

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

Regulatory Framework (B) Task Force Aug. 13, 2023, Minutes

Accident and Sickness Insurance Minimum Standards (B) Subgroup Aug. 7, 2023, Minutes (Attachment One)

Accident and Sickness Insurance Minimum Standards (B) Subgroup July 24, 2023, Minutes (Attachment Two)

Accident and Sickness Insurance Minimum Standards (B) Subgroup July 10, 2023, Minutes (Attachment Three)

Accident and Sickness Insurance Minimum Standards (B) Subgroup June 29, 2023, Minutes (Attachment Four)

Accident and Sickness Insurance Minimum Standards (B) Subgroup May 15, 2023, Minutes (Attachment Five)

Accident and Sickness Insurance Minimum Standards (B) Subgroup April 24, 2023, Minutes (Attachment Six)

Accident and Sickness Insurance Minimum Standards (B) Subgroup April 17, 2023, Minutes (Attachment Seven)

Accident and Sickness Insurance Minimum Standards (B) Subgroup March 27, 2023, Minutes (Attachment Eight)

Employee Retirement Income Security Act (ERISA) Working Group, Aug. 13, 2023, Minutes (Attachment Nine)

Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group March 23, 2023, Minutes (Attachment Ten)

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup July 27, 2023, Minutes (Attachment Eleven)

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup April 17, 2023, Minutes (Attachment Eleven-A)

Pharmacy Benefit Manager White Paper Draft, April 16, 2023 (Attachment Eleven-A1)

Pharmacy Benefit Manager White Paper Adopted by the Subgroup (Attachment Eleven-B)

## Draft Pending Adoption

Draft: 8/21/23

Regulatory Framework (B) Task Force  
Seattle, Washington  
August 13, 2023

The Regulatory Framework (B) Task Force met in Seattle, WA, Aug. 13, 2023. The following Task Force members participated: Sharon P. Clark, Chair (KY); Glen Mulready, Vice Chair, represented by Andy Schallhorn (OK); Michael Conway represented by Debra Judy and Jason Lapham (CO); Andrew N. Mais represented by Jared Kosky (CT); Karima M. Woods represented by Yohannes Negash (DC); Doug Ommen represented by Andria Seip (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 (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, Michael Muldoon, and Margaret Garrison (NE); D.J. Bettencourt (NH); Justin Zimmerman (NJ); Judith L. French represented by Laura Miller (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 Tanji J. Northrup (UT); Scott A. White represented by Julie Blauvelt and Jackie Myers (VA); Mike Kreidler represented by Ned Gaines (WA); Nathan Houdek represented by Jennifer Stegall and Rebecca Rebholz (WI); and Allan L. McVey represented by Erin K. Hunter and Joylynn Fix (WV). Also participating were: Erica Weyhenmeyer (IL); and Jane Beyer (WA).

### 1. Adopted its Spring National Meeting Minutes

Keen made a motion, seconded by Seip, to adopt the Task Force's March 22 minutes (*see NAIC Proceedings – Spring 2023, Regulatory Framework (B) Task Force*). The motion passed unanimously.

### 2. Adopted its Subgroup and Working Group Reports

Before asking for a motion to adopt the Task Force's subgroup and working group reports, Commissioner Clark explained that in adopting the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup's report and minutes, the Task Force is not adopting the pharmacy benefit manager (PBM) white paper, which the Subgroup adopted during its July 27 meeting. The Task Force plans to meet following the Summer National Meeting to discuss its next steps for the white paper.

Gaines made a motion, seconded by Seip, to adopt the following reports: 1) the Accident and Sickness Insurance Minimum Standards (B) Subgroup, including its Aug. 7 (Attachment One), July 24 (Attachment Two), July 10 (Attachment Three), June 29 (Attachment Four), May 15 (Attachment Five), April 24 (Attachment Six), April 17 (Attachment Seven), and March 27 (Attachment Eight) minutes; 2) the Employee Retirement Income Security Act (ERISA) (B) Working Group, including its Aug. 13 (Attachment Nine) minutes; 3) the Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group, including its March 23 (Attachment Ten) minutes; and 4) the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup, including its July 27 (Attachment Eleven) minutes. The motion passed unanimously.

### 3. Heard a Panel Discussion on Prior Authorization

Lucy Culp (Leukemia & Lymphoma Society—LLS), Emily Carroll (American Medical Association—AMA) and Beyer discussed prior authorization. Culp discussed patient and consumer experiences with prior authorization and how the prior authorization process can create a barrier to care. She highlighted a 2023 Kaiser Family Foundation (KFF) survey of consumer experiences with health insurance, which showed that six in 10 insured adults reported problems with their health insurance in the past year. Culp also discussed the NAIC consumer representatives'

## Draft Pending Adoption

work group on prior authorizations, appeals, and denials, including its areas of focus. She also identified opportunities and key policy reforms the states can take to address patient and consumer needs to: 1) improve access to evidence-based care; 2) ensure continuity of care; 3) promote transparency and fairness; 4) improve timely access to care; and 5) reduce administrative barriers.

Carroll discussed how prior authorization can harm patients, be burdensome to physician practices, and waste overall health care resources. She also discussed opportunities and solutions for state insurance regulators to reform the prior authorization process and provided examples of how certain states, including Washington, are acting on those solutions to reform the prior authorization process. Carroll also discussed federal actions complementing state actions to reform the prior authorization process.

Beyer discussed prior authorization in Washington, including the prior authorization rules adopted in 2017 and legislation enacted in 2023. She explained that Washington's prior authorization requirements apply to all health services, including prescription drugs. Washington requires carriers to use evidence-based clinical review criteria that are updated at least annually and can accommodate evidence regarding appropriate care for people of color and gender differences. Beyer said Washington's prior authorization requirements also include timeliness standards. She noted that Washington considers a prior authorization denial to be an adverse benefit determination that the health care provider or consumer can appeal.

Beyer discussed Washington's requirements for carriers to have a secure online process for a health care provider or facility to use to: 1) determine whether prior authorization is required; 2) find applicable clinical criteria and required documentation; and 3) submit prior authorization request with any needed documentation. She said that Washington has added new requirements for the online process to allow a health care provider or facility to submit and obtain a response to prior authorization requests using an application programming interface (API) beginning in 2025 for health care services (or 2026 if the federal interoperability proposed rule is not finalized by Sept. 13, 2023) and beginning in 2027 for prescription drugs.

Beyer discussed Washington's findings on how carriers use prior authorization based on the data it receives in accordance with its data reporting law, which was effective in 2020. She said that based on the data received, the services most frequently subject to prior authorization are: 1) physical therapy; 2) colonoscopy/endoscopy; 3) continuous positive airway pressure (CPAP) device; 4) imaging, including computed tomography (CT) and magnetic resonance imaging (MRI); and 5) room and board for both medical and behavioral health. She discussed the findings from a review of 2021 data for services with an approval rate of 98% or more and at least 50 requests processed. She highlighted the average standard response times for prior authorization requests from this review for current procedural terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) codes with the most prior authorization requests for medical-surgical versus mental health/substance use disorder (MH/SUD). She said the data showed that carriers generally take longer to approve or deny prior authorization requests for mental health/substance use disorder services than for medical-surgical services. She said the states can use this type of data as an indicator, operationally, of what more may be needed for comparability between the provision of MH/SUD services and medical-surgical services.

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

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/National Meetings/2023 Summer Meeting/RFTF 8-13-23  
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Draft: 8/9/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup  
Virtual Meeting  
August 7, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met Aug. 7, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Tara Smith (CO); Chris Struk (FL); Robert Wake (ME); Maggie Reinert (NE); Shari Miles (SC); Heidi Clausen (UT); Mary Block and Jamie Gile (VT); and Lichiou Lee (WA).

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

The Subgroup continued its discussion of the suggested revisions to the product statements in Section 9A—Required Disclosure Provisions 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 9A(12). The suggested revisions recommend deleting the first sentence, which states: "Except for riders or endorsements by which the insurer effectuates a request made in writing by the policyholder or exercises a specifically reserved right under the policy, all riders or endorsements added to a policy after date of issue or at reinstatement or renewal that reduce or eliminate benefits or coverage in the policy shall require signed acceptance by the policyholder." After discussion, the Subgroup decided to delete the clause beginning with "[e]xcept" and retain the remainder of the sentence. The Subgroup also accepted the non-substantive suggested revisions.

The Subgroup next returned to its discussion of the NAIC consumer representatives' suggested revisions to Section 9A(19) concerning the outline of coverages delivered to consumers for certain products regulated under Model #171 to include language on or attached to the first page of the outline of coverage stating that these products are not Medicare supplement policies. The Subgroup accepted the suggested revisions during its July 24 meeting. In continuing its discussion of this provision, the Subgroup discussed whether additional revisions were needed for consistency with the consumer disclosure language in Appendix C of the *Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act* (#651). The Subgroup also discussed whether there should be a distinction between the consumer disclosure notices received under Section 9A(12) for individuals eligible for Medicare by reason of age and individuals eligible for Medicare by reasons other than age. After discussion, the Subgroup decided to add a drafting note alerting the states that permit individuals under the age of 65 with Medicare coverage to purchase a Medicare Supplement (Medigap) policy to review how they should provide the notices required under Section 9A(12) to these individuals.

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9A(20). The NAIC consumer representatives suggest deleting the exception for direct response insurers to provide a specified disease insurance buyer's guide to any person applying for a specified disease insurance policy. For consistency with its other suggested revision to this provision, the NAIC consumer representatives also suggest deleting the language requiring direct response insurers to provide the buyer's guide upon request, but not later than the time the policy or certificate is delivered. The Subgroup accepted the suggested revisions.

The Subgroup next moved to the NAIC consumer representatives' suggested revisions for Section 9A(21) to Section 9A(29). The Subgroup agreed that the suggested revisions for these provisions, which concern consumer disclosure language for the products in Model #171 that must be on the first page of a policy or certificate, is already addressed with the previous revisions the Subgroup discussed and accepted for Section 9A(2).

2. Discussed Section 9B of Model #171

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9B establishing an outline of coverage requirements. Beginning with Section 9B(1), the Subgroup discussed the NAIC consumer representatives' clarifying revisions to this provision. The Subgroup accepted the suggested revisions.

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9B(2). Section 9B(2) establishes requirements for providing a substitute outline of coverage when there is a change from when the outline of coverage was provided at the time of application or enrollment. The NAIC consumer representatives' suggested revisions would require insurers to provide a substitute outline of coverage to applicants and enrollees at the time of renewal. After discussion, the Subgroup did not accept the suggested revisions because it felt the suggested revisions would expand the scope and intent of the current language. The Subgroup accepted the NAIC consumer representatives' suggested revisions for the drafting note. However, the Subgroup decided to return to the drafting note during its next meeting on Aug. 21 to consider some additional clarifying language. The Subgroup discussed the NAIC consumer representatives' suggestion to add a clarifying sentence to Section 9B(3) to specifically state that a policy or certificate cannot be sold or renewed until the commissioner approves the alternate outline of coverage. No comments were received on Section 9B(4).

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

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Draft: 8/3/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup  
Virtual Meeting  
July 24, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met July 24, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Howard Liebers (DC); Chris Struk (FL); Robert Wake (ME); Camille Anderson-Weddle (MO); Martin Swanson (NE); Heidi Clausen (UT); Anna Van Fleet and Jamie Gile (VT); and Lichiou Lee (WA).

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

The Subgroup continued its discussion of the suggested revisions to the product statements in Section 9A—Required Disclosure Provisions of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171). Jolie H. Matthews (NAIC) said that prior to the meeting, she distributed a document reflecting the Subgroup’s discussions on Section 9A to date. She said the document also reflects Bowden’s suggested revisions to streamline language related to the readability and accessibility requirements for the product statement disclosures. Bowden pointed out a proposed new sentence in Section 9A(2) stating: “The disclosures required by this section may be modified only as approved by the commissioner and as needed to approve the accuracy and clarity of the disclosure.” The Subgroup discussed the document and confirmed that it accurately reflected the Subgroup’s discussions to date. The Subgroup also accepted Bowden’s suggested streamlining revisions and her suggested new sentence in Section 9A(2). The Subgroup also discussed whether the proposed federal rule on short-term, limited-duration (STLD) plan and hospital indemnity and other fixed indemnity plan consumer disclosures would affect the Subgroup’s proposed language for the product disclosures in Section 9A. After discussion, because the federal rule is not final and because of other issues related to the proposed federal rule, the Subgroup decided to add a drafting note to Section 9A(2) alerting states that they may have to review the language in Section 9A and consider any changes, as appropriate, for consistency with state and/or federal rules applicable to such coverage that may have changed after the Model #171 revisions are adopted.

The Subgroup discussed the NAIC consumer representatives’ suggested product statement disclosure language for limited-scope dental coverage and limited-scope vision coverage. The Subgroup accepted the suggested language. The Subgroup also asked NAIC staff to review the language for consistency with the other product statement disclosures.

The Subgroup discussed the NAIC consumer representatives’ suggested product statement disclosure language for STLD health insurance coverage. The Subgroup discussed whether it should consider the disclosure language in the proposed federal rules instead of the NAIC consumer representatives’ suggested language. After discussion, the Subgroup decided to use the proposed federal rule’s disclosure language.

The Subgroup next discussed the NAIC consumer representatives’ suggested revisions to Section 9A(12). The suggested revisions recommend deleting the first sentence, which states: “Except for riders or endorsements by which the insurer effectuates a request made in writing by the policyholder or exercises a specifically reserved right under the policy, all riders or endorsements added to a policy after date of issue or at reinstatement or renewal that reduce or eliminate benefits or coverage in the policy shall require signed acceptance by the policyholder.” The Subgroup discussed whether this sentence should be deleted and why the NAIC consumer representatives suggest its deletion. Anna Howard (American Cancer Society Cancer Action Network—ACS CAN) suggested the NAIC consumer representatives recommend deleting the language for consistency with other

proposed revisions. The Subgroup deferred deciding whether to accept the suggested revisions until it could review any other language in Model #171 on riders that could affect its decision.

The Subgroup discussed and agreed to accept the NAIC consumer representatives' suggested revisions to Section 9A(13) to add the language "and the combined total premium clearly identified as such." The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9A(16) adding language requiring certain notices to be prominently printed in a specified manner. The Subgroup discussed revising this language for consistency with other similar language used in Section 9A or reorganizing and placing this provision in Section 9A's general language. The Subgroup did not reach a decision. Similarly, the Subgroup discussed whether it should also reorganize and place Section 9A(17) in Section 9A's general language. It did not reach a decision. The Subgroup next discussed the NAIC consumer representatives' clarifying suggested revisions to Section 9A(18). The Subgroup accepted the suggested revisions. The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9A(19) concerning the outline of coverages delivered to consumers for certain products regulated under Model #171 to include language on or attached to the first page of the outline of coverage stating that these products are not Medicare supplement policies. The Subgroup accepted the suggested revisions. It also requested NAIC staff to revise the suggested language for consistency with similar language in Section 9A.

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9A(20). The NAIC consumer representatives suggest deleting the exception for direct response insurers to provide a specified disease insurance buyer's guide to any person applying for a specified disease insurance policy. For consistency with its other suggested revision to this provision, the NAIC consumer representatives also suggest deleting the language requiring direct response insurers to provide the buyer's guide upon request, but not later than the time the policy or certificate is delivered. The Subgroup did not finish its discussion. The Subgroup plans to continue the discussion during its next meeting on Aug. 7.

