MINTZ

WINTER 2024

PBM

Policy and Legislative Update

TABLE OF CONTENTS

Page

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. Our team actively monitors these developments to provide you with this quarterly *PBM Policy and Legislative Update*. This *Winter 2024* update builds on prior issues and highlights federal and state activity from October, November, and December 2023. We also highlight a few of the major changes that have already occurred in 2024 in the *Since we went to publication…* section at the end of the *Update.* We will provide discussion on these updates and more in the *Spring 2024 Update*.

FEDERAL LEGISLATIVE ACTIVITY

Five more bills were introduced during the last quarter of 2023, for a total of 23 federal legislative initiatives directly targeting the PBM industry and PBM-related practices introduced in 2023. This is in addition to the many legislative initiatives targeting issues adjacent to the PBM industry such as drug pricing, opioid dispensing practices, and the 340B program, to name a few. In addition to the newly proposed legislation, several bills introduced earlier in the year moved forward through the legislative process, as outlined below. One thing was clear in the last quarter of 2023: lawmakers were firing on all cylinders to advance PBM legislation. But this all came to an abrupt halt in early 2024 with several reports out of Washington that Congress did not include any PBM-related reforms in the proposed federal government funding package. As we will discuss in further detail in our *Spring 2024 Update,* legislative priorities shift frequently and focus on the PBM industry will likely be renewed later in the legislative calendar. Below is a summary of federal legislative activity from October – December 2023.

- **Delinking Revenue from Unfair Gouging Act (H.R. 6283).** On November 8, 2023, Representatives Mariannette Miller-Meeks (R-IA), Nanette Diaz Barragan (D-CA), Lori Chavez-DeRemer (R-OR), Kathy E. Manning (D-NC), Nicole Malliotakis (R-NY), Bradley Scott Schneider (D-IL), Thomas H. Kean (R-NJ) and Abigail Davis Spanberger (D-VA) introduced the **Delinking Revenue from Unfair Gouging (DRUG) Act**, largely a companion bill to **S. 1542**, which we reported on in our ***Summer 2023 Update***. Taking a slightly different approach to the language, the House DRUG Act would, among other things, prohibit PBMs from deriving "remuneration from any entity for services, benefit administration or any other activities related to prescription drugs." However, the law would permit PBMs to charge flat bona fide services fees that are not directly or indirectly based on drug price, rebates, or other amounts prohibited by the Secretary. Like the Senate bill, the House DRUG Act would further prohibit PBMs from engaging in (i) spread pricing, (ii) paying a PBM-affiliated pharmacy more than an independent or unaffiliated pharmacy for the same service, and (iii) steering patients to PBM-owned, controlled, or affiliated pharmacies. The bill proposes to enforce its provisions by imposing a $10,000 civil monetary penalty for each day during which a PBM violates this law.

- **A bill to require the Secretary of Labor to conduct a study on the fiduciary duties of pharmacy benefit managers (S. 3330).** On November 15, 2023, Senators Mike Braun (R-IN), Margaret Wood Hassan (D-NH), Roger Marshall

(R-KS), Ted Budd (R-NC), Tim Kaine (D-VA), and Ben Ray Lujan (D-NM) introduced a bipartisan bill to require the Secretary of Labor to study and report to Congress on the impact of a change in policy whereby PBMs would be considered fiduciaries under ERISA. As fiduciaries under this policy, PBMs would be permitted to retain bona fide service fees, provided such bona fide service fees are not (i) based on drug price or drug benchmark price, (ii) based on discounts, rebates, fees or other remuneration, or (iii) otherwise determined by the Secretary to be unreasonable.

- **Ensuring PBM Competition Act (H.R. 6844).** On December 15, 2023, Representative Claudia Tenney (R-NY) introduced the **Ensuring PBM Competition Act**, which would prohibit Part D prescription drug plan sponsors from contracting with PBMs that directly or indirectly own, control, or have a financial interest in a pharmacy.

- **Prescription Drug Rebate Reform Act of 2023 (H.R. 6856).** On December 19, 2023, Representative Mike Gallagher (R-WI) introduced a bill that seeks to reform prescription drug pricing and reduce consumer out-of-pocket prescription drug costs at the pharmacy counter. If enacted, the **Prescription Drug Rebate Reform Act of 2023** would require group health plans and health insurance issuers to base a member's coinsurance obligations for covered drugs on such drug's net price, which is defined under this bill to mean the list price of the drug net of all prospective and retrospective rebates, discounts, concessions, and other adjustments applied to the amount paid by a PBM or a plan for such drug. As proposed, this bill would go into effect on January 1, 2025.

