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Pharmacy Benefit Manager Regulatory Issues (B) Subgroup

Louisville, Kentucky

March 22, 2023

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met in Louisville, KY, March 22, 2023. The following Subgroup members participated: TK Keen, Chair (OR); Ashley Scott and Molly Clinkscales, Vice Chair (NE); Kayla Erickson (AK); Jimmy Gunn, Reyn Norman, and Anthony L. Williams (AL); Beth Barrington (AR); Paul Lombardo (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt (KS); Daniel McIlwain (KY); Frank Opelka (LA); Anita G. Fox and Chad Arnold (MI); Amy Hoyt (MO); Matthew Eberhardt (MT); Ted Hamby (NC); Erin Porter and Ralph Boeckman (NJ); Paige Duhamel and Renee Blechner (NM); David Buono (PA); Scott McAnally (TN); Tanji J. Northrup (UT); Don Beatty (VA); Jennifer Kreitler and Ned Gaines (WA); Jennifer Stegall (WI); Erin K. Hunter (WV); and Jill Reinking (WY). Also participating was: Eamon G. Rock (NY).

1. Adopted its 2022 Fall National Meeting Minutes

Beatty made a motion, seconded by Commissioner Schmidt, to adopt the Subgroup’s Dec. 15, 2022, minutes (Attachment ?-A). The motion passed unanimously.

2. Heard an Update on the PBM White Paper Status

Keen said the Subgroup released a working draft of the proposed pharmacy benefit manager (PBM) white paper during its meeting at the 2022 Fall National Meeting. He said the Subgroup is working on edits to the working draft, such as adding language to the Recommendation section and making any necessary non-substantive edits. After this is complete, the Subgroup plans to release an official draft of the white paper for public comment by the end of March or early April. Keen said the Subgroup plans to set a 45-day public comment period. Following the end of the public comment period, the Subgroup plans to hold meetings to review the comments received and update the draft based on those discussions. He said the Subgroup hopes to finish its work on the white paper before the Summer National Meeting and forward it to the Regulatory Framework (B) Task Force for its consideration.

3. Heard an Update on Federal PBM-Related Legislative and Regulatory Activities

Brian R. Webb (NAIC) updated the Subgroup on recent federal PBM-related legislative and regulatory activities. He said the U.S. Senate (Senate) Committee on Commerce, Science, and Transportation passed the Pharmacy Benefit Manager Transparency Act of 2023 (S.127), which was sponsored by U.S. Sen. Maria Cantwell (D-WA) and U.S. Sen. Chuck Grassley (R-IA) on March 22. S.127 generally prohibits PBMs from engaging in certain practices when managing the prescription drug benefits under a health insurance plan, including charging the plan a different amount than the PBM reimburses the pharmacy. The bill also prohibits PBMs from arbitrarily, unfairly, or deceptively: 1) clawing back reimbursement payments; or 2) increasing fees or lowering reimbursements to pharmacies to offset changes to federally funded health plans.

Webb noted that S.127 provides that PBMs are not subject to these prohibitions if they: 1) pass along 100% of any price concession or discount to the health plan; and 2) disclose specified costs, prices, reimbursements, fees, markups, discounts, and aggregate payments received with respect to their PBM services. S.127 further requires PBMs to report annually to the Federal Trade Commission (FTC) certain information about payments received from health plans and fees charged to pharmacies. The FTC and state attorneys general are authorized to enforce the bill’s provisions. Webb explained that although this is a bipartisan bill, concerns have been raised by those accusing it of having the FTC involved in enforcing the legislation. He said he anticipates that S.127 will go to the Senate floor for a vote at some point; although, the exact timeline is unclear. If the Senate passes the bill, it is uncertain what will happen in the U.S. House of Representatives (House).

Webb said another bill of interest is the Prescription Pricing for the People Act of 2023 (S.113) introduced by Sen. Grassley, which passed the Senate Committee on the Judiciary on March 1. The bill requires the FTC to study the role of intermediaries in the pharmaceutical supply chain and merger activity. The FTC also must provide recommendations to increase transparency in the supply chain and prevent anticompetitive practices. Webb noted that like S.127, concerns involving the bill focus on the FTC’s role because of a feeling that the FTC is too political and untrustworthy.

Webb said NAIC staff will continue tracking both S.127 and S.113. He explained that because both bills are bipartisan, they could be incorporated into other Senate legislation or passed as standalone bills.

Webb said with respect to federal PBM-regulatory activity, in June 2022, the FTC launched a Section 6(b) of the Federal Trade Commission Act of 1914 (FTC Act) study to inquire into the prescription drug middleman industry, requiring the six largest PBMs to provide information and records regarding their business practices. He said the FTC’s investigation will closely examine how vertically integrated PBMs affect the availability and cost of prescription medications. He said as part of this investigation, the FTC issued mandatory orders to the six largest PBMs to submit to provide information and records regarding their business practices.

Webb said the inquiry is aimed at shedding light on several practices that have drawn scrutiny in recent years, including fees and clawbacks charged to unaffiliated pharmacies, methods to steer patients towards PBM-owned pharmacies, and the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients. He said the FTC gave the PBMs 90 days to respond, but he has not seen any reports from the FTC reflecting the PBM responses. He said NAIC staff are working with FTC staff to see if the FTC would be available to participate in a regulator-to-regulator meeting with the Subgroup to discuss any findings they may have at this point in the study.

Webb said in addition to this Section 6(b) study, in June 2022, the FTC issued a “Policy Statement on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products,” in which the FTC said this PBM business practice may violate anti-trust laws and bribery laws. The FTC intends to closely scrutinize the impact of rebates and fees on patients and payers to determine whether any of these provisions have been violated. In addition, it plans to monitor private litigation and file amicus briefs where it can aid courts in analyzing unlawful conduct that may raise drug prices. The FTC also plans to continue to study this issue to understand the full range of practices and implications.

