PBM Policy and Legislative Update

July 2023

The PBM regulatory landscape continues to evolve rapidly 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 in order to provide you with this quarterly *PBM Policy and Legislative Update*. This update builds on prior issues and highlights federal and state activity from April, May, and June 2023.

Federal Legislative Activity and Oversight

- **Pharmacy Benefit Manager Accountability Act (H.R. 2679)**: On April 18, 2023, Congresswoman Annie Kuster (D-NH), along with Representatives Earl "Buddy" Carter (R-GA), Anna Eshoo (D-CA), and Brett Guthrie (R-KY), introduced a bipartisan bill aimed at increasing transparency in the drug supply chain. If enacted, the Pharmacy Benefits Manager Accountability Act would, among other things, require PBM entities to annually report to plan sponsors (a) information collected from drug manufacturers on the total copayment assistance provided by such drug manufacturer to plan beneficiaries, (b) information pertaining to the PBMs' drug coverage, including but not limited to drugs covered and dispensed, the number of beneficiaries for whom the drug was filled, the wholesale acquisition cost, and total beneficiary out of pocket spending, (c) total gross and net spending on prescription drugs by the plan, (d) the dollar amount of rebates, fees, and discounts received by the PBM for certain therapeutic drugs, (e) total amount of rebates, discounts or other remuneration received from manufacturer or any other third party related to utilization of drugs or drug spending under the health plan, and (f) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the business to the PBM. The bill would also require PBMs to make these same reports to the GAO so that GAO can issue a report regarding PBM practices related to pharmacy networks, including pharmacies under common ownership with plan sponsors or PBM. The bill also sets forth enforcement guidelines for non-compliance with reporting obligations, including failure to provide timely information or for knowingly providing false information, by allowing the Secretary of Health and Human Services, in consultation with the Secretaries of Labor and Treasury, to impose civil monetary penalties. Finally, under the terms of this bill, PBMs would be prohibited from entering into contracts with manufacturers, rebate aggregators or any associated party that would limit the PBM from complying with the proposed reporting obligations.

Federal Legislative Activity and Oversight, cont.

- **Pharmacy Benefit Manager Reform Act (PBM Reform Act) (S. 1339)**: On April 25, 2023, the Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Bernie Sanders and Ranking Member Bill Cassidy introduced the bipartisan PBM Reform Act, which, if enacted, would require PBM entities to operate with increased transparency and limit certain avenues by which PBMs may retain profits. On May 11, 2023, the HELP Committee voted by an 18 to 3 margin to advance an amended version of the PBM Reform Act to the full Senate. The May markup proposes to (i) ban PBMs' use of spread pricing; (ii) require PBMs to disclose all fees, rebates, and other payments and remunerations received from manufacturers, and pass 100% of those proceeds to plan sponsors; (iii) require health issuers and/or PBMs to submit detailed annual and semi-annual reports; and (iv) commission certain studies to determine the effects of PBM regulation on the U.S. health care market. The markup added, among other provisions, (i) a requirement for the Secretary of Labor to conduct a study and report on the impact of a policy change that would result in PBMs being considered fiduciaries within the meaning of the Employee Retirement Income Security Act (ERISA) of 1974, and (ii) a ban on health issuers entering into agreements with PBMs that prevent or restrict third parties from accessing or using consumer decision-support tools. Although generally supported by the HELP Committee, the amended bill leaves out a proposal to "delink" PBM administrative fees from drug prices by banning PBMs from charging fees based on a percentage of a drug's list price.

* * * See our blog post for a detailed description of the PBM Reform Act. * * *

- **Pharmacy Benefit Manager Sunshine and Accountability Act (H.R. 2816)**: On April 25, 2023, Congresswoman Diana Harshbarger (R-TN) introduced another bipartisan bill focused on PBM reporting requirements. The PBM Sunshine and Accountability Act would expand PBM reporting requirements across nearly all health insurance markets and require PBMs to report information on (i) the aggregate dollar amount of all rebates, administrative fees, and any other revenue received from drug manufacturers, health insurers, or plan sponsors, including the dollar amount of all rebates and administrative fees received but not passed through, (ii) highest, lowest, and total aggregated retained rebate percentages, and (iii) post-adjudication payments, including any fees, reimbursements or other claw backs that PBMs collect from pharmacies. The bill would also require HHS to make the reported information publicly available.

