Pharmacy Benefit Managers
History, Business Practices, Economics, and Policy

T. Joseph Mattingly II, PharmD, MBA, PhD; David A. Hyman, MD, JD; Ge Bai, PhD, CPA

Abstract

IMPORTANCE Pharmacy benefit managers (PBMs) play a major role in the provision of pharmacy services by acting as intermediaries between pharmacies, plan sponsors (insurance companies and employers), pharmaceutical manufacturers, and drug wholesalers. As their role and visibility have increased, PBMs have come under increased scrutiny from policymakers. However, no prior literature has systematically described the history, business practices, and policymaking of PBMs.

OBJECTIVE To provide an overview of the PBM industry, including its history, the evolution of services provided by PBMs, an assessment of the current policy landscape, and analysis of how proposed policies could affect PBM practices and patient care.

EVIDENCE This work reviews historical events; previous and current industry practices and publications; prior academic literature, existing statutes, regulations, and court cases; and recent legislative reforms and agency actions regarding PBMs.

FINDINGS Pharmacy benefit managers evolved in parallel with the pharmaceutical manufacturing and health insurance industries. The evolution of the PBM industry has been characterized by horizontal and vertical integration and market concentration. The PBM provides 5 key functions: formulary design, utilization management, price negotiation, pharmacy network formation, and mail order pharmacy services. Criticism of the PBM industry centers around the lack of competition, pricing, agency problems, and lack of transparency. Legislation to address these concerns has been introduced at the state and federal levels, but the potential for these policies to address concerns about PBMs is unknown and may be eclipsed by private sector responses.

CONCLUSIONS AND RELEVANCE Pharmacy benefit managers are intermediaries in the pharmaceutical supply chain and perform multiple roles in the management and distribution of pharmaceuticals to patients. When regulating PBMs, it is important to adopt policies that address market failure problems by improving PBM competition as opposed to policies designed to serve the narrow financial interests of other market participants (eg, pharmacies, pharmaceutical manufacturers) without meeting the needs of consumers.


Introduction

Pharmacy benefit managers (PBMs) play a major role in the provision of pharmacy services by acting as the intermediary between pharmacies, plan sponsors (insurance companies and employers), pharmaceutical manufacturers, and drug wholesalers.1-4 Pharmacy benefit managers emerged in the late 1950s in response to demand for specialized management of prescription drug benefits. Over the decades, PBMs have expanded their influence in the pharmaceutical supply chain and now handle claims processing, formularies, pharmacy networks, mail order pharmacies, and contracting...
with wholesalers and manufacturers. As their role and visibility have increased, PBMs have come under increased scrutiny from policymakers. This Special Communication provides an overview of the PBM industry, including its history, evolution of services, economics, an assessment of the policy landscape, and an analysis of how proposed policies could affect PBM practices and patient care.

History of the PBM Industry

Early Regulation and Access to Pharmaceuticals

Our modern conception of pharmacies dispensing prescription drugs began with a prescription requirement imposed in 1914 for narcotics,5 which was expanded to nonnarcotics in 1951.6,7 Insurance companies started offering prescription coverage in the 1960s in response to the emergence of new medications and increased spending. In 1967, the US Department of Health, Education, and Welfare established the Task Force on Prescription Drugs,8 which found that both drug expenditures and number of prescriptions had expanded rapidly from 1950 to 1965. Only 4% of prescription drugs were covered by third-party sponsors in the 1960s, but this increased to 32% by 1980.9

Emergence of PBMs

The first PBMs were started by pharmacists. In 1958, Prescription Services, Inc was founded in Canada as a prepayment plan for prescriptions.10 PAID Prescriptions was founded in the US in 1965.10 In the early years, PAID contracts reimbursed pharmacies at usual and customary rates that represented the pharmacy's cash price, which was set by the pharmacy.10 By 1968, PAID began setting its own reimbursement rates for pharmacists wishing to enter PAID's pharmacy network.10 In 1969, Pharmaceutical Card System (PCS) was formed to process claims, funded by nominal charges on each claim.11 These pharmacist-led ventures were controversial; major pharmacy trade organizations complained about recordkeeping obligations, variability in coverage, and reimbursement rates.11