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

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Draft: 7/17/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup  
Virtual Meeting  
July 10, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met July 10, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Stephen F. Flick (DC); Christina Jackson (FL); Robert Wake (ME); Camille Anderson-Weddle (MO); Shari Miles (SC); Heidi Clausen and Shelley Wiseman (UT); Anna Van Fleet and Jamie Gile (VT); and Lichiou Lee (WA).

1. Discussed Small Stakeholder Group Revisions to Section 9A of Model #171

Prior to continuing its discussion of the suggested revisions to the product statements in Section 9A—Required Disclosure Provisions of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171), the Subgroup discussed the impact, if any, of the recently issued federal proposed rule on short-term, limited-duration (STLD) plans and hospital indemnity and other fixed indemnity plans. The Subgroup discussed if the rule would require the Subgroup to pause its work revising Model #171 and reopen Model #171's companion model act, the *Supplementary and Short-Term Health Insurance Minimum Standards Model Act* (#170). After discussion, the Subgroup decided to continue revising Model #171 but remain cognizant of the provisions in the federal proposed rule. The Subgroup also concluded that Model #170 most likely would need to be reviewed and possibly reopened after that review for additional revisions to reflect the provisions of the federal rule if it is finalized as proposed. However, this work would begin after the Subgroup finishes revising Model #171. The Subgroup reached these conclusions because, at this point, the federal rule is a proposed rule, which means that after a review of the comments received on it, the federal rule's final language could change. In addition, NAIC staff explained the Subgroup's approach to revising both Model #170 and Model #171 as being focused on state laws and regulations and tying both models' provisions to such laws and regulations, not federal laws and regulations.

Schallhorn said NAIC staff distributed prior to the meeting a revised document reflecting the Subgroup's June 29 discussion of the proposed language for the product statements. He asked for comments. The Subgroup agreed that the revised language accurately reflects the Subgroup's discussion. Bonnie Burns (consultant to consumer groups) expressed concern with the language in some of the product statements stating that the product is "supplementary and not intended to replace major medical insurance." She said the language is confusing to consumers. After discussion, the Subgroup agreed to revise the language to state: "This [policy] [certificate] is not major medical insurance and does not replace it."

Schallhorn expressed concern with the use of the word "for" in the proposed statement language for hospital indemnity and other fixed indemnity coverage. He said using this word seems to imply that the coverage will pay the cost of the actual expenses for a covered hospitalization or for a covered event resulting from a sickness or injury, which is not how these coverages function. He suggested deleting "for" and replacing it with "as a result of." Burns noted the Subgroup's extensive discussion during its June 29 meeting on the issue and the potential for consumers to not understand what that phrase means. After additional discussion, the Subgroup decided to accept Schallhorn's suggested revision. To avoid duplicative language, the Subgroup also agreed to revise the statement language for hospital indemnity to delete the words "resulting from" and replace them with "due to."

The Subgroup agreed to defer discussion of the remaining suggested statement language for STLD plans and dental and vision coverage until its July 24 meeting.



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

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Draft: 7/13/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup  
Virtual Meeting  
June 29, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met June 29, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Shannon Doheny (FL); Robert Wake (ME); Camille Anderson-Weddle (MO); Martin Swanson and Maggie Reinert (NE); Shari Miles (SC); Heidi Clausen (UT); Anna Van Fleet and Jamie Gile (VT); and Shari Maier (WA).

1. Discussed Small Stakeholder Group Revisions to Section 9A of Model #171

The Subgroup discussed the small stakeholder group's suggested revisions to Section 9A—Required Disclosure Provisions of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171) intended to reflect the Subgroup's discussion of the NAIC consumer representatives' suggested disclosure statement language during its May 15 meeting.

J.P. Wieske (Horizon Government Affairs) said following the Subgroup's May 15 meeting, a small group of stakeholders, including industry and consumer representatives, discussed potential revisions to the NAIC consumer representatives' suggested language for the disclosure statements required to be provided to consumers under Section 9A. This discussion aimed to address the Subgroup's concerns that the suggested language could be misleading to consumers about the type of benefit the product is providing. The Subgroup discussed the revised statement language for hospital indemnity and other fixed indemnity. After discussion, the Subgroup preliminarily agreed to the following revised statement language for hospital indemnity and other fixed indemnity:

**Hospital Indemnity**

"This [policy] [certificate] pays fixed dollar benefits for covered hospitalization resulting from a sickness or injury. The benefit amounts are not based on the cost of your medical expenses. These benefits are designed to be paid to the [policyholder] [certificate holder]. They are not intended to be paid directly to providers. This [policy] [certificate] is supplementary and not intended to replace major medical insurance. Read the description of benefits provided along with your [enrollment form /application] carefully."

**Other Fixed Indemnity**

"This [policy] [certificate] pays fixed dollar benefits for covered events resulting from a sickness or injury. The benefit amounts are not based on the cost of your medical expenses. These benefits are designed to be paid to the [policyholder] [certificate holder]. They are not intended to be paid directly to providers. This [policy] [certificate] is supplementary and not intended to replace major medical insurance. Read the description of benefits provided along with your [enrollment form /application] carefully."

The Subgroup also agreed to delete the word "review" in the last sentence of each of the revised statements and replace it with the word "read."

The Subgroup next discussed the disability income revised statement language. After discussion, the Subgroup agreed to revise the language to make it more consumer-friendly by deleting the words “set length of time” and substituting them with “specific period of time.” The Subgroup also agreed to delete the words “as a result of” and replace them with the word “from.”

The Subgroup next discussed the accident-only revised statement language. The Subgroup agreed to make the same revisions to the language it made to the disability income statement language.

The Subgroup discussed the revised statement language for specified disease coverage, specified accident coverage, and limited benefit coverage. After discussion, the Subgroup agreed to delete duplicative language in each.

The Subgroup asked NAIC staff to distribute prior to its next meeting on July 10 the revised statement language reflecting the Subgroup’s discussion for the Subgroup’s review during that meeting. The Subgroup also plans to continue its discussion of the NAIC consumer representatives’ comments on Section 9A during its July 10 meeting.

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

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Draft: 5/17/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup  
Virtual Meeting  
May 15, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met May 15, 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); Martin Swanson (NE); Shari Miles (SC); Tanji J. Northrup and Heidi Clausen (UT); Anna Van Fleet and Jamie Gile (VT); and Lichiou Lee (WA).

1. Continued Discussion of Comments Received on Section 9 of Model #171

The Subgroup continued its discussion of the comments received on Section 9—Required Disclosure Provisions of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171), beginning with the NAIC consumer representatives' comments for Section 9A(2)—Hospital Indemnity or Other Fixed Indemnity Coverage.

Jolie H. Matthews (NAIC) said that during its April 24 meeting, the Subgroup discussed, from a regulatory perspective, the appropriateness of including specific readability and accessibility requirements for consumer disclosures when such requirements are most likely already in other state laws and regulations, as well as other NAIC models. The Subgroup discussed this issue. After extensive discussion, the Subgroup decided not to accept the NAIC consumer representatives' suggested language on accessibility. The Subgroup decided to add a drafting note to Section 9A(2), alerting states to refer to their state laws and regulations and applicable NAIC models for provisions related to consumer disclosure readability and accessibility standards.

The Subgroup discussed the NAIC consumer representatives' suggested language for the statement in Section 9A(2) to be provided to consumers before submission of a completed application for coverage on hospital indemnity or other fixed indemnity coverage. The Subgroup raised a concern about the language because it seems to state that this type of coverage provides a benefit when it pays a fixed dollar amount triggered by a hospital stay or other covered health-related event regardless of the actual expense amount. The Subgroup discussed the issue, including other potential language to address it, but deferred deciding on what word to use until its May 22 meeting because of the NAIC consumer representatives' concerns that consumers would not understand the meaning of the word "trigger." The Subgroup did agree to bracket both "hospital stay" and "other covered health-related event."

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9A(3). This provision outlines the statement to be provided to consumers on disability income protection coverage. The other suggested language on readability and accessibility requirements for the statement is identical to the suggested language for Section 9A(2). Based on the Subgroup's discussion on Section 9A(2), the Subgroup agreed to make the same changes to Section 9A(3). The Subgroup discussed the suggested language for the statement. The Subgroup did not have any initial concerns with the suggested statement language.

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9A(4). This provision outlines the statement to be provided to consumers on accident-only coverage. The other suggested language on readability and accessibility requirements for the statement is identical to the suggested language for Section 9A(2). Based on the Subgroup's discussion on Section 9A(2), the Subgroup agreed to make the same

changes to Section 9A(4). The Subgroup discussed the suggested language for the statement. The Subgroup did not have any initial concerns with the suggested statement language.

The Subgroup next discussed the NAIC consumer representatives' suggested revisions to Section 9A(5). This provision outlines the statement to be provided to consumers on specified disease coverage. The other suggested language on readability and accessibility requirements for the statement is identical to the suggested language for Section 9A(2). Based on the Subgroup's discussion on Section 9A(2), the Subgroup agreed to make the same changes to Section 9A(5). The Subgroup discussed the suggested language for the statement. Like its discussion about the potential issues with the statement for hospital indemnity or other fixed indemnity coverage in Section 9A(2), the Subgroup discussed concerns that the statement could be misleading because it seems to imply the coverage to be provided under a specified disease policy is for diagnosing and treating a specified disease. The Subgroup agreed to revisit the issue during its May 22 meeting.

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

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Draft: 5/16/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup  
Virtual Meeting  
April 24, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met April 24, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Chris Struk and Shannon Doheny (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 and Jamie Gile (VT); and Ned Gaines (WA).

1. Discussed Comments Received on Section 9 of Model #171

The Subgroup discussed the comments received on Section 9—Required Disclosure Provisions of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171), beginning with the NAIC consumer representatives' comments. Before discussing the comments, Lucy Culp (Leukemia & Lymphoma Society—LLS) asked if the Subgroup is planning to return to the short-term, limited-duration (STLD) plan provision considering the potential changes to the federal rules regulating those plans. Jolie H. Matthews (NAIC) said she did not believe this would be necessary because the proposed language for the STLD plan provision in Model #171 links the regulatory requirements for these plans with the state's regulatory requirements. Matthews also noted that the revisions to Model #171's companion model, the *Supplementary and Short-Term Health Insurance Minimum Standards Model Act* (#170) (formerly known as the *Accident and Sickness Insurance Minimum Standards Model Act*), took a similar approach. J.P. Wieske (Horizon Government Affairs), as an employee of the Wisconsin Department of Insurance (DOI) and chair of the NAIC group that revised Model #170, agreed with Matthews.

The Subgroup discussed the NAIC consumer representatives' comments on Section 9A—General Rules. Before explaining the comments, Culp asked if the Subgroup would consider the NAIC consumer representatives' request to have another NAIC group, such as the Consumer Information (B) Subgroup, review this section because of its subject matter expertise in this area of consumer disclosures. The Subgroup discussed Culp's suggestion. After discussion, the Subgroup decided to move forward with its review of the comments received on Section 9.

Culp explained that the NAIC consumer representatives' suggested revisions would provide a specific disclosure provision for each type of product regulated under Model #171. She explained that the rationale for this approach is that the disclosure statement for each type of product would vary depending on the product. As such, it makes sense to allow for that variability and for the Subgroup to discuss the language for each disclosure statement and why it would be different based on the type of product rather than discussing a universal disclosure statement.

Chris Petersen (Arbor Strategies LLC) expressed concern with the NAIC consumer representatives' suggested new language for Section 9A(1), which states: "Any disclosures, and the documents to which they refer, must be delivered in the same written medium as the application to consumers. These documents must be available no later than 24 hours before a completed application is submitted by the consumer to the issuer." He said the language is problematic because it seems to prohibit providing the application and other documents electronically, despite a consumer requesting only electronic communications. He said another problem is that the language appears to suggest the insurer is to gather information about the consumer and deliver a disclosure before the consumer submits an application, which raises potential privacy concerns. The Subgroup discussed the potential new language. After discussion, the Subgroup revised the language to read as follows: "Any disclosures,

and the documents to which they refer, must be delivered in the written medium requested by the consumer. These documents must be available before the consumer submits a completed application.”

The Subgroup next discussed the NAIC consumer representatives’ suggested disclosure language for Section 8B—Hospital Indemnity or Other Fixed Indemnity Coverage. Culp explained that the NAIC consumer representatives suggest revising Section 9A(2)(a) so that it only applies to hospital indemnity or other fixed indemnity coverage. She said other revisions suggest using a sans-serif font for the required statement and the proximity of the statement to the applicant’s signature block. Petersen asked why the NAIC consumer representatives suggest the sans-serif font. Culp said NAIC consumer representatives with expertise in consumer disclosures suggested that font type. Petersen also questioned if any of these provisions related to font type and font size would conflict with other state readability laws and regulations. He asked if the *Uniform Individual Accident and Sickness Policy Provision Law* (#180) would include such requirements and, if so, whether it would be appropriate to include the NAIC consumer representatives’ suggested language in Model #171 instead of relying on Model #180’s provisions. Another stakeholder suggested the Subgroup review the *Life and Health Insurance Policy Language Simplification Model Act* (#575). Culp said she would be concerned with separating these requirements from Model #171 and having to refer to provisions in another model. Wieske raised an issue from a regulatory perspective with the NAIC consumer representatives’ product-by-product approach if an insurer combines products. He said if separate disclosures are required for each product, then it could be confusing to consumers if the insurer combines one or more products.

The Subgroup discussed a possible way to streamline the NAIC consumer representatives’ suggested language. The Subgroup also discussed whether to include a drafting note acknowledging the existence of other state readability and accessibility requirements.

In discussing the NAIC consumer representatives’ proposed statement for hospital indemnity or other fixed indemnity coverage, the Subgroup did not have any concerns with the proposed language. Cindy Goff (American Council of Life Insurers—ACLI) said there could be an issue with the statement’s accuracy if hospital indemnity and other fixed indemnity are sold separately. The Subgroup discussed her concern. Bowden said she would not object to including brackets around both “hospital stays” and “other covered health-related event” to address the concern. She said she could also support adding a drafting note alerting insurers that, subject to the insurance commissioner’s approval, they may modify the statement, as needed, for accuracy for a specific product type. The Subgroup did not reach a decision on whether to accept these suggested revisions.

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

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/Accident and Sickness Subgrp/Accident and Sickness Ins Min Stds Subgrp 4-24-23MtgMin.docx

Draft: 4/26/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup  
Virtual Meeting  
April 17, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met April 17, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Chris Struk (FL); Camille Anderson-Weddle (MO); Maggie Reinert (NE); Shari Miles (SC); and Tanji J. Northrup, Shelley Wiseman, and Heidi Clausen (UT).

1. Continued the Discussion of Section 7F of Model #171

The Subgroup continued its discussion of the comments received on Section 7F—Prohibited Policy Provisions of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171) beginning with the Texas Department of Insurance’s (DOI’s) comments. Section 7F prohibits a policy from limiting or excluding coverage by type of illness, accident, treatment, or medical condition, except as provided in the subsection.