- **Health Care Prices Revealed and Information to Consumers Explained Transparency Act (S. 3548).** On December 14, 2023, Senators Mike Braun (R-IN), Bernie Sanders (I-VT), Tina Smith (D-MN), and John W. Hickenlooper (D-CO) introduced a bipartisan bill aimed at providing hospital and insurer price transparency. If enacted, the "**Health Care PRICE Transparency Act 2.0**" would generally impose additional transparency requirements on a variety of health care providers and health plans, including the requirement to make publicly available the rate and payment information for medical and pharmacy services, including, as it pertains to prescription drugs, the in-network rates for drugs, the historical net price paid by health plans for such drugs, and the amount billed or charged by providers for such drugs. Additionally, a small part of the bill specifically addresses PBM transparency under ERISA, proposing for contracts or arrangements between group health plans and other entities (i.e., PBMs) to require the entities to enable group health plan access to all claims and encounter information, and, among other things, not limit (i) access to the claims and encounter information, (ii) disclosure of overpayment and overpayment recovery terms, (iii) disclosure of fees charged to group health plans related to plan administration and claims processing, and (iv) the right of the group health plan to select an auditor or define audit scope or frequency. As proposed, this bill would go into effect on January 1, 2025.

Fourth Quarter Updates on Previously Reported Federal Bills

The Lower Costs, More Transparency Act (H.R. 5378) was passed via a House vote on 12/11/2023. 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" preventing the group health plans or PBMs from meeting their reporting requirements.

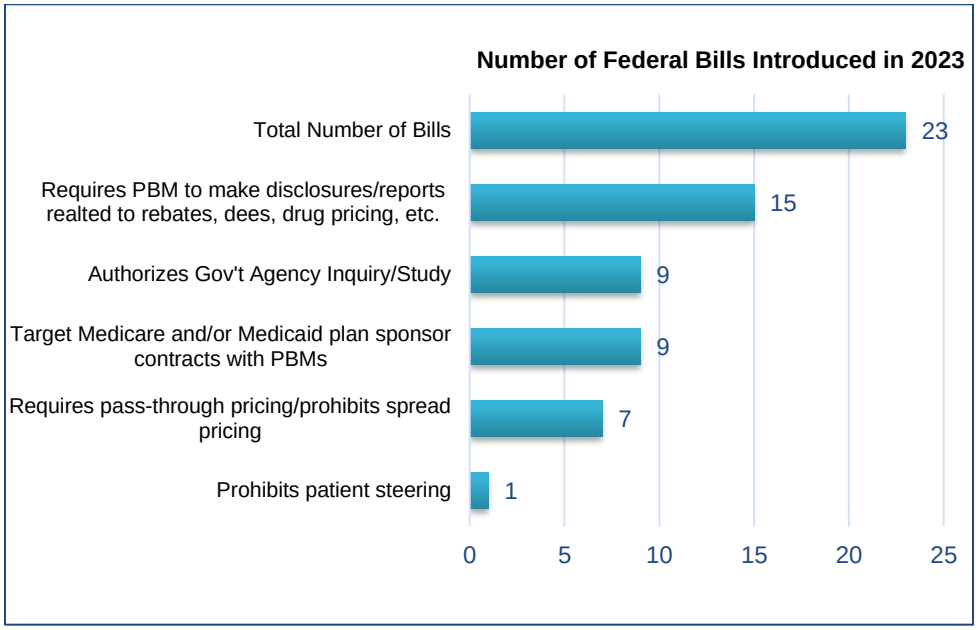
The Modernizing and Ensuring PBM Accountability (MEPA) Act (S. 2973), was amended for small clerical changes and placed on the senate legislative calendar. If enacted, the MEPA Act would, among other things, (i) require that contracts between PDP Sponsors and a PBM meet certain requirements starting in plan year 2026, (ii) require the HHS Secretary to institute standard Part D measures for assessing network pharmacy performance; (iii) ban PBM spread pricing in the Medicaid program; and (iv) require the HHS OIG to investigate the impact of vertical integration between PDP, PBMs, and pharmacies on beneficiary out-of-pocket costs and Medicare spending under the Part D program.

The Medicare PBM Accountability Act (H.R. 5385) was marked up and reported out of the House Committee on Energy and Commerce in December 2023. If enacted, this bipartisan bill 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).

The Pharmacy Benefit Manager Transparency Act of 2023 (S.127), was amended and reported to the Senate on 12/13/2023. If enacted, this bill would, among other things, prohibit PBMs from (i) clawing back reimbursement payments (amended to exempt situations in which the original claims were fraudulent, in violation of the applicable contract, or based upon services not rendered by a pharmacy or pharmacist), and (ii) increasing fees or lowering reimbursements to pharmacies to offset changes to federally funded health plans. The amendment to the bill also stipulated that its corresponding annual commission report should include an analysis of the Act's effects on PBM mergers, competition, and monopolies in the PBM space.

2023 Federal Legislative Activity

As we noted, there were more than 23 federal legislative initiatives directly targeting the PBM industry and PBM-related practices introduced in 2023. Many of the proposals overlap, with the goal of regulating the industry via transparency requirements, government studies, and targeted requirements for a variety of PBM relationships. The next two charts provide highlights from the proposals being considered at the federal level.



