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Pharmaceutical Benefit Management Regulatory Issues (B) Working Group
Denver, Colorado
November 18, 2024

The Pharmaceutical Benefit Management Regulatory Issues (B) Working Group of the Regulatory Framework (B) Task Force met in Denver, CO, Nov. 18, 2024. The following Working Group members participated: Joylynn Fix, Chair (WV); Ashley Scott, Vice Chair (OK); Lori Wing-Heier and Sarah Bailey (AK); Mark Fowler and Sheila Travis (AL); Lisa Watson (AR); Paul Lombardo (CT); Howard Liebers (DC); Samantha Heyn (FL); Doug Ommen and Andria Seip (IA); Ann Gillespie and Matthew Pickett (IL); Julie Holmes (KS); Sharon P. Clark (KY); Nina Hunter (LA); Parker Fisher and Danielle Torres (MI); Norman Barrett Wiik (MN); Amy Hoyt (MO); Charles Whitehead (NC); Eric Dunning, Cheryl Wolff, and Maggie Reinert (NE); Tim Stroud (NJ); Renee Blechner (NM); Richard Ramos and Krista Porter (NY); Numi Griffith (OR); Jodi Frantz (PA); Scott McAnally (TN); Jon Pike and Tanji J. Northrup (UT); Mike Kreidler (WA); Darcy Paskey (WI); and Jill Reinking and Lauren White (WY). Also participating were: Dean Cameron and Shannon Hohl (ID); Mike Chaney (MS); Chrystal Bartuska (ND); Scott Kipper (NV); and Allan L. McVey (WV).

1. Heard Presentations on PBMs and How They Function

The Working Group heard presentations from the Pharmaceutical Care Management Association (PCMA), the Pharmaceutical Research and Manufacturers of America (PhRMA), and jointly, the National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NADCS) on pharmacy benefit managers (PBMs) and how they function.

John Jones (PCMA) discussed PBMs and how they function from a PBM industry perspective. He explained what PBMs are and their core functions. Jones said that nearly all insurers use a PBM to perform a variety of those functions, particularly prescription drug claims processing. He explained how PBMs support patients by: 1) supporting patient safety by preventing potentially harmful drug interactions and reducing medication errors; 2) helping patients understand how and when to take their medication; and 3) improving care coordination. PBMs also support employers and other plan sponsors by helping them offer high-quality drug coverage to meet the needs of all kinds of people and organizations by: 1) negotiating with drug companies and pharmacies to lower drug costs; 2) providing business and operations expertise; and 3) providing prescription drug benefit design and coverage recommendations.

Jones explained how PBMs are paid for their services. He said employers and other plan sponsors decide how to pay for PBM services through three pricing models: 1) spread contracts, 2) rebate retention, or 3) administrative fees. He also described how an employer or plan sponsor might choose a PBM. Jones touched on the value PBMs provide to the U.S. health care system and the states. He said the use of PBM tools will save payers and patients nationally more than $1 trillion from 2023-2032 because PBMs drive down costs for prescription drugs by pushing drug manufacturers to compete to offer better prices for patients and families. PBMs negotiate with drug manufacturers, empowering the private market to drive down costs.

Scott Woods (PhRMA) discussed PBMs and how they function from a drug manufacturer's perspective. He said that since the NAIC began its work on PBMs, the market has changed drastically. In moving forward, he said the PhRMA suggests the Working Group focus its future work to examine these three market trends. The first is vertical integration, which amplifies PBMs' influence within the health care system. The second trend is perverse

incentives, which can allow PBMs to profit at the expense of patients, employers, and the health care system, and the third trend is PBM business practices that can challenge patient access to medicines.

Woods said the overall marketplace is far less competitive than the PBM industry leads stakeholders to believe. He said even though there are 70 full-service PBMs in the U.S. and more new entrants to the market every year disrupting the PBM industry, the market remains dominated by three PBMs that have 80% of the market share. Woods said the PhRMA is not just concerned with what these PBMs do with such market power, but the sheer volume of prescription claims they manage, which provide them with significant leverage to the detriment of patients and competition.

