The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met in San Diego, CA, Dec. 11, 2021. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair, and Martin Swanson (NE); Lori K. Wing-Heier (AK); Yada Horace (AL); Alan McClain (AR); Bruce Hinze (CA); Paul Lombardo and Kathy Belfi (CT); Andria Seip (IA); Julie Holmes (KS); Shawn Boggs (KY); Jeffrey Zewe (LA); Kathleen A. Birrane and Mary Kwei (MD); Chad Arnold (MI); Chloria Lindley-Myers and Cynthia Amann (MO); Tracy Biehn (NC); Gale Simon (NJ); Paige Duhamel (NM); Shannen Logue (PA); Brian Hoffmeister (TN); Tanji J. Northrup (UT); Don Beatty (VA); Molly Nollette (WA); Nathan Houdek and Jennifer Steggall (WI); Joelynn Fix (WV); and Denise Burke (WY). Also participating were: David Altmaier (FL); Jon Godfread (ND); and Glen Mulready and Kelli Price (OK).

1. **Heard an Update on the Pharmaceutical Care Management Association v. Wehbi Ruling**

Commissioner Godfread updated the Subgroup on the recent decision by the Eighth Circuit of the U.S. Court of Appeals in *Pharmaceutical Care Management Association v. Wehbi*. He said the Eight Circuit’s decision upheld two laws enacted during North Dakota’s 2017 legislative session. These laws were enacted as an effort to prohibit pharmacy benefit managers (PBMs) from engaging in what have been considered deceptive and anti-competitive practices, which ultimately draft up prescription drug costs. The *Pharmaceutical Care Management Association v. Wehbi* case is the first to consider at the federal appellate level the scope of the U.S. Supreme Court’s unanimous decision last year in *Rutledge v. Pharmaceutical Care Management Association*, which upheld an Arkansas state law regulating the abusive practices of PBMs.

Commissioner Godfread said based on the North Dakota Department of Insurance’s (DOI’s) legal analysis of the *Pharmaceutical Care Management Association v. Wehbi* decision, the North Dakota DOI believes the *Pharmaceutical Care Management Association v. Wehbi* decision significantly expands upon the *Rutledge v. Pharmaceutical Care Management Association* decision, which provided a framework that places a broader category of laws presumptively beyond the Employee Retirement Income Security Act’s (ERISA’s) preemptive scope—i.e., health care cost regulation—including state legislation regulating PBMs in this area. He said *Pharmaceutical Care Management Association v. Wehbi* took that a step further to uphold laws regulating PBMs against ERISA preemption where the laws regulate matters of transparency; the imposition of fees, fines, and arbitrary performance metrics; and other requirements upon pharmacy providers, thereby preventing anti-competitive practices by PBMs. He said he believes the *Rutledge v. Pharmaceutical Care Management Association and Pharmaceutical Care Management Association v. Wehbi* decisions now open the door for states to pass more laws that regulate PBMs more comprehensively and have those laws upheld as applied to ERISA plans, as long as the laws pass the ERISA “tests” established in these cases.

Mr. Keen thanked Commissioner Godfread for bringing the *Pharmaceutical Care Management Association v. Wehbi* decision to the Subgroup’s attention. He said he believes the Subgroup will find the North Dakota DOI’s analysis of the case helpful as it moves forward with its work to develop a white paper on issues related to the state regulation of certain PBM business practices. He also said he assumes the ERISA (B) Working Group will be examining the *Pharmaceutical Care Management Association v. Wehbi* decision as well. As such, the Subgroup will coordinate it discussions on the case with the Working Group.

2. **Heard from the States on the Implementation of PBM Laws**

Mr. Keen said the Subgroup’s next agenda item is to hear from Connecticut, Oklahoma, Virginia, and Wisconsin on their PBM laws. He said this agenda item was added at the request of Subgroup members wanting to know what other states have done with respect to PBM regulation and oversight. He said he believes this information will be helpful to the Subgroup as it moves forward with the white paper and potentially for additional Subgroup discussions about developing another draft PBM model.

