MINTZ

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PBM

Policy and Legislative Update

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The PBM regulatory landscape continues to evolve at both the 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 2024. Activity in this space did slow down a bit over the summer as Congress and state legislators were in recess and stakeholders were generally focused on the election.

FEDERAL LEGISLATIVE ACTIVITY AND OVERSIGHT

Federal Legislative Activity

House Committee on Oversight and Accountability Focuses on PBMs as the Cause of Rising Drug Costs. On July 23, 2024, the House Committee on Oversight and Accountability (HCOA) released a report titled *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* (Report). The Report was largely critical of the roles the three largest PBMs — CVS Caremark, Express Scripts, and OptumRx — have in the prescription drug market. The Report argues that these PBMs "have monopolized the pharmaceutical marketplace by deploying deliberate, anticompetitive pricing tactics that are raising prescription drug prices, undermining community pharmacies, and harming patients across the United States."

Following the release of the Report, HCOA held its third hearing in a series of hearings discussing PBMs and their role in the pharmaceutical market titled "The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part III: Transparency and Accountability." As we reported, the first two hearings featured providers, practitioners, and industry stakeholders (e.g., PhRMA, etc.) discussing the importance of PBM reform in reducing the costs of prescription drugs. The third hearing featured the CEOs of CVS Caremark, Express Scripts, and Optum Rx. During the hearing, the PBM executives pushed back against the Report's claims tying PBMs to increasing drug costs. Adam Kautzner of ESI explained to the Committee that ESI is responsible for lowering patient costs and often protects patients from high prices in the pipeline. David Joyner of CVS also highlighted the role that drug manufacturers have with respect to rising costs, specifically highlighting "patent abuses" that delay launches of less costly generic and biosimilar medicines and the rising launch prices of new drugs as a contributor to high drug costs.

In an August 28, 2024 letter, sent to each of the "Big 3" PBM executives, Chairman Comey urged the executives to "correct the record" over what the Chairman described as claims contradicting the committee's and FTC's findings regarding certain controversial practices such as contract negotiations, contract opt-outs, payments to owned-pharmacies, and inappropriately steering patients to their own pharmacies. The executives defended their statements and declined to revise their testimony.

It remains to be seen what steps the HCOA will take next in its ongoing bipartisan efforts to seek PBM reform.

Senate Hearings Intensify Focus on Novo Nordisk's Pricing of Ozempic and Wegovy. In a Senate committee hearing led by Sen. Bernie Sanders, Novo Nordisk CEO Lars Fruergaard Jørgensen faced bipartisan pressure over the high US prices of Ozempic and Wegovy. Sen. Sanders revealed commitments from major PBMs, including UnitedHealth and CVS, to maintain drug coverage if prices were reduced, contradicting Novo's assertion that PBM rebates drive high list prices. The hearing sparked bipartisan scrutiny of Novo's pricing practices, with some senators, like Sen. Ben Ray Luján and Sen. Mike Braun, urging greater transparency, while others, such as Sen. Roger Marshall and Sen. Mitt Romney, defended Novo and called for PBM reform instead. The session highlighted ongoing debates over US drug costs, the role of PBMs and pharmaceutical manufacturers, and patient access.

Other Federal Activity

FTC Takes Aim at Insulin Rebating Practices of Major PBMs. The Federal Trade Commission (FTC) filed an in-house administrative complaint against CVS Caremark, Express Scripts, and Optum Rx and each PBM's associated group purchasing organization (GPO). The FTC's complaint alleges that the PBMs engaged in unfair methods of competition and unfair acts or practices under Section 5 of the FTC Act resulting from the PBMs' insulin rebating practices. The FTC's complaint argues that the PBMs incentivized insulin manufacturers to increase list prices in exchange for larger rebates. According to the FTC, this practice created a system where PBMs allegedly prioritized maximizing their own profits through rebates, rather than securing lower drug prices for patients. This case demonstrates the FTC's ongoing campaign to address the rising costs of health care, and it could have significant implications for the future of certain drug pricing practices and, potentially, the role of PBMs in the pharmaceutical market.

