REGULATORY FRAMEWORK (B) TASK FORCE

Regulatory Framework (B) Task Force March 25, 2025, Minutes

- Regulatory Framework (B) Task Force March 10, 2025, Minutes (Attachment One)
  - Adopted Revised 2025 Charges for the Prescription Drug Coverage (B) Working Group (Attachment One-A)
- Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group March 25, 2025, Minutes (Attachment Two)
  - Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group Nov. 18, 2024, Minutes (Attachment Two-A)
- Prescription Drug Coverage (B) Working Group March 24, 2025, Minutes (Attachment Three)
  - Pharmaceutical Benefit Management Regulatory Issues (B) Working Group Nov. 18, 2024, Minutes (Attachment Three-A)

Draft Pending Adoption

Draft: 3/31/25

Regulatory Framework (B) Task Force
Indianapolis, Indiana
March 25, 2025

The Regulatory Framework (B) Task Force met in Indianapolis, IN, March 25, 2025. The following Task Force members participated: Grace Arnold, Chair (MN); Allan L. McVey, Vice Chair, represented by Joylynn Fix (WV); Lori K. Wing-Heier represented by Sarah Bailey (AK); Peter M. Fuimaono (AS); Barbara D. Richardson represented by Fausto Burruel (AZ); Michael Conway represented by Debra Judy (CO); Andrew N. Mais represented by Jared Kosky (CT); Karima M. Woods represented by Howard Liebers (DC); Michael Yaworsky represented by Sheryl Parker (FL); Doug Ommen represented by Andria Seip (IA); Dean L. Cameron represented by Weston Trexler (ID); Holly W. Lambert represented by Meggan Brumbaugh (IN); Vicki Schmidt represented by Julie Holmes (KS); Sharon P. Clark represented by Shaun Orme (KY); Michael T. Caljouw represented by Kevin P. Beagan (MA); Robert L. Carey represented by Marti Hooper (ME); Angela L. Nelson represented by Jo A. LeDuc and Amy Hoyt (MO); Mike Causey represented by Robert Croom (NC); Jon Godfread represented by Chrystal Bartuska (ND); Eric Dunning represented by Martin Swanson (NE); Scott Kipper represented by Alexia Emmermann (NV); Judith L. French represented by Laura Miller (OH); Glen Mulready represented by Ashley Scott (OK); Andrew R. Stolfi represented by Alex Cheng (OR); Michael Humphreys (PA); Larry D. Deiter represented by Jill Kruger (SD); Cassie Brown represented by Randall Evans (TX); Jon Pike represented by Tanji J. Northrup (UT); Scott A. White represented by Julie Blauvelt (VA); Patty Kuderer represented by Jane Beyer (WA); and Nathan Houdek represented by Rebecca Rebholz (WI).

1. Adopted its March 10, 2025; Feb. 28, 2025; and 2024 Fall National Meeting Minutes

The Task Force met March 10 and Feb. 28. During these meetings, the Task Force took the following action: 1) jointly adopted with the Health Insurance and Managed Care (B) Committee a motion to rename the Pharmaceutical Benefit Management Regulatory Issues (B) Working Group to the Prescription Drug Coverage (B) Working Group; and 2) adopted 2025 revised charges for the Prescription Drug Coverage (B) Working Group reflecting the Working Group's new name and its focus on prescription drug coverage issues and the recently established Pharmacy Benefit Management (D) Working Group focusing on pharmacy benefit management enforcement.

Swanson made a motion, seconded by Trexler, to adopt the Task Force's March 10, 2025 (Attachment One) minutes; Feb. 28, 2025 (*see NAIC Proceedings – Spring 2025, Health Insurance and Managed Care (B) Committee, Attachment One)*, minutes; and Nov. 17, 2024 *(see NAIC Proceedings – Fall 2024, Regulatory Framework (B) Task Force)* minutes. The motion passed unanimously.

2. Adopted its Working Group Reports

Trexler made a motion, seconded by Kosky, to adopt the following working group reports: 1) Employee Retirement Income Security Act (ERISA) (B) Working Group; 2) Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group (Attachment Two); and 3) Prescription Drug Coverage (B) Working Group (Attachment Three). The motion passed unanimously.

3. Heard a Summary of State PA Laws and Presentations on PA from the Provider, Patient and Consumer, and Insurer Perspectives

Commissioner Arnold said the Task Force has been tasked with developing a white paper on prior authorization (PA) arrangements. She said that given this, the Task Force decided to jump-start that work by having its meeting

at the Spring National Meeting focus on the PA issue, starting with an overview of state PA laws and then hearing presentations on the issue from the provider, consumer and patient, and insurer perspectives.

Olivea Myers (NAIC) said the NAIC Research Library and the NAIC Legal Division jointly searched state PA laws and compiled them into a chart included in the Task Force's meeting materials. She said state laws regulating PA fall into several categories, including response times, retrospective denials, clinical criteria, medical necessity, reviewer qualifications, gold carding, and peer-to-peer/appeal process. Myers also discussed state bulletins on PA. She highlighted existing research on the impact of PA reform, such as the federal Centers for Medicare & Medicaid Services (CMS) estimate that $15 billion in savings is due to the implementation of electronic PA (ePA) requirements.

Heather McComas (American Medical Association—AMA) discussed the impact of PA on stakeholders from a physician's perspective. She described AMA member survey responses indicating that PA harms patients. She said 29% of physicians reported that PA has led to a serious adverse event for a patient in their care. She said PA also wastes practice and health care resources. McComas highlighted potential solutions to solve identified problems with the PA process, such as: 1) requiring faster response times; 2) reducing the need for PA for care with high approval rates; and 3) preventing repeated PA requests for already approved treatment. She discussed current PA state and federal reform efforts seeking to implement some of these potential solutions. McComas discussed opportunities for state insurance regulators to address issues with PA, such as: 1) implementing state legislation; 2) enforcing existing laws; 3) pursuing additional data collection; and 4) monitoring and evaluating the impact of the use of artificial intelligence (AI) in PA on patients.

Carl Schmid (HIV+Hepatitis Policy Institute) and Lucy Culp (The Leukemia & Lymphoma Society—LLS) discussed the impact of PA from a patient and consumer perspective. Schmid said consumers and patients impacted by prioritization are frustrated. He said they are having a lot of difficulty and frustration in accessing covered health care services and prescription drugs that they or their employer have paid for in their premiums. Schmid discussed several research studies tracking claim denials and appeals and how difficult it is for consumers to appeal claim denials. He discussed the claim denial rates compiled by HealthCare.gov issuers by state for 2023, noting that the highest percentage of denials did not provide a specific reason for the denial. Schmid also discussed recently enacted state PA laws and states considering passing new PA laws. He also discussed how insurers, such as Blue Cross Blue Shield of Michigan, Cigna, and UnitedHealthcare, are seeking to reduce PA. The federal government has also implemented changes to PA that impact state reform efforts, such as the federal CMS Prior Authorization and Interoperability Final Rule and the federal CMS 2024 Medicare Advantage and Part D Final Rule. Schmid also discussed suggestions for increased transparency of the NAIC Market Conduct Annual Statement (MCAS) health data, such as sharing the full MCAS health data with all stakeholders, not just state insurance regulators.