- **Delinking Revenue from Unfair Gouging Act (DRUG Act) (S. 1542)**: On May 10, 2023 U.S. Senators Jon Tester (D-MT), Roger Marshall (R-KS), Tim Kaine (D-VA), Mike Braun (R-IN) and Shelley Capito (R-WV) introduced the Delinking Revenue from Unfair Gouging (DRUG) Act with the goal of "delinking" PBM fees from the price of prescription drugs. To this end, the bill would require PBMs to charge its clients flat service fees rather than fees based on, or contingent upon, drug prices, discounts, rebates, fees or other remuneration related to prescription drugs utilization. The bill also prohibits (i) spread pricing, (ii) reimbursing independent or unaffiliated pharmacies an amount that is less than the amount paid to an affiliated pharmacy, or (iii) steering patients to particular pharmacies. Compliance with these requirements would be enforced via civil monetary penalties in the amount of $10,000 per day for the duration of the violation.

Federal Legislative Activity and Oversight, cont.

What is "delinking" and why is it the talk of the town?

Our April 2023 PBM Legislative and Policy Update highlighted the Senate Finance Committee's newly introduced Bipartisan Framework for Reducing Prescription Drug Costs by Modernizing the Supply Chain and Ensuring Meaningful Relief at the Pharmacy Counter (Framework). This Framework makes specific recommendations to reduce drug costs for patients and taxpayers, the first of which is "delinking PBM compensation from drug prices to align incentives for lower costs."

Citing "misaligned incentives," the Senate Finance Committee believes that PBM payments that are based on a percentage of a drug's list price result in higher out-of-pocket costs for consumers. Senator Mike Crapo (R-ID) stated that, "Delinking PBM compensation from sticker prices would take a critical first step in ensuring that all supply chain participants seek out the best deals available, driving down out-of-pocket spending and promoting cost-cutting competition."

The Senate is moving quickly to advance the Framework with both the DRUG Act and PBM Act (detailed below) focused on "delinking" PBM compensation from the prices of prescription drugs. We expect the Senate Finance Committee to continue proposing new legislation that supports the goals laid out in the Framework.

- **Promoting Access to Treatment and Increasing Extremely Needed Transparency Act of 2023 (PATIENT ACT) (H.R. 3561)**: On May 24, 2023, the House Energy and Commerce Committee voted by a 49 to 0 margin to advance an amended version of the bipartisan Promoting Access to Treatments and Increasing Extremely Needed Transparency (PATIENT) Act of 2023, which would, among other things, increase drug pricing transparency and PBM oversight under the Medicaid program. The PATIENT Act would amend Section 1927(e) of the Social Security Act by adding pass-through pharmacy reimbursement requirements for any payments made by PBMs to pharmacies under PBM services contracts with states. The proposed bill would require (i) any payments for drugs to be limited to the ingredient cost and a professional dispensing fee, no less than the fee states would pay were they paying the dispensing fee directly, and for any such payments to pass through entirely to the pharmacy or the dispensing provider; (ii) any administrative fees paid for PBM services to be limited to cover reasonable costs of providing the administrative services; and (iii) managed care entities and PBMs, as applicable, to make available information pertaining to costs and payments for covered outpatient drugs and accompanying administrative service fees incurred, received or made by such managed care entity or PBM, including, but not limited to, any direct or indirect remuneration. Additionally, the proposed bill would ban spread pricing for the purpose of claiming federal matching payments under the law.

Federal Legislative Activity and Oversight, cont.

- **Patients Before Middlemen Act (PBM Act) (S. 1967)**: On June 14, 2023, the Senate Finance Committee Chairman Ron Wyden (D-OR), Senate Finance Ranking Member Mike Crapo (R-ID) alongside Senators Bob Menendez (D-NJ), Marsha Blackburn (R-TN), Jon Tester (D-MT), and Roger Marshall (R-KS) introduced the Patients Before Middlemen Act (PBM Act). The PBM Act would require that contracts between a Part D prescription drug plan sponsor ("PDP sponsor") and a PBM acting on behalf of such sponsor: (i) provide that the PBM derives no income with respect to services provided in connection with Part D utilization other than bona fide service fees, and (ii) set forth the amount of any bona fide service fee, which must be a flat dollar amount, cannot be passed on in whole or in part to another party, and cannot be directly or indirectly based on, or contingent upon, drug price, discounts rebates, fees, or other remuneration with respect to prescription drugs prescribed to enrollees in the plan. The PBM Act would also require the PDP sponsor and PBM to annually certify compliance with these requirements. Further, the bill would require PBMs to return to the Secretary any amounts received in violation of the PBM Act. Similar to the DRUG Act summarized above, the PBM Act is focused on "delinking" PBM compensation under Medicare Part D from drug prices.

