



NATIONAL MEETING FALL 2022

Revised: 12/7/22

*2022 Fall National Meeting
Tampa, Florida*

HEALTH INSURANCE AND MANAGED CARE (B) COMMITTEE

Wednesday, December 14, 2022

3:45 – 5:30 p.m.

JW Marriott—Tampa Bay Ballroom 5-9—Level 4

ROLL CALL

Glen Mulready, Chair	Oklahoma	Grace Arnold	Minnesota
Troy Downing, Co-Vice Chair	Montana	Chris Nicolopoulos	New Hampshire
Russell Toal, Co-Vice Chair	New Mexico	Andrew R. Stolfi	Oregon
Lori K. Wing-Heier	Alaska	Michael Humphreys	Pennsylvania
Michael Conway	Colorado	Jon Pike	Utah
John F. King	Georgia	Mike Kreidler	Washington
Amy L. Beard	Indiana	Allan L. McVey	West Virginia
Anita G. Fox	Michigan		

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

AGENDA

1. Consider Adoption of its Nov. 10 and Summer National Meeting Minutes
—*Commissioner Glen Mulready (OK)*
2. Consider Adoption of its Subgroup, Working Group, and Task Force Reports
—*Commissioner Glen Mulready (OK)*
 - A. Consumer Information (B) Subgroup—*Mary Kwei (MD)*
 - B. Health Innovations (B) Working Group—*Commissioner Andrew R. Stolfi (OR)*
 - C. Health Actuarial (B) Task Force—*Commissioner Andrew N. Mais (CT) and Paul Lombardo (CT)*
 - D. Regulatory Framework (B) Task Force—*Commissioner Vicki Schmidt (KS)*
 - E. Senior Issues (B) Task Force—*Commissioner Marlene Caride (NJ)*
3. Hear a Presentation on Pharmacy Benefit Managers (PBMs) and Their Business Practices from a Large Employer Perspective—*Teah Corley (EmployerAdvocates) and Brandon Long (ERISA Counsel)*
4. Hear an Update from the Federal Centers for Medicare & Medicaid Services' (CMS') Center for Consumer Information and Insurance Oversight (CCIIO) on its Recent Activities
—*Dr. Ellen Montz (CCIIO)*
5. Discuss Any Other Matters Brought Before the Committee—*Commissioner Glen Mulready (OK)*

6. Adjournment

Agenda Item #1

Consider Adoption of its Nov. 10 and Summer National Meeting Minutes
—*Commissioner Glen Mulready (OK)*

Draft: 11/15/22

Health Insurance and Managed Care (B) Committee
Virtual Meeting
November 10, 2022

The Health Insurance and Managed Care (B) Committee met Nov. 10, 2022. The following Committee members participated: Glen Mulready, Chair (OK); Russell Toal, Co-Vice Chair (NM); Lori K. Wing-Heier represented by Sarah Bailey (AK); Michael Conway represented by Tara Smith (CO); Amy L. Beard (IN); Anita G. Fox (MI); Grace Arnold represented by Galen Benshoof (MN); Chris Nicolopoulos represented by Michelle Heaton (NH); Andrew R. Stolfi represented by TK Keen (OR); Michael Humphreys represented by Sandra L. Ykema (PA); Jon Pike (UT); Mike Kreidler (WA); and Allan L. McVey (WV). Also participating was: Paul Lombardo (CT).

1. Adopted the Revisions to AG 44 and the New 2022 Tables

Lombardo said the Health Actuarial (B) Task Force is asking the Committee to consider adoption of *Actuarial Guideline XLIV—Group Term Life Waiver of Premium Disabled Life Reserves* (AG 44) and its accompanying tables and adjustments, the new 2022 Group Term Life Waiver Mortality and Recovery Tables (2022 Tables). He said the *Health Insurance Reserves Model Regulation* (#10) and the NAIC *Valuation Manual* (VM-25, Health Insurance Reserves Minimum Reserve Requirements) contain requirements for the calculation of waiver of premium due to disability reserves on group life insurance policies. The current version of AG 44 prescribes the use of the 2005 Group Term Life Waiver Mortality and Recovery Tables. He said the American Academy of Actuaries (Academy) and the Society of Actuaries Research Institute (SOARI) Group Life Waiver of Premium Valuation Table (GLWPVT) Work Group proposed new 2022 Tables that were developed using more recent experience data. The use of the 2022 Tables, as adopted by the Health Actuarial (B) Task Force on Sept. 28, required modifications to AG 44 to accommodate their application.

