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A GUIDE TO UNDERSTANDING PHARMACY BENEFIT MANAGER AND ASSOCIATED STAKEHOLDER REGULATION

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I. INTRODUCTION

The NAIC Regulatory Framework (B) Task Force established the NAIC Pharmacy Benefit Manager Regulatory Issues (B) Subgroup in 2018 to explore whether to develop a new NAIC model regulating pharmacy benefit managers (PBMs). In 2019, the Task Force adopted a charge for the Subgroup to, “[c]onsider developing a new NAIC model to establish a licensing or registration process for pharmacy benefit managers (PBMs). The Subgroup may consider including in the new NAIC model provisions on PBM prescription drug pricing and cost transparency.” The Subgroup developed a PBM model, which both the Regulatory Framework (B) Task Force and the NAIC Health Insurance and Managed Care (B) Committee adopted in 2021. However, at the NAIC 2021 Fall National Meeting, the proposed new PBM model failed to receive the necessary votes for adoption from the full NAIC membership. While it was discussing the proposed new PBM Model, in 2021, the Regulatory Framework (B) Task Force adopted a charge for the Subgroup to develop a white paper to: 1) analyze and assess the role PBMs, Pharmacy Services Administrative Organizations (PSAOs), and other supply chain entities play in the provision of prescription drug benefits; 2) identify, examine and describe current and emerging state regulatory approaches to PBM business practices, such as price transparency and reporting requirements, rebating, and spread pricing, including the implications of the *Rutledge vs. Pharmaceutical Care Management Association (PCMA)* decision on such business practices; and 3) discuss what challenges, if any, the states have encountered in implementing such laws and/or regulations.

After the proposed PBM model failed to receive sufficient votes for adoption, in early 2022, the Subgroup turned its focus on completing its charge to develop the white paper. Throughout 2022, the Subgroup held meetings to hear various perspectives from stakeholders, including consumers, PBMs, PSAOs, insurers, and pharmacists. The Subgroup also heard presentations from various states that have enacted state laws regulating PBM business practices. The states discussed the process of enactment, their implementation process, and outstanding issues related to enforcement, including, in some cases, a discussion of enforcement challenges and lessons learned.

As the Subgroup was hearing the last few stakeholder presentations in a series of regulator-to-regulator meetings in July 2022 through September 2022, the Subgroup reviewed and approved an outline of the PBM white paper. Based on the outline, the Subgroup leadership solicited and obtained volunteers from the Subgroup members to draft initial language for the various provisions in the PBM white paper. The Subgroup reviewed an initial draft of the PBM white paper in October 2022. The Subgroup released a working draft of the white paper during a meeting at the NAIC 2022 Fall National Meeting. Following the NAIC 2022 Fall National Meeting, the Subgroup met in early 2023 in a series of regulator-to-regulator meetings to discuss additional revisions to the working draft. On April 17, 2023, the Subgroup released a draft of the white paper for a 45-day public comment period ending June 1, 2023. After reviewing and incorporating some of the suggested revisions from the comments received, the Subgroup adopted the white paper draft on July 27, 2023, and forwarded it to the Regulatory Framework (B) Task Force for its consideration. The Health Insurance and Managed Care (B) Committee adopted the white paper on Nov. 2, 2023.

The Subgroup intends for this white paper to be considered a snapshot in time. It realizes that, as appropriate, this Subgroup, or any successor NAIC group, may want to revise it in the future to reflect changes related to the complex issues discussed in the white paper, particularly with respect to any court decisions made after its adoption.

II. KEY PLAYERS IN PHARMACEUTICAL DRUG PRICING ECOSYSTEM

Inherent in the Subgroup’s review of the drug pricing ecosystem are the concerns of the consumer, the one key player who cannot see all the levers before them but pays the price of the ecosystem that has been put in place. Until very recently, pricing of pharmaceuticals has been opaque to many consumers.¹ However, increased costs of pharmaceutical drugs, several active campaigns by players in the ecosystem, increased federal and state attention on drug pricing, and drug price transparency programs have all operated to raise the consumer’s knowledge of the cost levers of pharmaceutical drugs.

Pharmaceutical drugs are vital to both longevity and quality of life for many individuals. Not being able to afford lifesaving and life-improving prescriptions causes harm to patients and their families and contributes to additional burdens on our health care system. Some individuals can only afford prescriptions because they do so at the cost of other needs such as paying for housing and utility bills or addressing other medical issues. For these individuals there is a reduction in quality of life which can, and often does, affect overall health.² Affordability and access remain of high concern to consumers and lawmakers alike.

A 2021 poll by the Kaiser Family Foundation found that 60 percent of adults in the U.S. take at least one prescription drug and 25 percent take at least four per day. Of those prescribed medications, 29 percent of Americans reported not taking their medications as prescribed due to cost. They do this by not filling their medication, using an over-the-counter medication instead, or cutting the pills in half.³

It is the hope of the subgroup that by regulators gaining a greater understanding of the pharmaceutical drug ecosystem, research and price transparency programs, policymakers can better understand the levers that impact consumers. In so doing, consumers will see reduced costs for their pharmaceutical drugs.

Beyond the consumer, there are numerous players that make up the pharmaceutical drug ecosystem. Some of the key players in that ecosystem are described below.

A. PAYORS

Payors of health care services include health insurance providers, large and small employers, and government entities, such as state employee plans and Medicaid agencies. The entity making decisions about benefits – including the use of PBMs and the design of the prescription drug benefit – may depend on the market (individual, small group, large group) and the arrangement that the payor chooses. In this paper, when PBM functions are referenced, payors may choose to do those tasks internally.

¹ See, e.g., the recent proliferation of drug price transparency programs across states, available as referenced by the National Academy for State Health Policy (NASHP): <https://nashp.org/prescription-drug-pricing-transparency-law-comparison-chart/>. At the time of this report, there are 13 states with drug price transparency programs.

² As indicated by Kaiser Family Foundation polls, Hamel, Liz et al. “Public Opinion on Prescription Drugs and Their Prices.” Kaiser Family Foundation Polling, Oct. 20, 2022. <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>. Accessed Sept. 19, 2022. Discussed generally by Wisconsin’s “Report of the Governor’s Task Force on Reducing Prescription Drug Prices, p. 12, available at: <https://oci.wi.gov/Documents/AboutOCI/RxTaskForceFinalReport.pdf> and Oregon Drug Price Transparency reports 2019-2022 available at: <https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx>.

³ Hamel, Liz et al. “Public Opinion on Prescription Drugs and Their Prices.” Kaiser Family Foundation Polling, Oct. 20, 2022. <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>. Accessed Sept. 19, 2022.

1. Insurers

Insurers contract with PBMs to manage the pharmacy benefit portion of their health care benefits provided to their insureds and enrollees.⁴ Insurers contract with PBMs because of the increasing complexity of prescription drug benefit management.⁵ In addition, in response to increasing prescription drug costs some insurers contract with PBMs for their services that help reduce costs, including utilization management, prescription drug rebates, and negotiation of pharmacy fees and prescription drug reimbursement, and access to pharmacy networks.⁶ Ultimately, the scope of the PBM's role in managing this benefit depends on the insurer.⁷

Some insurers are part of integrated health systems, in which a common entity owns an insurer, hospitals, and employs networks of providers and provides all health care services to their enrollees. Because these entities more closely coordinate all care under their roof, insurers in integrated systems may not utilize PBMs to the same extent as more traditional insurers.

2. Employers/Unions/Taft Hartley Trusts

Employers have a variety of options available when designing the health benefits that they offer to their employees. They may choose a self-insured model, where the employer holds the risk, but sometimes hires an insurance company, PBM, or other benefit manager to administer the benefits. Employers choose how much of the benefits they will allow a contracted insurance provider or PBM to design and may choose to “carve out” the pharmacy administration and have external entities perform different functions.

3. Government Entities

Like private employers, government entities may contract with health insurers or PBMs to administer and/or design the health benefits plan that they provide. This may include a state employee health plan, coverage provided by cities or counties, or other benefit plans that cover government employees. Within Medicaid, there are a number of state variations in coverage, but for states that contract with Medicaid managed care organizations, those organizations are often in charge of administering the benefit plan that the state designs.

B. PRESCRIPTION DRUG MANUFACTURERS

1. Manufacturers

Pharmaceutical manufacturers research, develop, produce, market, and sell prescription drugs to treat medical conditions.⁸ The development of a new pharmaceutical product involves an investment of resources to create a product ready to be tested during clinical trials, where the safety and clinical efficacy of the drug are evaluated for a specific disease or condition.⁹ Manufacturers may also partner with the federal government to develop drugs, or license drugs developed with federal research funding. Manufacturers may also purchase prescription

⁴ As discussed generally by Wisconsin's “Report of the Governor's Task Force on Reducing Prescription Drug Prices, p. 21, available at: <https://oci.wi.gov/Documents/AboutOCI/RxTaskForceFinalReport.pdf>.

⁵ *Id.*

⁶ *Id.*; Horvath Health Policy, *Innovations in Health Financing Policy* Presentation to the NAIC Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, Aug. 15, 2019.

⁷ Report on Transparency Strategies for the Pharmaceutical Supply Chain – Pursuant to House Bill 4005 (2018), Oregon Joint Interim Task Force on the Fair Pricing of Prescription Drugs. November 2018.

[https://www.oregonlegislature.gov/committees/jfprx/Reports/House%20Bill%204005%20\(2018\)%20Report%20on%20Transparency%20Strategies.pdf](https://www.oregonlegislature.gov/committees/jfprx/Reports/House%20Bill%204005%20(2018)%20Report%20on%20Transparency%20Strategies.pdf).

⁸ As discussed generally by Wisconsin's “Report of the Governor's Task Force on Reducing Prescription Drug Prices, p. 18, available at: <https://oci.wi.gov/Documents/AboutOCI/RxTaskForceFinalReport.pdf>.

⁹ *Id.*

drugs developed by other manufacturers to market as their own. The U.S. Food and Drug Administration (FDA) reviews all applications for the sale of new drugs from manufacturers following clinical trials and decides whether the drug will be made available on the market to consumers.¹⁰ When a drug is approved, manufacturers then set the list price for medications and may change that price over time.¹¹

2. Brand-Name Drugs

Manufacturers who produce brand-name drugs may conduct the initial research and development of a new pharmaceutical product. Brand-name drugs receive patents and exclusivities from the FDA.¹² Manufacturers of these patent-protected brand-name products have market exclusivity to produce and sell their products during the life of the patent before therapeutically equivalent generic drugs can become available on the market.¹³

3. Generic Drugs

Once a brand-name drug is no longer patent-protected, generic manufacturers may begin producing therapeutically equivalent generic drug products. Similar to brand-name drugs, the FDA must approve a generic drug application to ensure its equivalence to the brand-name drug before it can be produced.¹⁴ Generic drugs comprise the largest portion of the pharmaceutical market, approximately 90 percent of all drugs dispensed to consumers.¹⁵

4. Biologic Drugs

Biologic drugs are distinct from traditional brand-name and generic drugs because they are made of living cells, such as monoclonal antibodies, antitoxins, and certain vaccines.¹⁶ Biologics are sometimes referred to as “large-molecule drugs.” Manufacturers of biologic drug products are also required to receive approval from the FDA to sell their products through a separate application process.¹⁷ Biologics approved by the FDA are granted 12 years of exclusivity, which is substantially longer than the five years typically granted to traditional small-molecule brand-name drugs.¹⁸ A biosimilar drug product may be produced following the expiration of the biologic’s patent and exclusivity period.¹⁹

5. Biosimilar Drugs

¹⁰ U.S. Food & Drug Administration. The FDA’s Drug Review Process: Ensuring Drugs are Safe and Effective. <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective> Visited October 2022.

¹¹ As discussed generally at “A Tangled Web: An examination of the drug supply and payment chains”, US Senate Committee on Finance, Minority Staff report, p. 4, available at: <https://www.finance.senate.gov/imo/media/doc/A%20Tangled%20Web.pdf>.

¹² U.S. Food & Drug Administration. Frequently Asked Questions on Patents and Exclusivity, available at: <https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity>.

¹³ *Id.*

¹⁴ U.S. Food & Drug Administration. Generic Drugs: Questions & Answers, available at: <https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers..>

¹⁵ U.S. Food & Drug Administration. Office of Generic Drugs 2021 Annual Report, available at: <https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2021-annual-report#:~:text=Currently%2090%20percent%E2%80%9494%20out,they%20are%20on%20the%20market.>

¹⁶ Patient Protection and Affordable Care Act, 42 U.S.C. §262(i) (definition of “biological product”).

¹⁷ U.S. Food & Drug Administration. *Development & Approval Process (CBER)*, available at: <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber>.

¹⁸ 42 U.S.C. §262(k)(7). Data exclusivity granted by the U.S. Food and Drug Administration to a drug manufacturer prevents other companies from relying on the same clinical data to obtain market approval.

¹⁹ 42 U.S.C. §262(k).

Because of biologic drugs' complexity, they are much more difficult to replicate than the chemically produced generics for other drugs. As a result, truly identical "generic" versions are virtually impossible to produce currently. However, once patents expire for the existing brand-name biologic drugs, "biosimilar" medicines can be produced, which is an occurrence that raises regulatory issues in the states. In recent years a cumulative total of at least 49 states have considered legislation establishing state standards for substitution of a "biosimilar" prescription product to replace an original biologic product.²⁰

Comparable to the relationship between brand-names and generics, biosimilars are required to be extremely similar to approved biologics by having no clinically meaningful differences – the same strength, dosage form, and route administration (such as injection).²¹ Biologics and biosimilars can be categorized as specialty drugs when their storage requirements and complexity of administering the product to a consumer are such that they cannot be filled routinely in traditional pharmacy settings. According to the FDA, biologic and biosimilar drug products are the fastest growing class of therapeutic products in the U.S.²² Some biosimilar drugs meet additional requirements set out by the FDA and may be substituted for the reference product at the pharmacy; these drugs are known as interchangeable biosimilars.

C. PHARMACY BENEFIT MANAGERS (PBMs)

PBMs negotiate and contract with all the various types of pharmacies, including independent pharmacies and pharmacy chains of all sizes, on reimbursement and pharmacy network related terms.²³ PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers.²⁴ PBMs are responsible for the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (drug coverage, out-of-pocket responsibilities for patients and utilization management protocols).²⁵ PBMs engage in the negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.²⁶

D. PHARMACIES

1. CHAIN

A pharmacy chain refers to a third-party entity that engages in a retail business and that owns or operates multiple retail outlets at which an individual consumer may have a prescription drug order filled. The pharmacy

²⁰ National Conference of State Legislatures, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars*, May 3, 2019, available at: <https://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>.

²¹ U.S. Food & Drug Administration. *Biosimilars: More Treatment Choices and Innovation*, available at: <https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices>.

²² U.S. Food & Drug Administration. *Biosimilar Product – Regulatory Review and Approval*, available at: <https://www.fda.gov/media/108621/download>.

²³ See, generally, "A Tangled Web" at p. 26-34.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

retail outlet may also provide services that include providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling.²⁷

2. INDEPENDENT

Independent pharmacies refer to pharmacies that are privately and independently owned and operated by one or more pharmacists, and whose primary function is to provide direct pharmaceutical care to patients. These services include dispensing drugs, providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling in the community setting.²⁸

E. PHARMACISTS

The basic duty of a community pharmacist is to assess the safety and efficacy of prescriptions from physicians and other authorized prescribers before dispensing the medication to the patients to ensure that the patients do not receive the wrong drugs or take an incorrect dose of medicine. Pharmacists also provide counseling on the use of prescriptions. In addition to the medication expertise pharmacists contribute during the dispensing process, pharmacists also provide numerous patient care services to their patients to optimize the safe and effective use of medications, increase access to acute and preventative care, and work collaboratively with other members of the healthcare team to assist patients in reaching their therapeutic goals.

F. PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS (PSAOs)

Pharmacy Services Administrative Organizations (PSAOs) are organizations that provide administrative services to independent pharmacies to support the evaluation and execution of a contract with PBMs or wholesalers.²⁹ In the majority of cases, an independent pharmacy's contract is with the PSAO, rather than with the PBM directly. The PSAO's overall administrative function is to assist with contract evaluation and execution, customer service, central payment and reconciliation, and patient data evaluation.³⁰ In many instances a PSAO is owned by a wholesaler.³¹

G. WHOLESALERS/DISTRIBUTORS

Wholesalers purchase drugs from manufacturers, store those drugs, and then sell and distribute them to pharmacies, hospitals, provider offices and mail-order pharmacies. About 92 percent of prescription drugs in the United States are distributed through wholesalers, with three companies accounting for more than 90 percent of wholesale drug distribution in the United States. Wholesalers own the largest PSAOs used by independent pharmacies.

²⁷ Wisconsin's "Report of the Governor's Task Force on Reducing Prescription Drug Prices, p. 20; "A Tangled Web" generally at p. 39-40.

²⁸ *Id.*

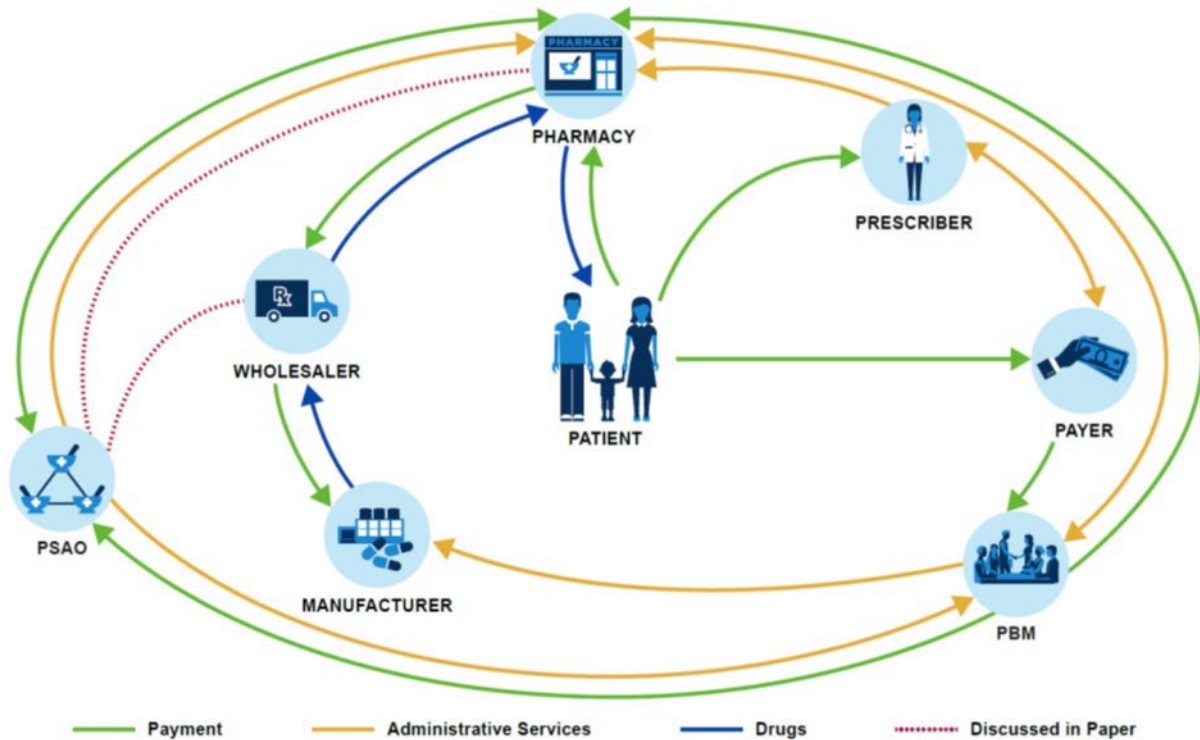
²⁹ "A Tangled Web", at p. 34, 41.