- **Protect Patient Access to Pharmacies Act (S. 2052)**: On June 20, 2023, Senators Jon Tester (D-MT), Shelley Moore-Capito (R-WV), Sherrod Brown (D-OH), and James Lankford (R-OK) introduced the bipartisan Protect Patient Access to Pharmacies Act, which, if enacted, would increase enforcement related to "any willing pharmacy" laws and would, among other things, (i) alter certain PBM practices related to patient access to pharmacies under Medicare Part D coverage, (ii) standardize the metrics PBMs and plans use to measure pharmacy performance and quality and ensure they are fairly applied, and (iii) ensure transparency in payments and fees issued by PBMs.

Modernizing Medicare's "Any Willing Pharmacy" Requirements

The Protect Patient Access to Pharmacies Act also tracks back to the Framework's goal of modernizing Medicare's "any willing pharmacy" requirements to reduce ambiguity in these requirements and to improve access for seniors. The Framework cites the need for standardization to preserve freedom of choice in the Medicare program in light of increased vertical integration, growth in pharmacy fees, and unpredictable performance-based quality measures.

Federal Legislative Activity and Oversight, cont.

- **House Committee on Oversight and Accountability PBM Investigation**: As previously reported, the House Committee on Oversight and Accountability (HCOA) Chairman James Comer (R-KY) launched an investigation into PBM industry practices on March 1, 2023. On June 13, 2023, Chairman Comer attended an Education and Workforce Committee hearing, at which Health Secretary Xavier Becerra was testifying, to highlight the HCOA's active investigation of PBMs. In response to Chairman Comer's comments, Secretary Becerra expressed the need to "get behind the curtain" and increase transparency within the PBM industry, noting that Secretary Becerra's team is ready to work with the Chairman and the HCOA on this matter.

    - As part of the investigation, Chairman Comer called on CMS, the Office of Personnel Management, and the Defense Health Agency to provide documents identifying how PBM practices impact the administration of federal healthcare programs. The investigation also requested that some of the largest PBMs provide records related to their business practices. HCOA held its first public hearing on May 23, 2023 to discuss PBMs' role in the healthcare industry and the need to closely examine PBMs' system of using rebates and fees.

- **FTC Investigation**: As previously reported, on June 7, 2022, the FTC issued compulsory orders to six of the largest PBMs, requiring these PBMs to provide certain information and records related to the PBMs' business practices. In issuing the orders under Section 6(b) of the FTC Act, the FTC notes that it aims to understand PBM practices, including fees charged to unaffiliated pharmacies, steering patients toward PBM-owed pharmacies, pharmacy reimbursement method, the negation of rebates, and other fees. On May 17, 2023, the FTC expanded its inquiry to include two group purchasing organizations that negotiate drug rebates, and on June 8, 2023, the FTC further expanded this inquiry to include a third group purchasing organization.

- **CMS proposed rulemaking to increase transparency of drug pricing in Medicaid-managed care programs**: In its May 23, 2023 notice of proposed rulemaking, CMS proposes, among other things, to increase the transparency of drug pricing in Medicaid managed care programs. The proposed rule would require contracts between states, Medicaid managed care plans, and PBMs to include provisions detailing PBM use of spread pricing arrangements, whereby the PBM pays pharmacies less than what they charge the Medicaid-managed care plan for the cost of drugs. Under the proposed rule, PBMs would be required to report the cost of drugs and the dispensing fees separately from any other costs and fees charged to the Medicaid-managed care program.

Federal Legislative Activity and Oversight, cont.

The flurry of federal activity during this Congress continues. It is clear that both the Senate and House are actively investigating PBM practices and proposing legislation to address perceived gaps, alongside continued agency action. The federal government seems intent on regulating the PBM space to some extent, and the scope of these proposals may change as each regulation is considered and as other regulations are proposed.

State Legislation and Litigation

Recently Enacted State Legislation

States enacted the following initiatives during the second 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)
Arizona	S.B. 1382: requires PBMs to apply for, obtain, and maintain a valid certificate of authority to operate as a PBM in the state of Arizona, subject to a number of conditions.	4/18/2023	12/31/2024
Colorado	H.B. 1227: among other things, this law (i) requires PBMs to register with the state's insurance commissioner; (ii) authorizes the commissioner to penalize PBM's for noncompliance with a number of state requirements, including, without limitation, contractual requirements, MAC list requirements, and prohibitions on retroactive fee adjustments.	5/10/2023	8/06/2023
	H.B. 1201: among other things, this law (i) prohibits spread pricing between amounts charged to policyholders and amounts paid to pharmacies, including in state MCO contracts; and (ii) requires PBMs to disclose to each policyholder or insurer, as applicable, specific prescription drug contract terms and the difference between contract terms in renewed contracts against terms from the prior year's contract.	5/10/2023	8/06/2023
	S.B. 195: requires health insurers and PBMs to, subject to certain conditions, include any payments made by or on behalf of a covered person in the calculation of a covered person's contributions toward out-of-pocket maximums or cost-sharing requirements under an applicable health benefit plan.	6/5/2023	9/04/2023

State Legislation and Litigation, cont.

