

## **NACDS COMMENTS**

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Comments are being requested on this draft by June 1, 2023. Comments should be sent only by email to Jolie Matthews at [jmatthews@naic.org](mailto:jmatthews@naic.org).

# **GUIDE TO UNDERSTANDING PHARMACY BENEFIT MANAGER AND ASSOCIATED STAKEHOLDER REGULATION**

NAIC White Paper Draft as of April 16, 2023

Drafted by the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup

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Deletions are denoted by ~~strikethrough~~

Additions are highlighted in yellow

### A. 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 pharmacy benefit managers (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 stakeholders’, including consumers, PSAOs, insurers, and pharmacists, perspective on its charge to develop the PBM white paper. 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 PBM 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 PBM white paper for a 45-day public comment period ending June 1, 2023.

***[ADDITIONAL LANGUAGE WILL BE ADDED AS THE DRAFTING PROCESS MOVES FORWARD]***

### B. 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 of the levers before them but ultimately pays the price of the ecosystem that has been

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put in place. Until very recently, pricing of pharmaceuticals has been opaque to many consumers.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>

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.

### 1. INSURERS

Insurers contract with PBMs to manage the pharmacy benefit portion of their health care benefits provided to their insureds and enrollees.<sup>4</sup> Insurers contract with PBMs because of the increasing complexity of prescription drug benefit management.<sup>5</sup> 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,

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<sup>1</sup> 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.

<sup>2</sup> 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>.

<sup>3</sup> 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.

<sup>4</sup> 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>.

<sup>5</sup> *Id.*

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and negotiation of pharmacy fees and prescription drug reimbursement, and access to pharmacy networks.<sup>6</sup> Ultimately, the scope of the PBM's role in managing this benefit depends on the insurer.<sup>7</sup>

### 2. PRESCRIPTION DRUG MANUFACTURERS

#### Manufacturers

Pharmaceutical manufacturers research, develop, produce, market, and sell prescription drugs to treat medical conditions.<sup>8</sup> 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.<sup>9</sup> 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.<sup>10</sup> When a drug is approved, manufacturers then set the list price for medications and may change that price over time.<sup>11</sup>

#### Brand manufacturers

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.<sup>12</sup> 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.<sup>13</sup>

#### Generic manufacturers

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 branded drug before it can be produced.<sup>14</sup> Generic drugs

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

<sup>7</sup> 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/lfprx/Reports/House%20Bill%204005%20\(2018\)%20Report%20on%20Transparency%20Strategies.pdf](https://www.oregonlegislature.gov/committees/lfprx/Reports/House%20Bill%204005%20(2018)%20Report%20on%20Transparency%20Strategies.pdf).

<sup>8</sup> 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>.

<sup>9</sup> *Id.*

<sup>10</sup> 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.

<sup>11</sup> 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>.

<sup>12</sup> 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>.

<sup>13</sup> *Id.*

<sup>14</sup> 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..>

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comprise the largest portion of the pharmaceutical market, approximately 90 percent of all drugs dispensed to consumers.<sup>15</sup>

### Biologic manufacturers

Manufacturers of biological products are entities that manufacture biological products as defined in 42 USC 262 (i) that are approved by the Food and Drug Administration under the Biologics License Application process. Biological products encompass reference biological products, biosimilar product, and biosimilar products that are interchangeable. Biologic manufacturers are distinct from traditional brand and generic manufacturers because they produce drug products made in living cells, such as monoclonal antibodies, antitoxins, and certain vaccines.<sup>16</sup> 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.<sup>17</sup> 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.<sup>18</sup> A biosimilar drug product may be produced following the expiration of the biologic’s patent and exclusivity period.<sup>19</sup>

### Biosimilar manufacturers

Manufacturers of biosimilar products are entities that manufacture biosimilar products and biosimilar products that are interchangeable as defined in 42 USC 262 (i) that are approved by the Food and Drug Administration under the Biologics License Application process as outlined in 42 USC 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 currently virtually impossible to produce. 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.<sup>20</sup>

Comparable to the relationship between brands 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).<sup>21</sup> Many biologics and biosimilars are can be categorized as specialty drugs due to their when their structures using living organisms, the storage requirements needed, and the cost and complexity of administering the product to a consumer are such that they cannot be filled routinely in

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<sup>15</sup> 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%94%20out,they%20are%20on%20the%20market.>

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

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

<sup>18</sup> 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.

<sup>19</sup> 42 U.S.C. §262(k).

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

<sup>21</sup> 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>.

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**traditional pharmacy settings.** According to the FDA, biologic and biosimilar drug products are the fastest growing class of therapeutic products in the U.S.<sup>22</sup>

### 3. PHARMACY BENEFIT MANAGERS

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.<sup>23</sup> PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers.<sup>24</sup> 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).<sup>25</sup> PBMs engage in the negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.<sup>26</sup>

### 4. PHARMACIES

#### a. CHAIN

A pharmacy chain refers to a ~~third-party entity that engages in a retail business~~ **entity** and that owns or operates multiple **(typically four or more)** retail outlets at which an individual consumer may have a prescription drug order filled. The pharmacy retail outlet may also provide services that include providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling.<sup>27</sup>

#### b. 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.<sup>28</sup>

### 5. PHARMACISTS **(suggest NAIC consult with NABP to determine whether there is a consistent definition)**

The basic duty of a **community** pharmacist is to check 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 ~~offer expertise in~~ **provide counseling on** the safe use of prescriptions. They also may conduct **other services including, but not limited to,** health and wellness screenings, provide immunizations, **administer medications,** oversee the medications given to patients, and provide advice on healthy lifestyles.

