

Policy Recommendations for Pharmacy Benefit Managers to Stem the Escalating Costs of Prescription Drugs: A Position Paper From the American College of Physicians

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Recent discussions about the increasing prices of prescription drugs have focused on pharmacy benefit managers (PBMs), third-party intermediaries for various types of employers and government purchasers who negotiate drug prices in health plans and thus play a crucial role in determining the amount millions of Americans pay for medications. In this position paper, the American College of Physicians expands on its position paper from 2016 by offering additional recommendations to im-

prove transparency in the PBM industry and highlighting the need for reliable, timely, and relevant information on prescription drug pricing for physicians and patients.

Ann Intern Med. 2019;171:823-824. doi:10.7326/M19-0035

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This article was published at Annals.org on 12 November 2019.

In 2016, the American College of Physicians (ACP) published "Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians," a series of recommendations to improve transparency, value, and competition for prescription drugs with the goal of creating a sustainable and affordable prescription drug marketplace (1). Since then, many policy proposals have been offered by stakeholders, government officials, and organizations with the intent of decreasing the prices of prescription drugs and costs to individuals and the health care system. One area of ongoing debate centers on the multifaceted nature of the drug supply chain. The drug supply chain is complex, and many entities play a role in how patients ultimately acquire and pay for their prescription medication. Public policy discussions have shifted toward looking at pharmacy benefit managers (PBMs) and the role they play in prices and costs paid by insurers, government health plans, and patients. Pharmacy benefit managers are for-profit companies that act as intermediaries for health insurers, self-insured employers, union health plans, Medicare Part D prescription drug benefit plans, and government purchasers in the selection, purchase, and distribution of pharmaceutical products for more than half the U.S. population (2). Although many patients are shielded from the high list prices of prescription medications, the number of patients with high-deductible health plans is increasing, and the rising prices of drugs mean more costs are being passed on to consumers in the form of deductibles, premiums, or coinsurance.

Pharmacy benefit managers originated for the purposes of claims processing, mail order pharmacy services, and retail pharmacy network management and started to evolve as employers began including broad prescription drug coverage in their employee benefit

packages. Their role increased in subsequent decades, particularly after passage of the Medicare Prescription Drug, Improvement, and Modernization Act in 2003. After passage of the act, PBMs generally represented Part D plans in negotiations with pharmaceutical manufacturers because the federal government was prohibited from negotiating prices directly with drug manufacturers (2). The function of a PBM is to negotiate rebates with pharmaceutical manufacturers in exchange for favorable placement of drugs on tiered formularies. The PBM then passes those rebates on to employers or plan sponsors, who in turn pass the savings from rebates on to employees or beneficiaries through lower premiums.

Pharmacy benefit managers have been criticized for a lack of transparency, and there can be confusion or misinformation about how they work, how they contract with employers or purchasers, how they make decisions about formularies, how much money they take in, and how much money is actually passed on to consumers. At the state and federal level, policymakers are attempting to improve transparency for PBMs and other parts of the supply chain. The ACP believes that transparency is an important component of the efforts to lower the cost of prescription drugs and can contribute to ongoing efforts to address the cost of the U.S. health care system.

METHODS

This position paper was drafted by the Health and Public Policy Committee of the ACP, which is charged

See also:

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* This paper, written by Hilary Daniel, BS, and Sue S. Bornstein, MD, was developed for the Health and Public Policy Committee of the American College of Physicians. Individuals who served on the Health and Public Policy Committee at the time of the paper's approval were Sue S. Bornstein, MD (*Chair*); Jan K. Carney, MD (*Vice Chair*); Thomas G. Cooney, MD; Lee S. Engel, MD; Heather E. Gantzer, MD; Tracey L. Henry, MD; Joshua D. Lenchus, DO; Bridget M. McCandless, MD; Molly B. Southworth, MD; Fatima Syed, MD; Jacob Quinton, MD; Mary Anderson Wallace, MD; and Alexandria Valdrighi. Approved by the ACP Board of Regents on 12 February 2019.

with addressing issues that affect the health care of the U.S. public and the practice of internal medicine and its subspecialties. The authors reviewed available studies, reports, and surveys related to health plans and PBMs from PubMed, Google Scholar, relevant news articles, policy documents, and Web sites and primarily looked at costs and spending associated with PBMs, PBM rebates and negotiations, and transparency.