Webb asked which NAIC staff could discuss with relevant Congressional committee staff, given the federal legislation and the recent U.S. Supreme Court decision in *Rutledge vs. Pharmaceutical Care Management Association (PCMA*) if the Subgroup is interested in pursuing trying to codify or clarify some of the issues related to the authority of state insurance regulators to regulate PBMs and their business practices. The Subgroup expressed support for Webb’s suggestion.

4. Heard a Legal Update on PBM-Related Litigation

Kay Noonan (NAIC) said as the Subgroup members and other stakeholders know, there has been a lot of PBM-related legislative activity by the states to address rising prescription drug costs. She noted the PCMA’s opposition to such legislation, which the PCMA asserts is preempted by the federal Employee Retirement Income Security Act of 1974 (ERISA), Medicare Part C program laws and regulations, and Medicare Part D program laws and regulations. She explained that the U.S. Supreme Court’s *Rutledge* decision potentially opened a pathway for states to regulate PBMs and their business practices. She discussed two major cases still pending in the courts—*PCMA v. Mulready* and *PCMA v. Wehbi*—considering the *Rutledge* decision, including their current litigation status and possible court decisions.

5. Heard a Discussion from the States on Recently Enacted and Pending State PBM Legislation

The Subgroup heard from various members and interested state insurance regulators on recently enacted and pending state PBM legislation. Beatty said in this year’s Virginia General Assembly session, two bills were introduced to include all self-funded plans in the definition of “carrier.” He said because of this proposed legislation, various stakeholders not previously involved in this issue, raised concerns. After discussion, the Virginia Joint Commission on Health Care (JCHC) was charged with conducting a study generally focusing on the *Rutledge* case and its implications and issuing a report on its findings. Beatty said he believes the idea of having the JCHC conduct this study and issue a report is to better educate legislators on the issues related to the *Rutledge* case and its impact on the ability of states to regulate PBMs and their business practices.

Seip updated the Subgroup on Iowa’s recently enacted PBM legislation. In this legislation, Iowa included a requirement that self-funding plans, defined as third-party payors, must comply with its provisions. She said based on this requirement, she has seen a big change in the reporting of information included in Iowa’s annual report concerning the collection of rebates and fees by plans, which previously only included such information from fully insured plans. She said this information is not public yet, but there is a big difference in the numbers. She said once the report is public, she would share it with the Subgroup.

Seip said Iowa is beginning to implement provisions of the law, including the provisions requiring the Iowa Department of Insurance (DOI) to collect complaints from pharmacies. She said the Iowa DOI has received many complaints, most focusing on the pharmacy being paid less than its drug acquisition cost. She said they have received a few complaints regarding the fees being charged. She said the Iowa DOI is turning its focus to examinations. She said she would be interested in what other states are doing in this area, how they implement this provision in their laws, and working together to figure out some best practices. Keen agreed and said he would work with NAIC staff to set up a future Subgroup regulator-to-regulator meeting to discuss examinations.

Rock provided an update on New York PBM-related legislation. He said in the Governor’s Executive Department proposed budget due April 1, there is a provision to provide the New York DOI with additional authority to regulate/register other prescription drug supply chain participants, such as pharmacy services administrative organizations (PSAOs), pharmacy switch companies, and rebate aggregators, as well as new requirements related to drug price disclosures of prescription drug manufacturers. He said for New York’s initial law, an 18-month implementation period was built in to allow time for the New York DOI to promulgate regulations, such as market conduct regulations, to implement its provisions. The New York DOI has had a number of open meetings discussing the proposed regulations and received many comments from stakeholders. He also noted that New York’s law gives the New York DOI the authority to conduct examinations. As such, he said he would support Iowa’s suggestion that the Subgroup hold a regulator-to-regulator meeting to discuss best practices in this area.

Duhamel discussed legislation just passed in New Mexico, which was introduced as co-payment accumulator legislation but later was amended to include provisions meant to lower the cost of prescription drugs. She said an additional amendment added provisions on federal Section 340B discrimination and new transparency and reporting requirements. She said she has not seen the final bill language, but she knows that based on the latest version of the bill, the New Mexico DOI will be busy this year working to implement the new law. Hoyt said based on Duhamel’s description, Missouri is seeing similar legislation being discussed in the state legislature. As such, she plans to follow what is going on in New Mexico as it works to implement the new law.

Lombardo discussed a bill just passed out of one of its committees that requires the Connecticut DOI to analyze the PBM distribution of prescription drugs and practices related to spread pricing, manufacturer rebates, and transparency and accountability. He said the proposed legislation also requires an examination of any impacts of ownership; governance; and vertical integration between PBMs, carriers, and pharmacies with respect to health care costs for consumers and any potential PBM anti-competitive practices in designing prescription drug formularies. He said he would keep the Subgroup apprised of what happens with the bill as it moves through the legislative process. He noted that Connecticut’s three largest domestic health insurers own the three largest PBMs. As such, if the bill is enacted, it could have a lot of significant implications. Keen asked about the timeline for the Connecticut DOI to complete its analysis if the bill passed without amendment. Lombardo said the bill requires the Connecticut DOI to finish its analysis and publish a report by Feb. 1, 2024. Beatty asked if the Connecticut DOI has calculated how much it will cost to conduct the analysis. Lombardo said based on internal discussions, the Connecticut DOI anticipates hiring an outside consulting firm to assist in the work, and it is working on developing a fiscal note reflecting this. He said the fiscal note is not intended to “kill” the bill, because the Connecticut DOI wants to conduct the analysis.

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

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