### 6. PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS (PSAOs)

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

<sup>23</sup> See, generally, “A Tangled Web” at p. 26-34.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> Wisconsin’s “Report of the Governor’s Task Force on Reducing Prescription Drug Prices, p. 20; “A Tangled Web” generally at p. 39-40.

<sup>28</sup> *Id.*

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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.<sup>29</sup> The PSAO overall administrative function is to assist with contract evaluation and execution, customer service, central payment and reconciliation, and patient data evaluation.<sup>30</sup> In many instances a PSAO is owned by a wholesaler.<sup>31</sup>

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<sup>29</sup> “A Tangled Web”, p. 34, 41.

<sup>30</sup> *Id.*

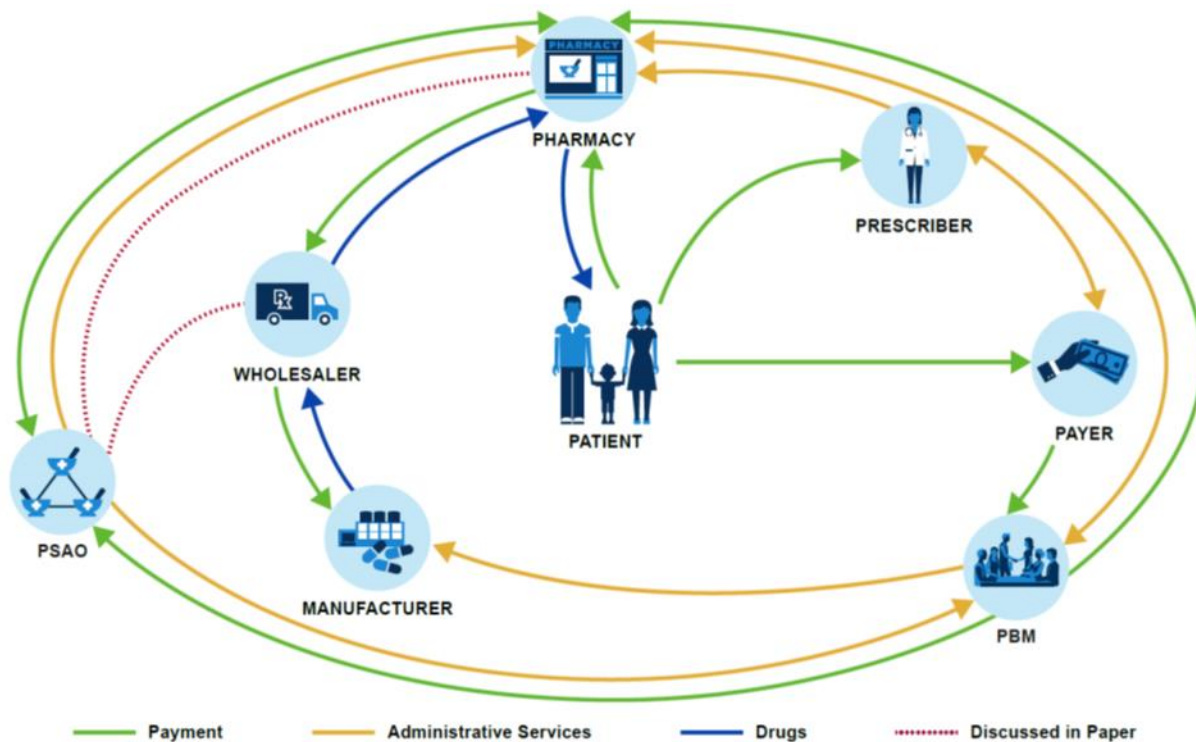
<sup>31</sup> Wisconsin’s “Report of the Governor’s Task Force on Reducing Prescription Drug Prices, p. 19.



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### 7. 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.<sup>32</sup>



The following 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.

#### Physical Drug Distribution Chain

##### *Pharmaceutical manufacturer and wholesaler*

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

##### *Wholesaler and pharmacy*

The wholesaler sells their drugs to a pharmacy in an amount based on the WAC.<sup>35</sup> 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.<sup>36</sup> The National Average Drug Acquisition Cost (NADAC) is a federal Centers

<sup>32</sup> 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

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

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*; and generally, "A Tangled Web" at 21-25.

<sup>36</sup> *Id.*

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for Medicare and Medicaid Services (CMS)-calculated value that also attempts to capture the average price wholesalers charge to pharmacies.<sup>37</sup>

### *Pharmacy and consumer*

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

### **Pharmacy Benefit Chain**

#### *Pharmaceutical manufacturer and PBM*

The PBM negotiates rebates with the 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.<sup>38</sup> Rebates create a market dynamic that may force up the "list" price of drugs by increasing the potential to generate "spread" profit.<sup>39</sup>

#### *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.<sup>40</sup> If the coupon constitutes a third-party paying the consumer's cost share, some state laws require insurers to count this payment towards the consumer's deductible and pharmacy benefit maximum out of pocket amount.