Express Scripts, Inc. Sues Federal Trade Commission for Defamatory Report. On September 17, 2024, Express Scripts, Inc. (ESI) filed a lawsuit against the FTC in the US District Court for the Eastern District of Missouri. The lawsuit challenges the FTC's July 9, 2024 interim staff report, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, alleging that the report is defamatory, unlawful, and violates ESI's statutory and constitutional rights. ESI asserts that the FTC report contains numerous factual errors and misrepresentations, including the assertion that PBMs control drug prices and that rebates inflate drug costs. The lawsuit also alleges that the report reflects FTC Chair Lina Khan's longstanding bias against PBMs. ESI seeks injunctive relief, including a declaration that the FTC report is defamatory, removal of the report from the FTC's website, and recusal of Chair Khan from all FTC actions involving ESI.

BREAKING NEWS…

On November 19, 2024, CVS, Cigna, and United sued the FTC, asking the US District Court for the Eastern District of Missouri to issue an injunction to halt proceedings in the FTC's in-house case against CVS Caremark, ESI, and OptumRx regarding insulin rebating practices. The companies argue that the FTC's private administrative forum violates the due process rights under the Fifth Amendment and further involves private rights that should be litigated in federal court.

From the desk of... ML STRATEGIES

The historic election earlier this month has spurred a lot of discussion around how the Trump administration and the Republican-controlled 119th Congress will act on a range of health care issues, including pharmacy benefit manager (PBM) reforms around transparency and pricing models.

During his first administration, President Trump showed his willingness to take on PBMs when he signed an executive order (EO) that would limit rebates paid to PBMs by drugmakers in Medicare. The Trump executive order would have removed safe harbor protections for such rebates under the Anti-Kickback Statute but created new, limited protections for certain point-of-sale discounts. The Trump EO blamed PBMs for the rising drug costs for Medicare patients, who "pay more than they should for drugs while the middlemen collect large 'rebate' checks." Four years later, the official Republican Party platform stated that "prescription drug prices are out of control" and pledges to "increase transparency" and "promote choice and competition" in the health care space.

On Capitol Hill, Republicans in both the House and Senate have supported a number of measures to regulate PBMs, focusing on the PBM pricing model and transparency. Bipartisan bills passed out of the House and a Senate committee would specifically end spread pricing, while other bills that have advanced with bipartisan support would increase transparency by requiring PBMs to publish reports on drug costs, rebates, and formulary placements. While these bills will likely serve as a starting point for the PBM activity in the next Congress, it is possible that legislative action could take place during the current post-election, "lame-duck" session — depending, of course, on whether a bipartisan consensus emerges as part of a broader, end-of-year omnibus appropriations package.

Needless to say, the next Congress will likely consider bipartisan PBM legislation that will focus on increased transparency for and scrutiny of PBMs.

When Republicans take the majority in Congress come January, they may be poised to act on the several bipartisan PBM pieces of legislation that have advanced in both chambers of the current Congress. In the Senate, the Modernizing and Ensuring PBM Accountability Act, introduced by Sen. Ron Wyden (D-OR) and voted 26-1 out of Committee, would prohibit spread pricing in Medicare and delink PBM compensation from the price of a drug in Medicare Part D. The PBM Transparency Act, introduced by Sen. Maria Cantwell (D-WA) and co-sponsored by 10 Republican Senators, would require that PBMs disclose information about rebates, including the amount passed through the plan sponsor, to the FTC. The bill was advanced to the full Senate by an 18-9 vote last year. And last December, the House passed the Lower Costs, More Transparency Act, introduced by Rep. Cathy Morris Rodgers (R-WA) and co-sponsored by Reps. Frank Pallone (D-NJ), Jason Smith (R-MO), and Virginia Foxx (R-NC). The bill would require that PBMs disclose information about rebates, including the amount passed through the plan sponsor, to the FTC. Interested stakeholders should pay close attention to all of these pieces of legislation, as they highlight the bipartisan PBM reform priorities that have emerged in Congress and that may guide the next Congress' activity on PBM reform.