³⁰ *Id.*

³¹ Wisconsin's "Report of the Governor's Task Force on Reducing Prescription Drug Prices, p. 19.

H. INTERRELATION OF PARTIES IN THE CHAIN AND TRANSACTION COSTS

The diagram below provides a simplified illustration of the pharmaceutical distribution chain and the major entities involved that will be discussed in more detail in this section.³²



The following section outlines the basic transactions that occur between the participants in the prescription drug supply chain system. For clarity, the transactions are organized into two categories: the physical distribution of a drug and the interactions on the pharmacy benefit side.

1. Physical Drug Distribution Chain

This subsection explains interactions between participants in the physical distribution of prescription drugs.

Pharmaceutical manufacturer and wholesaler

The pharmaceutical manufacturer provides prescription drugs to the wholesaler based on negotiated prices.³³ The average negotiated price is based on the wholesale acquisition cost (WAC) price set by the manufacturer.³⁴

Wholesaler and pharmacy

³² Pharmaceutical Care Management Association (PCMA), “The Value of Pharmacy Benefit Management,” Presentation to the NAIC Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, Aug. 9, 2022

³³ Jane Horvath, Georgetown University, “Basics of the Pharmaceutical Market & PBMs,” Presentation to the NAIC Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, Aug. 19, 2019.

³⁴ *Id.*

The wholesaler sells their drugs to a pharmacy in an amount based on the WAC.³⁵ There are additional savings that can be achieved via volume rebates, functional rebates, bundle rebates, prompt pay discounts, free goods, marketing funds, and trade show discounts/rebates. The average wholesale price (AWP) is an estimate of the price wholesalers charge for drugs.³⁶ The National Average Drug Acquisition Cost (NADAC) is a federal Centers for Medicare and Medicaid Services (CMS)-calculated value that also attempts to capture the average price wholesalers charge to pharmacies.³⁷

Pharmacy and consumer

The pharmacy provides drugs directly to the consumer and collects certain cost sharing that may include co-pays or co-insurance.

2. Pharmacy Benefit Management Chain

This subsection explains interactions between participants in the administration of the pharmacy benefit plan.

Pharmaceutical manufacturer and PBM

The PBM negotiates rebates with the pharmaceutical manufacturers, and rebates are typically based on volume. PBMs can offer manufacturers higher volume, and thus command higher rebates, by putting a manufacturer's drug on the PBM's formulary and/or in a formulary's less expensive cost sharing tier.³⁸ Rebates create a market dynamic that may force up the "list" price of drugs by increasing the potential to generate "spread" profit.³⁹

Pharmaceutical Manufacturer and consumer

Pharmaceutical manufacturers can offer coupons or occasionally free samples of medications to consumers. The coupons can reduce a consumer's cost sharing below what they would have paid had they used their pharmacy benefit plan.⁴⁰

PBM and PSAO

The PSAO assists the pharmacy in negotiating with the PBMs for reimbursement rates.⁴¹ Most reimbursement rates are set based on a percentage of AWP and are applicable to all drugs based on brand or specialty status and are not negotiated on an individual drug basis.⁴²

Pharmacy and PBM

The pharmacy negotiates with the PBM to determine a reimbursement rate for the drugs they dispense.⁴³ Pharmacies typically negotiate as a chain in the case of chain pharmacies or through a PSAO. Like the PBM/PSAO

³⁵ *Id.*; and generally, "A Tangled Web" at p. 21-25.

³⁶ *Id.*

³⁷ Jane Horvath, Georgetown University, "Basics of the Pharmaceutical Market & PBMs," Presentation to the NAIC Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, Aug. 19, 2019.

³⁸ Wisconsin's "Report of the Governor's Task Force on Reducing Prescription Drug Prices, p. 21; "A Tangled Web" at 27.

³⁹ Dr. Neeraj Sood, "PBM Economics," Presentation to the NAIC Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, Aug. 22, 2019.

⁴⁰ Wisconsin's "Report of the Governor's Task Force on Reducing Prescription Drug Prices, p. 50.

⁴¹ *Id.* at 19.

⁴² *Id.*

⁴³ Horvath; Wisconsin's "Report of the Governor's Task Force on Reducing Prescription Drug Prices, p. 21.

relationship, negotiations are based on AWP less a percentage and apply to all drugs.⁴⁴ In addition, PBMs negotiate a dispensing fee with the pharmacies. Actual Acquisition Cost (AAC) is the final price a pharmacy pays after all discounts have been subtracted.⁴⁵

PBMs and Payors

A PBM may perform a number of services on behalf of its payor clients: negotiate rebates with the manufacturer, negotiate with pharmacies, and may develop the formulary on behalf of the payor, the plan sponsor or the insurer, or sell the payor a pre-determined formulary. PBMs also offer payors medical management/utilization review and disease management services.⁴⁶

PBMs are paid by the payor through an administrative fee or through a spread-pricing calculation, as specified in the contract. For payment on an administrative fee basis, the payor will pay the PBM an administrative fee, which can be in the form of a retainer, a per claim fee, or other similar arrangement. With spread pricing, also known as a risk mitigation pricing model, the payor will either not pay or pay a reduced administration fee and the PBM will retain certain risk related to the difference between the price paid by the customer and the price paid to the pharmacy. This arrangement provides the payor with the assurance of a set price.⁴⁷ Payors have the ability to choose either option in its contract with the PBM. Payors report the amount paid to PBMs for their services (including retained rebates and concessions) as administrative cost on their annual Medical Loss Ratio filings. The amount of rebates the payors receive is deducted from their claims paid.⁴⁸

With this complex pharmaceutical drug ecosystem as a backdrop, state legislatures around the country have enacted various state laws to promote greater transparency of the actions taking place and put in place specific requirements around the activities of those in the ecosystem. State laws and enforcement mechanisms have at times encountered federal pre-emption issues. Those issues are further detailed in the sections that follow.

III. ENFORCEMENT AND FEDERAL PREEMPTION ISSUES

In general, states have wide leeway to regulate PBMs serving health benefit plans in the individual market, small group market, fully insured large group market, and Medicaid. Under recent U.S. Supreme Court precedent, states also have significant authority to regulate costs for PBMs serving self-insured federal Employee Retirement Income Security Act of 1974 (ERISA) plans, though the legal boundaries of this preemption continue to be tested. It remains unclear how much authority states may exercise over PBM pharmacy networks and other elements of PBM administration. State authority to regulate PBMs serving Medicare Part D plans is limited to areas where the federal government has not established related standards.

This section will discuss the scope of federal preemption of state laws regulating PBMs under ERISA, Medicare Part D, and Medicaid, including the implications of recent and ongoing litigation.

⁴⁴ Horvath.

⁴⁵ Horvath.

⁴⁶ Horvath; Wisconsin's "Report of the Governor's Task Force on Reducing Prescription Drug Prices, p. 21.

⁴⁷ Horvath.

⁴⁸ 2 CMS Medical Loss Ratio (MLR) Annual Reporting Form Filing Instructions for the 2021 MLR Reporting Year.

<https://www.cms.gov/files/document/2021-mlr-form-instructions.pdf>

A. ERISA: (SELF-INSURED AND FULLY INSURED)

ERISA governs all health benefit plans established by private-sector employers and certain employee organizations, such as unions.⁴⁹ ERISA's preemption clause, section 514, preempts all state laws to the extent that they "relate to" employer-sponsored health plans.⁵⁰ However, states are still permitted to maintain regulation of "the business of insurance" including for ERISA plans.⁵¹ This generally allows the states to regulate insurance carriers operating traditional insurance business, including regulation of plan design, solvency, and capital requirements for insurance companies.

However, ERISA explicitly prohibits states from regulating self-insured health plans where an employer bears the primary risk of claims and an insurer acts solely in an administrative capacity without bearing any risk.⁵² Under current federal court precedent, this effectively divides the large-group market into "fully insured" plans that are generally subject to state insurance law, and "self-insured" plans that are generally exempt from state insurance regulation.

Over the last 30 years, the U.S. Supreme Court has issued a series of opinions that narrow the scope of ERISA's preemption language. The most recent case, *Rutledge v. Pharmaceutical Care Management Association (PCMA)*,⁵³ decided in 2020, held that an Arkansas law (Act 900) requiring PBMs to reimburse pharmacies at a price equal to or greater than a pharmacy's wholesale cost was not preempted by ERISA. This suggests that states can regulate the conduct of PBMs that serve both fully insured and self-insured employer plans, to at least the same extent as the Arkansas law.

In *Rutledge*, the U.S. Supreme Court affirmed a legal standard stated in a prior decision, *Gobeille v. Liberty Mutual Insurance Company*.⁵⁴ To determine whether a state law has an impermissible connection with an ERISA plan, the Court asks whether the law "governs a central matter of plan administration or interferes with nationally uniform plan administration." In particular, a state law that "merely affects costs" will not be preempted, even where a cost regulation creates a significant economic incentive for a plan administrator, so long as it does not "force" a plan to adopt a certain "scheme of substantive coverage."⁵⁵

Taken together, this suggests that a state law comparable to Arkansas's Act 900 will not be preempted by ERISA, even if it applies to self-insured plans. The features of Act 900 upheld by *Rutledge* are as follows:

- (1) Requires PBMs to reimburse a pharmacy at a price equal to or greater than what the pharmacy paid to buy the drug from a wholesaler;

⁴⁹ Furrow, et al., "Health Law" Third Ed. (2014), p. 325-27.

⁵⁰ *Id.* at 328.

⁵¹ See, e.g., Furrow generally at p. 328-330.

⁵² *Id.* at 328.

⁵³ *Rutledge v. Pharmaceutical Care Management Association*, 141 S.Ct. 474 (2020).

⁵⁴ *Gobeille v. Liberty Mutual Insurance Company*, 577 US 312 (2016).

⁵⁵ *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 US 645 (1995). The Court found that a 13% surcharge that applied to all insurers other than Blue Cross / Blue Shield was not preempted by ERISA, despite creating a significant incentive for self-insured employers to choose Blue Cross / Blue Shield over other carriers. Since the law did not "force" plan administrators to make a particular choice, it was allowed by the court.

- (2) Requires PBMs to increase their reimbursement rate to cover a pharmacy's acquisition cost if that pharmacy is unable to acquire the drug at a lower price from a typical pharmaceutical wholesaler;
- (3) Requires PBMs to timely update their Maximum Allowable Cost (MAC) lists when drug wholesale prices increase;
- (4) Requires PBMs to provide an administrative appeals procedure for pharmacies to challenge MAC reimbursement that is below a pharmacy's acquisition cost;
- (5) Requires PBMs to permit a pharmacy to "reverse and rebill" any reimbursement claim affected by the pharmacy's inability to acquire the drug at a price equal to or less than a PBM's MAC reimbursement price;
- (6) Permits a pharmacy to decline to sell a drug to covered beneficiary if the relevant PBM will reimburse the pharmacy for less than the pharmacy's acquisition cost.

The PCMA argued that the enforcement mechanisms of the Arkansas law impermissibly interfere with ERISA plan management. The U.S. Supreme Court rejected this argument, noting that if taken to the extreme, the PCMA's proposed interpretation would preempt all state law mechanisms for resolving insurance payment disputes. However, beyond allowing Arkansas Act 900 to go into effect, the Court provided little guidance regarding what is or is not a matter "central to plan administration."

In a subsequent federal district court decision, *PCMA v. Mulready*⁵⁶, the court relied on *Rutledge* to conclude that Oklahoma's PBM law was not preempted by ERISA (the court's additional reasoning related to Medicare preemption is discussed below). The statute at issue in *Mulready* regulates both the network status of particular pharmacies as well as the conditions under which a PBM may reimburse for prescriptions, which the PCMA argued goes significantly beyond "mere cost regulation." However, the PCMA has appealed the *Mulready* decision, and it remains unclear whether the appeals court or other courts will follow its reasoning. On Aug. 15, 2023, the U.S. Court of Appeals for the 10th Circuit, issued a ruling reversing the federal district court's decision. The court held that ERISA and Medicare Part D preempt the four challenged provisions. It is anticipated that Oklahoma will appeal the ruling. Oklahoma has filed an en banc petition for rehearing with the 10th Circuit Court.

Another important aspect of the law at issue in *Rutledge* is that it is not applied exclusively to or even expressly to ERISA plans. Rather, it applies to PBMs whether or not they manage ERISA plans. Under prior U.S. Supreme Court precedent, a law may be preempted by ERISA if it "acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation."⁵⁷

Under the precedent of *Rutledge*, it seems clear that states have some leeway to regulate PBMs without concern for ERISA preemption. A law that distinguishes between ERISA and non-ERISA plans would be more likely to be preempted, particularly if it places a higher burden on ERISA plans than for other markets. A law that mandates particular pharmaceutical coverage, such as requiring reimbursement for a specific drug or diagnosis, would likewise be preempted as regulating plan design. In contrast, a law that applies to PBMs regardless of

⁵⁶ *Pharmaceutical Care Management Association v. Mulready*, 598 F.Supp.3d 1200 (2022).

⁵⁷ *Rutledge*, at 6.

market segment that merely regulates cost, similar to the Arkansas statute, would likely be upheld. Lesser regulations, such as transparency programs, are also unlikely to be preempted under ERISA.

B. MEDICARE PART D

Medicare Part D is an optional, federally supported prescription drug benefit available to Americans over the age of 65. The program’s authorizing legislation incorporates the federal preemption language from the Medicare Part C, or “Medicare Advantage (MA)” program, which provides: “the standards established under this part shall supersede any state law or regulation (other than state licensing laws or state laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.”⁵⁸

In general, courts have found that state laws are preempted under Medicare Part D where Congress or the CMS have established “standards” for the area regulated by said state laws. This means that the authority of states to regulate MA or Medicare Part D plans is significantly limited, though states explicitly retain the authority to regulate plan solvency. The Medicare Managed Care Manual indicates that state law should only be preempted where it would be impossible for a carrier to comply with both state and federal standards – a state standard that is stricter than the Medicare standard should not be preempted. However, courts have held that standards set by the CMS do not necessarily need to conflict with the provisions of state law for preemption to hold.

In *Mulready v. PCMA*, the federal district court ruled that many provisions of Oklahoma’s PBM statute were preempted with respect to Medicare Part D plans (the preceding section discussed the same court’s reasoning with respect to ERISA plans).⁵⁹

In its review of the statute at issue, the *Mulready* court found that several provisions of Oklahoma’s law were preempted by Medicare Part D. This included multiple elements of the law related to pharmacy reimbursement, including a ban on PBM service fees, a ban on PBMs reimbursing affiliated pharmacies at higher rates, and a ban on PBMs reducing pharmacy reimbursement after completion of a sale. Part D prohibits interference with negotiation between insurers and pharmacies, and Part D defines “negotiated price” by reference to the negotiations.⁶⁰ Accordingly, the federal district court agreed with the PCMA that these aspects of the state law were barred with respect to PBMs serving Medicare Part D plans as an impermissible interference in the price negotiations between PBMs, as the agents of Medicare Part D carriers, and pharmacies.⁶¹

The federal district court also ruled that Oklahoma’s retail-only pharmacy access standard was preempted because the CMS has established standards regulating convenient access to network pharmacies.

However, the federal district court held that the remaining provisions of the Oklahoma law challenged by the PCMA were not preempted by Medicare Part D.⁶² This includes the law’s requirements for preferred pharmacy networks, including the law’s any willing provider provision, affiliated pharmacy prohibition, and network provider restriction. The federal district court reasoned that while the CMS has promulgated a standard with respect to standard networks, there is no federal standard in place for preferred networks. Since all the relevant

⁵⁸ 42 CFR § 422.402.

⁵⁹ *Pharmaceutical Care Management Association v. Mulready*, 598 F.Supp.3d 1200 (2022).

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

provisions of Oklahoma law apply only to preferred network status, the federal district court ruled there was no applicable standard in place that would preempt Oklahoma’s law.

Finally, the federal district court rejected the PCMA’s challenge to Oklahoma’s contract approval provisions.⁶³ Under the Oklahoma statute, insurers who utilize the services of PBMs are required to approve all contracts between the PBM and the PBMs retail pharmacy network. In this instance, the PCMA again pointed to Medicare Part D’s ban on interference in contract negotiations. However, the federal district court reasoned that Medicare Part D’s bar applies only to negotiations between plan sponsors and PBMs, while Oklahoma’s law regulates negotiations between PBMs and pharmacies. Accordingly, the federal district court concluded that the contract approval provisions of Oklahoma’s law are not preempted by Medicare Part D.

The PCMA has appealed the federal district court’s decision. On Aug. 15, 2023, the 10th Circuit issued a ruling reversing the district court’s decision. The court held that ERISA and Medicare Part D preempt the four challenged provisions. It is anticipated that Oklahoma will appeal the ruling. Oklahoma has filed an en banc petition for rehearing with the 10th Circuit Court.

C. MEDICAID

Medicaid is a program that provides health benefits to certain low-income Americans and is jointly funded by the federal government and state governments.⁶⁴ It is structured very differently from either Medicare Part D or ERISA. Both Medicare and ERISA were set up with the intent of establishing uniformity of implementation nationwide – making preemption of state laws that conflict with the federal plan an important element of the program’s structure. Medicaid, however, is structured as a federal-state partnership and its implementation varies significantly from state to state. This means that the states have broad leeway to regulate PBMs serving Medicaid carriers, if those regulations do not come into conflict with the state’s Medicaid structure.

Each state implements Medicaid pursuant to a Medicaid plan submitted by the state and approved by the CMS.⁶⁵ Any changes a state makes to Medicaid implementation must also be approved by the CMS via a plan amendment process.⁶⁶ In some cases, states may also receive a waiver from certain terms of the Medicaid provisions in the Medicare and Medicaid Act (herein referred to as the Medicaid Act) under Section 1115 of the Social Security Act. So long as the PBM regulation is consistent with the terms of the state’s current Medicaid plan, it should be safe from federal preemption.