Culp discussed the NAIC consumer representatives' recommendations for the Task Force as it begins work on the PA white paper. She suggested that the Task Force first identify the challenges that consumers are facing and the policies that states are implementing to solve them. She said the Task Force could identify and include best practices other states could adopt in the white paper. Culp discussed a few challenges consumers face with PA, including misaligned PA criteria. She said such misalignment can be seen in several forms, from excessive and mid-course treatment PA requirements to repeated PA requirements for people with chronic conditions who are stable on the already approved treatment. Culp discussed the implications of such misalignment, including treatment delays or the inability to receive treatment altogether. She also noted that using AI for utilization management creates unique challenges and numerous risks to consumers concerning improper denials, data accuracy, quality testing, governance, and transparency. Culp acknowledged the work happening in the states related to PA reform. She said she anticipates there will be a lot of opportunities for the states to learn from each other and other stakeholders as the Task Force works through the white paper drafting process.

Amanda Motter (America's Health Insurance Plans—AHIP) and Danielle Lloyd (AHIP) discussed the PA issue from an insurer perspective. Motter said PA provides a vital check and balance to ensure patients receive safe, evidence-based care and to reduce low-value and inappropriate services so that coverage is as affordable as possible. She said low-value care significantly impacts the U.S. healthcare system, and more importantly, low-value care impacts patients by exposing them to harm and additional out-of-pocket healthcare costs. Motter said the U.S. spends more on healthcare than any other country in the world, and many experts agree that up to 25% of care is wasteful at best and harmful at worst. She described AHIP's work with physicians and other stakeholders to address this issue. Motter said health plans, doctors, and hospitals all need to work together to reduce the amount of low-value care and protect patients from unnecessary, potentially harmful care and those costs.

Motter explained that health plans use PA selectively and are working to improve the process. She identified efforts health plans are taking to improve PA, including: 1) selective use; 2) ensuring it is evidence-based; 3) utilizing ePA; and 4) waiving or reducing PA for providers with a track record. Lloyd discussed how ePA is improving the process, but there are still challenges with its use and opportunities for improvement. She detailed how ePA is being used and will be required to be used by certain payers by Jan. 1, 2027, as required under the federal CMS Prior Authorization and Interoperability Final Rule. Lloyd also discussed how AI could further streamline and simplify ePA.

Commissioner Arnold asked if there were questions for the presenters. Commissioner Humphreys discussed the work that Pennsylvania has done with respect to PA reform. He asked McComas if the AMA has determined what types of procedures are appropriate for PA. McComas said she would have to check with her colleagues and follow up with him. She noted, however, that right-sizing PA is the key rather than requiring PA for all procedures or eliminating PA altogether. She said there needs to be a sensible approach to its use.

Commissioner Arnold said NAIC staff have already solicited interest from Task Force members and interested regulators to serve on the drafting group that will develop an initial white paper draft. She said that if any Task Force members are interested but have not yet volunteered, they should reach out to her, Fix, or NAIC staff.

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

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Draft: 3/14/25

Regulatory Framework (B) Task Force
Virtual Meeting
March 10, 2025

The Regulatory Framework (B) Task Force met March 10, 2025. The following Task Force members participated: Grace Arnold, Chair (MN); Allan L. McVey, Vice Chair, and Joylynn Fix (WV); Lori K. Wing-Heier represented by Sarah Bailey, (AK); Mark Fowler represented by Yada Horace (AL); Barbara D. Richardson (AZ); Michael Conway represented by Debra Judy (CO); Andrew N. Mais represented by Jared Kosky (CT); Karima M. Woods represented by Howard Liebers (DC); Michael Yaworsky represented by Sheryl Parker (FL); Doug Ommen represented by Andria Seip (IA); Dean L. Cameron (ID); Holly W. Lambert represented by Alex Peck (IN); Vicki Schmidt represented by Kenneth Scott and Josh Carlson (KS); Sharon P. Clark (KY); Michael T. Caljouw represented by Rebecca Butler (MA); Robert L. Carey represented by Robert Wake (ME); Angela L. Nelson (MO); Mike Causey represented by Robert Croom (NC); Jon Godfread represented by Chrystal Bartuska (ND); Eric Dunning (NE); D.J. Bettencourt represented by Michelle Heaton (NH); Justin Zimmerman represented by David Wolf (NJ); Judith L. French represented by Laura Miller (OH); Glen Mulready (OK); Andrew R. Stolfi represented by Jesse O'Brien (OR); Michael Humphreys (PA); Larry D. Deiter represented by Travis Jordan and Ashley Severyn (SD); Cassie Brown represented by Rachel Bowden (TX); Jon Pike represented by Shelley Wiseman and Heidi Clausen (UT); Scott A. White represented by Julie Blauvelt (VA); Patty Kuderer represented by Ned Gaines (WA); and Nathan Houdek represented by Jody Ullman and Rebecca Rebholz (WI).

1. Adopted Revised 2025 Charges for the Prescription Drug Coverage (B) Working Group

Commissioner Arnold said the purpose of the Task Force's meeting was to consider adoption of the 2025 revised charges of the recently renamed Prescription Drug Coverage (B) Working Group. She explained that the revised charges reflect the Working Group's new name and the recently established working group under the Market Regulation and Consumer Affairs (D) Committee focusing on pharmacy benefit manager (PBM) enforcement.

Commissioner Arnold requested comments. For consistency with the other proposed revisions to the charges, Heaton suggested revising charge C to state: "Maintain a current listing of prescription drug laws and regulations and case law for reference by state insurance regulators."

Carl Schmid (HIV+Hepatitis Policy Institute), speaking on behalf of the NAIC consumer representatives, said the NAIC consumer representatives suggest two changes in the proposed revised charges. He said the first suggested change is to strike the word "coverage" in charge A. He explained that while coverage is paramount, there are other components, including costs and pricing. As such, the NAIC consumer representatives recommend that this language be broadened to read "prescription drug regulation." Schmid said the second suggestion is to add "patient costs" to the list of subjects the Working Group is to examine in charge B. He said that while all the issues listed are important, what matters most to consumers is how much they pay for their prescription drug once it is covered.

The Task Force discussed and heard comments from various stakeholders on the proposed revised charges. Director Richardson made a motion, seconded by Commissioner Clark, to adopt the revised charges.

Commissioner Arnold asked for any additional discussion, particularly on Heaton's suggested revision to charge C. Fix made a motion, seconded by Bartuska, to narrow the scope of Heaton's suggested revision by adding the word "coverage" after "prescription drug" and adding the words "as fall under the purview of state-based insurance"

at the end. The Task Force discussed the suggested revision. After discussion, the Task Force unanimously adopted the motion accepting Fix's suggested revision to charge C.

Commissioner Clark made a motion, seconded by Director Richardson, to adopt the Task Force's 2025 revised charges for the Prescription Drug Coverage (B) Working Group, as revised (Attachment One-A). The motion passed unanimously.