>> **Click here** to access slides from our recent webinar – *Flash Update: What the New Administration and Congress Mean for Health Plans and PBMs*.

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

STATE LEGISLATION AND LITIGATION

Recently Enacted State Legislation

States enacted the following initiatives during the third 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)
Illinois	S.B. 1479: Removes the requirement that a PBM under examination by the state must provide to the Director, or his or her designee, convenient and free access to all books, records, documents, and other papers relating to such pharmacy benefit manager's business affairs at all reasonable hours at its offices.	08/09/2024	01/01/2025
Michigan	S.B. 747: Requires PBMs to file an annual report with the Department containing information from the previous fiscal year, that includes, among other things: (i) the total number of drugs that were dispensed, (ii) the aggregate amount of rebates, discounts, and price concession that the PBM received for each drug on its formulary, (iii) the aggregate amount of administrative fees that the PBM received from pharmaceutical manufacturers, and (iv) the aggregate amount of reimbursements the PBM paid to contracting pharmacies.	07/30/2024	07/30/2024
New Hampshire	S.B. 560: Establishes a committee to study the impact of PBM operations on cost, administration, and distribution of prescription drugs.	07/03/2024	07/03/2024
	S.B. 555: Amends existing law to require PBMs to submit an annual or quarterly report to the Commissioner containing a list of health plans it administered and the rebates collected from pharmaceutical manufacturers that were attributable to patient utilization in the state of New Hampshire during the previous calendar year, as well as other specified information. The bill also requires at least 50% of all rebates be remitted directly to the covered person at the point-of-sale to reduce the out-of-pocket costs and the remainder of the rebates be remitted to the insurer to be applied by the insurer in its plan design and in future plan years to offset the premium of covered persons.	07/26/2024	09/24/2024
New York	S.B. 9040: Expands the "Gag Clause" prohibition, by amending existing law to prohibit PBMs from penalizing or prohibiting pharmacists or pharmacies from disclosing information to individuals, including without limitation, (i) the cost of the prescription medication or service to the individual, (ii) the cost of the prescription medication or service to the pharmacy, and (iii) the pharmacy's reimbursement for that prescription medication or service.	09/27/2024	09/27/2024

Pending State Legislation

The following state initiatives affecting (i) pricing methodology for PBM fees; (ii) PBM contract terms with pharmacies and providers; (iii) PBM contract terms with health insurers; (vi) pharmacy pricing and reimbursement requirements; (v) pharmacy network requirements; and/or (vi) PBM licensure and registration requirements were introduced in the third quarter of 2024.

JULY – SEPTEMBER 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)
Massachusetts	S.B. 2881 H. 4653	S.B. 2881: Introduced on 7/18/24 H. 4653: Committee of conference appointed, in concurrence on 7/24/24						X		X	
	H. 4910	Introduced on 7/24/24	X	X	X	X	X	X	X	X	X
	H.B. 1155	09/05 – House, accompanied a study order			X				X		
California	S.B. 516	08/27 – Pending in Assembly Health Committee							X		

State Law Challenges

As Legislative Efforts to Enact PBM Reform Continue, States Show Signs of Restraint. The first half of 2024 saw a continued trend of state legislative efforts to regulate PBMs. An ongoing analysis conducted by the National Academy for State Health Policy (NASHP) indicates that as many as 173 bills to regulate PBM activity have been introduced across 42 states. At the core of some of these state legislative proposals are efforts to limit or prohibit PBMs from engaging in spread pricing.

