California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item IV: Legislation Impacting the Board's Jurisdiction: Pharmacy Benefit Managers: AB 315 (Wood)

Attachment 1

This year a number of bills have been introduced in the California Legislature to address the seemingly ever-increasing cost of prescription medication. At the May board meeting, the board will have the opportunity to discuss and take positions on many of these various proposals.

At this March meeting, the board is being requested to consider a proposal that has been introduced to regulate pharmacy benefit managers (PBMs). Assemblymember Wood, chair of the Assembly Health Committee, is the author of this bill. As introduced, the bill would place the regulation of PBMs with the Board of Pharmacy.

Attachment 1 contains a background paper, prepared for a recent informational legislative hearing on PBMs. This short document provides a great overview of PBMs and their operations.

As the bill moves through the Legislature, various amendments to AB 315 will likely occur. At this meeting, the board will have the opportunity to indicate its interest in becoming an active part of the discussion.

Should California decide to regulate PBMs, and should the Legislature enact that the board be the regulator of these companies, the board's consumer protection mandate, coupled with the board's requirements to do business under parameters of the Open Meetings Act will shape the type of regulation California will have.

Attachment 1

Oversight Hearing of the Senate Committee on Business, Professions and Economic Development

Pharmacy Benefit Managers 101

Background Paper[1]

Introduction

It is familiar news that the United States spends more on prescription drug prices than other countries, and that drug costs are consuming a greater portion of our overall health care dollars.[2] Unfortunately, unwinding these costs is an inexact science because so many factors contribute to our tangled system. This paper will seek to explain the role of one player in this web, pharmacy benefit managers (PBMs).

PBMs are a key player in the prescription-drug supply chain, linking pharmacies, drug manufacturers, health plans, and consumers. According to the Pharmaceutical Care Management Association (PCMA), the PBM trade group, PBMs process prescriptions for the vast majority of Americans.[3] While PCMA estimates there are over 80 PBMs nationwide, only three firms, Express Scripts, CVSHealth, and OptumRx, constitute about 75 percent of the market.[4]

This background paper is intended to present a better understanding of PBMs' core and allied businesses, how they profit, and to what extent they are currently regulated.

PBM Basics

PBMs have been around since the early 1970s. Initially, PBMs' functions were limited -- they served merely as fiscal and administrative intermediaries between health plans, plan members, and pharmacies. What remains the same of PBMs, both in the past and currently, is their role as claims processor. Claims processing requires a pharmacy to contact a PBM to verify that a consumer has coverage for a requested prescription, determine whether the customer's plan covers the drug, and how much copay is required. Once the prescription is filled, the pharmacy

---

[1] This paper was prepared in collaboration with UC Hastings College of the Law, Center for State and Local Government Law. Many thanks to Jonathan Perrone, Kristian Zanis, and Samuel Chang for their invaluable research and writing.

[2] Henry J. Kaiser Family Foundation, *What are the recent and forecasted trends in prescription drug spending?* Available at http://www.healthsystemtracker.org/chart-collection/what-are-the-recent-and-forecasted-trends-in-prescription-drug-spending/?slide=2

[3] Testimony of Mark Merritt, President and CEO of the Pharmaceutical Care Management Association before the U.S. House of Representatives Committee on Energy & Commerce Subcommittee on Health, October 21, 2015. Available at http://docs.house.gov/meetings/IF/IF14/20151021/104071/HHRG-114-IF14-Wstate-MerrittM-20151021.pdf