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

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Draft: 3/10/25
Adopted by the Health Insurance and Managed Care (B) Committee, TBD
Adopted by the Regulatory Framework (B) Task Force, March 10, 2025

2025 Revised Proposed Charges

REGULATORY FRAMEWORK (B) TASK FORCE

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

Ongoing Support of NAIC Programs, Products, or Services

1. The **Regulatory Framework (B) Task Force** will:
   A. Coordinate and develop the provision of technical assistance to the states regarding state-level implementation issues raised by federal health legislation and regulations.
   B. Review managed health care reforms, their delivery systems occurring in the marketplace, and other forms of health care delivery. Recommend appropriate revisions to regulatory jurisdiction, authority, and structures.
   C. Consider the development of new NAIC model laws and regulations and the revision of existing NAIC model laws and regulations, including those affected by federal legislation and final federal regulations promulgated pursuant to such legislation.
   D. Continue to review NAIC models recommended for revision by the former Affordable Care Act (ACA) Model Review (B) Working Group and, as appropriate, appoint a working group or subgroup to revise the NAIC model(s) prioritized for revision in 2025.
   E. At the direction of the Health Insurance and Managed Care (B) Committee, through the work of the Employee Retirement Income Security Act (ERISA) (B) Working Group, monitor, analyze, and report developments related to association health plans (AHPs).
   F. Monitor, analyze, and report, as necessary, developments related to short-term, limited-duration (STLD) coverage.

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

4. The **Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group** will:
   A. Monitor, report, and analyze developments related to the MHPAEA, and make recommendations regarding NAIC strategy and policy with respect to those developments.
   B. Monitor, facilitate, and coordinate best practices with the states, the DOL, and the U.S. Department of Health and Human Services (HHS) related to the MHPAEA.

C. Develop and provide resources to the states to support a greater understanding of laws, policies, and market conditions related to the MHPAEA.
D. Provide supplemental resources to support documentation and reporting in the MHPAEA chapter of the *Market Regulation Handbook*.
E. Coordinate with and provide input to Market Regulation and Consumer Affairs (D) Committee groups, as necessary, regarding mental health parity market conduct examinations.

5. The **Prescription Drug Coverage (B) Working Group** will:
   A. Serve as a forum to educate state insurance regulators on issues related to ~~pharmacy benefit manager (PBM)~~ prescription drug coverage regulation and ~~other~~ stakeholders in the prescription drug ecosystem.
   B. Gather and share information, best practices, experience, and data to inform and support dialogue and information-sharing among state insurance regulators on issues related to ~~PBM~~ prescription drug coverage regulation, such as ~~examinations and contracting, and~~ pharmaceutical drug pricing and transparency, formularies, pharmacy payments, pharmacy benefit managers (PBMs), and coverage options.
   ~~C. As the subject matter experts (SMEs) and to promote uniformity across the states, while remaining sensitive to variation in state approaches, develop a chapter for inclusion in the *Market Regulation Handbook* establishing examination standards for PBMs and related regulated entities for referral and consideration by the Market Conduct Examination Guidelines (D) Working Group.~~
   ~~D.~~C. Maintain a current listing of all prescription ~~PBM~~ drug coverage laws and regulations and case law, as fall under the purview of state-based insurance ~~for reference by state insurance regulators~~.
   ~~E.~~D. Disseminate materials and reports~~,~~ via the NAIC~~,~~ to the states and the U.S. territories wishing to use the information gathered by the Working Group.
   E. Monitor, facilitate, and coordinate with the states and federal agencies to ensure compliance and enforcement efforts regarding prescription drug coverage and PBMs.
   F. Provide assistance and input to the Market Regulation and Consumer Affairs (D) Committee and/or any of its groups, as necessary, on matters related to PBM enforcement.

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

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Draft: 4/2/25

Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group
Indianapolis, Indiana
March 25, 2025

The MHPAEA (B) Working Group of the Regulatory Framework (B) Task Force met in Indianapolis, IN, March 25, 2025. The following Working Group members participated: Jane Beyer, Chair (WA); Chrystal Bartuska, Vice Chair (ND); Sarah Bailey and Jacob Lauten (AK); Crystal Phelps (AR); Cara Cheevers and Lila Cummings (CO); Kurt Swan (CT); Pratima Lele (DC); Andria Seip (IA); Julie Holmes (KS); T.J. Patton (MN); Teresa Kroll (MO); Robert Croom (NC); Michelle Heaton (NH); Kyla Dembowski (OH); Ashley Scott (OK); Lindsi Swartz (PA); Jill Kruger (SD); Stacie Parkes (TX); Tanji J. Northrup (UT); Julie Fairbanks (VA); Christina Keeley (WI); Jeffrey Black and Joylynn Fix (WV); and Jill Reinking (WY). Also participating was: Kevin Beagan (MA).

1. Adopted its 2024 Fall National Meeting Minutes

Bartuska made a motion, seconded by Heaton, to adopt the Working Group's Nov. 18, 2024, minutes (Attachment Two-A). The motion passed unanimously.

2. Heard an Update from the U.S. Department of Labor on the 2024 *Report to Congress on MHPAEA Enforcement and Implementation*

Matthew Meidell (U.S. Department of Labor—DOL) discussed the 2024 *Report to Congress on MHPAEA Enforcement and Implementation*. He shared statistics on MHPAEA enforcement by the DOL, which totaled 17 letters requesting comparative analyses, 45 insufficiency letters, and 13 initial determination letters finding that plans and issuers had violated MHPAEA's requirements for 21 non-quantitative treatment limits (NQTLs). He said the DOL, along with the U.S. Department of Health and Human Services (HHS) and the U.S. Department of the Treasury (Treasury Department), focused on six priority areas, including exclusions of key mental health and substance use disorder benefits and NQTLs related to network composition. Meidell said that compared to previous reports, some plans and issuers have provided more detailed comparative analyses and responses to the DOL and HHS. He noted the availability in the report of a sample settlement agreement that regulators can use to memorialize health plan and insurance issuer commitments to improve MHPAEA compliance.

3. Heard Presentations from Inseparable and the ABHW on State Legislation on Clinical Guidelines

David Lloyd (Inseparable) presented his organization's recommendations on why and how states should require health insurers to use generally accepted standards of care in making coverage decisions. He said patients more often report problems with coverage of mental health treatments than coverage of medical treatments. He said clinical review criteria are critical to how health insurers decide on medical necessity and utilization review. Lloyd said there is an opportunity to improve quality of care by aligning around clinical standards and avoiding opaque insurance rules. He said clinical standards from non-public sources like MCG and InterQual are often used to approve or deny care inappropriately. He said decisions may be driven by financial considerations, not patient needs. He said Inseparable is pushing for transparent criteria, accountability for inappropriate decisions, and care based on patient needs.

Lloyd highlighted a brief released by the American Medical Association (AMA) in recent weeks that cautions against criteria that are "based on" professional medical association recommendations, saying the original

recommendations should be used. He said national clinician groups wrote to the DOL to express concern about using proprietary, unpublished medical necessity criteria for the denial and approval of services. He said non-public criteria are shielded from review and scrutiny and may not be aligned with generally accepted standards of care.