In 1974, the Employee Retirement Income Security Act (ERISA) provided federal standards for employment-based retirement and health plans.12 ERISA allowed large employers to develop and deploy cost-containment strategies for their covered population, including hiring PBMs to manage their prescription drug benefits.13 However, ERISA created challenges for states attempting to pass policy reforms that affect employee benefit plans.14

Horizontal and Vertical Integration in the PBM Industry

The PBM industry experienced considerable vertical and horizontal integration beginning in the 1970s. In 1972, McKesson (a wholesaler) acquired PCS, marking the first step toward vertical integration in the pharmaceutical supply chain.15 In 1979, a home infusion company (Home Health Care of America) entered the PBM market.16 Home Health Care of America was renamed Caremark in 1985 and was subsequently sold to Baxter International, one of the largest manufacturers of hospital supplies in the US.16 Also in 1985, Medco Containment Services acquired PAID Prescriptions, becoming the second-largest PBM in the US.17

In the early 1990s, there was further vertical integration, this time between drug manufacturers and PBMs. In 1993, Merck & Co merged with Medco,18 and Eli Lilly and Company acquired PCS from McKesson.19 In the late 1990s, a different form of vertical integration emerged, as national pharmacy chains acquired PBMs. Rite Aid bought PCS from Eli Lilly in 1998, CVS Health acquired Caremark in 2007, and Express Scripts acquired Medco in 2012.18-20 Additionally, UnitedHealth, a large health insurance company, acquired PacifiCare (including its captive PBM) and subsequently took back the $11 billion drug benefits business outsourced to Medco.21,22 This PBM was later rebranded as OptumRx.23

Federal antitrust authorities have periodically examined the PBM industry and scrutinized particular acquisitions. In 2017, the US Department of Justice successfully blocked 2 major mergers
involving health insurers: Aetna-Humana and Anthem-Cigna. The Department of Justice challenges opened the door for CVS Health to acquire Aetna and for Cigna to merge with Express Scripts (both in 2018). Opposition to these mergers, and broader concerns about PBM business practices, caused the US Federal Trade Commission to open a sweeping inquiry into the PBM industry in 2022. Summaries of key events in the evolution of the industry are presented in Figure 1 and Table 1.

**Services Provided by PBMs**

Business practices of PBMs have evolved substantially over the past half century. However, their core function remains the same.

**Formulary Design**

The most important service provided by a PBM is the development and maintenance of a drug formulary. The formulary specifies which drugs the PBM will cover and the associated patient-level costs when the drug is dispensed. Formularies are typically developed by a committee of pharmacists and physicians, often called a pharmacy and therapeutics committee, who review clinical trials, US Food and Drug Administration approvals, and scientific literature to assess the value of different medications. Formulary determinations are multifaceted and incorporate medication safety and efficacy, ease of use, adherence factors, cost considerations, and preferences of plan sponsors. Formularies are regularly updated to reflect new drugs entering the market, changes in drug prices, or new clinical evidence.

Formulary design varies from less restricted “open” systems, where almost all drugs are listed and available, to a more restricted “closed” system, where relatively few drugs are approved for patient access. The PBM manages all processes of evaluating drugs to be included in the formulary, determining what tier an included drug will be placed on and what incentives are placed to encourage use of preferred drugs. Formulary tiers vary from 2 tiers (ie, preferred and nonpreferred) to multiple tiers that allow for more tailored restrictions and incentives, including higher out-of-pocket spending for drugs on higher tiers. The PBM typically maintains multiple formularies, each tailored to the preferences of a plan sponsor. Formulary design has a direct effect on whether patients can obtain prescribed medications and the associated out-of-pocket spending.

**Utilization Management**

Utilization management encompasses several common practices, including prior authorization, step therapy requirements, supply limits (on dosage or number of days), and various financial incentives.

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**Figure 1. Key Events in the Evolution of the Pharmacy Benefit Manager (PBM) Industry**

1946 Veteran’s Administration mailed prescriptions at no charge to veterans
1951 Durham-Humphrey Amendment
1958 PSI founded in Canada
1965 Paid Prescription Drugs formed
1966 PCS founded
1967 US Task Force on Prescription Drugs formed
1969 Paid Prescription Plans founded
1972 McKesson acquires PCS
1974 Employee Retirement Income Security Act
1975 Merck & Co acquires Medco
1983 Home Health Care of America founded
1985 Medco acquires PDQ
1987 Baxter acquires CaroCare
1993 Merck & Co acquires Medco Containment Services
1994 Eli Lilly acquires PCS from McKesson
1998 Rite Aid acquires Medco from Eli Lilly
2001 CVS acquires Caremark to form CVS Health
2005 UnitedHealth buys PacifiCare
2012 Express Scripts acquires Medco Health Solutions
2017 Anthem-Cigna merger blocked
2018 CVS Health acquires Express Scripts
2020 Rutledge v Pharmaceutical Care Management Association
2022 Federal Trade Commission inquiry into PBM practices

