guidance to clarify the rule.

The flurry of federal activity during this Congress continues. The federal government seems intent on regulating the PBM space to some extent, though it is not clear what effect, if any, the turnover of the Speaker of the House will have on legislative efforts.

II. State Legislation and Litigation

Recently Enacted State Legislation

As expected, state activity in this quarter slowed significantly given the general summer legislative calendar. Still, six bills were enacted during the third quarter of 2023. 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)
Hawaii	S.B.1381: Repeals section 328-106 of Hawaii Revised Statutes, which requires pharmacy benefit managers to maintain certain information related to the cost of prescription drugs and provide a process for a contracting pharmacy to appeal the maximum allowable cost for reimbursement, because outside of the Department's area of expertise.	7/5/2023	7/1/2050
Illinois	H.B. 3631: Amends the Pharmacy Benefit Managers Article of the Illinois Insurance Code to restrict a PBM from retaliating against a pharmacist or pharmacy for making disclosures of information in legal proceedings or to a government or law enforcement agency, if the pharmacist or pharmacy reasonably believes the disclosed information is evidence of a violation of State or federal laws, rules, or regulations.	8/4/2023	7/1/2023
Oregon	S.B. 192: Requires, among other things, (i) PBMs to annually report to the Department of Consumer and Business Services information about certain rebates, fees, price protection payments and other payments received from prescription drug manufacturers and (ii) the Department of Consumer and Business Services to publish aggregated information received from PBMs on the Department's website.	7/27/2023	9/24/2023 (takes effect on 91st day following adjournment of the eighty-second legislative assembly)
	H.B. 2725: Among other things, prohibits PBMs from (i) retroactively denying or reducing payment on a claim after adjudication unless, among other things, the pharmacy and PBM agree that payment was incorrect due to a clerical error, and (ii) imposing fees on pharmacies after the point of sale; and requires PBMs to provide notice to pharmacies of any claim denial or reduction in reimbursement, with specific information explaining the denial or reimbursement reduction.	7/31/2023	7/31/2023

State Legislation and Litigation, cont'd.

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
New Jersey	• S.B. 1616/A536: Establishes new transparency standards for PBMs, which shall, among other things, (i) require PBMs and pharmacy services administrative organizations to obtain a license or registration, as applicable, (ii) impose a duty of good faith and fair dealing on PBMs, (iii) require PBMs to remit certain compensation received from manufacturers directly to covered persons at the point of sale or to the covered person's insurance carrier, (iv) require PBMs to establish reasonable administrative appeals processes for pharmacies, (v) set requirements and restrictions relating to maximum allowable cost lists; (vi) prohibit "gag clauses" in contracts between PBMs and network pharmacies, and (vii) establish penalties for violation of the proposed provisions.	7/10/23	2/1/2025
	• S.B. 1615/A2840: Establishes reporting guidelines, which, among other things, (i) require PBMs to report information regarding specific drugs or drug groups, including but not limited to wholesale acquisition costs, total rebates, discounts, and prices concession received and total net income received for such drugs and (ii) require pharmacy services administrative organizations to annually report the reimbursement rate PBMs pay the organization for drugs and the fees charged by the organization to pharmacies.	7/10/23	9/1/2024

State Legislation and Litigation, cont'd.

Pending State Legislation

Six additional state initiatives were introduced in the third quarter of 2023. The proposed bills would impact (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.