Recommendations were based on reviewed literature and input from the ACP's Board of Governors, Board of Regents, Council of Early Career Physicians, Council of Resident/Fellow Members, Council of Student Members, and Council of Subspecialty Societies. The position paper and related recommendations were reviewed and approved by the ACP Board of Regents in February 2019. Financial support for the development of this position paper came exclusively from the ACP operating budget.

This executive summary provides a synopsis of the position paper. The full background and rationale are provided in the **Appendix** (available at Annals.org).

RECOMMENDATIONS

1. *ACP supports improved transparency, standards, and regulation for pharmacy benefit managers (PBMs), including a ban on "gag clauses" that prevent pharmacies from sharing pricing information with consumers. ACP supports stringent oversight and regulation of mergers and consolidation within the PBM market.*

2. *ACP supports the availability of accurate, understandable, and actionable information on the price of prescription medication. ACP urges health plans to make this information available to physicians and patients at the point of prescribing to facilitate informed decision making about clinically appropriate and cost-conscious care.*

3. *ACP believes health plans, PBMs, and pharmaceutical manufacturers should report the amount paid for prescription drugs, aggregate amount of rebates, and nonproprietary pricing information to the Department of Health and Human Services and make it publicly available. Any disclosure mandate should be struc-*

tured in a way that deidentifies negotiated rebates with specific companies and protects confidential information that could be considered trade secrets or could have the effect of increasing prices.

SUMMARY

Pharmaceutical manufacturers are solely responsible for setting prices for prescription drugs and largely bear responsibility for pricing medications. However, all stakeholders must commit to addressing areas where the existing system enables another stakeholder to keep prices artificially high, resulting in patients paying more than necessary for their prescriptions or added costs to the health care system. The ACP believes increased transparency is needed on the part of PBMs and health plans to provide greater understanding of drug prices, help patients make informed decisions, and support a more sustainable health care system.

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Financial Support: Financial support for the development of this position paper came exclusively from the ACP operating budget.

Disclosures: Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M19-0035.

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APPENDIX: BACKGROUND AND RATIONALE

Introduction

Pharmacy benefit managers are involved with the administration of prescription drugs for more than 266 million Americans in private and public health plans, making them the principal purchasers of prescription drugs in the United States. Some industry estimates show that the tools PBMs use, such as negotiating rebates and discounts from drug manufacturers, encouraging use of generic drugs, and offering alternative pharmacy channels, could result in savings of \$654 billion between 2016 and 2025, including \$350 billion in commercial plans and more than \$250 billion in Medicare Part D prescription drug plans (3). Analysts report that the total value of price concessions by pharmaceutical manufacturers in 2017 was \$127 billion (4). Pharmacy benefit managers claim they save consumers an average of \$941 per year (5).

Despite the potential cost savings, PBMs have faced increased scrutiny in light of rising drug prices. There is little transparency in PBMs, and the contracts negotiated between health plans and PBMs for fees and the share of a rebate that is retained by the PBM are considered confidential. Prices of prescription drugs have increased by more than 10% per year for each of the top 20 brand-name drugs prescribed to seniors, and PBMs negotiate rebates from those higher prices (6). Pharmaceutical companies claim that they increase prices to pay for the rebates demanded by PBMs, but PBMs refute this (7). Over the past decade, PBMs have seen increased revenue as list prices for drugs, particularly high-priced specialty drugs, have continued to increase. Operating profits for the 3 PBMs with the largest market share increased from \$3.4 billion in 2007 to \$12.4 billion in 2016 (8).