However, state laws that conflict with the terms of the Medicaid Act can still be theoretically preempted under the Supremacy Clause of the U.S. Constitution. Unlike Medicare Part D and ERISA, the Medicaid Act does not include any preemption language that goes beyond common law interpretation of the Supremacy Clause. Under common law, a state law will generally be preempted only if it is impossible for a regulated entity to comply with both the state and the federal statute. However, jurisprudence specifically related to Medicaid preemption is extremely limited, making definitive analysis difficult.

In many states, the state Medicaid agency contracts with one or more managed care organizations (MCOs) to administer all or a part of the state’s Medicaid program, including the management of the pharmacy program

⁶³ *Id.*

⁶⁴ See, e.g., Furrow generally at p. 460-462.

⁶⁵ Furrow at p. 490-492.

⁶⁶ *Id.*

through the MCO's contracted PBM. Some states also contract with PBMs directly to administer the pharmacy benefit, either in conjunction with or separate from an MCO. In other cases, the state Medicaid agency manages the Medicaid pharmacy program on its own.

To address rising costs, Congress passed legislation enacting the Medicaid Drug Rebate Program in 1990. Under this program, pharmaceutical manufacturers sign a master rebate agreement with the CMS, which administers the Medicaid program at the federal level. These rebates result in prescription drug cost savings that are paid for under the Medicaid program and are shared by both the state Medicaid agency and the CMS. State Medicaid programs are required to provide a pathway to coverage for any drug whose manufacturer has signed a rebate agreement with the CMS. Therefore, state Medicaid programs lack the flexibility that private insurers have to implement strict formularies to control prescription drug spending. Instead, state Medicaid programs are allowed to negotiate additional "supplemental rebates" with pharmaceutical manufacturers individually, and to develop preferred drug lists in consultation with state Drug Utilization Review (DUR) Boards and Pharmacy and Therapeutics (P&T) Committees.

In summary, Medicaid preemption should not be a significant concern for states looking to regulate PBMs that serve Medicaid MCOs or other Medicaid carriers. However, states should ensure that any changes to PBM regulation in the Medicaid space are consistent with the state's Medicaid plan or seek an appropriate plan amendment if they are not.

IV. FUNCTIONAL ISSUES

As the national conversation has evolved, most of the direct regulation has involved the practices of PBMs. As such, the most robust bodies of law and descriptions of practices have focused on PBM activities. Several functional issues within this ecosystem have been identified by state regulators as central to the ultimate pricing consumers pay or as having other significant marketplace impacts. Those functional issues are discussed in the sections that follow.

A. FORMULARY DESIGN

PBMs implement formularies or lists of covered drugs⁶⁷. PBMs' customers – payors, such as insurers or self-funded employer plans, may request open formularies, develop their own formularies, or purchase formularies from PBMs. Even closed formularies typically require coverage for at least one drug per therapeutic class.

For PBM developed formularies, PBMs employ panels of experts called Pharmacy and Therapeutics (P&T) Committees. These committees, made up of independent physicians, pharmacists, and other health care providers, evaluate clinical and medical literature to select the most appropriate medications for individual disease states and conditions.⁶⁸ The federal Affordable Care Act (ACA) introduced federal regulations on P&T Committees serving qualified health plans (QHPs).

⁶⁷ Derek J. Oestreicher, Office of the Montana State Auditor, "A Prescription for the Drug Price Epidemic," Presentation to the NAIC Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, Oct. 3, 2019.

⁶⁸ Horvath.

P&T Committees typically reviews drugs to identify those that are required (preferred), unacceptable and acceptable based on medical standards. The category of those that are determined acceptable is where there is leeway on the PBM's part to determine formulary inclusion.⁶⁹

PBMs review acceptable drugs that have been determined "clinically equivalent" and negotiate for the highest rebate and include these drugs in the formulary. PBMs negotiate drug costs with pharmaceutical manufacturers across the board for all customers using their volume of scale and then work with individual customers to create formularies.

Formularies provide lists of pharmaceutical drugs covered by payors and can be differentiated between preferred or discouraged products by dividing into three to five "tiers," each with a separate level of cost sharing.⁷⁰ By placing a drug in a preferred tier, PBMs can drive volume to that drug's manufacturer. This is an effective way for PBMs to generate rebates for either multi-source brands or competing brands in a therapeutic class.

Since formularies are essentially coverage decisions, a PBM's step-therapy protocol may be viewed as part of its formulary. Step-therapy, a utilization management tool, requires a patient to try a particular drug before another drug is covered. PBMs may shift drugs between tiers or add or remove them from the formulary entirely during a plan year, another utilization management practice which is known as "non-medical switching."⁷¹

B. REBATES

The negotiation between a pharmaceutical manufacturer and PBM may result in a rebate. The rebate flows back to the PBM from the manufacturer usually based on the volume of prescriptions generated by the placement of the manufacturer's drug on the PBM's formulary. The PBM may pass the rebate on to the plan sponsor according to their shared contract, which may allow the PBM to keep a percentage of the rebate; however, it is possible the PBM keeps the entire rebate with no direct benefit to the plan sponsor or the consumer.⁷²

Rebates are mostly used on brand-name and specialty drugs where similar competing drugs from other manufacturers exist. From a manufacturer's perspective, the rebate is a tool to incentivize PBMs to place the manufacturer's drugs on formularies within preferred tiers.⁷³ PBMs negotiate based on their volume of scale to obtain highest rebate for selected drugs.⁷⁴ From the PBM's perspective, a large rebate results in a smaller amount spent by their customers and more income for the PBM from proportional pass-through contracts.⁷⁵

⁶⁹ *Id.*

⁷⁰ Oregon Drug Price Transparency Report of 2019 at 10-11, available at:

<https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2019.pdf>.

⁷¹ See, e.g., National Conference of State Legislatures Glossary at: <https://www.ncsl.org/health/state-policy-options-and-pharmacy-benefit-managers#anchor16752>.

⁷² Oregon Drug Price Transparency Report of 2019 at 10-11; Sood; Oestreicher.

⁷³ Sood; Oestreicher.

⁷⁴ *Id.*

⁷⁵ *Id.*

Rebates are negotiated separately with each plan sponsor and can take different forms in how they are passed along.⁷⁶

- 100 percent pass-through – The PBM passes 100 percent of the rebate back to the plan sponsor. Most customers prefer this method.
- Proportional pass-through – The PBM keeps a percentage of the rebate and passes the remainder back to the plan sponsor.
- At Risk – The PBM keeps 100 percent of the rebate but guarantees a certain level of rebate to the customer. In this instance the PBM is “at risk” for the difference between the guarantee and actual rebates received. In exchange, this option provides cost predictability to the customer.

The existence of rebates alone is not a problem. However, the PBM’s ability to retain a percentage of the rebate creates a concern as they are also commonly in charge of formulary design. These two factors give PBMs a financial incentive to prioritize drugs in the formulary based on the highest rebate instead of the lowest total cost to the plan sponsor or consumer.⁷⁷ This could result in plan sponsors and consumers paying a higher cost for prescription drugs than is necessary, resulting in higher prescription drug coverage costs.

Approaches to curb the negative effects of rebates include:

- Rebate retention prohibitions: As part of their PBM laws, some states have enacted a provision stating that a PBM must pass through 100 percent of a pharmaceutical manufacturer rebate to a plan sponsor.⁷⁸
- Rebates at point-of-sale (POS): Some believe that rebates should be provided directly to consumers at POS to reduce deductibles or co-insurance amounts owed when the drug is purchased. As a result, these funds would no longer be used to offset the plan sponsor costs and could result in higher premiums for all members. Additionally, members with low or no prescription drug usage might experience a disproportional impact as they would be paying higher premiums and would not have a financial benefit from the POS rebates. Some insurers have indicated that passing the rebates to the consumer at POS would have a dramatic enough effect on drug adherence that it would cover the potential benefit of using the rebates against premiums and result in no additional premium cost.⁷⁹
- Elimination of rebates: Some have recently called for the elimination of rebates to provide more price transparency within the system. While the elimination of rebates might serve to achieve this, it could also cause a major disruption in current market conditions. In the short term, eliminating rebates without corresponding legislation to lower pharmaceutical manufacturer prices could lead to increasing the cost of drugs to PBMs, plan sponsors and ultimately consumers. In the longer term, eliminating rebates could lead to increased transparency in price competition between manufacturers of similar drugs as price setting would no longer happen in a private contractual setting with a PBM.⁸⁰

C. PRICING AND CONTRACTING PRACTICES

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ Horvath; Sood. Oestreicher.

⁷⁹ *Id.*

⁸⁰ *Id.*

PBMs negotiate with pharmaceutical manufacturers, health plans, and pharmacies. PBMs may also be affiliated with a health plan and a pharmacy. In particular, the unique market position and negotiating power of PBMs enables them to engage in contracting practices that may be detrimental to consumers and other market participants.⁸¹ A variety of pricing and contracting practices are used by PBMs and have received scrutiny from regulators. Several of these practices are described below:

- **Gag clauses:** The term “gag clause” refers to a stipulation in a pharmacy benefit contract that prohibits a pharmacy or pharmacist from informing consumers of an alternative option when purchasing a drug. For instance, a gag clause may prohibit a pharmacist from telling a consumer about a generic version of a prescription drug or if a prescription drug can be purchased at a lower price out-of-pocket rather than through their insurance plan.⁸²
- **Mandatory arbitration clause:** Most PBMs require that disputes be submitted to binding arbitration by including a mandatory arbitration provision in their pharmacy contracts. Some believe mandatory arbitration limits legal recourse for individual pharmacies and results in pharmacies foregoing potentially successful audit challenges.⁸³
- **Copay clawbacks:** A copay clawback is the PBM practice of taking back from a pharmacy the difference between a patient’s copay and the actual cost of the medication when the patient’s copay is larger than the cost of the drug.⁸⁴
- **MAC transparency:** A maximum allowable cost (MAC) list is a list that includes the maximum amount that a plan will pay for certain drugs.⁸⁵ MAC lists are often generated by the PBM. There is no standardization in the industry as to the criteria for the inclusion of drugs on MAC lists or for the methodology as to how the maximum price is determined, changed or updated. PBMs may sometimes use multiple MAC lists and pocketing the spread between the two. For example, PBMs might use a very low MAC list to reimburse pharmacies but a higher list when charging plan sponsors.⁸⁶
- **Rebates:** Rebates may provide incentive for a PBM to eliminate a less expensive, comparable medication from a formulary. Pharmaceutical manufacturers claim that these rebates are meant to be shared with plan sponsors or passed on to consumers in the form of lower drug prices. However, PBMs regularly keep a share of the rebates before passing the rest through to the plan sponsor.⁸⁷
- **Spread pricing:** Spread pricing is the practice of a PBM charging a plan sponsor a higher amount for a drug than they will reimburse the pharmacy and pocketing the difference. Pharmacy pricing is complex, and the process is not transparent. Plan sponsors are often unaware of the difference between the amount they are billed and the pharmacy reimbursement.⁸⁸
- **Pharmacy audit:** PBMs routinely audit pharmacies to validate data entry, ensure compliance with regulatory and contractual requirements, and to help identify and mitigate fraud, waste, and abuse of a

⁸¹ Sood.

⁸² “A Tangled Web,” p. 33, 44; National Conference of State Legislatures Glossary of PBM terms, available at: [State Policy Options and Pharmacy Benefit Managers \(ncsl.org\)](https://www.ncsl.org/state-policy/state-policy-options-and-pharmacy-benefit-managers).

⁸³ Oestreicher.

⁸⁴ *Id.*; “A Tangled Web,” p. 33.

⁸⁵ National Conference of State Legislatures Glossary of PBM terms, available at: [State Policy Options and Pharmacy Benefit Managers \(ncsl.org\)](https://www.ncsl.org/state-policy/state-policy-options-and-pharmacy-benefit-managers).

⁸⁶ “A Tangled Web,” p. 29-30.

⁸⁷ Horvath.

⁸⁸ Oestreicher.

prescription drug benefit. However, many pharmacists have stated that the audits are unfair and may result in stiff penalties and fees.

- Retroactive fees: PBMs engage in retroactive claim reviews, meaning they review a claim after it has been adjudicated. A retroactive claim review may result in a denial of a claim or a reduction in reimbursement after payment for the claim has been authorized.

Each of these practices has been addressed by one or more state laws around the country; however, the scope and method of regulation has varied by those states. More details are provided in the state-specific sections below.

D. VERTICAL INTEGRATION AND CONSOLIDATION

In business and economics, vertical integration means the combination in one company of at least two stages of production normally performed by separate companies. For example, an entity that manufactures a product may also be affiliated with a wholesale distributor and a retail store through common ownership.⁸⁹ The entities at the various levels of the integrated enterprise may deal exclusively with the parent company's goods or services or may offer non-integrated products or services.⁹⁰

The three largest PBMs are each affiliated with a health plan and a pharmacy, so the parent company owns or controls up to three stages of the drug supply chain.⁹¹ Some PBMs are also affiliated with health care providers, such as retail clinic services. Thus, one entity controls the diagnosis of a condition, the retail sale of a prescribed drug to the patient, the distribution of the drug from manufacturer to retail pharmacy, and the insurance payment to the pharmacy, including determination of the patient's cost-sharing amounts.

In theory, vertical integration allows a company to synergize operations between stages of production and pass the savings from smaller transaction costs to their customers. However, vertical integration can also be a contributing factor in the monopolization of markets due to market foreclosure, where the merger or acquisition of a stage of production denies competing businesses access to that firm's business.⁹²

Consolidation refers to the merger and acquisition of many smaller companies resulting in a few much larger companies. The benefit of consolidation is that a larger firm may be able to realize efficiencies of scale and pass the resulting cost savings to consumers. The downside of consolidation is that costs tend to rise when there are fewer existing firms around to compete on prices and the few remaining firms price their products to maximize profit.⁹³ Along with vertical integration, consolidation in the pharmacy benefit supply chain has led to current market conditions, which feature the three largest PBMs covering 79 percent of prescription drug claims.⁹⁴ Further, independent pharmacies are put at a competitive disadvantage compared to PBM-affiliated pharmacies when it comes to contracting.

⁸⁹ Sood.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ [PBMs ranked by market share: CVS Caremark is No. 1](#); Becker's Hospital Review (website); March 8th, 2022.

The proliferation of PBM-health insurer affiliations has resulted in inefficiencies in the market.⁹⁵ From the health insurer’s perspective, an affiliation with a PBM is incredibly valuable for two reasons: lower costs for pharmacy benefit services and exclusive or priority access to the PBM. From a market perspective, a PBM-health insurer relationship results in lower market competition, dealings within affiliated businesses and possible anti-competitive practices.⁹⁶ The three largest PBMs are all affiliated with health insurers, so other large health insurers not affiliated with a PBM are no longer able to find a PBM that operates on their scale that is not affiliated with a competitor.

A PBM-pharmacy affiliation creates several incentives for PBMs to act against the best interests of the consumer. PBMs have been found inserting language into pharmacy benefit contracts that requires enrollees to use PBM-owned mail pharmacy services for long-term (90 days or longer) “maintenance” medications.⁹⁷ This contractual requirement effectively eliminates any competition to fill these prescriptions, allowing the pharmacy to charge higher prices to the consumer. An affiliation with a pharmacy may also incentivize a PBM to do the following, which are all contrary to the best interests of consumers:

- Perform fewer generic substitutions;
- Switch patients to higher-cost therapeutic alternatives (“therapeutic interchange”); or,
- Repackage drugs in a manner that could lead to increased costs to plan sponsors, while maximizing revenue for the PBM (“package size pricing”).

E. PHARMACY NETWORK ADEQUACY

A pharmacy network is a list of pharmacies or pharmacists that a health plan or PBM has contracted with to provide prescription drug services to their members.⁹⁸ Pharmacy network adequacy is often defined as the distance between a patient’s residence and where services can be physically accessed.

Pharmacy access is an integral component of the standards established under section 1860D-4(b)(1)(C) of the federal Medicare Modernization Act of 2003. The standards require in part that each sponsor secure the participation in their pharmacy networks of a sufficient number of pharmacies to dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered drugs by plan enrollees. Several states have since followed suit, defining acceptable pharmacy network adequacy standards for network participation with respect to various regions of their states and across all health plan types. Pharmacy network adequacy provisions effectively prohibit a PBM from deciding to contract with a narrow pharmacy network, potentially limiting member access to prescription drugs.

Some states specify that mail order pharmacies cannot be used to determine compliance with pharmacy network adequacy standards, while others specify that a network must have a mix of both retail and mail order pharmacies. Standards can be established by time and distance standards relative to the state as a whole, or to counties, or zip codes. In determining whether a PBM complies with access requirements, states review and

⁹⁵ Sood.

⁹⁶ *Id.*

⁹⁷ “A Tangled Web,” p. 42-43.

⁹⁸ Horvath; National Conference of State Legislatures Glossary of PBM terms, available at: [State Policy Options and Pharmacy Benefit Managers \(ncsl.org\)](https://www.ncsl.org/state-policy/state-policy-options-and-pharmacy-benefit-managers).

consider the relative availability of physical pharmacies in a geographic service area.⁹⁹ Common pharmacy network adequacy requirements include:

- Defining what is a reasonably adequate retail pharmacy network;
- Making clear that mail-order pharmacies cannot be used to meet access standards;
- Requiring pharmacy networks to consist of both retail and mail order pharmacies in a specific geographic service area;
- Requiring ongoing monitoring of a PBM's capacity to furnish services;
- Network accessibility reporting requirements;
- A current, accurate, and searchable directory of pharmacies; and
- Requiring a minimum of at least one pharmacy per county, zip code, or other specifically defined service area.

About 35 percent of the states have some type of legislation that addresses PBM's placing heightened accreditation requirements upon pharmacies seeking to join the PBM's networks.¹⁰⁰ When this is the case, common legislative elements include prohibiting PBMs from imposing provider accreditation standards or certification requirements inconsistent with, or more stringent than the requirements of the state board of pharmacy or other state/federal agencies. Typically, the PBM must apply standards without regard to PBM affiliation and may not change the standards more than once every 12 months. The last common element is requiring PBMs to provide written disclosures upon request.

Commonly, PBMs, or the health plans they contract with, require members to have their prescriptions filled *only* at pharmacies with which the PBM, or the health plan, is affiliated or has an ownership interest in. This is considered "steering," and is sometimes prohibited by state law.¹⁰¹ Sometimes PBMs will even mine members' health data in an attempt to steer them to the PBM's affiliated pharmacies. This practice has become more popular as the number of health insurance companies that own PBMs has increased. Steering can limit a member's choice, increase costs, and lower quality of care to members.