Lombardo said the Academy and the SOARI GLWPVT Work Group drafted the AG 44 proposed revisions. The Health Actuarial (B) Task Force exposed the draft actuarial guideline revisions on July 11 for a public comment period ending Aug. 11. He said additional revisions were proposed during the Task Force's Sept. 6 meeting, which the Task Force exposed for a public comment period ending Sept. 22. He said the AG 44 revisions received substantial vetting during the Task Force's meetings. The Health Actuarial (B) Task Force adopted the final version of the AG 44 during its Sept. 28 meeting.

Superintendent Toal made a motion, seconded by Commissioner Pike, to adopt the revisions to AG 44 and the new 2022 Tables. The motion passed unanimously.

2. Adopted the Health Actuarial (B) Task Force's 2023 Proposed Charges

Lombardo said the Health Actuarial (B) Task Force discussed and adopted its 2023 proposed charges during its Sept. 28 meeting. He said the 2023 proposed charges are essentially the same as its 2022 charges.

Commissioner McVey made a motion, seconded by Superintendent Toal, to adopt the Task Force's 2023 proposed charges. The motion passed unanimously.

3. Adopted the Regulatory Framework (B) Task Force's 2023 Proposed Charges

Jolie H. Matthews (NAIC) said the Regulatory Framework (B) Task Force's 2023 proposed charges are substantively the same as its 2022 charges. She said the Task Force discussed and adopted the charges unanimously during its Oct. 11 meeting.

Commissioner Pike made a motion, seconded by Superintendent Toal, to adopt the Task Force's 2023 proposed charges. The motion passed unanimously.

4. Adopted the Senior Issues (B) Task Force's 2023 Proposed Charges

Matthews said the Senior Issues (B) Task Force discussed and adopted its 2023 proposed charges during its Oct. 17 meeting. She said the Task Force's 2023 proposed charges are the same as its 2022 revised charges.

Commissioner McVey made a motion, seconded by Commissioner Pike, to adopt the Task Force's 2023 proposed charges. The motion passed unanimously.

5. Adopted its 2023 Proposed Charges

Commissioner Mulready said NAIC staff distributed and posted the Committee's 2023 proposed charges on the Committee's web page prior to the meeting. He said the 2023 proposed charges are the same as its 2022 charges.

Superintendent Toal made a motion, seconded by Commissioner McVey, to adopt the Committee's 2023 proposed charges (Attachment One-A). The motion passed unanimously.

6. Discussed the NAIC/American Indian and Alaska Native Liaison Committee's Oct. 28 Meeting

Commissioner Mulready discussed the NAIC/American Indian and Alaska Native Liaison Committee's Oct. 28 meeting, which was held in regulator-to-regulator session. He said that for those who missed the meeting, there was a lot of valuable information discussed and shared concerning legal issues with the Sovereign Nations Health Consortium's (SNHC's) plan to have Sovereign Nations Insurance (SNI), which the SNHC characterizes as a tribal insurer, to offer and sell certain health insurance products to tribal members and potential non-tribal members without obtaining an insurance license from state departments of insurance (DOIs).

Commissioner Kreidler said he is meeting with representatives of the SNHC next week. He also thanked Commissioner Mulready for inviting the speaker who spoke during the NAIC/American Indian and Alaska Native Liaison Committee's Oct. 28 meeting about legal issues related to the SNHC and the SNI. He said he appreciated the opportunity to ask questions and thought it was a valuable discussion. He also said the information provided during that meeting will be useful for his upcoming meeting. Commissioner Mulready asked Commissioner Kreidler if he would be willing to provide a summary of his meeting with the SNHC to the Committee members and interested state insurance regulators. Commissioner Kreidler agreed to provide such a summary.

7. Discussed the Committee's Tentative Fall National Meeting Agenda

Commissioner Mulready said that although the Committee's meeting agenda for the Fall National Meeting is still being finalized, he has invited representatives of a large group employer to speak to the Committee about pharmacy benefit managers (PBMs) and their business practices from a large employer perspective. He said he invited them to speak because, to date, the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup has not

heard from this stakeholder group, and he thought it would be beneficial to the Committee to hear their perspective. He said representatives of the federal Centers for Medicare & Medicaid Services (CMS) have been invited to provide an update to the Committee on its recent activities.

Having no further business, the Health Insurance and Managed Care (B) Committee adjourned.

