REGULATORY FRAMEWORK (B) TASK FORCE

Regulatory Framework (B) Task Force Dec. 1, 2023, Minutes

- Regulatory Framework (B) Task Force Sept. 29, 2023, Minutes (Attachment One)
  - Regulatory Framework (B) Task Force 2024 Proposed Charges (Attachment One-A)
  - Pharmacy Benefit Manager White Paper Adopted by the Task Force Sept. 29, 2023 (Attachment One-B)
- Accident and Sickness Insurance Minimum Standards (B) Subgroup Oct. 2, 2023, Minutes (Attachment Two)
- Accident and Sickness Insurance Minimum Standards (B) Subgroup Sept. 18, 2023, Minutes (Attachment Three)
- Accident and Sickness Insurance Minimum Standards (B) Subgroup Aug. 21, 2023, Minutes (Attachment Four)
- Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group Aug. 14, 2023, Minutes (Attachment Five)

Draft Pending Adoption

Draft: 12/7/23

Regulatory Framework (B) Task Force
Orlando, Florida
December 1, 2023

The Regulatory Framework (B) Task Force met in Orlando, FL, Dec. 1, 2023. The following Task Force members participated: Sharon P. Clark, Chair (KY); Glen Mulready, Vice Chair (OK); Lori K. Wing-Heier represented by Sarah Bailey (AK); Mark Fowler represented by Yada Horace (AL); Andrew N. Mais represented by Jared Kosky (CT); Karima M. Woods represented by Howard Liebers (DC); Doug Ommen represented by Andria Seip (IA); Dean L. Cameron represented by Weston Trexler (ID); Amy L. Beard represented by Alex Peck, Meghann Leaird, and Claire Szpara (IN); Vicki Schmidt (KS); Gary D. Anderson represented by Niels Puetthoff (MA); Timothy N. Schott represented by Marti Hooper and Robert Wake (ME); Grace Arnold represented by Peter Brickwedde (MN); Jon Godfread represented by Chrystal Bartuska (ND); Eric Dunning represented by Maggie Reinert and Michael Muldoon (NE); D.J. Bettencourt (NH); Justin Zimmerman represented by Paul Lupo (NJ); Judith L. French represented by Laura Miller (OH); Andrew R. Stolfi represented by TK Keen (OR); Michael Humphreys represented by Shannen Logue (PA); Larry D. Deiter represented by Jill Kruger and Travis Jordan (SD); Jon Pike (UT); Scott A. White represented by Julie Blauvelt (VA); Mike Kreidler represented by Ned Gaines, Jane Beyer, and Lichiou Lee (WA); Nathan Houdek represented by Jennifer Stegall (WI); and Allan L. McVey represented by Joylynn Fix (WV). Also participating were: Erica Weyhenmeyer (IL); Carrie Couch and Camille Anderson-Weddle (MO); Paige Duhamel (NM); and Patrick Smock (RI).

1. Adopted its Sept. 29 and Summer National Meeting Minutes

The Task Force met Sept. 29 and took the following action: 1) adopted its 2024 proposed charges; and 2) adopted the white paper *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* (PBM white paper).

Keen made a motion, seconded by Commissioner Mulready, to adopt the Task Force's Sept. 29 (Attachment One) and Aug. 13 minutes (*see NAIC Proceedings – Summer 2023, Regulatory Framework (B) Task Force*). The motion passed unanimously.

2. Adopted its Subgroup and Working Group Reports

Kruger made a motion, seconded by Kosky, to adopt the following reports: 1) the Accident and Sickness Insurance Minimum Standards (B) Subgroup, including its Oct. 2 (Attachment Two), Sept. 18 (Attachment Three), and Aug. 21 (Attachment Four) minutes; 2) the Employee Retirement Income Security Act (ERISA) (B) Working Group; 3) the Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group, including its Aug. 14 (Attachment Five) minutes; and 4) the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup. The motion passed unanimously.

3. Heard a Presentation from the HIV+Hepatitis Policy Institute on the Results and Impact of the Copay Accumulator Adjustment Programs Lawsuit

Carl Schmid (HIV+Hepatitis Policy Institute) discussed the results and impact of the copay accumulator adjustment programs lawsuit, which challenged a federal rule that allows health insurers to avoid counting the value of drug manufacturer copay assistance toward patients' out-of-pocket cost obligations. He discussed the U.S. District Court for the District of Columbia's Sept. 29 decision vacating the 2021 Notice of Benefit and Payment Parameters (NBPP) to the extent it permitted health plans to use a copay accumulator policy. Schmid said the court based its ruling on both the federal rule's contradictory reading of the same statutory and regulatory language and the fact

that the federal agencies implementing the rule had yet to offer a definitive interpretation of its language that would support their authorization of copay accumulators.

Schmid explained that the HIV+Hepatitis Policy Institute believes that by its decision, the court fully understood and stated how copay assistance and accumulators work in practice: 1) increase consumer costs; 2) increase manufacturer costs; 3) increase payments to insurers; and 4) is not a discount from the cost of the prescription drug. He said the court also did not accept the federal government's argument that the case was not justiciable. He said the court's decision did not address issues such as: 1) the Internal Revenue Service's (IRS') guidance on copay assistance and high deductible health plans (HDHPs) and health savings accounts (HSAs); and 2) insurers collecting more money than permitted under the federal Affordable Care Act's (ACA's) cost-sharing limits and double billing. Schmid discussed steps after the decision. He said that because the court did not stay its decision, the decision was immediately effective.

Schmid said that on Nov. 28, the federal U.S. Department of Health and Human Services (HHS) filed a notice of appeal with the U.S. Court of Appeals for the D.C. Circuit. In addition, the HHS also filed a motion to clarify the extent of the court's Sept. 29 decision. Specifically, the HHS requested the court confirm it was not required to enforce the 2020 NBPP, which prohibited copay accumulators except where a medically appropriate generic alternative is available.

Trexler asked what, if anything, state insurance regulators should be doing with respect to the decision. Schmid said it is important that the state departments of insurance (DOIs) enforce the decision because the court did not stay its decision.

4. Heard a Presentation from the NABIP on "Cost: The Greatest Barrier to Access"

Jessica Brooks-Woods (National Association of Benefits and Insurance Professionals—NABIP) presented on "Cost: The Greatest Barrier to Access." She said that cost is one of the major issues keeping health insurance brokers up at night because the cost of health care affects access to such care. She said health care utilization is determined by the need for care, whether consumers know that they need care, whether they want to obtain care, and whether care can be accessed. Brooks-Woods noted the connection between the current health care cost trends and access to health care, even for those who have health insurance coverage. She said that according to the 2022 Commonwealth Fund Biennial Health Insurance Survey, about 29% of consumers with employer-based coverage and 44% of those with coverage purchased through the individual market and ACA marketplaces are underinsured.

Brooks-Woods explained that premiums are not the only cost affecting access to care. She said access to care is also affected by increasing out-of-pocket costs for consumers, particularly the differences between out-of-pocket maximums for in-network care and out-of-network care. She said that in an effort to reduce costs and continue to offer health insurance coverage to their employees, employers are increasingly shifting to and choosing to self-insure. Brooks-Woods offered a few suggestions to address the issues, such as identifying the true cost drivers, giving attention to the plight of the underinsured, and focusing on social determinants of health.

Beyer asked about the trend of employers to self-insurance, particularly small employers choosing to offer level-funded plans as a means to self-insure. Brooks-Woods said the NABIP believes the next issue to keep them awake at night is risk, particularly with respect to level-funded plans because of its concern that small employers do not understand their risk exposure and the low level of education they have about the risk associated with such plans when making the decision to offer them to their employees as an alternative to a fully insured plan.

Duhamel said New Mexico also is seeing small employers gravitate toward level-funded plans. She said the New Mexico DOI tries to educate these employers about the loss of state law consumer protections for their employees

when offering these plans. She said it is critical that agents and brokers also be educated on the loss of such protections in order for them to educate their clients.

Having no further business, the Regulatory Framework (B) Task Force adjourned.