Anti-steering state legislation typically prohibits PBMs from requiring drugs to be dispensed from specific contracted or affiliated pharmacies and prohibits PBMs from assessing additional fees when a prescription is filled by an in-network contracted pharmacy, but which is not specifically authorized by the PBM to fill certain types of prescriptions as a "specialty pharmacy." This occurs even when a pharmacy may otherwise have the credentials to do so, such as when it is a compounding pharmacy.

Such anti-steering legislation can have a major impact. It has been reported that even though less than 2 percent of the population uses specialty drugs, those prescriptions account for a staggering 51 percent of total pharmacy spending. This is a rapidly increasing trend. At a member level, plan sponsors see an average annual cost of \$38,000 to cover a specialty patient's drugs, compared to just \$492 for the coverage of a non-specialty patient's drugs. That is 75 times more to cover a specialty patient over the course of a year.¹⁰²

⁹⁹ National Conference of State Legislatures Glossary of PBM terms, available at: [State Policy Options and Pharmacy Benefit Managers \(ncsl.org\)](https://www.ncsl.org/legislative-services/healthcare/pbm-terms).

¹⁰⁰ See generally, PBM Law Compilations, available at: https://content.naic.org/cmte_b_pharmacy_bmri_sg.htm.

¹⁰¹ Sood.

¹⁰² See Evernorth Health Services, "What is Drug Trend and How to Manage It" last accessed February 27, 2023, available at: <https://www.evernorth.com/articles/specialty-drug-trends-and-utilization>.

These types of practices can result in harm, including increasing drug prices, overcharging members, restricting a member's choice of pharmacies, underpaying community pharmacies and other dispensers, and fragmenting and creating barriers to care, particularly in rural areas, and for members battling life-threatening illnesses and chronic diseases.

F. LICENSING OF DIFFERENT ENTITIES INVOLVED IN THE DISTRIBUTION/SUPPLY CHAIN

Even though PBMs are engaged in interstate commerce and are not purely in the business of insurance, the trade practices described herein have largely eluded federal regulatory oversight. Many states have enacted licensing schemes to regulate PBMs in the absence of federal oversight. These licensing schemes usually place PBMs under the regulatory authority of a state's insurance department. Most states have gone about this in two ways: 1) regulating PBMs under a third-party administrator (TPA) law; or 2) establishing a standalone license for PBMs. The various licensing laws address some of the issues herein through prohibition of certain behaviors, requiring transparency in business practices, or by requiring disclosures by the PBM.

Based on the conversations of the NAIC Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, a standalone PBM license is generally preferred among regulators. Anything less than licensure, including a registration requirement, is considered to lack significant enforcement mechanisms.

Other key players that are licensed in the distribution and supply chain are described in this section. The level of regulation imposed on other players in the supply chain demonstrates the uniquely minimal level of oversight PBMs have experienced and continue to experience in many jurisdictions.

1. Health insurers

Commercial health insurers are subject to federal and state oversight. Insurers providing fully insured employer or group plans and individual market coverage are regulated by states.¹⁰³ Self-insured health plans sponsored by employers or unions are subject to federal oversight pursuant to ERISA, although the *Rutledge v. PCMA* case does seemingly allow state regulation of certain PBM activities performed for ERISA plans.

2. Wholesalers

All 50 states and the District of Columbia require a wholesaler to be licensed. The structure of the statutes vary but all of the statutes incorporate federal regulation language. There are several federal regulations that establish the minimal licensing requirements for drug wholesalers in the states. Every wholesale distributor in a state must be licensed by the state licensing authority, and the state must require that personnel employed by distributors have the appropriate education and/or experience for the position that person is hired for.

Per 21 C.F.R. § 205.6, the following factors should be considered by the states before granting a wholesaler license:

- Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
- Any felony convictions of the applicant under federal, state, or local laws;
- The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
- The furnishing by the applicant of false or fraudulent material in any application made in connection with pharmaceutical manufacturing or distribution;

¹⁰³ Furrow at p. 308, 314-316.

- Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
- Compliance with licensing requirements under previously granted licenses, if any;
- Compliance with requirements to maintain and/or make available to the state licensing authority or to federal, state, or local law enforcement officials those records required under this section; and
- Any other factors or qualifications the state licensing authority considers relevant to and consistent with the public health and safety.

3. Manufacturers

Pharmaceutical manufacturers are required to be registered with the FDA within five days of starting operations (see 21 C.F.R. § 207 et seq). Applicants are required to provide standard business information as well as the list of drugs they produce as part of the application process. In addition to registering pharmaceutical manufacturers, the FDA also reviews all human drugs, including biologics, for safety, effectiveness, and quality. Each new drug has an application process; there is a licensing application for biologics. The FDA also inspects manufacturing facilities for drugs, including biologics, before drug production begins and according to their Compliance Program Guidance Manual (CPGM).

While most states require pharmaceutical manufacturers that produce or distribute drugs within their state to be licensed, states exercise little total control over pharmaceutical manufacturers. The FDA is responsible for approving new drugs and allowing for a given drug's patent protection period, which gives manufacturers a period of exclusivity before generics of that drug are allowed to be produced. Because the federal government is responsible for this function, there is little states can do about some of the life cycle management practices manufacturers engage in to extend the market exclusivity of their drugs. Pharmaceutical manufacturers commonly seek to extend their patent protection period by providing a new formulation of a drug or changing the route of administration for a drug.

4. Pharmacies

All 50 states and the District of Columbia require pharmacists to be licensed to practice within the state. To obtain a pharmacist license, states commonly require the applicant to satisfy the following criteria:

- Complete an application and pay the required fee;
- Proof of completion of a college degree in pharmacy from an approved college or other institution
- Completion of an approved internship, typically requiring between 1,000 and 1,750 hours;
- The applicant has passed the Multistate Pharmacy Jurisprudence Examination (MPJE) and the North American Pharmacist Licensure Examination (NAPLEX); and
- A fingerprint background check of some nature, normally including a criminal record search and/or production of a birth certificate and/or other vital documents.

All 50 states and the District of Columbia also require pharmacies to be licensed. Typically, the information needed for a license includes:

- Business entity information;
- The type of pharmacy (retail, hospital, sterile compounding, nuclear, etc.);
- Pharmacist-in-charge information, including license number;
- Articles of incorporation/formation;
- A list of officers and owners of the business;
- Disciplinary and criminal history for owners and officers of the pharmacy;
- A list of other licensed personnel who will operate the pharmacy, such as pharmacy technicians and pharmacist interns;

- Pharmacy hours of operation; and
- Application and license fees.

5. Pharmaceutical sales representatives (PSRs)

In comparison to other entities in the pharmaceutical supply chain, few states require pharmaceutical sales representatives (PSRs) to be licensed. PSRs have a large potential impact on the use and overuse of pharmaceutical drugs based on their interactions with prescribing health care providers.

PSR licenses generally require a pharmaceutical manufacturer to supply a list of all PSRs to the regulating entity. For licensure, the PSRs are generally required to take a professional education course that may include training ethics, pharmacology, and pharmaceutical marketing laws and rules. A licensed PSR is required to submit an annual report to the regulating entity that includes information on which health care providers they have contacted, which drugs they sold, any samples or gifts that were provided, and if the providers were compensated for their time.

In the absence of a law, the Pharmaceutical Research and Manufacturers of America (PhRMA) has instituted a Code on Interactions with Health Care Professionals.¹⁰⁴

The licensing of entities involved in the distribution/supply chain is an evolving area. Many activities performed by some of these entities may be captured by state TPA laws, although some may not be. The NAIC Pharmacy Benefit Manager Regulatory Issues (B) Subgroup continues to monitor developments in this area.

V. STATE LAWS IMPACTING THE DRUG SUPPLY CHAIN

In the last several years states have been working on legislative solutions to increase transparency and accountability for key players in the prescription drug supply chain and to increase affordability and accessibility of prescription drugs for consumers.

Over 40 states require PBMs to be licensed by or register with the state's Department of Insurance. In addition, a few states require PBMs to register as a TPA.¹⁰⁵ Based on NAIC member self-reporting, as of February 2023, states also have enacted legislation regulating certain PBM business practices. At least seven states give the state Department of Insurance (DOI) the authority to conduct PBM examinations. About eight states also have enacted legislation related to PBM pharmacy networks, including requirements related to network adequacy, prohibiting affiliate-only networks, and prohibiting PBMs from requiring consumers to use mail-order pharmacies. Numerous states have enacted laws prohibiting certain market conduct practices such as misleading advertising and solicitation. In addition, several states have enacted laws specifically prohibiting gag clauses, clawbacks, and spread pricing. Over 20 states have also enacted legislation regulating PBM pharmacy audit procedures. Rebating has also been a source of state legislation. Four states require PBMs to submit to the insurance commissioner annually or quarterly certain rebate information, including:

¹⁰⁴See PhRMA Code on Interactions with Health Professionals, last accessed February 27, 2023, available at: [PhRMA-Code---Final.pdf](#)

¹⁰⁵ <https://www.ncsl.org/health/state-policy-options-and-pharmacy-benefit-managers>.

- 1) the aggregate amount of rebates the PBM received;
- 2) the aggregate amount distributed to the appropriate healthcare payor; and
- 3) the aggregate amount passed on the enrollees of each healthcare payor at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount.

States have also enacted legislation requiring transparency in pricing. The most common type of legislation in this area requires PBMs to make reimbursement lists, including MAC lists, or payment methodologies available to network pharmacies. About 20 states have enacted such legislation. Other types of transparency legislation include requiring PBMs to provide advance written notice of formulary changes and substitutions. In a recently enacted Florida law, prescription drug manufacturers are required to notify the Florida Department of Business and Professional Regulation of manufacturer prescription drug price increases.

A. PBM REGULATION

As drug costs have risen, the influence of PBMs has expanded from its original role, growing more complex. This has prompted states to reevaluate regulations regarding licensure, reporting requirements, transparency, contract standards, health plan responsibility, spread pricing, network adequacy, and clawback issues.

Several states in the Subgroup provided summaries and key developments in their specific states. These summaries are meant to provide further detail to the updated list of laws offered by the Subgroup on the Subgroup's website.¹⁰⁶

1. Florida

Florida recently enacted new laws effective July 1, 2023, regulating prescription drug manufacturers and PBMs.¹⁰⁷ Under the new law, PBMs must obtain a certificate of authority from the Office of Insurance Regulation (OIR) by January 1, 2024. If a PBM fails to obtain a certificate of authority by that deadline but continues to operate, it will be subject to a \$10,000 fine per day.

Florida's law also regulates contracts between PBMs and pharmacy benefit plans requiring such to use a pass-through pricing model. In addition, the law prohibits PBMs from using "spread pricing" unless the difference is passed along to the pharmacy benefits plan. PBMs must also pass the entirety of all pharmaceutical manufacturer rebates received to the pharmacy benefits plan. In addition, Florida's law establishes requirements for pharmacy networks. PBMs must set up pharmacy networks that meet or exceed Medicare Part D standards for convenient access to network pharmacies. Other pharmacy network requirements prohibit PBMs from conditioning participation in one pharmacy network as a condition for participating in any other network and requiring participating pharmacies to meet accreditation standards that are more stringent than state pharmacy licensing requirements.

The Florida law also deals with contracts between PBMs and participating pharmacies, including prohibiting financial clawbacks, reconciliation offsets, and certain other types of recoupments. PBMs may no longer unilaterally change the terms of participation contracts with pharmacies. In addition, the Florida law includes gag clause provisions prohibiting PBMs from restricting pharmacists from disclosing to the consumer:

¹⁰⁶See generally, PBM Law Compilations, available at: https://content.naic.org/cmte_b_pharmacy_bmri_sg.htm.

¹⁰⁷<https://www.ausley.com/news-insights/florida-enacts-sweeping-new-legislation-regulating-pharmacy-benefit-managers>.

- 1) information about the nature of the treatment and possible side effects;
- 2) alternative forms of treatment;
- 3) information about any financial incentives used by the benefits program; and
- 4) information that may reduce the cost of pharmacist services.

2. New Jersey

New Jersey has a proposed bill that focuses on PBM transparency, licensing, and reporting requirements. Insurers would be required to maintain records of contracted PBMs including transaction records and compensation remittance. Insurers would also be required to have P&T Committees with no conflict of interest. Additionally, they must use more than one formulary.¹⁰⁸

3. Kentucky

Kentucky State Representative Steve Sheldon proposed HB 457 during the 2022 legislative session. Although the bill did not pass, it was drafted to address the ongoing abuses from PBMs in Kentucky. Some critics have stated this bill is one of the most comprehensive pieces of PBM regulation in the U.S. The bill proposed to prohibit PBMs from the following: mandatory mail order pharmacy use, mandatory use of PBM affiliated pharmacies, limited preferred networks, patient incentives to use PBM affiliated pharmacies, spread pricing, and higher reimbursements to PBM affiliated pharmacies. The bill also contained provisions that addressed contract changes, offered 340B protections and applied to most commercial plans in Kentucky.

4. Kansas

In 2022, Kansas enacted SB 28, which transformed the state's existing PBM registration requirements to a licensing scheme. As part of the license application, a PBM must submit a template contract, a network adequacy report, and a dispute resolution process that ultimately involves an independent fact finder between the PBM and the health insurer or the PBM and the pharmacy or pharmacy's contracting agent. The PBM Licensure Act also made updates to the MAC appeal law, gave the Commissioner some enforcement authority, but maintained an existing exemption for PBMs that hold a TPA registration in the state.

5. Maine

In 2019, Maine enacted a comprehensive package of legislation impacting PBMs and other entities in the pharmaceutical drug supply chain.¹⁰⁹ The four laws included in this legislative package: 1) impose stricter requirements on PBMs; 2) update Maine's drug transparency program to require more prescriptive data collection and enforcement mechanisms; 3) establish a drug affordability review board; and 4) express support for the state to pursue a wholesale drug importation program.

In looking at the requirements on PBMs, Maine's law establishes a PBM licensure requirement. The law also includes provisions making the health insurance carrier responsible for monitoring all activities of the PBM if the carrier uses PBMs to manage their prescription drug benefits. The Maine law also stipulates that PBMs have a fiduciary duty to their insurance carriers when managing their prescription drug benefits and as such, carriers are empowered to hold PBMs accountable for their financial dealings. The Maine law requires health insurance

¹⁰⁸ S.B. 220, 2022, 2022-2023 Reg. Sess. (NJ.2022). https://www.njleg.state.nj.us/bill-search/2022/S1616/bill-text?f=S2000&n=1616_l1.

¹⁰⁹<https://nashp.org/maine-forges-new-ground-and-enacts-comprehensive-drug-package/#:~:text=Maine's%20new%20law%20regulating%20PBMs,carriers%20with%20whom%20PBMs%20contract>.

carriers to use the prescription drug rebates that PBMs negotiate with pharmaceutical drug manufacturers to either lower health plan premiums or to reduce out-of-pocket costs for consumers when they purchase prescription drugs.

6. Oklahoma

In 2019, Oklahoma enacted HB2632, which created the Patient’s Right to Pharmacy Choice Act for the purpose of establishing uniform access to a pharmacy provider. As part of the regulatory framework, the Oklahoma Insurance Department must review retail pharmacy network access in addition to licensing PBMs and ensuring they are compliant with Oklahoma law. In addition to those provisions, the bill contains “any willing provider” language, prohibits PBMs from restricting individuals’ choice of in-network prescription drug providers and prohibits PBMs from taking certain actions, like incorporating “gag clauses” in their contracts with pharmacies. The bill established a fine amount of up to \$10,000 for any violation.

B. DRUG PRICE TRANSPARENCY REGULATION

The push for implementation of laws that would require PBMs to disclose drug pricing, cost information regarding rebates, payments, and their fees collected from pharmaceutical manufacturers, insurers, and pharmacies has begun in many states.¹¹⁰

1. Insurer Transparency

A number of states that require PBMs to disclose certain information about their costs also require health insurance providers to report similar prescription drug spending information to the state. Additionally, Section 204 of the transparency provisions of the Consolidated Appropriations Act of 2021 requires health plans to report information on premiums, plan medical costs, and prescription drug spending to the Secretaries of HHS, Labor, and Treasury, so that they may publish a report on prescription drug pricing trends and the contributions to health insurance premiums. The first filings under this law, known as the Prescription Drug Data Collection, or RxDC, were due in December 2022.¹¹¹

2. Drug Manufacturer Transparency

As drug costs have now become the largest expenditure of the premium dollar¹¹², states have moved to actively address by legislating transparency of drug prices. Multiple states have passed legislation requiring drug manufacturers to provide advance notice when the price of drugs being offered on the market will increase over a specific percentage or cost and to provide the reasoning behind those increases. For new drugs over a certain price threshold being placed on the market, drug manufacturers must provide advance notice and include reasoning on the price methodology. At least one state has limited their transparency laws to manufacturers that treat specific diseases. There has been a slight moderation of drug price increases which has paralleled the passage of these laws; however, the costs associated with new drugs have increased exponentially.¹¹³

3. PSAO Transparency

¹¹⁰ Colleen Becker, A. G. (2022, March 23). *State Policy Options and Pharmacy Benefit Managers (PBMs)*. State policy options and Pharmacy Benefit Managers (PBMs). Retrieved September 6, 2022, from <https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx>.

¹¹¹ <https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/prescription-drug-data-collection>

¹¹² <https://www.ahip.org/resources/where-does-your-health-care-dollar-go>

¹¹³ Drug Price Transparency Laws Position States to Impact Drug Prices. NASHP. January 10, 2022.

<https://nashp.org/drugprice-transparency-laws-position-states-to-impact-drug-prices/>

Some state laws have included PSAOs in their transparency laws, to understand the drugs with the highest reimbursement rates and/or year-to-year change in reimbursement rates, as well as the types of fees paid for the services provided by the PSAO.

C. OTHER RELEVANT PROPOSED OR IMPLEMENTED STATE LAW PROVISIONS

States have also implemented or considered implementing other laws that address the pharmaceutical drug ecosystem. A brief description of these approaches is contained below:

1. Affordability Review and Upper Payment Limits

Some states have proposed or implemented laws establishing prescription drug affordability review boards to set allowable rates for certain high-cost drugs, similar to the process states use to regulate utilities or insurance premiums. Under these laws, a state drug affordability review board would establish the maximum amount that certain payors would pay for individual drugs. The goal of these laws is to protect consumers and payors from over-priced drugs.

2. Unsupported Price Increases

Another approach to address high drug costs is enacting laws that would impose fines on pharmaceutical manufacturers whose drug price increases are unsupported by new clinical evidence. The state would use the revenue to provide cost assistance to consumers. Such laws impact the most frequently prescribed, high-cost drugs, and minimizes a state's administrative burden by using existing data sources.