Bowden said her first comment on whether the exclusions in Section 7F are appropriate for short-term, limited-duration (STLD) plans was addressed during the Subgroup’s March 27 meeting. The Subgroup discussed Bowden’s next comment on Section 7F(4) concerning the exclusion of an illness, treatment, or medical condition arising out of war or an act of war (whether declared or undeclared). The Subgroup discussed how this provision would apply to acts of terrorism. After discussion, the Subgroup decided to leave the provision unchanged because of certain court rulings and other decisions related to acts of terrorism, finding that acts of terrorism are generally not considered acts of war. The Subgroup next discussed Bowden’s comments on Section 7F(8) concerning the exclusion for treatment provided in a government hospital. After discussion, the Subgroup agreed to delete the provision because it is no longer an issue for industry. Bowden said the Subgroup addressed her next comment related to the exclusion for dental care or treatment during its March 27 meeting.

The Subgroup next discussed Bowden’s comment on the territorial limitations exclusion. The Subgroup discussed what this provision means and whether the exclusion is related to territories outside the U.S. or a specific state in the U.S. The Subgroup discussed whether it should clarify the provision to note that it applies to territories outside the U.S. After discussion, which included a discussion of the impact of such a change with respect to the U.S. territories and possible confusion on whether the exclusion applies to U.S. territories, the Subgroup decided to leave the provision unchanged but add a drafting note explaining the intent of the provision.

The Subgroup next discussed the Health Benefit Institute’s (HBI’s) suggestion to add an exclusion to Section 7F for “genetic testing not ordered by a medical provider, and not used to diagnose or treat a disease.” The Subgroup discussed the comments. During the discussion, the Subgroup discussed whether medical necessity requirements would address the situation without adding the suggested language. The Subgroup noted that states generally do not apply their utilization review requirements to excepted benefit plans; as such, there would not be a medical necessity review. Cindy Goff (American Council of Life Insurers—ACLI) said she believes the purpose of adding the suggested language is to ensure that insurers can include a requirement in the contract that a health care provider must order the genetic testing to be covered. If a health care provider does not order it, then coverage is excluded. Goff said without this provision, a covered person could challenge the denial of coverage. After additional discussion, the Subgroup agreed to add the exclusion.



The Subgroup next discussed the NAIC consumer representatives' suggestion to delete Section 7G. Section 7G provides that Model #171 shall not impair or limit the use of waivers to exclude, limit, or reduce coverage or benefits for the specifically named or prescribed preexisting diseases, physical conditions, or extra hazardous activities. The Subgroup discussed the rationale for having such a provision and why it appears to benefit consumers. Goff said she believes this provision benefits consumers because it allows insurers to exclude certain pre-existing conditions without having to exclude coverage for the entire disease. She said this provision gives insurers more flexibility with respect to decisions related to the coverage of pre-existing conditions and other conditions not related to the pre-existing condition. The Subgroup discussed how this provision may or may not relate to Model #171's disclosure provisions. After additional discussion, the Subgroup deferred deciding on whether to accept the NAIC consumer representatives' suggestion to delete Section 7G until it completes its review of all the comments received on Model #171.

The Subgroup next turned to the NAIC consumer representatives' suggestions for adding new provisions to Section 7. The Subgroup deferred discussion of the suggested additional provisions until it completes its review of all the comments received on Model #171.

## 2. Discussed the Comments Received on Section 8H of Model #171

The Subgroup next discussed the comments received on the proposed Section 8H—Short-Term, Limited-Duration Health Insurance Coverage. The Subgroup only received comments from the NAIC consumer representatives. Anna Howard (American Cancer Society Cancer Action Network—ACS CAN) explained that the NAIC consumer representatives' suggestion to revise Section 8H(1) for consistency with similar language in Model #171's companion model, the *Supplementary and Short-Term Health Insurance Minimum Standards Model Act* (#170) (formerly known as the *Accident and Sickness Insurance Minimum Standards Model Act*). The Subgroup accepted the suggested revisions.

The Subgroup next discussed the NAIC consumer representatives' suggestion to revise the coinsurance percentage in Section 8H(2)(ii) to no more than "50%" of covered charges to no more than "20%" of covered charges. They also suggest striking "or" and substituting "and." Howard said the NAIC consumer representatives believe that a 50% coinsurance of covered charges in an STLD plan is too high of a percentage for consumers to potentially pay. After discussion, the Subgroup decided not to accept the suggested revision to the coinsurance percentage. The Subgroup accepted the suggested revision to strike "or" and substitute "and." The Subgroup next discussed the NAIC consumer representatives' suggestion to revise the provision's drafting note to delete the sentence suggesting that those states that have severely limited coverage time frames with limited renewals or extensions should apply smaller annual and lifetime limits and out-of-pocket maximums. The Subgroup did not accept the suggested revision, but because of impending changes to the federal rules regulating STLD plans, the Subgroup agreed to delete the last sentence in the drafting note suggesting that those states that allow coverage up to the federal maximum of three years might want to consider different limits.

No comments were received on Section 8H(3). The Subgroup discussed the NAIC consumer representatives' suggestion to delete Section 8H(4)(iii). This provision would require an insurer to include a statement in the STLD plan that the insurer retains the right, at the time of policy renewal, to make changes to the premium rate by class. After discussion, the Subgroup agreed to delete the provision, but it agreed to revisit the decision, if necessary.

No comments were received on Section 8H(5). The Subgroup discussed the NAIC consumer representatives' suggestion to add the word "intentionally" to Section 8H(6) to provide that a carrier may not rescind an STLD plan during the coverage period unless the insured "intentionally" fails to disclose a prior diagnosis of a health condition. After discussion, the Subgroup accepted the suggested revision.

No comments were received on Section 8H(7). The Subgroup discussed the NAIC consumer representatives' suggestion to revise the number of days an insurer must notify an insured of policy cancellation or rescission prior to the cancellation or rescission from 20 days to 30 days in Section 8H(8). After discussion, the Subgroup accepted the suggested revision.

Jolie H. Matthews (NAIC) pointed out a sentence in the drafting note for Section 8H(8) referencing the current federal rules for STLD plans, which limit coverage under such plans to less than 12 months and provide for a maximum duration of coverage of no longer than 36 months. The Subgroup decided to retain the sentence and revisit it after the release of the anticipated federal proposed rules on STLD plans.

The Subgroup next discussed the NAIC consumer representatives' suggestion to add a new provision to Section 8H prohibiting an insurer from issuing an STLD plan during the annual enrollment periods for individual health insurance and individual health insurance marketplace plans. The Subgroup discussed the pros and cons of adding such a provision. The Subgroup decided to defer the discussion until a later date.

Matthews pointed out for the Subgroup's future discussion a note to the Subgroup at the end of Section 8H suggesting that the Subgroup may want to consider adding language on pre-existing conditions to the subsection. The note to the Subgroup also alerts the Subgroup that it will have to craft a definition of "pre-existing condition" for STLD plans because the current definition of "pre-existing condition" in Section 6J applies to all coverages regulated under Model #171 except STLD plans.

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

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Draft: 4/25/23

Accident and Sickness Insurance Minimum Standards (B) Subgroup  
Virtual Meeting  
March 27, 2023

The Accident and Sickness Insurance Minimum Standards (B) Subgroup of the Regulatory Framework (B) Task Force met March 27, 2023. The following Subgroup members participated: Andy Schallhorn, Co-Chair (OK); Rachel Bowden, Co-Chair (TX); Debra Judy (CO); Howard Liebers (DC); Chris Struk (FL); Camille Anderson-Weddle (MO); Maggie Reinert (NE); Shari Miles (SC); Shelley Wiseman and Heidi Clausen (UT); Anna Van Fleet, Jamie Gile, and Mary Block (VT); and Ned Gaines (WA).

1. Continued Discussion of Section 7F of Model #171

The Subgroup continued its discussion of the comments received on Section 7F—Prohibited Policy Provisions of the *Model Regulation to Implement the Accident and Sickness Insurance Minimum Standards Model Act* (#171) beginning with the NAIC consumer representatives' comments on this subsection. Section 7F prohibits a policy from limiting or excluding coverage by type of illness, accident, treatment, or medical condition, except as provided in the subsection.

The Subgroup discussed the NAIC consumer representatives' suggestion to delete Section 7F(2), which provides an exclusion for "mental or emotional disorders, alcoholism and drug addiction." Jackson Williams (Dialysis Patient Citizens—DPC) said the NAIC consumer representatives' suggestion to delete this exclusion relates to the issue of whether the products regulated under Model #171 should include a mental health parity component. He said he has identified someone to speak on this issue, and he requested that the Subgroup defer discussion of this issue until this individual could present during an upcoming Subgroup meeting. The Subgroup discussed the issue, noting that federal mental health parity requirements do not apply to excepted benefit plans. The Subgroup also discussed whether there should be a difference between what short-term, limited-duration (STLD) plans should be required to cover versus what excepted benefit plans should be required to cover. After discussion, the Subgroup decided not to accept the NAIC consumer representatives' suggestion to delete Section 7F(2). In addition, the Subgroup decided not to hold a broad discussion of the mental health parity coverage issue related to excepted benefit plans, noting that based on the discussion, few states would require excepted benefit plans to cover mental health benefits. The Subgroup agreed to add a drafting note to the subsection explaining that states should decide if any of the exclusions allowed in Section 7F should apply to STLD plans.

The Subgroup next discussed the NAIC consumer representatives' suggestion to delete Section 7F(4)(b) concerning an exclusion related to suicide and Section 7F(4)(e) concerning an exclusion for incarceration with respect to disability income protection policies. The Subgroup discussed the rationale for such exclusions. The Subgroup returned to its discussion about how Section 7F should apply to STLD plans and whether there should be a specific carve-out included in this provision for STLD plans. After additional discussion, the Subgroup decided not to accept the NAIC consumer representatives' suggestion to delete Section 7F(3)(b) and Section 7F(3)(e). The Subgroup also agreed to revise the drafting note it had agreed to add earlier concerning STLD plans to add a sentence that some of the exclusions listed in Section 7F may not be appropriate for STLD plans, and each state will have to determine which should apply, if any, to such plans. The Subgroup did not accept the NAIC consumer representatives' suggested drafting note for Section 7F(5) because it seems unnecessary. The Subgroup decided during its March 13 meeting to preliminarily accept the NAIC consumer representatives' suggestion to add the language "to improve the function of a malformed body part," subject to additional clarification on the meaning of "malformed."

The Subgroup accepted the NAIC consumer representatives' suggestion to clarify Section 7F(7) by adding the word "chiropractic."

The Subgroup accepted the NAIC consumer representatives' suggestion to add language to Section 7F(9) modifying the exclusion to have it not apply when the provision of dental services is medically necessary due to the underlying medical condition or clinical status of the covered person. The Subgroup did not accept the NAIC consumer representatives' suggested new drafting note for the provision.

The Subgroup next discussed the NAIC consumer representatives' suggestion to delete "routine physical examinations" in Section 7F(11). The Subgroup did not accept the suggestion.

The Subgroup next discussed the Vermont Department of Insurance's (DOI's) suggestion to add a drafting note to Section 7F(2), noting that the exclusion related to mental or emotional disorders, alcoholism, and drug addiction is optional, and states should review the desirability of its use for certain products regulated under the Model #171.

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

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## Draft Pending Adoption

Attachment Nine  
Regulatory Framework (B) Task Force  
8/13/23

Draft: 8/17/23

Employee Retirement Income Security Act (ERISA) Working Group  
Seattle, Washington  
August 13, 2023

The Employee Retirement Income Security Act (ERISA) (B) Working Group of the Regulatory Framework (B) Task Force met Aug. 13, 2023. The following Working Group members participated: Andria Seip, Chair (IA); Crystal Phelps (AR); Debra Judy (CO); Julie Holmes (KS); Robert Wake, (ME); Carrie Couch (MO); Michael Muldoon, Maggie Reinert, and Margaret Garrison (NE); Ted Hamby (NC); Laura Miller and Craig Kalman (OH); Andrew Schallhorn (OK); Jill Kruger (SD); Tanji J. Northrup (UT); Charles Malone (WA); and Jennifer Stegall (WI). Also participating were: D.J. Bettencourt (NH); and Erin K. Hunter (WV).

### 1. Heard an Update from the DOL

Amber Rivers (U.S. Department of Labor—DOL) and Beth Baum (DOL) gave an update on two tri-agency proposals from the DOL, the U.S. Department of Health and Human Services (HHS), and the Internal Revenue Service (IRS). Rivers explained that the short-term, limited-duration insurance (STLDI)/fixed indemnity notice of proposed rulemaking (NPRM) proposes rules to amend the definition of STLDI, which is excluded from the definition of individual health insurance coverage under the federal Public Health Service Act and sets forth proposed amendments to the requirements for hospital indemnity or other fixed indemnity insurance to be considered an excepted benefit in the group and individual health insurance markets. Rivers said the proposed rule also solicits comments on the specified disease excepted benefits coverage and level-funded arrangements. Rivers said lastly, there is a proposal from the U.S. Department of the Treasury (Treasury Department) and the IRS that would clarify the tax treatment of certain fixed amount benefit payments under employer-provided accident and health plans.

Rivers explained that historically, STLDI coverage was designed to fill temporary gaps in coverage when an individual is transitioning from one plan to another. She said the proposal focuses on amending the definitions to better align with that original purpose by shortening some of the key terms. Rivers also pointed out that the proposal also clarifies responsibilities for sales through group trusts or associations, including that group market reforms apply when plans are marketed to employers as employer-sponsored coverage. She emphasized that the DOL would like help identifying additional strategies to make clear the difference between short term limited duration (STLD)/fixed indemnity plans and comprehensive health coverage.

Rivers explained that level-funded arrangements are an increasingly popular method of funding for group health plans, particularly with small employers. She said numbers from the Kaiser Family Foundation (KFF) reported that in 2020, 13% of small employers were using level-funded arrangements compared to 42% of small employers reporting in 2021. She said the plan purports to be self-funded. However, employers make set monthly payments to cover estimated claims and administrative costs, as well as the premiums for stop loss insurance for when claims surpass a maximum dollar amount. She said that, usually, if the number of claims paid during the year is lower than what the contributions are, the plan sponsor may receive a refund or carry it over to the next year.

Rivers said that while level-funded arrangements self-identify as self-funded, they have certain features that look like fully insured plans. She said there are concerns when these arrangements are used by small employers with particularly low attachment points. One of the concerns the DOL has heard is that a lot of benefits are being provided under the stop loss coverage, which is not required to comply with federal reforms or state laws that apply to health insurance coverage. Rivers explained that the DOL is concerned that level-funded plans may be

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used to deny or limit individual claims in a way that would otherwise be prohibited. She said that small employers may not understand the type of arrangement they are in because that monthly payment looks like a premium, and they do not realize they are actually on the hook for outstanding charges. She said the DOL would like to better understand what is going on in the marketplace to determine whether additional guidance is needed. Comments on the STLD/fixed indemnity NPRM are due Sept. 11, and Rivers encouraged the NAIC and the individual states to submit comments.