Bill Name	Requires Pass-Through Pricing/ Prohibits Spread Pricing	Prohibits Patient Steering	Requires PBMs to Make Disclosures/Reports related to Rebates, Fees, and/or Drug Cost, etc.	Impacts Medicare and/or Medicaid Plan Sponsor Contracts with PBMs	Authorized Govt Agency to Investigate, Regulate, Study, and/or Publish Information about PBMs
Better Mental Health Care, Lower-Cost Drugs, and Extenders Act of 2023				X	
Delinking Revenue from Unfair Gouging Act	X	X			
Drug Transparency in Medicaid Act of 2023	X				
Ensuring PBM Competition Act				X	
Health Care Prices Revealed and Information to Consumers Explained Transparency Act			X		
Health Data Act of 2023			X		
Hidden Fee Disclosure Act of 2023			X		
Lower Costs, More Transparency Act	X		X		X
Medicare PBM Accountability Act			X	X	X
Modernizing and Ensuring PBM Accountability Act			X	X	X
Neighborhood Options for Patients Buying Medicines Act				X	
Patients Before Middleman Act				X	
Pharmacy Benefit Manager (PBM) Transparency Act of 2023	X		X		X
Pharmacy Benefit Manager Reform Act	X		X		X
Pharmacy Benefit Manager Sunshine and Accountability Act			X		X
Pharmacy Benefits Manager Accountability Act			X		X
Prescription Pricing for the People Act of 2023					X
Promoting Access to Treatments and Increasing Extremely Needed Transparency Act of 2023	X		X		X
Protect Patient Access to Pharmacies Act				X	
Protecting Patients Against PBM Abuses Act	X		X	X	
Strengthening Pharmacy Access for Seniors Act			X	X	
The Health Care Price Transparency Act of 2023			X		
Transparency in Coverage Act of 2023			X		

Enforcement Activity and Litigation

United and Optum Under Increased Scrutiny Related to Antitrust Concerns

As **reported** by the Wall Street Journal on February 27, 2024, the U.S. Department of Justice launched an antitrust investigation into UnitedHealth Group. According to individuals familiar with the investigation, DOJ conducted interviews of groups in the healthcare industry where UnitedHealth operates. Investigators have purportedly asked about the relationship between UnitedHealthcare insurance unit and its Optum health services arm, which offers several healthcare services including pharmacy benefit management, financial consultation, and mental health support.

This DOJ investigation is in addition to a class action lawsuit filed in December by Osterhaus Pharmacy Inc., an independent pharmacy in Iowa, alleging that OptumRx engaged in an illegal scheme that ties access to its Medicare Part D beneficiaries to the payment of fees for the opportunity to provide prescription services. The Plaintiff's had previously filed a lawsuit in September 2023 against CVS Pharmacy alleging similar claims. The lawsuit is believed to have been part of an effort to pressure government officials to increase scrutiny over PBM relationships and practices.

Elk River Pharmacy Inc et al v. Express Scripts Inc et al. Four retail pharmacies filed an antitrust **class action lawsuit** in October 2023 claiming that ESI and Prime engaged in price-fixing with respect to reimbursement rates and fees. The complaint argues the two PBMs entered into an agreement in 2019 effectively eliminating competition and reducing quality and convenience of pharmacy services to consumers without economic benefits. The retail pharmacies allege that the PBMs agreed to set reimbursement rates and transaction fees at ESI's more competitive prices while Prime transferred its commercial and Medicaid networks to ESI; however, the pharmacies claim that the transition of Prime's networks to ESI was merely "euphemistic and in name only." The complaint asserts that the product and geographic market power of the PBMs derived from the 2019 agreement violates federal antitrust law under the Sherman Act.

STATE LEGISLATION AND LITIGATION

Recently Enacted State Legislation

There were only two states initiatives enacted during the fourth quarter of 2023 that 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)
California	S.B. 786: Prohibits a PBM from discriminating against a covered entity and certain pharmacies 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.	10/07/2023	1/1/2024
Michigan	H.B. 4276: restricts the department from contracting with a Medicaid MCO that relies on a PBM that does not, among other things, agree to (i) reimburse a claim at or above the rate in effect at the time of POS, (ii) move to a transparent pass-through pricing model, (iii) not create new pharmacy administration fees or increase current fees more than the rate of inflation. In addition, the law requires PBMs who receive reimbursement, either directly or through Medicaid contracted health plan, to disclose to the department by January 15th of each year certain drug-related information for the previous fiscal year, including but not limited to: (i) the total number of prescriptions dispensed, (ii) the aggregate WAC for each drug on its formulary, (iii) the aggregate amount of rebates, discounts, and price concessions that the PBM received for each drug on its formulary, (iv) the aggregate amount of administrative fees that the PBM received from all pharmaceutical manufacturers, (v) the aggregate amount of reimbursements the PBM pays to contracting pharmacies, and (vi) any other information considered necessary by the department.	12/8/2023	2/13/2024

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 third quarter of 2023.