3. Anti-Price-Gouging

These laws prohibit pharmaceutical manufacturers from sharply increasing prices for generic and off-patent drugs. Price increases that surpass a specific threshold identified in the law trigger action by a state's attorney general. Pharmaceutical manufacturers that price-gouge face fines and must stop charging the excessive price.

4. Importation

This legislative approach would create a state wholesale importation program to purchase lower-cost drugs from Canada and make them available to state residents through an existing supply chain that includes local pharmacies.

5. State Purchasing Pool Buy-in

These laws allow small businesses and individuals to buy into a state employee prescription drug benefit purchasing pool. They typically authorize non-state public employers, self-insured private employers, and insurance carriers who cover small groups or individuals to purchase drugs for their beneficiaries under the purchasing authority of the state. By adding more lives to a purchasing pool, purchasers can negotiate better prices for public employees and others who join the purchasing pool.

6. Licensing Pharmaceutical Sales Representatives

This approach gives states the authority to license pharmaceutical sales representatives to increase transparency surrounding their activities and influence and to require training on ethical standards. For example, the laws would require representatives to disclose the wholesale acquisition cost of the drugs they market and to share the names of generic options in the same therapeutic class when available.

VI. FEDERAL INTEREST AND POSSIBLE REGULATIONS

Increasing state regulations have been brought before state legislators to help regulate PBMs. Many believe that state regulation is not enough, and that the federal government will need to get involved. Given the overall expense of pharmaceutical drugs, some stakeholders have called for a federal overlay or federal preemption to create a uniform set of regulations for multistate PBMs. There are signs of increased interest from the federal government in PBM-related activities, as described below.

A. PHARMACY BENEFIT MANAGER TRANSPARENCY ACT OF 2022

Introduced on May 24, 2022, the Pharmacy Benefit Manager Transparency Act of 2022, was a bipartisan bill sponsored by Senators Maria Cantwell (D-WA) and Charles Grassley (R-IA). The act proposed disclosure requirements on PBMs and the prevention of questionable PBM practices, such as three practices that could be deemed unfair or deceptive which would have been expressly outlawed by the proposed legislation. These included spread pricing; reducing, canceling, or obtaining back any reimbursement payment made to a pharmacist or pharmacy for the price of a prescription drug's ingredients or dispensing charge arbitrarily, unfairly, or falsely; and deceptively reducing reimbursement to a pharmacy or arbitrarily raising fees to offset changes in reimbursement requirements.

Beginning no later than one year after the proposed legislation's adoption, the act would have mandated that PBMs provide the following data to the Federal Trade Commission (FTC) annually:

- 1) the difference between the sum that each health plan paid the PBM for prescription medications and the sum that the PBM paid each pharmacy on behalf of the health plan;
- 2) the total of all fees, including those for the generic effective rate, compensation fees, or other price breaks offered to any pharmacy, and payments withheld from reimbursements to any pharmacy;
- 3) if the PBM shifted a prescription drug to a formulary tier with a higher cost, higher copayment, higher coinsurance, or higher deductible to a consumer or lower reimbursement to a pharmacy, an explanation for why the drug was moved to a different tier, including whether the move was requested by a prescription drug manufacturer or another entity; and
- 4) information regarding any variations in reimbursement rates or practices, remuneration fees or other price concessions, and clawbacks between a pharmacy owned, controlled, or affiliated with the PBM and all other pharmacies, for any PBM that owns, controls, or is affiliated with a pharmacy.

The FTC would have been required to submit two reports to the Senate Committee on Commerce, Science, and Transportation and the House Committee on Energy and Commerce -- one on general enforcement actions under the act and the other on PBM formulary design or placement practices. Under the proposed legislation, an annual report on enforcement activity would be filed. The report would have included:

- 1) an anonymized summary of the annual reports that PBMs have submitted to the FTC;
- 2) the number of enforcement actions the FTC brought to enforce the act and the results of those actions;
- 3) the number of investigations and inquiries into potential violations of the act;
- 4) the number and nature of complaints the FTC received alleging violations of the act; and

5) recommendations for strengthening enforcement actions in response to violations of the act.

The agency's report to Congress on PBM formulary design or placement practices would have been due within a year of the proposed law's passage. It would have included information on whether PBMs use formulary design or placement to boost gross revenue without also enhancing patient access or lowering patient costs, as well as whether such PBM activities violated section 5(a) of the Federal Trade Commission Act (45 U.S.C. 45(a)).

Employees in the healthcare sector who report violations of the act or take part in administrative, judicial, or investigative processes to enforce its provisions would not be fired, demoted, suspended, reprimanded, or subject to any other type of punishment under the proposed legislation. The proposed legislation would have also forbidden companies from requiring employees to sign pre-dispute arbitration agreements in exchange for employment to make them give up their right to whistleblower protections under the act. The FTC and state attorneys general would have been given permission to carry out the proposed legislation's enforcement measures. Additionally, under the proposed law, offenders would have been exposed to civil penalties of up to \$1 million in addition to the penalties provided under the Federal Trade Commission Act (15 U.S.C. 41 et seq.). The bill was adopted and forwarded to the full Senate by the Senate Committee on Commerce, Science, and Transportation on June 22, 2022.¹¹⁴ The bill was never voted out of committee.

Additionally, the act would have incentivized fair and transparent PBM practices by providing exceptions to liability for PBMs that pass along 100 percent of rebates to health plans or payors and fully disclose prescription drug rebates, costs, prices, reimbursements, fees, and other information to healthcare plans, payors, pharmacies, and federal agencies.¹¹⁵

B. THE FEDERAL TRADE COMMISSION

In June 2022, the FTC announced it will launch an inquiry into the PBM industry, requiring the six largest PBMs to provide information and records regarding their business practices. The agency's investigation will closely examine how vertically integrated PBMs affect the availability and cost of prescription medications. The FTC will issue mandatory orders to CVS Caremark, Express Scripts, Inc., OptumRx, Inc., Humana Inc., Prime Therapeutics LLC, and MedImpact Healthcare Systems, Inc. as part of this investigation.

VII. KEY JURISPRUDENCE

As states continue to pass laws related to the pharmaceutical drug ecosystem, a body of jurisprudence has begun to develop that outlines the limits of state authority vis a vie federal authority. The key cases to date are described below.

¹¹⁴ Jang, T., & Shotlander, D. (2022, September 28). *Senate bill and FTC 6(b) study turn the heat on pharmacy benefit managers amid drug pricing concerns*. Food and Drug Law Institute (FDLI). Retrieved October 6, 2022, from <https://www.fdpi.org/2022/09/senate-bill-and-ftc-6b-study-turn-the-heat-on-pharmacy-benefit-managers-amid-drug-pricing-concerns/>.

¹¹⁵ Dowell, M. A. (2022, August 16). *State PBM regulations protecting community pharmacies*. U.S. Pharmacist – The Leading Journal in Pharmacy. Retrieved September 6, 2022, from <https://www.uspharmacist.com/article/state-pbm-regulations-protecting-community-pharmacies>.

A. RUTLEDGE v. PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, 141 S.Ct. 474 (2020)

In *Rutledge v. PCMA*, the U.S. Supreme Court held that ERISA did not preempt an Arkansas law, Act 900, which required PBMs¹¹⁶ to reimburse pharmacies at a price equal to or higher than what the pharmacy paid to buy the drug. Act 900 required PBMs to provide administrative appeal procedures for pharmacies to challenge reimbursement prices that are below the pharmacies' acquisition costs, and it also authorized pharmacies to decline to dispense drugs when a PBM would provide a below-cost reimbursement. Unlike the PBM laws in some states, Act 900 was not strictly structured as an insurance law. It applied to all transactions between PBMs and pharmacies, including transactions where the PBM was acting on behalf of a self-insured ERISA plan, so Arkansas could not rely on the saving clause as its defense against an ERISA preemption challenge.

In a suit brought by the PCMA, a national trade association representing 11 PBMs, the Eastern District of Arkansas ruled that Act 900 was preempted by ERISA, and the 8th Circuit affirmed.¹¹⁷ Both courts relied on a recent 8th Circuit decision striking down a similar Iowa law because it "made 'implicit reference' to ERISA by regulating PBMs that administer benefits for ERISA plans"¹¹⁸ and "was impermissibly 'connected with' an ERISA plan because, by requiring an appeal process for pharmacies to challenge PBM reimbursement rates and restricting the sources from which PBMs could determine pricing, the law limited the plan administrator's ability to control the calculation of drug benefits."¹¹⁹

The U.S. Supreme Court, however, concluded that "[t]he logic of *Travelers* decides this case,"¹²⁰ and ruled that Act 900 was not preempted by ERISA. The Court compared its decisions in *Gobeille*, where it held that a state law is preempted if it "governs a central matter of plan administration or interferes with nationally uniform plan administration,"¹²¹ and *Travelers*, where it held that ERISA does not preempt state price regulations that "merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage,"¹²² even if the law "affects an ERISA plan or causes some non-uniformity in plan administration."¹²³ The Court explained that ERISA is "primarily concerned with preempting laws that require ... structure[ing] benefit plans in particular ways, such as by requiring payment of specific benefits, or by binding plan administrators to specific rules for determining beneficiary status. A state law may also be subject to pre-emption if 'acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage.'"¹²⁴ The Court observed that Act 900 "does not require plans to provide any particular benefit to any particular beneficiary in any particular way,"¹²⁵ and determined that like the law at issue in *Travelers*, "Act 900 is merely a form of cost regulation."¹²⁶

¹¹⁶ As the term is spelled in Act 900. Supreme Court style refers to "pharmacy benefit managers."

¹¹⁷ *PCMA v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018).

¹¹⁸ 141 S.Ct. at 479, quoting *PCMA v. Gerhart*, 852 F.3d 722, 729 (8th Cir. 2017).

¹¹⁹ *Id.* at 479, quoting *Gerhart*, 852 F.3d at 726, 731.

¹²⁰ *Id.* at 481.

¹²¹ *Id.* at 480, quoting *Gobeille*, 577 U.S. at 320.

¹²² *Id.* at 480, citing *Travelers*, 514 U.S. at 668.

¹²³ *Id.*

¹²⁴ *Id.*, quoting *Gobeille*, 577 U.S. at 320.

¹²⁵ *Id.* at 482.

¹²⁶ *Id.* at 481.

The Court reviewed the standards it has established for interpreting ERISA’s preemption clause, which preempts all state laws “insofar as they ... relate to any employee benefit plan”¹²⁷ unless some exception to preemption applies. The Court explained that a state law triggers the preemption clause when it “has a connection with or reference to” an ERISA plan.¹²⁸ The Court rejected the PCMA’s contention “that Act 900 has an impermissible connection with an ERISA plan because its enforcement mechanisms both directly affect central matters of plan administration and interfere with nationally uniform plan administration.”¹²⁹ The Court acknowledged that Act 900 required ERISA plan administrators to “comply with a particular process” and standards,¹³⁰ but explained that those enforcement mechanisms “do not require plan administrators to structure their benefit plans in any particular manner, nor do they lead to anything more than potential operational inefficiencies” for PBMs.¹³¹ The Court held further that ERISA did not preempt Act 900’s decline-to-dispense provision, even though it “effectively denies plan beneficiaries their benefits” because any denial of benefits would be the consequence of the lawful state regulation of reimbursement rates and the PBM’s refusal to comply.¹³²

Finally, the Court rejected the PCMA’s claim that the law had an impermissible “reference to” ERISA. As the Court explained, Act 900 “applies to PBMs whether or not they manage an ERISA plan,” and Act 900 did not treat ERISA plans differently than non-ERISA plans.¹³³ However, the Court only considered the provisions of the Arkansas PBM law as they stood at the time the PCMA filed its preemption challenge, not the amendments the legislature subsequently made while *Rutledge* was making its way through the appellate courts, so it is important that *Rutledge* not be read as a finding that the Court analyzed Arkansas’ PBM law as it existed in 2020. Additionally, the Court did not address preemption under Medicare Part D.

B. PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION v. WEHBI, 18 F.4th 956 (2021)

In 2021, the 8th Circuit Court of Appeals issued its decision in *PCMA v. Wehbi*. This case was not appealed to the U.S. Supreme Court. At issue in the *Wehbi* case were two North Dakota laws prohibiting PBMs from engaging in deceptive and anti-competitive practices.

Ultimately, the court determined that none of the challenged provisions met the “connection-with” standard and all survived preemption by ERISA.¹³⁴ The court concluded that some of the state law provisions “merely authorize pharmacies to do certain things,” such as:

- disclose certain information to plan sponsors;
- provide relevant information to patients;

¹²⁷ 29 U.S.C. § 1144(a).

¹²⁸ 141 S.Ct. at 477.

¹²⁹ *Id.* at 481–482.

¹³⁰ *Id.* at 482, quoting PCMA brief at 24.

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.* at 481.

¹³⁴ 18 F.4th 956, 968.

- mail or deliver drugs to patients as an ancillary service; and
- charge shipping and handling fees to patients who request that their prescriptions be mailed or delivered.¹³⁵

The court also upheld provisions that “constitute, at most, regulation of a noncentral ‘matter of plan administration’ with de minimis economic effects.”¹³⁶ The court held that “whatever modest non-uniformity in plan administration [the sections] might cause does not warrant preemption.”¹³⁷ These provision include:

- limits on accreditation requirements a PBM may impose on pharmacies as a condition for participation in its network;
- requirements for PBMs to disclose basic information to pharmacies and plan sponsors upon request; and
- conditions on PBMs that have “an ownership interest in a patient assistance program and a mail order specialty pharmacy.”

In *Wehbi*, the court expands upon *Rutledge* in that the North Dakota statutes go beyond health care price/cost regulation and into disclosure requirements of PBMs, by prohibiting PBMs from preventing pharmacies from disclosing certain information (in compliance with the Health Insurance Portability and Accountability Act) to patients or plan sponsors. North Dakota’s laws, the court concluded, amount to regulation of a PBMs’ functions that have no or limited impact on plan administration, rather than regulation of an ERISA plan itself; therefore, they are not preempted by ERISA.

For the Medicare Part D preemption, not all the North Dakota provisions were preempted by Medicare laws. The court held that preemption exists for some of the contested provisions because Medicare Part D directly governs some of the same matters that the state law attempts to regulate.

With respect to Medicare Part D, the court determines preemption by either of these questions:

1. Do the laws regulate the same subject matter as a federal Medicare Part D standard? If so, the state law is *expressly* preempted; or
2. Do the state laws otherwise frustrate the purpose of a federal Medicare Part D standard? If yes, then they are *impliedly* preempted.¹³⁸

C. PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION v. MULREADY, 598 F.Supp.3d 1200 (2022)

In 2022, the U.S. District Court in the Western District of Oklahoma ruled in favor of the Oklahoma Insurance Commissioner Glen Mulready. The Patient’s Right to Pharmacy Choice Act (“Act”) passed in 2019 was challenged by PCMA as being preempted by ERISA, as well as Medicare Part D laws. The court held that the state law is not preempted by ERISA but agreed with PCMA that some of the law’s provisions are preempted by Medicare laws. PCMA has appealed the decision to the 10th Circuit Court of Appeals. On Aug. 15, 2023, the 10th Circuit Court of

¹³⁵ *Id.*

¹³⁶ *Id.*, quoting *Gobeille*, 577 U.S. 312, 320.

¹³⁷ *Id.*, citing *Rutledge*, 141 S. Ct. at 480.

¹³⁸ *Id.* at 972.

Appeals issued a ruling reversing the district court's decision. The 10th Circuit Court held that ERISA and Medicare Part D preempt the four challenged provisions. It is anticipated that Oklahoma will appeal the ruling.

The Oklahoma laws at issue protect Oklahoma consumers' access to pharmacy providers through pharmacy network requirements, pharmacy reimbursement standards and prohibitions, and contract approval requirements. Relying on *Rutledge*, the district court concluded that all PCMA's ERISA preemption claims fail as a matter of law. The district court holds that "[the provisions] do not have a 'connection with' an ERISA plan" and that "[w]hile these provisions may alter the incentives and limit some of the options that an ERISA plan can use, none of the provisions forces ERISA plans to make any specific choices." Finally, regarding the Promotional Materials provision, the district court holds that the law "does not regulate benefit design disclosures to beneficiaries but regulates how PBMs can advertise its providers" and that it "does not relate to a central matter of plan administration nor undermine the uniform regulation of ERISA plans."

As it relates to PCMA's ERISA preemption claim in totality, the district court found that ERISA does not preempt enforcement of the following: "any willing provider" provisions; retail pharmacy network access standards; affiliated pharmacy prohibition; network provider choice restrictions; probation-based pharmacy limitations; cost sharing discounts; promotional material prohibitions; post-sale price reduction prohibitions; and affiliated pharmacy price match prohibitions on PBMs from reimbursing a pharmacy an amount less than the amount the PBM reimburses to a pharmacy it owns or is affiliated with.¹³⁹

With respect to preemption by Medicare Part D, the district court found that about half of the PCMA's preemption claims failed, while about half were meritorious. Specifically, the court ruled that Medicare Part D *does* preempt these provisions in the Act: retail pharmacy network access standards; promotional material prohibitions; cost sharing discounts; service fee prohibitions; post-sale price reduction prohibitions; and affiliated pharmacy price match prohibitions on PBMs from reimbursing a pharmacy an amount less than the amount the PBM reimburses to a pharmacy it owns or is affiliated with.¹⁴⁰

It is anticipated that additional cases will make their way to the U.S. Supreme Court and provide greater insights into the parameters of *Rutledge* and state regulation. The *Wehbi* and *Mulready* cases are instructive as to the parameters of *Rutledge*, but there is no doubt more decisions are forthcoming.

