

VIEWPOINT

Kevin A. Schulman, MD

Department of Medicine, Duke University School of Medicine, Durham, North Carolina; and Harvard Business School, Boston, Massachusetts.

Barak D. Richman, JD, PhD

Duke Law School, Durham, North Carolina.

The Evolving Pharmaceutical Benefits Market

Pharmaceutical benefit managers (PBMs), a once obscure segment of the health care financing landscape, have become industrial behemoths in the US health sector. In 2017, the top PBMs had revenues that exceeded those of the top pharmaceutical manufacturers, for example, Express Scripts reported revenue of \$100 billion while Pfizer had revenues of \$52 billion. By one count, “drug channel” companies, which include PBMs and drug distributors, comprise 6 of the top 25 companies on the Fortune list of the top 500 US companies ranked by revenue.

Although often maligned as intermediaries, PBMs play an important role in administering outpatient prescription drug benefits. PBMs perform this role for insurers and large employers and organize the Medicare Part D benefit for the Centers for Medicare & Medicaid Services. PBMs set formulary policies for patients, negotiate with drug manufacturers to assign products to formulary tiers, and distribute drugs to patients through mail order programs.

Although physicians do not focus much attention on PBMs, recent events across the PBM industry reflect broader changes in the health care market and raise issues moving forward that warrant their careful consideration.

The Growth of PBMs

One reason physicians have paid little attention to PBMs is that prescription drug coverage was historically administered separately from medical and hospital benefits of health insurance. In 1960, for example, the outpatient prescription drug market was only \$2.7 billion, and 96% of the retail US prescription drug market

Pharmaceutical benefit managers (PBMs), a once obscure segment of the health care financing landscape, have become industrial behemoths in the US health sector.

was financed out of pocket by individuals.¹ As medications became more effective and expensive, employers began to offer prescription drug coverage, often administered by PBMs. As recently as 1990, the market for prescription drugs was \$38 billion, but out-of-pocket payments had declined from 96% to 57%.¹ By 2000, the \$121 billion prescription drug market was financed 28% through out-of-pocket payments; by 2010, the \$253 billion market was financed 18% through out-of-pocket payments; and in 2017, the estimated \$360 billion market was financed only 13% by out-of-pocket payments.²

The remarkable growth of PBMs was fueled by a business model that involved generally assuming no

financial risk for drug benefits but rather was built alongside a dominant fee-for-service health insurance system. PBMs provided discrete services to employers and acted as intermediaries between manufacturers and patients.³ PBMs generally consider the cost of the administered drug benefit as revenue even if the PBM is not involved in dispensing medications. However, one business practice of PBMs involves negotiating discounts from manufacturers (*rebates*) or payments to PBMs from manufacturers based on total sales volume of prescription drugs. These private negotiations are not transparent in terms of the payment to the PBM and the distribution of these payments to employers, insurers, and patients. Retaining a share of these enormous rebates enabled the largest stand-alone PBM to enjoy higher profit margins than all of the health insurers without a PBM. In 2016, adjustments to revenues and payments from pharmaceutical manufacturers to intermediaries in the market totaled \$144 billion.⁴

PBM Acquisitions—Toward an Integrated Model?

In the past few months, PBMs have been active in the business news. In October of 2017, health insurer Anthem announced it will start its own PBM. CVS, which acquired PBM Caremark in 2006, announced in December of 2017 that it will acquire health insurer Aetna. In March of 2018, health insurer Cigna announced it will acquire the largest free-standing PBM, ExpressScripts. Also in March of 2018, United Health, which acquired PBM Catamaran to add to its Optum PBM in 2015, announced it will change its PBM business model and share rebate dollars directly with consumers for the first time.⁵ These numerous changes likely reflect the substantial cost of drugs in the United States, particularly compared with other countries, and the unique role of intermediaries benefiting from the significant difference between discounted and undiscounted drug prices in the United States.⁶ In a recent analysis, Papanicolas et al found that the difference in drug costs was among the major contributors to the difference in overall health care spending between the United States and other high-income countries.⁶

These acquisitions could signal a major change in the way pharmaceuticals are purchased and used. With these mergers, health insurers could consider changing the structure of health benefits altogether. Integrating health insurance and pharmaceutical benefits might mean that pharmaceutical benefits will no longer be considered in isolation from medical and hospital benefits. When benefits are separate, pharmaceutical products are considered a cost, even if use

Corresponding Author: Kevin A. Schulman, MD, Duke Clinical Research Institute, PO Box 17969, Durham, NC 27715 (kevin.schulman@duke.edu).

of these products could offset substantial costs elsewhere in the health care system. Moreover, drug rebates are a major source of profits in a stand-alone PBM. Integration could mean that decisions related to formulary tiers would be based on holistic assessments of the costs and benefits of particular drugs, rather than on profits from rebates.

Further, health insurers could restructure pharmaceutical benefits to fit evolving payment models. For example, in a transition to a value-based payment model, patient adherence with prescription drugs for conditions such as diabetes or hypertension could be directly incorporated into professional payments for physicians. In a capitated payment model, physicians could be directly responsible for the cost of pharmaceutical products, while also subject to performance metrics on clinical outcomes.