State	Description of Measure(s)	Most Recent Status(es)
Florida	S.B. 228: Proposes to require health insurers and their PBMs to (i) apply payments by or on behalf of an insured toward the insured's total contribution to any cost-sharing requirement, and (ii) disclose this policy on their website. These requirements would apply to any policy issued, delivered, or renewed after January 1, 2025. H.B. 363: Similarly proposes to, among other things, require PBMs and health insurers that provide prescription drug coverage in the state of Florida to apply any amount paid for a prescription drug by or on behalf of an insured person, including but not limited payments through financial assistance, manufacturer copay cards, product vouchers, or any other out-of-pocket expense reductions, toward such person's total contribution to any cost-sharing requirement if the prescription drug (i) does not have a generic equivalent or (ii) has a generic equivalent and the insured person obtained certain authorizations for such prescription drug.	Referred to Banking and Insurance, Health Policy, and Appropriations Committees on 11/07/2023. In Select Committee on Health Innovation on 11/22/2023.
Massachusetts	S.B. 2520: Proposes to, among other things, (i) define "PBM"; (ii) require PBM licensure for contracting with health carriers; (iii) require PBMs to provide notice of conflicts of interest with health carriers; (vi) prohibit PBMs from making payments to a pharmacy benefit consultant or broker if the payment constitutes a conflict of interest as determined by the commissioner; (iv) require that health carriers that contract with a PBM perform an audit of the operations of such PBM every three years to ensure compliance with the law and to examine pricing and rebates applicable to prescription drugs that are provided to such carrier's members. The bill also proposes to require PBMs to submit data and report information to the Massachusetts Center for Health Information and Analysis in accordance with the standards and methods specified by the Center.	Read and referred to the committee on House Ways and Means on 11/20/23.

State	Description of Measure(s)	Most Recent Status(es)
Michigan	H.B. 5338: Proposes to amend certain sections of the previously enacted "Pharmacy Benefit Manager Licensure and Regulation Act" by, among other things, (i) modifying the definitions of (a) PBM, (b) rebate, and (c) spread pricing, and (ii) adding a new section that (x) prohibits PBMs from disclosing certain information regarding rebates and products that qualify as trade secrets and (y) outlines penalties for violations of the act.	Introduced on 11/14/2023.
Missouri	S.B. 1105/H.B. 1627/S.B. 843: Proposes to, among other things, (i) prohibit PBMs from penalizing or restricting covered persons from obtaining services from contracted pharmacies; (ii) require PBMs to owe a fiduciary duty to the entities with which it contracts; (iii) specify that no entities contracting with pharmacies to sell, provide, pay, or reimburse pharmacies for prescription drugs shall prohibit a plan sponsor or a contracted pharmacy from discussing any health benefit plan information or costs; (iv) prohibit PBMs from charging a health benefit plan or payer different amounts for prescription drugs' ingredient costs or dispensing fees than the PBM reimburses the pharmacy for such costs if the PBM retains any amount of the difference; and (v) prohibit PBMs from reimbursing a pharmacist or pharmacy in the state an amount less than the amount that the PBM reimburses a PBM affiliate. S.B. 1106/S.B. 1190/H.B. 1628/S.B. 844: Proposes to amend Section A Chapter 376 RSMo by defining cost-sharing, outlining requirements for calculating an enrollee's overall contribution to any out-of-pocket maximum or cost-sharing requirement, and specifying that nothing in the section prohibits step therapy. S.B. 751: Proposes to prohibit PBMs from, among other things, imposing any penalty, impediment, differentiation, or limitation on (i) a participating provider for obtaining clinician-administered drugs from an out of network provider, including paying such participating provider less than the contracted payment amount, (ii) a covered person for receiving clinician-administered drugs from a participating provider that obtains such drugs from an out of network provider, including interfering with a covered person's ability to obtain such drugs from the covered person's provider or pharmacy of choice, (iii) any pharmacy that is dispensing medically necessary clinician-administered drugs regardless of whether the participating provider obtains such drugs from an out of network provider. Additionally, the bill proposes to require PBMs that provide coverage for a reference product or a biological product that is biosimilar to provide coverage for the reference product and all biological products that have been deemed biosimilars.	Prefiled on 12/01/2023. Each prefiled on 12/01/2023. Prefiled on 12/01/2023.

State	Description of Measure(s)	Most Recent Status(es)
	S.B. 1213: Proposes to, among other things, (i) require PBMs to sustain an appeal and increase reimbursement to a pharmacy to cover the cost of purchasing the drug if a reimbursement to such contracted pharmacy is below the pharmacy's cost to purchase the drug, and (ii) annually require health carriers to submit a written certification that the health carrier accounted for all pharmaceutical rebates in calculating premiums for health benefit plans, whereby rebates are defined as any discount, negotiated concession, or other payment provided by a pharmaceutical manufacturer, pharmacy, or other entity in the state for the dispensation or administration of a prescription drug on behalf of itself or another entity.	Prefiled on 12/01/2023.
New Hampshire	S.B. 354: Proposes to, among other things, require PBMs and insurers in certain circumstances to include any amounts paid by or on behalf an enrollee when calculating such enrollee's overall contribution to any cost-sharing requirements.	Introduced on 12/11/2023; to be reintroduced 1/03/2024 and Referred to Health and Human Services.
	S.B. 555: Proposes to revise the annual reporting requirement for PBMs regarding pharmaceutical rebates to include information on the aggregate number of rebates and total value received by the PBM and distributed to health insurers, and the individual and aggregate amounts paid by health insurers to PBMs for pharmacy services itemized by pharmacy, by product (at the NDC level), and by goods and services, among other required reports. The bill further proposes to require that at least 50% of all rebates remitted to a PBM or a health insurer related to prescription drug benefits are remitted directly to the covered members at the point of sale for specific prescription drugs.	Introduced on 12/14/2023. To Be Introduced 1/03/2024 and Referred to Health and Human Services.
New Jersey	S.B. 3604: Proposes to, among other things, 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 for a prescription drug, even if the covered person maintains health insurance coverage. The bill proposes to define "healthcare platform" as an internet-based service through which a consumer, who may or may not have separate health insurance coverage, may set-up an account or become a member to obtain discounts on prescription or non-prescription drugs or devices and through which other services, including telemedicine, may be provided.	Passed Senate on 12/21/23