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/2022 Fall National Meeting/B Cmte 11-10-22 MtgMin.docx

DRAFT

Draft Pending Adoption

Draft: 8/22/22

Health Insurance and Managed Care (B) Committee
Portland, Oregon
August 11, 2022

The Health Insurance and Managed Care (B) Committee met in Portland, OR, Aug. 11, 2022. The following Committee members participated: Glen Mulready, Chair (OK); Troy Downing, Co-Vice Chair (MT); Russell Toal Co-Vice Chair, represented by Paige Duhamel (NM); Lori K. Wing-Heier (AK); Michael Conway (CO); Amy L. Beard represented by Alex Peck (IN); Anita G. Fox (MI); Grace Arnold (MN); Chris Nicolopoulos (NH); Andrew R. Stolfi and TK Keen (OR); Michael Humphreys (PA); Jon Pike (UT); Mike Kreidler and Molly Nollette (WA); and Allan L. McVey represented by Erin Porter (WV). Also participating were: Vicki Schmidt (KS); Larry D. Deiter (SD); and Cassie Brown (TX).

1. Adopted its Spring National Meeting Minutes

Director Wing-Heier made a motion, seconded by Director Fox, to adopt the Committee's April 7 minutes (*see NAIC Proceedings – Spring 2022, Health Insurance and Managed Care (B) Committee*). The motion passed unanimously.

2. Adopted its Subgroup, Working Group, and Task Force Reports

Commissioner Pike made a motion, seconded by Ms. Peck, to adopt the following reports: 1) the Consumer Information (B) Subgroup; 2) the Health Innovations (B) Working Group, including its Aug. 10 minutes (Attachment One); 3) the Health Actuarial (B) Task Force; 4) the Regulatory Framework (B) Task Force; and 5) the Senior Issues (B) Task Force. The motion passed unanimously.

3. Heard a Panel Discussion on Why States Should Create SBEs

J.P. Wieske (Horizon Government Affairs), Heather Korbolic (GetInsured), and Randy Pate (StatesWork) discussed options and opportunities for states to establish state-based exchanges (SBEs). Mr. Wieske outlined four reasons why states should set up their own SBE: 1) the cost of technology associated with operating an SBE has dropped, which means that a state most likely can operate an exchange at a cheaper rate than what a state is paying the federal government to operate an exchange in their state; 2) the ability to gather information and data directly to assist in understanding the state's own health insurance market rather than relying on what information and data a state may receive from the federal government; and 3) the ability to have control over what is going on in the state; and 4) flexibility for states to set their own rules.

Ms. Korbolic discussed the different SBE operation models. She said the move from HealthCare.gov to an SBE is risk-free now that end-to-end (call center, technology, and operations) solutions are readily available from private vendors with a proven track record. She explained that Healthcare.gov is built to support many states with an inflexible infrastructure that does not easily support policy flexibility. Ms. Korbolic reiterated some of the reasons Mr. Wieske discussed as reasons why states should establish an SBE, including: 1) cost savings, which can be repurposed for reinsurance; 2) independence from the federal government; 3) lower premium growth rates along with the ability to innovate with state policy; and 4) better churn management between Medicaid and commercial insurers. Ms. Korbolic said GetInsured has developed model legislation that states can tailor to fit their needs and use as the enacting legislation for an SBE.

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Mr. Pate also explained the benefits of a state establishing its own SBE already discussed. He also suggested that having an SBE would give states greater flexibility to innovate using the federal Affordable Care Act (ACA) Section 1332 waiver process.

Director Wing-Heier asked the panel how a state would begin the process of exploring establishing an SBE. Mr. Pate said a state should first look at its needs, population, enrollment, and the user fees it is paying the federal government to operate the federally facilitated exchange (FFE). He also suggested that if the “math” does not seem to work for a smaller state to establish an SBE, the state may want to consider establishing a shared services exchange. A shared services exchange would allow a small state to share with another state the costs of operating certain higher costs operations, such as call centers, to lower operational costs.

Commissioner Mulready asked the panel members what they have seen as the biggest hurdles for a state establishing an SBE. Ms. Korbolic said the biggest hurdles GetInsured has seen include: 1) political will; 2) making a financial argument; and 3) managing risk, particularly related to technology. Mr. Wieske said that with respect to political will, the ability to control their own market and wanting more flexibility will be important factors for states considering establishing an SBE.

Ms. Nollette said she knows there are vendors providing the websites and the technical support for multiple SBEs. She asked if any states are actually sharing the same platform. Ms. Korbolic said there are eight different SBEs on the GetInsured platform, and those states share in the cost of any technical changes or policy changes multiple states want to make.

4. Heard a Presentation on Medicaid Redeterminations Following the End of the COVID-19 PHE

Miranda Motter (America’s Health Insurance Plans—AHIP) presented to the Committee on “The End of the Public Health Emergency: Medicaid Redeterminations.” She provided an overview of the COVID-19 authorities, federal and state emergency declarations, and the public health emergency (PHE). She also discussed and provided examples of key requirements and flexibilities tied to the PHE. She said that once the PHE ends, most requirements and flexibilities tied to the PHE will likely end automatically.