¹³⁹ 36 O.S. § 6961 (OSCN 2023) available at (last accessed February 27, 2023): <https://www.oscn.net/applications/oscn/deliverdocument.asp?lookup=Previous&listorder=167560&dbCode=STOKST36&year=>

¹⁴⁰ 36 O.S. § 6961 (OSCN 2023) available at (last accessed February 27, 2023): <https://www.oscn.net/applications/oscn/deliverdocument.asp?lookup=Previous&listorder=167560&dbCode=STOKST36&year=>

APPENDIX I. LIST OF SUBGROUP MEETINGS AND TOPICS

Meeting #	Date	Presenter/Topic
Meeting #1	August 15, 2019	<ul style="list-style-type: none"> • Jane Horvath (Horvath Health Policy and Research Faculty, Georgetown University) presentation on “Basics of the Pharmaceutical Market & PBMs.” • Leanne Gassaway (America’s Health Insurance Plans—AHIP) presentation on “Pharmacy Benefit Managers Overview & Background.”
Meeting #2	August 22, 2019	<ul style="list-style-type: none"> • Dr. Neeraj Sood (Sol Price School of Public Policy, University of Southern California) presentation on “PBM Economics.” • Saiza Elayda (Pharmaceutical Research and Manufacturers of America—PhRMA) presentation on the pharmaceutical supply chain and how the pharmaceutical distribution and payment system shapes the prices of brand name medicines.
Meeting #3	August 29, 2019	<ul style="list-style-type: none"> • April Alexander (Pharmaceutical Care Management Association—PCMA) and J.P. Wieske (Horizon Government Affairs) presentation on the history, role, and services PBMs provide in managing prescription drug benefits. • Anne Cassity (National Community Pharmacists Association—NCPA) and Matthew Magner (NCPA) presentation on the community pharmacy industry’s perspective regarding PBMs and managing prescription drug benefits. • Claire McAndrew (Families USA) discussed the effect of PBMs and prescription drug costs on consumers. • Amy Killelea (National Alliance of State and Territorial AIDS Directors—NASTAD) discussed PBMs and their impact on consumer access and affordability of prescription drugs.
Meeting #4	October 3, 2019	<ul style="list-style-type: none"> • Kentucky discussed its PBM licensing process. • Arkansas discussed its PBM licensing law and other provisions related to PBM business practices.

Meeting #	Date	Presenter/Topic
		<ul style="list-style-type: none"> • Montana discussed the history, purpose, and provisions of S.B. 71 to address issues related to PBMs, which passed in the legislature but was ultimately vetoed by the Governor. • New Mexico discussed its PBM law focusing on its reimbursement provisions. • Oregon discussed its PBM law, including its PBM registration requirements, and Oregon’s Prescription Drug Price Transparency program.
Meeting #5	December 11, 2021	<ul style="list-style-type: none"> • North Dakota discussion on the <i>Pharmaceutical Care Management Association (PCMA) v. Wehbi</i> ruling. • Connecticut discussion on its PBM law and white paper. • Virginia discussion on its PBM law. • Oklahoma discussion on its PBM law and the <i>PCMA v. Mulready</i> case. • Wisconsin discussion on the work of the Governor’s Task Force on Reducing Prescription Drug Prices and its PBM law.
Meeting #6	March 16, 2022	<ul style="list-style-type: none"> • Montana discussion on its PBM law. • Employee Retirement Income Security Act (ERISA) (B) Working Group update on the U.S. Supreme Court’s ruling in <i>Rutledge v. PCMA</i> and the <i>ERISA Handbook</i> analysis and case summary.
Meeting #7	April 4, 2022	<ul style="list-style-type: none"> • Oklahoma update on its PBM law. • Oregon discussion on its PBM law and transparency in prescription drug pricing and Oregon Prescription Drug Affordability Board (PDAB) initiatives. • Discussion from a consumer perspective on the Subgroup’s charge to develop a white paper on PBMs and their business practices.
Meeting #8	April 25, 2022	<ul style="list-style-type: none"> • Dr. Neeraj Sood and Dr. Karen Van Nuys, University of Southern California (USC) Price School on Public Policy-

Meeting #	Date	Presenter/Topic
		presentation on “How Well Are PBM Markets Functioning?”
Meeting #9	June 15, 2022	<ul style="list-style-type: none"> • National Community Pharmacists Association (NCPA) presentation on the Subgroup’s charge to develop a white paper on PBMs and their business practices from an independent pharmacist perspective.
Meeting #10	July 29, 2022	<ul style="list-style-type: none"> • Healthcare Distribution Alliance (HDA) presentation on the Subgroup’s charge to develop a white paper on PBMs and their business practices from a pharmaceutical distributor perspective. • Presentation on the Subgroup’s charge to develop a white paper on PBMs and their business practices from a pharmacy services administrative organization (PSAO) perspective.
Meeting #11	August 9, 2022	<ul style="list-style-type: none"> • Presentation from the Pharmaceutical Care Management Association (PCMA) discussing the value of PBMs and the services PBMs provide with respect to pharmacy benefit management. • Presentation from the Pharmaceutical Research and Manufacturers of America (PhRMA) on the lack of transparency in PBM practices. • Oregon Primary Care Association (OPCA) presentation on the federal 340B prescription drug program.
Meeting #12	October 24, 2022	<ul style="list-style-type: none"> • America’s Health Insurance Plans (AHIP) presentation on the Subgroup’s charge to develop a white paper on PBMs and their business practices from an insurer perspective. • BlueCross and BlueShield Association (BCBSA) presentation on the Subgroup’s charge to develop a white paper on PBMs and their business practices from an insurer perspective. • Civica presentation on its work with the BCBSA and several Blues plans to bring lower-priced generics to market.

APPENDIX II. COMMENTS RECEIVED ON JULY 27, 2023, WHITE PAPER DRAFT



601 Pennsylvania Avenue, NW T 202.778.3200
South Building, Suite 500 F 202.331.7487
Washington, D.C. 20004 ahip.org

September 15, 2023

Commissioner Sharon P. Clark
Chair, Regulatory Framework (B) Task Force
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001-1512

Forwarded via email: Jolie H. Matthews

RE: AHIP's Previously Submitted Comments on NAIC PBM White Paper Draft (7.23.23 version)

Dear Commissioner Clark,

We greatly appreciate the opportunity to resubmit a condensed version of AHIP's comments to the NAIC PBM White Paper ("Paper"; 7.23.2023 version) as accepted by the Regulatory Framework Committee during the NAIC summer meeting. Our comments provided below, as requested, are abbreviated, focusing on those issues that remain unaddressed. AHIP's full set of comments are available at: [July 27 comments](#); June 1 [comments](#).

Remove Bias. The Paper still includes several sections that reflect only one perspective. This one-sided perspective is presented as undisputed fact even after AHIP shared numerous academic and impartial sources that provide a different perspective. Once again, we ask that either both viewpoints are presented, or the Paper only include factual statements for which evidence can be cited.

- 1. Spread Pricing & MAC Transparency:** Using a term like "pocketing the difference/spread" is a biased description intended to convince the reader to oppose the practice rather than providing a factual and neutral discussion of the payment methodology. Recommendation 1 and 2 includes redlines necessary to remove this bias terminology from the Paper.

Language: Spread pricing – page 20 (clean version)

Spread pricing: ~~Spread pricing is the practice of a PBM charging a plan sponsor a higher amount for a drug than they will reimburse the pharmacy and pocketing the difference. Pharmacy pricing is complex, and the process is not transparent. Plan sponsors are often unaware of the difference between the amount they are billed and the pharmacy reimbursement.~~

Instead, we urge you to use the more neutral definition already in the Paper on page 12 (clean version)

Spread pricing: A risk mitigation pricing model, the payor will either not pay or pay a reduced administration fee and the PBM will retain certain risk related to the difference between the price paid by the customer and the price paid to the pharmacy. This arrangement provides the payor with the assurance of a set price.

Language: MAC transparency – page 19 (clean version)

MAC transparency: A maximum allowable cost (MAC) list is a ~~list-tool~~ that establishes a competitive unit price ~~includes the maximum amount that a plan-PBM will pay for certain drugs.~~⁴ Most states have passed MAC laws that require PBMs to be transparent about what sources they use to create their MAC lists. MAC lists are often generated by the PBM. There is no standardization in the industry as to the criteria for the inclusion of drugs on MAC lists or for the methodology as to how the maximum price is determined, changed or updated. PBMs may sometimes use multiple MAC lists and **pocketing the spread between the two**. For example, PBMs might use a very low MAC list to reimburse pharmacies but a higher list when charging plan sponsors.

- 2. Rebates:** As part of a health plan's contract with their PBM vendor, they will negotiate and determine what percentage of the rebates received – if any – the PBM is allowed to keep as compensation for its services. No data supports the statements included in the Paper that follow. AHIP has repeatedly submitted sources that illustrate the contrary is true, and provided balanced language; however, these incorrect and biased claims remain. Further background is on page 2 of AHIP's July 27 comments which are included.

Language: Pharmaceutical manufacturer and PBM: page 10 (clean version)

Pharmaceutical manufacturers set list prices for their prescription drugs to have a maximum impact on revenue. The PBM then negotiates rebates with the pharmaceutical manufacturers, to lower the cost of those drugs; ~~and~~ rebates are typically based on volume. PBMs can offer manufacturers higher volume, and thus command higher rebates, by putting a manufacturer's drug on the PBM's formulary and/or in a formulary's less expensive cost sharing tier. Rebates create a market dynamic that may force up the "list" price of drugs by increasing the potential to generate "spread" profit.

Language: Rebates: page 18 (clean version)

~~The existence of rebates alone is not a problem. However, the PBM's ability to retain a percentage of the rebate creates a concern as they are also commonly in charge of formulary design. These two factors give PBMs a financial incentive to prioritize drugs in the formulary based on the highest rebate instead of the lowest total cost to the plan sponsor or consumer. This could result in plan sponsors and consumers paying a higher cost for prescription drugs than is necessary, resulting in higher prescription drug coverage costs. Rebates are paid throughout the year and then trued up between the PBM and the payor at the conclusion of the contracted year and reported within their medical loss ratio filings. Most state employee plans and Medicaid contracts establish a preferred drug list (PDL) which allows them to negotiate supplemental rebates for favorable placement on the PDL.~~

- 3. Vertical Integration and Consolidation.** The following section claims that a PBM-pharmacy affiliation drives higher costs, but none of the accusations below cite any data or evidence to show they are happening. The opposing perspective is that integration has given companies the negotiating leverage to finally push back against drug manufacturers' abusive pricing tactics; however, that viewpoint is not included in the Paper. Once again, we ask that either both

viewpoints are presented, or the Paper only include factual statements for which evidence can be cited.

Language: Vertical Integration and Consolidation – page 21 (clean version).

~~A PBM-pharmacy affiliation creates several incentives for PBMs to act against the best interests of the consumer. PBMs have been found inserting language into pharmacy benefit contracts that requires Benefit designs sometimes requires enrollees to use PBM-owned mail pharmacy services for long-term (90 days or longer) “maintenance” medications. This may eliminate contractual requirement effectively eliminates any competition to fill these prescriptions, however, in many cases, mail order pharmacies are less expensive and more convenient for enrollees who prefer to receive prescriptions at their homes. Employers sometimes prefer these benefit designs to help control the cost of providing coverage to their employees. allowing the pharmacy to charge higher prices to the consumer. An affiliation with a pharmacy may also incentivize a PBM to do the following, which are all contrary to the best interests of consumers:~~

- ~~— Perform fewer generic substitutions;~~
- ~~— Switch patients to higher-cost therapeutic alternatives (“therapeutic interchange”); or,~~
- ~~— Repackage drugs in a manner that could lead to increased costs to plan sponsors, while maximizing revenue for the PBM (“package size pricing”).~~

Make Necessary Technical Updates. The Paper must be updated to reflect the current state of the law and the Subgroup’s stated charges.

1. **Update Legal Sections;** On August 15, 2023, the U.S. Court of Appeals for the Tenth Circuit issued a decision in *PCMA v. Mulready*, No. 22-6074 (10th Cir. 2023), finding that certain provisions of Oklahoma state law governing how PBMs operate are preempted under both ERISA and the Medicare Part D statute. The case reverses an earlier decision by the district court upholding those same provisions.

The 10th Circuit Court reversed the District’s court’s view of the Supreme Court’s earlier *Rutledge* decision largely excluded PBMs from ERISA preemption. The court found that certain PBM-related network restrictions are preempted under federal law because they “govern a central matter of plan administration” by either directing or forbidding an element of plan structure or benefit design.

In considering the Oklahoma law’s application to PBMs providing services to Part D plans, the court found that Medicare Part D statute’s preemption provision is “broad”, “sweeping”, and “akin to field preemption.” Accordingly, the court concluded that the provision “precludes States from regulating Part D plans except for licensing and plan solvency.” This reading reverses the approach that Medicare Part D preemption only exists if there is an overlapping or on-point federal standard. The *Mulready* decision by the 10th Circuit follows a First Circuit decision in *Medicaid & Medicare Advantage Prods. Ass’n of P.R., Inc. v. Hernández*, 58 F.4th 5, 11 (1st Cir. 2023), in affirming how and when Medicare Part D preempts state law.

The Paper references the earlier *Mulready* decision:

- On page 14, the ERISA section mentions the court’s decision in the context of *Rutledge*.
- On pages 14-15, *Mulready* is discussed in the context of Part D.
- On pages 34-35, there is a full summary of the *Mulready* decision.

- These discussions must be either updated or deleted because they no longer represent the current state of the law in that Circuit.
 - Members of the PBM Subgroup discussed on July 27 including language prefacing the pages listed above that legal proceedings were not yet resolved. Language, such as “The court cases discussed in the following section may not be resolved and encourage further review of the current legal environment.”
2. **Remove Recommendations.** The PBM Subgroup had specific three charges for the Paper, and they are to: 1) analyze the role of supply chain entities of the drug cycle chain, 2) identify regulatory approaches, and 3) discuss challenges of implementations. The recommendations should be deleted given the Subgroup was not charged with identifying recommendations as part of the Paper. In addition, the supply chain entities were briefly outlined in the Paper but their roles within the drug pricing environment were not detailed, comprehensive, or consistent with the level of review of PBMs, which is just one entity of the supply chain. This remains inconsistent with the unanimously agreed to charges.

While AHIP remains concerned about the direction of the Paper, we are grateful for NAIC’s continued focus on high-price drugs set by drug manufacturers. This is important to ensure impactful reform and relief to individuals, families, employers, and taxpayers. For further information or continued dialogue, please contact me khathaway@ahip.org or 202.870.4468. Thank you very much for your consideration.

Sincerely,



Kris Hathaway
Vice President, State Affairs
AHIP

America’s Health Insurance (AHIP) is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.



601 Pennsylvania Avenue, NW T 202.778.3200
South Building, Suite 500 F 202.331.7487
Washington, D.C. 20004 ahip.org

July 27, 2023

Mr. TK Keen
Chair, PBM Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001-1512

Forwarded via email: Jolie H. Matthews

RE: AHIP Comments on NAIC PBM White Paper Draft – Rereleased July 23

Dear Mr. Keen,

On behalf of AHIP and our member plans, we would like to voice our concerns with the pending draft of the PBM white paper (paper) re-released on July 23, 2023, and the related review process.

Background: In 2019, the NAIC established the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup (Subgroup) and developed their charge to consider the development of a new NAIC model to establish a licensing or registration process for PBMs. When the draft model was not able to gain consensus and pass through the Executive Plenary, the Subgroup changed their charge in 2021 to develop a white paper to analyze all the various supply chain entities' roles in the provision of prescription drugs and examine state regulatory approaches to PBM business practices.

Subgroup's Process: The paper was drafted by multiple authors and released by the Subgroup on April 16, with public comments due June 1. The paper was then updated with authors deciding which comments to incorporate and released on July 23. Although the Subgroup indicated that stakeholders would be given "sufficient time to allow everyone to review it before the meeting" the revised 40-page paper was released with only 3 ½ days for stakeholders to review changes for a potential vote on July 27.

AHIP's Objections: AHIP has consistently raised three major issues with the Subgroup's paper. Those issues are:

1. The paper must be revised to fulfill the Subgroup's stated and agreed to charges. The paper as currently drafted continues to fall short of expanding the focus beyond PBMs to discuss the role of payors, wholesalers, PSAsOs, etc.
2. The paper must be revised to remove non-objective, biased perspective. There are several sections of the paper that provide only one viewpoint. A white paper should provide regulators and interested readers a fact-based, balanced, and non-biased approach to the issues.
3. The paper must be revised to synthesize and streamline sections.

Per AHIP's review of the version released July 23 we remain deeply concerned with the extent of bias and opinion included in many sections of the paper.

Major Concerns With Revised Paper: There are several sections that continue to provide only one perspective, presented as undisputed fact – even after AHIP shared numerous academic and unbiased sources that provide a different perspective. Two of the sources cited often are presentations to the committee that do not contain the type of academic, peer-reviewed research that one would expect NAIC to point to as the basis for such a paper. Following, are examples of the most notable components of the

paper which should raise questions by Subgroup members about whether this paper meets NAIC's standards of presenting a neutral, balanced, and fact-based discussion of the issues:

1. **Spread pricing:** On page 11, spread pricing is aptly defined as "spread pricing, also known as a risk mitigation pricing model, the payor will either not pay or pay a reduced administration fee and the PBM will retain certain risk related to the difference between the price paid by the customer and the price paid to the pharmacy." However, on page 19, spread pricing is defined as "Spread pricing is the practice of a PBM charging a plan sponsor a higher amount for a drug than they will reimburse the pharmacy and **pocketing the difference**. Pharmacy pricing is complex, and the process is not transparent. Plan sponsors are often unaware of the difference between the amount they are billed and the pharmacy reimbursement." AHIP raised this flag citing the biased and inflammatory language in the latter definition and recommended that page 19 refer back to the earlier definition on page 11, which is a more neutral and fact-based explanation of the practice.

Plan sponsors have the ability to choose (or allow for their contracted health insurance providers to decide) whether they want to contract with their PBM vendors utilizing a spread pricing model or administrative fee model. Each has pros and cons and payors can choose the option that best fits their needs and the needs of their enrollees. **Using a term like "pocketing the difference" is a biased description intended to convince the reader to oppose the practice rather than providing a factual and neutral discussion of differing viewpoints.**

2. **MAC transparency:** As stated in example 1, "pocketing the difference" was also used in defining MAC transparency on page 19. The paper states, "PBMs may sometimes use multiple MAC lists and **pocketing the spread between the two**. For example, PBMs might use a very low MAC list to reimburse pharmacies but a higher list when charging plan sponsors." Most states currently have MAC laws in place to ensure that such practices do not occur. Yet the paper continues to include this scenario without our suggested addition to provide more context about how state laws have changed since the paper's cited source over five years ago in June 2018.
3. **Rebates:** On page 10, the paper claims rebates "create a market dynamic that may force up the "list" price of drugs by increasing the potential to generate "spread" profit." Not only does the cited source provide **no data to support this supposition, but multiple studies have been submitted to demonstrate this assertion is not true**. In fact, one of our cited sources (the US House Oversight & Reform Committee's Drug Pricing Investigation) explicitly stated "this data, which has never before been shared with the public, undermines industry (drug manufacturers) claims that price increases are primarily due to increasing rebates and discounts paid to pharmacy benefit managers." And yet, the unsubstantiated claim about rebates driving higher list prices remains and no additional context was added.

On page 19, the paper notes "Rebates may provide incentive for a PBM to eliminate a less expensive, comparable medication from a formulary. Pharmaceutical manufacturers claim that these rebates are meant to be shared with plan sponsors or passed on to consumers in the form of lower drug prices. However, PBMs regularly keep a share of the rebates before passing the rest through to the plan sponsor." As part of a health plan's contract with their PBM vendor, they will negotiate and determine what percentage – if any – the PBM is allowed to keep as compensation for its services. This context should have been added to the paper to provide the full explanation of how rebates are shared.