a. **Connecticut**

Mr. Lombardo discussed Connecticut’s PBM law. He said Connecticut requires PBMs to register with the state. He discussed Connecticut Gen Stat § 38a-479ppp (2019), which was enacted under Public Act 18-41. He said this statute requires PBMs for insured business in the state to file a report each year with the commissioner that includes information on the aggregate dollar amount of all rebates for outpatient prescription drugs the PBM collected from pharmaceutical manufacturers and the aggregate
dollar amount of all rebates for outpatient prescription drugs, excluding any portion of the rebate received by health carriers, the PBM collected from the pharmaceutical manufacturers. He said Connecticut received the first of this data at the beginning of 2020 and will receive the second set of data at the beginning of 2022. He said this information will be made public sometime in the first quarter of 2022. He said although not strictly related to PBMs, Public Act 18-41 also requires health insurers to provide information on their rebate practices. He said based on this information, the commissioner prepares an annual report, which is posted on the DOI’s website, containing: 1) an explanation of the manner in which health carriers accounted for rebates in calculating premiums for health care plans delivered, issued for delivery, renewed, amended, or continued during such year; 2) a statement disclosing whether, and describing the manner in which, health carriers made rebates available to insureds at the point of purchase during such year; 3) any other manner in which health carriers applied rebates during such year; and 4) such other information as the commissioner, in the commissioner's discretion, deems relevant. He also discussed a provision in Connecticut law modeled after a California law requiring health insurers as part of their rate filing to provide data on prescription drugs; i.e., the top 25 most costly drugs and the top 25 most utilized drugs.

Ms. Belfi discussed Connecticut’s review of affiliated agreements health insurers have with PBMs as part of the DOI’s financial analysis requirements of the companies. Mr. Lombardo explained that as part of this financial analysis work, the Connecticut DOI realized it needs to learn more about every aspect of the prescription drug distribution system, which ultimately resulted in a draft, non-public white paper that Connecticut has shared with the Subgroup. He noted that as part of this process, the Connecticut DOI came to realize the possibility of unintended consequences of any PBM legislation meant to address one aspect of PBM business practices, such as rebating, on other aspects of the prescription drug distribution system.

b. Oklahoma

Ms. Price discussed Oklahoma’s Patient’s Right to Pharmacy Choice Act, which was effective Nov. 1, 2019. She explained that the Act establishes minimum and uniform access to a provider and standards and prohibitions on restrictions of a patient’s right to choose a pharmacy provider. These minimum standards include provisions: 1) barring PBMs from reimbursing independent pharmacies at a lesser amount than PBM-owned pharmacies; 2) outlining geographical requirements for urban, suburban, and rural pharmacy access; and 3) prohibiting incentives related to mail-order, cost-sharing, co-payments, or other discounts. She explained how the Rulledge v. Pharmaceutical Care Management Association case and, ultimately, the U.S. Supreme Court’s decision in that case affected the Oklahoma DOI’s implementation and enforcement of the Act.

Ms. Price also discussed the Oklahoma DOI’s initiatives related to ensuring PBM compliance and enforcement of the Act. She said the Oklahoma DOI created a division focused solely on PBM compliance and enforcement. It hired staff, including an industry expert/pharmacist consultant, with the applicable knowledge and expertise in these areas. Ms. Price said the Oklahoma DOI created a process on its website for consumers to submit complaints about PBMs online. As part of this, and to make the process as smooth as possible, the division developed templates for typical correspondence sent to PBMs and consumer complainants, including a “blue sheet” specific to PBM alleged violations, which can be used for Oklahoma DOI investigators to succinctly summarize their investigations and more quickly refer cases to the legal division for enforcement actions. Based on the Oklahoma DOI’s experiences, Ms. Price also offered suggestions to states considering PBM legislation and currently implementing PBM laws.

Ms. Price said since Sept. 1, 2020, the Oklahoma DOI has received and reviewed over 135,000 alleged violations of the Act. She said approximately 27,000 have been resolved to date, and 32 alleged violations have been referred to the Oklahoma legal division for an enforcement action.

Mr. Houdek asked Ms. Price if staff hired for the new division were newly hired staff or repurposed staff. Ms. Price said it was a combination of new staff and repurposed staff. Mr. Houdek asked Ms. Price about the nature of complaints filed. Ms. Price said most of the complaints related to transaction fee issues and maximum allowable cost (MAC) pricing appeals and reimbursement amounts. Ms. Arp asked about the fiscal note attached to the Act. Commissioner Mulready said such a fiscal note would have been approximately $500,000 from the Oklahoma DOI’s perspective. Ms. Duhamel asked about the MAC appeals. Ms. Price described how the Oklahoma DOI has uncovered such violations. She explained that the pharmacy services administrative organizations (PSAOs) have alerted the Oklahoma DOI about alleged MAC pricing appeal violations.

