NAIC NATIONAL MEETING SPRING 2023

Revised date: 3/3/23

2023 Spring National Meeting
Louisville, Kentucky

PHARMACY BENEFIT MANAGER REGULATORY ISSUES (B) SUBGROUP
Wednesday, March 22, 2023
2:00 – 3:00 p.m.
Kentucky Convention Center—Ballroom A—Main Concourse Level

ROLL CALL

TK Keen, Chair	Oregon	David Dachs	Montana
Ashley Scott/Molly Clinkscales, Co-Vice Chairs	Oklahoma	Cheryl Wolff	Nebraska
		Ralph Boeckman/ Erin Porter	New Jersey
Steve Dozier	Alabama		
Lori K. Wing-Heier/ Kayla Erickson/Sarah Bailey	Alaska	Renee Blechner/ Paige Duhamel	New Mexico
Beth Barrington	Arkansas	Robert Croom/Ted Hamby	North Carolina
Jessica Ryan	California	Melissa Greiner	Pennsylvania
Paul Lombardo/ Michael Shanahan	Connecticut	Carlos Vallés	Puerto Rico
		Katrina Rodon	South Carolina
Howard Liebers	District of Columbia	Scott McAnally	Tennessee
Andria Seip	Iowa	Tanji J. Northrup	Utah
Vicki Schmidt	Kansas	Don Beatty	Virginia
Daniel McIlwain	Kentucky	Jennifer Kreitler/ Ned Gaines	Washington
Jeff Zewe	Louisiana		
Chad Arnold/Joe Stoddard	Michigan	Ellen Potter/Michael Malone	West Virginia
Andrew Kleinendorst	Minnesota	Nathan Houdek/ Jennifer Stegall	Wisconsin
Chlora Lindley-Myers/ Amy Hoyt/Cynthia Amann	Missouri		
		Jill Reinking	Wyoming

NAIC Support Staff: Jolie H. Matthews

AGENDA

1. Consider Adoption of its 2022 Fall National Meeting Minutes —*TK Keen (OR)* — Attachment A

2. Hear an Update on Federal Pharmacy Benefit Manager (PBM)-Related Legislation and Regulatory Activities—*Brian R. Webb (NAIC)*

3. Hear a Legal Update on PBM-Related Litigation—*Kay Noonan (NAIC)*

4. Hear a Discussion from the States on the Implementation of Recently Enacted State PBM Laws—*TK Keen (OR)*

5. Discuss Any Other Matters Brought Before the Subgroup—*TK Keen (OR)*

6. Adjournment

Agenda Item #1

Consider Adoption of its 2022 Fall National Meeting Minutes—TK Keen (OR)

Draft: 1/4/22

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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Draft: 11/9/22

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Virtual Meeting
October 24, 2022

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met Oct. 24, 2022. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair (NE); Sarah Bailey (AK); Anthony L. Williams (AL); Beth Barrington (AR); Jessica Ryan (CA); Michael Shanahan and Kathy Belfi (CT); Howard Liebers (DC); Robert Koppin (IA); Craig VanAalst (KS); Sharon P. Clark and Daniel McIlwain (KY); Crystal Lewis (LA); Chad Arnold and Joe Stoddard (MI); Andrew Kleinendorst (MN); Amy Hoyt (MO); David Dachs (MT); Ted Hamby and Robert Croom (NC); Ralph Boeckman and Erin Porter (NJ); Paige Duhamel and Renee Blechner (NM); Kelli Price (OK); Michael Humphreys and Ana Paulina Gomez (PA); Katrina Rodon (SC); Michael Driver and Rhonda Bowling-Black (TN); Shelley Wiseman (UT); Julie Blauvelt (VA); Jennifer Kreitler (WA); Nathan Houdek and Jennifer Stegall (WI); Joylynn Fix (WV); and Bryce Hamilton (WY).

