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Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Tampa, Florida
December 15, 2022

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met in Tampa, FL, Dec. 15, 2022. The following Subgroup members participated: TK Keen, Chair, Numi Rehfield-Griffith, Doug Hartz, Veronica Murray, and Ralph Magrish (OR); Laura Arp, Vice Chair (NE); Sarah Bailey (AK); Mark Fowler (AL); Crystal Phelps (AR); Paul Lombardo and Jared Kosky (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt (KS); Daniel McIlwain, Rob Roberts, and Jonathan Abbott (KY); Chad Arnold and Joe Stoddard (MI); Norman Barrett Wiik (MN); Amy Hoyt and Carrie Couch (MO); David Dachs (MT); Robert Croom (NC); Ralph Boeckman and Erin Porter (NJ); Paige Duhamel (NM); Kelli Price (OK); Ana Paulina Gomez (PA); Scott McAnally (TN); Tanji J. Northrup (UT); Don Beatty and Stephen Hogge (VA); Ned Gaines and Molly Nollette (WA); Nathan Houdek, Rachel Cissne Carabell, and Jennifer Stegall (WI); Ellen Potter (WV); and Tana Howard (WY). Also participating were: Chris Struk (FL); Michelle B. Santos (GU); Chris Nicolopoulos (NH); and Cassie Brown (TX).

1. Adopted its Oct. 24 and Summer National Meeting Minutes

The Subgroup met Oct. 24 and Aug. 9. During these meetings, the Subgroup heard presentations from America's Health Insurance Plans (AHIP), the Blue Cross and Blue Shield Association (BCBSA), and the Pharmaceutical Care Management Association (PCMA) on issues from their perspective on the Subgroup's 2022 charge to develop a white paper to: 1) analyze and assess the role pharmacy benefit managers (PBMs), pharmacy services administrative organizations (PSAOs), and other supply chain entities play in the provision of prescription drug benefits; 2) identify, examine, and describe current and emerging state regulatory approaches to PBM business practices, such as price transparency and reporting requirements; rebating; and spread pricing, including the implications of the *Rutledge vs. PCMA* decision on such business practices; and 3) discuss any challenges, if any, the states have encountered in implementing such laws and/or regulations.

Beatty made a motion, seconded by Commissioner Houdek, to adopt the Subgroup's Oct. 24 (Attachment ?-A) and Aug. 9 (*see NAIC Proceedings – Summer 2022, Regulatory Framework (B) Task Force, Attachment Eight*), minutes. The motion passed unanimously.

2. Discussed its Work to Develop an Initial PBM White Paper Draft

Keen said the Subgroup just released a working draft of the PBM white paper. He said that the Subgroup's aim in developing the white paper was to have it focus on the current state of play as far as PBMs and PBM regulation and business practices are concerned, as well as not have it try to predict any future changes in such regulation or business practices. He said that over the next few months, the Subgroup plans to edit and refine the document before releasing an official draft for a 30-day public comment period, which includes adding language to the introduction and recommendation sections. Keen said the main purpose of this meeting is for the Subgroup to hear from the leaders of each of the white paper section drafting groups on their process for developing an initial draft of their section and its focus.

Gaines discussed Section B—Key Players in the Drug Pricing Ecosystem. He said Section B focuses on the main players in the prescription drug supply chain, including insurers, pharmaceutical manufacturers, PBMs, pharmacists, PSAOs and the interrelation of the parties in the chain and transaction costs. He said with respect to

 

the pharmaceutical manufacturers, Section B describes the various entities within this category—brand drug manufacturers, generic drug manufacturers, and biologic manufacturers. Gains said the subsection on pharmacies describes both chain pharmacies and independent pharmacies. He explained that there are a few subsections in Section B that the drafting group needs to write, but it plans to complete them soon and have NAIC staff incorporate them into the white paper draft the Subgroup will expose for public comment.

Rehfield-Griffith discussed Section C—Enforcement and Federal Preemption Issues. She said Section C examines the scope of federal preemption of state laws regulating PBMs under the federal Employee Retirement Income Security Act of 1974 (ERISA), Medicare Part D, and Medicaid, including the implications of recent court decisions and ongoing litigation, and implications for states considering enacting similar laws. She said the subsection on ERISA focuses mostly on the recent U.S. Supreme Court decision in *Rutledge* and how that decision provides some leeway for the states to regulate PBMs without being concerned about ERISA preemption, but states need to be careful in crafting such legislation because it is unclear how far the facts of *Rutledge* and the precedent of that case would extend to state laws that may not mirror the Arkansas law that was the subject of that case. Rehfield-Griffith said the Medicare Part D subsection discusses the *Mulready v. PCMA* case extensively and outlines the provisions in the Oklahoma law a federal district court found were preempted by ERISA. She said this subsection concludes that Medicare Part D preemption may remain an obstacle to state insurance regulation and that state insurance regulations are likely going to be preempted in areas where a standard has been directly articulated by the federal government, such as in the provisions related to Medicare Part D.