State	Description of Measure(s)	Most Recent Status
California	S.B. 786: Proposes to prohibit PBMs from discriminating against a covered entity or its pharmacy in connection with dispensing a drug subject to federal drug requirements or preventing a covered entity from retaining a benefit of discounted pricing for those drugs.	Enrolled and presented to the Governor on 9/11/2023
	S.B. 873: Proposes an act to amend the Health and Safety Code and Insurance Code to require health care service plans to report information on rebates collected directly or indirectly from pharmaceutical manufacturers, enrollees' premiums and cost-sharing responsibilities, and details on the payments to PBMs.	Hearing on 9/1/2023, held in committee and under submission
	S.B. 516: Proposes to introduce additional requirements on health service plans and PBMs under contract to administer prior authorization or drugs, including: (a) prohibition to require a health professional to complete or obtain a prior authorization for any covered service if the plan approved or would have approved not less than 90% of the prior authorization requests submitted in the most recent completed 1 year contracted period, (b) set standards for prior authorization denial, rescission, and appeal, (c) require the provision of electronic prior authorization process, and (d) require the plan to have a process for annually monitoring prior authorization appropriately.	Re-referred to Committee on Appropriations on 09/14/23
Illinois	H.B. 4126: Amends the Illinois Insurance Code with emergency rule-making to improve network adequacy and transparency. Outlines the process for the Director to examine PBMs with potential violations.	Introduced 08/17/2023
Michigan	H.B. 4890: Proposes to make the cost of insulin more affordable through regulating production and distribution including requirements on the private.	Introduced 07/18/2023
New York	A.B. 8067: Proposes to amend the insurance law and public health law to require insurers to, among other things, (1) provide access to certain drugs at reasonable prices, (2) allow patients with chronic conditions to obtain standing prior authorizations for a drug and to provide information relating to its prior authorization policies on its website, (3) provide formulary exceptions for drugs under certain circumstances, (4) allow for prescription synchronization, and (5) limit the copayment and coinsurance amounts it charges for certain drugs.	Introduced on 9/27/23 and referred to insurance committee

State Law Challenges

Pharmaceutical Care Management Association (PCMA) v. Mulready.

As states continue to craft PBM-focused legislation, questions surrounding the extent and permissibility of state authority in the area are once again on shaky ground after the 10th Circuit's recent decision in *Mulready*. As we've discussed in the past, prior attempts to challenge such regulations on grounds that existing federal legislation, such as the Employee Retirement Income Security Act of 1974 (ERISA) and Medicare Part D, preempts state efforts to regulate the PBM industry have often failed given the Supreme Court's 2020 *Rutledge* decision.

However, in an August [decision](#), a three-judge panel of the 10th Circuit overturned portions of the District Court for the Western District of Oklahoma's ruling, finding instead that certain provisions of the state's 2019 Patient's Right to Pharmacy Choice Act were in fact preempted by ERISA.² The panel, relying on *Rutledge* and prior ERISA precedent, distilled the analysis into a condensed two-prong question: "Does the state law 'govern a central matter of plan administration or interfere with nationally uniform plan administration?'"

In its analysis, the panel rejected Oklahoma's argument that because the law regulates PBMs directly, and not health plans, that the law escapes ERISA preemption analysis. It noted that because PBMs are central to how health plans administer prescription drug benefits, a preemption analysis was still warranted. The panel characterized the four provisions as falling into two distinct categories: (1) network restrictions (the Access, Discount, and AWP provisions) and (2) integrity and quality restrictions (the Probation provision). Analyzing the network restrictions, the panel found that the Oklahoma law impermissibly mandated certain benefit structures amongst ERISA plans by dictating a pharmacy network's: (1) scope (which pharmacies would be included) and (2) differentiation (the cost-sharing arrangements those pharmacies would participate in the network), both of which it considered to be central components of ERISA plan designs. Likewise, analyzing the integrity and quality restriction, the panel found that the Probation provision impermissibly dictated which pharmacies must be included in an ERISA plan's PBM network. Therefore, according to the panel, the provisions govern a central matter of plan administration, and thus, have an impermissible connection with ERISA plans and are preempted by federal law.³

² The four provisions at issue are as follows:

1. Access Standards – outline various geographic parameters that PBMs must satisfy in fashioning their Oklahoma pharmacy networks;
2. Discount Prohibitions – bar PBMs from promoting in-network pharmacies to beneficiaries by offering cost-sharing discounts, such as reduced copayments;
3. Any Willing Provider (AWP) Provision – requires PBMs to admit every pharmacy that is willing to accept the PBM's preferred-network terms into that preferred network; and
4. Probation Provision – bars PBMs from denying, limiting, or terminating a pharmacy's contract because one of its pharmacists is on probation with the Oklahoma State Board of Pharmacy.

³ Note that the 10th Circuit's panel also examined whether the AWP provision was preempted by Medicare Part D. As a threshold matter, and like the ERISA analysis, the panel found that preemption analysis was warranted as Oklahoma's legislation regulates Part D plans because it establishes a rule that governs their PBM pharmacy networks. According to the panel, Oklahoma's law does so by instituting requirements that overlap with existing federal Part D regulations related to pharmacy networks. Given this overlap, the panel found that the AWP provision is similarly preempted by Medicare Part D.