"Spread pricing" refers to arrangements in which the PBM's payment to a pharmacy is less than the amount the PBM receives from its client for the same prescription. Spread Pricing has long been decried by the National Community Pharmacists Association (NCPA) as a key contributor to the closure of numerous independent pharmacies across the United States. This past February, the NCPA released the results of a survey of independent pharmacy owners and managers. The survey highlighted some of the financial difficulties independent pharmacies have faced lately. According to the survey, over 99% of pharmacies indicated a reduction in reimbursements for prescribed medicines at the point of sale. The survey also showed that roughly one-third of respondents have considered closing their pharmacy in response to the financial strain. NCPA's report also shows that independent pharmacies are largely placing the blame for low reimbursements on the country's largest PBMs.

Such findings, and continued lobbying from entities such as the NCPA, likely contribute to the consistent state legislative activity surrounding PBM activity. An earlier analysis conducted by NASHP in 2023 found that state laws to regulate PBM activity include some or all of the following provisions:

- Prohibitions of gag clauses on pharmacies
- Limits on patient cost-sharing
- PBM licensing/registration
- Prohibitions on discrimination against non-affiliated or independent pharmacies
- Prohibitions on clawbacks and retroactive denials
- Prohibitions on spread pricing
- Other practices

While plenty of states have charged forward with implementing such restrictions, there are others that continue to debate the best approach to regulate the PBM industry. **Massachusetts**, for example, has debated for well over a year on legislation such as H. 1215. This proposed bill, first introduced in February 2023, seeks to ban spread pricing in the state and would also prohibit PBMs operating in Massachusetts from reimbursing any pharmacy less than the amount the PBM would reimburse to a PBM-affiliated pharmacy. The Massachusetts bill has been championed by pharmacy advocacy organizations such as the National Association of Chain Drug Stores (NACDS). This past June, NACDS joined a coalition media event in Boston to urge state lawmakers to enact PBM reform, including H. 1215. The proposed bill remains pending.

In a surprise to PBM reform advocates, **California** did not join with other states in enacting PBM legislation. California's Senate Bill 966 would have been one of the nation's most comprehensive pieces of PBM reform legislation to date. The bill, which passed the legislature with near unanimous support, was unexpectedly vetoed by Governor Gavin Newsom on September 28, 2024. The vetoed law borrowed heavily from various enacted PBM legislation across the country. If approved, the bill would have established a PBM licensing requirement with the California Department of Insurance, introduced annual PBM reporting obligations, prohibited PBMs from engaging in certain "anticompetitive" practices directed at nonaffiliated and independent pharmacies, including steering patients to use PBM-affiliated pharmacies. The law would have also required the

insertion of certain contractual provisions in agreements between PBMs and health plans, such as a requirement that the PBM pass through 100% of rebates received to the health plan clients.

In a statement released by Governor Newsom alongside the veto, he stated "I believe that PBMs must be held accountable to ensure that prescription drugs remain accessible throughout pharmacies across California and available at the lowest price possible. However, I am not convinced that [Senate Bill] 966's expansive licensing scheme will achieve such results, we need more granular information to fully understand the cost drivers in the prescription drug market and the role that PBMs play in pricing." While the Governor's veto and subsequent statement may come as a surprise because of the bill's strong support in the state legislature, it largely aligns with the "wait and see" approach adopted by federal lawmakers.

Massachusetts and California may ultimately move forward with PBM legislation in the near future, but the current state-level discussions and calls for more research and understanding of the effects of PBM on drug pricing and pharmacy operations offer a seemingly rare glimpse of restraint that may or may not be adopted across other states looking to further expand their own PBM regulation efforts.

State Drug Pricing Activities

PRESCRIPTION DRUG AFFORDABILITY BOARDS

As Colorado and Maryland Prescription Drug Affordability Boards (PDABs) Implement Upper Payment Limits, Cracks Show. Two of the nation's most active PDABs continue to inch towards implementing upper payment limits (UPLs) on drugs identified as unaffordable by their respective committees. However, recent changes to state Medicaid guidance by the federal government may require PDABs to reassess how they conduct and ultimately implement their drug affordability findings.