#### *PBM and PSAO*

The PSAO assists the pharmacy in negotiating with the PBMs for reimbursement rates.<sup>41</sup> 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.<sup>42</sup>

#### *Pharmacy and PBM*

The pharmacy (mostly chains outside of PSAOs) negotiate with the PBM to determine a reimbursement rate for the drugs they dispense.<sup>43</sup> Like the PBM/PSAO relationship, negotiations are based on AWP less a percentage and apply to all drugs.<sup>44</sup> 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.<sup>45</sup>

#### *PBMs and Payors*

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

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

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

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

<sup>41</sup> *Id.* at 19.

<sup>42</sup> *Id.*

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

<sup>44</sup> Horvath.

<sup>45</sup> Horvath.

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A PBM negotiates rebates with the manufacturer, negotiates 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.<sup>46</sup>

PBMs are reimbursed by the payor on either a pass-through basis or a spread-pricing basis. Payors may have the ability to choose either option in its contract with the PBM. Payors may also have the options of retaining rebates or allowing their members or insureds to receive point of sale rebates.

Pass through – The payor will pay the actual amount owed to the pharmacy under the contract on a per prescription basis and will pay the PBM an administration fee.

Spread pricing – 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 (whether the spread is profitable will vary from drug to drug). This provides set price assurance to the payor.<sup>47</sup>

Through these definitions and descriptions of the pharmaceutical drug ecosystem, legislatures 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.<sup>48</sup> State laws and enforcement mechanisms have from time to time butted up against federal pre-emption issues and those issues are further detailed in the sections that follow.

### **C. 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 **which may be** 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.

#### **1. EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974 (ERISA): (SELF-INSURED AND FULLY INSURED)**

The federal Employee Retirement Income Security Act of 1974 (ERISA) governs all health benefit plans established by private-sector employers and certain employee organizations, such as unions.<sup>49</sup> ERISA's preemption clause, section 514, preempts all state laws to the extent that they "relate to" employer-sponsored health plans.<sup>50</sup> However, states are still permitted to maintain regulation of "the business of insurance" including for ERISA plans.<sup>51</sup> 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.

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

<sup>47</sup> Horvath.

<sup>48</sup> 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.

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

<sup>50</sup> *Id.* at 328.

<sup>51</sup> See, e.g., Furrow generally at 328-330.

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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.<sup>52</sup> 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)*,<sup>53</sup> decided in 2020, held that an Arkansas law (Act 900) requiring, **in part**, 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*.<sup>54</sup> 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.”<sup>55</sup>

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;
- (2) Requires PBMs to timely update their Maximum Allowable Cost (MAC) lists when drug wholesale prices increase;
- (3) Requires PBMs to provide an administrative appeals procedure for pharmacies to challenge MAC reimbursement that is below a pharmacy’s acquisition cost;
- (4) 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;
- (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.

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<sup>52</sup> *Id.* at 328.

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

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

<sup>55</sup> *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.

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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, 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*<sup>56</sup>, the lower 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 PCMA argued goes going 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.

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."<sup>57</sup>

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. On the other hand, a law that applies to PBMs regardless of 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.

## 2. 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."<sup>58</sup>

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 be in conflict with the provisions of state law for preemption to hold.

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

<sup>57</sup> *Rutledge*, at 6.

<sup>58</sup> 42 CFR § 422.402.

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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).<sup>59</sup>

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 said negotiations.<sup>60</sup> Accordingly, the 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.<sup>61</sup>

The 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 district court held that the remaining provisions of the Oklahoma law challenged by the PCMA were not preempted by Medicare Part D.<sup>62</sup> 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 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 provisions of Oklahoma law apply only to preferred network status, the district court ruled there was no applicable standard in place that would preempt Oklahoma’s law.

Finally, the district court rejected the PCMA’s challenge to Oklahoma’s contract approval provisions.<sup>63</sup> 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 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 district court concluded that the contract approval provisions of Oklahoma’s law are not preempted by Medicare Part D.

The PCMA has appealed the district court’s decision. It is unknown whether the 10th Circuit or other courts will follow the same reasoning with respect to the scope of Medicare Part D preemption of state PBM laws.

### 3. MEDICAID

Medicaid is a federally funded program that provides health benefits to certain low-income Americans.<sup>64</sup> 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

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

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> See, e.g., Furrow generally 460-462.

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states have broad leeway to regulate PBMs serving Medicaid carriers, as long as 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.<sup>65</sup> Any changes a state makes to Medicaid implementation must also be approved by the CMS via a plan amendment process.<sup>66</sup> 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 through the MCO's contracted PBM. **It is increasingly common for MCOs and PBMs to share common ownership with a parent organization, raising important conflict of interest concerns.** 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 companies sign a master rebate agreement with the CMS, which administers the Medicaid program at the federal level. These rebates result in cost savings on prescription drugs 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 do not have the flexibility that insurers in the private market do 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 managed care 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.

### **D. 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 key to the ultimate pricing

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<sup>65</sup> Furrow at 490-492.