Lloyd said inappropriately denied care can lead to worsened mental and physical health conditions and higher costs for families and taxpayers. He said high-quality, transparent criteria can benefit everyone. He said more than half of states require public or commercial plans to use criteria from the American Society of Addiction Medicine (ASAM). Lloyd said the Level of Care Utilization System (LOCUS) is available for mental health conditions. He said criteria from these sources are developed through an open process, validated through peer-reviewed research, and are publicly available for review.

Lloyd said several states have taken action to prevent inappropriate denials, with legislation in California, Colorado, Illinois, Oregon, and Maryland. He said New York also reviewed level of care criteria from nearly 60 plans and rejected them all. Lloyd said two major health insurers use high-quality criteria—United HealthCare (UHC) and Aetna.

Lloyd said underutilized mental health and substance use disorder treatment leads to higher physical health care and social costs. He said his organization recommends aligning around transparent clinical standards and that states can help control costs and level the playing field by putting in place requirements to use transparent criteria.

Bartuska asked how ASAM criteria compares to LOCUS. Lloyd clarified that ASAM criteria apply to treatment for substance use disorder while LOCUS provides level of care determinations for mental health conditions. He said many utilization review questions fall outside of these criteria, so other sources are needed to address the broader range of questions.

Seip asked how regulators should look at medical necessity decisions given that departments of insurance (DOI) do not have clinical staff. Lloyd said relying on transparent criteria and recommendations makes it easier to review decisions since the question becomes, “Were the standards followed?” rather than “What was the appropriate treatment for this patient?”

Cheevers asked how states should implement requirements to use LOCUS. Lloyd said states should work with stakeholders and flesh out as many details as possible in the regulatory process.

Kathryn Cohen (Association for Behavioral Health and Wellness—ABHW) spoke on the limitations of nonprofit clinical criteria from the perspective of health plans. She said ABHW member health plans have worked since the passage of MHPAEA to implement parity, innovate new approaches in benefits, combat provider shortages, and improve patient outcomes.

Cohen said clinical practice guidelines have become an increasingly important in the health care system. She said they have been applied to utilization management more recently. She said health plans sought out guidelines from MCG and InterQual because they are independent, peer-reviewed, and updated annually. She said the guidelines are developed based on published, peer-reviewed evidence and objective analysis of large data sets. Cohen said the guidelines are built on and used in conjunction with nonprofit provider association guidelines like ASAM and LOCUS. She said it is a misconception that nationally recognized guidelines are industry-driven rather than independently created and vetted. She said many of the private guidelines cite American Psychiatric Association (APA) research when appropriate.

Cohen said the LOCUS criteria are distributed by a for-profit software vendor. She said clinical guidelines should not be limited to those created by professional provider societies. She said her organization is not aware of evidence that limiting guidelines to nonprofit sources improves care.

Cohen said the ABHW perspective is that for-profit criteria do not lead to more denials or cut-offs to treatment and would welcome evidence showing that LOCUS leads to better outcomes. She said state legislation to limit health insurers to nonprofit sources gives undue power to a narrow set of organizations and does not allow the full range of evidence. She said ABHW members do not see a difference in how MCG guidelines and LOCUS are created and sold to health plans. Cohen said LOCUS does not determine treatment modalities within a level of care, nor does it determine the length of care. Because it is not peer-reviewed, she said LOCUS is not a complete medical necessity instrument. She said MCG takes into account LOCUS criteria and is also updated annually. She said professional society guidelines are not updated as frequently.

Cohen said most health plans use the same tools to perform utilization review for medical/surgical and mental health/substance use disorder (SUD) services, consistent with parity. She said a requirement to use a certain set of tools only for mental health/SUD services can put parity at risk. She said mandating only nonprofit guidelines could mandate experimental, unproven, or higher-cost treatments.

Cohen said ABHW should encourage the Working Group to consider a broad array of sources for clinical guidelines. She said research does not show one set of guidelines is preferential to another.

Fix asked about InterQual's ownership by UHC. Cohen said that research has not shown a difference in the rate of denials between MCG, InterQual, and nonprofit sources. Cohen said she would provide the research she referenced with the Working Group.

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

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Draft: 11/27/24

Mental Health Parity and Addiction Equity Act (MHPAEA) (B) Working Group
Denver, Colorado
November 18, 2024

The MHPAEA (B) Working Group of the Regulatory Framework (B) Task Force met in Denver, CO, Nov. 18, 2024. The following Working Group members participated: Jane Beyer, Chair (WA); Chrystal Bartuska, Vice Chair (ND); Crystal Phelps (AR); Stesha Hodges (CA); Cara Cheevers and Debra Judy (CO); Paul Lombardo (CT); Howard Liebers (DC); Elizabeth Nunes (GA); Andria Seip (IA); Joanna Coll (IL); Julie Holmes (KS); Mary Kwei (MD); T.J. Patton (MN); Amy Hoyt and Teresa Kroll (MO); Charles Whitehead (NC); Michelle Heaton (NH); Kyla Dembowski (OH); Landon Hubbart (OK); Lindsi Swartz (PA); Jill Kruger (SD); Daniel McAdams (TX); Julie Blauvelt (VA); Darcy Paskey (WI); Joylynn Fix (WV), and Tana Howard (WY).

1. Heard Presentations on the Final Federal Rule on Mental Health Parity

   A. Federal DOL

Beth Baum (U.S. Department of Labor—DOL) discussed the final rule, particularly the content requirements for comparative analyses. She said a recorded webinar with more information is available on the DOL's website. Baum said the final rule includes six steps for comparative analyses, with each building on the previous one. She said plans are expected to paint a detailed picture of how they comply with parity requirements and must provide, upon request, a list of all non-quantitative treatment limits (NQTLs) they apply. The first step is to describe the NQTL, but there is no need to include the entire policy. Plans must also identify all benefits the NQTL applies to and which classification they fit into. The next step is to identify and define the factors and evidentiary standards used to develop the NQTL, including sources. Plans can also use this step to describe how they cured previous discrimination in factors considered. The third step is to describe how the factors are used in the application of the NQTL, including how decisions on the NQTL are made and who makes them. Next, plans must demonstrate compliance with parity laws as written. She said this includes quantitative data or calculations used in designing and applying the NQTL, as well as forms and procedure manuals. She said the bulk of the material will be in the fifth step, a review of compliance with parity in operation. This is meant to be a comprehensive analysis, including data, documentation of outcomes, explanations of material differences in access, and discussion of reasonable steps taken in response to material differences. Baum said plans may describe a lack of data, but DOL expects this to be used only in narrow circumstances. The final step is to find and draw conclusions on whether the plan is compliant with parity laws. For Employee Retirement Income Security Act (ERISA) plans, a fiduciary must certify that they selected a provider to perform the analysis and monitor its completion.

Bartuska asked for confirmation on requirements applicable to qualified health plans (QHPs). Baum said the federal Centers for Medicare & Medicaid Services (CMS) could speak more directly to QHP certification requirements, but her understanding is that the rule applies the same standards to individual market plans as group plans. Bartuska asked about the certifications required for ERISA plans and whether states would receive copies of the certifications in cases when an ERISA plan is fully insured and thus subject to state regulation. Baum said the certification does not need to be included for non-ERISA plans, and they only need to provide copies of the comparative analysis to beneficiaries when they have an adverse benefit determination. She said sending copies to states would depend on how the comparative analysis is requested.