PCS indicates Pharmaceutical Card System; PSI, Prescription Services Inc.
(eg, deductibles, co-payments, coinsurance). Prior authorization refers to a prospective utilization review focusing on evaluating the appropriateness of the prescribed therapy. Prior authorization often requires the prescribing physician to submit additional information before the PBM will approve payment. Step therapy requires the patient to try a preferred medication and experience treatment failure before approving a nonpreferred medication. The PBM may also restrict the

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
<th>Relevance</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1946</td>
<td>Veterans Administration mailed prescriptions at no charge to veterans</td>
<td>First mail order pharmacy in the US</td>
<td>Morgan et al, 1990</td>
</tr>
<tr>
<td>1951</td>
<td>Durham-Humphrey Amendment of 1951</td>
<td>Clarified the definition of drugs that require a prescription vs over-the-counter drugs</td>
<td>Swann, 1994</td>
</tr>
<tr>
<td>1958</td>
<td>Prescription Services Inc</td>
<td>First reported plan established for prepayment of prescription services sponsored by area pharmacists in Windsor, Ontario, Canada</td>
<td>Campbell and Hammel, 1973</td>
</tr>
<tr>
<td>1965</td>
<td>PAID Prescriptions signs first contract to pay prescription drug benefits</td>
<td>Established by pharmacists as described as a pharmacy Blue Shield</td>
<td>Morgan, 1977</td>
</tr>
<tr>
<td>1966</td>
<td>Prepaid prescription plans founded</td>
<td>First indemnity type of plan where policyholders are reimbursed a percentage of the total prescription charge</td>
<td>Campbell, 1973</td>
</tr>
<tr>
<td>1967</td>
<td>Task Force on Prescription Drugs formed</td>
<td>Final report in 1969 determined that a drug insurance program under Medicare was needed</td>
<td>Oliver et al, 2004</td>
</tr>
<tr>
<td>1969</td>
<td>Pharmaceutical Card System (PCS) founded</td>
<td>Company often credited as the first PBM</td>
<td>Campbell, 1973</td>
</tr>
<tr>
<td>1972</td>
<td>McKesson acquires PCS</td>
<td>First integration of a PBM with a wholesale distributor</td>
<td>Mergr, 2023</td>
</tr>
<tr>
<td>1974</td>
<td>Employee Retirement Income Security Act of 1974 (ERISA)</td>
<td>Sets minimum standards for most voluntarily established retirement and health plans in the private sector</td>
<td>US Department of Labor, 2023</td>
</tr>
<tr>
<td>1979</td>
<td>Home Health Care of America founded</td>
<td>A home infusion business that would eventually become one of the largest PBMs known as Caremark</td>
<td>Arlen, 2008</td>
</tr>
<tr>
<td>1985</td>
<td>Medco Containment Services acquires PAID Prescriptions</td>
<td>The acquisition makes Medco the second largest PBM</td>
<td>Rosoff, 1997</td>
</tr>
<tr>
<td>1987</td>
<td>Baxter International acquires Caremark</td>