Integration of these benefits could have significant effects on the specialty pharmaceutical market, which is expected to constitute an estimated 50% of the pharmaceutical revenue by 2019. Changes in the benefit structure could change payment models for these products, which are often administered directly in physician offices and hospital outpatient settings. Accordingly, integration could substantially jeopardize hospital revenues that rely on administering drugs, including products that benefit from the often maligned 340 (b) program.

Under any of these scenarios, out-of-pocket costs for prescription drugs could be reduced as part of the strategy to help increase patient adherence with medical therapy.

However, a remaining concern is that these large transactions might not be transformative at all. The integration of PBMs and health insurers might instead retain elements of the current PBM business model, and the acquisitions might serve merely to lock in populations for each PBM business. Further, health insurers without a PBM may be at a significant disadvantage in competing to offer insurance to employers when they have to bid with a competitor to offer comprehensive health benefits. All of these practices could continue the drive to higher prescription drug prices for consumers. With the departure of the last major free-standing PBM from the market, there will be little publicly available information on PBM business practices to assuage these concerns.

What Integration Means for Patients

Patients, as well as their physicians, could benefit from an integrated approach to benefits design. Medical and pharmaceutical benefits will not be at cross-purposes, and if the health insurance business model is built atop a value-based or capitated payment system, patients should receive cost-effective care. But will these health care savings transfer to lower insurance premiums and lower costs for patients? A leading concern with the current pharmaceutical marketplace is that rebates may fuel high list prices for drugs and drive up the cost of care for consumers. Will insurers' involvement, after assuming control over another enormous market segment, drive different results?

If insurers merely use their acquisitions to lock in their subscribers to traditional, lucrative PBM business models, then patients are unlikely to benefit. Health insurance premiums are unlikely to be affected, and patients and employers will additionally lose from a loss of competition in the PBM market. Alternatively, an integrated model could transform the market and reduce costs for patients. If the health insurance market is competitive, offering consumers meaningful choice among integrated products, and if insurers bring pricing rationality to the pharmaceuticals they cover, then the efficiencies will likely trickle down to patients. If insurers continue expanding into more market segments, regulators need to ensure that these combinations continue to provide benefits to consumers.

At this early stage, it is unclear what implications these mergers and insurer policy changes will have for patients and prescribing physicians, either in terms of costs of pharmaceutical products or in terms of changes to the formulary and prescribing processes. In a recent editorial that accompanied the article by Papanicolas et al,⁶ Emanuel suggested that the cost of drugs must be a major focus of reform if the goal is to reduce the rate of increasing health care costs.⁷ Continued scrutiny of business practices of PBMs and calls for transparency of pricing models in the pharmaceutical market will remain important to ensure that patients are protected and directly benefit from these major changes in the health care financing system. However, the potential benefits to patients from integrated care, to health care competition from value-based payments, and to physicians from rationalizing care all are reasons for cautious optimism.

ARTICLE INFORMATION

Published Online: April 6, 2018.
doi:10.1001/jama.2018.4269

Conflict of Interest Disclosures: Both authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Schulman reports receipt of grants from Amylin, Janssen Research and Development, and Merck and Company; personal fees from Anthello (board membership), Banner Health, Cytokinetics, Genentech, McKesson, NeuroCog Trials, Nutrition Science Initiative (scientific advisory board), and the American Hospital Association (senior associate editor, *Health Services Research*); equity and board membership with Faculty Connection, Physician Education Leadership Initiative, Bivarus, and Grid Therapeutics; equity in a private company with Cancer Consultants; equity and scientific advisory board membership with Cardinal Analytix; and equity and limited partnership with Rolling Hill Ventures, outside the submitted work. No other disclosures were reported.

REFERENCES

- Berndt ER. The US pharmaceutical industry: why major growth in times of cost containment? *Health Aff (Millwood)*. 2001;20(2):100-114.
- Centers for Medicare & Medicaid Services. National health expenditure amounts by type of expenditure and source of funds: calendar years 1960-2026. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>. Accessed March 12, 2018.
- Dabora MC, Turaga N, Schulman KA. Financing and distribution of pharmaceuticals in the United States. *JAMA*. 2017;318(1):21-22.
- QuintilesIMS Institute. Outlook for Global Medicines Through 2021: Balancing Cost and Value. December 2016. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-outlook-for-medicines-through-2021.pdf?la=en&hash=6EA26BACA0FID81EA93A74C50FF60214044CIDAB>. Accessed April 4, 2018.
- Abelson R. UnitedHealthcare says it will pass on rebates from drug companies to consumers. March 6, 2018. <https://www.nytimes.com/2018/03/06/health/unitedhealth-drug-prices.html>. Accessed March 7, 2018.
- Papanicolas I, Woskie LR, Jha AK. Health care spending in the United States and other high-income countries. *JAMA*. 2018;319(10):1024-1039.
- Emanuel EJ. The real cost of the US health care system. *JAMA*. 2018;319(10):983-985.