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
Connecticut	H.B. 6669: establishes, among other things, (i) a requirement of the Office of Health Strategy to (a) report an analysis of PBM practices, including, but not limited to spread pricing arrangements, financial incentives for adding drugs to health plan formularies, and evaluation of prescription drug distribution by PBMs in other states, and (b) provide recommendations for reducing consumer prescription drug costs and regulating PBM practices, and (ii) a prohibition on using certain contract terms in agreements between PBMs and 340B-covered entities.	6/27/2023	(i) 6/27/2023; (ii) 1/1/2024
Florida	S.B. 1550: establishes additional obligations for PBMs, including but not limited to, requiring, (1) PBMs apply for a certificate of authority to act as an administrator, (2) PBMs identify certain ownership affiliations and report any changes to such ownership information, (3) contracts between a PBM and a pharmacy benefit plan or program comply with the following requirements: (i) use a pass through pricing model, (ii) prohibition of spread pricing, (iii) requirement of the PBM to pass 100% of all rebates received to the plan or program, (iv) network adequacy requirements that meet or exceed Medicare Part D program standards for convenient access to the network pharmacies, and (v) a prohibition from conditioning participation in one pharmacy network on participation in any other network, (4) contracts between a PBM and a participating pharmacy include, among other things: (i) information about adjudication for claims and reimbursement, (ii) a prohibition of financial clawbacks, (iii) a prohibition of a pharmacy from offering mail or delivery service on an opt-in basis, and (iv) reasonable administrative appeal procedures.	5/4/2023	7/1/2023

State Legislation and Litigation, cont.

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
Florida, cont'd	The law also includes a list of PBM prohibited practices. Among other things, PBMs may not (1) restrict a pharmacy from disclosing any information to any person or the governmental agencies and offices, that it deems appropriate, (2) communicate at the point-of-sale or otherwise require a cost sharing obligation amount that exceeds the lesser of the applicable cost sharing amount or the usual and customary price, and (3) fail to make any payment to a pharmacy for an adjudicated claim unless for fraud or required by law. PBMs are also required to notify the office of specified complaints, settlements, or discipline within specified timeframes. S.B. 1552: classifies PBMs as administrators that are subject to additional records production, examination, and investigation provisions, all of which will be confidential.	5/3/2023	7/1/2023
Idaho	H.B. 215: requires PBMs to register with the department of insurance and establishes mandatory steps for PBMs to place a drug on a MAC list. It also restricts PBMs from (1) prohibiting a pharmacist or retail pharmacy from providing a covered person information on the amount of the cost share for a drug and the clinical efficacy of a more affordable alternative drug, and (2) penalizing a pharmacist or retail pharmacy for disclosing such information or for selling to the covered person a more affordable alternative drug, if one is available.	4/6/2023	7/1/2023
Illinois	S.B. 1298: establishes a process for any pharmacy audits, which, among other things, sets (i) notification and audit period requirements, (ii) limitations on the scope of audits and (iii) prohibitions on certain chargeback and recoupment practices.	6/16/2023	1/1/2024
Indiana	H.B. 1004: establishes the Health Care Cost Oversight Task Force, which, among other things, is to review and make recommendations concerning required reporting to be made by PBMs to the state's department of insurance.	5/4/3023	5/4/2023

State Legislation and Litigation, cont.

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
Indiana, cont'd	S.B. 0008: among other things, this law (1) requires PBMs to report to the department of insurance at least once every six months: (i) the overall aggregate amount charged to a health plan for all pharmaceutical claims the PBM processed on such plan's behalf, and (ii) the overall aggregate amount the PBM paid to pharmacies for claims it processed; (2) requires a covered individual's cost-sharing requirements to be calculated at the point of sale, and which amount must be reduced by an amount equal to at least 85% of all reabtes received for the dispensing of such drug; and (3) requires health insurers to pass through 100% of rebates received on behalf of a plan sponsor to such plan sponsor.	5/4/2023	7/1/2023
	H.B. 1445: establishes certain additional audit procedures for audits conducted by the Attorney General of PBMs contracted with the state Medicaid program.	5/4/2023	5/4/2023
Kentucky	S.B. 209: prohibits PBMs from (1) imposing a cost-sharing amount greater than the amount required to purchase the drug without coverage, (2) with limited exceptions, excluding cost-sharing amounts paid by an insured or on behalf of the insured for a prescription drug when calculating the insured's contribution to any applicable cost-sharing requirement, and (3) restricting a pharmacist from discussing cost-sharing information.	3/29/2023	3/29/2023
Maryland	H.B. 374: requires PBMs contracted with MCOs to conduct audits of pharmacies or pharmacists under contract with such PBMs, and to recoup any funds or charge any fees for certain identified discrepancies. This law also sets forth additional parameters and requirements around such audits.	5/3/2023	1/1/2024
	H.B. 785 / S.B. 515: prohibits PBMs from requiring more than a specified limit of prior authorizations for certain prescription drugs and provides additional regulations around prior authorization requirements.	5/3/2023	1/1/2024

State Legislation and Litigation, cont.