Baum said that the DOL will be presenting Aug. 14 at the Mental Health Parity and Equity Addiction Act (MHPAEA) (B) Working Group meeting. She said that a package was released in July that includes: 1) proposed rules; 2) a technical release requesting comments; 3) the second MHPAEA comparative analysis report to the U.S. Congress (Congress); and 4) an enforcement fact sheet for cases closed in the fiscal year 2022. Baum said there are two components to the proposed rules package. The first component proposed changes to the existing regulations that are designed to strengthen protections and ensure that participants and beneficiaries have access to mental health and substance use disorder (MH/SUD) coverage. She said a lot of those changes are in the sections of the rules that apply to non-quantitative treatment limitations (NQTs). The second component proposed changes to some of the defined terms in the existing regulations, as well as a new section of the regulations with more specific requirements for the comparative analysis required for NQTs. Baum said the technical release is a kind of companion to the proposed rules and includes what would be a new requirement for plans and issuers to collect and evaluate relevant data on outcomes. The technical release requests comments on outcomes data that plans and issuers would be required to collect and evaluate. The comment deadline for this rule is Oct. 2.

### 2. Received an Update on Revisions to the NAIC MEWA/ MET Chart.

Jennifer Cook (NAIC) explained that she is in the process of surveying state insurance departments for the purpose of updating the NAIC chart on state laws addressing multiple employer welfare arrangements (MEWAs) and multiple employer trusts (METs). She said that Wake suggested that the chart could be a template for answering initial and follow-up questions, such as: 1) If a MEWA is not fully insured by an authorized insurer, does your state require some sort of MEWA-specific license or registration before the MEWA can lawfully provide coverage in your state? If so, what are the requirements?; 2) Can a MEWA based out-of-state lawfully provide coverage in your state? If so, what are the requirements?; 3) Can a domestic MEWA lawfully provide coverage in other states? If so, does your state have any specific regulatory requirements that apply?; and 4) What are your requirements for fully-insured MEWAs? Do they include standards requiring the maintenance of specified levels of reserves and specified levels of contributions, as authorized under ERISA § 514 (b)(6)(A)(i)? Cook said she would be following up after the meeting to solicit additional information for updating the chart. Seip said she would like to know how other states address MEWAs and that she supports the development of a comprehensive chart.

Wake said that it would be helpful to have a resource, as he is often the point person for state questions about MEWAs. He explained that there are several common questions about how to handle MEWAs that states should consider. One common question is how to handle MEWAs when there is no MEWA-specific state law, especially in cases where the MEWA is operating in more than one state. Wake said in interstate cases, it is important to coordinate, especially if a state is looking to defer to the domiciliary state or if the law requires it. He said another question that comes up is what the enforcement perspective is of a state when an arrangement starts doing business in a state and says it is not a MEWA, or if the arrangement does not really fit under the state's laws. Wake said that if the arrangement is not fully insured and not specifically authorized by the state, it is prohibited. Wake said states could also require some sort of license. Congress has left most of the regulation of MEWAs to the states for the past 40 years, and it is important for states to think about their options and how to interpret their own laws.

## Draft Pending Adoption

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Regulatory Framework (B) Task Force  
8/13/23

The ERISA (B) Working Group adjourned into regulator-to-regulator session, pursuant to paragraph 2 (pending investigations), paragraph 3 (specific companies, entities or individuals), and paragraph 8 (consideration of strategic planning issues relating to federal legislative and regulatory matters) of the NAIC Policy Statement on Open Meetings, to continue work on its goals.

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Draft: 4/10/23

Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group  
Louisville, Kentucky  
March 23, 2023

The MHPAEA (B) Working Group of the Regulatory Framework (B) Task Force met in Louisville, KY, March 23, 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); Peter Brickwedde (MN); Carrie Couch and Amy Hoyt (MO); Matthew Eberhardt (MT); Tracy Biehn (NC); Santana Edison (ND); Maureen Belanger (NH); Ralph Boeckman (NJ); Laura Miller (OH); Landon Hubbard and Ashley Scott (OK); David Buono (PA); Glynda Daniels (SC); Jill Kruger (SD); Rachel Bowden (TX); Tanji J. Northrup (UT); Julie Fairbanks (VA); Barbara Belling (WI); and Erin K. Hunter (WV).

1. Heard Presentations on *Wit v. United Behavioral Health*

Weyhenmeyer said speakers would inform the Working Group about the *Wit v. United Behavioral Health* case and its implications for mental health parity enforcement.

Brian Hufford (Zuckerman Spaeder) presented on the *Wit* case. He said the suit does not allege parity violations because the plaintiffs wanted to focus on the delivery of mental health services and not compare them to medical and surgical services. He said parity nonetheless had an impact on why the case was brought. He said plans used medical necessity guidelines to limit treatment even further than the quantitative limitations applied before the MHPAEA was passed. He said United Behavioral Health (UBH) limited its treatment to acute care and reduced the level of care after an acute episode. He said a trial court agreed that guidelines were overly restrictive in a 2019 decision. However, the Ninth Circuit appeals court overturned the decision and then later updated its decision to uphold in part the original ruling. He said four states require claims administrators to use specific guidelines.

Hufford said the newest decision included damaging findings related to the federal Employee Retirement Income Security Act (ERISA). He said plaintiffs had argued the company applied flawed guidelines. Therefore, the claims should be reprocessed. However, the Ninth Circuit ruled that reprocessing was not necessary. It also ruled that all class members had to have exhausted their administrative remedies such as internal and external appeals. He said plaintiffs are seeking further review of the decision, with support from 15 states; Washington, DC; and other organizations.

Hufford said UBH's guidelines were more restrictive than commonly accepted treatment standards. He provided examples, including applied behavioral analysis (ABA) and the treatment criteria established by the American Society for Addiction Medicine (ASAM). He said the court found that UBH lied to state insurance regulators regarding the guidelines they employed.

David Lloyd (The Kennedy Forum) provided comments on the importance of the *Wit* case. He said inappropriate medical necessity denials are a primary barrier to care. He said the Kennedy Forum has been pushing for inclusion of a definition of medical necessity in state and federal law. He said it has also advocated for making utilization review criteria consistent with generally accepted standards of care. He said some states have added a definition to their laws and that recently Georgia added it. Lloyd said professional medical societies have developed tools to show the level of care needed for patients, which provides a common standard for patients, providers, and payers. He said care decisions should be made using these tools and said some states have adopted rules to require them to be used. He said federal agencies have also made progress, including a federal Centers for Medicare & Medicaid



Services (CMS) requirement that Medicare Advantage plans made medical necessity determinations using appropriate guidelines. He said that regardless of the final decision in the Wit case, the issues will not go away.

Klug asked which state law definitions of medical necessity could serve as models for other states. Lloyd said laws in California, Georgia, Illinois, and Oregon are good models. Hufford said states should tie guidelines to generally accepted standards developed by medical societies, not those developed by private companies. He said that plans continue to limit treatment to only some parts of the ASAM guidelines. Klug asked whether the CMS definition of medical necessity used in Medicare is a good model. Lloyd said that it is pretty good.

Hoyt asked about exhaustion of administrative remedies. She said Missouri state law does not require internal review before a patient seeks external review. Hufford said prior decisions under federal law have required only a class representative to exhaust such remedies, but in the Wit case, the ruling requires all class members to do so. He said state laws would not be applicable to ERISA cases.

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.

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/National Meetings/2023 Summer Meeting/MHPAEAWG Min 3.23.docx

Draft: 8/3/23

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup  
Virtual Meeting  
July 27, 2023

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met July 27, 2023. The following Subgroup members participated: TK Keen, Chair (OR); Ashley Scott and Molly Clinkscales, Co-Vice Chairs (OK); Kayla Erickson and Sarah Bailey (AK); Steve Dozier (AL); Crystal Phelps (AR); Jared Kosky (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt (KS); Sharon P. Clark and Daniel McIlwain (KY); Nina Hunter (LA); Chad Arnold and Karin Gyger (MI); Amy Hoyt, Cynthia Amann, and Camille Anderson-Weddle (MO); David Dachs (MT); Ted Hamby (NC); Cheryl Wolff (NE); Erin Porter (NJ); Paige Duhamel and Renee Blechner (NM); Eamon G. Rock (NY); Jodi Frantz (PA); Maggie Rosa (SC); Scott McAnally (TN); Ryan Jubber (UT); Don Beatty (VA); Jennifer Kreitler (WA); Jennifer Stegall (WI); and Jill Reinking and Tana Howard (WY).

1. Adopted its April 17 and Spring National Meeting Minutes

The Subgroup met April 17 to expose a draft of the pharmacy benefit manager (PBM) white paper for a 45-day public comment period ending June 1.

Scott made a motion, seconded by Arnold, to adopt the Subgroup's April 17 (Attachment Eleven-A) and March 22 (see *NAIC Proceedings – Spring 2023, Regulatory Framework (B) Task Force, Attachment Five*) minutes. The motion passed unanimously.

2. Adopted the PBM White Paper

Keen discussed the Subgroup's work to date on the PBM white paper. He noted the Subgroup's thoughtful discussions on extraordinarily complex issues and the collaborative process it followed throughout its work drafting the white paper. He said the current white paper draft the Subgroup is considering for adoption during this meeting includes revisions based on the comments received during the public comment period ending June 1. He asked for comments from Subgroup members.

Stegall expressed support for the white paper given the complexities of the issue. She said she believes it will be a great resource to state insurance regulators. Gyger also expressed support for the Subgroup's work, noting the Subgroup's collaborative process in drafting the white paper. She also noted the extensive stakeholder participation in the drafting process. She acknowledged that some stakeholders think additional edits should be made, but after almost two years of work, she believes the current white paper draft reflects the current state of play in the pharmaceutical drug supply chain and ecosystem and that it is time to move forward to the next step in the adoption process.

Kosky asked about the process moving forward assuming the Subgroup adopts the white paper during today's meeting. Keen said that if the Subgroup adopts the white paper during today's meeting, it will forward it to the Regulatory Framework (B) Task Force for its consideration and adoption. Following the Task Force's adoption, the Health Insurance and Managed Care (B) Committee would consider the white paper for adoption. Kosky said he wanted to make sure that this was the process moving forward because Connecticut still has concerns with the accuracy of some the information in the current white paper draft. He said that in addition, parts of the white paper lack citations for some of the statements. He said, generally, Connecticut is concerned with the overall lack of diversity and sources used for some of the information included in the white paper. He said Connecticut has concerns with the tone of some of the language as well. Kosky said that despite these concerns, Connecticut would

vote to support moving the white paper on to the next step in the process because it is important to move it along after more than two years of work. He said Connecticut will consider raising these concerns to the Regulatory Framework (B) Task Force as it considers the white paper.

Commissioner Clark echoed many of the comments already made about the Subgroup's work developing the white paper. Noting that its language will never be perfect to everyone, she expressed support for the white paper and moving it forward to the Regulatory Framework (B) Task Force for its consideration. Hoyt also expressed support for the white paper. She suggested, however, that because the white paper is intended to reflect a snapshot in time concerning the pharmaceutical drug supply chain and ecosystem, the Subgroup should consider including language in it clearly stating that intention. Keen expressed support for such language and the Regulatory Framework (B) Task Force adding it during its discussions on the white paper. He said there is an introduction section in the white paper that NAIC staff are using to track the white paper's development, which could be used to include the language she suggests. He also said that he considers the white paper to be the initial version, Version 1.0, because he believes that, as appropriate, other NAIC groups may want to revise it in the future to reflect changes, particularly with respect to any court decisions made after its adoption.

Keen asked for comments from interested parties. Carl Schmid (HIV+Hepatitis Policy Institute) noted the NAIC consumer representatives had suggested that the Subgroup develop the white paper. He also highlighted the Subgroup's work of approximately two years to complete the white paper and its inclusive process. He expressed support for moving the white paper forward despite the Subgroup not accepting many of the NAIC consumer representatives' suggested revisions.

Kris Hathaway (America's Health Insurance Plans—AHIP) also noted the Subgroup's deliberative and inclusive process in drafting the white paper. She said AHIP has three major concerns with the white paper as currently written. To address those concerns, AHIP believes the Subgroup should revise the white paper to: 1) fulfill the Subgroup's stated and agreed to charges because its focus is on PBMs and its failure to discuss the role of payors, wholesalers, pharmacy services administrative organizations (PSAOs), and other entities involved in the pharmaceutical supply chain; 2) remove non-objective, biased perspectives because there are sections of the white paper providing only one viewpoint; and 3) synthesize and streamline sections. Keen acknowledged AHIP's concerns. He said, however, that at this point in the process, he does not believe everyone agrees with AHIP's concerns about the white paper's biased language.

Peter Fjelstad (Pharmaceutical Care Management Association—PCMA) said the PCMA does not believe the current white paper version is a consensus document. He said the PCMA opposes its adoption. He suggested that because the PCMA does not consider it to be a consensus document, the Subgroup should include the comment letters it received on the white paper with their differing perspectives as an appendix to the paper. Keen acknowledged Fjelstad's comments. He explained that for him, the white paper is a consensus document because of the way the Subgroup members, given their different viewpoints, worked together and compromised on what the white paper should and should not include.

Joel Kurzman (National Community Pharmacists Association—NCPA) expressed appreciation for the Subgroup's work in developing the white paper. He said the NCPA has concerns about a few provisions in the white paper, particularly the language describing spread pricing. He said recent white paper revisions describing spread pricing as a risk mitigation pricing model legitimizes the practice. He said the real-life experience of NCPA members with spread pricing is vastly different. He also suggested that the white paper be carefully reviewed to ensure it does not include inaccurate and outdated views. Kurzman said that as other interested parties stated, the current white paper version does not reflect the NCPA's comments. He expressed hope that if the white paper is adopted, including its recommendation to consider developing model legislation, the NAIC would develop a robust model giving NAIC members the necessary tools to rigorously enforce PBM regulation. He said that assuming the

Subgroup adopts the white paper, he looks forward to working with the Regulatory Framework (B) Task Force to ensure that it incorporates moving forward some of the NCPA's previous suggestions, such as including language in the white paper recommending the creation of a standardized state-based system form for PBM complaints that will enable the NAIC and its Members to analyze and enforce regulation.

Will Dane (Healthcare Distribution Alliance—HDA) said the HDA submitted a comment letter suggesting the Subgroup revise a provision in the white paper concerning PSAOs for accuracy. Keen acknowledged the HDA's suggested revisions.

Sandra Guckian (National Association of Chain Drug Stores—NACDS) said that as other commenters have said, the NACDS' comments are not reflected in the current white paper draft. She said given this, as other comments have said, the NACDS may offer additional comments as the white paper moves forward to the Regulatory Framework (B) Task Force. She said like the NCPA, the NACDS would particularly like to add more language concerning the PBM complaint process.

Commissioner Clark made a motion, seconded by Scott, to adopt the PBM white paper (Attachment Eleven-B). The motion passed unanimously with the following Subgroup members present and voting: Alaska, Arkansas, California, Connecticut, District of Columbia, Iowa, Kansas, Kentucky, Michigan, Missouri, Montana, Nebraska, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, South Carolina, Tennessee, Utah, Virginia, Washington, Wisconsin, and Wyoming.

Having no further business, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adjourned.