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Draft: 10/10/23

Regulatory Framework (B) Task Force
Virtual Meeting
September 29, 2023

The Regulatory Framework (B) Task Force met Sept. 29, 2023. The following Task Force members participated: Sharon P. Clark, Chair (KY); Glen Mulready, Vice Chair, represented by Ashley Scott (OK); Lori K. Wing-Heier represented by Sarah Bailey (AK); Mark Fowler represented by Anthony L. Williams (AL); Ricardo Lara represented by Tyler McKinney (CA); Michael Conway represented by Debra Judy (CO); Andrew N. Mais represented by Jared Kosky (CT); Doug Ommen represented by Andria Seip and Brad Biren (IA); Dean L. Cameron represented by Weston Trexler (ID); Amy L. Beard represented by Alex Peck (IN); Vicki Schmidt represented by Julie Holmes (KS); Gary D. Anderson represented by Kevin Beagan and Rebecca Butler (MA); Timothy N. Schott (ME); Mike Causey represented by Jackie Obusek and Ted Hamby (NC); Jon Godfread (ND); Eric Dunning represented by Martin Swanson (NE); D.J. Bettencourt represented by Michelle Heaton (NH); Justin Zimmerman represented by Paul Lupo (NJ); Judith L. French represented by Craig Kalman (OH); Andrew R. Stolfi represented by TK Keen (OR); Michael Humphreys (PA); Larry D. Deiter represented by Jill Kruger (SD); Cassie Brown represented by Rachel Bowden (TX); Jon Pike represented by Shelley Wiseman (UT); Scott A. White represented by Julie Fairbanks and Jackie Myers (VA); Mike Kreidler represented by Ned Gaines (WA); Nathan Houdek represented by Jennifer Stegall (WI); and Allan L. McVey represented by Joylynn Fix, Erin K. Hunter, and Mary Jo Lewis (WV). Also, participating was: Chlora Lindley-Myers (MO).

1. Adopted its 2024 Proposed Charges

Commissioner Clark said that prior to the meeting, NAIC staff circulated the Task Force's 2024 proposed charges. She explained that the 2024 proposed charges revise one of the Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group's charges to better align with its current work. Commissioner Clark also explained that for now, the Task Force proposes retaining the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup's charges from 2023. She said she anticipates that after the white paper *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* (PBM white paper) is finalized, the Task Force will consider revised charges for the Subgroup or a successor group early next year after the Task Force is reappointed for 2024. She said the Task Force did not receive any comments on its 2024 proposed charges.

Kruger made a motion, seconded by Gaines, to adopt the Task Force's 2024 proposed charges (Attachment One-A). The motion passed unanimously.

2. Adopted the PBM White Paper

Commissioner Clark said the Task Force's next item of business is to consider adoption of the PBM white paper. She said the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adopted the PBM white paper on July 27 after almost two years of work. She said the Task Force received comments on the white paper, which were distributed and posted on the Task Force's web page.

Commissioner Clark said that prior to this meeting, NAIC staff distributed a revised draft of the PBM white paper, which included some suggested updates following its July 27 adoption. Jolie H. Matthews (NAIC) said the suggested updates include revisions to the PBM white paper's Introduction section noting the Subgroup's July 27 adoption. She said the suggested updates also add language discussed during the Subgroup's July 27 meeting highlighting the Subgroup's intent that the white paper be considered a snapshot in time and subject to future revision because of the complex issues involved and ongoing and future litigation. Matthews said other suggested

updates revise the Enforcement and Federal Preemption Issues section reflecting the federal 10th Circuit Court of Appeals recent decision in the *Pharmaceutical Care Management Association (PCMA) v. Mulready* case.

Commissioner Clark asked for comments. Commissioner Godfread expressed concerns about the PBM white paper's Recommendation section. He said that given the inclusion of language noting that the PBM white paper is intended to reflect a snapshot in time and the potential continuation of work, the recommendations seem to be more like future charges for the Subgroup or its successor group. He said that because of this, he believes the Recommendation section should be removed and considered separately later as the work moves forward with the current Subgroup or its successor group. Swanson and Kosky expressed support for Commissioner Godfread's comments. Commissioner Godfread made a motion, seconded by Swanson, to remove the Recommendation section. The motion passed.

Commissioner Clark asked for additional comments. Kosky said Connecticut cannot support the PBM white paper's adoption because it believes it is flawed in many respects, particularly its lack of adequate citations and diversity in the sourcing of its language, biased tone in some areas, and inaccuracies. He explained that during the Subgroup's almost two years of work on the white paper, Connecticut noted these objections. He explained that Connecticut voted in favor of the motion to adopt the PBM white paper and move it forward for the Task Force's consideration to keep the process moving forward. He said that given these issues, Connecticut is concerned about whether this is an effective white paper. Kosky said that for Connecticut, when talking about a white paper it should be an authoritative research-based document that presents clear and accurate information and provides expert analysis about a topic. He also noted the lack of information in the PBM white paper concerning employers and consumers. He said the point of the PBM white paper was to try to find solutions to lower the cost of prescription drugs to consumers, and because of this, it should be a factual statement to assist state insurance regulators in making decisions related to the issues discussed. Keen acknowledged Kosky's comments. He said the Subgroup worked through the comments it received and addressed them as best it could due to the wide range of opinions on the issues the white paper discusses. Keen noted that the white paper's focus is on PBM regulation and the role PBMs play in the prescription drug ecosystem.

Commissioner Godfread expressed support for many of Kosky's comments. He noted that North Dakota has fundamental issues with the PBM white paper and the role of state insurance regulators in regulating PBMs. He said because of these concerns and issues, North Dakota will oppose adopting the white paper. Swanson said Nebraska also cannot support the PBM white paper's adoption because of concerns about its tone and some of its conclusions. He also said Nebraska already has a statute related to the issues discussed in the white paper and, as such, it is looking for what is next on these issues. Holmes also said that based on Connecticut's, Nebraska's, and North Dakota's comments, Kansas also would be voting to oppose the PBM white paper's adoption.

Commissioner Humphreys discussed the reason why the Subgroup developed the white paper. He noted that initially the Subgroup was charged with developing an NAIC model regulating PBMs. The proposed NAIC model failed to receive sufficient votes from the Executive (EX) Committee and Plenary for adoption. Following that action, the Subgroup pivoted to developing the PBM white paper for those states interested in looking at what other states are doing in the area related to PBM regulation and outlining and defining general issues that states might want to consider if they are looking to regulate PBMs. He acknowledged that the white paper might not be perfect and probably will never be perfect, but it is a good resource for state insurance regulators to obtain information on issues related to PBM regulation and the role PBMs play in the prescription drug ecosystem. He said that for these reasons, Pennsylvania supports the PBM white paper's adoption. Director Lindley-Myers expressed support for Commissioner Humphreys' comments. Although Missouri is not a Task Force member, she urged the Task Force to adopt the PBM white paper as a resource for state insurance regulators to use if they like to help inform them on issues related to the PBM regulation and the role they play in the prescription drug ecosystem.

Chris Petersen (Arbor Strategies LLC), speaking on behalf of the PCMA, said the PCMA supports Connecticut's, Kansas', Nebraska's, and North Dakota's comments. He said that in reading the comments submitted to the Task Force, there is still significant concern with the PBM white paper. He said that typically before an NAIC product is considered for adoption, all the issues are worked out and there is consensus. He said the PCMA is afraid that in adopting the current version of the PBM white paper, stakeholders not involved in the drafting process will believe that it is a consensus document when there is still significant opposition to some of its provisions. Therefore, he said the PCMA urges the Task Force not to adopt it.

J.P. Wieske (Horizon Government Affairs—HGA) discussed the history related to the PBM white paper. He explained that when he chaired the Task Force on behalf of Wisconsin, in 2018, the Task Force established the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup because of the discussion by the Executive (EX) Committee members and Plenary during the adoption of the revisions to the *Health Carrier Prescription Drug Benefit Management Model Act* (#22). He said concerns were raised that the revisions to Model #22 did not directly regulate the activities of PBMs in their role as managers of prescription drug benefits. He noted that after the proposed PBM model, which would have established a licensing or registration process for PBMs, failed to receive sufficient votes for adoption, the Subgroup turned to developing a white paper to educate state insurance regulators on PBM regulation and the role PBMs play in the prescription drug ecosystem because of this strong interest in learning more about these issues.