Seip asked whether the DOL would update its compliance guide or other resources to help state insurance regulators apply the new rules. Baum said the DOL would update its self-compliance tool as well as its next Report to Congress and is considering guidance on what data must be collected under the final rule.

B. BCBSA

Jennifer Jones (Blue Cross Blue Shield Association—BCBSA) presented concerns health plans have with the final rule. She said BCBSA shares the goal of improving access to mental health services for all Americans. She said BCBSA's plans have made investments to support this goal, including offering robust benefits and high-quality networks.

Jones said BCBSA is concerned that the latest parity rule will make it harder for patients to access care. She said the language on "no more restrictive" benefits could reduce medical management and access to higher acuity providers and remove guardrails that encourage providers to use evidence-based medicine. She said provider standards are problematic because some providers already have full panels, so bringing them in-network will not open appointments. She said the rule does not clarify what defines an NQTL, so some care management and other decision support could be treated as NQTLs. Jones identified some technical challenges with the rule. She said the timing is tight for implementation, with some going into effect in January 2025 and others in 2026. She said the departments should work to resolve ambiguity and differences in interpretation.

Jones asked for collaboration in addressing underlying barriers to mental health care, including expanding the use of non-clinical personnel, telehealth, and the pipeline of mental health providers.

C. LAC

Deborah Steinberg (Legal Action Center—LAC) spoke on behalf of NAIC consumer representatives. She provided examples of consumer barriers to care and offered suggestions to state insurance regulators for supporting consumers of mental health and substance use services and reducing the burden on them.

Steinberg said updated definitions in the rule will help include parity protections for benefits for those with autism, eating disorders, and gender dysphoria. She recommended states align their definitions because some state laws define these services as medical. She said the requirement for meaningful benefits would help ensure coverage for autism spectrum disorders (ASDs) and opioid use disorder. Steinberg said plans may look to different sources for standards of medical care than do providers or consumers. Consumer representatives recommend that states require plans to use non-profit professional societies' standards of care criteria, as five states do already. She said the updated non-exhaustive list of NQTLs and the requirement for evaluating outcomes data are very important for consumers.

Steinberg said the data show that mental health and substance use service providers are paid less than comparably trained medical/surgical professionals. She said consumers go out of network for mental health care at a much higher rate than for medical/surgical services. She said this data must be collected on a plan level. Steinberg said states should define the data elements to be collected rather than let plans decide. She encouraged states to adopt network adequacy standards, citing Maryland's standards as a good model because of their specificity. She said prohibiting discriminatory factors in developing NQTLs is an important element of the rule. She provided an example of a plan using out-of-network payment rates from 1983 to show that plans continue to use practices from before the passage of MHPAEA. She said it is critical for states to require the submission of comparative analyses on an annual basis because plan practices change each year. She said this will allow states to proactively address discriminatory plan elements. Steinberg said states should train front-line consumer assistance staff on parity red flags and allow them to forward complaints to investigators. She said consumers are

not equipped to file parity complaints themselves. She requested that the Working Group develop standardized guidance and templates incorporating the new rules.

Cheevers asked Jones about consumers who cannot find in-network providers and what incentives BCBSA plans use to attract providers to join networks. Jones said plans have quality expectations for any provider joining their network. Jones said patient volume is the primary leverage plans have to encourage providers to join. Plans can also offer providers data on their patient population. For mental health, she said plans have found ways to streamline the credentialing process and better support sole practitioners and other providers with less infrastructure. She said plans have supported integrating behavioral health into primary care to relieve burdens on behavioral health providers when patients are interested in having their conditions managed by primary care doctors.

Coll asked Jones whether plans are considering increasing payment amounts to behavioral health providers or revising requirements for payment through a third-party vendor. Jones said there are examples where plans have made substantial increases in payment to encourage providers to come in-network, but these plans have not seen significant gains in providers coming in-network. She said some plans believe there are providers who have full panels and would not choose to come in-network at any payment level.

Heaton asked Jones for an example of how the definition of NQTLs may limit the care management benefits that plans offer. Jones said that when care or case management is labeled as an NQTL, there is an expectation that it is delivered the same for behavioral health as medical and surgical services. She said this constrains the design and expansion of these programs, and care management does not function the same for medical and mental health needs.

Coll asked about plans that increased payment and did not see significant network growth. Jones said she would have to check with the plan to find more details. Beyer said that a Washington analysis using the state's all-payer claims database found that behavioral health providers were paid less than Medicare rates, on average, while primary and specialist medical providers were paid more than Medicare rates.

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/2025 Spring National Meeting/MHPAEAWG Min 11.18.24.docx

Draft: 4/1/25

Prescription Drug Coverage (B) Working Group
Indianapolis, Indiana
March 24, 2025

The Prescription Drug Coverage (B) Working Group of the Regulatory Framework (B) Task Force met in Indianapolis, IN, March 24, 2025. The following Working Group members participated: Joylynn Fix, Chair (WV); Ashley Scott, Vice Chair (OK); Jacob Lauten and Molly Nollette (AK); Jimmy Gunn (AL); Crystal Phelps (AR); Paul Lombardo (CT); Howard Liebers (DC); Sheryl Parker (FL); Andria Seip (IA); Dean L. Cameron, Shannon Hohl, and Weston Trexler (ID); Matthew Pickett (IL); Vicki Schmidt and Julie Holmes (KS); Shaun Orme (KY); Frank Opelka (LA); Joe Stoddard and Julie Merriman (MI); Norman Barrett (MN); Amy Hoyt and Cynthia Amann (MO); Robert Croom (NC); Cheryl Wolff, Michael Muldoon, and Maggie Reinert (NE); Erin Porter and Tim Stroud (NJ); Krista Porter (NY); Viara Ianakieva (NM); Cassie Soucy (OR); Dave Yanick (PA); Jud Jones (TN); Tanji J. Northrup (UT); Jane Beyer (WA); and Jill Reinking and Lauren White (WY). Also participating were: Kevin Beagan (MA); Chrystal Bartuska (ND); Christine Moller (OH); Jill Kruger and Travis Jordan (SD); and Patrick Smock (RI).

1. Heard Opening Remarks

Fix discussed the changes to the Working Group's focus since it last met. She said that based on its revised charges and new name, the Working Group will focus on prescription drug coverage, pharmacy benefit managers (PBMs), and other stakeholders in the prescription drug ecosystem. She said the new Pharmacy Benefit Management (D) Working Group, under the Market Regulation and Consumer Affairs (D) Committee, will focus on PBM enforcement, including taking over the work of the Working Group to develop a PBM examination chapter for inclusion in the *Market Regulation Handbook*. Fix encouraged all those interested in PBM enforcement issues to join the Pharmacy Benefit Management (D) Working Group, which will be meeting for the first time March 25.