Further, on page 17, the paper states, “it is possible the PBM keeps the entire rebate with no direct benefit to the plan sponsor or the consumer.” also citing Dr. Sood. The cited sources provide no evidence that this practice is occurring today. It is prejudicial, misleading, and **unjustifiable to include a hypothetical concept in this paper.**

4. **PBM Practices:** Page 18 states that the integration of health plans, PBMs, and pharmacies, enables PBMs to “**engage in contracting practices that may be detrimental to consumers and other market participants**” and on page 20 “A PBM-pharmacy affiliation creates several incentives for PBMs to act against the best interests of the consumer.” again citing Dr. Sood.

Continuing with the myopic view of PBMs, the paper continues to state on page 21, “An affiliation with a pharmacy may also incentivize a PBM to do the following, which are all contrary to the best interests of consumers:

- Perform fewer generic substitutions;
- Switch patients to higher-cost therapeutic alternatives (“therapeutic interchange”); or,
- Repackage drugs in a manner that could lead to increased costs to plan sponsors, while maximizing revenue for the PBM (“package size pricing”).”

None of these accusations include data or evidence to show they are happening, and the mere inclusion of the word “may” does not negate the negative opinion the paper continues to espouse about the PBM industry. The opposing perspective is that integration has allowed given companies the negotiating leverage to finally push back against drug manufacturers’ abusive pricing tactics; however, that viewpoint is not included in the paper.

5. **DOI Licensing:** Page 23 starts a descriptive listing of the licensure requirements of various entities involved in the pricing of drugs. Health insurance providers are listed as the first entity with 2 sentences describing our involvement, while all other entities are described in full. While AHIP understands that regulators already are fully aware of carrier licensure parameters, the paper is intended to be used as an educational resource for those not as familiar with the drug industry. AHIP’s redlines provided a short but comprehensive list of those requirements, none of which were included. By not providing a more balanced perspective of insurers oversight, the paper continues the discourse that there is little oversight on carriers’ operations.

In addition to the bias illustrated above, various ERISA sections would have benefited from additional context and clarifications on the status of cases as well as highlighting the importance of, and updates to, NAIC’s ERISA handbook of which the Subgroup received a presentation in 2022.

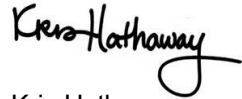
AHIP believes in NAIC’s mission and role in bringing together all stakeholders to allow for a discourse that produces the best end product for consumers. **We urge Subgroup members to reevaluate the biased, unsubstantiated accusations and request further analyses of the paper.** The preferences included in the current draft jeopardize the credibility of an NAIC resource, which should inform, educate, and provide factual information to its audience.

While AHIP remains concerned about the direction of the paper, we are grateful for NAIC’s continued focus on high-price drugs as you appreciate and understand their impact to your constituency and our customers. We hope to continue working together to find solutions to address this critical issue within the health care market.

July 27, 2023
Page 4

For further information or continued dialogue, please contact me khathaway@ahip.org or 202.870.4468.
Thank you very much for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Kris Hathaway". The signature is written in a cursive style with a large, looping "H" and a long tail on the "y".

Kris Hathaway
Vice President, State Affairs
AHIP

cc Commissioner Sharon P. Clark
Chair, Regulatory Framework (B) Task Force
National Association of Insurance Commissioners

America's Health Insurance (AHIP) is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.



1310 G Street, N.W.
Washington, D.C. 20005
202.626.4800
www.BCBS.com

September 15, 2023

Commissioner Sharon Clark, Chair
Regulatory Framework (B) Task Force
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001-1512

Submitted electronically to Jolie H. Matthews (JMatthews@naic.org)

Re: BCBSA Comments on NAIC PBM White Paper Draft

Dear Commissioner Clark:

The Blue Cross Blue Shield Association (BCBSA) would like to thank NAIC for the consideration and incorporation of several of our recommendations in the PBM white paper, "A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation."

We appreciate the opportunity to resubmit our previous recommendations that were not incorporated into the latest version of the white paper. As the Taskforce reviews the white paper, we encourage you to employ more neutral language in reference to the entities highlighted in the paper, make additional changes that will adhere to the Subgroup's white paper charge, and carefully consider whether the "Recommendations" warrant inclusion in an educational resource. Below, we highlight three priority recommendations from our June 1 comment letter, that address critical aspects BCBSA believes could further enhance the white paper:

1. **Incorporate additional details on the role of manufacturer copay coupons.** Specifically, inclusion of language noting: (1) copay coupons can increase utilization of expensive drugs when more affordable options are available and (2) copay coupons are prohibited in government programs.
2. **Provide additional discussion of rebates.** We recommend including additional examples and context for when rebates are and are not available to provide a more comprehensive description of the issue.

3. **Include details on patent thickets.** BCBSA recommends including details, under the section covering manufacturer licensing, on how patent thickets delay competition. This occurs when pharmaceutical manufacturers obtain multiple patents that cover one drug or minor variations of the drug.

In our June 1 letter, we suggested the following edits to address these three recommendations:

1. **Incorporate additional details on the role of manufacturer copay coupons** [Pg. 11]

- *Pharmaceutical manufacturer and consumer*
Pharmaceutical manufacturers can offer coupons or occasionally free samples of medications to consumers. The coupons can reduce a consumer's cost sharing below that which they would have paid had they used their pharmacy benefit plan. While coupons lower costs for some patients at the pharmacy counter, they mask the true costs, promote the use of high-cost drugs and increase sales for branded drug companies by over 60%, even when lower cost generics may be available. (<https://www.aeaweb.org/articles?id=10.1257/pol.20150588>) Coupons are prohibited for use by beneficiaries enrolled in Medicare, Medicaid and other government programs because they "induce the purchase of Federal health care program items or services" – that is, the drug manufacturer offering the coupon is directly benefitting from its use. (https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf)

2. **Provide additional discussion of rebates**

- The white paper discusses the role of rebates in the pharmaceutical drug ecosystem, and we recommend additional examples and context for when rebates are and are not available. [Pg. 17]
 - Rebates are mostly used on brand-name and specialty drugs where similar competing drugs from other manufacturers exist. Manufacturers commonly do not offer rebates on brand drugs and biologics when competition from other drugs does not exist; and, 64% of Medicare Part D brand drugs analyzed did not have rebates. (<https://www.ahip.org/resources/prescription-drug-rebates-and-part-d-drug-costs-analysis>)
- In describing the proportional rebate pass-through model, we note the PBM keeps a percentage of the rebate *as the fee for administering the pharmacy benefit* and passes the remainder back to the plan sponsor. This clarifies the rebate retention acts as the service fee to the PBM [Pg. 17].
 - Proportional pass-through – The PBM keeps a percentage of the rebate as the fee for administering the pharmacy benefit and passes the remainder back to the plan sponsor.
- The paper also discusses providing rebates at the point-of-sale and cites that some insurers have indicated it would result in no additional premium cost [pg.

18]. We recommend citing studies on the impact of rebates at point-of-sale on premiums.

- Rebates at point-of-sale (POS): ... Additionally, members with low or no prescription drug usage might experience a disproportional impact as they would be paying higher premiums and would not have a financial benefit from the POS rebates. In a 2017 proposed rule regarding Medicare Part D plans, CMS requested feedback on a proposal to pass on rebates to beneficiaries at the point-of-sale. According to CMS, this proposal would raise premiums by up to \$28 billion and taxpayer costs by up to \$82 billion over the following decade. (Centers for Medicare & Medicaid Services. Proposed Rule. "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.") Some insurers have indicated...

3. Include details on patent thickets [Pg. 24]

- [Start new paragraph] Pharmaceutical manufacturers commonly seek to extend their patent protection period by providing a new formulation of a drug or changing the route of administration for a drug. This can result in a situation where multiple patents, often overlapping or with complex dependencies, create a dense and complex web of patents hindering competition and innovation. Also referred to as, patent thickets, this practice inhibits or delays generic drugs or biosimilars from entering the market. The Initiative for Medicines, Access, and Knowledge (I-MAK), an organization advocating for affordable access to medicines, released a report on the top ten selling drugs in the United States revealed that, 66% of patent applications were filed after the FDA approved the drug to be on the market (<https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf>). Additionally, lower-cost generic and biosimilar versions of three top selling drugs - Humira, Eliquis, and Enbrel - launched in Europe an average of 7.7 years earlier than their expected U.S. entry. During this time, Americans will spend an estimated \$167 billion on branded versions of just these three drugs (Ibid.).

We believe that these recommendations can contribute to the comprehensiveness of the white paper, aligning it more closely with the PBM Subgroup's related charge and the evolving landscape of the Rx drug supply chain and regulations of entities in it.

BCBSA remains concerned with NAIC pursuing any new model guidelines (recommendation #1 in the white paper) or updated model legislation (recommendation #3 in the white paper). The uncertainty of ERISA and Medicare Part D legal issues and the current low uptake of Model 22 across states, creates a policy landscape in which adoption of new model guidelines would likely be low.

We appreciate NAIC's commitment to an inclusive and iterative approach to refining this white paper. If you require any additional information or clarification, please do not hesitate to contact [Randi Chapman](#), managing director, state affairs. Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink that reads "Clay S. McClure". The signature is written in a cursive, flowing style.

Clay S. McClure
Executive Director, State Affairs
Blue Cross Blue Shield Association

FROM THE NAIC CONSUMER REPRESENTATIVES

September 15, 2023

To: Commissioner Sharon Clark, Chair of the Regulatory Framework (B) Task Force

RE: Consumer Representatives' Comments on "NAIC White Paper Draft-A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation"

On behalf of the undersigned Consumer Representatives to the National Association of Insurance Commissioners (NAIC) who have been working with the PBM Subgroup, we voice our strong support of the **NAIC White Paper Draft-A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation** and urge its adoption. Additionally, we urge the NAIC to move forward with its recommendations as soon as possible.

Due to the profound impact pharmacy benefit managers (PBMs) play in the drug pricing and delivery system and on consumer access and affordability of prescription medications, we recommended that such a White Paper be drafted. We appreciate the thoughtful approach the Subgroup has taken over the past two years in soliciting comments from the consumer representatives and interested parties along with learning from states that have taken various steps in regulating PBMs and their activities.

Specific Draft White Paper Comments

While we believe the Subgroup has adequately addressed its charges and has done so in a neutral manner, we are disappointed that some of the specific recommendations included in our June 1, 2023 [comments](#) were not included in the final draft. At this time, we would like to reiterate some of them:

- 1) We had suggested on page 4 in the section Key Players in Pharmaceutical Drug Pricing Ecosystem a statement on the *importance of consumers to receive the prescription drugs prescribed by their provider.*
- 2) We are deeply disappointed that our suggestions of several PBM practices that directly impact consumers and the state laws that address them were not included in the section Other Relevant Proposed or Implemented State Law Provisions of the final draft that begins on page 29. We had suggested and included descriptions of the following topics: *a) Utilization management tools; b) Copay accumulator adjustment programs; c) Copay maximizer programs; and d) Alternative Funding Programs.*
- 3) We believe that the section Federal Interest and Possible Regulations that begins on page 29 should be updated to include additional and more current Congressional action that has been proposed and/or occurred.

For any questions, please contact Carl Schmid, HIV+Hepatitis Policy Institute at cschmid@hivhep.org.

Thank you very much.

Sincerely,

Ashley Blackburn

Deborah Darcy

Kara Hinkley

Anna Schwamlein Howard

Carl Schmid

On behalf of CVS Health, we are submitting a priority list of remaining concerns with the “PBM White Paper” that was accepted by the NAIC Regulatory Framework Task Force during the summer meeting.

- **Remove the Recommendations (pages 35-36)** – this is supposed to be an informational white paper which outlines the issues that should be addressed and provides an overview of the various parties in the prescription drug benefit system. As discussed by the working group, this paper is a snapshot in time of how the system currently works and the issues that are present in the market today. Therefore, it is more appropriate to discuss these recommendations as future charges of the working group, as opposed to including them in an informational white paper.
- **Revise the section on “Steering” (pages 22-23)** – This section provides a reader a good overview of network adequacy. However, the tone of this section and certain sentences are extremely biased and unsupported. At the very least, there are two instances of this extreme bias that we would request be deleted:
 - *“Steering can limit a member’s choice, increase costs, and lower quality of care to members.”* This is unsupported by any data and in fact, using affiliated pharmacies can lower the cost for the enrollee and the plan sponsor. More importantly, there is absolutely no evidence that use of an affiliated pharmacy lowers the quality of care for a member.
 - *“These types of practices can result in harm, including increasing drug prices, overcharging members, restricting a member’s choice of pharmacies, underpaying community pharmacies and other dispensers, and fragmenting and creating barriers to care, particularly in rural areas, and for members battling life-threatening illnesses and chronic diseases.”* This closing statement proports that consumers are being harmed by the required or incentivized use of affiliated pharmacies. There is no data to support such a misleading and inflammatory assertion. We strongly request these sentences be deleted.
- **Revise the section on Vertical Integration (pages 20-21)** – Although it is tangentially connected to how various PBMs in the market are structured, this section has been written in a manner that is extremely biased and pejorative. There is a substantial lack of data to support the assertions and most of this section is aligned with one presentation that was made by Dr. Sood, which was cited extensively as the basis of this section. However, Dr. Sood’s assertions are only in a working paper that has not been peer-reviewed and no sufficient counter perspective has been included in the paper. For these reasons, the following assertions should be removed as follows:

“D. VERTICAL INTEGRATION AND CONSOLIDATION

....

Consolidation refers to the merger and acquisition of many smaller companies resulting in a few much larger companies. The benefit of consolidation is that a larger firm may be able to realize efficiencies of scale and pass the resulting cost savings to consumers. The downside of consolidation is that costs tend to rise when there are fewer existing firms around to compete on prices and the few remaining firms price their products to maximize profit.¹

¹ *Id.*

Along with vertical integration, consolidation in the pharmacy benefit supply chain has led to current market conditions, which feature the three largest PBMs covering 79 percent of prescription drug claims.² ~~Further, independent pharmacies are put at a competitive disadvantage compared to PBM-affiliated pharmacies when it comes to contracting.~~

~~The proliferation of PBM health insurer affiliations has resulted in inefficiencies in the market.³ From the health insurer's perspective, an affiliation with a PBM is incredibly valuable for two reasons: lower costs for pharmacy benefit services and exclusive or priority access to the PBM. From a market perspective, a PBM health insurer relationship results in lower market competition, dealings within affiliated businesses and possible anti-competitive practices.⁴ The three largest PBMs are all affiliated with health insurers, so other large health insurers not affiliated with a PBM are no longer able to find a PBM that operates on their scale that is not affiliated with a competitor.~~

~~A PBM-pharmacy affiliation creates several incentives for PBMs to act against the best interests of the consumer. PBMs have been found inserting language into pharmacy benefit contracts that requires enrollees to use PBM-owned mail pharmacy services for long term (90 days or longer) "maintenance" medications.⁵ This contractual requirement effectively eliminates any competition to fill these prescriptions, allowing the pharmacy to charge higher prices to the consumer. An affiliation with a pharmacy may also incentivize a PBM to do the following, which are all contrary to the best interests of consumers:~~

- ~~• Perform fewer generic substitutions;~~
- ~~• Switch patients to higher cost therapeutic alternatives ("therapeutic interchange"); or,~~
- ~~• Repackage drugs in a manner that could lead to increased costs to plan sponsors, while maximizing revenue for the PBM ("package size pricing").~~

Please see the appendix for a more detailed explanation regarding our concerns with this language.

Thank you for considering the above concerns and do not hesitate to reach out if you have any questions or would like to further discuss (leanne.gassaway@cvshealth.com or 202-997-9827).

² [PBMs ranked by market share: CVS Caremark is No. 1](#); Becker's Hospital Review (website); March 8th, 2022.

³ Sood.

⁴ *Id.*

⁵ "A Tangled Web," p. 42-43.

APPENDIX

Sentence	Reason for Removal
<p>“Further, independent pharmacies are put at a competitive disadvantage compared to PBM-affiliated pharmacies when it comes to contracting.”</p>	<p>There is no data to substantiate this claim and it conflicts with the significant power that PSAOs can levy on behalf of the independent pharmacies they represent as discussed in the white paper.</p>
<p>“The proliferation of PBM-health insurer affiliations has resulted in inefficiencies in the market.⁶ From the health insurer’s perspective, an affiliation with a PBM is incredibly valuable for two reasons: lower costs for pharmacy benefit services and exclusive or priority access to the PBM. From a market perspective, a PBM-health insurer relationship results in lower market competition, dealings within affiliated businesses and possible anti-competitive practices.⁷ The three largest PBMs are all affiliated with health insurers, so other large health insurers not affiliated with a PBM are no longer able to find a PBM that operates on their scale that is not affiliated with a competitor.”</p>	<p>This paragraph does not provide any data to support the inefficiencies noted, and in fact, the text could be construed to provide efficiencies for employers and consumers who could realize lower premiums through the integration of care and a more streamlined benefit experience. Again, these perceived “inefficiencies” are not supported by data or studies and should not be included.</p>
<p>“A PBM-pharmacy affiliation creates several incentives for PBMs to act against the best interests of the consumer.</p> <p>PBMs have been found inserting language into pharmacy benefit contracts that requires enrollees to use PBM-owned mail pharmacy services for long-term (90 days or longer) “maintenance” medications.⁸ “This contractual requirement effectively eliminates any competition to fill these prescriptions, allowing the pharmacy to charge higher prices to the consumer.”</p> <p>“An affiliation with a pharmacy may also incentivize a PBM to do the following, which are all contrary to the best interests of consumers:</p> <ul style="list-style-type: none"> • Perform fewer generic substitutions; • Switch patients to higher-cost therapeutic alternatives (“therapeutic interchange”); or, 	<p>This paragraph makes many unsubstantiated assertions. There is no data or clinical evidence provided to support anything that is stated here related to PBM-pharmacy affiliation and is intentionally pejorative as opposed to informative as a white paper should be. PBMs are hired to help plan sponsors provide a robust pharmacy benefit while also providing cost savings for the plan and their members.</p> <p>PBMs do not “insert language” into contracts with their clients that they are unaware of and further, it is the client, themselves that selects whether to use the mail order pharmacy. Home delivery programs have been used by plan sponsors for decades as a result of the savings that their enrollees obtain on 90-day supplies of their medications. Several studies have shown that home delivery of 90-day maintenance medications leads to higher adherence and better clinical outcomes. (See JAHA, Dec 21,</p>

⁶ Sood.

⁷ *Id.*

⁸ “A Tangled Web,” p. 42-43.