Commissioner Clark acknowledged the comments from Task Force members and interested parties. She said the white paper is not perfect given the myriad of different stakeholder perspectives and opinions. She said that despite this, she believes the PBM white paper is a good resource for state insurance regulators to learn more about the issues. She also noted the federal government's interest in these issues as well. She urged the Task Force members to adopt the white paper and forward it to the Health Insurance and Managed Care (B) Committee for its consideration and next steps.

Keen made a motion, seconded by Scott, to adopt the white paper, as revised, and include in an appendix the comments received by the Task Force on the July 27 version of the white paper (Attachment One-B). The motion passed with: 1) the following Task Force members voting in favor of the motion: Alaska, Iowa, Maine, New Hampshire, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Virginia, Washington, and Wisconsin; 2) the following Task Force members voting against the motion: Connecticut, Kansas, Nebraska, North Carolina, North Dakota, and South Dakota; and 3) the following Task force members abstaining: Idaho, Indiana, Massachusetts, and West Virginia.

Having no further business, the Regulatory Framework (B) Task Force adjourned.

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Draft: 10/4/23
Adopted by the Executive (EX) Committee and Plenary, Dec. __, 2023
Adopted by the Health Insurance and Managed Care (B) Committee, TBD
Adopted by the Regulatory Framework (B) Task Force, Sept. 29, 2023

2024 Proposed Charges

REGULATORY FRAMEWORK (B) TASK FORCE

The mission of the Regulatory Framework (B) Task Force is to: 1) develop NAIC model acts and regulations for state health care initiatives; and 2) consider policy issues affecting state health insurance regulation.

Ongoing Support of NAIC Programs, Products, or Services

1. The **Regulatory Framework (B) Task Force** will:
   A. Coordinate and develop the provision of technical assistance to the states regarding state-level implementation issues raised by federal health legislation and regulations.
   B. Review managed health care reforms, their delivery systems occurring in the marketplace, and other forms of health care delivery. Recommend appropriate revisions to regulatory jurisdiction, authority, and structures.
   C. Consider the development of new NAIC model laws and regulations and the revision of existing NAIC model laws and regulations, including those affected by federal legislation and final federal regulations promulgated pursuant to such legislation.
   D. Continue to review NAIC models recommended for revision by the former Affordable Care Act (ACA) Model Review (B) Working Group and, as appropriate, appoint a working group or subgroup to revise the NAIC model(s) prioritized for revision in 2024.
   E. At the direction of the Health Insurance and Managed Care (B) Committee, through the work of the Employee Retirement Income Security Act (ERISA) (B) Working Group, monitor, analyze, and report developments related to association health plans (AHPs).
   F. Monitor, analyze, and report, as necessary, developments related to short-term, limited-duration (STLD) coverage.

2. The **Accident and Sickness Insurance Minimum Standards (B) Subgroup** will:
   A. Review and consider revisions to the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171).

3. The **ERISA (B) Working Group** will:
   A. Monitor, report, and analyze developments related to ERISA, and make recommendations regarding NAIC strategy and policy with respect to those developments.
   B. Monitor, facilitate, and coordinate with the states and the U.S. Department of Labor (DOL) efforts related to sham health plans.
   C. Monitor, facilitate, and coordinate with the states and the DOL regarding compliance and enforcement efforts regarding the ACA that relate to ERISA.
   D. Review the *Health and Welfare Plans Under the Employee Retirement Income Security Act: Guidelines for State and Federal Regulation* (ERISA Handbook) and modify it, as necessary, to reflect developments related to ERISA. Report annually.

REGULATORY FRAMEWORK (B) TASK FORCE *(continued)*

4. The **Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group** will:
   A. Monitor, report, and analyze developments related to the MHPAEA, and make recommendations regarding NAIC strategy and policy with respect to those developments.
   B. Monitor, facilitate, and coordinate best practices with the states, the DOL, and the U.S. Department of Health and Human Services (HHS) related to the MHPAEA.
   C. Develop and provide resources to the states to support a greater understanding of laws, policies, and market conditions related to the MHPAEA.
   D. Provide supplemental resources to support documentation and reporting in the MHPAEA chapter of the *Market Regulation Handbook*.
   E. Coordinate with and provide input to Market Regulation and Consumer Affairs (D) Committee groups, as necessary, regarding mental health parity market conduct examinations.

5. The **Pharmacy Benefit Manager Regulatory Issues (B) Subgroup** will:
   A. 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 v. Pharmaceutical Care Management Association (PCMA)* decision on such business practices; and 3) discuss any challenges, if any, the states have encountered in implementing such laws and/or regulations.
   B. Consider developing a new NAIC model to establish a licensing or registration process for PBMs. Based on issues identified in the white paper, the Subgroup may consider including in the new NAIC model provisions on PBM prescription drug pricing and cost transparency.

NAIC Support Staff: Jolie H. Matthews/Jennifer R. Cook

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Adopted by the Regulatory Framework (B) Task Force, 9/29/23
Adopted by the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, 7/27/23
Revised: 9/29/23

A GUIDE TO UNDERSTANDING PHARMACY BENEFIT MANAGER AND ASSOCIATED STAKEHOLDER REGULATION

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I. INTRODUCTION

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

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

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

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

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

II. KEY PLAYERS IN PHARMACEUTICAL DRUG PRICING ECOSYSTEM

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

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

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

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

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

A. PAYORS

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

1. Insurers

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

Some insurers are part of integrated health systems, in which a common entity owns an insurer, hospitals, and employs networks of providers and provides all health care services to their enrollees. Because these entities

more closely coordinate all care under their roof, insurers in integrated systems may not utilize PBMs to the same extent as more traditional insurers.

2. Employers/Unions/Taft Hartley Trusts

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

3. Government Entities

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

B. PRESCRIPTION DRUG MANUFACTURERS

1. Manufacturers

Pharmaceutical manufacturers research, develop, produce, market, and sell prescription drugs to treat medical conditions.[8] The development of a new pharmaceutical product involves an investment of resources to create a product ready to be tested during clinical trials, where the safety and clinical efficacy of the drug are evaluated for a specific disease or condition.[9] Manufacturers may also partner with the federal government to develop drugs, or license drugs developed with federal research funding. Manufacturers may also purchase prescription drugs developed by other manufacturers to market as their own. The U.S. Food and Drug Administration (FDA) reviews all applications for the sale of new drugs from manufacturers following clinical trials and decides whether the drug will be made available on the market to consumers.[10] When a drug is approved, manufacturers then set the list price for medications and may change that price over time.[11]

2. Brand-Name Drugs

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

3. Generic Drugs

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

4. Biologic Drugs

Biologic drugs are distinct from traditional brand-name and generic drugs because they are made of living cells,

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

5. Biosimilar Drugs

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

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

C. PHARMACY BENEFIT MANAGERS (PBMs)

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

D. PHARMACIES

1. CHAIN

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

2. INDEPENDENT

Independent pharmacies refer to pharmacies that are privately and independently owned and operated by one

or more pharmacists, and whose primary function is to provide direct pharmaceutical care to patients. These services include dispensing drugs, providing immunizations, performing health screenings, testing at point-of-care, and providing medication counseling in the community setting.[28]