PBM Consolidation and New Models

Recent consolidation of the PBM market has placed greater leveraging and negotiating power in the hands of a few large PBMs. Although approximately 60 PBMs operate in the United States, consolidation has resulted in 3 of them (CVS Caremark, OptumRx, and Express Scripts) representing as much as 85% of the market share (9). Two mergers between PBMs and health insurers have raised concerns among providers, patients, and other stakeholders that the increased market concentration resulting from the mergers may result in reduced competition and increased prices for patients. The first merger involved the acquisition of Express Scripts by Cigna and was approved by the Department of Justice in September 2018 (10). The second involved CVS Health acquiring Aetna as CVS sought to expand its MinuteClinic model and provide additional medical services at its locations (11). The American Medical Association strongly opposed the merger, citing the potential for reduced competition in the market and increased prices for consumers (12). On 10 October 2018, the Department of Justice approved the merger, with a requirement that CVS divest Aetna's Medicare Part D prescription drug plan business (13).

As the market continues to consolidate, companies like Amazon are exploring the option of becoming market disrupters by selling prescription drugs and medical devices directly to consumers, in the belief that eliminating the middleman will result in cost savings. Some insurance companies have decided to end their relationship with PBMs indefinitely and create their own in-house PBMs. For example, Anthem announced in 2017 that it would end its relationship with Express Scripts and develop its own pharmacy benefit management arm, called IngenioRx, by 2020 (14).

In the U.S. pharmaceutical market, where competition and consumer choice are cornerstones of a healthy market system, consolidation that limits these factors can create scenarios in which PBMs are not motivated to bargain with manufacturers to keep drug costs down. In addition, PBMs have been criticized for "clawbacks," which occur when patient copayments or coinsurance are set at a rate that is higher than the acquisition cost of the drug for the insurer. A recent study showed that in 2013, patients overpaid for their prescriptions by at least \$2.00 twenty-three percent of the time, with an average overpayment of \$7.69 and total overpayments of \$135 million (15). With the increased visibility and criticism of PBMs, lawsuits, including class action lawsuits, have been filed against PBMs claiming illegal pricing schemes, violations of anti-kickback statutes, and other misconduct (16).

Examples of Enacted State-Level PBM Legislation

There have been many bills at the state level to bring additional transparency or oversight to PBMs. Be-

tween 2017 and 2018, 27 states enacted laws that would prohibit “gag clauses” restricting pharmacists from telling consumers when they can obtain their medications for a lower price if they pay for the drug out of pocket instead of through their insurance plan. In addition, some states have introduced or passed legislation that requires PBMs to disclose business relationships with pharmacies and health plans. In total, there are 191 pieces of legislation in 46 states related to PBMs, which include various provisions to improve transparency, pricing, and licensing (17).

Connecticut

The Pharmacy Benefits Manager & Records Act was enacted on 10 July 2017 and prohibits gag clauses on pharmacists that prevent them from disclosing specified information to a person purchasing a drug, such as the availability of other, less expensive medications. The bill also prohibits a health carrier or PBM from requiring a person to pay an amount for a covered prescription that is greater than the lowest of the applicable copayment; the allowable claim amount (the amount the health carrier or PBM agreed to pay the pharmacy); or the amount a person would pay for the drug if he or she had no insurance plan, benefits, or discounts. Finally, the bill authorizes the insurance commissioner to audit pharmacy services' contracts for compliance and to respond to violations by voiding contracts that contain unfair trade practices (18).