Colorado's PDAB decided at its July 2024 meeting to pursue UPLs on three of the drugs the PDAB previously designated as unaffordable, Amgen's Embrel, J&J's Stelara, and Novartis' Cosentyx. At its September and October meetings, the PDAB outlined the process for implementing an UPL and the information that the PDAB would utilize to make such a determination. The PDAB confirmed in its meeting materials that it will first make changes to the affordability review rulemaking process and will then begin the rulemaking process for initiating UPLs on the three designated "unaffordable" drugs.

Despite being the first PDAB in the nation, Maryland continues to lag behind its fellow states. In fact, this summer, members of the Maryland PDAB expressed frustration with the PDAB's slower-than-expected cost-review process at one of its public meetings. PDAB Chair Van T. Mitchell was quoted by a state publication as saying, "We've been at this now for four years … I think it's important for us to find a timeline and know exactly whether we're going to hit them or not[.] They're [board members are] at a point where they want to get it across the finish line." In May of this year, Maryland's PDAB had previously selected six drugs as unaffordable. Although the executive director of the PDAB indicated that a timeline for the cost-review process could be ready by November, PDAB members, such as Mitchell, stressed the importance of such a timeline, whenever it is released, being complete and accurate to allow the PDAB to move forward with its business.

One potential snag for state PDABs lies in guidance to states provided by the Centers for Medicare & Medicaid Services (CMS) in the Medicaid Drug Rebate Program Final Guidance released on September 26, 2024. Although the Final Rule dealt primarily with drug manufacturer compliance with the federal drug rebate program, CMS did finalize a proposal that could affect the type of information that state PDABs can consider in their affordability review. The Final Rule required that state Medicaid assessments of professional dispensing fees to pharmacy providers, which are paid in addition to reimbursement for drug ingredient costs and are frequently reviewed by PDABs, "must be based on pharmacy cost data, and [...] cannot be solely determined or supported by a market-based review or by an assessment or comparison of what other payers may reimburse pharmacies for dispensing prescriptions." CMS also clarified that if a state seeks to change the amount by which it reimburses pharmacy providers for drug ingredient costs, those changes not only "must be consistent with [actual acquisition costs], [but] States must support determinations or proposed changes [...] with adequate cost based data." 89 Fed. Reg. at 79062.

This new CMS provision is likely to affect the ability of PDABs to mandate UPLs. Rather than permitting states to adopt a one-size-fits-all approach developed from a broad market-based review, CMS is requiring states to use actual acquisition costs in its determinations and proposed reimbursement changes for Medicaid. It remains to be seen how states will respond to the requirement and how this will affect the affordability review process and associated state reporting requirements.

INSULIN CASES

Sanofi Settles Minnesota Insulin Price Case. Minnesota Attorney General Keith Ellison announced a settlement agreement with Sanofi that requires the drugmaker to offer insulin at no more than $35 per month for five years to Minnesotans whether they have insurance or not. The terms of the settlement were set to take effect within 90 days of July 19, 2024, and the settlement concludes the AG's 2018 lawsuit against Sanofi that claimed the drug manufacturer "deceptively priced" its insulin products. The settlement, which mirrors a similar agreement Minnesota reached with Eli Lilly earlier this year, includes provisions for patients to enroll in savings programs and receive information about low-cost insulin options. The settlement is part of a broader litigation effort by Minnesota against insulin manufacturers for alleged price inflation. The state's case against Novo Nordisk, which along with Sanofi and Eli Lilly produces roughly 90% of the global insulin supply, is still ongoing.