E. PHARMACISTS

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

F. PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS (PSAOs)

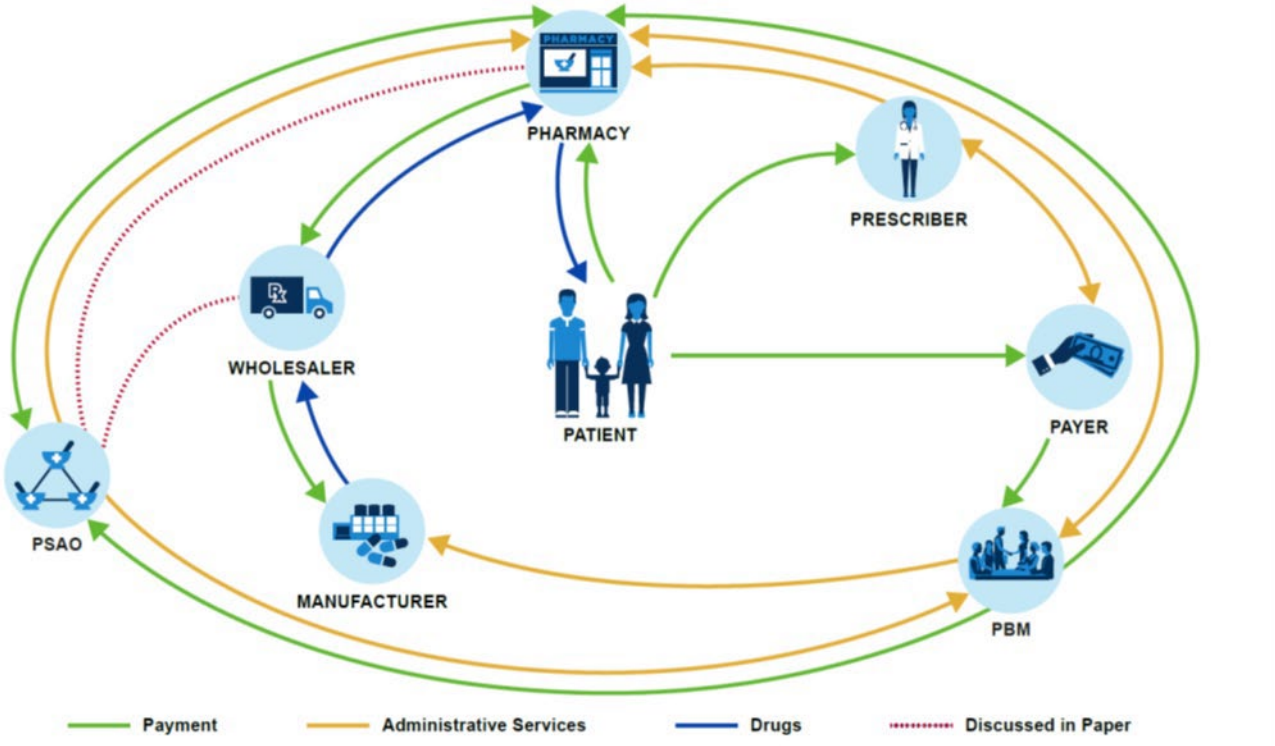
Pharmacy Services Administrative Organizations (PSAOs) are organizations that provide administrative services to independent pharmacies to support the evaluation and execution of a contract with PBMs or wholesalers.[29] In the majority of cases, an independent pharmacy's contract is with the PSAO, rather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

G. WHOLESALERS/DISTRIBUTORS

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

H. INTERRELATION OF PARTIES IN THE CHAIN AND TRANSACTION COSTS

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



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

1. Physical Drug Distribution Chain

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

Pharmaceutical manufacturer and wholesaler

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

Wholesaler and pharmacy

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

Pharmacy and consumer

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

2. Pharmacy Benefit Management Chain

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

Pharmaceutical manufacturer and PBM

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

Pharmaceutical Manufacturer and consumer

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

PBM and PSAO

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

Pharmacy and PBM

The pharmacy negotiates with the PBM to determine a reimbursement rate for the drugs they dispense.[43] Pharmacies typically negotiate as a chain in the case of chain pharmacies or through a PSAO. Like the PBM/PSAO relationship, negotiations are based on AWP less a percentage and apply to all drugs.[44] In addition, PBMs negotiate a dispensing fee with the pharmacies. Actual Acquisition Cost (AAC) is the final price a pharmacy pays after all discounts have been subtracted.[45]

PBMs and Payors

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

PBMs are paid by the payor through an administrative fee or through a spread-pricing calculation, as specified in the contract. For payment on an administrative fee basis, the payor will pay the PBM an administrative fee, which can be in the form of a retainer, a per claim fee, or other similar arrangement. With spread pricing, also known as a risk mitigation pricing model, the payor will either not pay or pay a reduced administration fee and the PBM will retain certain risk related to the difference between the price paid by the customer and the price

paid to the pharmacy. This arrangement provides the payor with the assurance of a set price.[47] Payors have the ability to choose either option in its contract with the PBM. Payors report the amount paid to PBMs for their services (including retained rebates and concessions) as administrative cost on their annual Medical Loss Ratio filings. The amount of rebates the payors receive is deducted from their claims paid.[48]

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

III. ENFORCEMENT AND FEDERAL PREEMPTION ISSUES

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

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

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

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

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

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

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

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

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

(2) Requires PBMs to increase their reimbursement rate to cover a pharmacy's acquisition cost if that pharmacy is unable to acquire the drug at a lower price from a typical pharmaceutical wholesaler;

(3) Requires PBMs to timely update their Maximum Allowable Cost (MAC) lists when drug wholesale prices increase;

(4) Requires PBMs to provide an administrative appeals procedure for pharmacies to challenge MAC reimbursement that is below a pharmacy's acquisition cost;

(5) Requires PBMs to permit a pharmacy to "reverse and rebill" any reimbursement claim affected by the pharmacy's inability to acquire the drug at a price equal to or less than a PBM's MAC reimbursement price;

(6) Permits a pharmacy to decline to sell a drug to covered beneficiary if the relevant PBM will reimburse the pharmacy for less than the pharmacy's acquisition cost.

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

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

Another important aspect of the law at issue in *Rutledge* is that it is not applied exclusively to or even expressly

to ERISA plans. Rather, it applies to PBMs whether or not they manage ERISA plans. Under prior U.S. Supreme Court precedent, a law may be preempted by ERISA if it "acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation."[57]

Under the precedent of *Rutledge*, it seems clear that states have some leeway to regulate PBMs without concern for ERISA preemption. A law that distinguishes between ERISA and non-ERISA plans would be more likely to be preempted, particularly if it places a higher burden on ERISA plans than for other markets. A law that mandates particular pharmaceutical coverage, such as requiring reimbursement for a specific drug or diagnosis, would likewise be preempted as regulating plan design. In contrast, a law that applies to PBMs regardless of market segment that merely regulates cost, similar to the Arkansas statute, would likely be upheld. Lesser regulations, such as transparency programs, are also unlikely to be preempted under ERISA.

B. MEDICARE PART D

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

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

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

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

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

However, the federal district court held that the remaining provisions of the Oklahoma law challenged by the PCMA were not preempted by Medicare Part D.[62] This includes the law's requirements for preferred pharmacy networks, including the law's any willing provider provision, affiliated pharmacy prohibition, and network

provider restriction. The federal district court reasoned that while the CMS has promulgated a standard with respect to standard networks, there is no federal standard in place for preferred networks. Since all the relevant provisions of Oklahoma law apply only to preferred network status, the federal district court ruled there was no applicable standard in place that would preempt Oklahoma's law.

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

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

C. MEDICAID

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

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

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

In many states, the state Medicaid agency contracts with one or more managed care organizations (MCOs) to administer all or a part of the state's Medicaid program, including the management of the pharmacy program through the MCO's contracted PBM. Some states also contract with PBMs directly to administer the pharmacy benefit, either in conjunction with or separate from an MCO. In other cases, the state Medicaid agency manages the

Medicaid pharmacy program on its own.

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

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

IV. FUNCTIONAL ISSUES

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

A. FORMULARY DESIGN

PBMs implement formularies or lists of covered drugs[67]. PBMs' customers – payors, such as insurers or self-funded employer plans, may request open formularies, develop their own formularies, or purchase formularies from PBMs. Even closed formularies typically require coverage for at least one drug per therapeutic class.