State	Description of Measure(s)	Most Recent Status(es)
New York	A.B. 7197: In addition to certain requirements for PBMs participating in Medicaid or Medicaid managed care, proposes to prohibit PBMs from limiting an individual's option to receive prescription or over-the-counter medications from non-mail order pharmacies via in-person delivery or through other mail or courier services, regardless of the individual's choice in delivery type or distance from such non-mail order pharmacy.	Enacting clause stricken on 10/13/2023.
Oklahoma	S.B. 1390: Proposes to amend the Oklahoma Patient's Right to Pharmacy Choice Act by, among other things, (i) adding a definition of "Pharmacy Benefits Management" which shall mean a service provided to covered entities to facilitate the provision of prescription drug benefits to covered individuals within the state, including, but not limited to, negotiating pricing and other terms (i.e., rebates) with drug manufacturers and providers, and (ii) expanding the rights of the Attorney General to investigate potential violations of state laws and regulations by PBMs, including through the use of protected health information, and by, among other things, allowing the Attorney General to set penalties for a PBM's violation of the law, including restitution for economic loss suffered by pharmacies or patients due to such violation.	Published on 12/15/2023 to be introduced on 02/05/2024.
Wisconsin	A.B. 626/S.B. 705: Proposes to, among other things, prohibit a PBM from penalizing a pharmacy or pharmacist for dispensing a prescribed drug or device that is prescribed for a use other than a use approved by the federal Food and Drug Administration if the prescribed drug or device is dispensed pursuant to a valid prescription order. S.B. 719/A.B. 748: Proposes to, among other things, (i) impose fiduciary and disclosure requirements on PBMs (such as, but not limited to, annually reporting of indirect profits and payments to consultants or brokers and amounts received from drug manufacturers that are retained by PBMs and not passed through to health plans) and (ii) require the commissioner to develop a pilot project under which a PBM and pharmaceutical manufacturer are directed to create a cost-reducing arrangement for prescription diabetes medication.	A.B. 626 – Read first time and referred to Committee on Health, Aging and Long-Term Care on 11/08/2023. S.B. 705 – Read first time and referred to Committee on Health on 11/21/2023. S.B. 719 – Fiscal estimate received on 12/11/2023. A.B. 748 – Fiscal estimate received on 12/18/2023.

State	Description of Measure(s)	Most Recent Status(es)
	S.B. 737/A.B. 773: Proposes to, among other things, (i) require PBMs to pay a pharmacy or pharmacist a professional dispensing fee at a rate not less than is paid by the state under the state's medical assistance program for each pharmaceutical product that the pharmacy/pharmacist dispenses to an individual; (ii) prohibit PBMs from assessing, charging, or collecting any form of remuneration that passes from a pharmacy/pharmacists to a PBM including claim-processing fees, performance-based fees, network-participation fees, or accreditation fees; (iii) restrict PBMs from using any certification or accreditation requirements as determinants of pharmacy network participation that is inconsistent with or more stringent than federal requirements for licensure as a pharmacy and requirements for licensure under state law; and (iv) require PBMs to allow a participant/beneficiary of a pharmacy benefits plan that the PBM manages to use any pharmacy/pharmacist in this state that is licensed by the state; and (v) prohibit PBMs from charging different copayments, or additional fees, or providing incentives to beneficiaries, for the use of a pharmacy/pharmacist in a particular network. The bill also proposes certain requirements for a PBM's use of maximum allowable cost lists, including but not limited to setting limitations on pharmaceutical products that PBMs may place on a maximum allowable cost list; and requires PBMs that use maximum allowable cost lists to provide a process for appeals and dispute resolution for pharmacies/pharmacists. S.B. 807/A.B. 836: Proposes to prohibit PBMs, insurers, and utilization review organizations from requiring step therapy protocols for certain drugs prescribed for metastatic cancer or a cancer-associated condition.	S.B. 737 – A public hearing was held on 12/6/2023. Fiscal Estimate received on 12/18/2023. S.B. 807 - Read first time and referred to Committee on Insurance and Small Business on 12/12/2023. A.B. 836 - Read first time and referred to Committee on Health, Aging and Long-Term Care on 12/22/2023.

