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 payers, 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.