Ms. Motter said the end of the PHE was most recently extended to Oct. 13. She said the Biden Administration has said that it will provide the states 60-day notice before the PHE expires. She explained that to provide the promised 60-day notice, the Biden Administration would need to provide notice by Aug. 14 if the PHE is to end Oct. 13. If no notice is provided by that date, then the PHE is automatically extended for another 90 days ending Jan. 10, 2023. She said the Biden Administration would have to provide the states notice by Nov. 12 if the PHE is to end Jan. 10, 2023.

Ms. Motter provided an in-depth discussion of the Medicaid redetermination process, including the process pre-PHE, during the PHE, and post-PHE. She explained that the significant change in the process is that as a condition of receiving the enhanced federal medical assistance percentage (FMAP) under the federal Families First Coronavirus Responses Act, states are required to maintain enrollment of their Medicaid enrollees through the end of the PHE with no redeterminations. She said that when the PHE ends, states must resume the Medicaid redetermination processes.

Ms. Motter outlined the reasons why this is significant: 1) the volume of Medicaid redeterminations within the condensed time frame is unprecedented; 2) the states will have 12 months to initiate and 14 months to complete a full renewal of all individuals enrolled in Medicaid and the federal Children’s Health Insurance Program (CHIP); and 3) the states, counties, and beneficiaries have not done this over two years. She explained why the stakes are high for the states, counties, beneficiaries, providers, and other stakeholders with respect to Medicaid redeterminations.

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Ms. Motter listed 10 fundamental actions for states to take to prepare for the unwinding of the PHE, including creating a comprehensive state unwinding operational plan and coordinating with partners, including state, tribal, and state and federal government partners.

5. Heard an Update from the CCIIO on its Recent Activities

Ellen Montz (federal Center for Consumer Information and Insurance Oversight—CCIIO) provided an update on activities of interest to the Committee. She focused her remarks on the end of the PHE and the CCIIO's work to bring about a successful and smooth transition from Medicaid or CHIP to the private health insurance marketplace. Dr. Montz said this unwinding presents both an opportunity and a challenge. She said the federal Centers for Medicare & Medicaid Services (CMS) is committed to providing a 60-day notice of the ending of the PHE. As Ms. Motter noted, if the PHE is to end Oct. 13, the CMS would have to provide notice by Aug. 14. If the CMS does not provide that notice, then the PHE is automatically extended an additional 90 days to January 2023.

Dr. Montz said it is vitally important that all stakeholders plan and prepare for when the PHE ends. She said the CCIIO is developing a comprehensive plan for mitigating coverage lost. She said that part of CCIIO's preparation includes improving consumer notices and streamlining application processes to eliminate extra paperwork. She said the CCIIO is also planning aggressive outreach and enrollment strategies for unwinding. The CCIIO also will harness the power of its partnerships with stakeholders, including SBEs, state Medicaid agencies, health carriers, navigators, and state insurance regulators. She said the CCIIO's partnership with health carriers that offer Medicaid managed care organizations (MCOs) and qualified health plans (QHPs) will be vital because they can conduct outreach to Medicaid and CHIP enrollees during the redetermination process both before and after an individual loses coverage to assist in the transition to marketplace coverage. She said the CCIIO is also encouraging these health carriers to coordinate across their business lines and with their state Medicaid agencies and state departments of insurance (DOIs) to facilitate a smooth and seamless transition for consumers.

Dr. Montz encouraged state insurance regulators to work with these health carriers to assist them in their efforts. She said another area state insurance regulators can help will be outreach. She said it will be vital that there is open communication and successful feedback loop between all stakeholders involved in the redetermination process and unwinding to ensure a smooth transition and great consumer experience.

6. Heard a Federal Legislative and Regulatory Update

Brian R. Webb (NAIC) provided an update on federal legislative and regulatory activities of interest to the Committee. He focused his remarks on the recent extension of two subsidies for three additional years under the federal American Rescue Plan Act (ARPA) of 2021 due to the passage of the federal Inflation Reduction Act of 2022. He said this could be a challenge for the states in finalizing rates for 2023 because the deadline to submit those rates to HealthCare.gov is Aug. 17.

Mr. Webb provided an update on the status and attention received from the U.S. Congress on the letters the NAIC has sent to the Congress and federal agencies on addressing issues such as the so-called "family glitch." He said that just prior to the time the NAIC sent its letter, the CMS issued a proposed rule to address the issue. He said the public comment period has ended, and the CMS is reviewing the comments. It is anticipated that a final rule will be issued soon and apply for plans issued in 2023. He said the NAIC also sent letters on issues related to health savings accounts (HSAs) and the copayment accumulator. He said that to date, NAIC staff have not received any response related to the issues raised in this letter.