California's Case against CVS Caremark and ESI Regarding Insulin Prices Will Remain in Federal Court. The Ninth Circuit Court of Appeals ruled that California's case against CVS Caremark and ESI will proceed in federal court, reversing a US district court's order to keep the case in state court. The decision is the latest procedural development in the California's AG case against CVS Caremark and ESI, brought in January 2023, for allegedly inflating the price of insulin. After the case was filed, the PBMs removed the case to federal court, citing the federal officer removal statute and the work they do for federal government health programs. California objected to the move, arguing that its case was not challenging the work the PBMs did in connection with federal health programs. In June 2023, a federal district court sided with California, sending the case back to state court, while the PBMs appealed the decision to the Ninth Circuit. Now, the Ninth Circuit has sent the case back to the district court to analyze California's arguments for remanding to state court.

OTHER INDUSTRY NEWS

OPIOID SUITS AGAINST PBMs

We continue to track the ongoing litigation governments at the federal, state, and municipal levels have brought against PBMs for their alleged contribution to the national opioid crisis.

Pending Lawsuits

In September, Kentucky's Attorney General filed a complaint against ESI alleging that ESI worsened the opioid crisis in Kentucky by colluding with drug manufacturers in deceptive marketing of opioids and failing to limit the amount of opioids prescribed amidst the opioid crisis. Specifically, the Kentucky AG contends that ESI encouraged the use of opioids by placing opioids on its national "self-serving" formulary and through its lack of utilization management tools to restrict prescribing and dispensing. The complaint alleges that ESI had knowledge and data regarding the opioid crisis that "provided [ESI] with the extraordinary ability to control the opioid supply through the United States."

An ongoing multidistrict opioid case sitting in Ohio federal court, *In Re: National Prescription Opiate Litigation*, proceeds as the federal judge overseeing the litigation denied a joint motion to dismiss from PBM-defendants, ESI and OptumRx. Previously, both the PBM-defendants and the municipality-plaintiffs filed motions alleging that both parties failed to maintain and destroyed evidence pertaining to four bellwether cases. Although the federal judge has yet to respond to these discovery allegations, the federal judge denied a motion to dismiss by the PBMs on August 22, 2024. In their motion, the PBMs alleged that the municipalities' federal racketeering (RICO) and state law claims are time-barred by the legal statutes of limitations. The court found that the PBMs' time-bar contentions were not supported by an adequate record at this point in the litigation because the plaintiffs showed they were unable to discover important facts fundamental to their arguments, noting that the municipalities will have to demonstrate "new harms 'over and above' any the plaintiffs sustained prior to the limitations period" at later stages. The PBMs further argued that the municipalities failed to allege direct injuries to business or property. The judge emphasized that "at this stage," plaintiffs have sufficiently shown injury but will later be tasked with identifying specific properties to prove diminished value. The case remains in discovery, and we expect to see more substantive determinations at the summary judgment stage.

Recent Settlements

Baltimore Settlement(s) with CVS and Cardinal Health. On August 9, 2024, the city of Baltimore and CVS reached a $45 million settlement for CVS' alleged role in distributing hydrocodone and other opioid prescriptions to its Baltimore pharmacies between the years 2006 and 2014. Under the terms of the settlement agreement, CVS must pay the entire settlement amount by the end of the year.

Also in August, Baltimore announced another opioid-related settlement with Cardinal Health, resulting in a $152.5 million payment from Cardinal Health. In Baltimore's case against both defendants, it alleged that as distributors of opioid medications, defendants failed to limit fraudulent or suspicious distribution and thus escalated the widespread opioid use in the city. The city has committed to using the settlement recoveries to address the opioid crisis, allocating funds to various substance-use treatment centers and community organizations throughout the city. Baltimore has received a total of $242.5 million in recoveries from the two settlement agreements and an earlier settlement with Allergan this summer.

OTHER CASES AGAINST PBMS

Vermont Joins the List of States Suing PBMs for Driving Up Prescription Drug Costs. In July 2024, Vermont filed suit against CVS and ESI for inflating the costs of prescription drugs by giving preferred formulary placement to drug manufacturers that paid substantial amounts of money in the form of rebates. The lawsuit further alleges the companies' actions violated Vermont's Consumer Protection Act by misrepresenting that their practices lower the cost of prescription drugs.