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

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

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

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

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

B. REBATES

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

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

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

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

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

Approaches to curb the negative effects of rebates include:

- Rebate retention prohibitions: As part of their PBM laws, some states have enacted a provision stating

that a PBM must pass through 100 percent of a pharmaceutical manufacturer rebate to a plan sponsor.[78]

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

C. PRICING AND CONTRACTING PRACTICES

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

- Gag clauses: The term “gag clause” refers to a stipulation in a pharmacy benefit contract that prohibits a pharmacy or pharmacist from informing consumers of an alternative option when purchasing a drug. For instance, a gag clause may prohibit a pharmacist from telling a consumer about a generic version of a prescription drug or if a prescription drug can be purchased at a lower price out-of-pocket rather than through their insurance plan.[82]
- Mandatory arbitration clause: Most PBMs require that disputes be submitted to binding arbitration by including a mandatory arbitration provision in their pharmacy contracts. Some believe mandatory arbitration limits legal recourse for individual pharmacies and results in pharmacies foregoing potentially successful audit challenges.[83]
- Copay clawbacks: A copay clawback is the PBM practice of taking back from a pharmacy the difference between a patient’s copay and the actual cost of the medication when the patient’s copay is larger than the cost of the drug.[84]
- MAC transparency: A maximum allowable cost (MAC) list is a list that includes the maximum amount that a plan will pay for certain drugs.[85] MAC lists are often generated by the PBM. There is no standardization in the industry as to the criteria for the inclusion of drugs on MAC lists or for the methodology as to how the maximum price is determined, changed or updated. PBMs may sometimes use multiple MAC lists and pocketing the spread between the two. For example, PBMs might use a very

low MAC list to reimburse pharmacies but a higher list when charging plan sponsors.[86]

- Rebates: Rebates may provide incentive for a PBM to eliminate a less expensive, comparable medication from a formulary. Pharmaceutical manufacturers claim that these rebates are meant to be shared with plan sponsors or passed on to consumers in the form of lower drug prices. However, PBMs regularly keep a share of the rebates before passing the rest through to the plan sponsor.[87]
- Spread pricing: Spread pricing is the practice of a PBM charging a plan sponsor a higher amount for a drug than they will reimburse the pharmacy and pocketing the difference. Pharmacy pricing is complex, and the process is not transparent. Plan sponsors are often unaware of the difference between the amount they are billed and the pharmacy reimbursement.[88]
- Pharmacy audit: PBMs routinely audit pharmacies to validate data entry, ensure compliance with regulatory and contractual requirements, and to help identify and mitigate fraud, waste, and abuse of a prescription drug benefit. However, many pharmacists have stated that the audits are unfair and may result in stiff penalties and fees.
- Retroactive fees: PBMs engage in retroactive claim reviews, meaning they review a claim after it has been adjudicated. A retroactive claim review may result in a denial of a claim or a reduction in reimbursement after payment for the claim has been authorized.

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

D. VERTICAL INTEGRATION AND CONSOLIDATION

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

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

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

Consolidation refers to the merger and acquisition of many smaller companies resulting in a few much larger companies. The benefit of consolidation is that a larger firm may be able to realize efficiencies of scale and pass the resulting cost savings to consumers. The downside of consolidation is that costs tend to rise when there are fewer existing firms around to compete on prices and the few remaining firms price their products to maximize profit.[93] Along with vertical integration, consolidation in the pharmacy benefit supply chain has led to current

market conditions, which feature the three largest PBMs covering 79 percent of prescription drug claims.[94] Further, independent pharmacies are put at a competitive disadvantage compared to PBM-affiliated pharmacies when it comes to contracting.

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

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

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

E. PHARMACY NETWORK ADEQUACY

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

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

Some states specify that mail order pharmacies cannot be used to determine compliance with pharmacy network adequacy standards, while others specify that a network must have a mix of both retail and mail order pharmacies. Standards can be established by time and distance standards relative to the state as a whole, or to counties, or zip codes. In determining whether a PBM complies with access requirements, states review and consider the relative availability of physical pharmacies in a geographic service area.[99] Common pharmacy

network adequacy requirements include:

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

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

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

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

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

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

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

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

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

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

1. Health insurers

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

2. Wholesalers

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

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

- Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
- Any felony convictions of the applicant under federal, state, or local laws;
- The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
- The furnishing by the applicant of false or fraudulent material in any application made in connection with pharmaceutical manufacturing or distribution;
- Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
- Compliance with licensing requirements under previously granted licenses, if any;
- Compliance with requirements to maintain and/or make available to the state licensing authority or to federal, state, or local law enforcement officials those records required under this section; and
- Any other factors or qualifications the state licensing authority considers relevant to and consistent with the public health and safety.

3. Manufacturers

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

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

4. Pharmacies

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

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

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

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

5. Pharmaceutical sales representatives (PSRs)

In comparison to other entities in the pharmaceutical supply chain, few states require pharmaceutical sales

representatives (PSRs) to be licensed. PSRs have a large potential impact on the use and overuse of pharmaceutical drugs based on their interactions with prescribing health care providers.

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

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

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

V. STATE LAWS IMPACTING THE DRUG SUPPLY CHAIN

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

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

1) the aggregate amount of rebates the PBM received;

2) the aggregate amount distributed to the appropriate healthcare payor; and

3) the aggregate amount passed on the enrollees of each healthcare payor at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount.

States have also enacted legislation requiring transparency in pricing. The most common type of legislation in this area requires PBMs to make reimbursement lists, including MAC lists, or payment methodologies available to network pharmacies. About 20 states have enacted such legislation. Other types of transparency legislation include requiring PBMs to provide advance written notice of formulary changes and substitutions. In a recently

enacted Florida law, prescription drug manufacturers are required to notify the Florida Department of Business and Professional Regulation of manufacturer prescription drug price increases.

A. PBM REGULATION

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

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

1. Florida

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

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

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

1) information about the nature of the treatment and possible side effects;

2) alternative forms of treatment;

3) information about any financial incentives used by the benefits program; and

4) information that may reduce the cost of pharmacist services.

2. New Jersey

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

3. Kentucky

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

4. Kansas

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

5. Maine

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

In looking at the requirements on PBMs, Maine's law establishes a PBM licensure requirement. The law also includes provisions making the health insurance carrier responsible for monitoring all activities of the PBM if the carrier uses PBMs to manage their prescription drug benefits. The Maine law also stipulates that PBMs have a fiduciary duty to their insurance carriers when managing their prescription drug benefits and as such, carriers are empowered to hold PBMs accountable for their financial dealings. The Maine law requires health insurance carriers to use the prescription drug rebates that PBMs negotiate with pharmaceutical drug manufacturers to either lower health plan premiums or to reduce out-of-pocket costs for consumers when they purchase prescription drugs.

6. Oklahoma

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

B. DRUG PRICE TRANSPARENCY REGULATION

The push for implementation of laws that would require PBMs to disclose drug pricing, cost information regarding rebates, payments, and their fees collected from pharmaceutical manufacturers, insurers, and

pharmacies has begun in many states. [110]

1. Insurer Transparency

A number of states that require PBMs to disclose certain information about their costs also require health insurance providers to report similar prescription drug spending information to the state. Additionally, Section 204 of the transparency provisions of the Consolidated Appropriations Act of 2021 requires health plans to report information on premiums, plan medical costs, and prescription drug spending to the Secretaries of HHS, Labor, and Treasury, so that they may publish a report on prescription drug pricing trends and the contributions to health insurance premiums. The first filings under this law, known as the Prescription Drug Data Collection, or RxDC, were due in December 2022.[111]

2. Drug Manufacturer Transparency

As drug costs have now become the largest expenditure of the premium dollar[112], states have moved to actively address by legislating transparency of drug prices. Multiple states have passed legislation requiring drug manufacturers to provide advance notice when the price of drugs being offered on the market will increase over a specific percentage or cost and to provide the reasoning behind those increases. For new drugs over a certain price threshold being placed on the market, drug manufacturers must provide advance notice and include reasoning on the price methodology. At least one state has limited their transparency laws to manufacturers that treat specific diseases. There has been a slight moderation of drug price increases which has paralleled the passage of these laws; however, the costs associated with new drugs have increased exponentially.[113]

3. PSAO Transparency

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

C. OTHER RELEVANT PROPOSED OR IMPLEMENTED STATE LAW PROVISIONS

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

1. Affordability Review and Upper Payment Limits

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

2. Unsupported Price Increases

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

3. Anti-Price-Gouging

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

4. Importation

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

5. State Purchasing Pool Buy-in

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

6. Licensing Pharmaceutical Sales Representatives

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

VI. FEDERAL INTEREST AND POSSIBLE REGULATIONS

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

A. PHARMACY BENEFIT MANAGER TRANSPARENCY ACT OF 2022

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

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

> 1) the difference between the sum that each health plan paid the PBM for prescription medications and the sum that the PBM paid each pharmacy on behalf of the health plan;

2) the total of all fees, including those for the generic effective rate, compensation fees, or other price breaks offered to any pharmacy, and payments withheld from reimbursements to any pharmacy;

3) if the PBM shifted a prescription drug to a formulary tier with a higher cost, higher copayment, higher coinsurance, or higher deductible to a consumer or lower reimbursement to a pharmacy, an explanation for why the drug was moved to a different tier, including whether the move was requested by a prescription drug manufacturer or another entity; and

4) information regarding any variations in reimbursement rates or practices, remuneration fees or other price concessions, and clawbacks between a pharmacy owned, controlled, or affiliated with the PBM and all other pharmacies, for any PBM that owns, controls, or is affiliated with a pharmacy.