<td>After changing its name in 1985, Caremark was acquired by Baxter, a leading manufacturer of hospital supplies</td>
<td>Arlen, 2008</td>
</tr>
<tr>
<td>1993</td>
<td>Merck &amp; Co acquires Medco</td>
<td>One of the first major manufacturer and PBM integrations</td>
<td>Lipton et al, 1999</td>
</tr>
<tr>
<td>1994</td>
<td>Eli Lilly and Company acquires PCS from McKeon</td>
<td>Second major manufacturer-PBM integration</td>
<td>Eichenwald, 1994</td>
</tr>
<tr>
<td>1998</td>
<td>Rite Aid acquires PCS from Eli Lilly</td>
<td>One of the first PBM purchases by a national pharmacy chain</td>
<td>Lipton et al, 1999</td>
</tr>
<tr>
<td>2005</td>
<td>UnitedHealth buys PacifiCare</td>
<td>UnitedHealth buys PacifiCare to enter the Medicare market, and PacifiCare had its own PBM that is now rebadged under UnitedHealth as OptumRx</td>
<td>Freudenheim, 2005 and Byers, 2018</td>
</tr>
<tr>
<td>2007</td>
<td>CVS acquires Caremark to form CVS Health</td>
<td>Second major PBM-pharmacy integration deal</td>
<td>Richman and Adashi, 2023</td>
</tr>
<tr>
<td>2012</td>
<td>Express Scripts acquires Medco Health Solutions</td>
<td>Express Scripts and Medco were 2 of the largest PBMs at the time and required an 8-mo review by the US Federal Trade Commission</td>
<td>Krauskopf, 2012</td>
</tr>
<tr>
<td>2017</td>
<td>Aetna-Humana merger blocked</td>
<td>US Justice Department successfully challenges Aetna-Humana merger, citing that the merger would harm seniors relying on Medicare Advantage plans</td>
<td>Gluck and Greaney, 2017</td>
</tr>
<tr>
<td>2017</td>
<td>Anthem-Cigna merger blocked</td>
<td>Second successful merger challenge from the Department of Justice</td>
<td>Dranove, 2017</td>
</tr>
<tr>
<td>2018</td>
<td>Cigna acquires Express Scripts</td>
<td>Major health insurance-PBM integration deal</td>
<td>Abelson, 2018</td>
</tr>
<tr>
<td>2018</td>
<td>CVS Health acquires Aetna</td>
<td>Health insurance-PBM-pharmacy integration deal</td>
<td>Frakt and Garthwaite, 2018</td>
</tr>
<tr>
<td>2020</td>
<td>Rutledge v Pharmaceutical Care Management Association</td>
<td>US Supreme Court decision that ERISA did not preempt Arkansas’s law regulating PBMs, allowing states more power in regulating PBM practices</td>
<td>Fuse Brown and McCuey, 2020 and Knox et al, 2021</td>
</tr>
<tr>
<td>2022</td>
<td>Federal Trade Commission inquiry into PBM practices</td>
<td>Agency announced inquiry that will scrutinize the effect of vertically integrated PBMs on the access and affordability of prescription drugs</td>
<td>Federal Trade Commission, 2022</td>
</tr>
</tbody>
</table>
quantity or dose for acute conditions or set limits on the amount the patient can receive from a retail pharmacy. The PBM often requires patients to obtain maintenance doses for chronic conditions from an affiliated mail order pharmacy.33

