March 31, 2023

Senate Finance Committee Hearing on Pharmacy Benefit Managers

On Thursday (March 30), the Senate Finance Committee held a hearing, "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers," which was notable for its display of bipartisanship with Committee leaders and members expressing aligned interests in examining the pharmacy benefit manager (PBM) market and promoting policies to increase transparency and address incentives for unfair market practices to lower costs for patients.

During the hearing, Committee members heard testimony from a panel of five witnesses, including academics, a startup PBM, and a lawyer who represents pharmacies, all of whom, except for one, spoke in favor of greater transparency among PBMs,. The Senate Finance Committee is one of several congressional committees looking at the role PBMs play in drug prices. Most recently, the Senate Commerce Committee advanced the Pharmacy Benefit Manager Transparency Act (S. 127), which aims to increase transparency and prevent PBM practices that may increase costs, such as spread pricing. Leaders of the Senate HELP Committee have also expressed an interest in holding future hearings on the issue.

- *For more information*: https://www.finance.senate.gov/hearings/pharmacy-benefit-managers-and-the-prescription-drug-supply-chain-impact-on-patients-and-taxpayers

Opening Statements

Chair Ron Wyden (D-OR). In his opening statement, Chair Wyden said, "In recent years, it's increasingly apparent that PBMs are using their data, market power, and know-how to keep prices high and pad their profits instead of sharing the benefits of the prices they negotiate with consumers and the Medicare program." He said those practices have "serious consequences" for federal health care programs and consumers and that both he and Sen. Crapo "have agreed to take on this issue together." Full Testimony.

Ranking Member Mike Crapo (R-ID). In his opening statement, Ranking Member Crapo praised the passage of the Medicare Part D program and said the committee has "an obligation … to address access and affordability gaps where we find them." He said, "We need an all-of-the-above approach to transparency" and need to "assess the various incentives that operate within the medication supply chain." Crapo also noted the "tremendous common ground and shared goals" on the topic and expressed optimism that lawmakers can identify meaningful solutions. Full Testimony.

Witness Testimony

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law and Director of the Center For Innovation, Hastings College Of Law, University of California. Ms. Feldman said PBMs originally stepped in to help health plans negotiate better prices for prescription drugs, but "rather than act as honest brokers …, PBMs have acted in their own self-interest." She said the current rebate model creates an incentive for drug companies to set higher list prices, which in turn mean higher co-insurance and costs for both insured and uninsured patients. In addition, she said, PBMs operate opaquely and do not disclose to the health plans the details of the deals made on the plans' behalf. Full Testimony.

Karen Van Nuys, Executive Director, Value of Life Sciences Innovation, Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California. Ms. Van Nuys said PBMs "play a central role" in the drug supply system and "[e]vidence indicates they leverage their position to extract profits in ways that are detrimental to patients, payers, and the drug innovation system more broadly." She said the rebate system "distorts incentives" and "increases list prices for brand drugs." In addition, she said PBMs can "steer patients toward more expensive drugs." She encouraged Committee members to increase transparency to "shed light on how widespread such practices are, and their overall impact on drug prices and spending. Greater transparency could also provide purchasers better information about the prices and alternatives they face, and help lower costs to patients and taxpayers." Full Testimony.

Lawton Robert Burns, James Joo-Jin Kim Professor of Health Care Management And Co-Director of the Roy & Diana Vagelos Program in Life Sciences & Management, Wharton School, University of Pennsylvania. Dr. Burns said his goal for the hearing is "not to *praise* PBMs but to *bury* some concerns about them." He said PBMs are often the "scapegoat" for high prescription drug prices, but challenged lawmakers to look to other players in the system, including health plans. Further, he argued, "vertical integration may have important, positive consequences for competition" – and argued that consolidation in the PBM sector is no greater than other health care markets. Full Testimony.

Jonathan E Levitt, Founding Partner, Frier Levitt Attorneys at Law. In his testimony, Mr. Levitt said he is a "trial lawyer in the trenches within the drug space," representing various health care and life sciences companies, including independent specialty and retail pharmacies. He said, "PBMs force manufacturers to raise their list price, in exchange for formulary placement" and levy direct and indirect remuneration (DIR) fees on pharmacies serving the sickest patients. He said, "PBMs' tactics are driving independent pharmacies out of business, creating pharmacy 'deserts,' especially in rural areas; fueling list drug prices higher for all Americans; and delaying and denying treatment for the sickest Americans, those with cancer and other serious diseases." Full Testimony.