Maine

Maine passed 2 bills that attempt to address potential issues related to PBMs. The Clean Claims Submitted by Pharmacies Act “prohibits a health insurance carrier or [PBM] from imposing on an enrollee a copayment or other charge that exceeds the claim cost of a prescription drug” and “prohibits a carrier or [PBM] from penalizing a pharmacy provider for providing information (“gag clause”) related to an enrollee's out-of-pocket cost or the clinical efficacy of a prescription drug or alternative medication” (19). The Maximum Allowable Cost Pricing Lists Act “establishes requirements for maximum allowable cost (MAC) pricing lists used by [PBMs],” “requires [PBMs] to make disclosures regarding that pricing and the methods used to establish that pricing to plan sponsors,” “establishes an appeal process for pharmacies for disputes relating to maximum allowable cost pricing,” and “provides for financial penalties for violations” (20). In addition, the state passed An Act Regarding Maximum Allowable Cost Pricing Lists Used by Pharmacy Benefit Managers, which requires prescription drug cost disclosure by PBMs to plan sponsors of the maximum allowable cost pricing list (20).

North Dakota

In 2017, North Dakota enacted 2 laws aimed at providing comprehensive reform to PBM operations in the state. This included prohibiting PBMs from charging pharmacies certain fees, including after the point of sale (also known as direct or indirect remuneration fees); requiring PBMs to share the amount a pharmacy is reimbursed for a prescription; banning gag clauses; prohibiting PBMs from imposing accreditation standards beyond federal and state licensing requirements on pharmacies to enter into their networks; and instituting conflict-of-interest provisions (21). The Pharmaceutical Care Management Association challenged the laws in court, claiming that they were preempted by the federal Employee Retirement Income Security Act of 1974. In November 2017, a judge in the U.S. District Court for the District of North Dakota found that neither law referenced Employee Retirement Income Security Act plans or had a connection to the act that would be successful on merits and denied the Pharmaceutical Care Management Association's request for injunction. The court ultimately ruled that neither the Employee Retirement Income Security Act of 1974 nor Medicare preempted the state laws and that they could be enforced in their entirety, with the exception of the plan disclosure provision (22).

Recommendations

1. *ACP supports improved transparency, standards, and regulation for pharmacy benefit managers (PBMs), including a ban on “gag clauses” that prevent pharmacies from sharing pricing information with consumers. ACP supports stringent oversight and regulation of mergers and consolidation within the PBM market.*

The continued lack of transparency from PBMs and insurers can hinder how patients, physicians, and others view the drug supply chain and can make it difficult to identify whether a particular entity is inappropriately driving up drug prices. This lack of transparency can also prevent viable policy solutions from being identified and further delays reforms that would help to rein in spending on prescription drugs. Although there have been many calls for transparency on the part of pharmaceutical companies and greater support for transparency in health care generally, all stakeholders must commit to improving transparency as the health care community works toward creating an innovative but sustainable prescription drug market. The Trump administration included addressing PBM transparency in its “American Patients First” drug pricing blueprint and issued a request for information on how to improve transparency around PBMs and the prices patients pay at the pharmacy (23).

The National Academy for State Health Policy drafted a model act relating to PBMs that consists of various provisions from proposed and enacted state

legislation, including licensure, fiduciary responsibility, a prohibition on gag clauses, limits on patient out-of-pocket costs, conflicts of interest, consumer protection, rebate transparency, and limits on PBM requirements for pharmacies (24). The purpose of the act was to bring greater transparency and improved business practices to what has traditionally been a furtive industry. Banning gag clauses that prevent pharmacists from informing patients when lower-cost alternatives are available, such as paying cash for a prescription instead of going through one's insurance coverage, is a reasonable step that has garnered bipartisan support. Recently, the Centers for Medicare & Medicaid Services sent a letter to Medicare Part D plan administrators telling them that such clauses are "unacceptable and contrary to our efforts to promote drug price transparency and lower drug prices" (25).

The consolidation of the PBM market raises concerns about potential antitrust issues and has been shown to increase prices for patients (26). Although many smaller regional PBMs exist, the large national PBMs that take up the vast majority of the market share continue to wield leverage with pharmaceutical companies. As consolidation continues, agreements among PBMs, insurers, or other entities should undergo strict review for both potential antitrust issues and effects on other aspects of the drug supply chain, such as generic and biosimilar market entry.

2. ACP supports the availability of accurate, understandable, and actionable information on the price of prescription medication. ACP urges health plans to make this information available to physicians and patients at the point of prescribing to facilitate informed decision making about clinically appropriate and cost-conscious care.