Price Negotiation

The PBM negotiates with pharmacies, wholesalers, and drug manufacturers on behalf of plan sponsors.38 As noted above, drug manufacturers offer rebates and discounts to ensure that their branded (high-cost) pharmaceuticals are included in a formulary and/or placed on a preferred tier. Pharmacies negotiate the terms on which they will be paid for both brand and generic pharmaceuticals to ensure that they are included in the network covered by a particular plan sponsor. The result of these pricing negotiations is that the net price to the plan sponsor may be substantially less than commonly cited list prices, including the average wholesale price and the wholesale acquisition cost.39,40 Net prices are known to the plan sponsor (through the contracting process) but are not publicly available.

Pharmacy Network

Another service provided by the PBM is the creation and management of a network of pharmacies (including specialty pharmacies) at which a plan sponsor’s beneficiaries can access prescriptions. By restricting access to the network, competition is heightened, and pharmacies are encouraged to offer the lowest possible prices for the chance to serve the PBM’s patient network.2 The PBM generally ensures that beneficiaries have access to a mix of local retail pharmacies, specialty pharmacies, and mail order pharmacies. Some PBMs own pharmacies and encourage use of their affiliated pharmacies.

Mail Order Pharmacy Services

Pharmacy benefit managers have played a major role in the expansion of mail order pharmacy services. While existing mail order pharmacies are almost exclusively tied to PBMs, the Veterans Administration pioneered this practice in the 1940s prior to the first PBM.29 Vertically integrated with their own mail order pharmacies, PBMs helped increase mail order industry sales from $100 million in 1981 to $1.5 billion by 1989.29 As mail order pharmacies expanded, concerns regarding conflicts of interests and generic dispensing rate differences led the US Congress to request a study of this issue.41 While mail order pharmacy has become synonymous with PBM ownership, prescription delivery has been a common practice for more than half a century, and new cash-only pharmacy companies also use mail order services to reach their customers.42

Economics of the PBM Industry

According to the Pharmaceutical Care Management Association, which serves as the trade association for the PBM industry, PBMs rely on 3 contracting strategies to generate profits.43 The first is rebate retention contracting in which the plan sponsor pays the list price and the PBM is entitled to some or all of the rebates it negotiates with pharmaceutical manufacturers. Research indicates that PBMs retain 0.4% of rebates in Medicare Part D and 9% (2012) to 22% (2016) of rebates in the commercial market.44,45 The second strategy is spread pricing contracting, in which the plan sponsor pays a fixed amount for each drug no matter how much (or little) the PBM pays the pharmacy for dispensing. The difference is the PBM’s gross profit (spread) on that claim. The third strategy involves the plan sponsor paying the actual cost of dispensed prescriptions (net of all rebates) and paying the PBM an administrative fee for its services.43

These contracting strategies create predictable incentives for PBMs. Rebate retention incentivizes the PBM to maximize rebates, even if doing so results in offering a preferred formulary position to drugs with higher list prices. Spread pricing contracts incentivize PBMs to squeeze lower costs out of their pharmacy networks. These strategies create an environment that favors larger
PBMs with more negotiating leverage, incentivizing horizontal integration through mergers and acquisitions. The same dynamics also create an incentive toward vertical integration with PBM-owned or PBM-affiliated pharmacies, particularly for high-cost specialty pharmaceuticals, which have a massively disproportionate impact on total drug spending (ie, approximately 2%-3% of prescription fills, representing 40% of total spending).46-48

In executing their core functions, PBMs affect the financial interest of various stakeholders (Figure 2). For drug manufacturers, PBMs have control over branded drugs’ sales volume through formulary design and utilization management. They also affect branded drug manufacturers’ net sales revenue through price concessions. For pharmacies, PBMs influence patient access to retail, mail order, and specialty pharmacies (thereby affecting pharmacies’ sales), and PBM-pharmacy contracts determine reimbursement amounts.49,50 For plan sponsors, PBMs manage pharmacy benefit spending, including the extent to which manufacturer or network pharmacy price concessions are passed through to those responsible for paying insurance premiums. Ultimately, for patients, both premiums and out-of-pocket spending are largely determined by PBMs.3,51 In light of the financial implications of PBMs on other stakeholders, PBM practices generate criticisms. These criticisms can be broadly grouped into 4 interrelated categories: (1) market concentration, (2) pricing, (3) agency problem, and (4) transparency.

Market Concentration
Limited competition in the PBM industry has been a consistent issue in health policy (Figure 1). Currently, 3 PBMs account for 79% of prescription drug claims, and 6 PBMs handle 96%.52 The largest PBM (CVS-Caremark) accounts for 33% for all prescription drug claims, followed by Express Scripts (24%), OptumRx (22%), Humana (8%), Prime Therapeutics (5%), and MedImpact (4%). Furthermore, 5 of the 6 largest PBMs are vertically integrated with a health insurer.52 This degree of horizontal and vertical integration is likely to be a major factor in the Federal Trade Commission’s broad investigation launched in 2022 and helps explain policy efforts to regulate PBM practices.

When a PBM creates financial incentives for consumers to use pharmacies owned by the PBM, it impacts business opportunities available to nonaffiliated pharmacies. In response, several states have attempted to regulate PBM-pharmacy relationships by enacting “any willing provider” laws that make it difficult for PBMs to steer patients to a PBM-owned pharmacy over a nonaffiliated pharmacy.2

Pricing
Branded drug manufacturers have long been the target of criticism for their pricing practices, but over the past decade, the focus has shifted to PBMs and the rebates and discounts they receive.53 Drug manufacturers in competitive therapeutic areas may have an incentive to offer, and some PBMs may have an incentive to accept, a high-list-price/high-rebate strategy. As noted above, a PBM may
prefer products with high list prices for which it can negotiate high rebates, rather than comparable drugs with lower list prices and smaller rebates, if the PBM retains some percentage of the rebates and its contract with the plan sponsor does not require 100% pass-through. These pricing incentives have led multiple manufacturers, such as Amgen and Viatris, to launch the same drug products at different list prices—a low-price product with no rebate and a higher-price version with rebates—to appeal to different purchasers. Although it seems counterintuitive that any purchaser would prefer a higher price, both companies expect the high-list-price/high-rebate option to be more attractive to PBMs that retain some of the rebates.