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
Nevada	S.B. 161: establishes, among other things, a requirement that, when PBMs manage prescription drug benefits on behalf of a health insurer, they comply with the provisions of the Nevada Insurance Code applicable to health insurers if such health insurers were to manage prescription drug benefits themselves.	6/12/2023	1/1/2024
New Mexico	S.B. 51: establishes additional obligations for insurers, including but not limited to, (1) crediting the enrollee for the full value of any discounts provided or payments made by third parties at the time of the prescription drug claim, (2) prohibiting the insurer from charging different cost-sharing amounts for (i) prescription drugs or pharmacy services obtained at a non-affiliated pharmacy or (ii) administration of prescription drugs at different infusion sites, and (3) prohibiting the insurer from requiring an insured to make payment at the point of sale for a drug in an amount greater than the least of the (i) applicable cost-sharing amount for the drug, (ii) amount an insured would pay for the drug if the insured purchased the drug without using a health benefit plan or any other source of drug benefits or discounts, (iii) total amount the pharmacy will be reimbursed for the drug from the insurer, or (iv) value of the rebate from the manufacturer provided to the insurer or the PBM for the drug. The law also prohibits PBMs from (1) offering pharmacy benefit services without first disclosing to the purchaser of the services of the option to contract for pharmaceutical drug cost-sharing protections, and (2) discriminating against an entity on the basis of its participation in the 340B program.	4/7/2023	4/7/2023

State Legislation and Litigation, cont.

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
North Dakota	S.B. 2378: prohibits PBMs, from, among other things, (1) requiring a patient, as a condition of payment or reimbursement, to purchase drugs exclusively through a mail-order pharmacy or an affiliate, (2) increasing patient costs if the patient chooses to not use a mail order pharmacy or an affiliate, but instead uses another provider, (3) interfering with patient's provider of choice, (4) limiting or excluding availability of a clinician-administered drug if not through an affiliate, and (5) offering differing payments to a participating provider if they are not an affiliate.	4/7/2023	4/7/2023
Oklahoma	H.B. 1843/S.B. 879: prohibits PBMs from, among other things, (1) advertising, promoting or making any representation that is untrue, deceptive or misleading; (2) charging pharmacies a fee related to the adjudication of a claim; (3) reimbursing non-affiliated pharmacies at a lesser amount than the amount the PBM reimburses a pharmacy owned by or under common ownership for providing the same services; (4) denying a provider the opportunity to participate in any pharmacy network at preferred participation status if the provider is willing to accept the terms and conditions that the PBM set up for other providers; (5) retroactively denying or reducing reimbursement for a covered service claim unless it meets 2 specified conditions; (6) conducting spread pricing; and (7) charging a pharmacist or pharmacy a fee related to participation in a retail pharmacy network. The bill also governs PBM contracts, including by prohibiting such contracts from penalizing or discouraging pharmacies from informing an individual of any cost differential between out-of-pocket cost/coverage versus purchasing the drug directly, among other things.	5/25/2023	11/1/2023
South Dakota	H.B. 1135: requires PBMs to disclose information relating to drug utilization and revenue received, as well as any other information requested by a third-party payer. Failure to do so could result in suspension of revocation of a PBM's license.	3/27/2023	3/27/2023

State Legislation and Litigation, cont.

State	Description of Measure(s)	Date(s) Enacted	Effective Date(s)
Texas	H.B. 4611: establishes, among other things, certain contracting requirements and audit procedures for PBMs providing services to Medicaid-managed care plans.	6/12/2023	4/1/2025
	H.B. 999: requires PBMs to apply any third-party payment or other reduction in out-of-pocket expenses to the enrollee's deductible, copayment, cost-sharing responsibility, or out-of-pocket maximum.	6/10/2023	9/1/2023
	S.B. 1342: clarifies that PBMs are subject to the state Medicaid program's prior authorization rules as a "third-party health insurer."	6/1/2023	9/1/2023

Recently Introduced 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 second quarter of 2023.