Patients are asked to take greater responsibility for their health care as they shoulder a larger cost-sharing burden through high-deductible health plans and coinsurance. Therefore, they may be more likely to talk with their physicians about the cost of certain treatments. However, physicians often do not have the necessary information to communicate with patients who ask about prescription drugs and may incorrectly estimate costs. A survey showed that although most physicians indicated they "should consider cost in their decision making," they "have a limited knowledge of cost estimates" (27). One study found that physicians correctly estimated the price of a prescription medication less than half the time (28).

Providing cost and pricing information to physicians can be associated with positive outcomes. One study found that using an electronic drug reference database that included information on patients' drug coverage resulted in prescription of more diverse medications, increased the likelihood of generic drug pre-

scribing, and resulted in a shorter time to prescription of new generics (29). Studies have also shown that giving formulary and drug cost information to providers is associated with smaller increases in total drug costs; however, this may not result in lower out-of-pocket costs or greater medication use (30). Further study is needed to determine how to maximize potential cost savings. It is also important for the information provided to be accurate, up-to-date, and actionable. A review of formulary accuracy in electronic health records showed that for the family medicine medication records reviewed, the electronic health record was accurate 95.3% of the time for Medicaid patients but only 78.2% of the time for those with private insurance (31).

As the health care system has shifted to placing a higher value on the quality rather than the quantity of care, consumers have borne a greater responsibility for the costs of health care goods and services and have become more engaged in their care. Despite this emphasis on the consumer, physicians and other health care professionals drive a substantial amount of health care spending (32). Though the drive for better engagement among payers, physicians, and patients has been a recent focus, large gaps remain and additional efforts are needed to make progress (32). Health plans should explore strategies, such as value-based insurance design, which has been shown to improve medication adherence and decrease out-of-pocket costs for patients. Additional research on value-based insurance design is needed to identify the best design to optimize quality and improve cost savings (33).

3. ACP believes health plans, PBMs, and pharmaceutical manufacturers should report the amount paid for prescription drugs, aggregate amount of rebates, and nonproprietary pricing information to the Department of Health and Human Services and make it publicly available. Any disclosure mandate should be structured in a way that deidentifies negotiated rebates with specific companies and protects confidential information that could be considered trade secrets or could have the effect of increasing prices.

There is strong interest among policymakers and the public in increasing transparency with regard to pricing and payment for prescription drugs. Legislation at the federal level would bring additional transparency to PBMs by requiring disclosures and requiring that a certain amount of rebates be passed on to insurers and consumers. Introduced in the Senate, the Creating Transparency to Have Drug Rebates Unlocked Act would address a lack of transparency in PBMs, particularly Medicare. It would require PBMs to disclose the aggregate amount of the rebates they receive from pharmaceutical companies and how much of those rebates are given back to Medicare beneficiaries. The disclosures would be made public on the Centers for

Medicare & Medicaid Services Web site. After a certain period, a minimum percentage of the rebates would be passed to a health plan from the PBM with the purpose of decreasing premiums or other cost sharing. Cost sharing for Part D beneficiaries would be based on the negotiated drug price as opposed to the list price, providing greater benefit (34). Reporting of rebates could help to address an issue in Medicare Part D in which plan sponsors underestimate the amount of the rebates they receive. An Office of the Inspector General report noted that in 2008, plan sponsors underestimated their plan bids 69% of the time, resulting in higher premiums for beneficiaries (35).

The primary concern about such mandates is that disclosure of pricing or rebate information may encourage tacit collusion among manufacturers, which may lead to higher prices (36). In addition, entities may claim that this information could be considered a trade secret. Approaches to alleviate concerns about disclosure mandates include provisions that companies must disclose unless they are able to prove that the information would constitute a trade secret, or engaging other experts in a field, such as researchers or patient advocates, who would analyze data and release it in a way such that it would no longer constitute a trade secret (37).

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