<sup>66</sup> *Id.*

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consumers pay or as having other significant marketplace impacts. Those functional issues are discussed in the sections that follow.

### 1. FORMULARY DESIGN

PBMs implement formularies or lists of covered drugs<sup>67</sup>. 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 use 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.<sup>68</sup> The federal Affordable Care Act (ACA) introduced federal regulations on P&T Committees serving qualified health plans (QHPs).

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.<sup>69</sup>

The PBM will look at 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.<sup>70</sup> 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. The PBM then keeps the rebates or shares all or a percentage of the rebate with the plan sponsor or patient, depending on the PBMs contract with the plan sponsor.<sup>71</sup>

Since formularies are essentially coverage decisions, a PBM's step-therapy protocol may be viewed as part of its formulary. Step-therapy 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, a practice which is known as "non-medical switching."

### 2. 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 manufacturer's drug's placement on the PBM's formulary. The PBM may pass the rebate on to the health

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<sup>67</sup> 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.

<sup>68</sup> Horvath.

<sup>69</sup> *Id.*

<sup>70</sup> 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>.

<sup>71</sup> Horvath.



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benefit plan according to their shared contract, which may allow the PBM to keep a percentage of the rebate, but it is possible the PBM keeps the entire rebate with no direct benefit to the plan or the consumer.<sup>72</sup>

Rebates are mostly used on branded and specialty drugs where there exist similar competing drugs from other manufacturers. From a manufacturer's perspective, the rebate is a tool to incentivize PBMs to place the manufacturer's drugs on formularies within preferred tiers.<sup>73</sup> PBMs negotiate based on their volume of scale to obtain highest rebate for selected drugs.<sup>74</sup> 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.<sup>75</sup>

Rebates are negotiated separately with each plan sponsor and can take the form of a number of different options in how rebates get passed along.<sup>76</sup>

- 100 percent pass-through – The PBM passes 100 percent of the rebate back to the plan sponsor. Most clients 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.<sup>77</sup> This could result in health plans 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: Some states have enacted as part of their PBM laws a provision stating that a PBM must pass through 100 percent of a pharmaceutical manufacturer rebate to a plan sponsor.<sup>78</sup>
- 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.<sup>79</sup>

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<sup>72</sup> *Id.*; Sood; Oestreicher.

<sup>73</sup> Sood; Oestreicher.

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> Horvath; Sood. Oestreicher.

<sup>79</sup> *Id.*

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- 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 could lead to increasing the cost of drugs to PBMs, plan sponsors and ultimately consumers without corresponding legislation to lower pharmaceutical manufacturer prices. 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.<sup>80</sup>

### 3. PRICING AND CONTRACTING PRACTICES

PBMs negotiate with pharmaceutical manufacturers, health plans, and pharmacies. PBMs may also be affiliated with a health plan and a pharmacy. As discussed below, the unique market position and negotiating power of the three largest PBMs enables them to engage in contracting practices that may be detrimental to consumers and other market participants.<sup>81</sup> The below terms and descriptors identify the most common pricing and contracting practices that have received scrutiny from regulators:

**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.<sup>82</sup>

**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.<sup>83</sup>

**Below-cost reimbursement practices:** One of the most common ways for PBMs to generate profits is to ensure that the reimbursement they pay to pharmacies is lower than the revenue they generate for managing prescription drug benefits on behalf of a plan sponsor. Additionally, PBMs have adopted other tactics which introduce additional complexity into the system, which they in turn rely on to exert control over reimbursement processes. These practices are discussed in more detail in the following categories. In addition to reform efforts in the areas listed below, many states have either enacted or are considering legislation to establish a “rate floor,” or a minimum payment which guarantees consistent and adequate reimbursement for pharmacy services. Rate floors are typically tied to a national reimbursement standard (such as national average drug acquisition cost, or NADAC) which covers the ingredient cost for the pharmacy to acquire the drug, plus a dispensing fee which considers other operating costs such as pharmacy work related to clinical services (e.g., medication management, patient counseling), payroll, personnel expenses, inventory and auditing services, warehouse expenses, insurance, pharmacy building, and equipment. Ensuring pharmacies are appropriately reimbursed for dispensing prescription drugs can improve medication adherence and lead to better health for patients and cost savings in other areas of the healthcare ecosystem.

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<sup>80</sup> *Id.*

<sup>81</sup> Sood.

<sup>82</sup> “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).

<sup>83</sup> Oestreicher.

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Copay clawbacks: 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.<sup>84</sup>

MAC transparency: A maximum allowable cost (MAC) list is a list that includes the maximum amount that a plan will pay for certain drugs.<sup>85</sup> 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, they might use a very low MAC list to reimburse pharmacies but a higher list when charging health plans.<sup>86</sup>

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.<sup>87</sup>

**Retroactive Fees: retroactive fees comprise all or a portion of a drug reimbursement paid to a pharmacy or other dispenser that is either recouped or reduced following adjudication of a claim for any reason. These fees are typically assessed after an audit of a pharmacy (discussed in further detail below) and are claimed by PBMs to have resulted from adjustments based on performance on a set of quality measures. However, there is often a lack of transparency and standardization in relation to the measures that PBMs use to evaluate pharmacies, and in the amounts and frequency of the fees assessed to pharmacies.**

Spread pricing: Spread pricing is the PBM practice of 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.<sup>88</sup>

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

Each of these practices have been regulated to a degree by regulation in some states; however, the degree and method of regulation has varied by those states. More details are provided in the state-specific sections below.

