NAIC NATIONAL MEETING
FALL 2022

Revised: 11/15/22

2022 Fall National Meeting
Tampa, Florida

PHARMACY BENEFIT MANAGER REGULATORY ISSUES (B) SUBGROUP
Thursday, December 15, 2022
8:30 – 9:30 a.m.
JW Marriott—Tampa Bay Ballroom 1 - 4—Level 4

ROLL CALL

TK Keen, Chair	Oregon	Ralph Boeckman/	New Jersey
Laura Arp, Vice Chair	Nebraska	Erin Porter	
Anthony L. Williams	Alabama	Renee Blechner/	New Mexico
Lori K. Wing-Heier/	Alaska	Paige Duhamel	
Kayla Erickson/Sarah Bailey		Robert Croom/Ted Hamby	North Carolina
Beth Barrington	Arkansas	Kelli Price	Oklahoma
Jessica Ryan	California	Ana Paulina Gomez	Pennsylvania
Paul Lombardo/	Connecticut	Carlos Vallés	Puerto Rico
Michael Shanahan		Katrina Rodon	South Carolina
Howard Liebers	District of Columbia	Scott McAnally/	Tennessee
Andria Seip	Iowa	Brian Hoffmeister	
Vicki Schmidt	Kansas	Tanji J. Northrup	Utah
Daniel McIlwain	Kentucky	Don Beatty	Virginia
Frank Opelka	Louisiana	Jennifer Kreitler/	Washington
Chad Arnold/Joe Stoddard	Michigan	Ned Gaines	
Andrew Kleinendorst	Minnesota	Ellen Potter/Michael Malone	West Virginia
Chlora Lindley-Myers/	Missouri	Nathan Houdek/	Wisconsin
Amy Hoyt/Cynthia Amann		Jennifer Stegall	
David Dachs	Montana	Tana Howard	Wyoming

NAIC Staff Support: Jolie H. Matthews

AGENDA

1. Consider Adoption of its Oct. 24 and Summer National Meeting Minutes —*TK Keen (OR)*

2. Discuss Work on the Initial Draft of the Pharmacy Benefit Manager (PBM) White Paper—*TK Keen (OR)*

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

4. Adjournment

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Agenda Item #1

Consider Adoption of its Oct. 24 and Summer National Meeting Minutes—TK Keen (OR)

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.

Draft: 8/17/22

Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
Portland, Oregon
August 9, 2022

The Pharmacy Benefit Manager Regulatory Issues (B) Subgroup of the Regulatory Framework (B) Task Force met in Portland, OR, Aug. 9, 2022. The following Subgroup members participated: TK Keen, Chair (OR); Laura Arp, Vice Chair, and Eric Dunning (NE); Sarah Bailey (AK); Jimmy Dunn, Reyn Norman, and Sheila Travis (AL); Crystal Phelps (AR); Paul Lombardo and Mike Shanahan (CT); Howard Liebers (DC); Andria Seip (IA); Vicki Schmidt and LeAnn Crow (KS); Daniel McIlwain and Rob Roberts (KY); Chad Arnold (MI); T.J. Patton (MN); Amy Hoyt (MO); Mary Belcher (MT); Robert Croom (NC); Ralph Boeckman and Erin Porter (NJ); Paige Duhamel (NM); Kelli Price (OK); Karen Feather (PA); Melissa Manning (SC); Scott McAnally and Brian Hoffmeister (TN); Tanji J. Northrup (UT); Don Beatty (VA); Jennifer Kreitler and Molly Nollette (WA); Nathan Houdek and Jennifer Stegall (WI); Allan McVey and Jamie Taylor (WV); and Bryce Hamilton (WY). Also participating were: Weston Trexler (ID); Paul Meyer (MD); and Larry D. Deiter (SD).

1. Adopted its July 29, June 15, April 25, and Spring National Meeting Minutes

The Subgroup met July 29, June 15, April 25, and April 4. During these meetings, the Subgroup heard presentations from various stakeholders on issues from their perspective on the Subgroup's 2022 charge to develop a white paper on pharmacy benefit manager (PBM) business practices.

Mr. Lombardo made a motion, seconded by Mr. Roberts, to adopt the Subgroup's July 29 (Attachment Eight-A), June 15 (Attachment Eight-B), April 25 (Attachment Eight-C), and April 4 (Attachment Eight-D) minutes. The motion passed unanimously.

2. Heard a Presentation from the PCMA

Peter Fjelstad (Pharmaceutical Care Management Association—PCMA) discussed the value of PBMs and the services they provide with respect to pharmacy benefit management. He said PBMs are committed to helping patients. PBMs are the only entity in the pharmaceutical supply chain advocating for lower prescription drug costs for patients and payers. He explained that the plan sponsor is the PBM's client, who always has the final say when creating and designing a prescription drug benefit plan to include elements such as formulary management, specialty and mail order pharmacies, preferred pharmacy networks, and negotiation of rebates. There is no one-size-fits all model because each plan sponsor has unique needs.