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/PBM Regulatory Issues Subgrp/PBM Reg Issues MtgMin 7-27-23.docx

Draft: 4/18/23

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup  
Virtual Meeting  
April 17, 2023

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met April 17, 2023. The following Subgroup members participated: TK Keen, Chair (OR); Ashley Scott and Molly Clinkscales, Vice Chair (OK); Anthony L. Williams (AL); Crystal Phelps (AR); Paul Lombardo and Michael Shanahan (CT); Brad Biren, Robert Koppin, and Brent Jambor (IA); Julie Holmes and Craig VanAalst (KS); Sharon P. Clark, Daniel McIlwain, Beth A. Taylor, and Jonathan Abbott (KY); Joshua Guillory (LA); Chad Arnold and Joe Stoddard (MI); Julia Dreier (MN); Amy Hoyt, Cynthia Amann, and Camille Anderson-Weddle (MO); Ted Hamby (NC); Cheryl Wolff (NE); Renee Blechner (NM); Eamon G. Rock (NY); Melissa Greiner (PA); Maggie Rosa (SC); Scott McAnally (TN); Tanji J. Northrup (UT); Don Beatty (VA); Ned Gaines (WA); Jennifer Stegall (WI); Michael Malone (WV); and Jill Reinking (WY).

1. Exposed a PBM White Paper for Public Comment

Keen said since the Subgroup's release of a working draft of the proposed pharmacy benefit manager (PBM) white paper during its meeting at the 2022 Fall National Meeting, the Subgroup has been working to refine and edit the working draft. He said the Subgroup met April 14 in regulator-to-regulator session to review a revised working draft and discuss issues related to the revised working draft. During this meeting, the Subgroup decided to expose the draft during today's meeting for a 45-day public comment period ending June 1. Keen said following the end of the public comment period, the Subgroup plans to hold meetings to review the comments received and update the draft based on those discussions. After the Subgroup completes its work, the Subgroup will forward the PBM white paper draft to the Regulatory Framework (B) Task Force for its consideration and adoption. Keen said following the Regulatory Framework (B) Task Force's adoption, the PBM white paper draft will be forwarded to the Health Insurance and Managed Care (B) Committee for its consideration and adoption.

Anna Howard (American Cancer Society Cancer Action Network—ACS CAN) asked about the type of comments stakeholders should submit and the Subgroup's process for reviewing the comments, such as a line-by-line review. Keen said the Subgroup is looking for comments on the language currently in the draft and additional language that should be added. He said for comments suggesting additional language, such comments should include the specific language to be added, not just a general comment. He said the Subgroup will determine its review process based on the type of comments received. He said he does not anticipate the Subgroup discussing the comments on a line-by-line basis, which is generally the review process for developing or revising NAIC models, but the Subgroup will determine its review process based on the type of comments received.

Without objection, the Subgroup exposed the PBM white paper draft (Attachment Eleven-A1) for a 45-day public comment period ending June 1.

Having no further business, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup adjourned.

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Draft: 4/16/23

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

# GUIDE TO UNDERSTANDING PHARMACY BENEFIT MANAGER AND ASSOCIATED STAKEHOLDER REGULATION

NAIC White Paper Draft as of April 16, 2023

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

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## **A. INTRODUCTION**

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

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

As the Subgroup was hearing the last few stakeholder presentations in a series of regulator-to-regulator meetings in July 2022 through September 2022, the Subgroup reviewed and approved an outline of the PBM white paper. Based on the outline, the Subgroup leadership solicited and obtained volunteers from the Subgroup members to draft initial language for the various provisions in the PBM white paper. The Subgroup reviewed an initial draft of the PBM white paper in October 2022. The Subgroup released a working draft of the PBM white paper during a meeting at the NAIC 2022 Fall National Meeting. Following the NAIC 2022 Fall National Meeting, the Subgroup met in early 2023 in a series of regulator-to-regulator meetings to discuss additional revisions to the working draft. On April 17, 2023, the Subgroup released a draft of the PBM white paper for a 45-day public comment period ending June 1, 2023.

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

## **B. KEY PLAYERS IN PHARMACEUTICAL DRUG PRICING ECOSYSTEM**

Inherent in the Subgroup’s review of the drug pricing ecosystem are the concerns of the consumer, the one key player who cannot see all of the levers before them but ultimately pays the price of the ecosystem that has been



put in place. Until very recently, pricing of pharmaceuticals has been opaque to many consumers.<sup>1</sup> However, increased costs of pharmaceutical drugs, several active campaigns by players in the ecosystem, increased federal and state attention on drug pricing, and drug price transparency programs have all operated to raise the consumer's knowledge of the cost levers of pharmaceutical drugs.

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

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

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

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

## 1. INSURERS

Insurers contract with PBMs to manage the pharmacy benefit portion of their health care benefits provided to their insureds and enrollees.<sup>4</sup> Insurers contract with PBMs because of the increasing complexity of prescription drug benefit management.<sup>5</sup> In addition, in response to increasing prescription drug costs some insurers contract with PBMs for their services that help reduce costs, including utilization management, prescription drug rebates,

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

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

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

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

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

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

## 2. PRESCRIPTION DRUG MANUFACTURERS

### Manufacturers

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

### Brand manufacturers

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

### Generic manufacturers

Once a brand-name drug is no longer patent-protected, generic manufacturers may begin producing therapeutically equivalent generic drug products. Similar to brand-name drugs, the FDA must approve a generic drug application to ensure its equivalence to the branded drug before it can be produced.<sup>14</sup> Generic drugs

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

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

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

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

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

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

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

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

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

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

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

### **Biologic manufacturers**

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

### **Biosimilar manufacturers**

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

Comparable to the relationship between brands and generics, biosimilars are required to be extremely similar to approved biologics by having no clinically meaningful differences – the same strength, dosage form, and route administration (such as injection).<sup>21</sup> Many biologics and biosimilars are categorized as specialty drugs due to their complex structures using living organisms, the storage requirements needed, and the cost and complexity of administering the product to a consumer. According to the FDA, biologic and biosimilar drug products are the fastest growing class of therapeutic products in the U.S.<sup>22</sup>

## **3. PHARMACY BENEFIT MANAGERS**

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<sup>15</sup> U.S. Food & Drug Administration. Office of Generic Drugs 2021 Annual Report, available at: <https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2021-annual-report#:~:text=Currently%2090%20percent%E2%80%94%20out,they%20are%20on%20the%20market.>

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

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

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

<sup>19</sup> 42 U.S.C. §262(k).

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

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

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

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

#### **4. PHARMACIES**

##### **a. CHAIN**

A pharmacy chain refers to a third party entity that engages in a retail business 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.<sup>27</sup>

##### **b. INDEPENDENT**

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

#### **5. PHARMACISTS**

The basic duty of a pharmacist is to check prescriptions from physicians and other authorized prescribers before dispensing the medication to the patients to ensure that the patients do not receive the wrong drugs or take an incorrect dose of medicine. Pharmacists also offer expertise in the safe use of prescriptions. They also may conduct health and wellness screenings, provide immunizations, oversee the medications given to patients, and provide advice on healthy lifestyles.

#### **6. 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.<sup>29</sup> The PSAO overall administrative function is to assist with contract evaluation and execution, customer service,

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

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

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

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

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

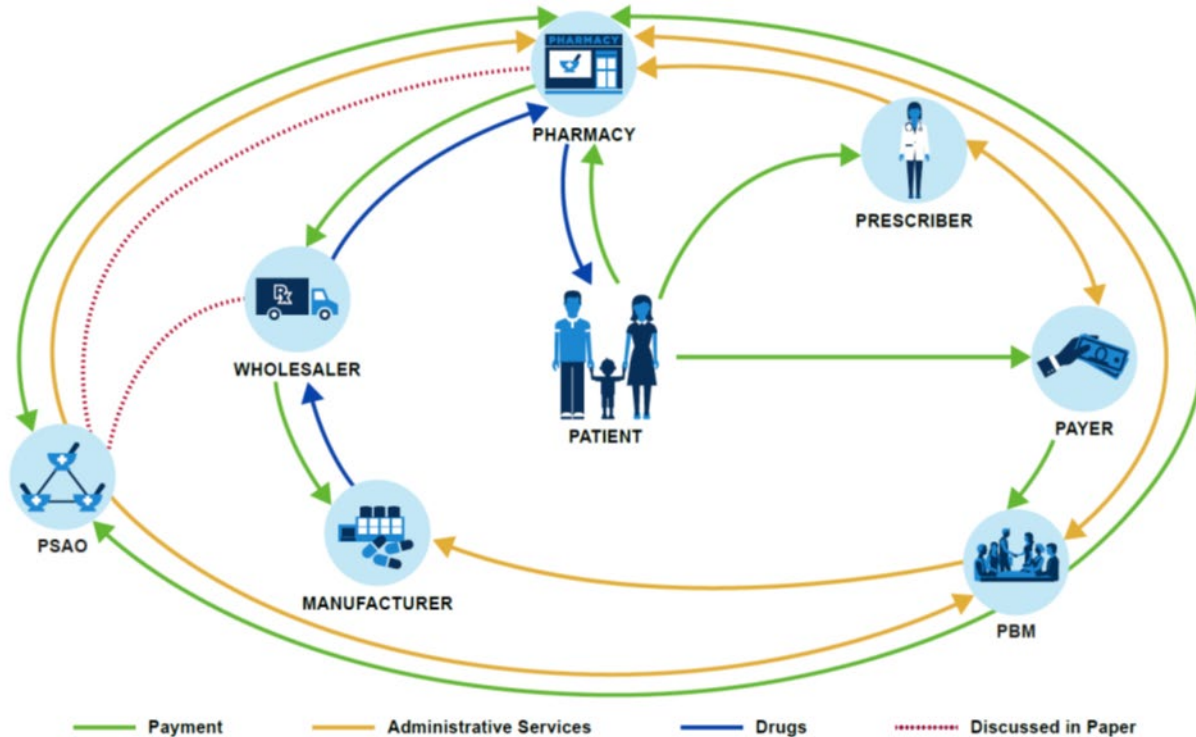
<sup>28</sup> *Id.*

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

central payment and reconciliation, and patient data evaluation.<sup>30</sup> In many instances a PSAO is owned by a wholesaler.<sup>31</sup>

## 7. INTERRELATION OF PARTIES IN THE CHAIN AND TRANSACTION COSTS

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



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

### Physical Drug Distribution Chain

#### *Pharmaceutical manufacturer and wholesaler*

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

#### *Wholesaler and pharmacy*

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

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

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

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

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

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

#### *Pharmacy and consumer*

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

### **Pharmacy Benefit Chain**

#### *Pharmaceutical manufacturer and PBM*

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

#### *Manufacturer and consumer*

Pharmaceutical manufacturers can offer coupons or occasionally free samples of medications to consumers. The coupons can reduce a consumer's cost sharing below that which they would have paid had they used their pharmacy benefit plan.<sup>40</sup> If the coupon constitutes a third-party paying the consumer's cost share, some state laws require insurers to count this payment towards the consumer's deductible and pharmacy benefit maximum out of pocket amount.

#### *PBM and PSAO*

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

#### *Pharmacy and PBM*

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

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

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

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

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

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

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

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

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

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

and apply to all drugs.<sup>44</sup> In addition, PBMs negotiate a dispensing fee with the pharmacies. Actual Acquisition Cost (AAC) is the final price a pharmacy pays after all discounts have been subtracted.<sup>45</sup>

### *PBMs and Payors*

A PBM negotiates rebates with the manufacturer, negotiates with pharmacies, and may develop the formulary on behalf of the payor, the plan sponsor or the insurer, or sell the payor a pre-determined formulary. PBMs also offer payors medical management/utilization review and disease management services.<sup>46</sup>

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

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

Spread pricing – The payor will either not pay or pay a reduced administration fee and the PBM will retain certain risk related to the difference between the price paid by the customer and the price paid to the pharmacy (whether the spread is profitable will vary from drug to drug). This provides set price assurance to the payor.<sup>47</sup>

Through these definitions and descriptions of the pharmaceutical drug ecosystem, legislatures have enacted various state laws to promote greater transparency of the actions taking place, and put in place specific requirements around the activities of those in the ecosystem.<sup>48</sup> State laws and enforcement mechanisms have from time to time butted up against federal pre-emption issues and those issues are further detailed in the sections that follow.

## **C. ENFORCEMENT AND FEDERAL PREEMPTION ISSUES**

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

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

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

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<sup>44</sup> Horvath.

<sup>45</sup> Horvath.

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

<sup>47</sup> Horvath.

<sup>48</sup> See, e.g., the recent proliferation of drug price transparency programs across states, available as referenced by the National Academy for State Health Policy (NASHP): <https://nashp.org/prescription-drug-pricing-transparency-law-comparison-chart/>. At the time of this report, there are 13 states with drug price transparency programs.

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

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

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

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

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

- (1) Requires PBMs to reimburse a pharmacy at a price equal to or greater than what the pharmacy paid to buy the drug from a wholesaler;
- (2) Requires PBMs to timely update their Maximum Allowable Cost (MAC) lists when drug wholesale prices increase;

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

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

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

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

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

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

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



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

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

In a subsequent federal district court decision, *PCMA v. Mulready*<sup>56</sup>, the lower court relied on *Rutledge* to conclude that Oklahoma's PBM law was not preempted by ERISA (the court's additional reasoning related to Medicare preemption is discussed below). The statute at issue in *Mulready* regulates both the network status of particular pharmacies as well as the conditions under which a PBM may reimburse for prescriptions, arguably going significantly beyond "mere cost regulation." However, the PCMA has appealed the *Mulready* decision, and it remains unclear whether the appeals court or other courts will follow its reasoning.

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

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

## 2. MEDICARE PART D

Medicare Part D is an optional, federally supported prescription drug benefit available to Americans over the age of 65. The program's authorizing legislation incorporates the federal preemption language from the Medicare Part C, or "Medicare Advantage (MA)" program, which provides: "the standards established under this

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

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

part shall supersede any state law or regulation (other than state licensing laws or state laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.”<sup>58</sup>

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

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

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

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

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

Finally, the district court rejected the PCMA’s challenge to Oklahoma’s contract approval provisions.<sup>63</sup> Under the Oklahoma statute, insurers who utilize the services of PBMs are required to approve all contracts between the PBM and the PBMs retail pharmacy network. In this instance, the PCMA again pointed to Medicare Part D’s ban on interference in contract negotiations. However, the district court reasoned that Medicare Part D’s bar applies only to negotiations between plan sponsors and PBMs, while Oklahoma’s law regulates negotiations between

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<sup>58</sup> 42 CFR § 422.402.

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

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

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

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

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

PBMs and pharmacies. Accordingly, the district court concluded that the contract approval provisions of Oklahoma’s law are not preempted by Medicare Part D.

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

### 3. MEDICAID

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

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

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

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

To address rising costs, Congress passed legislation enacting the Medicaid Drug Rebate Program in 1990. Under this program, pharmaceutical companies sign a master rebate agreement with the CMS, which administers the Medicaid program at the federal level. These rebates result in cost savings on prescription drugs that are paid for under the Medicaid program and are shared by both the state Medicaid agency and the CMS. State Medicaid programs are required to provide a pathway to coverage for any drug whose manufacturer has signed a rebate agreement with the CMS. Therefore, state Medicaid programs do not have the flexibility that insurers in the private market do to implement strict formularies to control prescription drug spending. Instead, state Medicaid programs are allowed to negotiate additional “supplemental rebates” with pharmaceutical manufacturers

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

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

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

individually, and to develop preferred drug lists in consultation with state Drug Utilization Review (DUR) Boards and Pharmacy and Therapeutics (P&T) Committees.

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

#### **D. FUNCTIONAL ISSUES**

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

##### **1. FORMULARY DESIGN**

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

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

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

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

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

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

<sup>68</sup> Horvath.