- Repackage drugs in a manner that could lead to increased costs to plan sponsors, while maximizing revenue for the PBM (“package size pricing”).”

2020,
<https://doi.org/10.1161/JAHA.119.016215>).

Additionally, approximately 91% of all drugs dispensed are generics and PBMs have helped with this through encouraging generic substitution and the use of lower cost options. The assertion that PBM-owned pharmacies perform fewer generic substitutions is not supported by any evidence and not in line with the current high dispensing rates for generics.

Lastly, PBMs do not “switch” patients, as their licensed provider is responsible for writing the prescription and it is illegal for a PBM to arbitrarily switch a patient’s medication without provider consent. Therefore, such an assertion as made here is not supported by any evidence.

PATIENTS MOVE US.

National Association of Insurance Commissioners
The Honorable Sharon Clark, Chair
The Honorable Glen Mulready, Vice Chair
Regulatory Framework (B) Task Force of the Health Insurance & Managed Care (B) Committee
444 North Capitol Street NW, Suite 701
Washington, D.C. 20001

September 15, 2023

Attention: Jolie Matthews

Re: Draft PBM White Paper | Summary of Healthcare Distribution Alliance (HDA) Comments

Chair Clark, Vice Chair Mulready, and Honorable Members of the NAIC Regulatory Framework (B) Task Force of the Health Insurance & Managed Care (B) Committee:

As always, the Healthcare Distribution Alliance (HDA) appreciates the opportunity to engage as a stakeholder and applauds the longstanding work of the PBM Regulatory Issues (B) Subgroup in finalizing a draft white paper. As requested by Chair Clark, we have consolidated our comments pertaining to the draft into the points below. Our June 1 and July 27 comment letters remain available on the PBM Regulatory Issues (B) Subgroup Document webpage, as well.

1. Page Nine, Section F – Remove Wholesalers from the Definition of Pharmacy Services Administrative Organizations (PSAOs)
 - HDA respectfully requests the removal of wholesalers from the definition of PSAOs to ensure the accuracy of the white paper.
 - Pharmacy Services Administrative Organizations evaluate and execute contracts with PBMs, yet PSAOs do **not** evaluate and execute contracts with wholesalers. Notably, the draft white paper cites pages 34 and 41 of the U.S. Senate Committee of Finance’s 2018 Report entitled “[A Tangled Web](#)²⁹” as a reference for the description of PSAOs which neglects to mention wholesalers.
2. Page Eleven, Section H (Pharmacy Benefit Management Claim, PBM & PSAOs) – Clarify Reimbursement Rate Negotiation
 - Reimbursement rates are set on a percentage **discount off** (minus) average wholesale price (AWP). Specialty drugs may be listed in an addendum specific to an individual drug and thus not always applicable to **all** drugs as stated in the draft.

As always, we are happy to answer any questions or provide information to ensure accuracy in the final document. Please reach out to Will Dane at wdane@hda.org or (571) 287-3020 with any questions.

Thank you,



Will Dane
Director, State Government Affairs
Healthcare Distribution Alliance

²⁹ “A Tangled Web”, at p. 34, 41.



September 13, 2023

The Honorable Sharon Clark
Commissioner, Kentucky Department of Insurance
Chair, Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001

Attn: Jolie Matthews, Senior Health Policy Advisor and Counsel
Via Email: jmatthews@naic.org

Dear Commissioner Clark:

The National Association of Benefit and Insurance Professionals (NABIP), which was previously known as the National Association of Health Underwriters (NAHU), provided comments to the PBM Regulatory Issues (B) Subgroup in June regarding its draft white paper titled, "Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation." NABIP has an active Prescription Drug working group, which reviewed the draft white paper in detail. Overall, we found the paper to be a very fair and factual account of PBM regulation and related ongoing policy issues. However, we did have some specific suggestions for improvement that were not included in the latest draft paper. As per your request, we have summarized them below.

Section B – Key Players in the Drug Pricing Ecosystem

1. As per NABIP's initial suggestion, the revised version of the paper includes the addition of Employers/Unions/Taft Hartley Plans as key players. However, we believe this text should be enhanced to show the differences between a health insurance carrier as a payor and a self-funded group plan sponsor, as well as the differences between those group plans that elect to carve out their PBM services and those who choose integrated services, which then affects both transparency to group and rebate distribution. Ideally these differences would be reflected in the paper's distribution chain graphic.

Section C – Enforcement and Federal Preemption Issues

2. Adding more detail to the subsections addressing Medicaid and Medicare to explain the unique roles PBMs play in each of these public programs, so that readers understand the differences in functional responsibilities of PBMs when it comes to Medicare and Medicaid and the commercial marketplace.

Section D – Functional Issues

3. In subsection one, titled Formulary Design, the addition of a sentence explaining the Medicare Part D rule that requires the inclusion of at least two drugs per therapeutic class.
- 4.
5. In subsection three, we suggest adding additional definitional information and explanatory text regarding average wholesale price and maximum allowable cost pricing, as well as the



- differences between them. While both MAC and AWP pricing are mentioned elsewhere, we suggest adding a paragraph addressing both common pricing methodologies together.
6. We suggest including the role that PBMs play in conducting utilization management of pharmacy benefits for health insurers and group health plan sponsors.
 - 7.
 8. We suggest including the role of manufacturer assistance in the pharmacy benefit management process. Some concerns in this area are currently being litigated in *Johnson & Johnson Healthcare Systems v. Save On SP, LLC*. Another issue is co-payment assistance and how it may or may not be applied by a PBM on behalf of a health plan sponsor toward a participant's deductible and out-of-pocket limits.

We truly appreciate the opportunity to comment on this draft white paper and your willingness to consider the views of all stakeholders. If you need any additional information or have any questions, please do not hesitate to contact me at (703) 496-0796 or jessica@forwardhealthconsulting.com.

Sincerely,

Jessica F. Waltman
Regulatory Consultant
National Association of Benefits and Insurance Professionals



Sharon P. Clark, Kentucky, Chair
Glen Mulready, Oklahoma, Vice Chair
Regulatory Framework (B) Task Force of the Health Insurance and Managed Care (B) Committee
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001

Submitted via email to Jolie H. Matthews at jmatthews@naic.org

RE: Pharmacy Benefit Manager White Paper

Chair Clark and Vice Chair Mulready,

On behalf of our member pharmacies, NACDS extends our sincere appreciation for another opportunity to weigh in on the important work being undertaken by the PBM Regulatory Issues Subgroup through the adoption of its PBM white paper. NACDS has been engaged in each step of this process and we continue to express our strong support of any efforts which encourage greater transparency of PBM practices. As instructed by Commissioner Clark, we have included a brief list of items below we feel are still either missing from the report or could be strengthened:

- Page 4 – could add effects of vertical integration to Insurer section (not mentioned until page 19)
- Page 7 – chain pharmacy definition – add “typically with 4 or more stores”
- Page 9 – group purchasing organizations (GPOs) not mentioned
- Page 11 – important to note the parties in this agreement don’t know what is billed or paid – PBMs only one who knows
- Page 11 – again mention vertical integration and related enforcement
- Page 16 – could address exclusion formularies
- Page 17 – no mention of below-cost reimbursement practices which threaten pharmacy viability
- Page 17 – address transparency & GPOs on rebates
- Page 25 – Texas reports rebates publicly as one number but also disclose how many PBMs reported. They report total, amount back to patients, amount back to plan and amount kept by PBM (could be a model for rebate reporting)
- Page 26 – more comprehensive list of recent PBM reform legislation – what states are missing?
- Page 36 – would like PBM-specific model compliance (complaint reporting by pharmacies or consumers)

We stand ready to assist NAIC should there be interest in adopting any of these suggestions. Feel free to contact Sandra Guckian, VP of State Pharmacy and Advocacy, for questions or further discussion at sguckian@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores
CC: Regulatory Framework (B) Task Force Members

September 15, 2023

Members of the Regulatory Framework Task Force:

Thank you for the continued opportunity to provide perspective about the draft PBM white paper. Below please find a summary of our previously submitted comments, which were co-signed by 78 other organizations. Although we believe the white paper could always be perfected, we appreciate the PBM Regulatory Issues Subgroup's hard work and lengthy process to date. We respectfully ask you to adopt the document as currently drafted keeping in mind our feedback below.

Characterization of relationships among key players in the pharmaceutical ecosystem

- White paper does not accurately characterize the asymmetrical relationship between PBMs and community independent pharmacies. How can a small business realistically negotiate contract terms with Fortune 10 companies?
- Vertical integration both upstream and downstream: affiliated upstream insurance provider and downstream group purchasing organizations, mail-order, specialty, and retail pharmacies. Increased incentives for steering patients to affiliated pharmacies¹.

Uniform PBM regulation and enforcement in states without ERISA exemption

- We acknowledge implications stated on page 12 of the draft white paper regarding *Rutledge* that regulation must not be applied differently to ERISA and non-ERISA plans.
- We acknowledge some states expressly mention ERISA exemption in their statutes. NAIC should track state laws as they pertain to expressly mentioning ERISA exemption.
- If state law is silent on ERISA exemption, NAIC members should apply and enforce the law equally to all health plans and PBMs as it pertains to price, rate, and cost regulation per court rulings such as *Rutledge* and *Wehbi*.

Enforcement: Made possible by authority, expertise, and resources

- White paper does not recognize that PBM-relevant expertise and resources are needed in state insurance departments to enforce PBM laws: to train, hire personnel to oversee, review reporting, and/or audit PBMs as appropriate per state law.

¹ Vertical relationships among insurers, PBMs, GPOs, pharmacies and other providers <https://ncpa.org/sites/default/files/2023-03/verical-bus-chart.pdf>


- White paper does not provide a model PBM enforcement scheme or best practices for Departments of Insurance and their Commissioners to enforce existing laws and regulations.
- NAIC should recommend a standardized state-based system form with electronic standards for PBM complaints that will enable NAIC and its members to collect and analyze online complaints and to enforce regulations.

Feedback on recommendations

- General support for all recommendations, provided community independent pharmacy stakeholders are engaged and at the table.
- Recommendation #1 (Model Guidelines to Address PBM Regulation): any model language should include a model enforcement scheme, including structure for audits, fines, suspensions, and discontinuation.
- Recommendation #6 (Dialogue with Federal Agencies): we support, provided that it does not slow or replace the current process of honing state-level regulation of PBMs. States are leading the way on PBM reform and this process must not be slowed.

NCPA and its 78 co-signing organizations appreciate NAIC's continued engagement of issues related to PBM regulation and believes NAIC's best contributions are yet to come. If you have any questions, please don't hesitate to contact me at (703) 600-1186 or joel.kurzman@ncpa.org.

Sincerely,

A handwritten signature in black ink that reads "Joel Kurzman". The signature is written in a cursive, flowing style.

Joel Kurzman
Director, State Government Affairs



September 15, 2023

Commissioner Sharon P. Clark
Chair, Regulatory Framework (B) Task Force
National Association of Insurance Commissioners
444 North Capitol Street, NW, Suite 700
Washington, DC 20001
EMAIL: JMatthews@naic.org

SENT VIA EMAIL

Re: *Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* a/k/a the NAIC's PBM White Paper

Dear Chair Clark:

I write on behalf of the Pharmaceutical Care Management Association ("PCMA") to express our concerns with the draft white paper titled, "Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation" (hereinafter referred to as the "White Paper").

PCMA is a national trade association representing pharmacy benefit managers ("PBMs"). PCMA member companies administer drug benefits for more than 275 million Americans, who have health coverage through employer-sponsored health plans, commercial health insurance plans, union plans, Medicare Part D plans, managed Medicaid plans, state employee health plans, and others. PBMs use a variety of benefit management tools to help these plans provide high quality, cost-effective prescription drug coverage to plan beneficiaries.

PCMA believes the White Paper, as presently drafted is seriously flawed and should not be adopted or at a minimum should include an appendix to highlight alternative perspectives. PCMA reached this conclusion, as set forth in more detail below, because we believe the White Paper:

- Does not adhere to the charges adopted by the NAIC's PBM Regulatory Issues (B) Subgroup;
- Reads like a biased advocacy piece rather than an objective source of information and guidance;
- Is not appropriately sourced;
- Includes many unsupported claims;
- Relies on biased information;
- Contains numerous factual errors; and
- Was developed with a lack of process, as well as a lack of transparency.

Lastly, there was no charge that the PBM (B) Subgroup offer recommendations as part of the PBM White Paper. A "white paper" is supposed to be an educational document. It is not supposed to be a biased advocacy document with recommendations. By including recommendations, this White Paper is further delegitimized. And without significant changes to

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org



the White Paper, the NAIC is risking its reputation as an unbiased resource for state regulators and their staffs.

The White Paper does not adhere to the specific charges adopted by the Subgroup

The first charge for the Subgroup was to “analyze and assess the role of pharmacy benefit managers (PBMs), Pharmacy Services Administrative Organizations (PSAOs), and other supply chain entities play in the provision of prescription drug benefits.”

The second charge for the Subgroup to include in the White Paper was to “identify, examine and describe current and emerging state regulatory approaches to PBM business practices, such as price transparency and reporting requirement, rebating and spread pricing, including the implications of the *Rutledge vs. Pharmaceutical Care Management Association (PCMA)* decision on such business practices.”

The third charge for the Subgroup to consider when drafting the White Paper was to “discuss what challenges, if any, the states have encountered in implementing such laws and/or regulations.”

The White Paper fails on all these charges.

The White Paper does not serve as an objective source of information and guidance

As background, following the failure of the PBM Model Act in late-2021, the PBM Subgroup elected to move forward with the development of this White Paper. The intent was to draft a document that would be an authoritative guide to state insurance commissioners and their staffs regarding prescription drug supply chain. Merriam-Webster defines “White Paper” as:

1. *A government report on any subject; and/or*
2. *A detailed or authoritative report.*¹

This draft White Paper fails under both definitions. At no time was this White Paper ever intended to be a completely biased advocacy document.

The White Paper is Not Properly Sourced

There is a plethora of publicly available and widely accepted material regarding PBMs and the overall pharmaceutical supply chain that the blatant failure to cite most of it in the White Paper poses a number of questions. Was it always the intent to avoid any of this material? And was this White Paper reverse-engineered to support a biased conclusion, causing the drafters to cherry-pick poor quality citations that align with their views?

The White Paper includes numerous unsupported claims

A White Paper should include factually correct statements with proper citations for claims that are not widely accepted or understood. This White Paper fails to follow this standard and

¹ Merriam-Webster Dictionary. (<http://www.merriam-webster.com/dictionary/white%20paper>).



includes a substantial number of unsupported claims. Below is one blatant example to illustrate this failure – specific to the federal preemption section of the White Paper.

Federal preemption

Regarding health plans organized under the federal Employee Retirement Income Security Act (“ERISA”) of 1974, the White Paper states:

It remains unclear how much authority states may exercise over PBM pharmacy networks and other elements of PBM administration.

It does not remain unclear. The U.S. Supreme Court’s decision in *Rutledge* was very narrow and allows for state regulation of reimbursement in maximum allowable cost (“MAC”) appeals. This is the result of a narrow case on reimbursement having to do with Arkansas Act 900. Thus, the Supreme Court did not deviate from 50 years of ERISA jurisprudence.

Moreover, a recent decision for the U.S. Court of Appeals for the Tenth Circuit recently clarified the question of federal preemption. In a unanimous decision on the *Mulready* case, the Court sustained a challenge to four provisions of a misguided Oklahoma state law by finding them to be preempted under federal ERISA law, as well as the federal Medicare Part D program. The Court explicitly stated:

- Federal law preempts state laws that “relate to” covered benefit plans, including state laws that directly regulate plan design;
- The provider network is a crucial component of an employer-sponsored health plan’s benefit design;
- The challenged provisions of Oklahoma law are preempted according to these principles;
- Allowing this kind of state regulation of network design would erode the protections of federal preemption and threaten the nationwide benefits enjoyed by millions of Americans.

Beyond the problems with the White Paper’s section on federal preemption, there are various problems with its sections on formulary design, as well as rebates.

The White Paper relies on biased information

The White Paper relies extensively on three main sources – Sood, Horvath, and Oestreicher – who made presentations to the PBM Subgroup at different points over the past few years. These presentations are slide-decks posted on the PBM Subgroup’s website. However, they are not widely known, nor generally accepted sources. Nor do they contain readily verifiable supporting information. They also contain instances of contradictory claims and statistics. Therefore, there is no way for an individual reading the White Paper to properly evaluate the quality of these sources and the claims made with their alleged support.

Importantly, Dr. Casey Mulligan also made a presentation to the PBM Subgroup on October 24, 2022, yet his presentation is nowhere to be found in the White Paper. In fact, his name is the only one missing from the list of presenters on page 39 of the White Paper. The complete

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org



exclusion of Dr. Mulligan is stunning, and his work directly calls into question the objectivity and validity of the White Paper.

The White Paper contains many factual errors

This White Paper contains multiple false statements. Those false statements take the form of unsupported claims and/or opinions. On page 11, the current version of the White Paper states:

Rebates create a market dynamic that may force up the “list” price of drugs by increasing the potential to generate “spread” profit.

This statement is simply incorrect and illogical. Rebates do not drive “spread.” And there is no scenario where they would. Moreover, the citation for this statement is a presentation to the PBM Subgroup, given by Dr. Neeraj Sood. To include a citation to a presentation given to a Subgroup of the NAIC rather than rigorous and widely available and cited research is a stain on this draft White Paper. There are many such errors throughout the White Paper.

PBM Subgroup lack of process & transparency

Throughout 2022 and 2023, there were small pieces of information distributed by the PBM Subgroup, usually verbally via Subgroup member comments, regarding progress with the White Paper. Ultimately, the White Paper was drafted in closed sessions with no public input rather than a few solicitations for feedback within specific timeframes.

Due to the aforementioned issues, PCMA and its member companies respectfully request that the Regulatory Framework (B) Task Force do not move forward with the adoption of the White Paper. However, should the Task Force decide to move forward with some sort of finalization of the White Paper, then we respectfully request that our comments be included as an addendum to the White Paper to show the multitude of concerns that a large segment of stakeholders have with it.

Finally, it should be concerning to NAIC membership more broadly, that in a May 11, 2023, letter from the NAIC to the U.S. Federal Trade Commission (“FTC”), this White Paper is referenced as a document in development for the purposes of state regulation of PBMs. If this White Paper moves forward without substantial changes—involving a complete restructuring and the removal of biased content and inclusion of input from all stakeholders—the NAIC will undermine the objectivity of its “white paper” and its own credibility as a fair and unbiased standard setting organization for the industry.

Sincerely,

Peter Fjelstad

Peter Fjelstad, Director, State Legal & Regulatory Affairs, PCMA

CC: Jolie Matthews, Senior Health and Life Policy Counsel, NAIC

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