A related issue is patients’ cost sharing. Pharmacy benefit managers leverage the formulary design and medication access restrictions to negotiate larger rebates from manufacturers. These price concessions from the drug manufacturer can result in drug placement on a preferred formulary tier. But patient cost sharing is frequently linked to a percentage of a drug's list price rather than to the postrebate net price. As the gap between list price and net price widens (ie, as more and larger rebates are offered), the patient's share of the drug spending increases. A recent study found that increased rebate payments are associated with increased out-of-pocket costs. The US Department of Health and Human Services's 2020 Drug Formulary Rebate Rule, which is limited to Medicare Part D, linked patient out-of-pocket spending to a net (postrebate) price. This rule should reduce patients' out-of-pocket costs once it goes into effect but could increase premiums.

Pharmacists and pharmacy organizations criticize PBMs for low reimbursement levels and for direct and indirect remuneration fees, which are retroactive price adjustments after the point of sale. Arkansas sought to address this issue with legislation, which was challenged by the trade association of PBMs as a violation of ERISA. Lower courts concluded that the law violated ERISA, but the US Supreme Court upheld the legislation in 2020 in an opinion that gave states more flexibility to regulate in this area.

**Agency Problem**

Another set of criticisms and controversies falls within the realm of agency theory. The PBM (the agent) is hired to work for a plan sponsor (the principal). But agents sometimes serve their own interests or fail to pursue the interests of the principal, particularly when interests are not aligned or when it is difficult for the principal to monitor the behavior of the agent. Mergers between plan sponsors and PBMs solved one level of agency problem, but they may have worsened the overall principal-agent problem. When PBMs retain some or all of the rebates, they have a significant incentive to place high-list-price/high-rebate therapies on lower formulary tiers. Stated differently, although formularies generally enhance the efficiency of drug markets, when the PBM market is highly concentrated and contracts limit the sharing of rebates between PBMs and their principals, the value created by these formularies may be captured by the PBM.

To be sure, PBMs profit by performing functions deemed important by their principals (ie, clients such as employers, insurers, and the federal and state governments). These clients are sophisticated purchasers who have a variety of consultants and contract strategies at their disposal. It may be false to assume that plan sponsors are not acting in their own best interests when electing to enter in a PBM agreement that rewards the PBMs with rebate and/or spread pricing retention. These types of contracts may offer cash flow advantages for plan sponsors who will have fewer to no fees up front and would receive cash inflows in the form of rebates throughout the contract, making it attractive from a cash accounting perspective.

**Transparency**

Finally, PBMs are frequently criticized for a lack of transparency. Some patients, plan sponsors, and physicians complain that PBMs conceal their financial transaction details with manufacturers and unilaterally move a drug from one tier to another, or exclude a drug from the formulary entirely, without providing a clinical or financial justification. Similarly, pharmacies cite a lack of transparency regarding how PBMs set the rates at which pharmacies will be paid and the basis for retroactive price
adjustments. Calls for enhanced transparency aim to address this issue, but evidence is lacking on whether such reforms will actually have the desired effects.

**Current Policy Landscape**

**State-Level Policy**

All 50 states have imposed regulatory limitations on PBM practices that address pricing and reimbursement, pharmacy operations, pharmacy network, licensure and registration, and transparency and reporting. Many of the state regulations sought to address some of the issues identified above but lacked concrete measures to ensure that there would be total savings for the system or consumers, better health outcomes, or enhanced quality of care or patient experience. Rather, some of the PBM-focused state legislation was narrowly crafted to serve the financial interests of pharmacies (reimbursement requirements, maximum allowable cost list limitations, network exclusion limitations, and audit practice limitations), so there was no reason to expect that such legislation would lead to savings for patients or the health care system.

**Federal Policy**

Recent increased interest in PBM business practices by lawmakers has led to the introduction of several new bipartisan bills. As of August 2023, 4 bills were pending in Congress (Table 2). These bills primarily target PBM business practices related to mandatory pass-through of manufacturer rebates to plan sponsors, prohibition of spread pricing, requirement for multiple levels of reporting, prohibition of retroactive price changes, and delinking of PBM revenue from drug list prices (including any discounts or rebates). All 4 bills also require multiple levels of reporting. It remains to be seen whether any of these bills will become law, but they signal considerable legislative interest in PBM business practices. A major limitation of these policy efforts is that they do not address the lack of competition that is considered a major underlying cause of PBM industry failures to meet the needs of their principals.