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

<sup>70</sup> Oregon Drug Price Transparency Report of 2019 at 10-11, available at:

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

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

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

## 2. REBATES

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

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

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

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

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

Approaches to curb the negative effects of rebates include:

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<sup>71</sup> Horvath.

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

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

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

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

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

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

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

### 3. PRICING AND CONTRACTING PRACTICES

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

**Gag clauses:** The term “gag clause” refers to a stipulation in a pharmacy benefit contract that prohibits a pharmacy or pharmacist from informing consumers of an alternative option when purchasing a drug. For instance, a gag clause may prohibit a pharmacist from telling a consumer about a generic version of a prescription drug or if a prescription drug can be purchased at a lower price out-of-pocket rather than through their insurance plan.<sup>82</sup>

**Mandatory arbitration clause:** Most PBMs require that disputes be submitted to binding arbitration by including a mandatory arbitration provision in their pharmacy contracts. Some believe mandatory arbitration limits legal recourse for individual pharmacies and results in pharmacies foregoing potentially successful audit challenges.<sup>83</sup>

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

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

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

<sup>81</sup> Sood.

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

<sup>83</sup> Oestreicher.

Copay clawbacks: Copay clawback is the PBM practice of taking back from a pharmacy the difference between a patient's copay and the actual cost of the medication when the patient's copay is larger than the cost of the drug.<sup>84</sup>

MAC transparency: A maximum allowable cost (MAC) list is a list that includes the maximum amount that a plan will pay for certain drugs.<sup>85</sup> MAC lists are often generated by the PBM. There is no standardization in the industry as to the criteria for the inclusion of drugs on MAC lists or for the methodology as to how the maximum price is determined, changed or updated. PBMs may sometimes use multiple MAC lists and pocketing the spread between the two. For example, they might use a very low MAC list to reimburse pharmacies but a higher list when charging health plans.<sup>86</sup>

Rebates: Rebates may provide incentive for a PBM to eliminate a less expensive, comparable medication from a formulary. Pharmaceutical manufacturers claim that these rebates are meant to be shared with plan sponsors or passed on to consumers in the form of lower drug prices. However, PBMs regularly keep a share of the rebates before passing the rest through to the plan sponsor.<sup>87</sup>

Spread pricing: Spread pricing is the PBM practice of charging a plan sponsor a higher amount for a drug than they will reimburse the pharmacy and pocketing the difference. Pharmacy pricing is complex, and the process is not transparent. Plan sponsors are often unaware of the difference between the amount they are billed and the pharmacy reimbursement.<sup>88</sup>

Pharmacy 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.

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

#### 4. VERTICAL INTEGRATION AND CONSOLIDATION

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

The three largest PBMs are each affiliated with a health plan and a pharmacy, so the parent company owns or controls up to three stages of the drug supply chain.<sup>91</sup> Some PBMs are also affiliated with health care providers,

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

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

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

<sup>87</sup> Horvath.

<sup>88</sup> Oestreicher.

<sup>89</sup> Sood.

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

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

such as retail clinic services. Thus, one entity controls the diagnosis of a condition, the retail sale of a prescribed drug to the patient, the distribution of the drug from manufacturer to retail pharmacy, and the insurance payment to the pharmacy, including determination of the patient's cost-sharing amounts.

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

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

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

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

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

## 5. PHARMACY NETWORK ADEQUACY

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

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

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

<sup>95</sup> Sood.

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

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



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

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

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

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

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

Commonly, PBMs, or the health plans they contract with, require members to have their prescriptions filled *only* at pharmacies with which the PBM, or the health plan, is affiliated or has an ownership interest in. This is considered "steering," and is sometimes prohibited by state law.<sup>101</sup> Sometimes PBMs will even mine members'

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

<sup>99</sup> National Conference of State Legislatures Glossary of PBM terms, available at: [State Policy Options and Pharmacy Benefit Managers \(ncsl.org\)](https://www.ncsl.org/state-policy/state-policy-options-and-pharmacy-benefit-managers).

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

<sup>101</sup> Sood.

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.<sup>102</sup>

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

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

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

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

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

### Health insurers

Commercial health insurers are subject to federal and state oversight. Insurers providing fully insured employer or group plans and individual market coverage are regulated by states.<sup>103</sup> Self-insured health plans sponsored by

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

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

employers or unions are subject to federal oversight pursuant to the ERISA, although the *Rutledge v. PCMA* case does seemingly allow state regulation of certain PBM activities performed for ERISA plans.

### **Wholesalers**

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

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

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

### **Manufacturers**

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

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

### **Pharmacies**

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

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

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

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

### **Pharmaceutical sales representatives**

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

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

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

The licensing of entities involved in the distribution/supply chain is an evolving area. Many activities performed by some of these entities may be captured by state TPA laws, although some may not be. The Subgroup plans to continue to monitor developments in this area.

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

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

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

## 1. PBM REGULATION

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

### a. State Laws and Approaches

Several states on the Subgroup offered up summaries and key developments on their specific states. These summaries are meant to provide further detail to the updated list of laws offered by the Subgroup on the Subgroup's website.<sup>107</sup>

#### i. Florida

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

#### ii. New Jersey

New Jersey has a bill that focuses on PBM transparency, licensing, and reporting requirements. Carriers would be required to maintain records of contracted PBMs including transaction records and compensation remittance. Carriers would also be required to have pharmacy and therapeutics committees with no conflict of interest. Additionally, they must use more than one formulary.<sup>108</sup>

#### iii. Kentucky

Kentucky State Representative Steve Sheldon proposed HB 457 during the 2022 legislative session. Although the bill did not pass, it was drafted to address the ongoing abuses from PBMs in Kentucky. Some critics have stated this bill is one of the most comprehensive pieces of PBM regulation in the United States. The bill proposed to

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

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

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

<sup>108</sup> S.B. 220, 2022, 2022-2023 Reg. Sess. (NJ.2022). [https://www.njleg.state.nj.us/bill-search/2022/S1616/bill-text?f=S2000&n=1616\\_11](https://www.njleg.state.nj.us/bill-search/2022/S1616/bill-text?f=S2000&n=1616_11).

prohibit PBMs from the following: mandatory mail order pharmacy use, mandatory use of PBM affiliated pharmacies, limited preferred networks, patient incentives to use PBM affiliated pharmacies, spread pricing, and higher reimbursements to PBM affiliated pharmacies. The bill also contained provisions that addressed contract changes, offered 340B protections and applied to most commercial plans in Kentucky.

**iv. Kansas**

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

**2. PBM DRUG PRICE TRANSPARENCY REGULATION**

The push for implementation of laws that would require PBMs to disclose drug pricing, cost information regarding rebates, payments, and their fees collected from pharmaceutical manufacturers, insurers, and pharmacies has begun in many states.<sup>109</sup> The following states have proposed or implemented laws requiring transparency reporting: Delaware, Iowa, Michigan, Minnesota, New York, Oklahoma, Oregon, Texas, Washington, and West Virginia.

**3. OTHER RELEVANT STATE LAWS AND PROPOSED LAWS**

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

**Affordability Review and Upper Payment Limits**

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

**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.

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<sup>109</sup> Colleen Becker, A. G. (2022, March 23). *State Policy Options and Pharmacy Benefit Managers (PBMs)*. State policy options and Pharmacy Benefit Managers (PBMs). Retrieved September 6, 2022, from <https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx>

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

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

### **Importation**

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

### **State Purchasing Pool Buy-in**

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

### **Licensing Pharmaceutical Representatives**

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

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

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

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

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

Beginning no later than one year after the proposed legislation's adoption, the act mandates that PBMs provide the following data to the FTC annually: 1) the difference between the sum that each health plan paid the PBM

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

The Senate Committee on Commerce, Science, and Transportation and the House Committee on Energy and Commerce would also need to receive two reports from the FTC-- one on general enforcement actions under the act and the other on PBM formulary design or placement practices. Under the proposed legislation, an annual report on enforcement activity would be filed. The report would include: 1) an anonymized summary of the annual reports that PBMs have submitted to the FTC; 2) the number of enforcement actions the FTC brought to enforce the act and the results of those actions; 3) the number of investigations and inquiries into potential violations of the act; 4) the number and nature of complaints the FTC received alleging violations of the act; and 5) recommendations for strengthening enforcement actions in response to violations of the act.

The agency's report to Congress on PBM formulary design or placement practices would be due within a year of the proposed law's passage. It would include information on whether PBMs use formulary design or placement to boost gross revenue without also enhancing patient access or lowering patient costs, as well as whether such PBM activities violate section 5(a) of the Federal Trade Commission Act (45 U.S.C. 45(a)). Employees in the healthcare sector who report violations of the act or take part in administrative, judicial, or investigative processes to enforce its provisions would not be fired, demoted, suspended, reprimanded, or subject to any other type of punishment under the proposed legislation. The proposed legislation also forbids companies from requiring employees to sign pre-dispute arbitration agreements in exchange for employment to make them give up their right to whistleblower protections under the act. The FTC and state attorneys general are given permission to carry out the proposed legislation's enforcement measures. Additionally, under the proposed law, offenders might face extra civil penalties of up to \$1 million in addition to the penalties provided under the Federal Trade Commission Act (15 U.S.C. 41 et seq.). The bill was adopted and forwarded to the full Senate by the Senate Committee on Commerce, Science, and Transportation on June 22, 2022.<sup>110</sup>

Additionally, the Act would incentivize fair and transparent PBM practices by providing exceptions to liability for PBMs that pass along 100 percent of rebates to health plans or payors and fully disclose prescription drug rebates, costs, prices, reimbursements, fees, and other information to healthcare plans, payors, pharmacies, and federal agencies.<sup>111</sup>

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<sup>110</sup> Jang, T., & Shotlander, D. (2022, September 28). *Senate bill and FTC 6(b) study turn the heat on pharmacy benefit managers amid drug pricing concerns*. Food and Drug Law Institute (FDLI). Retrieved October 6, 2022, from <https://www.fdpi.org/2022/09/senate-bill-and-ftc-6b-study-turn-the-heat-on-pharmacy-benefit-managers-amid-drug-pricing-concerns/>.

<sup>111</sup> Dowell, M. A. (2022, August 16). *State PBM regulations protecting community pharmacies*. U.S. Pharmacist – The Leading Journal in Pharmacy. Retrieved September 6, 2022, from <https://www.uspharmacist.com/article/state-pbm-regulations-protecting-community-pharmacies>.



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

## 2. THE FEDERAL TRADE COMMISSION

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

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

## G. KEY JURISPRUDENCE

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

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

In *Rutledge v. PCMA*, the U.S. Supreme Court held that ERISA did not preempt an Arkansas law, Act 900, which required PBMs<sup>114</sup> to reimburse pharmacies at a price equal to or higher than what the pharmacy paid to buy the drug. Act 900 required PBMs to provide administrative appeal procedures for pharmacies to challenge reimbursement prices that are below the pharmacies' acquisition costs, and it also authorized pharmacies to decline to dispense drugs when a PBM would provide a below-cost reimbursement. Unlike the PBM laws in some states, Act 900 was not strictly structured as an insurance law. It applied to all transactions between PBMs and pharmacies, including transactions where the PBM was acting on behalf of a self-insured ERISA plan, so Arkansas could not rely on the saving clause as its defense against an ERISA preemption challenge.

In a suit brought by the PCMA, a national trade association representing 11 PBMs, the Eastern District of Arkansas ruled that Act 900 was preempted by ERISA, and the Eighth Circuit affirmed.<sup>115</sup> Both courts relied on a recent Eighth Circuit decision striking down a similar Iowa law because it "made 'implicit reference' to ERISA by

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

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

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

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

regulating PBMs that administer benefits for ERISA plans”<sup>116</sup> and “was impermissibly ‘connected with’ an ERISA plan because, by requiring an appeal process for pharmacies to challenge PBM reimbursement rates and restricting the sources from which PBMs could determine pricing, the law limited the plan administrator’s ability to control the calculation of drug benefits.”<sup>117</sup>

The U.S. Supreme Court, however, concluded that “[t]he logic of *Travelers* decides this case,”<sup>118</sup> and ruled that Act 900 was not preempted by ERISA. The Court compared its decisions in *Gobeille*, where it held that a state law is preempted if it “governs a central matter of plan administration or interferes with nationally uniform plan administration,”<sup>119</sup> and *Travelers*, where it held that ERISA does not preempt state price regulations that “merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage,”<sup>120</sup> even if the law “affects an ERISA plan or causes some non-uniformity in plan administration.”<sup>121</sup> The Court explained that ERISA is “primarily concerned with preempting laws that require ... structure[ing] benefit plans in particular ways, such as by requiring payment of specific benefits, or by binding plan administrators to specific rules for determining beneficiary status. A state law may also be subject to pre-emption if ‘acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage.’”<sup>122</sup> The Court observed that Act 900 “does not require plans to provide any particular benefit to any particular beneficiary in any particular way,”<sup>123</sup> and determined that like the law at issue in *Travelers*, “Act 900 is merely a form of cost regulation.”<sup>124</sup>

The Court reviewed the standards it has established for interpreting ERISA’s preemption clause, which preempts all state laws “insofar as they ... relate to any employee benefit plan”<sup>125</sup> unless some exception to preemption applies. The Court explained that a state law triggers the preemption clause when it “has a connection with or reference to” an ERISA plan.<sup>126</sup> The Court rejected the PCMA’s contention “that Act 900 has an impermissible connection with an ERISA plan because its enforcement mechanisms both directly affect central matters of plan administration and interfere with nationally uniform plan administration.”<sup>127</sup> The Court acknowledged that Act 900 required ERISA plan administrators to “comply with a particular process” and standards,<sup>128</sup> but explained that those enforcement mechanisms “do not require plan administrators to structure their benefit plans in any particular manner, nor do they lead to anything more than potential operational inefficiencies” for PBMs.<sup>129</sup> The Court held further that ERISA did not preempt Act 900’s decline-to-dispense provision, even though it “effectively denies plan beneficiaries their benefits” because any denial of benefits would be the consequence of the lawful state regulation of reimbursement rates and the PBM’s refusal to comply.<sup>130</sup>

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

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

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

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

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

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

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

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

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

<sup>125</sup> 29 U.S.C. § 1144(a).

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

<sup>127</sup> *Id.* at 481–482.

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

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

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

Finally, the Court rejected the PCMA’s claim that the law had an impermissible “reference to” ERISA. As the Court explained, Act 900 “applies to PBMs whether or not they manage an ERISA plan,” and Act 900 did not treat ERISA plans differently than non-ERISA plans.<sup>131</sup> However, the Court only considered the provisions of the Arkansas PBM law as they stood at the time the PCMA filed its preemption challenge, not the amendments the legislature subsequently made while *Rutledge* was making its way through the appellate courts. Additionally, the Court did not address preemption under Medicare Part D.