#### 4. VERTICAL INTEGRATION AND CONSOLIDATION

In business and economics, vertical integration means a 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 through common ownership a wholesale distributor and a retail store.<sup>89</sup> The entities

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<sup>84</sup> *Id.*; "A Tangled Web," p. 33.

<sup>85</sup> 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).

<sup>86</sup> "A Tangled Web," p. 29-30.

<sup>87</sup> Horvath.

<sup>88</sup> Oestreicher.

<sup>89</sup> Sood.

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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.<sup>90</sup>

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.<sup>91</sup> 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.<sup>92</sup>

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.<sup>93</sup> 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.<sup>94</sup> Further, independent **and chain** 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.<sup>95</sup> 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.<sup>96</sup> 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.<sup>97</sup> 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,

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<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

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

<sup>95</sup> Sood.

<sup>96</sup> *Id.*

<sup>97</sup> "A Tangled Web," p. 42-43.

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

### 5. 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.<sup>98</sup> 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 consider the relative availability of physical pharmacies in a geographic service area.<sup>99</sup> 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.<sup>100</sup> 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.

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<sup>98</sup> 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).

<sup>99</sup> 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).

<sup>100</sup> See generally, PBM Law Compilations, available at: [https://content.naic.org/cmte\\_b\\_pharmacy\\_bmri\\_sg.htm](https://content.naic.org/cmte_b_pharmacy_bmri_sg.htm).

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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.<sup>101</sup> 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.” PBMs classify many drugs as “specialty” even when they do not meet standardized criteria to be designated as such. Examples of generally accepted criteria for drugs to be classified as specialty include: requirements for special handling or storage; complex and extended patient education or counseling; intensive monitoring or clinical oversight; or the drug is used to treat chronic, complex, or rare medical conditions that can be progressive or that can be debilitating or fatal if left untreated or undertreated. This occurs. The practice of steering patients by using specialty designations occurs even when a pharmacy may otherwise have the credentials to ~~do so~~ fill the prescription routinely, 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.<sup>102</sup>

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.

### 6. 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 put 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 in significant enforcement mechanisms.

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<sup>101</sup> Sood.

<sup>102</sup> 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>.

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Other key players that are licensed in the distribution and supply chain are described below:

### 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.<sup>103</sup> Self-insured health plans sponsored by employers or unions are subject to federal oversight pursuant to the ERISA, although the *Rutledge v. PCMA* case does seemingly allow state regulation of certain PBM activities performed for ERISA plans.

### Wholesalers

All 50 states and the District of Columbia require a wholesaler to be licensed. The structure of the statutes varies but attempt to 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;
- 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.

### 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

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<sup>103</sup> Furrow at 308, 314-316.

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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.

### 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 to 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.

### Pharmaceutical sales representatives

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.<sup>104</sup>

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



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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 Subgroup plans to continue to monitor developments in this area.

### E. STATE LAWS THAT OPERATE IN THE SUPPLY CHAIN

Suggest making the NAIC comprehensive list of state actions more prominent in this section (perhaps even linking to it in the body rather than as a footnote) and including further detail for states which have adopted comprehensive PBM reforms, such as Arkansas, Florida, and West Virginia.

In the last several years states have been working on legislation regarding the impact that Pharmacy Benefit Managers have on increasing prescription drug costs and what that means to consumers.

#### 1. PBM REGULATION

The role of PBMs has changed from intermediaries for pharmacies, drugmakers, wholesalers and others within the prescription drug supply chain to facilitate transactions. Vertical integration of pharmacies, PBMs, and insurers, along with opaque contracting has created a disruption within the drug supply chain. The influence of PBMs has expanded from its original role, growing more complex and opaque, causing transparency concerns. This has prompted states to reevaluate regulations regarding licensure, reporting requirements, transparency, contract standards, health plan responsibility, spread pricing, network adequacy, and clawback issues. At least 20 states have begun the task of improving their regulations and laws<sup>105</sup> and 18 states have either amended or established new PBM licensure requirements within the last few years.<sup>106</sup>

##### a. State Laws and Approaches

Several states on the Subgroup offered up summaries and key developments on 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.<sup>107</sup>

##### i. Florida

Florida enacted the Florida Pharmacy Act to their Insurance Code, which gives the Florida Office of Insurance Regulation (OIR) the authority to enforce provisions, respond to potential violations, establish more protection for pharmacies in relation to audits, establish a \$10,000 penalty for PBMs that do not register with the OIR, and authorize pharmacies to appeal audit findings by PBMs and health plans. However, the responsibility of establishing rules for pharmacy provisions will be managed by the Board of Pharmacy.