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.	Assembly read for a second time; Ordered third read on 07/13/2023
Illinois	H.B. 3631: proposes to amend 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.	Sent to the Governor on 6/16/23
Louisiana	S.B. 171: proposes to require each PBM licensed with the commissioner to develop, execute, and report on a program that provides incentive payments to eligible independent network pharmacies for achieving benchmarks or complying with strategies aimed at improving health outcomes for Louisiana residents.	Failed to pass; re-engrossed on 5/31/2023
	H.B. 529: proposes to, *inter alia*, limit the compensation PBMs receive pursuant to any contract to solely an all-inclusive administrative free and to prohibit spread pricing and PBM reimbursement of pharmacies at amounts less than the sums of the actual acquisition costs.	Scheduled for floor debate on 5/16/2023

State Legislation and Litigation, cont.

State	Description of Measure(s)	Most Recent Status
New Jersey	S.B. 1615/A2840: Proposes to, among other things (i) require PBMs to annually 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 certain drugs and the fees charged by the organization to pharmacies. S.B. 1616/A536: Proposes to establish 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) setting 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.	S.B.1615 - Assembly approved on 07/10/2023 A2840 – Substituted by S.B.1615 on 6/30/2023 S.B. 1616 - Substituted by A536 06/30/2023 A536 - Senate approved 7/10/23
New York	S.B. 6738: proposes to, among other things, (i) require registration of rebate aggregators, PSAOs, and pharmacy switch companies; (ii) require certain annual disclosures for each of the aforementioned entity types, including, with respect to rebate aggregators, the fee structure provisions of any contract with a PBM. A.B. 7197: applies to the state's Medicaid program and proposes to, among other things: (i) reduce amounts collected by MCOs and PBMs as administrative fees and set forth minimum pharmacy reimbursement requirements in order to increase pharmacy reimbursement rates; (ii) prohibit MCOs or PBMs from reimbursing an affiliated pharmacy at a higher rate than nonaffiliated pharmacies; and (iii) prohibit PBMs from restricting an individual's choice of pharmacy. A.B. 7789: proposes to prohibit PBMs from denying, prohibiting, or otherwise limiting the dispensing of drugs from a covered entity or from imposing restrictive requirements on entities that do not participate in the 340B program.	Referred to Committee on Insurance on 5/8/2023 Referred to Committee on Health on 5/12/2023 Referred to Committee on Health on 6/15/2023
Ohio	H.B. 177: proposes to require PBMs to comply with all applicable cost-sharing requirements regarding prescribing, receipt, administration, or coverage of a prescription drug currently applicable to health insurance issuers.	Referred to House Public Health Policy Rules and Reference Committee on 6/13/2023

State Legislation and Litigation, cont.

State	Description of Measure(s)	Most Recent Status
Oregon	S.B. 192: proposes to, among other things, (i) require 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) require the Department of Consumer and Business Services to publish aggregated information received from PBMs on the Department's website.	Sent to Governor for signature on 6/29/2023
	H.B. 3013: proposes to, among other things, (i) require PBMs to be licensed by the Department of Consumer and Business Services, (ii) modify procedures for pharmacies to appeal PBM payments, and (iii) appropriate funds from the Department of Consumer and Business Services for the purpose of employment assistance in regulating PBMs.	In Senate; third reading completed on 6/25/2023
	H.B. 2725: proposes, among other things, to (i) prohibit PBMs from retroactively denying or reducing payments after adjudicating claims unless such payment was incorrect due to clerical error, (ii) prohibit PBMs from imposing fees on rural pharmacies after the point of sale, (iii) require PBMs to provide notice to pharmacies of specific claim denials or reductions and an explanation of any such denial or reduction.	Sent to Governor for signature on 6/27/2023
Pennsylvania	H.B. 969: proposes to require PBMs to share the cost, benefit, and coverage data with a covered individual, the covered individual's healthcare practitioner, or a third party on behalf of the covered individual or health care practitioner, upon request.	Referred to Committee on Insurance on 4/24/2023
Vermont	S.B. 151: proposes to, among other things, (i) require the state's Green Mountain Care Board to review health care contracts and fee schedules to increase pricing transparency; (ii) set forth certain criteria relating to when prior authorization requests may or may not be made to health care providers; and (iii) make permanent certain prohibitions applicable to PBMs that provide services relating to 340B claims.	Referred to Committee on Health and Welfare on 4/27/2023

State Legislation and Litigation, cont.