Fix said she and Scott are seeking input from Working Group members and interested regulators on topics the Working Group should discuss this year. She said she has already received some suggestions, such as prior authorization (PA), accreditation, formulary placement and design, and specialty drugs. She said anyone with additional suggestions should reach out to her, Scott, or NAIC staff.

2. Adopted its 2024 Fall National Meeting Minutes

Beyer made a motion, seconded by Scott, to adopt the Working Group's Nov. 18, 2024, minutes (Attachment Three-A). The motion passed unanimously.

3. Heard a Presentation from the HIV+Hepatitis Policy Institute on PBMs and How They Function from the Consumer Perspective

Carl Schmid (HIV+Hepatitis Policy Institute) discussed the role of PBMs in patient access and affordability of prescription drugs. He explained how PBMs impact prescription drug coverage and prescription drug benefit design. He cited information showing the rise in the number of products on PBM formulary exclusion lists from the three largest PBMs between 2012 and 2025. Schmid provided an example of one health plan placing all HIV drugs, including generics, on the highest tier and not covering some of the recommended treatments for HIV. He said another plan in the New England area was not covering some of the HIV treatment recommended drugs, but the state stepped in to address the issue by requiring the plan to add the drugs back to the formulary. Schmid also

discussed how the placement of certain prescription drugs on higher tiers impacts consumer out-of-pocket costs, which have increased over the years, causing many consumers to not pick up their prescription drugs at the pharmacy.

Schmid discussed drug manufacturer copay assistance programs. Schmid said insurers have implemented copay accumulator adjustment policies (CAAPs), allowing them to not count drug manufacturer copay assistance toward a beneficiary's out-of-pocket costs, which also leads to higher out-of-pocket costs for consumers, particularly consumers living with chronic and serious illnesses, such as HIV, hepatitis, and other conditions requiring high-cost specialty medications. He explained how PBMs were the middlemen in this process. Schmid cited The AIDS Institute's (TAI's) recently released annual report on insurer CAAPs. According to its findings, more than 40% of individual health plans reviewed for 2025 include CAAPs. He said the analysis also revealed that 39 U.S. states had at least one insurer with a CAAP. Schmid said that in 11 states (Colorado, Delaware, Georgia, Illinois, Louisiana, North Carolina, Oklahoma, Oregon, Tennessee, Texas, and Washington), at least one insurer continues to include CAAPs, in apparent violation of state law.

Schmid thanked the NAIC for its recent letter to the Trump Administration asking for clarity on the CAAP issue and the enforcement of federal rules governing their use since litigation invalidated the U.S. Department of Health and Human Services (HHS) rule from the 2021 Notice of Benefit and Payment Parameters giving insurers wide discretion on how they use copay accumulator programs. The court decision left a previous 2020 rule in place. Under the 2020 rule, insurers could only use copay accumulators in limited circumstances. Since 2023, however, HHS has declined to enforce the 2020 rule and has promised updated rulemaking. State insurance regulators are asking for greater clarification from HHS on the status of federal rules so that they can provide consistent guidance to health insurers on these programs.

Schmid highlighted actions taken on the federal level concerning PBMs. The Federal Trade Commission (FTC) issued two interim staff reports. The first interim staff report looked at the top three PBMs, showing the concentration of the market, how they work with insurers, their ownership, how they function with rebates and extra fees they charge, and how they steer patients to certain pharmacies at the expense of independent pharmacies. He said the PBM industry's response to this report was to sue the FTC. Schmid touched on the role of PBMs and the Section 340B Drug Pricing Program. He also touched on state PBM activities, noting that all 50 states have some type of PBM law, and more and more states are considering PBM laws, particularly laws requiring more transparency and disclosure related to rebates and fees.

4. Heard a Presentation on PBMs and Conflicting Incentives

Edward Kaplan (Segal) presented on PBMs and conflicting incentives. He explained that Segal represents buyers, employers, unions, and governments that purchase PBM services. Segal receives no money from PBMs or drug manufacturers. Its revenue comes from planned sponsors. Kaplan said that from this perspective, he plans to focus his presentation on practical solutions and practical implications concerning PBMs, given how complicated the prescription drug benefit industry is. He provided a high-level overview of the prescription drug benefit industry, including how pharmaceutical therapies as a health plan expense are an increasing share of total health plan spending and some possible reasons for such increases.

Kaplan discussed the current PBM marketplace and explained that the top five PBMs control over 90% of the PBM market. He also provided an overview of the specialty pharmacy industry. He discussed the value that PBMs provide, such as catching physician prescribing errors, providing member support services, and improving

medication adherence rates. He said PBMs are now moving into drug manufacturing by acquiring or owning existing drug manufacturers or taking equity positions with drug manufacturers and distributors.

Kaplan highlighted the need for greater transparency in drug pricing. He discussed how the gap between prescription drug list prices and net prices continues to grow. He also discussed how certain side deals between drug manufacturers and middlemen, such as PBMs, distributors, and retailers, are complex and potentially misaligned with plan sponsor objectives. He noted that PBMs and drug manufacturers do not want to disclose specific drug rebates, which impacts the ability of plan sponsors to see true head-to-head prices and limits competition. To gain greater transparency, Kaplan suggested that plan sponsors: 1) mandate disclosure of all forms of payments to PBMs and their subsidiaries; 2) insist on head-to-head comparisons of competing drugs regarding side effects and efficacy to provide more informed prescribing; and 3) prohibit gag order contracts with pharmacies. He touched on traditional versus transparent pricing models.

Kaplan suggested the following tips for state insurance regulators to reduce waste and abuse: 1) review the competitive landscape of PBMs; 2) apply new contracting terms that move away from inflationary PBM definitions; 3) require drug-specific rebate disclosure; and 4) explore cost risk-sharing strategies in future contracts that tie PBM incentives to containing future price increases. He highlighted specific strategies that plan sponsors are using to more effectively manage the drug trend and reduce costs, such as: 1) smart plan design; 2) comprehensive utilization management; 3) PBM contract alignment with plan objectives; and 4) decisive action. Kaplan discussed best practices that plan sponsors can use with respect to PBM requests for proposals (RFPs)/contracting and rebate contracting. He also highlighted other PBM tools to support policyholders, including 1) developing custom drug formularies; 2) clinical program reviews (CPRs); 3) potential fraud and abuse reviews (PFARs); and 4) PBM audits.

Fix asked if anyone had any questions. Seip said there is transparency between the PBM and the plan sponsor but no transparency regarding the PBM and its payment methodologies with pharmacies. She said Iowa is struggling to make PBMs provide more transparency regarding their payment methodologies with pharmacies. She said this is challenging because Iowa feels its only enforcement tool is administrative, but there does not seem to be a financial penalty large enough to incentivize them to comply. Seip asked if Kaplan had any suggestions to encourage a more transparent relationship between PBMs and state insurance regulators so state insurance regulators can understand how pharmacies are being paid. Kaplan said there is no easy answer other than enacting legislation to require such transparency. Kaplan also said another option is to use an insured-type per member per month (PMPM) model, changing the PBM payment incentive.