##### ii. New Jersey

New Jersey has a bill that focuses on PBM transparency, licensing, and reporting requirements. Carriers would be required to maintain records of contracted PBMs including transaction records and compensation

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<sup>105</sup> Shaikh, H., & Keller, B. A. (2022). PBM Regulatory Roundup (Spring 2022): The 8th Circuit Rules and More States Issue Regulations. *The National Law Review*, XII(88). Retrieved September 6, 2022, from <https://www.natlawreview.com/article/pbm-regulatory-roundup-spring-2022-8th-circuit-rules-and-more-states-issue>.

<sup>106</sup> Imber, S. L., Osborn, J. M., & Liby, J. T. (2022). Pharmacy Benefit Managers Licensing and Compliance Developments. *National Law Review*, XII(31). Retrieved September 6, 2022, from <https://www.natlawreview.com/article/pharmacy-benefit-managers-licensing-and-compliance-developments>.

<sup>107</sup> See generally, PBM Law Compilations, available at: [https://content.naic.org/cmte\\_b\\_pharmacy\\_bmri\\_sg.htm](https://content.naic.org/cmte_b_pharmacy_bmri_sg.htm).

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remittance. Carriers would also be required to have pharmacy and therapeutics committees with no conflict of interest. Additionally, they must use more than one formulary.<sup>108</sup>

### iii. 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 United States. 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.

### iv. 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 to include 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; and a network adequacy report. 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.

## 2. PBM 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.<sup>109</sup> The following states have proposed or implemented laws requiring transparency reporting: Delaware, Iowa, Michigan, Minnesota, New York, Oklahoma, Oregon, Texas, Washington, and West Virginia.

## 3. OTHER RELEVANT STATE LAWS AND PROPOSED LAWS

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

### 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.

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<sup>108</sup> 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\\_I1](https://www.njleg.state.nj.us/bill-search/2022/S1616/bill-text?f=S2000&n=1616_I1).

<sup>109</sup> 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>

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### **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 minimize a state's administrative burden by using existing data sources.

### **Anti-Price-Gouging**

These laws prohibit pharmaceutical manufacturers from hiking 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.

### **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.

### **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.

### **Licensing Pharmaceutical 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.

## **F. FEDERAL INTEREST AND POSSIBLE REGULATIONS**

More and more state regulations have been brought before state legislators to help regulate PBMs. Many people think that mere state regulation is not enough, and that the federal government will need to step in to help. 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.

### **1. PHARMACY BENEFIT MANAGER TRANSPARENCY ACT OF 2022**

Introduced on May 24, 2022, the Pharmacy Benefit Manager Transparency Act of 2022, is a bipartisan bill sponsored by Senators Maria Cantwell (D-WA) and Charles Grassley (R-IA). The act would enforce necessary disclosure requirements on PBMs and strive to prevent questionable PBM practices, such as three practices that could be deemed unfair or deceptive which are expressly outlawed by the proposed legislation. These include spread pricing, the practice of charging a health plan or payor a different amount for a prescription drug's ingredient cost or dispensing charge than the PBM reimburses a pharmacy for those costs, and keeping the difference as profit; 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;

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and deceptively reducing reimbursement to a pharmacy or arbitrarily raising fees to offset changes in reimbursement requirements would also be forbidden.

Beginning no later than one year after the proposed legislation's adoption, the act mandates that PBMs provide the following data to the 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; 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 Senate Committee on Commerce, Science, and Transportation and the House Committee on Energy and Commerce would also need to receive two reports from the FTC-- 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 include: 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 be due within a year of the proposed law's passage. It would include 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 violate 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 also forbids 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 are given permission to carry out the proposed legislation's enforcement measures. Additionally, under the proposed law, offenders might face extra 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.<sup>110</sup>

Additionally, the Act would incentivize 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

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<sup>110</sup> 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/>.

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rebates, costs, prices, reimbursements, fees, and other information to healthcare plans, payors, pharmacies, and federal agencies.<sup>111</sup>

Democrats and Republicans have both turned their attention to PBMs in recent years as they try to control the soaring cost of prescription drugs. The PBM sector claims that their job is to reduce costs for health plans, but detractors claim that they raise list prices of prescription pharmaceuticals by requesting more rebates or discounts from pharmaceutical manufacturers, which in turn raises prices for consumers.<sup>112</sup>

### 2. THE FEDERAL TRADE COMMISSION

In June 2022, the FTC announced that it will launch an inquiry into the prescription drug middleman industry, requiring the six largest pharmacy benefit managers to provide information and records regarding their business practices. The agency's investigation will closely examine how vertically integrated pharmacy benefit managers 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.

Even though many individuals are unaware of them, pharmacy benefit managers exert a significant amount of influence on the nation's prescription drug system, according to Lina M. Khan, chair of the FTC. This investigation will shed insight on the procedures used by PBMs.<sup>113</sup>

### G. 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 vis federal authority. The key cases to date are described below.

#### 1. **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 PBMs<sup>114</sup> 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.

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<sup>111</sup> 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>.

<sup>112</sup> Manville, G., & Dross, D. (2022, July 7). *Congress takes aim at PBM Business Practices*. Mercer US. Retrieved October 10, 2022, from <https://www.mercer.us/our-thinking/healthcare/congress-takes-aim-at-pbm-business-practices.html#:~:text=Bipartisan%20legislation%20requiring%20pharmacy%20benefit,practices%20are%20advancing%20in%20Congress>.