State Law Challenges

The Tenth Circuit heard arguments in *Pharmaceutical Care Management Association (PCMA) v. Mulready* on May 16, 2023. Reports suggest that the Tenth Circuit seemed skeptical of the state's reliance on Rutledge, questioning whether Rutledge applies to these laws. Further, as we reported in our last issue, the U.S. DOL filed an amicus brief agreeing with PCMA that three of the four provisions are preempted. Thus it seems possible that the Tenth Circuit may find in favor of PCMA and curb the scope of the rapid expansion of state legislation. We will continue to monitor any decisions in this appeal.

As we have reported, in *Pharmaceutical Care Management Association (PCMA) v. Mulready* the U.S. District Court for the Western District of Oklahoma, relying on *Rutledge v. PCMA*, found that parts of Oklahoma's Patient's Right to Pharmacy Choice Act, including a service fee prohibition at issue between the Oklahoma Insurance Department and CVS, are preempted by Medicare Part D. Similar to the analysis in *Rutledge* and its progeny, including *PCMA v. Webhi,* the District Court did not find any of the challenged provisions to be preempted by ERISA. PCMA filed an appeal with the Tenth Circuit, arguing that only four of the state provisions are preempted by ERISA and Medicare Part D, compared to the 14 it had originally challenged. A primer on the Supreme Court's decision in *Rutledge* can be found here.

Inflation Reduction Act of 2022 (IRA) Updates

The Centers for Medicare & Medicaid Services (CMS) continues to advance key provisions of the IRA:

- **Insulin Cost-Sharing Caps Expand to Medicare Part B and Medicare Advantage as of July 1, 2023:** Beginning July 1st, Medicare beneficiaries with Part B coverage or who are enrolled in Medicare Advantage and who receive insulin through a traditional pump, will have their insulin costs capped at $35 per month per each covered insulin. As we reported in our last issue, millions of Medicare Part D beneficiaries are already benefiting from the IRA's $35 monthly cap. Note that CMS created a series of guidance documents regarding insulin and vaccine coverage under the IRA.

- **Adult Vaccine Coverage to Expand beginning October 1, 2023:** CMS issued guidance to states regarding the implementation of new mandatory Medicaid coverage for adult vaccines, without cost-sharing, under the IRA. Additional details can be found on this CMS fact sheet.

- **Revised Guidance For Medicare Drug Price Negotiation Program:** As previously reported, the IRA formally established the Medicare Drug Price Negotiation Program (the "Negotiation Program"). Despite an increasing number of lawsuits challenging the constitutionality of the IRA's Negotiation Program (discussed in more detail below), CMS continues to forge ahead with preparations to operationalize the Negotiation Program. To this end, on June 30, 2023, CMS published revised guidance for implementation of the Negotiation Program for initial price applicability year 2026. This follows CMS' initial guidance published March 15, 2023, in which CMS solicited comments on a number of key aspects related to implementation of the Negotiation Program.

Inflation Reduction Act of 2022 (IRA) Updates, cont.

- **Changes to CMS' Policies for Implementation of Negotiation Program:** In the revised guidance, CMS details clarifications and changes to the initial guidance's policies in response to the feedback CMS received from stakeholders:

    - **Negotiation Process:** CMS published a number of clarifications and revisions with respect to the following aspects of the negotiation process between CMS and manufacturers, including:

        - How CMS will identify drugs selected for negotiation (i.e. CMS will only consider active designations and approvals when evaluating a drug for the Orphan Drug Exclusion, etc.)
        - How CMS will consider the negotiation factors when evaluating a drug for selection.
        - Additional detail regarding the timeline and various steps in the negotiation process and requirements applicable to participating manufacturers whose drugs are selected.
        - CMS' oversight of manufacturer compliance and imposition of Civil Monetary Penalties (CMPs).

    - **Impact on Part D:** CMS indicated that the maximum fair price (MFP) for a selected drug must be made available to all Medicare beneficiaries who use their Part D plan, including Medicare Advantage Prescription Drug (MA-PD) or Employer Group Waiver Plans, for coverage of that selected drug. The revised guidance requires Part D plans to include on their formularies all dosage forms and strengths of a selected covered Part D drug for which the MFP is in effect. CMS will expect Part D plans to provide reasonable justification to support plan designs with non-preferred tier placement of a selected drug with a MFP. CMS also further clarified that the MFP for a selected drug is not included in the "Average Manufacturer Price" (AMP) for a selected drug and thus will not affect calculation of Part D inflation rebates.

    - **Confidentiality of Negotiations:** Following criticism of CMS's confidentiality policy regarding the negotiation process between CMS and the manufacturers, CMS has revised its stance in the interest of promoting transparency. In the revised guidance, CMS will publish a "narrative explanation of the negotiation process," the mutually agreed-upon maximum fair price of a selected drug, and non-proprietary or redacted data received from the manufacturer and other information, including the exchange of offer and counter offers.