Rehfield-Griffith said the remaining subsection in Section C, which focuses on Medicaid, does not focus on any court cases because there is little case law or precedent in this area. She said the subsection describes how the Medicaid program is set up as a federal-state partnership, which differs in how both Medicare and ERISA are set up. Because of such a partnership, states have more leeway to regulate PBMs serving Medicaid carriers as long as those regulations do not conflict with the state's Medicaid structure and are consistent with the terms of a state's current Medicaid plan. She said this subsection concludes that unlike the potential for ERISA or Medicare Part D preemption, Medicaid preemption should not be a significant concern for states looking to regulate PBMs that service Medicaid managed care plans or other Medicaid health carriers. However, states should ensure that any changes in PBM regulation in the Medicaid space are consistent with the state's Medicaid plan or seek an appropriate plan amendment if they are not.

Stoddard discussed Section D, which examines PBM functional areas, including formulary design, rebates, pricing and contracting practices, vertical integration and consolidation, pharmacy network adequacy, and the licensing of the different entities involved in the prescription drug supply chain. He discussed the main points of each of these areas as written in the subsection. He explained that the pricing and contracting practices subsection does not include any language related to mandatory arbitration as had been contemplated in the white paper outline because no one in the section drafting group had any information on this. He said the section drafting group is open to including such language if anyone in the Subgroup has this information or could clarify what this means.

Abbott discussed Section E—State Laws that Operate in the Supply Chain. He said Section E discusses the role of PBMs in the prescription drug supply chain and state laws enacted regulating PBMs and PBM business practices because of this expanding and evolving role. He described the Section E drafting group's approach and research used in writing the section, including examining different state laws and recent updates to those laws. He noted that recently there has been a push on both the state and federal level to enact laws requiring PBMs to provide more transparency in their business practices, such as disclosure of prescription drug pricing, cost information related to rebates, payments and fees collected from pharmaceutical manufacturers, insurers, and pharmacies.

Jolie H. Matthews (NAIC) said she would be speaking on behalf of the leader of the Section F drafting group. She said Section F concerns federal interest in PBMs and PBM business practices. The section focuses on the Federal Trade Commission's (FTC's) recently announced study on PBMs. She said the Section F drafting group developed the language for Section F using information found through targeted online searches for articles on the subject. The Section F drafting group summarized the information found in the articles to include in Section F.

Price discussed Section G—Key Jurisprudence. She said Section G focuses on the three cases, to date, that have shaped state PBM laws and regulations—the *Rutledge* case, the *PCMA v. Wehbi* case, and the *Mulready* case. She explained that to some extent, Section G repeats some of the same information provided in Section C. Price discussed the details, arguments, findings, and key takeaways for each of the cases as detailed in Section G.

Arp reminded the Subgroup members and other stakeholders that the PBM white paper draft is just a draft, not an official draft the Subgroup is exposing for public comment. She said the purpose of providing the draft for this meeting is to let Subgroup members and other stakeholders know that the Subgroup is working diligently to complete its charge and the status of this work now before exposing an official draft for public comment. Keen asked for comments.

Carl Schmid (HIV+Hepatitis Policy Institute) expressed support for the Subgroup's work to date, particularly the work the Subgroup has been doing to hear from a wide range of stakeholders on issues related to the Subgroup's work to develop the PBM white paper. He said the NAIC consumer representatives look forward to providing comments on the draft white paper once the Subgroup exposes it for public comment. Schmid noted that the current working draft includes little information on the impact—good or bad—of PBMs and their business practices, such as mail-order service requirements or high cost-sharing requirements on certain prescription drugs for consumers. He reiterated that the NAIC consumer representatives stand ready to assist the Subgroup with addressing these initial concerns. Kris Hathaway (AHIP) also expressed support for the Subgroup's work to date related to the PBM white paper. She suggested, however, that the Subgroup expand the current working draft to incorporate and examine high prescription drug costs and issues related to such high costs. J.P. Wieske (Horizon Government Affairs) suggested that the Subgroup include a discussion in the white paper on the NAIC's previous work related to PBMs, such as the work done in revising the *Health Carrier Prescription Drug Benefit Management Model Act* (#22). Chris Petersen (Arbor Strategies LLC), speaking on behalf of the PCMA, said the PCMA shares some of the concerns of AHIP, particularly with the Subgroup potentially setting a 30-day public comment period for stakeholders to submit comments on the official PBM white paper draft. He suggested a longer public comment period, such as 60 days, would be more appropriate given the white paper's complexity.

3. Discussed Next Steps

Keen reiterated that the Subgroup plans to make additional edits to the PBM white paper working draft. Following this work, the Subgroup will release an official draft for a public comment period. Keen said he anticipates this will happen in January 2023. Noting that it is her last NAIC meeting, he also thanked Arp for her work as the Subgroup's vice chair.

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

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