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

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

Ultimately, the court determined that none of the challenged provisions met the “connection-with” standard and all survived preemption by ERISA.<sup>132</sup> The court concluded that some of the state law provisions “merely authorize pharmacies to do certain things,” such as:

- disclose certain information to plan sponsors;
- provide relevant information to patients;
- mail or deliver drugs to patients as an ancillary service; and
- charge shipping and handling fees to patients who request that their prescriptions be mailed or delivered.<sup>133</sup>

The court also upheld provisions that “constitute, at most, regulation of a noncentral ‘matter of plan administration’ with de minimis economic effects.”<sup>134</sup> The court held that “whatever modest non-uniformity in plan administration [the sections] might cause does not warrant preemption.”<sup>135</sup> These provision include:

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

In *Wehbi*, the court expands upon *Rutledge* in that the North Dakota statutes go beyond health care price/cost regulation and into disclosure requirements of PBMs, by prohibiting PBMs from preventing pharmacies from disclosing certain information (in compliance with HIPAA) to patients or plan sponsors. The court stops short of saying that PBM regulation cannot be preempted by ERISA. North Dakota’s laws, the court concluded, amount to regulation of a PBMs’ functions, rather than regulation of an ERISA plan itself so they are not preempted by ERISA.

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

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

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

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

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

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

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

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

2. Do the state laws otherwise frustrate the purpose of a federal Medicare Part D standard? If yes, then they are *impliedly* preempted.<sup>136</sup>

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

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

The Oklahoma laws at issue protects Oklahoma consumers and their access to pharmacy providers and protects Oklahoma pharmacies from certain self-dealing and self-serving practices of PBMs that can harm consumers and put rural and independent pharmacies out of business. Relying on *Rutledge*, the court concluded that all of PCMA’s ERISA preemption claims fail as a matter of law. The court holds that “[the provisions] do not have a ‘connection with’ an ERISA plan” and that “[w]hile these provisions may alter the incentives and limit some of the options that an ERISA plan can use, none of the provisions forces ERISA plans to make any specific choices.” Finally, with regard to the Promotional Materials provision, the court holds that the law “does not regulate benefit design disclosures to beneficiaries but regulates how PBMs can advertise its providers” and that it “does not relate to a central matter of plan administration nor undermine the uniform regulation of ERISA plans.”

As it relates to PCMA’s ERISA preemption claim in totality, the court found that ERISA does not preempt enforcement of the following: “any willing provider” provisions; retail pharmacy network access standards; affiliated pharmacy prohibition; network provider choice restrictions; probation-based pharmacy limitations; cost sharing discounts; promotional material prohibitions; post-sale price reduction prohibitions; and affiliated pharmacy price match prohibitions on PBMs from reimbursing a pharmacy an amount less than the amount the PBM reimburses to a pharmacy it owns or is affiliated with.<sup>137</sup>

With respect to preemption by Medicare Part D, the court found that about half of the PCMA’s preemption claims failed, while about half were meritorious. Specifically, the court ruled that Medicare Part D *does* preempt these provisions in the Act: retail pharmacy network access standards; promotional material prohibitions; cost sharing discounts; service fee prohibitions; post-sale price reduction prohibitions; and affiliated pharmacy price

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

<sup>137</sup> 36 O.S. § 6961 (OSCN 2023) available at (last accessed February 27, 2023):

<https://www.oscn.net/applications/oscn/deliverdocument.asp?lookup=Previous&listorder=167560&dbCode=STOKST36&year=>

match prohibitions on PBMs from reimbursing a pharmacy an amount less than the amount the PBM reimburses to a pharmacy it owns or is affiliated with.<sup>138</sup>

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

## H. RECOMMENDATIONS

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

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

The Subgroup recognizes the critical role that the pharmaceutical drug ecosystem plays on consumer costs and the role states can play in understanding and best regulating the ecosystem. The body of knowledge gained by

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<sup>138</sup> 36 O.S. § 6961 (OSCN 2023) available at (last accessed February 27, 2023):  
<https://www.oscn.net/applications/oscn/deliverdocument.asp?lookup=Previous&listorder=167560&dbCode=STOKST36&year=>

the subgroup over the last two years, and related resources provided to state regulators provides a solid foundation to continue to examine these key issues.

**APPENDIX I.**

Meeting #	Date	Presenter/Topic
Meeting #1	August 15, 2019	<ul style="list-style-type: none"> <li>• Jane Horvath (Horvath Health Policy and Research Faculty, Georgetown University) presentation on “Basics of the Pharmaceutical Market &amp; PBMs.”</li> <li>• Leanne Gassaway (America’s Health Insurance Plans—AHIP) presentation on “Pharmacy Benefit Managers Overview &amp; Background.”</li> </ul>
Meeting #2	August 22, 2019	<ul style="list-style-type: none"> <li>• Dr. Neeraj Sood (Sol Price School of Public Policy, University of Southern California) presentation on “PBM Economics.”</li> <li>• Saiza Elayda (Pharmaceutical Research and Manufacturers of America—PhRMA) presentation on the pharmaceutical supply chain and how the pharmaceutical distribution and payment system shapes the prices of brand name medicines.</li> </ul>
Meeting #3	August 29, 2019	<ul style="list-style-type: none"> <li>• April Alexander (Pharmaceutical Care Management Association—PCMA) and J.P. Wieske (Horizon Government Affairs) presentation on the history, role, and services PBMs provide in managing prescription drug benefits.</li> <li>• Anne Cassity (National Community Pharmacists Association—NCPA) and Matthew Magner (NCPA) presentation on the community pharmacy industry’s perspective regarding PBMs and managing prescription drug benefits.</li> <li>• Claire McAndrew (Families USA) discussed the effect of PBMs and prescription drug costs on consumers.</li> <li>• Amy Killelea (National Alliance of State and Territorial AIDS Directors—NASTAD) discussed PBMs and their impact on consumer access and affordability of prescription drugs.</li> </ul>
Meeting #4	October 3, 2019	<ul style="list-style-type: none"> <li>• Kentucky discussed its PBM licensing process.</li> <li>• Arkansas discussed its PBM licensing law and other provisions related to PBM business practices.</li> <li>• Montana discussed the history, purpose, and provisions of S.B. 71 to address issues related to PBMs, which</li> </ul>

Meeting #	Date	Presenter/Topic
		<p>passed in the legislature but was ultimately vetoed by the Governor.</p> <ul style="list-style-type: none"> <li>• New Mexico discussed its PBM law focusing on its reimbursement provisions.</li> <li>• Oregon discussed its PBM law, including its PBM registration requirements, and Oregon’s Prescription Drug Price Transparency program.</li> </ul>
Meeting #5	December 11, 2021	<ul style="list-style-type: none"> <li>• North Dakota discussion on the <i>Pharmaceutical Care Management Association (PCMA) v. Wehbi</i> ruling.</li> <li>• Connecticut discussion on its PBM law and white paper.</li> <li>• Virginia discussion on its PBM law.</li> <li>• Oklahoma discussion on its PBM law and the <i>PCMA v. Mulready</i> case.</li> <li>• Wisconsin discussion on the work of the Governor’s Task Force on Reducing Prescription Drug Prices and its PBM law.</li> </ul>
Meeting #6	March 16, 2022	<ul style="list-style-type: none"> <li>• Montana discussion on its PBM law.</li> <li>• Employee Retirement Income Security Act (ERISA) (B) Working Group update on the U.S. Supreme Court’s ruling in <i>Rutledge v. PCMA</i> and the <i>ERISA Handbook</i> analysis and case summary.</li> </ul>
Meeting #7	April 4, 2022	<ul style="list-style-type: none"> <li>• Oklahoma update on its PBM law.</li> <li>• Oregon discussion on its PBM law and transparency in prescription drug pricing and Oregon Prescription Drug Affordability Board (PDAB) initiatives.</li> <li>• Discussion from a consumer perspective on the Subgroup’s charge to develop a white paper on PBMs and their business practices.</li> </ul>
Meeting #8	April 25, 2022	<ul style="list-style-type: none"> <li>• Dr. Neeraj Sood and Dr. Karen Van Nuys, University of Southern California (USC) Price School on Public Policy- presentation on “How Well Are PBM Markets Functioning?”</li> </ul>
Meeting #9	June 15, 2022	<ul style="list-style-type: none"> <li>• National Community Pharmacists Association (NCPA) presentation on the Subgroup’s charge to develop a</li> </ul>



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

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/PBM Regulatory Issues Subgrp/PBM White Paper Draft 4 16 23.docx

*Adopted by the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup – 7/27/23*

Draft: 7/21/23

# 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.

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

## 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.<sup>1</sup> However, increased costs of pharmaceutical drugs, several active campaigns by players in the ecosystem, increased federal and state attention on drug pricing, and drug price transparency programs have all operated to raise the consumer's knowledge of the cost levers of pharmaceutical drugs.

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

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

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

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

## **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**

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

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

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

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

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.<sup>8</sup> The development of a new pharmaceutical product involves an investment of resources to create a product ready to be tested during clinical trials, where the safety and clinical efficacy of the drug are evaluated for a specific disease or condition.<sup>9</sup> 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)

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

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

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

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

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

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

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



reviews all applications for the sale of new drugs from manufacturers following clinical trials and decides whether the drug will be made available on the market to consumers.<sup>10</sup> When a drug is approved, manufacturers then set the list price for medications and may change that price over time.<sup>11</sup>

## 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.<sup>12</sup> Manufacturers of these patent-protected brand-name products have market exclusivity to produce and sell their products during the life of the patent before therapeutically equivalent generic drugs can become available on the market.<sup>13</sup>

## 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.<sup>14</sup> Generic drugs comprise the largest portion of the pharmaceutical market, approximately 90 percent of all drugs dispensed to consumers.<sup>15</sup>

## 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.<sup>16</sup> Biologics are sometimes referred to as “large-molecule drugs.” Manufacturers of biologic drug products are also required to receive approval from the FDA to sell their products through a separate application process.<sup>17</sup> Biologics approved by the FDA are granted 12 years of exclusivity, which is substantially longer than the five years typically granted to traditional small-molecule brand-name drugs.<sup>18</sup> A biosimilar drug product may be produced following the expiration of the biologic’s patent and exclusivity period.<sup>19</sup>

## 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

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

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

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

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

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

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

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

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

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

<sup>19</sup> 42 U.S.C. §262(k).

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.<sup>20</sup>

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).<sup>21</sup> 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.<sup>22</sup> 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.<sup>23</sup> PBMs design, negotiate, implement, and manage formulary designs for prescription drugs, including negotiating rebates and drug coverage terms with pharmaceutical manufacturers.<sup>24</sup> PBMs are responsible for the design and implementation of preferred and non-preferred pharmacy networks, metric-based payment arrangements, and formulary design elements (drug coverage, out-of-pocket responsibilities for patients and utilization management protocols).<sup>25</sup> PBMs engage in the negotiation and financial transactions between pharmaceutical manufacturers, health plans, and pharmacies.<sup>26</sup>

### **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.<sup>27</sup>

#### **2. INDEPENDENT**

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

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

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

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

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

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

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

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

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

#### **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.<sup>29</sup> In the majority of cases, an independent pharmacy's contract is with the PSAO, rather than with the PBM directly. The PSAO overall administrative function is to assist with contract evaluation and execution, customer service, central payment and reconciliation, and patient data evaluation.<sup>30</sup> In many instances a PSAO is owned by a wholesaler.<sup>31</sup>

#### **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.

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

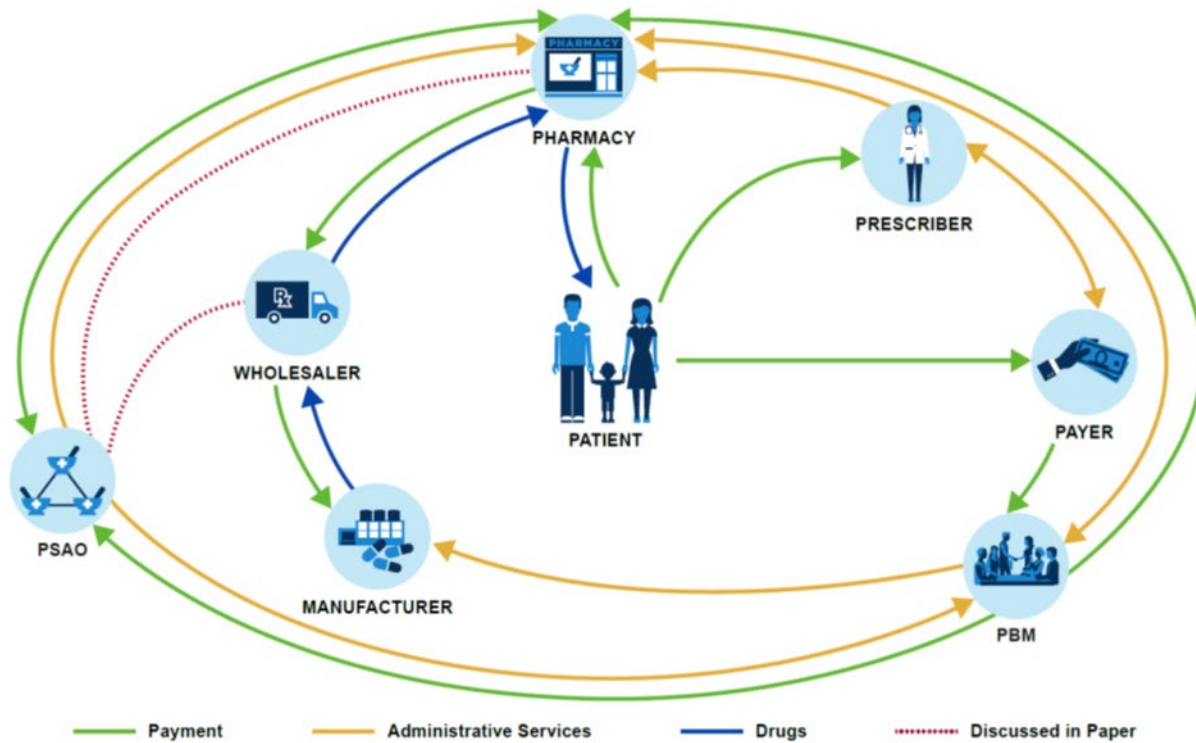
<sup>29</sup> "A Tangled Web", at p. 34, 41.

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

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

## 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.<sup>32</sup>



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.<sup>33</sup> The average negotiated price is based on the wholesale acquisition cost (WAC) price set by the manufacturer.<sup>34</sup>

#### *Wholesaler and pharmacy*

The wholesaler sells their drugs to a pharmacy in an amount based on the WAC.<sup>35</sup> There are additional savings that can be achieved via volume rebates, functional rebates, bundle rebates, prompt pay discounts, free goods, marketing funds, and trade show discounts/rebates. The average wholesale price (AWP) is an estimate of the

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

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

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

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

price wholesalers charge for drugs.<sup>36</sup> 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.<sup>37</sup>

#### *Pharmacy and consumer*

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

## **2. Pharmacy Benefit Management Chain**

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

#### *Pharmaceutical manufacturer and PBM*

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

#### *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.<sup>40</sup>

#### *PBM and PSAO*

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

#### *Pharmacy and PBM*

The pharmacy negotiates with the PBM to determine a reimbursement rate for the drugs they dispense.<sup>43</sup> 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.<sup>44</sup> In addition, PBMs negotiate a dispensing fee with the pharmacies. Actual Acquisition Cost (AAC) is the final price a pharmacy pays after all discounts have been subtracted.<sup>45</sup>

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

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

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

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

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

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

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

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

<sup>44</sup> Horvath.

<sup>45</sup> Horvath.