Mr. Fjelstad outlined the plan sponsor request for proposal (RFP) process and how PBMs bid in this competitive process by offering various design models and compensation terms, depending on the plan sponsor's specific needs. He detailed the types of pharmacy benefit management services PBMs can provide to plan sponsors. He also discussed the tools PBMs use to reduce prescription drug costs for patients and payors, which include: 1) negotiating rebates from prescription drug manufacturers; 2) reducing waste; 3) encouraging use of generics and preferred brand name drugs; 4) improving adherence; and 5) managing high-cost specialty medications. Mr. Fjelstad said that research shows that the current use of these PBM tools will save plan sponsors and consumers more than $1 trillion in prescription drug costs from 2020 to 2029. He discussed the results of a 2020 survey of company benefit managers and human resource directors indicating high satisfaction with their

company's PBM, PBM contract transparency, and the PBM's effectiveness in reducing prescription drug costs for their company.

Mr. Fjelstad discussed a PBM's role in the pharmaceutical supply chain. He suggested that the Subgroup examine and identify in the white paper the role each entity plays in the pharmaceutical supply chain. He said the pharmaceutical drug manufacturer is the only entity in the supply chain that sets the list price of drugs. He also said that an analysis of data from 2016 to 2020, published in January 2022, indicates that manufacturer prescription drug price increases are unrelated to PBM negotiated rebates.

Mr. Fjelstad highlighted how PBM technology and expertise helps patients to lead healthier lives. PBMs administer prescription drug benefits for 266 million Americans, which means immediate access to the right prescription drugs at the right time and place for thousands of patients each day. PBMs continue to innovate, providing information on cost-sharing and drug coverage through real-time benefit tool (RTBT) access to 82% and electronic approval coverage for drugs that need authorization to 98% of patients who have coverage through contracted health plans and PBMs. He said PBMs are also developing technology to directly engage with patients and enhance their lives, which not only improves clinical outcomes, but also gives patients greater control over their own health.

Commissioner Schmidt asked Mr. Fjelstad about PBM vertical integration with PBMs owning pharmacies and concerns that because of such market consolidation, there is less transparency about PBM business practices. She also noted that the statistics cited during the presentation did not include any statistics on independent community pharmacist satisfaction with PBMs, which would probably show a much different level of satisfaction as compared with the level of satisfaction indicated for company benefit managers and human resource directors. Mr. Fjelstad said there is more of an adversarial relationship between independent community pharmacists and PBMs than perhaps other entities in the pharmaceutical supply chain. He said that about 83% of independent community pharmacies use pharmacy services administrative organizations (PSAOs), which are large conglomerates, to negotiate their contracts with PBMs on their behalf. Therefore, it is not like these pharmacies do not have any leverage or are mismatched in their business dealings with PBMs. He said with respect to vertical integration, the health care industry has seen a lot of integration whether it be PBMs and health insurers owning PBMs and a chain of retail pharmacies. He said increased state and federal regulatory requirements since the enactment of the federal Affordable Care Act (ACA) has led to smaller independent community pharmacies going out of business because they do not necessarily have the expertise, time, or manpower to keep up with these regulatory compliance requirements, such as those involved in dispensing prescription drugs under the federal 340B program. He said this is a factor in the market consolidation among the entities in the pharmaceutical supply chain. Commissioner Schmidt disagreed with Mr. Fjelstad's argument that independent community pharmacies lack the expertise necessary to stay in business due to increased regulatory requirements and competition with large "big box" chain pharmacies.

Mr. Beatty said that statistics are not needed to know that there is tension between independent community pharmacists and PBMs. He asked Mr. Fjelstad about the actions the PCMA, on behalf of the PBM industry, could do voluntarily to alleviate this tension without involving state and federal regulators. Mr. Fjelstad suggested that meetings such as this meeting on the local and state level where all the stakeholders are participating would help alleviate such tensions. Mr. Lombardo asked about spread risk pricing and the recent enactment in some states prohibiting it and the impact, if any, on PBM revenue, when spread risk pricing is eliminated. Mr. Fjelstad said he would be happy to follow up with Mr. Lombardo regarding his specific question. He said, generally, in a spread risk pricing model, or risk mitigation model, the PBM takes the risk to either lose money or gain a profit or a margin. However, which risk mitigation model is chosen depends on the plan sponsor. The plan sponsor decides

whether it wants to use a pass-through model where rebates are shared with specific entities or a spread risk pricing model. He said he believes that the PBM industry's position on this issue is that the states should not intrude on the private contractual negotiations between the plan sponsor and the PBM. Mr. Lombardo said his concern with eliminating spread pricing, which would increase the payments to pharmacies and allow PBMs to increase their administrative fees to make up lost revenue, is that it would add cost to the pharmaceutical distribution system. As such, he would appreciate follow-up information on what actions PBMs are taking, if any, in response to the elimination of spread risk pricing.