Mr. Webb said another letter the NAIC sent concerns Medicare Advantage marketing requesting that the federal government make the states the primary regulator because the states can more effectively address and resolve

Draft Pending Adoption

the marketing abuses that the states have been following and have documented. He said there has been a lot of interest from the Congress on this issue, and NAIC staff have been talking to key congressional staff about it as well. He said a similar issue getting a lot of attention is the improper marketing of health plans. He said NAIC staff have been talking to key congressional staff on ways that the federal government might be able to assist the states in addressing the issue, particularly when those engaging in these deceptive marketing practices are foreign entities and operating through the internet.

Mr. Webb said that another big issue NAIC staff are working with the CCIIO, and other federal agencies, is the implementation of the federal No Surprises Act (NSA). He said one of the main issues is enforcement and the role of, and how, the states can work with and coordinate with the CCIIO to enforce the rules.

Mr. Webb said another issue is the implementation of the federal network adequacy requirements beginning with the 2023 plan year. He said that for QHPs in FFEs, beginning with plan year 2023, the CMS will begin implementing time/distance standards for various types of providers and facilities, and beginning in plan year 2024, the CMS will begin implementing wait time standards. To comply with the time and distance standards, at least 90% of QHP enrollees must live within the maximum distance to at least one provider of each type. He said NAIC staff are working with the CCIIO as they move forward with implementation.

Mr. Webb also noted that health plan transparency requirements recently became effective July 1. He said the states are the primary regulators in enforcing these requirements. However, the CCIIO is conducting a thorough review of the information provided by the plans. He encouraged the states to reach out to the CCIIO if they receive complaints.

7. Received an Update on the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup's Work

Mr. Keen said the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup has been meeting to hear presentations from various stakeholder groups providing their perspective on the Subgroup's charge to develop a white paper examining pharmacy benefit manager (PBM) business practices. He said that to date, the Subgroup has heard presentations from about 17 stakeholder groups.

Mr. Keen said he anticipates the Subgroup holding at least one more meeting in late August during which it would hear from at least one additional stakeholder group on the Subgroup's upcoming work on the white paper. He said he anticipates the Subgroup beginning its work on the white paper in September. He said that on Aug. 15, the Subgroup plans meet in regulator-to-regulator session, pursuant to paragraph 3 (specific companies, entities or individuals), paragraph 8 (consideration of strategic planning issues), and paragraph 9 (any other subject required to be kept confidential) of the NAIC Policy Statement on Open Meetings, to: 1) discuss its approach to the white paper; 2) discuss a draft white paper outline; and 3) seek volunteers from among the Subgroup members to begin drafting sections of the white paper. He said he hopes the Subgroup can complete its work on the white paper by the end of the year. However, to allow for robust discussion and comments from all stakeholders, the Subgroup's work on the white paper could extend into early 2023. He said he would continue to provide updates to the Committee and the Regulatory Framework (B) Task Force on the Subgroup's progress to complete the white paper.

8. Received an Update on the Special (EX) Committee on Race and Insurance Workstream Five's Work

Commissioner Arnold provided an update to the Committee on Workstream Five's work to date since her last update to the Committee at the Spring National Meeting. She said that since the Workstream's last update to the Committee at the Spring National Meeting, the Workstream announced the dates and times and focus of four meetings it plans to hold before the end of the year. She said the Workstream has held the first two meetings already. The first meeting was June 30. Its focus was on provider network composition.

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Commissioner Arnold said that during its June 30 meeting, the Workstream heard from two NAIC consumer representatives who discussed cultural competency in provider networks. The Workstream also heard from the Colorado DOI on its work through the Colorado Option to improve racial health equity for consumers purchasing health insurance in the individual and small group markets. She said the Workstream held its second meeting on July 26. The focus of this meeting was on barriers to care with respect to providers.

Commissioner Arnold said during its July 26 meeting, the Workstream heard a presentation from Quest Analytics on emerging ideas and approaches state insurance regulators might consider to close the health equity gap when developing plan network adequacy requirements. The Workstream also heard a presentation from an NAIC consumer representative, who discussed barriers that people of color and other historically underrepresented populations encounter when trying to obtain treatment from network providers, particularly for those who have plans with narrow networks. She said the American Medical Association (AMA) presented on the work it is doing related to provider directories and associated challenges, including their accuracy and issues associated with the inclusion of provider race and ethnicity information. The Blue Cross Blue Shield Association (BCBSA) and one of its member plans discussed challenges and efforts to mitigate race-based barriers to insurance. They also discussed ways that state insurance regulators can increase access to culturally competent care.