**New Business Models May Change the Dynamics**

Several recent business developments are instilling competition and disrupting current PBM business models, which may reduce the need for legislative intervention. In the generic market, GoodRx and similar platforms offer competitive PBM-adjudicated net prices to direct-pay patients. In response, OptumRx, a large PBM, launched Price Edge to lower out-of-pocket spending for beneficiaries. Amazon Pharmacy’s RxPass Program also provides a $5-a-month direct-pay subscription, using its own PBM to adjudicate transactions. Mark Cuban Cost Plus Drug Company sells several generic drugs at usual and customary rates (or cash prices) and does not accept rebate-based PBM contracts, similar to the Walmart and Kroger “$4 List” offerings from the early 2000s.

For insulin, 3 pharmaceutical manufacturers (Eli Lilly, Novo Nordisk, and Sanofi) announced up to a 75% reduction in the list prices of their insulin products and a monthly cost cap of $35 for commercially insured and uninsured patients. Additionally, Novo Nordisk announced a partnership in 2021 with Walmart to launch private brand insulin products, discounting list prices from 58% to 75%. More recently, Blue Shield of California announced that it will discontinue PBM services from CVS-Caremark and instead use Mark Cuban Cost Plus Drug Company for prescription drugs through retail pharmacies, Amazon Pharmacy for mail order delivery, and Abarca Health for claims processing. These developments were not necessarily the direct result of government regulation. If more drug manufacturers adopt similar pricing strategies and more insurance companies abandon the traditional PBM model, the ripple effect could disrupt the traditional PBM business model and invite new entrants and instill competition.

In contrast, legislative approaches to addressing problems in the PBM industry are subject to 2 challenges. First, PBMs are likely to adapt their business models in response to regulatory changes, thus minimizing or neutralizing the hoped-for effects. This approach has been observed in other
industries, such as the expansion of shadow banking entities following the passage of the Dodd-Frank Act\textsuperscript{71} and market consolidation of media companies following the Telecommunications Act of 1996 that was intended to increase competition.\textsuperscript{72}

Second, even if PBMs cannot fully adapt their business models in response to regulatory change, it is far from clear that plan sponsors and patients, as opposed to other players in the pharmaceutical supply chain, would actually benefit. Plan sponsors and patients may only benefit if pharmaceutical manufacturers, wholesalers, and pharmacies are willing to offer lower prices in the absence of PBMs or with PBMs that are significantly weakened. Policy reforms that ban spread pricing or require 100% rebate pass-throughs in the contracts between PBMs and plan sponsors may actually go too far in weakening the incentives of PBMs to negotiate with pharmacies and manufacturers.\textsuperscript{73} Under such a regulatory regime, PBMs would continue to provide the services that plan sponsors want (eg, utilization management, rebate negotiation, pharmacy network management, mail order), but without incentives tied to rebate negotiation or reducing pharmacy payments, administrative fee-based contracting may not generate the same amount of savings to the plan sponsor.

Long-run improvements in the pharmaceutical market may come from reforms that enhance competition, such as removing impediments to generic and biosimilar entry, more rapid designation of specialty drugs, and methods to protect patients from unexpected price increases often called “surprise billing.”\textsuperscript{74} Such reforms are necessary to reduce prices and drive down costs, and they would also increase the ability of PBMs to negotiate lower drug costs for their clients.