State Law Challenges

PCMA v. Mulready. The State of Oklahoma has pursued various avenues to overturn the 10th Circuit's August 2023 **decision** in *PCMA v. Mulready*, in which a three-judge panel found that certain portions of a 2019 Oklahoma statute regulating PBMs were preempted by ERISA and Medicare Part D,. In addition to preparing to file a certiorari petition with the Supreme Court, the State has also (i) petitioned for the full 10th Circuit to rehear the case, and (ii) filed a motion requesting that the panel stay its mandate certifying the preemption decision until the Supreme Court has an opportunity to hear the case. The latter request would have allowed Oklahoma to continue enforcing the challenged provisions against ERISA and Medicare Part D plans while the Supreme Court considered the State's certiorari petition. But both requests were denied by the 10th Circuit. Thus, at this time, the 10th Circuit panel's ruling remains in effect and the State will not be able to enforce the challenged provisions against ERISA or Medicare Part D plans located in the state. Oklahoma has not yet filed its certiorari petition with the Supreme Court and it remains uncertain whether the Court will choose to hear the case.

Employer Health Plans May Prefer Federal Legislation to a Patchwork of State Laws. As the number of states enacting laws in the wake of *Rutledge,* concerns have grown among employer health plans who fear that they will soon face a patchwork of regulatory requirements. At the heart of this concern is the idea that undermining ERISA preemption "would be catastrophic for ERISA-governed self-insured health plans and could potentially have destructive impacts on ERISA-governed retirement plans as well," as outlined in a **letter sent** by employer groups to Senate Committee on Health, Education, Labor and Pensions (HELP) Chair Bernie Sanders (I-Vt.) and ranking member Bill Cassidy (R-La.) in September 2023.

In a statement given to **Bloomberg Law**, PCMA explained that, "[w]ithout strong preemption protections, inconsistent and often conflicting state policies would raise costs and administrative burdens for employers and health plans." The organization further added that increased regulation would mean that, "[i]n turn, workers and their families would be exposed to increased premiums and cost sharing, decreased benefits, and stagnant wages."

It is possible, given the developments in *Mulready,* that state legislative activity could slow. In fact, Glen Mulready, the Oklahoma Insurance Commissioner at the heart of the *Mulready* decision noted in an interview that states may be on a "little bit of a stand down" with respect to passing their own legislation or pushing legal challenges.

State Litigation

City of Boston Claims that ESI Fueled Opioid Epidemic. On the heels of other similar lawsuits, the city of Boston filed a **complaint** January 12, 2024, against Express Scripts (ESI) and OptumRx, alleging the PBMs' preferential treatment of opioid drugs on their formularies, purportedly for the PBM's financial gain, caused a public nuisance to the city of Boston. The complaint goes on to claim that ESI and OptumRx knew of and ignored illegitimate prescribing and sales of opioid drugs to boost profits, placed opioids on their formularies with preferred status and without limits on approval for their use, and colluded with Purdue Pharma to deceptively market opioids to increase sales of the drugs in exchange for rebates. The PBMs, according to the city of Boston, are at fault given their access to data indicating diversion, misuse, and abuse of opioids and their utilization review tools in place to address these specific instances, placing them with unique knowledge.

Insulin Cases

As we have been following, state and local governments continue to explore all avenues to lower insulin costs, including (1) litigation against manufacturers and PBMs, and (2) insulin price caps. As of December 13, 2023, more than 40 lawsuits in 20 states allege that drug manufacturers and PBMs have illegally inflated the price of insulin through deceptive pricing practices. These cases have recently been consolidated in a federal court in New Jersey. Attorneys watching these cases view them as a more effective way to reform drug pricing than federal legislation, which has stalled in Congress.

Below we summarize recent updates in the flurry of state and local activity aimed at insulin prices:

Eli Lilly and Minnesota AG Agree to Settle in Insulin Price Case. In Minnesota, Eli Lily's insulin products may soon be available for no more than $35 per month. A **proposed settlement agreement** between Eli Lily and the state's AG, if accepted by a court, would end a 2018 case brought by the AG alleging that Eli Lily, along with Novo Nordisk and Sanofi, inflated the price of insulin and paid PBMs large rebates in exchange for favorable formulary treatment of their insulin products. Under the agreement, which resembles an agreement made by New York's AG with the three aforementioned drug companies last year, Eli Lily's insulin products would be available for $35 per month for all Minnesotans with or without insurance.

Utah Joins Other States with its New Lawsuit. On November 16, 2023, Utah's Attorney General and the Division of Consumer Protection filed a **lawsuit** against the leading insulin manufacturers – Eli Lilly, Novo Nordisk, and Sanofi – and the PBMs they contract with – CVS Caremark, Express Scripts, and OptumRx – alleging that the parties conspired to raise the price of insulin by 1000% over the past decade. According to the complaint, the insulin manufacturers and PBMs used deceptive pricing practices to illegally inflate the price of insulin. The drug manufacturers are alleged to have raised the list price of insulin and paid a portion of the higher price to PBMs, who in exchange gave the insulin products favorable formulary treatment.