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

1) an anonymized summary of the annual reports that PBMs have submitted to the FTC;

2) the number of enforcement actions the FTC brought to enforce the act and the results of those actions;

3) the number of investigations and inquiries into potential violations of the act;

4) the number and nature of complaints the FTC received alleging violations of the act; and

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

The agency's report to Congress on PBM formulary design or placement practices would have been due within a year of the proposed law's passage. It would have included information on whether PBMs use formulary design or placement to boost gross revenue without also enhancing patient access or lowering patient costs, as well as whether such PBM activities violated section 5(a) of the Federal Trade Commission Act (45 U.S.C. 45(a)). Employees in the healthcare sector who report violations of the act or take part in administrative, judicial, or investigative processes to enforce its provisions would not be fired, demoted, suspended, reprimanded, or subject to any other type of punishment under the proposed legislation. The proposed legislation would have also forbidden companies from requiring employees to sign pre-dispute arbitration agreements in exchange for employment to make them give up their right to whistleblower protections under the act. The FTC and state attorneys general would have been given permission to carry out the proposed legislation's enforcement measures. Additionally, under the proposed law, offenders would have been exposed to civil penalties of up to $1 million in addition to the penalties provided under the Federal Trade Commission Act (15 U.S.C. 41 et seq.). The bill was adopted and forwarded to the full Senate by the Senate Committee on Commerce, Science, and Transportation on June 22, 2022. [114] The bill was never voted out of committee.

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

B. THE FEDERAL TRADE COMMISSION

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

VII. KEY JURISPRUDENCE

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

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

In *Rutledge v. PCMA*, the U.S. Supreme Court held that ERISA did not preempt an Arkansas law, Act 900, which required PBMs[116] to reimburse pharmacies at a price equal to or higher than what the pharmacy paid to buy the drug. Act 900 required PBMs to provide administrative appeal procedures for pharmacies to challenge reimbursement prices that are below the pharmacies' acquisition costs, and it also authorized pharmacies to decline to dispense drugs when a PBM would provide a below-cost reimbursement. Unlike the PBM laws in some states, Act 900 was not strictly structured as an insurance law. It applied to all transactions between PBMs and pharmacies, including transactions where the PBM was acting on behalf of a self-insured ERISA plan, so Arkansas could not rely on the saving clause as its defense against an ERISA preemption challenge.

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

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

particular benefit to any particular beneficiary in any particular way," [125] and determined that like the law at issue in *Travelers*, "Act 900 is merely a form of cost regulation."[126]

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

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

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

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

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

- disclose certain information to plan sponsors;
- provide relevant information to patients;
- mail or deliver drugs to patients as an ancillary service; and
- charge shipping and handling fees to patients who request that their prescriptions be mailed or delivered.[135]

The court also upheld provisions that "constitute, at most, regulation of a noncentral 'matter of plan administration' with de minimis economic effects."[136] The court held that "whatever modest non-uniformity in

plan administration [the sections] might cause does not warrant preemption."[137] Theses provision include:

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

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

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

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

1. Do the laws regulate the same subject matter as a federal Medicare Part D standard? If so, the state law is *expressly* preempted; or

2. Do the state laws otherwise frustrate the purpose of a federal Medicare Part D standard? If yes, then they are *impliedly* preempted.[138]

C. ***PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION v. MULREADY, 598_F.Supp.3d_1200 (2022)***

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

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

The Oklahoma laws at issue protect Oklahoma consumers' access to pharmacy providers through pharmacy network requirements, pharmacy reimbursement standards and prohibitions, and contract approval requirements. Relying on *Rutledge*, the district court concluded that all PCMA's ERISA preemption claims fail as a matter of law. The district court holds that "[the provisions] do not have a 'connection with' an ERISA plan" and that "[w]hile these provisions may alter the incentives and limit some of the options that an ERISA plan can use, none of the provisions forces ERISA plans to make any specific choices." Finally, regarding the Promotional Materials provision, the district court holds that the law "does not regulate benefit design disclosures to

beneficiaries but regulates how PBMs can advertise its providers" and that it "does not relate to a central matter of plan administration nor undermine the uniform regulation of ERISA plans."

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

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

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

APPENDIX I. LIST OF SUBGROUP MEETINGS AND TOPICS

Meeting #	Date	Presenter/Topic
Meeting #1	August 15, 2019	• Jane Horvath (Horvath Health Policy and Research Faculty, Georgetown University) presentation on "Basics of the Pharmaceutical Market & PBMs." • Leanne Gassaway (America's Health Insurance Plans—AHIP) presentation on "Pharmacy Benefit Managers Overview & Background."
Meeting #2	August 22, 2019	• Dr. Neeraj Sood (Sol Price School of Public Policy, University of Southern California) presentation on "PBM Economics." • Saiza Elayda (Pharmaceutical Research and Manufacturers of America—PhRMA) presentation on the pharmaceutical supply chain and how the pharmaceutical distribution and payment system shapes the prices of brand name medicines.
Meeting #3	August 29, 2019	• April Alexander (Pharmaceutical Care Management Association—PCMA) and J.P. Wieske (Horizon Government Affairs) presentation on the history, role, and services PBMs provide in managing prescription drug benefits. • Anne Cassity (National Community Pharmacists Association—NCPA) and Matthew Magner (NCPA) presentation on the community pharmacy industry's perspective regarding PBMs and managing prescription drug benefits. • Claire McAndrew (Families USA) discussed the effect of PBMs and prescription drug costs on consumers. • Amy Killelea (National Alliance of State and Territorial AIDS Directors—NASTAD) discussed PBMs and their impact on consumer access and affordability of prescription drugs.

Meeting #4	October 3, 2019	• Kentucky discussed its PBM licensing process. • Arkansas discussed its PBM licensing law and other provisions related to PBM business practices.
Meeting #	**Date**	**Presenter/Topic**
		• Montana discussed the history, purpose, and provisions of S.B. 71 to address issues related to PBMs, which passed in the legislature but was ultimately vetoed by the Governor. • New Mexico discussed its PBM law focusing on its reimbursement provisions. • Oregon discussed its PBM law, including its PBM registration requirements, and Oregon's Prescription Drug Price Transparency program.
Meeting #5	December 11, 2021	• North Dakota discussion on the *Pharmaceutical Care Management Association (PCMA) v. Wehbi* ruling. • Connecticut discussion on its PBM law and white paper. • Virginia discussion on its PBM law. • Oklahoma discussion on its PBM law and the *PCMA v. Mulready* case. • Wisconsin discussion on the work of the Governor's Task Force on Reducing Prescription Drug Prices and its PBM law.
Meeting #6	March 16, 2022	• Montana discussion on its PBM law. • Employee Retirement Income Security Act (ERISA) (B) Working Group update on the U.S. Supreme Court's ruling in *Rutledge v. PCMA* and the *ERISA Handbook* analysis and case summary.

Meeting #7	April 4, 2022	• Oklahoma update on its PBM law. • Oregon discussion on its PBM law and transparency in prescription drug pricing and Oregon Prescription Drug Affordability Board (PDAB) initiatives. • Discussion from a consumer perspective on the Subgroup's charge to develop a white paper on PBMs and their business practices.
Meeting #8	April 25, 2022	• Dr. Neeraj Sood and Dr. Karen Van Nuys, University of Southern California (USC) Price School on Public Policy-
Meeting #	**Date**	**Presenter/Topic**
		presentation on "How Well Are PBM Markets Functioning?"
Meeting #9	June 15, 2022	• National Community Pharmacists Association (NCPA) presentation on the Subgroup's charge to develop a white paper on PBMs and their business practices from an independent pharmacist perspective.
Meeting #10	July 29, 2022	• Healthcare Distribution Alliance (HDA) presentation on the Subgroup's charge to develop a white paper on PBMs and their business practices from a pharmaceutical distributor perspective. • Presentation on the Subgroup's charge to develop a white paper on PBMs and their business practices from a pharmacy services administrative organization (PSAO) perspective.
Meeting #11	August 9, 2022	• Presentation from the Pharmaceutical Care Management Association (PCMA) discussing the value of PBMs and the services PBMs provide with respect to pharmacy benefit management. • Presentation from the Pharmaceutical Research and Manufacturers of America (PhRMA) on the lack of transparency in PBM practices. • Oregon Primary Care Association (OPCA) presentation on the federal 340B prescription drug program.