### Table 2. Comparison of Current Pharmacy Benefit Manager (PBM)-Related Federal Legislation

<table>
<thead>
<tr>
<th>Type of insurance</th>
<th>PBM Transparency Act (S.127)\textsuperscript{63}</th>
<th>PBM Reform Act (S.1339)\textsuperscript{64}</th>
<th>Patients Before Middlemen Act (S.1967)\textsuperscript{65}</th>
<th>PATIENT Act (HR.3561)\textsuperscript{66}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business practices</td>
<td>Group health plans, employer-based health insurance, any plan sponsored by federal or state governments</td>
<td>Group health plans, employer-based health insurance</td>
<td>Medicare Part D</td>
<td>Group health plans, employer-based health insurance, Medicare, Medicaid</td>
</tr>
<tr>
<td>Manufacturer rebates</td>
<td>100% Rebate pass-through to health plans</td>
<td>100% Rebate pass-through to health plans</td>
<td>Delinking PBM revenue from drug list prices</td>
<td>No pass-through requirement</td>
</tr>
<tr>
<td>Spread pricing</td>
<td>Prohibits spread pricing broadly to both government and commercial health plans</td>
<td>Prohibits spread pricing in commercial health plans</td>
<td>No explicit prohibition, but PBM is not allowed to make income outside of service fees</td>
<td>Prohibits spread pricing specifically in Medicaid</td>
</tr>
<tr>
<td>Retroactive price changes or clawbacks</td>
<td>Prohibits clawbacks that are arbitrary, unfair, or deceptive</td>
<td>No prohibition</td>
<td>No prohibition</td>
<td>No prohibition</td>
</tr>
<tr>
<td>Reporting requirements</td>
<td>Disclosure of pricing information including the aggregate amount of all remuneration the PBM receives and retains</td>
<td>Report co-pay assistance from manufacturers, detailed claim information, and the WAC price of the drug</td>
<td>No requirement</td>
<td>PBM must report the negotiated price for covered Medicare Part D drugs, amount of DIR paid by pharmacies, and rebates passed through to the plan; for commercial plans, in addition to pricing information, PBM must report rationale for formulary placement</td>
</tr>
<tr>
<td>Reporting to plan sponsor</td>
<td>Annual reporting to FTC</td>
<td>Annual reporting to GAO</td>
<td>Annual certification of compliance to HHS</td>
<td>Annual reporting to GAO</td>
</tr>
<tr>
<td>Reporting to executive branch of government</td>
<td>FTC reports annually to congress, including any investigations as well as formulary design and placement; within 1 year of enactment, GAO shall submit a report to congress that addresses the role PBMs play in the supply chain and state of competition</td>
<td>Within 1 year of enactment, ASPE would be required to conduct a study on the effect of the changes and report back to Congress</td>
<td>No requirement</td>
<td>Within 1 year of enactment, secretary of HHS shall submit a report of specialty drug coverage and reimbursement to Congress; MEDPAC must also submit a report to Congress every 2 years on the effects of vertical integration on Medicare</td>
</tr>
</tbody>
</table>

*Abbreviations: ASPE, Assistant Secretary for Planning and Evaluation; DIR, direct and indirect remuneration; FTC, Federal Trade Commission; GAO, Government Accountability Office; HHS, US Department of Health and Human Services; MEDPAC, Medicare Payment Advisory Commission; PATIENT, Promoting Access to Treatments and Increasing Extremely Needed Transparency; WAC, wholesale acquisition cost.*
of over-the-counter status, and greater competition from compounding pharmacies. In addition, spread pricing and rebates for multisource brand drugs would disappear, and drug spending would drop if, as some researchers proposed, insurance stops covering generics and multisource brand drugs. Congress could consider adopting this proposal for publicly funded programs and loosening restrictions on using health savings accounts so that plan sponsors, while saving on premiums by removing these drugs from coverage, can offer cash contributions to health savings accounts for beneficiaries to purchase these drugs in the competitive direct pay market.

Conclusions

Pharmacy benefit managers are intermediaries in the pharmaceutical supply chain, and intermediaries are not always popular. States have already taken steps to regulate PBMs, and the US Supreme Court has given them a green light to do more of the same. Federal legislation is also pending. However, when regulating, it is important to distinguish between market failure problems that require regulatory intervention vs initiatives that are designed to serve the financial interests of other market participants (eg, pharmacies, pharmaceutical manufacturers). If we want regulation to serve the public interest, improving PBM market competition is the best way to do so.

ARTICLE INFORMATION

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Corresponding Author: Ge Bai, PhD, CPA, Johns Hopkins University, 100 International Dr, Baltimore, MD 21202 (gba@jhu.edu).

Author Affiliations: Department of Pharmacotherapy, University of Utah College of Pharmacy, Salt Lake City (Mattingly); Health Law & Policy, Georgetown University, Washington, DC (Hyman); Johns Hopkins Carey Business School, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (Bai).

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Acquisition, analysis, or interpretation of data: Mattingly, Hyman.

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REFERENCES


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