COMMENTARY

Pharmacy Benefit Managers in the Eye of the Storm: Growing Multipartite Scrutiny

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The high cost of prescription drugs in the U.S. remains an ongoing national challenge. A recurring focal point in discussions over this distressing steady state is the role(s) played by Pharmacy Benefit Managers (PBMs) who negotiate drug prices with pharmaceutical manufacturers, conduct drug utilization reviews, engage in disease management, and see to formulary creation. At their inception, the multiple newly established PBMs were arguably intent on constraining the rise of prescription drug prices. At the time of this writing, however, the lion share of a far less competitive PBM market is controlled by CVS Caremark, Express Scripts, and OptumRx. It is this evolving reality which could be interpreted to mean that the PBMs may have become part of the problem, rather than part of the solution. Expanded scrutiny of the PBMs by Federal and State authorities as well as by Professional Medical Associations must not be delayed with an eye toward affording the public with relief from the high cost of prescription drugs. (J Am Board Fam Med 2023;36:000–000.)

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The high cost of prescription drugs in the U.S. remains an ongoing national challenge. According to a 2021 RAND Corporation study, the U.S. spent twice as much per capita on prescription drugs in 2018 as did comparably wealthy nations.[1] The prices of prescription drugs in the U.S. are 2.4 times higher than the average of nine other high-income nations.[2] A recurring focal point in discussions over this distressing steady state is the role(s) played by Pharmacy Benefit Managers (PBMs). As the middlemen in the pharmaceutical marketplace, PBMs manage and administer prescription drug benefits on behalf of employers, public programs such as Medicare and Medicaid, private insurers, and others. By leveraging their size and coverage, PBMs negotiate rebates and fees with drug manufacturers, create drug formularies, and theoretically are in a position to help drive down costs. At their inception, the multiple newly-established PBMs were arguably intent on constraining the rise of prescription drug prices. However, at the time of this writing, the "PBM market is highly consolidated, with three main players—CVS Caremark, OptumRx, and Express Scripts— accounting for 77% of the market in 2020."[3] Further, the general lack of transparency of the PBM's multi-layered, proprietary business models makes it difficult to determine whether any cost savings are passed on to consumers and the extent, if any, of the damage or benefit their practices are having on patients and the marketplace.[3] The combination of lack of transparency and consolidation with health plans and pharmacies has spurred heightened scrutiny in an effort to understand how PBMs shape drug coverage and to what extent they may have become part of the problem, rather than part of the solution. In this *Commentary* we review the ever-growing multipartite scrutiny of the PBMs by Federal and State authorities as well as by Professional Medical Associations.

On June 7, 2022, on the strength of a unanimous 5–0 vote, the *Federal Trade Commission* (FTC) launched an inquiry into the business practices of the PBMs.[4] To this end, the FTC required the six largest

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PBMs (CVS Caremark, Express Scripts, OptumRx, Humana, Prime Therapeutics, and MedImpact Healthcare Systems) to provide it with information and records pertaining to their business operations.[4] The FTC's intention is to shed light on several of the business practices of the PBMs whereas assessing the possibility of violation of competition and consumer protection laws.[4] On May 17, 2023, the FTC expanded its compulsory orders to two group purchasing organizations (Zinc Health Services and Ascent Health Services).[5] In remarks delivered by FTC Chair Lina M. Kahn to the American Economic Liberties Project and the National Community Pharmacists Association, the Chair noted that "PBMs and other intermediaries now play a critical role that have enormous consequences on people's day-to-day lives." Chair Kahn also pointed out that the decisions made by PBMs "help to determine which medicines are prescribed, which pharmacies patients can use, and the prices that patients ultimately pay at the pharmacy counter."[6] In yet another relevant Executive branch effort, the Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) is investigating whether states provide adequate oversight of Medicaid Managed Care Organizations (MCO) to ensure accountability over amounts paid for prescription drug benefits to its PBMs. An initial OIG report determined that the PBM practice of spread pricing "may increase the cost of Medicaid prescriptions for both the MCO and the Medicaid program and, if not correctly accounted for, inflate the cost of the drugs. Limiting spread pricing may decrease Federal and State spending through lower payments to MCOs."[7]