3. Heard a Presentation from the PhRMA on Issues Related to the Lack of Transparency in PBM Practices

Emily Donaldson (Pharmaceutical Research and Manufacturers of America—PhRMA) discussed issues related to the lack of transparency in PBM practices. She explained that this lack of transparency has led to misaligned incentives, which can cause an increase in costs throughout the health care system. She said that there is evidence that shows one such misaligned incentive appears to provide PBMs incentives to prefer medicines with higher list prices and large rebates. She discussed how PBMs have increased their influence in the pharmaceutical supply chain through horizontal and vertical consolidation.

Ms. Donaldson said a large—and growing—share of the rebates paid by manufacturers are not being used to reduce patient costs at the pharmacy counter. She provided an example of how consumers do not directly benefit from the rebates and discounts with respect to prescription drugs unlike the direct benefits consumers receive with respect to medical services. She said consumers can end up paying a greater share of total cost for their prescription drugs than their health insurers.

Ms. Donaldson discussed policy solutions to address misaligned incentives in the pharmaceutical supply chain. She suggested these policy solutions: 1) anti-steering policies prohibiting PBMs from directing patients to affiliate pharmacies, which would improve competition and reduce incentives for PBMs to self-deal; 2) sharing rebates at the point-of-sale; and 3) "delinking" PBM compensation from the price of medicines, which would prevent PBMs from skirting regulation on rebates.

4. Heard a Presentation from the OPCA on the Federal 340B Prescription Drug Program

Marty Carty (Oregon Primary Care Association—OPCA) discussed the federal 340B prescription drug program. He said the program began in 1992 and requires pharmaceutical manufacturers to sell drugs at a discount to "covered entity" providers. These providers include federally qualified health centers (FQHCs), Ryan White clinics, and disproportionate share hospitals (DSHs). Mr. Carty outlined the 340B program requirements for participants, which include: 1) registration and recurring recertification; 2) subject to federal audits; 3) must work to avoid duplicate discounts on a single drug; and 4) ensure appropriate use of 340B program savings. He highlighted how the 340B program has assisted two entities, the Neighborhood Health Center and the Siskiyou Community Health Center, in enhancing and enabling them to provide much needed assistance to patients by covering the cost of prescription medications, medical and dental care, food, and transportation.

Mr. Carty discussed how in 2016–2017 community health centers began fighting state-by-state to retain 340B savings on prescription drugs reimbursed under Medicaid managed care and how this so-called "pick-pocketing" continues to expand rapidly. He said to combat these actions, states began enacting 340B anti-discrimination legislation. He said 22 states prohibit PBMs from: 1) refusing to contract with 340B program participating providers; 2) reimbursing at a lower amount; 3) imposing different fees; and 4) otherwise discriminating against

a 340B covered entity. He asked that the state insurance regulators use the tools available to them to protect the 340B program.

Director Dunning asked about rebates and the 340B program, particularly any rebates paid back to those patients receiving services from an FQHC who are commercially insured. Mr. Carty said he does not have information about commercially insured patients. He said a majority of those receiving services through an FQHC are either uninsured or Medicaid recipients. Mr. Carty agreed to follow up with any information he might have about rebates and patients receiving services through a FQHC who are commercially insured.

Commissioner Schmidt said she has worked with FQHCs and the 340B program and appreciates the work that they do. She said she believes the Subgroup should discuss the issues Mr. Carty raised with respect to discriminatory pricing that some 340B program participating providers have experienced.

Mr. Keen asked Mr. Carty that because enforcement of the anti-discrimination laws that have been enacted rests with state insurance regulators, if he was aware of any enforcement actions taken by the states. Mr. Carty said he is not aware of any such actions, but he would follow up with Mr. Keen after he does some research. Ms. Seip asked Mr. Carty if he had any examples of discriminatory pricing and what that contract language would look like that he could share with the Subgroup. Mr. Carty said he would follow up with Ms. Seip to provide such examples.

5. Discussed Next Steps

Mr. Keen said he anticipates the Subgroup meeting within the next few weeks to complete its work on hearing from various stakeholders on issues from their perspective on the Subgroup's 2022 charge to develop a white paper examining PBM business practices. He said that he also anticipates during this meeting a discussion of the implications, if any, of a provision in the federal Inflation Reduction Act of 2022 allowing Medicare to negotiate for prescription drug prices.

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

SharePoint/NAIC Support Staff Hub/Member Meetings/B CMTE/RFTF/PBM Regulatory Issues Subgrp/PBM Reg Issues MtgMin 8-9-22.docx

Agenda Item #2

Discuss Work on the Initial Draft of the Pharmacy Benefit Manager (PBM) White Paper —TK Keen (OR)

Agenda Item #3

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