<sup>113</sup> *FTC launches inquiry into prescription drug middlemen industry*. Federal Trade Commission. (2022, June 7). Retrieved October 10, 2022, from <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry>.

<sup>114</sup> As the term is spelled in Act 900. Supreme Court style refers to “pharmacy benefit managers.”

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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 Eighth Circuit affirmed.<sup>115</sup> Both courts relied on a recent Eighth Circuit decision striking down a similar Iowa law because it “made ‘implicit reference’ to ERISA by regulating PBMs that administer benefits for ERISA plans”<sup>116</sup> 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.”<sup>117</sup>

The U.S. Supreme Court, however, concluded that “[t]he logic of *Travelers* decides this case,”<sup>118</sup> 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,”<sup>119</sup> 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,”<sup>120</sup> even if the law “affects an ERISA plan or causes some non-uniformity in plan administration.”<sup>121</sup> 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.’”<sup>122</sup> The Court observed that Act 900 “does not require plans to provide any particular benefit to any particular beneficiary in any particular way,”<sup>123</sup> and determined that like the law at issue in *Travelers*, “Act 900 is merely a form of cost regulation.”<sup>124</sup>

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”<sup>125</sup> 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.<sup>126</sup> 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.”<sup>127</sup> The Court acknowledged that Act 900 required ERISA plan administrators to “comply with a particular process” and standards,<sup>128</sup> 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.<sup>129</sup> The Court held further that ERISA did not preempt Act 900’s decline-to-dispense provision, even though it

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<sup>115</sup> *PCMA v. Rutledge*, 891 F.3d 1109 (8<sup>th</sup> Cir. 2018).

<sup>116</sup> 141 S.Ct. at 479, quoting *PCMA v. Gerhart*, 852 F.3d 722, 729 (8<sup>th</sup> Cir. 2017).

<sup>117</sup> *Id.* at 479, quoting *Gerhart*, 852 F.3d at 726, 731.

<sup>118</sup> *Id.* at 481.

<sup>119</sup> *Id.* at 480, quoting *Gobeille*, 577 U.S. at 320.

<sup>120</sup> *Id.* at 480, citing *Travelers*, 514 U.S. at 668.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*, quoting *Gobeille*, 577 U.S. at 320.

<sup>123</sup> *Id.* at 482.

<sup>124</sup> *Id.* at 481.

<sup>125</sup> 29 U.S.C. § 1144(a).

<sup>126</sup> 141 S.Ct. at 477.

<sup>127</sup> *Id.* at 481–482.

<sup>128</sup> *Id.* at 482, quoting PCMA brief at 24.

<sup>129</sup> *Id.*

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“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.<sup>130</sup>

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.<sup>131</sup> 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. Additionally, the Court did not address preemption under Medicare Part D.

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

In 2021, the Eighth 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.<sup>132</sup> 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;
- 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.<sup>133</sup>

The court also upheld provisions that “constitute, at most, regulation of a noncentral ‘matter of plan administration’ with de minimis economic effects.”<sup>134</sup> The court held that “whatever modest non-uniformity in plan administration [the sections] might cause does not warrant preemption.”<sup>135</sup> 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 HIPAA) to patients or plan sponsors. The court stops short of saying that PBM regulation cannot be preempted by ERISA. North Dakota’s laws, the court concluded, amount

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<sup>130</sup> *Id.*

<sup>131</sup> *Id.* at 481.

<sup>132</sup> 18 F.4th 956, 968.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*, quoting *Gobeille*, 577 U.S. 312, 320.

<sup>135</sup> *Id.*, citing *Rutledge*, 141 S. Ct. at 480.

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to regulation of a PBMs' functions, rather than regulation of an ERISA plan itself so 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.<sup>136</sup>

### **3. 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 Tenth Circuit Court of Appeals.

The Oklahoma laws at issue protects Oklahoma consumers and their access to pharmacy providers and protects Oklahoma pharmacies from certain self-dealing and self-serving practices of PBMs that can harm consumers and put rural and independent pharmacies out of business. Relying on *Rutledge*, the court concluded that all of PCMA's ERISA preemption claims fail as a matter of law. The 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, with regard to the Promotional Materials provision, the 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 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.<sup>137</sup>

With respect to preemption by Medicare Part D, the 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

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<sup>136</sup> *Id.* at 972.

<sup>137</sup> 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&y ear=>



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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.<sup>138</sup>

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 no doubt more decisions are to come.

### H. RECOMMENDATIONS

The Subgroup acknowledges that issues in the pharmaceutical drug ecosystem are complex and often opaque; to the end consumer, many of these issues are difficult to understand. The most mature body of regulation has developed around PBM activities, but as noted throughout the paper, PBMs are not the only influential player in the ecosystem. Based on the information received by the subgroup over the last two years, the subgroup makes the following recommendations:

1. The NAIC should consider tasking the PBM subgroup or similar group with drafting a model guideline to address PBM regulation based on other state laws and recent jurisprudence;
2. The NAIC should consider expanding information sharing between the states through additional committees on the topic of pharmaceutical drug pricing and transparency;
3. The NAIC should consider any necessary updates to Model 22 out of the emergence of greater regulation in the prescription drug ecosystem;
4. The NAIC should consider impacts of this work on an ongoing basis on the federal 340B drug pricing program;
5. The NAIC should consider facilitating and maintaining a nationwide database of PBM contracting provisions. This would allow states to become familiar with common PBM contractual provisions and more easily identify issues that arise from them;
6. The NAIC should consider developing an open dialogue with Federal agencies that is broader than just PBM regulation. The discussion should consider regulation of all the stakeholders in the prescription drug ecosystem from a more holistic view and may be best achieved through a coordinated effort involving state and federal regulators; and
7. This subgroup, and successive subgroups, should continue to maintain a current listing of PBM laws and regulations and case law for reference by other states.