1. Heard a Presentation from AHIP

Kris Hathaway (America's Health Insurance Plans—AHIP) and Sergio Santiviago (AHIP) discussed the role of health insurance providers in keeping prescription drugs affordable. She focused her remarks on prescription drug costs. She explained how prescription drug prices and spending have increased over the years, growing at a rate that AHIP believes is unsustainable. She said an AHIP study found that in 2020, seven of the top 10 largest pharmaceutical companies spent more on marketing than on developing new drugs. She highlighted a 2020 Institute for Clinical and Economic Review (ICER) report, which was updated in 2022, that identified the top 10 drugs causing the greatest increase in drug spending and reviewed them for clinical evidence to justify the increases. She discussed five drugs the ICER reviewed that found no clinical reason for the drug price increase. She said prescription drug costs have decreased overall, but even small net price increases have large impacts on prescription drug spending nationally. She also noted the high costs of new drugs entering the market. She said anecdotally, it seems that recently enacted state prescription drug price transparency laws seem to be having some impact on prescription drug price increases.

Santiviago discussed the value of pharmacy benefit managers (PBMs) to health insurance providers in helping to contain costs. He said health insurance providers use PBMs to help contain costs by: 1) utilizing contract models with administrative fee payment structures and spread pricing; 2) using medication and drug management programs, such as PBM pharmacy and therapeutics (P&T) committees; and 3) developing pharmacy networks that include mail order pharmacy options and specialty pharmacies. He discussed how some of these cost containment tools, such as spread pricing and rebating, work to reduce costs and can reduce premiums in some cases. He also discussed the role of P&T committees in the development of formulary designs to help enrollees obtain safe and effective medications at the best value.

Santiviago discussed how these cost-saving tools are under attack from certain programs, such as drug manufacturer copay coupons. He also discussed how drug manufacturer rebates are not driving higher prescription drug price increases and how rebates benefit all consumers.

The AHIP presentation also included recommendations to the Subgroup related to the development of the white paper on PBM business practices. Those recommendations included suggesting that any policies included in the white paper consider both the individual consumer perspective and the overall cost to all people in the risk pool and health care system. AHIP also recommends the inclusion of all stakeholders in the process and that the white paper provide all perspectives on issues equally because each drug issue has multiple perspectives.

2. Heard a Presentation from the BCBSA

Randi Chapman (Blue Cross Blue Shield Association—BCBSA) focused her remarks on the roles of the various entities in the prescription drug supply chain, the BCBSA's policy positions related to prescription drug pricing and prescription drug financial assistance programs, and Blues plan initiatives to provide pharmacy benefits and member access to prescription drugs and affordable medications.

Chapman said the BCBSA agrees with state insurance regulators and many of the stakeholders who have presented to the Subgroup on the need to curve the high cost of prescription drugs. The BCBSA knows that each entity in the prescription drug supply chain, including payers, pharmacies, PBMs, and pharmacy services administrative organizations (PSAOs), play a role and share the responsibility of ensuring that consumers have access to the most effective and affordable medication. Chapman said given this, the BCBSA supports the Subgroup's direction to expand the white paper's scope to include an analysis and assessment of the roles of each supply chain player.

Chapman said the BCBSA supports state departments of insurance (DOIs) having oversight of PBMs rather than state boards of pharmacy or other provider-type state boards. She said the BCBSA also supports state prescription drug transparency laws, and it hopes the white paper includes a robust discussion of such transparency measures.

Chapman said because AHIP has already provided a thorough explanation of prescription drug costs, she would not discuss that issue in any detail. However, she noted that prescription drug manufacturers set the price of prescription drugs and administer patient assistance programs. She said in 2021, prescription drug manufacturers raised prices on 822 brand name drugs by an average of 4.6%. She said a Kaiser Family Foundation (KFF) analysis completed earlier this year showed that between July 2019 and July 2020, half of all Medicare Part D covered drugs and nearly half of the Medicare Part B covered drugs had price increases greater than inflation. She said another study found that 60% of adults between the ages of 18 and 64 recorded being prescribed at least one medication in the previous year, but 29% of them said they were not taking prescribed medication due to cost. She said stories like this one, and many others, show how the consistent rise in prescription drugs has a real and tangible impact on enrollees.

Chapman said because of this, the BCBSA supports improved prescription drug manufacturer price transparency, particularly in patient assistance programs offered by prescription drug manufacturers. She said in addition, the Blues plans and the BCBSA actively support transparency in their practices and are fully compliant with state and federal reporting requirements for claims and discounts. She said as AHIP alluded to, patient assistance programs help individual patients, but in effect, these programs hide the real costs of the drug and can prevent the utilization of generic drugs and spread costs across the system, which ultimately leads to higher premiums and higher costs overall.