Meeting #12	October 24, 2022	• America's Health Insurance Plans (AHIP) presentation on the Subgroup's charge to develop a white paper on PBMs and their business practices from an insurer perspective. • BlueCross and BlueShield Association (BCBSA) presentation on the Subgroup's charge to develop a white paper on PBMs and their business practices from an insurer perspective. • Civica presentation on its work with the BCBSA and several Blues plans to bring lower-priced generics to market.

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

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/National Meetings/2023 Fall Meeting/PBM White Paper Draft Adopted RFTF 9-29-23 Final Version.docx

Draft: 10/11/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
October 2, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Oct. 2, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Chris Struk (FL); Frank Opelka (LA); Camille Anderson-Weddle (MO); Eric Dunning (NE); Shari Miles (SC); Tanji J. Northrup and Heidi Clausen (UT); Anna Van Fleet and Mary Block (VT); and Lichiou Lee (WA).

1. Continued Discussion of Section 9G of Model #171

The Subgroup continued its discussion of the proposed revisions to Section 9G—Limited Benefit Health Coverage (Outline of Coverage) of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171). Jolie H. Matthews (NAIC) said that during its last meeting on Sept. 18, the Subgroup completed its review of Section 9G. She said that during its review, the Subgroup discussed what type of coverage would be considered limited benefit coverage under Model #171. However, the Subgroup did not reach any specific conclusion, but it agreed that this issue would need further discussion after the Subgroup completes its review of the comments received on Model #171. The Subgroup confirmed its decision.

2. Discussed Section 9H of Model #171

The Subgroup next discussed the NAIC consumer representatives' suggested language for the outline of coverage for short-term, limited-duration (STLD) health insurance coverage in Section 9H. Matthews reminded the Subgroup that for the consumer disclosure application language in Section 9A, the Subgroup agreed to use the consumer disclosure language in the federal proposed regulation for STLD plans, which is not reflected in the NAIC consumer representatives' suggested language. The Subgroup agreed to revise Section 9H(1) to reflect the Subgroup's previous discussion for the other outline of coverage provisions. In addition, the Subgroup asked NAIC staff to review and revise Section 9H(2) for consistency with the language in Section 9A for this product. In discussing Section 9H(3), the Subgroup agreed to not include the language "that would be covered by an Affordable Care Act qualified plan" because of the potential complexity for insurers to comply with this requirement due to the different and varied options for the type of benefits that can be included in STLD coverage in comparison to a federal Affordable Care Act (ACA) qualified plan. Consistent with its previous decisions, the Subgroup did not accept the NAIC consumer representatives' suggestion to add a provision requiring insurers to include a specific coverage example for an STLD health insurance coverage plan like those in the Summary of Benefits and Coverage.

3. Discussed Section 9I and J of Model #171

The Subgroup next discussed the NAIC consumer representatives' suggested language for the outline of coverage for limited-scope dental coverage in Section 9I and limited-scope vision in Section 9J. The Subgroup accepted the NAIC consumer representatives' suggested revisions for these provisions.

4. Discussed Section 10 of Model #171

The Subgroup next discussed the comments received on Section 10—Requirements for Replacement of Individual Supplementary and Short-Term Health Insurance Coverage. No comments were received on Section 10A.

The Subgroup discussed the NAIC consumer representatives' suggested revision for Section 10B to delete the provision excluding direct response insurers from the provision's requirements. The Subgroup discussed the implications of deleting this language and why the exclusion exists. After discussion, the Subgroup decided not to accept the NAIC consumer representatives' suggested revision because the Subgroup wants to retain the current framework of having two replacement notices—one for insurers other than direct response insurers under Section 10C and one for direct response insurers under Section 10D. The Subgroup reached this decision because of the slightly different language in the notices reflecting the fact that for direct response insurers, no insurance agent or company representative is involved in the initial transaction related to the policy being replaced.

The Subgroup discussed the NAIC consumer representatives' suggested revisions to Section 10C. The Subgroup agreed to accept the suggested revisions with a few stylistic changes, such as changing "may" to "might." The Subgroup also discussed the NAIC consumer representatives' suggested revisions to Section 10D, which are the same as those suggested for Section 10C. The Subgroup accepted the suggested revisions with the same stylistic changes as those agreed on for Section 10C.

Matthews said Section 10 is the last section for which the Subgroup requested comments from interested parties.

Jackson Williams (Dialysis Patient Citizens—DPC) reminded the Subgroup that he had submitted an article titled "Addressing Low-Value Insurance Products with Improved Consumer Information: The Case of Ancillary Health Products" during the Subgroup's public comment period for Sections 9 and 10. He said the information included in his article should be considered. The Subgroup discussed his request. After discussion, the Subgroup co-chairs said they would work with NAIC staff to determine the Subgroup's next steps regarding its work to revise Model #171.

Having no further business, the Accident and Sickness Insurance Minimum Standards (B) Subgroup adjourned.

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Draft: 10/5/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
September 18, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Sept. 18, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Stephen F. Flick (DC); Chris Struk (FL); Camille Anderson-Weddle (MO); Maggie Reinert (NE); Shari Miles (SC); Shelley Wiseman and Heidi Clausen (UT); Anna Van Fleet, Mary Block, and Jamie Gile (VT); and Ned Gaines (WA).

1. Continued Discussion of Section 9E of Model #171

Before continuing its discussion of the comments received on Section 9E—Accident-Only Coverage (Outline of Coverage) of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171), Jolie H. Matthews (NAIC) walked through a revised staff draft of proposed revisions to Section 9A—General Rules of Model #171 reflecting the Subgroup's discussions up to its last meeting on Aug. 21. She explained that based on the Subgroup's discussion during its Aug. 21 meeting, it seemed that in discussing the revisions to outline of coverage provisions in Section 9, the Subgroup is relying on revisions it has preliminarily approved for the consumer product statements in Section 9A. As such, she said she wants to walk through the Section 9A proposed revisions.

After completion of the review of the Section 9A proposed revisions, the Subgroup returned to its discussion of the NAIC consumer representatives' suggested revisions to Section 9E. After discussion, the Subgroup confirmed its decision to revise the language in Section 9E(2) for consistency with the language in Section 9A for this type of coverage.

2. Discussed Section 9F of Model #171

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9F—Specified Disease or Specified Accident Coverage (Outline of Coverage) of Model #171. After discussion, the Subgroup decided to delete Section 9F(1). The Subgroup agreed to accept the suggested revisions to Section 9F(2). The Subgroup also agreed to revise Section 9F(3) for consistency with the language in Section 9A for this type of coverage and include the reference to the *Buyer's Guide to Specified Disease Insurance* from Section 9F(1). Consistent with its previous discussions, the Subgroup did not accept the NAIC consumer representatives' suggestion to add a provision requiring insurers to include a specific coverage example like those in the Summary of Benefits and Coverage for a specified disease or specified accident coverage.

3. Discussed Section 9G of Model #171

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9G—Limited Benefit Health Coverage (Outline of Coverage) of Model #171. The Subgroup agreed to accept the suggested revisions for Section 9G(1). Consistent with its previous discussions, the Subgroup agreed to revise Section 9G(2) for consistency with the language in Section 9A for this type of coverage. Also, consistent with its previous discussions, the Subgroup did not accept the NAIC consumer representatives' suggestion to add a provision requiring insurers to include a specific coverage example like those in the Summary of Benefits and Coverage for limited benefit health coverage. The Subgroup also discussed what type of coverage would be considered limited benefit coverage under Model #171. The Subgroup did not reach any specific conclusion, but it agreed that this

issue would need further discussion after the Subgroup completes its review of the comments received on Model #171.

Having no further business, the Accident and Sickness Insurance Minimum Standards (B) Subgroup adjourned.

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Draft: 9/7/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup
Virtual Meeting
August 21, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Aug. 21, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Debra Judy (CO); Stephen F. Flick (DC); Chris Struk (FL); Robert Wake (ME); Camille Anderson-Weddle (MO); Martin Swanson and Maggie Reinert (NE); Shari Miles (SC); Shelley Wiseman and Heidi Clausen (UT); Anna Van Fleet, Mary Block, and Jamie Gile (VT); and Lichiou Lee (WA).