c. Virginia

Mr. Beatty discussed Virginia’s PBM law, which was effective Oct. 1, 2020. He explained that Virginia’s PBM law places the responsibility on the health insurer for compliance with the law. Under the law, PBMs must be licensed. Mr. Beatty explained that if the PBM fills out the application correctly, the PBM law requires the Virginia DOI to issue the license. He described the PBM law’s prohibitions on certain conduct by a health carrier or by a PBM under contract with a carrier. These prohibitions
include: 1) reimbursing a pharmacy or pharmacist an amount less than the amount the PBM reimburses a PBM affiliate for providing the same pharmacist services; and 2) penalizing or retaliating against a pharmacist or pharmacy for exercising rights provided under the law. He said the Virginia law also prohibits a health carrier or a PBM under contract with a carrier from: 1) including any mail order pharmacy or PBM affiliate in calculating or determining network adequacy; and 2) conducting spread pricing.

Mr. Beatty said currently, Virginia has 39 licensed PBMs. He said the Virginia DOI has not received a lot of complaints related to its law. He explained that because of this seemingly lack of complaints, the Virginia DOI decided to create and post on its website a specific complaint form that can be used to file complaints related to the PBM law. He said even with the specific complaint form, the Virginia DOI still has not received a lot of complaints specific to the PBM law.

Mr. Beatty also described Virginia’s quarterly reporting requirements related to rebates and its examination requirements. He said the Virginia DOI plans to submit legislation for consideration during the 2022 legislative session changing the quarterly rebate reporting requirements to an annual report since the Virginia DOI will not review the information until the end of each calendar year.

Ms. Arp asked Mr. Beatty about the confidentiality of the examination reports and the fee for such examinations. Mr. Beatty described the Virginia law’s confidentiality requirements, which is consistent with the NAIC’s model confidentiality language regarding examination reports and any working papers, documents, reports, and other information compiled during an examination. He explained that the Virginia DOI does not charge companies for financial or market conduct examinations. The money to pay for examinations comes from the Virginia DOI’s general assessment.

d. Wisconsin

Mr. Houdek discussed the work of the Governor’s Task Force on Reducing Prescription Drug Prices before Wisconsin’s proposed PBM law was introduced. He said the Task Force held eight public meetings from November 2019 to August 2020. The Task Force heard from 24 organizations representing a multitude of stakeholders. He said the Task Force issued a report in October 2020, which centered on the following key policy provisions: 1) lowering prices and controlling costs; 2) increasing transparency and consumer protections; and 3) access for vulnerable populations.

Mr. Houdek said with respect to increasing transparency and consumer protections, among its recommendations, the Task Force recommended the creation of the Office of Prescription Drug Affordability. He said similar to Oklahoma’s approach, the Task Force recognized that the Wisconsin DOI does not have the capacity and appropriate expertise to implement and enforce the requirements for a law regulating PBMs and the prescription drug market.

Mr. Houdek said 20 of the Task Force’s recommendations were included in the governor’s 2021–2023 biennial budget. He said during the budget process, the Task Force’s recommendations were removed and introduced as separate, stand-alone bills and packaged as “Less for Rx.” However, due to the COVID-19 public health emergency and other circumstances, the PBM legislation died during the 2020 legislative session. Mr. Houdek said a slimmed down version of what was initially introduced was introduced in January 2021 and enacted in March 2021 (2021 Wisconsin Act 9). Key provisions in the law include: 1) a prohibition on gag clauses; 2) an annual PBM rebate reporting requirement; 3) a PBM licensure requirement; and 4) limitations on a PBM’s ability to retroactively deny or reduce a pharmacy’s claim after adjudication.

Mr. Houdek discussed the Wisconsin DOI’s next steps, which include: 1) tracking complaints and correspondence received; 2) learning from the efforts of other states as they implement their PBM oversight laws; and 3) continuing to work with stakeholders to build support to advance the other Task Force recommendations. He also said the fiscal note for the initial PBM bill included: 1) seven new staff; and 2) $500,000 in information technology (IT) upgrades. He said this fiscal note request was attached to the January 2021 legislation; but ultimately, the Wisconsin DOI received no new dollars to assist with implementation and enforcement. He said the Wisconsin DOI’s market regulation division has been tasked with implementing the new PBM law and has been working over the past few months to create a dedicated website and develop complaint templates, consumer-facing materials, and other information necessary for a smooth implementation process.

3. **Discussed its Next Steps**

Mr. Keen said the Subgroup will continue its discussions on its white paper charge during a meeting early next year.

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