Inflation Reduction Act of 2022 (IRA) Updates, cont.

IRA Litigation

CMS is scheduled to publish the list of the first 10 drugs selected for negotiation for price year 2026 by September 1, 2023 and opponents of the Negotiation Program are eager to halt the process before it begins. Notably, Merck, Bristol Myers Squibb, PhRMA, and the U.S. Chamber of Commerce have all filed lawsuits against the Department of Health and Human Services (HHS) and CMS over the last two months alleging the Negotiation Program violates the constitution and seeking to block implementation of the Negotiation Program.

- ***Merck & Co. Inc. v. Becerra et al.*** and ***Bristol Myers Squibb Co. v. Becerra et al.*****:** In June 2023, both Merck & Co. Inc. and Bristol Myers Squibb Co. filed complaints against HHS, CMS, and Secretary Xavier Becerra seeking to block CMS's new authority under the IRA to negotiate prices of certain drugs that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). Merck filed its complaint on June 9th in U.S. District Court, in D.C., alleging that its drug Januvia will almost certainly be included on the first list of negotiated drugs. BMS filed its lawsuit in U.S. District Court in N.J., alleging that its anticoagulant medication Eliquis is among those likely to face Medicare-negotiated prices in the coming years, and its drug Opdvio will likely be chosen for a subsequent round. The Merck and BMS complaints are very similar and make essentially the same claims. Both companies claim that the drug price negotiation program violates the Fifth Amendment, which prohibits the government taking property without just compensation, and the First Amendment, which prohibits compelled speech. The drug manufacturers allege that their property (i.e. the patented pharmaceuticals) will be taken and forced to be sold, resulting in a *per se* taking of its property in violation of the Fifth Amendment. The manufacturers also argue that a the IRA compels them to speak in two ways violating their First Amendment rights: (1) by forcing it to communicate that it has "agreed" to an HHS-mandated price, and (2) to endorse the viewpoint that HHS's price is "fair" while any higher market-based price would be *unfair.*

- ***Dayton Area Chamber of Commerce et al., v. Becerra et al.*** and ***Nat'l Infusion Ctr. Ass'n et al. v. Becerra et al.*****:** On June 9, 2023 and on June 21, 2023, the Dayton Chamber of Commerce, Ohio Chamber of Commerce, Michigan Chamber of Commerce and U.S. Chamber of Commerce (collectively, the "Chambers") and the Pharmaceutical Research and Manufacturers of America, along with the National Infusion Center Association and the Global Colon Cancer Association (collectively, "PhRMA") each filed their own lawsuits, respectively, against HHS, CMS and Secretary Becerra arguing that the provisions of the IRA establishing the Medicare drug price negotiation program violate the Constitution. Specifically, the companies argue that drug price negotiation program violations (1) the Constitution's non-delegation doctrine, which prohibits Congress from transferring to another branch "powers which are strictly and exclusively legislative," (2) the Fifth Amendment's due process clause, based on the lack of opportunity to be truly heard prior to the price being determined and manufacturers' property interests being adversely affected, and (3) the Eighth Amendment's prohibition on excessive fines, alleging that the excise tax is an excessive fine

Since we went to publication…

To highlight how quickly this landscape is evolving, here is a brief run-down of noteworthy developments from July 2023. These topics will be included in our next update.

- **New Senate Legislation:** Three new bills were introduced by Senate Finance Committee members: "Medicare PBM Accountability Act," which is focused on transparency, the "Neighborhood Options for Patients Buying Medicines (NO PBMs) Act," which proposes to modernize Medicare any willing pharmacy laws, and the "Modernizing and Ensuring PBM Accountability Act," which appears to be a conglomeration of the numerous pieces of legislation introduced this year, focused on Medicare and Medicaid. The PBM bills were scheduled for markup on July 26th, ahead of the August recess.

- **New House Legislation:** House democrats introduced the "Lowering Drug Costs for American Families Act" on July 26th, which would increase the number of drugs subject to Medicare negotiation each year from twenty to fifty, and would require manufacturers to offer the negotiated prices and inflation rebates in other insurance markets.

- **FTC Developments:** 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."

- **IRA Litigation:** J&J and Astellas each filed new lawsuits, joining the growing number of manufacturers challenging the IRA Medicare drug price negotiation program.

- **Additional State Laws:** Laws proposed in Illinois, New Jersey and Oregon were enacted/signed into law.

As expected, the PBM industry continues to face an unrelenting flurry of legislative and oversight activity. At the federal level, the hyperfocus on PBMs and their role in the pharmaceutical supply chain appears poised to result in additional legislation this year. We will be watching closely to see what happens after the August recess.

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