Kruger asked Kaplan what makes a specialty drug a “specialty drug.” Kaplan said her question is common because there is no federal or industry definition. He said some of his clients require a PBM to provide a prospective list of its specialty drugs, which means the PBM can only change what it considers to be specialty drugs at policy or contract renewal.

Beyer asked about biosimilar drugs and formulary designs. She asked whether the PBM includes both the brand name drug and the biosimilar drug on the formulary when there is a biosimilar drug equivalent. She said an issue Washington has seen is that when both are on the formulary, the brand drug is preferred, which means that due to rebate considerations, the consumer ends up paying more. Kaplan said he has seen PBMs take various approaches to this issue. There is no consensus.

Commissioner Schmidt asked Kaplan how his clients, particularly those who are self-insured, have addressed transparency and rebates. She asked if they have required PBMs by contract to disclose all forms of payment they

receive from drug manufacturers. Kaplan said some of his clients have tried such an approach, but PBMs still manage to not disclose all fees and rebates because they state that some fees cannot be disclosed for confidential reasons. He reiterated his suggestion that to increase transparency, state insurance regulators should require PBMs to disclose rebates by drug to facilitate a head-to-head comparison.

Director Cameron asked Kaplan if he saw any changes in the marketplace that would change the dynamics, such as new emerging players like Amazon Pharmacy. Kaplan said the federal action to negotiate drug prices for Medicare Part D is a good start in changing some marketplace dynamics.

Having no further business, the Pharmaceutical Benefit Management Regulatory Issues (B) Working Group adjourned.

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Pharmaceutical Benefit Management Regulatory Issues (B) Working Group
Denver, Colorado
November 18, 2024

The Pharmaceutical Benefit Management Regulatory Issues (B) Working Group of the Regulatory Framework (B) Task Force met in Denver, CO, Nov. 18, 2024. The following Working Group members participated: Joylynn Fix, Chair (WV); Ashley Scott, Vice Chair (OK); Lori Wing-Heier and Sarah Bailey (AK); Mark Fowler and Sheila Travis (AL); Lisa Watson (AR); Paul Lombardo (CT); Howard Liebers (DC); Samantha Heyn (FL); Doug Ommen and Andria Seip (IA); Ann Gillespie and Matthew Pickett (IL); Julie Holmes (KS); Sharon P. Clark (KY); Nina Hunter (LA); Parker Fisher and Danielle Torres (MI); Norman Barrett Wiik (MN); Amy Hoyt (MO); Charles Whitehead (NC); Eric Dunning, Cheryl Wolff, and Maggie Reinert (NE); Tim Stroud (NJ); Renee Blechner (NM); Richard Ramos and Krista Porter (NY); Numi Griffith (OR); Jodi Frantz (PA); Scott McAnally (TN); Jon Pike and Tanji J. Northrup (UT); Mike Kreidler (WA); Darcy Paskey (WI); and Jill Reinking and Lauren White (WY). Also participating were: Dean Cameron and Shannon Hohl (ID); Mike Chaney (MS); Chrystal Bartuska (ND); Scott Kipper (NV); and Allan L. McVey (WV).

1. Heard Presentations on PBMs and How They Function

The Working Group heard presentations from the Pharmaceutical Care Management Association (PCMA), the Pharmaceutical Research and Manufacturers of America (PhRMA), and jointly, the National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NADCS) on pharmacy benefit managers (PBMs) and how they function.

John Jones (PCMA) discussed PBMs and how they function from a PBM industry perspective. He explained what PBMs are and their core functions. Jones said that nearly all insurers use a PBM to perform a variety of those functions, particularly prescription drug claims processing. He explained how PBMs support patients by: 1) supporting patient safety by preventing potentially harmful drug interactions and reducing medication errors; 2) helping patients understand how and when to take their medication; and 3) improving care coordination. PBMs also support employers and other plan sponsors by helping them offer high-quality drug coverage to meet the needs of all kinds of people and organizations by: 1) negotiating with drug companies and pharmacies to lower drug costs; 2) providing business and operations expertise; and 3) providing prescription drug benefit design and coverage recommendations.

Jones explained how PBMs are paid for their services. He said employers and other plan sponsors decide how to pay for PBM services through three pricing models: 1) spread contracts, 2) rebate retention, or 3) administrative fees. He also described how an employer or plan sponsor might choose a PBM. Jones touched on the value PBMs provide to the U.S. health care system and the states. He said the use of PBM tools will save payers and patients nationally more than $1 trillion from 2023-2032 because PBMs drive down costs for prescription drugs by pushing drug manufacturers to compete to offer better prices for patients and families. PBMs negotiate with drug manufacturers, empowering the private market to drive down costs.

Scott Woods (PhRMA) discussed PBMs and how they function from a drug manufacturer's perspective. He said that since the NAIC began its work on PBMs, the market has changed drastically. In moving forward, he said the PhRMA suggests the Working Group focus its future work to examine these three market trends. The first is vertical integration, which amplifies PBMs' influence within the health care system. The second trend is perverse

incentives, which can allow PBMs to profit at the expense of patients, employers, and the health care system, and the third trend is PBM business practices that can challenge patient access to medicines.

Woods said the overall marketplace is far less competitive than the PBM industry leads stakeholders to believe. He said even though there are 70 full-service PBMs in the U.S. and more new entrants to the market every year disrupting the PBM industry, the market remains dominated by three PBMs that have 80% of the market share. Woods said the PhRMA is not just concerned with what these PBMs do with such market power, but the sheer volume of prescription claims they manage, which provide them with significant leverage to the detriment of patients and competition.

Woods discussed prescription drug costs and how the PBM business model influences patient out-of-pocket costs. According to the National Health Expenditures (NHE) data report, medicines account for just 14% of total health care spending in this country. That figure is expected to remain stable over the next few years, even as many novel medicines and therapies come on the market. Woods said even though the net prices for brand medicines have grown below the rate of inflation for the past five years, and even with stable or in some cases, declining medicine prices, it does not feel that way for patients because insurers and PBMs have increasingly shifted more health care costs to them. He noted that more than half of every $1 spent on brand medicines went to PBMs, health plans, providers, and other stakeholders in 2020. He suggested that when more than half of what is spent on medicines goes to entities that have nothing to do with making them, the system needs to change. Woods explained that the slide in the PCMA presentation illustrating the share of the drug dollar did not include prescriptions by the PBM's own mail order and specialty pharmacies, and the slide also neglected to include drug dollars that go to health plans, hospitals, physicians, and other intermediaries.

Woods cited a 2023 Nephron Pharmaceuticals Corporation report, which found that the share of PBM profits from fees charged to manufacturers, pharmacies, health insurers, and employers increased by over 300% over the last decade and that PBMs are increasing shifting their business model to rely less on commercial rebates to administrative fees and specialty pharmacy. He also discussed how vertical integration—PBMs owning pharmacies—has had an impact on prescription drug costs because the PBM can prefer its own affiliated pharmacy rather than an unaffiliated pharmacy. Woods cited a Federal Trade Commission (FTC) study as evidence of such practices. Woods discussed how the middlemen in the prescription drug distribution system are shifting costs to patients through co-insurance and deductibles and how this cost-sharing is based on the undiscounted list price of the medicine, even when the PBM is receiving a rebate fee or other discounts on that medicine, which leads to non-adherence and resulting poor health outcomes and drives up overall health care spending. He also discussed the impact of accumulator adjustment programs, copayment maximizers, and alternative funding programs on out-of-pocket costs. He suggested that the Working Group should explore market problems and consider policy solutions to address these issues that adversely impact patient access.