State Legislation and Litigation, cont'd.

Following the panel's decision, Oklahoma petitioned for rehearing *en banc*, before the entire Tenth Circuit. In its petition, Oklahoma challenges the panel's ERISA and Medicare Part D preemption analyses as well as its interpretation of ERISA's savings clause, which Oklahoma argues requires that "nothing" in ERISA's preemption clause "shall be construed to exempt or relieve any person from any law of any State which regulates insurance." Following Oklahoma's petition, the panel instructed PCMA to submit a response to Oklahoma's petition.

State Enforcement re Drug Pricing

- *Cameron vs. Insulin Makers and the PBM Industry*. On August 2, 2023, Kentucky Attorney General Daniel Cameron filed a [lawsuit](#) against CVS Caremark, Optum Rx, Express Scripts, Novo Nordisk, Eli Lilly, and Sanofi-Aventis, among other affiliated entities, alleging that the PBMs worked together with the named insulin manufacturers to influence and increase insulin prices. The lawsuit amends an existing complaint against the insulin manufacturers Eli Lilly and Co., Sanofi-Aventis, and Novo Nordisk Inc. that alleged the same behavior. Cameron alleges, among other things, that the named PBMs have used their market share to increase total manufacturer rebates and fee payments in exchange for preferential formulary placement, which has led to "inflated" list prices for insulin products. Cameron's lawsuit brings claims under the Kentucky Consumer Protection Act, the Kentucky False Advertising Statute, as well as claims of unjust enrichment and civil conspiracy.

Similar actions were previously filed by Attorneys General in Arkansas, California, Illinois, Kansas, Louisiana, Mississippi and Montana in previous years. On August 3, 2023, the Panel on Multidistrict Litigation [granted the request](#) filed by Arkansas, Illinois, Mississippi, Montana and Kansas to centralize the state actions and ordered these actions to be transferred to the District of New Jersey for litigation. It is not yet known whether the Kentucky case will also be transferred to the District of New Jersey.

- *State of Hawaii v. CaremarkPCS Health, LLC, Express Scripts, Inc., and OptumRx, Inc.* On October 4th, Hawaii Attorney General Anne Lopez filed a [lawsuit](#) alleging CVS Caremark, Express Scripts, and OptumRx engage in unfair and deceptive business practices, contributing to rising drug prices and barriers to patient access of prescription drugs. The complaint argues that defendants misrepresent their role in reducing drug prices, exclude drugs from their formularies to increase rebates, and drive list price inflation by negotiating drug rebates amounts that force manufacturers to increase wholesale acquisition costs. Lopez argues that these alleged practices violate Hawaii antitrust laws, which makes it unlawful to engage in unfair methods of competition and unfair or deceptive acts or practices of any trade.

State Legislation and Litigation, cont'd.

Other State Actions

- *Los Angeles County v. Express Scripts and OptumRx, et. al.* On August 30, 2023, Los Angeles County Counsel Dawyn R. Harrison filed a [lawsuit](#) against Express Scripts and OptumRx, among others, alleging that the defendants contributed to the opioid epidemic in collaborating with opioid manufacturers to exchange rebates and other payments for favorable placement on formularies with preferred statuses and with little to no limits on approval for use. The complaint further alleges that the defendants used deceptive marketing to promote the drugs in an effort to generate greater profits. The County's lawsuit brings claims under the California nuisance laws and seeks for defendants to be enjoined from performing any further acts in violation of such laws. Similar lawsuits were previously filed in Texas, Virginia, and Ohio; these included additional claims of unjust enrichment, fraud, civil conspiracy, and state consumer protection violations.
- *Oregon Secretary of State Audit Report on PBMs.* On August 21, 2023, the Oregon Secretary of State published [the state audit report on Pharmacy Benefit Managers \(PBMs\)](#) detailing the results of an audit conducted by the Oregon Audits Division on the role of PBMs in Oregon's Medicaid program. The report specifically describes Oregon's use of the "coordinated care" model to deliver services, whereby PBMs contract with coordinated care organizations (CCOs) to manage prescription benefits for Medicaid beneficiaries. The report also examines the Medicaid reimbursement rates for independent and national chain pharmacies. The audit had four (4) major findings: (1) the current structure of PBMs is too complex for the state to fully assess and understand the value PBMs provide and couldn't conclude whether PBMs in Oregon were further driving up prescription drug costs or saving the state money, (2) the state's regulation of PBMs is limited and fragmented, (3) there is a significant difference in pharmacy reimbursements between independent pharmacies and national chains, which are owned by PBMs or PBM parent companies, and (4) the Oregon Health Authority (OHA) does not ensure sufficient transparency and compliance from PBMs. The auditors made two recommendations to the OHA for more immediate improvements, who later agreed with both recommendations. The auditors recommended that the OHA should improve transparency and compliance from its current relationship with PBMs – through the CCOs – by proactively monitoring and enforcing its contracts, and that OHA should assign staff without a conflict of interest to monitor CCO and PBM compliance.