Chapman said the Blues plans are looking at and initiating innovative solutions to support community-based approaches to ensure access to affordable medications. She provided examples of these approaches, such as prescription drug transparency with real-time cost information to providers and patients and outcomes-based agreements. She said overall, these approaches are trying to support their members' ability to make educated and informed choices with their providers about the prescription drugs they use and promote the affordability of those medications. She said the BCBSA believes prescription drug price transparency and quality information empowers consumers and ultimately drives larger changes in the prescription drug marketplace.

Chapman discussed the role PBMs play in the prescription drug supply chain, including the tools PBMs use to encourage patients, working with their physicians to select the safest and most effective drugs at the lowest possible price. She also discussed the BCBSA's position related to pharmacies and PSAOs. She said the BCBSA

believes specific types of pharmacy providers should not have financial advantages through mandated contract terms between pharmacies and PBMs or mandated coverage of drugs at acquisition cost. She also said the BCBSA believes further study is necessary to understand how PSAOs affect the prescription drug supply chain and what state actions are needed to lower prescription drug costs, and it urges the Subgroup to do this research when developing the white paper.

Allan Coukell (Civica) discussed how Civica is working with the BCBSA and several Blues plans to bring lower-priced generics to market. He said Civica entered into a partnership in 2020 with the BCBSA to create a new, nonprofit subsidiary, named CivicaScript, dedicated to lowering the cost of select, outpatient generic drugs. He said CivicaScript will develop and manufacture six to 10 common, but high-priced general prescription drug medicines, for which there is not enough market competition to drive down prices. He said Civica has about 10 prescription drug products in development; two of those drugs are expected to be marketed later this year.

Coukell focused his remarks on Civica's work related to generic insulin in both pen and vial form. He said in March 2022, the BCBSA and 12 Blue Cross Blue Shield (BCBS) companies announced a partnership with Civica to increase access to affordable insulin. He said Civica will produce three insulins and biologics corresponding to and interchangeable with brand name insulin. He said the cost of these generics to consumers will be no more than $30 per vial or $55 for a box of five pens starting in 2024.

Keen asked if the BCBSA owns Civica. Coukell said Civica is a standalone nonprofit organization. There are no equity owners. Coukell said CivicaScript is also a nonprofit organization, which was capitalized by health plans and other founding members. He said these founding members sit on the board, which also includes a PBM representative, but it is really a mission-driven organization. Keen asked about any hurdles to setting up such nonprofit organizations. Coukell said one major hurdle is obtaining tax-exempt status from the Internal Revenue Service (IRS) as a nonprofit prescription drug manufacturer due to the so-called "commerciality doctrine."

Acting Commissioner Humphreys said the Pennsylvania Capital Blue Cross announced plans to collaborate with the Mark Cuban Cost Plus Drug Company to help bring high-quality, low-cost prescriptions to its members. He asked Chapman if the BCBSA knows of any other companies contemplating such action. She said she would have to reach out to her colleagues to provide an answer, but she said she would be happy to follow up with him later. Santiviago said he believes initiatives and collaborations like Civica and the Mark Cuban Cost Plus Drug Company are a good thing because they bring more competition and supply, which can ultimately drive down prescription drug costs.

4. Heard a Presentation from the PCMA

Casey Mulligan (University of Chicago), presenting on behalf of the Pharmaceutical Care Management Association (PCMA), discussed key findings from his research related to the value of PBMs. He said a managed plan is more valuable than an unmanaged plan. A managed plan provides plan member benefits and net external benefits. He said his research shows that an estimated $145 billion per year in net value is added by PBM prescription drug plan management. He explained how he arrived at this figure, including how part of this net value is achieved by better drug utilization and inducing providers, such as prescription drug manufacturers and pharmacies, to compete more vigorously. He also explained how prescription drug benefit management reduces drug prices while rewarding drug innovation.

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

Agenda Item #2

Hear an Update on Federal Pharmacy Benefit Manager (PBM)-Related Legislation and Regulatory Activities—Brian R. Webb (NAIC)

Agenda Item #3

Hear a Legal Update on PBM-Related Litigation—Kay Noonan (NAIC)

Agenda Item #4

Hear a Discussion from the States on the Implementation of Recently Enacted State PBM Laws—TK Keen (OR)

Agenda Item #5

Discuss Any Other Matters Brought Before the Subgroup—TK Keen (OR)