Commissioner Arnold said the Workstream's next meeting is Aug. 23. She said the focus of this meeting is on barriers to care related to benefit design. She said the Workstream has invited speakers to discuss what ways the structure of available benefits, such as cost-sharing or utilization management, can sometimes uniquely disadvantage communities of color, and what actions can state insurance regulators take to remedy such benefit designs. She said the Workstream anticipates hearing presentations from Mila Kofman (DC Health Benefit Exchange Authority—DCHBX), a representative from the American Academy of Actuaries' (Academy's) Health Equity Work Group, and a panel of NAIC consumer representatives. She said the Workstream's last scheduled meeting is Sept. 20, which will focus on innovations in benefit design. She said the Workstream's planned speakers for this meeting include speakers to discuss standardized plans and value-based insurance designs.

Commissioner Arnold said the Workstream's next series of meetings will focus on effective consumer education and engagement, as well as mechanisms to understand barriers at the community level. She said the Workstream is in the process of finalizing those meeting agendas.

Having no further business, the Health Insurance and Managed Care (B) Committee adjourned.

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/2022 Summer National Meeting/08-Bmin

Agenda Item #2

Consider Adoption of its Subgroup, Working Group and Task Force Reports
—*Commissioner Glen Mulready (OK)*

Agenda Item #3

Hear a Presentation on Pharmacy Benefit Managers (PBMs) and Their Business Practices from a Large Employer Perspective—*Teah Corley (EmployerAdvocates) and Brandon Long (ERISA Counsel)*



NAIC Presentation

The Impact of PBM Regulation on large, Multi-State Employers

Teah Corley and Brandon Long

12/14/2022

The Understood Need for PBM Regulation

The Call for PBM Regulation

- Lack of Transparency
- Rising Costs of Pharmaceuticals
- Waste, Fraud & Abuse in the System
- Changing Definition of Rebates
 - Undisclosed Rebate Retention
- Claw back Provisions
- Self-Serving, Competition Inhibiting, Trade Practices at PBM Level

Identifying and Aligning the Interest Groups

The Pharmacy Industry

- Pharmaceutical Manufacturers
- Pharmacy Wholesalers and Distributors
- National Pharmacy Chains
- Independent Pharmacies
- Pharmacists
- Pharmacy Services Administrative Organizations (PSAOs)
- Pharmacy Benefit Managers

The Health Plans (the Payers)

- Employers Who Offer Healthcare to Employees
 - Fully Insured Health Plans
 - Self-Funded Health Plans

The End Users (the Consumers)

- Patients

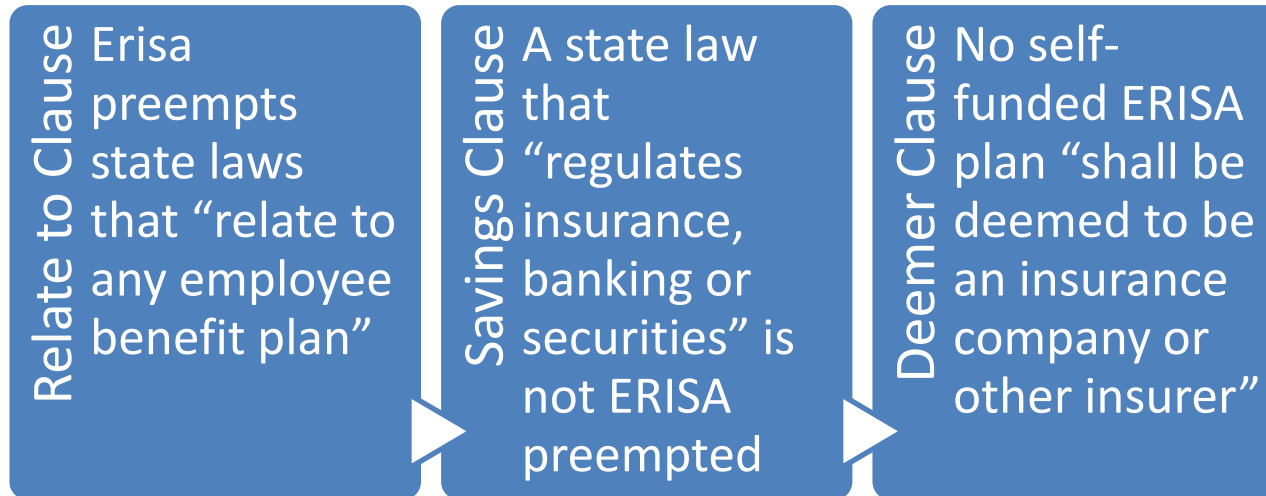
How Patients Access Pharmacy Benefits

- Patient Access to Pharmacy
 - Approximately 54.3% of Americans receive access to pharmacy benefits through employer-sponsored health plans
 - 10.2% direct purchase
 - Remainder Medicare, Medicaid, VA/CHAMPVA, Medishare, or Uninsured
- Fully Insured Health Plans
 - Approximately 35% of covered workers are covered by fully insured plans*
 - Historically regulated by State Insurance Departments
 - Direct purchase plans are typically fully insured
- Self-Funded Health Plans
 - Approximately 65% of covered workers are covered by self-funded plans*
 - Historically regulated by ERISA