III. Other Related Updates

With increased attention on insulin prices, Amazon Pharmacy rolled out a new coupon program to reduce customer out of pocket costs for insulin. On August 15, 2023, Amazon introduced "automatic coupons" to put a cap on the out-of-pocket costs, which would start at \$35 for medication made by over 15 insulin and diabetes care brands. The coupons can only be used by beneficiaries not otherwise entitled to receive benefits from any state or federal healthcare program.



From the Desk of the IRA Update...

- In September, we launched the [Mintz IRA Update](#), a quarterly publication focused on the numerous developments under the Inflation Reduction Act of 2022 (“IRA”) impacting the health care industry.

The IRA is the most significant legislation relating to prescription drug pricing and coverage since the creation of Medicare Part D – and has the potential to fundamentally change the Medicare drug pricing landscape with provisions that impact manufacturers, PBMs, payors, and pharmacies. To help our clients track and stay up-to-date with the IRA, each edition of the *Mintz IRA Update* will analyze current health care related developments and provide expert analysis on the issues that directly affect your business. Future editions, along with other IRA-related resources, will be made available on a new resource page coming in the new year.

Since we went to publication...

- **New Senate Legislation:** The Senate Finance Committee voted on November 8th to pass a comprehensive [draft health care package](#) that includes provisions aimed at reducing Medicare and Medicaid prescription drug costs by, among other things, regulating certain PBM practices.
- **New House Legislation:** House republicans and democrats introduced a version of the Senate’s [“Delinking Revenue from Unfair Gouging \(DRUG\) Act”](#) on November 8th, which would prohibit PBMs from receiving any remuneration that is not a bona fide service fee, engaging in spread pricing, patient steering, and paying affiliated pharmacies more than other pharmacies for the same services.
- **Additional State Laws:** California enacted [S.B. 786](#), which prohibits a PBM from discriminating against a covered entity or its pharmacy in connection with dispensing a drug subject to federal pricing requirements or preventing a covered entity from retaining the benefit of discounted pricing for those drugs.
- **Copay Accumulators and Maximizers:** [HHS signaled](#) in a November 27th [Motion to Clarify](#) that it “intends to address, through rulemaking, the issues left open by the [D.C. District Court’s] opinion, including whether financial assistance provided to patients by drug manufacturers qualifies as ‘cost sharing’ under the Affordable Care Act[.]” Further, and equally important, HHS stated that it “does not intend to take any enforcement action against issuers or plans based on their treatment of such manufacturer assistance” until that rulemaking is issued.



Mintz's PBM Practice



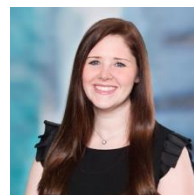
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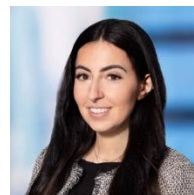
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Our Health Law Practice is unique in terms of the depth and scope of experience our attorneys have within the PBM industry. We understand how difficult it is for PBMs and the entities with which they engage to operate under today's complex web of federal and state laws and regulations. Our comprehensive knowledge of the PBM industry, the legal landscape, and relevant policy initiatives enables us to provide insightful and strategic counsel to PBMs on all aspects of their operations. [Click here](#) to learn more.