1. Continued Discussion of Section 9B of Model #171

The Subgroup continued its discussion of the suggested revisions to the product statements in Section 9B—Outline of Coverage Requirements of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171). The Subgroup returned to its discussion of the NAIC consumer representatives' suggested revisions to Section 9B(2). The Subgroup specifically revisited the suggested revisions to the consumer notice language. After discussion, the Subgroup confirmed its decision to accept the suggested revisions.

2. Discussed Section 9C of Model #171

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9C—Hospital Indemnity or Other Fixed Indemnity Coverage (Outline of Coverage) of Model #171. After discussion, the Subgroup agreed to accept the suggested revisions with some changes. The Subgroup decided to delete the sentence in Section 9C(1): "Only the actual [policy] [certificate] provisions control." The Subgroup decided that the sentence is unnecessary and could be confusing to consumers.

The Subgroup next discussed Section 9C(2). The Subgroup discussed whether the language in the last sentence explaining potential policy benefit limitations for this type of coverage is confusing. After discussion, the Subgroup decided to revise the sentence to: "The fixed amount stated in your [policy] [certificate] may be less than what you are charged." The Subgroup also requested that NAIC staff review the language the Subgroup agreed to include in the application section for consistency.

The Subgroup next discussed Section 9C(3). No comments were received on this provision, but the Subgroup discussed whether the language should be revised for clarity to ensure that insurers understand what this provision requires. After discussion, the Subgroup decided to revise Section 9C(3) to state when benefits are payable/triggered, how long the benefits will be paid (duration), and the dollar amount of the benefits. The Subgroup also discussed whether the word "daily" should be deleted because the use of this word could be misleading and inaccurate for this type of coverage. The Subgroup decided to delete "daily." The Subgroup also requested that NAIC staff search the document to determine whether "daily" is used in other provisions of Model #171.

The Subgroup discussed and agreed not to accept the NAIC consumer representatives' suggestion to add a sentence to Section 9C requiring insurers to include a specific coverage example like those in the Summary of Benefits and Coverage because of the complexity of creating such a specific coverage example, given the nature of the product and the possibility that the coverage example could be misleading to consumers.

3. Discussed Section 9D of Model #171

Next, the Subgroup discussed the NAIC consumer representatives' suggested revisions to Section 9D—Disability Income Protection Coverage (Outline of Coverage) of Model #171. As discussed and decided for Section 9C(1), the Subgroup agreed to delete the sentence in Section 9D(1): "Only the actual [policy] [certificate] provisions control." The Subgroup next discussed the suggested revisions for Section 9D(2). Like its discussion for Section 9C(2), the Subgroup asked NAIC staff to align the language in this provision with the language in the application provisions. The Subgroup also asked NAIC staff to remove the references to "basic hospital, basic medical-surgical, or major medical expenses." After discussion of the last sentence in Section 9D(2), the Subgroup agreed to delete the word "may" and replace it with "might."

Like its decision for Section 9C, the Subgroup did not accept the NAIC consumer representatives' suggestion to add a provision requiring insurers to include a specific coverage example like those in the Summary of Benefits and Coverage for disability income protection coverage.

Having no further business, the Accident and Sickness Insurance Minimum Standards (B) Subgroup adjourned.

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Draft: 8/24/23

Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group
Seattle, Washington
August 14, 2023

The MHPAEA (B) Working Group of the Regulatory Framework (B) Task Force met in Seattle, WA, August 14, 2023. The following Working Group members participated: Erica Weyhenmeyer, Chair (IL); Jane Beyer, Vice Chair (WA); Jimmy Harris (AR); Erin Klug (AZ); Kate Harris (CO); Kurt Swan (CT); Howard Liebers (DC); Andria Seip (IA); Julie Holmes (KS); Mary Kwei (MD); Paul Hanson (MN); Carrie Couch (MO); Ted Hamby (NC); Chrystal Bartuska (ND); DJ Bettencourt (NH); Ralph Boeckman (NJ); Paige Duhamel (NM); Laura Miller (OH); Ashley Scott (OK); Lindsi Swartz (PA); Glynda Daniels (SC); Jill Kruger (SD); Rachel Bowden and Matthew Tarpley (TX); Tanji J. Northrup (UT); Julie Blauvelt and Julie Fairbanks (VA); Barbara Belling (WI); Erin K. Hunter (WV), and Tana Howard (WY). Also participating was Kevin Beagan (MA).

1. Heard Presentations on Autism Treatment Standards

Lorrie Unumb (Council of Autism Service Providers—CASP) said more than 330 service providers are members of CASP, whose mission is to advocate for best practices in autism services. She highlighted a resource from CASP, *Applied Behavior Analysis: Treatment of Autism Spectrum Disorder*. She said every practitioner who utilizes applied behavior analysis should abide by the standards outlined in document and payers should incorporate it into their medical necessity standards. She said the CASP offers training on the guidelines to payers and others.

Daniel Unumb (Autism Legal Resource Center) said applied behavior analysis (ABA) is the most proven and effective evidence-based treatment for conditions related to autism. He said ABA is not a typical treatment regime because of its tiered service delivery model, with a certified or licensed behavior analyst supervising behavior technicians, sometimes with a middle tier of assist behavior analysts.

Daniel Unumb said exclusions for ABA are not as common for fully insured plans as for self-insured plans. For individual market plans, he said cover is often mandated by a state's essential health benefits. But where that is not the case, there is case law stating that ABA exclusions violate MHPAEA. He cited *Doe v. United Behavioral Health* (UBH).

Daniel Unumb said quantitative treatment limitations are rare for fully insured plans. He said self-insured plans may include limits because a state mandate includes limiting language. They may no longer be applied but could have a chilling effect on providers. He said some insurers impose caps on certain assessment codes, but this is not consistent with generally accepted professional standards and often violates the "substantially all" test under the MHPAEA. He said one insurer's medical necessity criteria includes a cap on hours, which is inconsistent with the CASP guidelines. He said caps on speech, occupational, or physical therapy may also violate the MHPAEA even if a similar cap is applied for medical conditions because of the substantially all test.

Daniel Unumb described several nonquantitative treatment limits (NQTLs) of concern. He said some plans limit who may diagnose autism or what assessment tools may be used. He said prior authorization or the need for a treatment plan may be applied more stringently than they are for medical conditions. He said requirements for progress and the need for each treatment step to have a clear evidence base are not generally present for medical conditions. He said a need for parent participation is often inappropriate and is not applied on the medical side. He said some plans require that a certain percentage of treatment goals be met, which is not something applied to medical conditions.

Daniel Unumb said the CASP and the Autism Legal Resource Center host an Autism Law Summit that brings together payers, providers, families, regulators, and other stakeholders for informal, educational discussions.

Seip asked about *Doe v. UBH*. Daniel Unumb said the case concluded that an exclusion of ABA violated two prongs of the MHPAEA, that the exclusion was applied only to mental health and eliminated the core treatment for autism.

Beyer asked about state legislation to require medical necessity standards to recognize generally accepted standards of care and whether states with these laws have better coverage of ABA. She also said some carriers limit ABA only to autism spectrum disorders and not allow it for other intellectual developmental disorders (IDDs). Lorrie Unumb said California has legislation on medical necessity and regulations in that state specifically cite the CASP guidelines. She said the state is seeing progress. Daniel Unumb said limits on ABA for IDDs other than autism would violate anti-discrimination law in Section 1557 of the federal Affordable Care Act (ACA) if it is a disabling condition and could violate the MHPAEA if the condition is a mental health condition.

Couch asked about denials of services during transition to adulthood. Daniel Unumb said that is an area of discrimination even though many studies show ABA is effective for adults.

Duhamel said age limits may be discriminatory under essential health benefits (EHBs) requirements and Section 1557 of the ACA. She said New Mexico's law requires insurers to cover ABA regardless of whether they are ordered or provided in school. Daniel Unumb said California law also requires coverage regardless of whether other entities have coverage obligations.

Having no further business, the MHPAEA (B) Working Group adjourned into regulator-to-regulator session, pursuant to paragraph 8 (consideration of strategic planning issues) of the NAIC Policy Statement on Open Meetings, to continue work on its goals.

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