Woods discussed prescription drug costs and how the PBM business model influences patient out-of-pocket costs. According to the National Health Expenditures (NHE) data report, medicines account for just 14% of total health care spending in this country. That figure is expected to remain stable over the next few years, even as many novel medicines and therapies come on the market. Woods said even though the net prices for brand medicines have grown below the rate of inflation for the past five years, and even with stable or in some cases, declining medicine prices, it does not feel that way for patients because insurers and PBMs have increasingly shifted more health care costs to them. He noted that more than half of every $1 spent on brand medicines went to PBMs, health plans, providers, and other stakeholders in 2020. He suggested that when more than half of what is spent on medicines goes to entities that have nothing to do with making them, the system needs to change. Woods explained that the slide in the PCMA presentation illustrating the share of the drug dollar did not include prescriptions by the PBM's own mail order and specialty pharmacies, and the slide also neglected to include drug dollars that go to health plans, hospitals, physicians, and other intermediaries.

Woods cited a 2023 Nephron Pharmaceuticals Corporation report, which found that the share of PBM profits from fees charged to manufacturers, pharmacies, health insurers, and employers increased by over 300% over the last decade and that PBMs are increasing shifting their business model to rely less on commercial rebates to administrative fees and specialty pharmacy. He also discussed how vertical integration—PBMs owning pharmacies—has had an impact on prescription drug costs because the PBM can prefer its own affiliated pharmacy rather than an unaffiliated pharmacy. Woods cited a Federal Trade Commission (FTC) study as evidence of such practices. Woods discussed how the middlemen in the prescription drug distribution system are shifting costs to patients through co-insurance and deductibles and how this cost-sharing is based on the undiscounted list price of the medicine, even when the PBM is receiving a rebate fee or other discounts on that medicine, which leads to non-adherence and resulting poor health outcomes and drives up overall health care spending. He also discussed the impact of accumulator adjustment programs, copayment maximizers, and alternative funding programs on out-of-pocket costs. He suggested that the Working Group should explore market problems and consider policy solutions to address these issues that adversely impact patient access.

Woods said the PhRMA suggests the following policy solutions to address these issues: 1) delink PBM compensation from the list price of medicines, and limit PBM compensation to flat service fees; 2) pass on savings negotiated between drug manufacturers and PBMs directly to patients; 3) ensure patients benefit from drug manufacturer assistance programs and foundation support, and prohibit the use of accumulator adjustment programs, copayment maximizers, and alternative funding programs; and 4) hold PBMs and health plans accountable for providing quality patient care, and increase oversight of utilization management and enhance the data available to identify PBM and health plan abuse.

Joel Kurzman (NCPA) and Sandra Guckian (NACDS) discussed PBMs and how they function from a community pharmacist perspective. They discussed the role community pharmacists play in consumer access to prescription

drugs, particularly in underserved areas, and the other services they provide to the community. Guckian said current PBM practices are adversely impacting patients as well as independent and chain pharmacies. She explained that the NACDS is a trade association representing chain pharmacy companies, including traditional drug stores, supermarkets with pharmacies, and mass merchants with pharmacies. She said the NACDS members include regional chains with four or more stores and national companies. She said these regional chains employ nearly three million individuals, including over 150,000 pharmacists, fill three billion prescriptions annually, and help patients use medications correctly and safely while offering innovative services focused on health and wellness.

Kurzman discussed the uneven playing field for community pharmacists in their dealings with PBMs. He highlighted a number of these inequities, including 1) take-it-or-leave-it contracts, 2) lack of transparency in reimbursement pricing, 3) retaliatory audits, 4) network exclusion, 5) no process for appeals or remedy for unfair practices, and 5) the unpredictability of retroactive fees. He said that for many community pharmacists, this is an unsustainable business model.

Kurzman said one of the biggest challenges for pharmacies is having to negotiate with Fortune 10 companies that have 80% of the market share, which Woods discussed. The other challenge is vertical integration. He said independent community pharmacies are trying to compete with pharmacies that are owned by PBMs. Kurzman said PBMs have suggested that these narrow networks are an opportunity to bring value by bringing down costs. He said that when networks are limited and community pharmacies are forced out, consumers are harmed because their choices are limited, which is particularly evident in rural areas with 10% closing between 2013 and 2022.