State Limits on Insulin Pricing. In addition to lawsuits, state insulin price caps are another tool increasingly used by states in their efforts to make insulin more affordable for patients. Lawmakers in Wisconsin recently introduced legislation to cap insulin copayments at $35 per month, joining the 25 states that have instituted insulin copayment caps for commercial health plans. While drug pricing analysts view state insulin caps as an effective means of making insulin more affordable for patients, analysts point out that the caps do not address the factors that may be inflating the price of insulin, including, they allege, pricing schemes between drug manufacturers and PBMs. Furthermore, analysts contend that the caps do not go far enough, because they don't extend to people with no insurance or who get insurance from a non-state-regulated commercial plan.

Other State Activities

State Drug Affordability Boards. While the federal government takes aim at negotiating high drug prices in the Medicare program, state prescription drug affordability boards (PDABs) in at least nine states (CO, MD, ME, MI, MN, NH, OH, OR, and WA) continue to move forward with efforts to evaluate drug costs and, in some instances, institute their own upper payment limits (UPLs). Although some states institute prescription drug affordability **policies** that apply to all state-regulated health plans, others, like Maryland, only regulate public plans such as Medicaid and state employee health plans. Similarly, at least three PDABs (ME, NH, and OH) lack authority to institute UPLs on high-priced drugs.

The various state PDAB efforts have remained under high scrutiny by pharmaceutical manufacturers. Commentators expect state-level lawsuits to be launched by drugmakers and industry groups that challenge the state authority to set UPLs. Potential challenges could adopt legal reasoning that UPLs are preempted by federal law, such as the Medicare Drug Price Negotiation Program, or that state efforts violate the Dormant Commerce Clause by discriminating against or unnecessarily burdening drugmakers engaged in interstate commerce.

The outcome of the lawsuits challenging the IRA's Medicare Drug Price Negotiation Program will be Critical to PDAB efforts to control the affordability of drugs. Some states, such as Minnesota, have tied their UPL to the maximum fair price (MFP) under the federal government's program. It is also possible PDABs shift their focus from drug manufacturers to other entities in the pharmaceutical supply chain. As in some **critics worry** that PDABs are targeting the wrong entities in their regulation efforts and believe that more focus should be placed on PBMs and understanding their role in prescription drug affordability.

OTHER INDUSTRY NEWS

Employee-Employer Drug Pricing Lawsuits. On February 5, 2024, an employee filed a class action **lawsuit** against Johnson & Johnson (*Lewandowski v. Johnson and Johnson*, U.S. District Court for the District of New Jersey, No.1:24-cv-00671), accusing J&J of breaching its fiduciary duty under ERISA to prudently manage employee benefit plans. ERISA sets standards of conduct for those who manage employee benefit plans, including employee group health plans. If acting as a fiduciary, an entity will be subject to **certain standards of conduct** such as acting solely in the interest of plan participants and their beneficiaries, carrying out their duties prudently, and, among other things, paying only reasonable plan expenses.

The lawsuit provides examples of instances where the self-funded health plans paid "inflated" prices to PBMs for certain generic drugs when compared to a drug's pharmacy acquisition cost. The lawsuit also alleges that the drug benefit design "steers" patients to the PBM's pharmacies and causes the plan to "waste[] thousands of dollars in plan assets." The lawsuit alleges that these actions constituted a breach of J&J's fiduciary duty under ERISA and provided several other examples of purported fiduciary violations. The Plaintiff seeks to establish a nationwide class of other J&J health plan participants and beneficiaries and seeks damages and other penalties under ERISA. This lawsuit is believed to be the first brought under ERISA's

fiduciary duty rules for the mismanagement of health plan funds. The ramifications of the decision and subsequent cases across jurisdictions could introduce significant challenges to PBM contracting with self-funded health plans.

JC Resources, LLC v. OptumRx. On December 26, 2023, the Florida Second District Court of Appeals ruled in favor of OptumRx, allowing OptumRx to move forward with compelling forced arbitration over claims brought by over 500 independent pharmacies nationwide, claiming that OptumRx, among other things, reimbursed these pharmacies below contractual rates. This case was brought by OptumRx in early 2022 in response to a letter OptumRx received from a band of pharmacies alleging OptumRx engaged in improper reimbursement practices. While the pharmacies hoped to forego arbitration, the court sided with OptumRx noting that the pharmacies agreed to the arbitration clause in the agreement with OptumRx to access the thousands of health plans and drug reimbursement benefits offered by OptumRx.

CVS to Launch CostVantage to Simplify Its Drug Pricing Model. On December 4, 2023, CVS announced its new initiative, CostVantage, set to launch in 2025 to simplify the drug pricing model used to reimburse pharmacies for prescription drugs. As part of its initiative, CostVantage will use a reimbursement model with a formula based on a drug's cost, a limited fixed markup, and flat fees that appropriately cover the value of the services provided by pharmacies. This announcement comes at a time when other players in the industry are taking similar steps to increase transparency and subdue the criticism aimed at PBMs. Specifically, we have seen similar activity from (i) Express Scripts in its announcement of launching a cost-based model, and (ii) Cost Plus Drug Company and its cost-plus model.