** Source: Kaiser Francis 2021 Health Benefits Survey*

ERISA Preemption Framework (Basics)

ERISA preemption generally involves a three-step analysis using three parts of the statute



- Arkansas passed Act 900 which regulated Pharmacy Benefits Managers (“PBMs”). It controlled pricing and other things with respect to PBMs.
- The Act established a reimbursement floor by requiring PBMs to reimburse pharmacies at a rate that reflected the pharmacies’ acquisition costs.
- The Act required publication of PBM prices, an appeal process allowing pharmacies to challenge reimbursement rates, and allowing pharmacies to refuse to fill prescriptions if reimbursement fell below acquisition costs.

Rutledge (cont.)

- State laws have a “connection with” ERISA plans if they “require providers to **structure 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**.’ As a shorthand for these considerations, this Court asks whether a state law ‘governs a **central matter of plan administration** or interferes with **nationally uniform plan administration**.’ If it does, it is pre-empted.

Rutledge (cont.)

- “Crucially, not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan. That is especially so if a law merely affects costs.” *Rutledge*, 141 S. Ct. at 480.
- *Rutledge’s* example: NY’s 13% hospital surcharge for non-Blue Cross insurers. “[S]uch an ‘indirect economic influence’ did not create an impermissible connection between the New York law and ERISA plans because it did not ‘bind plan administrators to any particular choice.’” *NY State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U. S. 645, 659 (1995).
- “In short, ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage.” *Rutledge*, 141 S. Ct. at 480.

Rutledge (cont.)

Rutledge joins a long line of cases holding that states can regulate third-parties who act as **vendors** for ERISA-regulated plans even though the state regulation might have an effect on such plans:

- **HMOs** (*Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002));
- **Insurance Companies** (*KY Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003); *Metro. Life Ins. Co. v. MA*, 471 U.S. 724 (1985));
- **Hospitals** (*De Buono v. NYSA-ILA Med. & Clinical Serv's Fund*, 520 U.S. 806 (1997); *NY State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U. S. 645 (1995)).

Sample State-Level Regulation Provisions

- Restrictions on Mandatory Mail Order
- Any Willing Provider (Pharmacy)
- Minimum Access within Certain Mile Range Requirements
- Restrictions on Specialty Locks
- Mandatory Minimum Independent Pharmacy Reimbursements
- Required Specific Reimbursement Methodology (Cost Plus vs. AWP Minus)
- Limits on Removal of Pharmacies and/or Pharmacists from a Network
- Messaging and Communications to Patients

How Did Self-Funded Employers Manage Before PBM Regulation?

- Contractual Negotiations
 - Pre-qualifiers in RFPs
 - Audit rights and continual monitoring
 - Pass-through pricing
 - Control of formulary
 - Network selection
 - True-up provisions
 - Direct contracting strategies
 - Own pharmacy networks
 - Own pharmacies
 - Accessing MediSpan database for checks and balances
- Competitive Bidding
- Ongoing Audits

Challenges for Multi-State Employers

- Administrative Challenges – Loss of Uniformity
 - Keeping up with Differing Laws Across 50 States
 - Differing State Restrictions on Mandatory Mail Order
 - Differing State Restrictions on Pharmacy Steerage
 - Differing State Restrictions on Specialty Locks
 - Differing State Restrictions on Own-Use Pharmacies
 - Differing State Mandatory Access Within a Certain Mile Radius Across States
 - Differing State Restrictions on Reimbursement Requirements
- Cost Challenges - Maintaining Sustainable Healthcare and Pharmacy Plans with Loss of Payer Control
 - Inability to Steer to Lowest Cost, Highest Quality Pharmacies
 - Loss of Ability to Streamline Quality of Care for Specialty Medications
 - Loss of Ability to Streamline Access to Manufacturer Copay and Assistance Pass-Through Opportunities
 - Limiting Own-Use Considerations