Guckian said there is a growing consensus on the need for PBM reform. She noted the state legislative activity over the past few years aimed at addressing an array of PBM business practices. She also referred to several state-level reports and findings related to PBMs and recent PBM enforcement actions. Guckian also noted the ability of states to regulate PBMs because of recent court decisions, such as the U.S. Supreme Court's decision in *Rutledge v. the Pharmaceutical Care Management Association*. She also referenced the number of state laws requiring PBM licensure or registration with the state insurance department. Guckian said the NCPA, the NACDS, and the American Pharmacists Association (APhA) urge the NAIC and its members to prioritize the implementation and enforcement and oversight of PBM state rules and laws.

Kurzman highlighted a 50-state resource document the NCPA developed and maintains to help its members file complaints with state insurance regulators because enforcement is key. The NCPA also has developed its *Best Practices for Enforcement of PBM Regulation*.

Lombardo asked Woods and Kurzman what savings, if any, would be realized if their suggested policy solutions were implemented. He said that in Connecticut, the percentage of premium for prescription drug coverage increased from 11% of premium in 2014 to 26% of premium in 2024. Kurzman discussed what states are doing in this area with respect to their Medicaid-managed care plans. He said that after these states identified large amounts of spread pricing and moved to a transparent reimbursement methodology, it brought down costs and states could bank those savings. Woods said the federal Congressional Budget Office (CBO) scored potential federal PBM reform legislation. He said that based on the provisions in that legislation, including changing the way PBMs are compensated from being based on the price of the medicine to being based on the value of the services they provide, the CBO scored a savings of $700 million. The CBO also scored provisions requiring more transparency in the PBM market resulting in over a billion dollars in savings. Woods also discussed the Blue Shield of California's business decision to terminate its contract with CVS Health for certain prescription drug benefit

services and moving those services to Amazon Pharmacy and Mark Cuban's Cost Plus Drugs because it felt that it was being overcharged and that cost was being passed on to its members in the form of higher premiums. Jones said the examples Kurzman and Woods discussed illustrate the market at work.

Acting Director Gillespie asked about the impact on medical loss ratios (MLRs) in the vertical integration situation where the insurer is the parent and owns the specialty pharmacy—all part of the same PBM structure. Woods said PhRMA has a lot of information on this and how much vertical integration helps insurers and plans potentially skirt the spirit of the federal Affordable Care Act's (ACA's) 80% to 85% MLR requirement in the commercial market. He said he would be happy to provide specific data and other information on this after the meeting.

Commissioner Chaney asked about the National Average Drug Acquisition Cost (NADAC), which is a standard price used to calculate how much a pharmacy is reimbursed for a prescription drug or essentially, the average price a pharmacy pays to acquire a drug and used as a basis for calculating reimbursement rates versus the average wholesale price (AWP), which is a pharmaceutical industry standard used to calculate how much third-party payors, like insurance companies and government programs, reimburse health care providers for prescription drugs. Kurzman provided a history of the NADAC benchmark and the intent behind its initial development by the federal Centers for Medicare & Medicaid Services (CMS) in 2016. Jones said NADAC and AWP are both benchmarks and just one component of payment. He noted that stakeholders will prefer one benchmark over the other, but they make the choice.

Commissioner Ommen asked Jones about the information included in the PCMA describing savings to the states from using PBMs. He asked if it was net savings or something else. Jones said he would need to check the source material because he is not familiar with the methodology used to generate the numbers. He said he would follow up with the Working Group after the meeting.

2. Heard a Discussion on Providing Potential Assistance to the Producer Licensing Uniformity (D) Working Group

Scott said the Producer Licensing Uniformity (D) Working Group has approached the Working Group seeking its assistance to help it create a new section on PBM licensure best practices and uniform standards in the *State Licensing Handbook*. She said anyone interested in providing such assistance when the Producer Licensing Uniformity (D) Working Group begins its work in 2025 to let her, Fix, or NAIC staff know.

3. Heard an Update on the Working Group's Work on the PBM Examination Chapter

Fix updated the Working Group on the progress of its work related to its charge to develop a chapter for inclusion in the *Market Regulation Handbook* establishing examination standards for PBMs and related regulated entities for referral and consideration by the Market Conduct Examination Guidelines (D) Working Group. She said the drafting group assignments have been circulated. However, there is still an opportunity for both state insurance regulators and non-regulators to serve on the drafting group. She said those interested should reach out to her, Scott, or NAIC staff.

Having no further business, the Pharmaceutical Benefit Management Regulatory Issues (B) Working Group adjourned.

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