COMMENTARY

Aiming at the Right Targets on Drug Price Reform

Stacie B. Dusetzina

Keywords: Pharmacy Benefits Managers, Price Transparency, Drug Rebates

Abstract: A lack of transparency and concerns over patients costs at the pharmacy counter have increased Congressional focus on pharmacy benefits management practices. However, applying regulations without transparency into pharmacy benefits managers practices could do more harm than good.

Pharmacy benefit manager reform has been at the top of mind for multiple Congressional committees over recent months. In a divided Congress, this is one consistent area of bipartisan agreement, though deciding what reforms would be most productive has been a challenge. Pharmacy benefits managers are easy to malign — they are the true "middlemen" in a complex system that sometimes seems more concerned with profit maximization than with patient care. There is also a lack of transparency into pharmacy benefits manager business practices, and concerns that the current compensation structure drives up prices for patients at the pharmacy counter. However, a rush to regulate pharmacy benefits managers could do more harm than good. To understand why, it is worth considering what role they play in the prescription drug supply chain today.

Stacie B. Dusetzina, Ph.D. *is a professor at the Vanderbilt University School of Medicine, Department of Health Policy, Nashville, TN and Ingram Professor at Vanderbilt-Ingram Cancer Center, Nashville, TN.*

Pharmacy benefit managers (PBMs) act as the negotiators for prescription drug prices for insured individuals, including those in Medicare's outpatient drug benefit. There is a common misconception that Medicare does not negotiate prescription drug prices. While the program does not negotiate across all members, private plan sponsors that provide Medicare Part D coverage engage pharmacy benefits managers to negotiate prescription drug prices for their insured members. Given consolidation in both Medicare Part D and in PBM services, these companies tend to negotiate on behalf of very large populations and receive deep discounts for some covered drugs.

As with all negotiations, leverage is important. PBMs can use formulary inclusion (whether a drug will be covered or not), formulary placement or tiering (how much will it cost patients to use the drug), and utilization management (how many hoops patients and clinicians must go through before getting the drug) as leverage for negotiations with drug manufacturers. Because Medicare Part D plans must meet basic coverage requirements, this leverage can vary across products. For example, if there are multiple drugs in a class that work in the same way, a PBM can threaten to exclude a drug from the formulary altogether (a very strong lever). To ensure that beneficiaries have access to needed medications, the Center for Medicare and Medicaid Services requires that all Part D plans cover at least two drugs in most commonly prescribed categories and classes, and they require that plans cover all drugs in certain "protected classes."[1] In cases where there is only one drug in a class or for drugs in protected classes, plans and their PBMs can only use levers that increase costs to beneficiaries who use

The Journal of Law, Medicine & Ethics, 51 S2 (2023): 55-57. © 2023 The Author(s)
DOI: 10.1017/jme.2023.160

the drug or that make it more difficult for clinicians to prescribe the drug.

Applying federal regulations to PBMs without a clear understanding of their current business practices could result in ineffective or counterproductive policies. For example, the Trump administration's "rebate rule" attempted to eliminate the safe harbor exception to the federal Anti-Kickback Statute for rebates negotiated by PBMs in Medicare Part D (with the exception of rebates that are passed on to patients at the point of sale) with the hopes that drug manufacturers would voluntarily reduce their list prices in response.[2] Manufacturers responded under oath that they would not lower their list prices[3] and, as a result, the Congressional Budget Office determined that such a policy would dramatically increase Medicare Part D spending.[4] This example demonstrates how naïvely applying policies to an opaque and complex system could backfire. A representative from the parent company of one of the largest PBMs in the country recently noted that PBMs would find ways to maintain profit levels if Congressional reforms were enacted.[5]

The recent testimony to the United States House of Representatives Committee on Ways and Means provided by Dr. Rome[6] highlights these issues, along with some suggestions for how Congress could carefully approach pharmacy benefit manager reform. Specifically, Dr. Rome suggests that Congress should ensure that plans do not tie patient cost-sharing to drug list prices, require that pharmacy benefits managers provide all rebates back to plan sponsors, eliminate spread pricing or paying pharmacy benefits managers as a percentage of a drug's price, and investigate vertical integration between plan sponsors, pharmacy benefits managers, and pharmacies.

Since the time of Dr. Rome's testimony, Congressional committees have advanced several PBM reform bills,[7] with most targeting greater transparency into contractual relationships and limiting how PBMs can be compensated by the insurers and employers that hire them. In late July 2023, the Senate Finance Committee approved a bipartisan legislative package[8] focused on increasing transparency of PBM practices. The bill would change PBM compensation to a "bona fide service fee" structure, rather than allowing companies to receive compensation tied to drug list prices. It also requires that pharmacy benefits managers provide data to Part D plan sponsors and the Secretary of Health and Human Services regarding prices, medication use, and formulary placement for covered drugs. PBMs would still negotiate for rebates, discounts, and price concessions, but these funds would be fully returned to Part D plan sponsors and, presumably, to beneficiaries in those plans through lower premiums or slower premium growth. The bill also increases opportunities for oversight into compensation practices among vertically integrated plans, evaluating efforts by parent companies that represent Part D plan sponsors, PBMs, and pharmacies from excessively profiting from these arrangements. Increased visibility into current business practices will allow for more carefully crafted policies that hope to maintain the benefits of PBM services while reducing potential abuses and overpayments in the system today.