Matthew Gibbs, President, Capital Rx. In his testimony Dr. Gibbs said he has over 20 years in the pharmacy benefit management and managed care industry. Historically, he said PBMs "have played a critical role in the pharmacy and overall health care supply chain," leading technology and the development of the National Council for Prescription Drug Programs used by every pharmacy today to communicate near, real-time data. But recently, he said, PBMs' business models have shifted. He said, "In my opinion, the traditional PBMs have trained everyone to believe that drug pricing is unstable, but they are utilizing complex algorithms to minimize their contractual reimbursements to pharmacies while at the same time not sharing the 'savings' from this reimbursement reduction with the patient or the payer. This spread pricing game must stop." He said Capital Rx sought to change the model by abandoning the traditional Average Wholesale Price (AWP) model and using the National Average Drug Acquisition Cost (NADAC) index as the primary pricing benchmark and disclosing their administrative fee in client contracts and invoices so there is "no gray area." Full Testimony.

Q&A

Chair Wyden asked about the impact of PBMs collecting fees based on a drug's list price and the high markups of drugs. Dr. Van Nuys said the lack of transparency in the markets allow PBMs to conduct spread pricing in which they pay the pharmacy one price, charge the insurer a higher price and keep the difference, because the plans cannot see what is being paid to the pharmacy.

At the end of the hearing, Chair Wyden asked each witness to provide a policy recommendation. Ms. Feldman said, "Perverse incentives happen when incentives are not aligned"; Dr. Van Nuys said, "Publicly release pricing information throughout the supply chain"; Dr. Burns said prices paid should be pegged to net prices, not to list

prices and that Part D health plans need to have more fiscal responsibility in the catastrophic phase; Mr. Levitt said there needs to be more transparency in PBMs and rebate aggregators on spread pricing and rebates paid; and Dr. Gibbs said the price should be made public and anyone should be able to see it at any time.

Ranking Member Crapo asked about policies to improve transparency in the Medicare Part D system for patients, plan sponsors, and pharmacies. Mr. Levitt suggested creating a rebate safe-harbor that limits the size of the rebates, while Dr. Van Nuys suggested requiring the collection and public disclosure of aggregate pricing data similar to CMS' NADAC, that focuses on other parts of the distribution system, such as PBM reimbursements to pharmacies or prices health plans pay to PBMs to settle claims. Dr. Gibbs said we need to get rid of average benchmarks that are not reflective of actual drug costs.

Sen. Debbie Stabenow (D-MI) asked about PBM practices driving up the costs of drugs in the U.S. and the impact of DIR fees on the sickest patients. Mr. Levitt said DIR fees disproportionately impact the sickest patients, such as those with cancer, because they pay the maximum co-pay and end up in catastrophic coverage phase. "The sickest patients are the biggest losers," he said.

Sen. Chuck Grassley (R-IA) noted that several congressional committees are working on bills related to PBMs, but said lawmakers must first better understand the PBM market and encouraged enactment of provisions from the Grassley-Wyden Prescription Drug Pricing Reduction Act bill to improve transparency. He also discussed the Cantwell-Grassley PBM Transparency Act, which he said requires transparency reporting to shine light on prices and fees. Dr. Van Nuys said transparency "is an important first step" because it will help policymakers and researchers better understand the industry and give consumers more insight into their costs. Mr. Levitt said transparency will help shine a light on how much PBMs are profiting off of their practices and lower the list cost of drugs, which would benefit the entire system and patients.

Sen. John Cornyn (R-TX) said the pharmaceutical industry is entitled to a return on their investments but raised concerns about the level of "gamesmanship" occurring in the industry. "Without specific transparency the market can't work," Sen. Cornyn said. Dr. Van Nuys said Costco can get lower prices because it operates in a cash system and there is no intermediary similar to a PBM. When asked about his company's goals, Dr. Gibbs said, "Our goal is … transparency options regardless of channels." He explained that unlike traditional PBMs, Capital RX uses a price index like NADAC. He said, "The only way is to level set. We have the tools already we just need to enforce them."

Sen. Benjamin Cardin (D-MD) said he strongly supports transparency in this market but also raised concerns about drug shortages in the United States and asked how PBMs could use their leverage to address that problem. Dr. Burns said the source of the shortage problem is drug manufacturers and the lack of resiliency within the system. Mr. Levitt said PBMs could put low-cost drugs that are in short supply on their formularies and give pharmacies and drug manufacturers a fair return and incentive to keep them in supply.

Sen. Bill Cassidy (R-LA) pushed Dr. Burns on some of his findings and the role PBMs play in rising drug prices. In response, Dr. Burns said Part D health plans also play a role in rising costs because they have an incentive to get patients to the catastrophic drug phase where the federal government picks up more of the tab. When asked about the impact of vertical integration among health plans and PBMs, Dr. Burns said vertical integration of health plans owning PBMs is a more recent trend. Dr. Levitt added that while the trend may be recent the potential for collusion is concerning. Overall, Sen. Cassidy said while the Committee needs to better understand PBMs, they also need to broaden their view to see how PBMs and insurance companies are operating together and impacting prices.