Case Study

- Hobby Lobby Case Study – Potential Impact
 - Administrative Challenges
 - Loss of Specialty Steerage in Some States
 - Inability to Streamline Access to Manufacturer Assistance Programs
 - Loss of Access to Specialty Case Management for Highest Quality Patient Care and Outcomes
 - Potential Mandates for Pharmacy Reimbursement
 - Limits competition and negotiation
 - Administrative challenges of Mandatory Reimbursement Methodology
 - Cost plus in some states; AWP minus standard in others
 - Inability to Encourage Mail Order in markets where needed
 - Own-Use Restrictions

Potential Call to Action

- Recognition of ERISA preemption for self-funded employers to re-establish and reinforce uniformity across state lines. Rutledge did not say ERISA does not preempt any state PBM law.
- Encourage state legislators to allow NAIC to issue uniform guidance to help synchronize state laws relating to PBMs

Questions

Open Table – Questions and Discussion

HOBBY LOBBY

Legal

December 5, 2022

National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001

Statement from Hobby Lobby

As an employer serving 45,000 employees across 47 states, Hobby Lobby has historically relied on the uniformity afforded by ERISA preemption to govern its health and welfare plans.

ERISA promotes continuity and uniformity in benefits administration by preempting “any and all state laws insofar as they may now or hereafter relate to” any ERISA benefit plan. Section 514(a) of ERISA, known as the statute’s preemption provision, is intended to protect plan sponsors and fiduciaries from operating under countless and potentially conflicting state and local regulations on benefits administration.

The variety of state laws that “relate to” an ERISA plan for purposes of Section 514(a) is very broad, and encompasses “all laws, decisions, rules, regulations, or other State action having the effect of law, of any State.” This would apply to both common law and statutory laws. A state law “relates to” an ERISA plan for purposes of Section 514 preemption if it bears either a “reference to,” or a “connection with,” the plan.

It is a core purpose of ERISA to create uniformity and continuity for employers managing benefits across multiple state lines. Until the *Rutledge* case in 2020, this approach had gone unchallenged. The United States Supreme Court in *Rutledge* looked at one very narrow Arkansas state law and ultimately concluded that it was not preempted by ERISA. Unfortunately, legislators – and frankly, insurance departments – have used *Rutledge* to act as if ERISA does not exist at all and pass laws and regulations specifically targeting self-funded employers (under the cloak of laws and regulations supposedly targeting “PBMs”).

This is creating significant challenges for multi-state employers like Hobby Lobby.

The potential deterioration of ERISA preemption and the uniformity it affords for multi-state employers is very concerning.

Below are just a few of the challenges multiple-state employers will face if ERISA does not preempt state law with respect to pharmacy benefit management legislation:

- **Administrative Challenges:**
 - Maintaining consistency and continuity of 47 different state laws for one health and welfare plan impacting 45,000+ employees and their families.
 - Ensuring consistent treatment of all plan members, avoiding potentially discriminatory disparate treatment.
 - Balancing (a) the publicity and expense of filing lawsuits challenging overreaching state laws and regulations, against (b) the need to run a business and managing costs.
- **Cost and Sustainability Considerations:**
 - Varying requirements across state lines creates increased complexity that leads to increased costs of administration both internally for the employer, but also for PBMs. This translates to the PBMs increasing their costs that are then passed on to the employer in addition to the employer's increased internal costs.
 - Maintaining the fiduciary obligation to defray reasonable expenses to the plan with varying state laws creating increased administration and oversight. This is exacerbated by some state laws that prohibit plan sponsors from implementing effective cost-containment strategies.
 - Varying limitations on specialty steerage in some states threatens the long-term sustainability of offering employer-sponsored pharmacy benefits.
 - Members in some states could lose access to specialty pharmacy case management and concierge navigators, resulting in reduced quality of care and potential outcomes that lead to the increased likelihood of catastrophic episodes.
 - Loss of efficient, streamlined, processes made available through employer-preferred specialty pharmacies leads to potential depletion of manufacturer cost sharing in states that impose restrictions.
 - Loss of ability to leverage negotiations and steerage to the lowest cost, highest quality pharmacies, leads to increased total cost of care which reduces long-term sustainability.
 - Loss of ability to encourage mail order in markets with limited access threatens the member medication adherence.

We appreciate the opportunity to address the Honorable Commissioners of the National Association of Insurance Commissioners to raise awareness as to the challenges facing multi-state employers with varying state laws specific to Pharmacy Benefit Managers.

Respectfully,



Peter M. Dobelbower
General Counsel, Senior Vice President of Legal

Agenda Item #4

Hear an Update from the Federal Centers for Medicare & Medicaid Services' (CMS) Center for Consumer Information and Insurance Oversight (CCIIO)—*Dr. Ellen Montz (CCIIO)*

Agenda Item #5

Discuss Any Other Matters Brought Before the Committee
—*Commissioner Glen Mulready (OK)*