At least five other states have filed similar lawsuits in an attempt to recoup money for the residents of their states, and more than 70 lawsuits from cities and counties in Maryland, Tennessee, New York, and other states have been consolidated into multidistrict litigation against PBMs for their role in rising prescription drug costs and failure to pass through rebates. CVS has reiterated that drug manufacturers are solely responsible for setting the prices of their drugs and that consumers would pay much higher prices for their drugs if CVS Caremark, as the PBM, did not go "head-to-head with drug manufacturers." That said, CVS recently agreed to pay Illinois a $45 million settlement over claims that it did not pass through manufacturer rebates to the state over a four-year period.

AIDS Healthcare Foundation Sues ESI. In July 2024, AIDS Healthcare Foundation, the world's largest HIV/AIDS health care organization, brought a lawsuit alleging that ESI and its specialty pharmacy Accredo, deliberately sought to destroy competition from specialty pharmacies by (i) using unattainable rebate programs; (ii) using "opaque, complex, and conditional" contract terms meant to obscure the true cost of the drugs from the specialty pharmacies until well after the point of sale; (iii) enforcing arbitrary contract terms on specialty pharmacies while knowing that the pharmacies have no alternative to the PBM given the PBM's large market share; and (iv) providing advantages to Accredo.

Government Intervention in *PCMA v. Mulready*. On October 7, 2024, the Supreme Court of the United States (SCOTUS) requested the US solicitor general file a brief in *PCMA v. Mulready*, a move that could signal SCOTUS is gearing up to hear the case. As noted in our last PBM Update, in May 2024, 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 argued 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. In its opposition brief filed in July 2024, PCMA argued that Oklahoma's bid for review was based inappropriately on (i) an inaccurate reading of the Court's ruling in *Rutledge v. PCMA* and (ii) "the Tenth Circuit's description of the act and how it works." Oklahoma's insurance commissioner filed a reply brief in August 2024, arguing that nothing in the Oklahoma law should have been preempted by ERISA and that the Tenth Circuit's decision "stretches ERISA preemption far beyond its breaking point." SCOTUS's decision to hear this case could lead the Court to refine and more clearly define the applicable legal standards to be used when considering ERISA and Part D preemption challenges. As such, we will continue to monitor this case closely.

Audit Finds ESI Overcharged USPS. A federal audit found that ESI overcharged USPS employees by $45 million, primarily by withholding drug rebates that were contractually owed to the workers' health plan. This report highlights concerns over PBMs' impact on drug pricing, with ESI agreeing to refund the rebates.

INDUSTRY-RELATED NEWS

Plans and Employers Shift Toward Smaller PBMs, Start-ups. Health plans and employers are leveraging the power of smaller PBMs, PBM start-ups, or both to support their prescription drug benefits plans. For example, Tyson Foods, based in Arkansas, reportedly made the leap from CVS Caremark to Rightway to manage rising drug costs. Founded in 2017, Rightway is a full-service PBM. Tyson Foods told *CNBC* that its gamble is paying off, citing Rightway's lower costs and enhanced customer service experience. Despite this marked shift in the PBM market status quo, smaller PBMs may not be able to solve for every customer need: For example, smaller PBMs may still be reliant on a Big 3–owned GPO to negotiate rebates, *Drug Channels* reports. The impact of this changing market paradigm could increase the potential for more competitive offerings.

Boehringer Ingelheim Partners with GoodRx. In July, Boehringer Ingelheim announced an exclusive patient affordability initiative with GoodRx for Cyltezo, Boehringer's biosimilar to Humira. Boehringer is offering its biosimilar at a 92% discount exclusively to patients who buy the product on GoodRx. Cyltezo is the first biosimilar that GoodRx is offering at a discounted price system.

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