Woods said the PhRMA suggests the following policy solutions to address these issues: 1) delink PBM compensation from the list price of medicines, and limit PBM compensation to flat service fees; 2) pass on savings negotiated between drug manufacturers and PBMs directly to patients; 3) ensure patients benefit from drug manufacturer assistance programs and foundation support, and prohibit the use of accumulator adjustment programs, copayment maximizers, and alternative funding programs; and 4) hold PBMs and health plans accountable for providing quality patient care, and increase oversight of utilization management and enhance the data available to identify PBM and health plan abuse.

Joel Kurzman (NCPA) and Sandra Guckian (NACDS) discussed PBMs and how they function from a community pharmacist perspective. They discussed the role community pharmacists play in consumer access to prescription

drugs, particularly in underserved areas, and the other services they provide to the community. Guckian said current PBM practices are adversely impacting patients as well as independent and chain pharmacies. She explained that the NACDS is a trade association representing chain pharmacy companies, including traditional drug stores, supermarkets with pharmacies, and mass merchants with pharmacies. She said the NACDS members include regional chains with four or more stores and national companies. She said these regional chains employ nearly three million individuals, including over 150,000 pharmacists, fill three billion prescriptions annually, and help patients use medications correctly and safely while offering innovative services focused on health and wellness.

Kurzman discussed the uneven playing field for community pharmacists in their dealings with PBMs. He highlighted a number of these inequities, including 1) take-it-or-leave-it contracts, 2) lack of transparency in reimbursement pricing, 3) retaliatory audits, 4) network exclusion, 5) no process for appeals or remedy for unfair practices, and 5) the unpredictability of retroactive fees. He said that for many community pharmacists, this is an unsustainable business model.

Kurzman said one of the biggest challenges for pharmacies is having to negotiate with Fortune 10 companies that have 80% of the market share, which Woods discussed. The other challenge is vertical integration. He said independent community pharmacies are trying to compete with pharmacies that are owned by PBMs. Kurzman said PBMs have suggested that these narrow networks are an opportunity to bring value by bringing down costs. He said that when networks are limited and community pharmacies are forced out, consumers are harmed because their choices are limited, which is particularly evident in rural areas with 10% closing between 2013 and 2022.

Guckian said there is a growing consensus on the need for PBM reform. She noted the state legislative activity over the past few years aimed at addressing an array of PBM business practices. She also referred to several state-level reports and findings related to PBMs and recent PBM enforcement actions. Guckian also noted the ability of states to regulate PBMs because of recent court decisions, such as the U.S. Supreme Court's decision in *Rutledge v. the Pharmaceutical Care Management Association*. She also referenced the number of state laws requiring PBM licensure or registration with the state insurance department. Guckian said the NCPA, the NACDS, and the American Pharmacists Association (APhA) urge the NAIC and its members to prioritize the implementation and enforcement and oversight of PBM state rules and laws.

Kurzman highlighted a 50-state resource document the NCPA developed and maintains to help its members file complaints with state insurance regulators because enforcement is key. The NCPA also has developed its *Best Practices for Enforcement of PBM Regulation*.

Lombardo asked Woods and Kurzman what savings, if any, would be realized if their suggested policy solutions were implemented. He said that in Connecticut, the percentage of premium for prescription drug coverage increased from 11% of premium in 2014 to 26% of premium in 2024. Kurzman discussed what states are doing in this area with respect to their Medicaid-managed care plans. He said that after these states identified large amounts of spread pricing and moved to a transparent reimbursement methodology, it brought down costs and states could bank those savings. Woods said the federal Congressional Budget Office (CBO) scored potential federal PBM reform legislation. He said that based on the provisions in that legislation, including changing the way PBMs are compensated from being based on the price of the medicine to being based on the value of the services they provide, the CBO scored a savings of $700 million. The CBO also scored provisions requiring more transparency in the PBM market resulting in over a billion dollars in savings. Woods also discussed the Blue Shield of California's business decision to terminate its contract with CVS Health for certain prescription drug benefit

services and moving those services to Amazon Pharmacy and Mark Cuban's Cost Plus Drugs because it felt that it was being overcharged and that cost was being passed on to its members in the form of higher premiums. Jones said the examples Kurzman and Woods discussed illustrate the market at work.

Acting Director Gillespie asked about the impact on medical loss ratios (MLRs) in the vertical integration situation where the insurer is the parent and owns the specialty pharmacy—all part of the same PBM structure. Woods said PhRMA has a lot of information on this and how much vertical integration helps insurers and plans potentially skirt the spirit of the federal Affordable Care Act's (ACA's) 80% to 85% MLR requirement in the commercial market. He said he would be happy to provide specific data and other information on this after the meeting.

Commissioner Chaney asked about the National Average Drug Acquisition Cost (NADAC), which is a standard price used to calculate how much a pharmacy is reimbursed for a prescription drug or essentially, the average price a pharmacy pays to acquire a drug and used as a basis for calculating reimbursement rates versus the average wholesale price (AWP), which is a pharmaceutical industry standard used to calculate how much third-party payors, like insurance companies and government programs, reimburse health care providers for prescription drugs. Kurzman provided a history of the NADAC benchmark and the intent behind its initial development by the federal Centers for Medicare & Medicaid Services (CMS) in 2016. Jones said NADAC and AWP are both benchmarks and just one component of payment. He noted that stakeholders will prefer one benchmark over the other, but they make the choice.

Commissioner Ommen asked Jones about the information included in the PCMA describing savings to the states from using PBMs. He asked if it was net savings or something else. Jones said he would need to check the source material because he is not familiar with the methodology used to generate the numbers. He said he would follow up with the Working Group after the meeting.

2. Heard a Discussion on Providing Potential Assistance to the Producer Licensing Uniformity (D) Working Group

Scott said the Producer Licensing Uniformity (D) Working Group has approached the Working Group seeking its assistance to help it create a new section on PBM licensure best practices and uniform standards in the *State Licensing Handbook*. She said anyone interested in providing such assistance when the Producer Licensing Uniformity (D) Working Group begins its work in 2025 to let her, Fix, or NAIC staff know.

3. Heard an Update on the Working Group's Work on the PBM Examination Chapter

Fix updated the Working Group on the progress of its work related to its charge to develop a chapter for inclusion in the *Market Regulation Handbook* establishing examination standards for PBMs and related regulated entities for referral and consideration by the Market Conduct Examination Guidelines (D) Working Group. She said the drafting group assignments have been circulated. However, there is still an opportunity for both state insurance regulators and non-regulators to serve on the drafting group. She said those interested should reach out to her, Scott, or NAIC staff.

Having no further business, the Pharmaceutical Benefit Management Regulatory Issues (B) Working Group adjourned.

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