Congress, too, has been scrutinizing PBMs. Both the House of Representatives and the Senate held hearings on the potential role(s) of the PBMs in the prescription drug price crisis. In May 2022, for example, the Senate Subcommittee on *Consumer Protection, Product Safety, and Data Security*, examined the apparent lack of competition in the PBM market and steps Congress might take to increase transparency in drug prices, require PBMs to operate fairly, and ensure the FTC has the authority it needs to stop unfair practices in the prescription drug market. This has been a bipartisan issue: In December 2021, the Democratic staff of the House Committee on Oversight and Reform issued a report on the "Role of Pharmacy Benefit Managers on Pharmaceutical Markets," while House Republicans urged the Governmental Accountability Office (GAO) in June 2022 to investigate the role of PBMs in the pharmaceutical supply chain and commercial health plans. The level of Congress's interest in this topic is indicated by the introduction of approximately 50 PBM-focused bills in the 117th Congress, and another 18 introduced thus far in the current 118th Congress. Amongst the potentially more impactful proposals, the Pharmacy Benefit Manager Transparency Act of 2023 (S.127) is the product of bipartisan collaboration between Senators Maria Cantwell (D-Wash), chair of the Committee on Commerce, Science and Transportation, and Chuck Grassley (R-Iowa), ranking member of the Budget Committee. The bill seeks to empower the FTC and State Attorneys General to increase drug pricing transparency and hold PBMs accountable for unfair and deceptive practices that drive up the costs of prescription drugs at the expense of consumers. According to Sen. Cantwell, "Pharmacy Benefit Managers are middlemen in the drug pricing supply chain ... operating out of the view of regulators. This committee has heard testimony showing how PBMs' substantial market power and opaque practices impact patients, providers and pharmacies."[8] The proposed bill enjoys the support of multiple organizations including the National Community Pharmacists Association, the American Pharmacy Cooperative, and the American Pharmacists Association, to name a few.

Concurrently, a growing number of states have been actively seeking to increase their oversight of the PBMs. At the time of this writing, all 50 states have enacted one or more statutes intent on enhancing PBM oversight through registration and licensure with an eye toward enhancing transparency and accountability.[4] States have also taken to implementing data transparency and reporting requirements, establishing copay adjustment programs, creating prescription drug affordability boards (PDABs), as well as requiring PBMs to compete for a state's business via a reverse auction.[9] More recently, on May 11, 2022, New York State Governor Kathy Hochul went a step further by announcing the establishment of the first Pharmacy Benefits Bureau in the nation.[10] The new entity is being tasked with implementing and overseeing new licensing and reporting requirements that impact PBMs in New York State. Governor Hochul went on to note that the Pharmacy Benefits Bureau will increase the transparency of the process by which PBMs negotiate drug prices with an eye toward lowering drug and health insurance costs for New York State residents.

Several professional medical associations have weighed in as well on the role of the PBMs with an eye toward enhancing patients' access to affordable prescription drugs. A recent analysis by the American Medical Association (AMA) found a "widespread lack of competition in local markets across the United States" wherein PBMs provide services to commercial health insurers.[11] A position paper of the American College of Physicians, for its part, called for "improved transparency in the PBM industry."[12] Comparable calls were issued by the American Society of Clinical Oncology (ASCO), the American Psychiatric Association (APA), the National Community Pharmacists Association (NCPA), and the American Hospital Association (AHA).

The system for pricing prescription drugs in the U.S. is complex to the point of dysfunction in the eyes of many regulators and industry analysts. Such complexity infers that corrective actions aimed at any single target are unlikely to solve the problem entirely, and may even potentially have unintended consequences. But PBMs, first established to process claims and negotiate lower prices with drug manufacturers, play a significant role in the system, presently administering prescription drug plans for more than 250 million Americans whose health insurance is sponsored by Medicare Part D plans, the Federal Employees Health Benefits Program, and state government employee plans to name a few. A key aim of many of the PBM-focused governmental actions currently under review is to elucidate the precise role of the PBMs in inflating the ever-rising U.S. prescription drug bill. And although price comparisons with other countries is fraught with caveats (given different overall healthcare systems, diverse regulatory environments, varyingreimbursement policies, etc.), the U.S. prescription drug bill in light of the experience of other wealthy nations remains a stark reminder that inaction is not an option.

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