Unlikely bedfellows? Smaller PBMs are aligned with federal legislation. Smaller PBMs are challenging larger rivals for business by (1) offering clients a more transparent business model and (2) reportedly lobbying Congress for legislation that would regulate and "rein in" larger PBMs.

OptumRx partners with independent pharmacies to address care gaps. OptumRx launched The Bridge to Healthy Baby program in three states—Louisiana, Michigan and New Mexico—to offer prenatal checkups and vitamins at an independent pharmacy. This is part of a larger initiative to leverage the relationships independent pharmacies have with their patients to address care gaps in rural areas.

FROM THE DESK OF THE IRA UPDATE…

We published our second edition of the ***Mintz IRA Update*** in February 2024. In this edition of the Update, you'll find (i) a discussion of the status of the negotiations underway between CMS and manufacturers pursuant to the Medicare Drug Price Negotiation Program; (ii) analyses of other drug pricing–related IRA initiatives, including Part D benefit design changes going into effect this year and the inflation rebate programs under Parts B and D; (iii) a status update on the current legal challenges against the Negotiation Program; and (iv) overviews of the IRA's small biotech exemption, the implications associated with removing the AMP-cap from the Medicaid Drug Rebate Program, and the Biden administration's proposed draft guidance on patent "march-in" rights.

IRA implementation continues to move forward quickly, along with the Medicare Drug Price Negotiation Program (all manufacturers recently

submitted a counteroffer to CMS) and related litigation. Here are a few updates from the desk of the *IRA Update*:

- On February 15, 2024, the Centers for Medicare and Medicaid Services (CMS) released the **Medicare Prescription Payment Plan Draft Part Two Guidance** (Part Two Guidance) as part of the Inflation Reduction Act's (IRA) efforts to tackle high prescription drug costs. See our **blog post** analyzing this guidance for additional details.

- On February 29, 2024 CMS finalized its **part one guidance** for the new **Medicare Prescription Payment Plan**. According to CMS, the "final part one guidance — which considered public comments received in response to the **draft part one guidance** released on August 21, 2023 — focuses on outlining the necessary operational requirements for Medicare Part D plan sponsors as they prepare for the new program. The guidance addresses topics such as identifying Medicare Part D enrollees likely to benefit from the program, the opt-in process for Part D enrollees, program participant protections, and the data collection needed to evaluate the program."

  The final part one guidance requires Part D sponsors to notify a pharmacy to provide information on the program for anyone who meets a $600 out-of-pocket threshold based on a single prescription at the point-of-sale. The final guidance also requires Part D sponsors to process election requests within 24 hours during the plan year. These requirements will be in addition to those set out in the draft part two guidance. See our **blog post** analyzing the draft part one guidance for additional details.

- **Medicare Drug Price Negotiation Program Litigation**. On March 1st, Chief Judge Colm F. Connolly of the US District Court for the District of Delaware ruled that the court lacks jurisdiction over AstraZeneca's APA claim and that the manufacturer's due process claim fails as a matter of law.

  AstraZeneca has the right to appeal to the Third Circuit, which could lead to the first appellate decision on this issue. AstraZeneca could also try to seek emergency relief from a higher court or ask for an expedited briefing schedule, but next steps remain to be seen. More broadly, manufacturers are still searching for their first win compared to the government's current 3-0 record. The momentum is thoroughly on the government's side, which can color how other judges think about an issue. And any judge writing up a decision contrary to the AstraZeneca and Chambers decisions will feel forced to explain why those courts got it wrong. In that vein, the decision will also likely play a prominent role in the March 7th oral argument in the four New Jersey cases, Bristol Myers Squibb, Johnson & Johnson, Novartis, and NovoNordisk.

SINCE WE WENT TO PUBLICATION…

- Congress did not include PBM reform in its upcoming package to fund the federal government, indicating a shift in legislative priorities. Of course, PBM reform could be revived at any time.

- FTC's Lina Khan and Mark Cuban of Cost Plus Drugs, along with other industry leaders, participated in a **White House Roundtable** on March 4th to discuss PBM industry reform that "promote transparency and competition in

pharmaceutical markets, support independent pharmacies, and lower drug costs." PBMs were not included in the roundtable.

At the Roundtable, it was reported that Khan stated some PBMs have not yet complied with FTC's investigational orders to submit documents and data. She noted that the FTC will use its authority to ensure compliance.

- Attorneys General from 39 states across the U.S. sent a **letter** to House and Senate leaders urging legislation to address "potential abuses" by PBMs. The letter, sent by the National Association of Attorneys General, cited three bills that were introduced to transform PBM practices – The DRUG Act (S.1542/H.R. 6283), Protecting Patients Against PBM Abuses Act (H.R. 2880), and The Lower Costs, More Transparency Act (H.R. 5378).

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