### *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.<sup>46</sup>

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.<sup>47</sup> 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.<sup>48</sup>

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)**

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

<sup>47</sup> Horvath.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (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*<sup>56</sup>, the lower court relied on *Rutledge* to conclude that Oklahoma's PBM law was not preempted by ERISA (the court's additional reasoning related to Medicare preemption is discussed below). The statute at issue in *Mulready* regulates both the network status of particular pharmacies as well as the conditions under which a PBM may reimburse for prescriptions, which 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.

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

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

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

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



Medicare Part C, or “Medicare Advantage (MA)” program, which provides: “the standards established under this part shall supersede any state law or regulation (other than state licensing laws or state laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.”<sup>58</sup>

In general, courts have found that state laws are preempted under Medicare Part D where Congress or the CMS have established “standards” for the area regulated by said state laws. This means that the authority of states to regulate MA or Medicare Part D plans is significantly limited, though states explicitly retain the authority to regulate plan solvency. The Medicare Managed Care Manual indicates that state law should only be preempted where it would be impossible for a carrier to comply with both state and federal standards – a state standard that is stricter than the Medicare standard should not be preempted. However, courts have held that standards set by the CMS do not necessarily need to 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).<sup>59</sup>

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

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

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

Finally, the district court rejected the PCMA’s challenge to Oklahoma’s contract approval provisions.<sup>63</sup> Under the Oklahoma statute, insurers who utilize the services of PBMs are required to approve all contracts between the PBM and the PBMs retail pharmacy network. In this instance, the PCMA again pointed to Medicare Part D’s ban on interference in contract negotiations. However, the district court reasoned that Medicare Part D’s bar applies only to negotiations between plan sponsors and PBMs, while Oklahoma’s law regulates negotiations between

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<sup>58</sup> 42 CFR § 422.402.

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

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

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

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

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

PBMs and pharmacies. Accordingly, the district court concluded that the contract approval provisions of Oklahoma’s law are not preempted by Medicare Part D.

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

### 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.<sup>64</sup> It is structured very differently from either Medicare Part D or ERISA. Both Medicare and ERISA were set up with the intent of establishing uniformity of implementation nationwide – making preemption of state laws that conflict with the federal plan an important element of the program’s structure. Medicaid, however, is structured as a federal-state partnership and its implementation varies significantly from state to state. This means that the 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.<sup>65</sup> Any changes a state makes to Medicaid implementation must also be approved by the CMS via a plan amendment process.<sup>66</sup> In some cases, states may also receive a waiver from certain terms of the Medicaid provisions in the Medicare and Medicaid Act (herein referred to as the Medicaid Act) under Section 1115 of the Social Security Act. So long as the PBM regulation is consistent with the terms of the state’s current Medicaid plan, it should be safe from federal preemption.

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

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

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

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

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

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

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<sup>67</sup>. PBMs' customers – payors, such as insurers or self-funded employer plans, may request open formularies, develop their own formularies, or purchase formularies from PBMs. Even closed formularies typically require coverage for at least one drug per therapeutic class.

For PBM developed formularies, PBMs 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.<sup>68</sup> The federal Affordable Care Act (ACA) introduced federal regulations on P&T Committees serving qualified health plans (QHPs).

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

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.<sup>70</sup> By placing a drug in a preferred tier, PBMs can drive volume to that drug's manufacturer. This is an

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

<sup>68</sup> Horvath.

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

<sup>70</sup> Oregon Drug Price Transparency Report of 2019 at 10-11, available at:

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

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."<sup>71</sup>

## **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.<sup>72</sup>

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.<sup>73</sup> PBMs negotiate based on their volume of scale to obtain highest rebate for selected drugs.<sup>74</sup> From the PBM's perspective, a large rebate results in a smaller amount spent by their customers and more income for the PBM from proportional pass-through contracts.<sup>75</sup>

Rebates are negotiated separately with each plan sponsor and can take different forms in how they are passed along:<sup>76</sup>

- 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

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

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

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

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

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

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

cost to the plan sponsor or consumer.<sup>77</sup> 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.<sup>78</sup>
- Rebates at point-of-sale (POS): Some believe that rebates should be provided directly to consumers at POS to reduce deductibles or co-insurance amounts owed when the drug is purchased. As a result, these funds would no longer be used to offset the plan sponsor costs and could result in higher premiums for all members. Additionally, members with low or no prescription drug usage might experience a disproportional impact as they would be paying higher premiums and would not have a financial benefit from the POS rebates. Some insurers have indicated that passing the rebates to the consumer at POS would have a dramatic enough effect on drug adherence that it would cover the potential benefit of using the rebates against premiums and result in no additional premium cost.<sup>79</sup>
- 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.<sup>80</sup>

### 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.<sup>81</sup> 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.<sup>82</sup>
- Mandatory arbitration clause: Most PBMs require that disputes be submitted to binding arbitration by including a mandatory arbitration provision in their pharmacy contracts. Some believe mandatory

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

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

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

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

<sup>81</sup> Sood.

<sup>82</sup> “A Tangled Web,” p. 33, 44; National Conference of State Legislatures Glossary of PBM terms, available at:

[State Policy Options and Pharmacy Benefit Managers \(ncsl.org\)](https://www.ncsl.org/state-policy/state-policy-options-and-pharmacy-benefit-managers).

arbitration limits legal recourse for individual pharmacies and results in pharmacies foregoing potentially successful audit challenges.<sup>83</sup>

- 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.<sup>84</sup>
- MAC transparency: A maximum allowable cost (MAC) list is a list that includes the maximum amount that a plan will pay for certain drugs.<sup>85</sup> MAC lists are often generated by the PBM. There is no standardization in the industry as to the criteria for the inclusion of drugs on MAC lists or for the methodology as to how the maximum price is determined, changed or updated. PBMs may sometimes use multiple MAC lists and pocketing the spread between the two. For example, PBMs might use a very low MAC list to reimburse pharmacies but a higher list when charging plan sponsors.<sup>86</sup>
- Rebates: Rebates may provide incentive for a PBM to eliminate a less expensive, comparable medication from a formulary. Pharmaceutical manufacturers claim that these rebates are meant to be shared with plan sponsors or passed on to consumers in the form of lower drug prices. However, PBMs regularly keep a share of the rebates before passing the rest through to the plan sponsor.<sup>87</sup>
- 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.<sup>88</sup>
- 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.<sup>89</sup> The entities

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<sup>83</sup> Oestreicher.

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

<sup>85</sup> National Conference of State Legislatures Glossary of PBM terms, available at:

[State Policy Options and Pharmacy Benefit Managers \(ncsl.org\)](https://www.ncsl.org/state-policy/state-policy-options-and-pharmacy-benefit-managers).

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

<sup>87</sup> Horvath.

<sup>88</sup> Oestreicher.

<sup>89</sup> Sood.

at the various levels of the integrated enterprise may deal exclusively with the parent company's goods or services or may offer non-integrated products or services.<sup>90</sup>

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

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

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

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

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

- Perform fewer generic substitutions;

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

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

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

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

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

<sup>95</sup> Sood.

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

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

- 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.<sup>98</sup> Pharmacy network adequacy is often defined as the distance between a patient’s residence and where services can be physically accessed.

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

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

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

About 35 percent of the states have some type of legislation that addresses PBM’s placing heightened accreditation requirements upon pharmacies seeking to join the PBM’s networks.<sup>100</sup> When this is the case, common legislative elements include prohibiting PBMs from imposing provider accreditation standards or certification requirements inconsistent with, or more stringent than the requirements of the state board of pharmacy or other state/federal agencies. Typically, the PBM must apply standards without regard to PBM

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

<sup>99</sup> National Conference of State Legislatures Glossary of PBM terms, available at: [State Policy Options and Pharmacy Benefit Managers \(ncsl.org\)](https://www.ncsl.org/state-policy/state-policy-options-and-pharmacy-benefit-managers).

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



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.<sup>101</sup> Sometimes PBMs will even mine members’ health data in an attempt to steer them to the PBM’s affiliated pharmacies. This practice has become more popular as the number of health insurance companies that own PBMs has increased. Steering can limit a member’s choice, increase costs, and lower quality of care to members.

Anti-steering state legislation typically prohibits PBMs from requiring drugs to be dispensed from specific contracted or affiliated pharmacies and prohibits PBMs from assessing additional fees when a prescription is filled by an in-network contracted pharmacy, but which is not specifically authorized by the PBM to fill certain types of prescriptions as a “specialty pharmacy.” 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.<sup>102</sup>

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

## **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.

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<sup>101</sup> Sood.

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

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.<sup>103</sup> 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

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

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.<sup>104</sup>

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.<sup>105</sup> 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**

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

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

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.<sup>106</sup>

### **1. Florida**

Florida recently enacted new laws effective July 1, 2023, regulating prescription drug manufacturers and PBMs.<sup>107</sup> 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

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<sup>106</sup>See generally, PBM Law Compilations, available at: [https://content.naic.org/cmte\\_b\\_pharmacy\\_bmri\\_sg.htm](https://content.naic.org/cmte_b_pharmacy_bmri_sg.htm).

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

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.<sup>108</sup>

### 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.<sup>109</sup> 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

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<sup>108</sup> S.B. 220, 2022, 2022-2023 Reg. Sess. (NJ.2022). [https://www.njleg.state.nj.us/bill-search/2022/S1616/bill-text?f=S2000&n=1616\\_11](https://www.njleg.state.nj.us/bill-search/2022/S1616/bill-text?f=S2000&n=1616_11).

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

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.<sup>110</sup>

### **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.<sup>111</sup>

### **2. Drug Manufacturer Transparency**

As drug costs have now become the largest expenditure of the premium dollar<sup>112</sup>, 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.<sup>113</sup>

### **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:

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

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

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

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

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

### **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 forbade 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.<sup>114</sup> 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.<sup>115</sup>

## **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 vis 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<sup>116</sup> to reimburse pharmacies at a price equal to or higher than what the pharmacy paid to buy the drug. Act 900 required PBMs to provide administrative appeal procedures for pharmacies to challenge reimbursement prices that are below the pharmacies' acquisition costs, and it also authorized pharmacies to

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

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

<sup>116</sup> As the term is spelled in Act 900. Supreme Court style refers to “pharmacy benefit managers.”

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.<sup>117</sup> Both courts relied on a recent 8<sup>th</sup> Circuit decision striking down a similar Iowa law because it “made ‘implicit reference’ to ERISA by regulating PBMs that administer benefits for ERISA plans”<sup>118</sup> and “was impermissibly ‘connected with’ an ERISA plan because, by requiring an appeal process for pharmacies to challenge PBM reimbursement rates and restricting the sources from which PBMs could determine pricing, the law limited the plan administrator’s ability to control the calculation of drug benefits.”<sup>119</sup>

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

The Court reviewed the standards it has established for interpreting ERISA’s preemption clause, which preempts all state laws “insofar as they ... relate to any employee benefit plan”<sup>127</sup> unless some exception to preemption applies. The Court explained that a state law triggers the preemption clause when it “has a connection with or reference to” an ERISA plan.<sup>128</sup> The Court rejected the PCMA’s contention “that Act 900 has an impermissible connection with an ERISA plan because its enforcement mechanisms both directly affect central matters of plan administration and interfere with nationally uniform plan administration.”<sup>129</sup> The Court acknowledged that Act

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

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

<sup>119</sup> *Id.* at 479, quoting *Gerhart*, 852 F.3d at 726, 731.

<sup>120</sup> *Id.* at 481.

<sup>121</sup> *Id.* at 480, quoting *Gobeille*, 577 U.S. at 320.

<sup>122</sup> *Id.* at 480, citing *Travelers*, 514 U.S. at 668.

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

<sup>124</sup> *Id.*, quoting *Gobeille*, 577 U.S. at 320.

<sup>125</sup> *Id.* at 482.

<sup>126</sup> *Id.* at 481.

<sup>127</sup> 29 U.S.C. § 1144(a).

<sup>128</sup> 141 S.Ct. at 477.

<sup>129</sup> *Id.* at 481–482.

900 required ERISA plan administrators to “comply with a particular process” and standards,<sup>130</sup> but explained that those enforcement mechanisms “do not require plan administrators to structure their benefit plans in any particular manner, nor do they lead to anything more than potential operational inefficiencies” for PBMs.<sup>131</sup> 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.<sup>132</sup>

Finally, the Court rejected the PCMA’s claim that the law had an impermissible “reference to” ERISA. As the Court explained, Act 900 “applies to PBMs whether or not they manage an ERISA plan,” and Act 900 did not treat ERISA plans differently than non-ERISA plans.<sup>133</sup> However, the Court only considered the provisions of the Arkansas PBM law as they stood at the time the PCMA filed its preemption challenge, not the amendments the legislature subsequently made while *Rutledge* was making its way through the appellate courts, 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 8<sup>th</sup> Circuit Court of Appeals issued its decision in *PCMA v. Wehbi*. This case was not appealed to the U.S. Supreme Court. At issue in the *Wehbi* case were two North Dakota laws prohibiting PBMs from engaging in deceptive and anti-competitive practices.

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

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

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

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<sup>130</sup> *Id.* at 482, quoting PCMA brief at 24.

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

<sup>132</sup> *Id.*

<sup>133</sup> *Id.* at 481.

<sup>134</sup> 18 F.4<sup>th</sup> 956, 968.

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*, quoting *Gobeille*, 577 U.S. 312, 320.

<sup>137</sup> *Id.*, citing *Rutledge*, 141 S. Ct. at 480.

- 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.<sup>138</sup>

### **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.

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 court concluded that all of PCMA’s ERISA preemption claims fail as a matter of law. The court holds that “[the provisions] do not have a ‘connection with’ an ERISA plan” and that “[w]hile these provisions may alter the incentives and limit some of the options that an ERISA plan can use, none of the provisions forces ERISA plans to make any specific choices.” Finally, regarding the Promotional Materials provision, the court holds that the law “does not regulate benefit design disclosures to beneficiaries but regulates how PBMs can advertise its providers” and that it “does not relate to a central matter of plan administration nor undermine the uniform regulation of ERISA plans.”

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<sup>138</sup> *Id.* at 972.

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

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

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

## VIII. RECOMMENDATIONS

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

1. The NAIC should consider tasking the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup or similar group with drafting a model guideline to address PBM regulation based on other state laws and recent jurisprudence;
2. The NAIC should consider expanding information sharing between the states through additional committees on the topic of pharmaceutical drug pricing and transparency;
3. The NAIC should consider any necessary updates to the *Health Carrier Prescription Drug Benefit Management Model Act* (#22) out of the emergence of greater regulation in the prescription drug ecosystem;
4. The NAIC should consider impacts of this work on an ongoing basis on the federal 340B Drug Pricing Program;

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

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

5. The NAIC should consider facilitating and maintaining a nationwide database of PBM contracting provisions. This would allow states to become familiar with common PBM contractual provisions and more easily identify issues that arise from them;
6. The NAIC should consider developing an open dialogue with Federal agencies that is broader than just PBM regulation. The discussion should consider regulation of all the stakeholders in the prescription drug ecosystem from a more holistic view and may be best achieved through a coordinated effort involving state and federal regulators; and
7. This Subgroup, and successive groups, should continue to maintain a current listing of PBM laws and regulations and case law for reference by other states.

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

**APPENDIX I. LIST OF SUBGROUP MEETINGS AND TOPICS**

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



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

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

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