The Subgroup recognizes the critical role that the pharmaceutical drug ecosystem plays on consumer costs and the role states can play in understanding and best regulating the ecosystem. The body of knowledge gained by the subgroup over the last two years, and related resources provided to state regulators provides a solid foundation to continue to examine these key issues.

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<sup>138</sup> 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=>

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### APPENDIX I.

Meeting #	Date	Presenter/Topic
Meeting #1	August 15, 2019	<ul style="list-style-type: none"><li>Jane Horvath (Horvath Health Policy and Research Faculty, Georgetown University) presentation on “Basics of the Pharmaceutical Market &amp; PBMs.”</li></ul>

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Meeting #	Date	Presenter/Topic
		<ul style="list-style-type: none"> <li>• Leanne Gassaway (America’s Health Insurance Plans—AHIP) presentation on “Pharmacy Benefit Managers Overview &amp; Background.”</li> </ul>
Meeting #2	August 22, 2019	<ul style="list-style-type: none"> <li>• Dr. Neeraj Sood (Sol Price School of Public Policy, University of Southern California) presentation on “PBM Economics.”</li> <li>• 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.</li> </ul>
Meeting #3	August 29, 2019	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Claire McAndrew (Families USA) discussed the effect of PBMs and prescription drug costs on consumers.</li> <li>• Amy Killelea (National Alliance of State and Territorial AIDS Directors—NASTAD) discussed PBMs and their impact on consumer access and affordability of prescription drugs.</li> </ul>
Meeting #4	October 3, 2019	<ul style="list-style-type: none"> <li>• Kentucky discussed its PBM licensing process.</li> <li>• Arkansas discussed its PBM licensing law and other provisions related to PBM business practices.</li> <li>• 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.</li> <li>• New Mexico discussed its PBM law focusing on its reimbursement provisions.</li> </ul>

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Meeting #	Date	Presenter/Topic
		<ul style="list-style-type: none"> <li>• Oregon discussed its PBM law, including its PBM registration requirements, and Oregon’s Prescription Drug Price Transparency program.</li> </ul>
Meeting #5	December 11, 2021	<ul style="list-style-type: none"> <li>• North Dakota discussion on the <i>Pharmaceutical Care Management Association (PCMA) v. Wehbi</i> ruling.</li> <li>• Connecticut discussion on its PBM law and white paper.</li> <li>• Virginia discussion on its PBM law.</li> <li>• Oklahoma discussion on its PBM law and the <i>PCMA v. Mulready</i> case.</li> <li>• Wisconsin discussion on the work of the Governor’s Task Force on Reducing Prescription Drug Prices and its PBM law.</li> </ul>
Meeting #6	March 16, 2022	<ul style="list-style-type: none"> <li>• Montana discussion on its PBM law.</li> <li>• 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.</li> </ul>
Meeting #7	April 4, 2022	<ul style="list-style-type: none"> <li>• Oklahoma update on its PBM law.</li> <li>• Oregon discussion on its PBM law and transparency in prescription drug pricing and Oregon Prescription Drug Affordability Board (PDAB) initiatives.</li> <li>• Discussion from a consumer perspective on the Subgroup’s charge to develop a white paper on PBMs and their business practices.</li> </ul>
Meeting #8	April 25, 2022	<ul style="list-style-type: none"> <li>• Dr. Neeraj Sood and Dr. Karen Van Nuys, University of Southern California (USC) Price School on Public Policy- presentation on “How Well Are PBM Markets Functioning?”</li> </ul>
Meeting #9	June 15, 2022	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
Meeting #10	July 29, 2022	<ul style="list-style-type: none"> <li>• Healthcare Distribution Alliance (HDA) presentation on the Subgroup’s charge to develop a white paper on</li> </ul>

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Meeting #	Date	Presenter/Topic
		<p>PBMs and their business practices from a pharmaceutical distributor perspective.</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul>
Meeting #11	August 9, 2022	<ul style="list-style-type: none"> <li>• Presentation from the Pharmaceutical Care Management Association (PCMA) discussing the value of PBMs and the services PBMs provide with respect to pharmacy benefit management.</li> <li>• Presentation from the Pharmaceutical Research and Manufacturers of America (PhRMA) on the lack of transparency in PBM practices.</li> <li>• Oregon Primary Care Association (OPCA) presentation on the federal 340B prescription drug program.</li> </ul>
Meeting #12	October 24, 2022	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Civica presentation on its work with the BCBSA and several Blues plans to bring lower-priced generics to market.</li> </ul>