Sen. Robert Menendez (D-NJ) spoke about the current financial structure and asked if patients would benefit if the supply chain focused on net prices instead of list prices. Mr. Levitt said patients would pay less under such a system because they would pay a percentage of the net price, which is lower than the list price. Sen. Menendez

also cited the recent introduction of biosimilars for Humira and noted that one biosimilar has a high list price and high rebate and the other has a low list price and low rebate and that the current system incentives PBMs to place the higher price version on their formularies. Mr. Levitt attributed this incentive to so-called rebate aggregators that incentivize PBMs to choose the higher rebate drug and not pass those rebate savings onto the consumer. Mr. Levitt suggested creating a safe-harbor for rebates defined by the federal government.

Sen. Thomas Carper (D-DE) spoke about a bill he co-sponsored, the Creating Transparency to Have Drug Rebates Unlocked Act, to ensure cost savings from rebates are passed on and asked for policy suggestions to ensure patients benefit from rebates. Dr. Van Nuys said it is hard to lower patient costs in one place without impacting another, but suggested lawmakers could identify existing savings, such as the money Medicare overpaid for generic drugs, and figure out ways to take that money out of the current system and direct it toward patients.

Sen. John Thune (R-SD) asked about the impact of PBM practices on the 340B Drug Discount Program. Mr. Levitt said the vertical integration among PBMs takes money away from 340B entities. "The 340B program is completely frustrated by PBMs, their specialty pharmacies, their retail pharmacies and third-party administrators," Mr. Levitt said. He explained each of those businesses takes a percentage of the intended 50% hospital profit, leaving hospitals with a small portion of the funds to invest in patient care.

Sen. Thom Tillis (R-NC) spoke about the lack of transparency within the entire drug supply chain and said we need to look at the whole system to improve access to affordable drugs.

Sen. Sherrod Brown (D-OH) said we can build on the success of the Inflation Reduction Act's (IRA) drug price negotiation policies by addressing DIR fees and streamlining quality measures that pharmacies are judged on. Mr. Levitt said CMS should clarify current guidance related to "reasonable" reimbursement rates and what constitutes adherence for pharmacies.

Sen. Catherine Cortez Masto (D-NV) said she introduced legislation, the Lower Cost Drugs for Families Act, to extend the IRA's drug inflation penalties to the commercial market. She then asked Dr. Gibbs how his PBM model is different and what it means for patients. Dr. Gibbs said Capital RX works off of a single-ledger model, meaning what they bill the pharmacies is what they reimburse their clients, and they pass pharmaceutical contract fees back to patients. He said, "The supply chain is complex and needs transparency before it can be improved."

Sen. Sheldon Whitehouse (D-RI) also said we need to look at the entire supply chain and examine pharmaceutical pricing as we look at PBM behavior. He asked whether federal agencies should have a more robust oversight role. Mr. Levitt said PBMs are breaking safe-harbor laws in their administrative and data fees and that the executive branch should look at Medicare bids submitted by prescription drug plans and compare them across other payers.

Sen. James Lankford (R-OK) spoke about tiering and the impact on generic drugs when they are left out of formularies. Mr. Levitt said CMS should look hard at this issue and that big employer groups should look at their contracts. He warned that "PBMs are driving independent pharmacies out of business." However, Dr. Burns warned that when you increase transparency you have to be concerned about collusion among players on what data is being shared, and argued most transparency hasn't benefited consumers because they do not know how to use the information that is available.

Sen. Elizabeth Warren (D-MA) also said the committee needs to look at the entire supply chain, particularly how pharmaceutical companies use intellectual property laws to drive out competition, particularly related to practices to extend patents. She praised recent CMS guidance implementing the IRA's drug price negotiation provisions for using the earliest approval of all of the formulations of a drug to determine eligibility for Medicare drug price negotiation, saying it will prevent drugmakers from using "patent tricks" to keep their drugs off of negotiation lists. Ms. Feldman said CMS guidance is an important step to ensure drug companies cannot evade the law.

Sen. Marsha Blackburn (R-TN) spoke about patient steering practices that direct patients toward higher-priced drugs in their formularies. Both she and Mr. Levitt discussed Tennessee's Any Willing Provider law as a potential model for federal legislation. She also spoke about the impact of PBMs on the 340B program and reducing funding for community health centers.

Sen. Ron Johnson (R-WI) spoke about the murkiness of the drug supply chain and the need for transparency. He suggested that the structure of insurance benefits keep patients from understanding or caring about the actual price of drugs. Overall, he said we don't have competition in the PBM market and need more transparency.

If you have questions, please contact Heather Meade or Heather Bell.