Much of the ire over PBM pricing practices has been driven by how these practices harm patients who pay for their medications based on the drug's list price. While the bills that have been advanced to date do not address this issue directly,[9] the changes anticipated with the Inflation Reduction Act's redesign of Medicare Part D may do so indirectly, at least for Medicare beneficiaries. For example, under a typical Medicare Part D plan offered today, most beneficiaries using preferred brand-name drugs pay flat-fee copayments during the initial benefit phase but transition to a coinsurance during the "coverage gap" phase (currently 25%). For highly-rebated drugs, beneficiaries are ultimately paying much more than 25% of the post-rebate (net) price for these prescriptions.[10] Under the redesigned Part D benefit — which will be fully implemented in 2025 — the coverage gap is removed from the benefit design, likely resulting in plans offering preferred brand-name drugs at a flat fee for all fills up to the $2,000 out-of-pocket cap. For higher-priced drugs where coinsurance is nearly always used, beneficiaries may also be protected from excessive spending

Because these changes shield most Medicare beneficiaries from overpaying for highly-rebated drugs, it allows Congress to focus on reforms in the Medicare program that will do the most to lower overall spending on drugs and that can help to keep premiums in check in the long run.

The Journal of Law, Medicine & Ethics, 51 S2 (2023): 55-57. © 2023 The Author(s)

through the annual out-of-pocket cap. Because these changes shield most Medicare beneficiaries from overpaying for highly-rebated drugs, it allows Congress to focus on reforms in the Medicare program that will do the most to lower overall spending on drugs and that can help to keep premiums in check in the long run. Separate PBM and rebate reform efforts may still be needed for commercially insured beneficiaries, given the increased use of deductibles and coinsurance under those plans over time.

The recent focus on improving transparency in the prescription drug supply chain is a welcome step that should allow Congress to craft reforms that will best meet the goals of lowering costs to consumers and taxpayers without inadvertently reducing leverage that pharmacy benefits managers and plans need to obtain lower prices for Medicare. PBMs have profited handsomely from the opacity of the prescription drug supply chain, often at the expense of patients. It is time for reforms that put patients first and prevent entities from profiting from high drug prices.

Note

Dr. Dusetzina's effort is supported by the Commonwealth Fund and Arnold Ventures. Dr. Dusetzina is a member of the Institute for Clinical and Economic Review (ICER) Midwest Comparative Effectiveness Public Advisory Council and served on the National Academy of Sciences, Engineering, and Medicine Committee "Ensuring Patient Access to Affordable Drug Therapies." She serves on the Medicare Payment Advisory Commission. The views expressed in this article are the author's own and do not reflect the view of the Commission.

References

1. *What Medicare Part D Drug Plans Cover* (2023), Medicare.gov, *available at* <https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover> (last visited August 28, 2023).
2. R. Sachs, *Trump Administration Releases Long-Awaited Drug Rebate Proposal* (February 1, 2019), Health Affairs Blog, *available at* <https://www.healthaffairs.org/content/forefront/trump-administration-releases-long-awaited-drug-rebate-proposal> (last visited August 28, 2023).
3. C. Rowland, *Drug Executives Grilled in Senate over High Prices* (February 26, 2019), Washington Post, *available at* <https://www.washingtonpost.com/business/economy/drug-executives-grilled-in-senate-over-high-prices/2019/02/25/abc89c04-393f-11e9-aaae-69364b2ed137_story.html> (last visited August 28, 2023).
4. *Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029* (May 2019), Congressional Budget Office, *available at* <https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf> (last visited August 28, 2023).
5. B. Herman, *CVS Warns PBM Reforms "Could Lead to Higher Costs"* (May 31, 2023), STAT, *available at* <https://www.statnews.com/2023/05/31/cvs-pbm-reforms-rebates-spread-pricing/> (last visited August 28, 2023).
6. *See* Examining Policies That Inhibit Innovation and Patient Access: Hearing before the House Ways and Means Subcommittee on Health, 118th Cong., (2023) (testimony of Benjamin N. Rome, M.D., M.P.H.) *available at* <https://waysandmeans.house.gov/wp-content/uploads/2023/05/Rome-Testimony.pdf> (last visited November 27, 2023).
7. E. Slifer and A. Llamas, *Bipartisan Congressional Support for PBM Reform Grows* (June 21, 2023), The Commonwealth Fund, *available at* <https://www.commonwealthfund.org/blog/2023/bipartisan-congressional-support-pbm-reform-grows> (last visited August 28, 2023).
8. Senator Ron Wyden, *Wyden Statement at Finance Committee Markup of the Modernizing and Ensuring PBM Accountability Act* (July 26, 2023), United States Senate Committee on Finance, available at <https://www.finance.senate.gov/chairmans-news/wyden-statement-at-finance-committee-markup-of-the-modernizing-and-ensuring-pbm-accountability-act> (last visited August 28, 2023).
9. J. Cohen, *PBM Reform Legislation may be One Step Closer to Reality, but It's Missing Two Key Components* (May 13, 2023), Forbes, *available at* <https://www.forbes.com/sites/joshuacohen/2023/05/13/pbm-reform-legislation-may-be-one-step-closer-to-reality-but-its-missing-two-key-components/> (last visited August 28, 2023).
10. S.B. Dusetzina et al., "Association of Prescription Drug Price Rebates in Medicare Part D With Patient Out-of-Pocket and Federal Spending," *JAMA Internal Medicine* 177 (2017): 1185–8.

The Journal of Law, Medicine & Ethics, 51 S2 (2023): 55-57. © 2023 The Author(s)