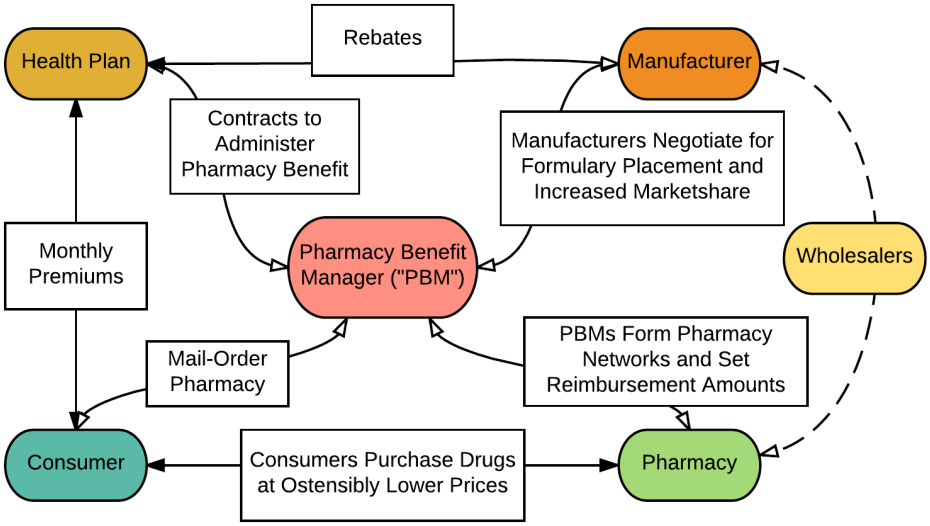
[4] Adam Fein, *CalPERS Bids Reveal Big Three PBMs' Drug Trend Forecasts and Pricing Strategies*, Drug Channels (2016). Available at http://www.drugchannels.net/2016/05/calpers-bids-reveal-big-three-pbms-drug.html

transmits patient details -- the health plan number, the physician's prescription, and the drug price -- to the PBM. The PBM responds by approving or disapproving the transaction, and then forwards the reimbursement from the health plan to the retail pharmacy.

Nearly every health plan, whether sponsored by an employer, a union, Medicare, or self-purchased, employs a PBM, and PBMs' functions have evolved over time from merely claims processing to include managing their clients' entire pharmacy benefit. The functions offered to clients may now include:

- Negotiating prices for drugs, including discounts, rebates, and other concessions, with pharmaceutical manufacturers;
- Conducting drug-utilization reviews (i.e., compiling information regarding the projected volume of plan members who use a given drug);
- Disease management (i.e., managing the chronic conditions of high-risk, high-cost patients);
- Determining the composition of pharmacy and wholesaler networks;
- Running mail-order and affiliated specialty pharmacies; and,
- Creating and managing formularies.

While PBMs establish the frameworks for their services, the final decisions on formularies, pharmacy networks, and reimbursements are ultimately made by the client.



Pharmacies

PBMs contract with pharmacies to create networks for their clients based on clients' needs and state laws, which may include geographic retail requirements and limitations on mail-order pharmacies.

Because nearly every individual with a pharmacy benefit must interact with a PBM, it follows that joining PBMs' pharmacy networks is more than good business practice -- it is essential for

pharmacies' survival. Pharmacies' revenues from drug dispensing are primarily derived from health plans' reimbursement for the drug's cost, a dispensing fee, and a patient's copay.

Contracts for inclusion in PBMs' pharmacy networks are extensive and frequently-updated. Common provisions include basic inventory requirements, professional codes of conduct, reimbursement amounts, reimbursement criteria, and applicable federal and state laws. Most contracts offered by PBMs to retail pharmacies are fairly boilerplate, meaning they consist of standardized terms and conditions that are routinely repeated with different parties. Disputes and grievances between PBMs and pharmacies are typically resolved through PBMs' in-house dispute committees or by mandatory arbitration. Pharmacies are also subject to periodic, routine audits from PBMs during which time a pharmacy's accounts are reviewed to reconcile reimbursements, fees, and ensure compliance with the contract terms.

While large pharmacies deal with PBMs directly, smaller pharmacies may contract with a pharmacy services administrative organization (PSAO) for leverage. A PSAO can represent the pharmacy in PBM contract negotiations and manage drug reimbursement claims, among other administrative offerings. PSAOs charge pharmacies fees for their services, and do not get any reimbursements from PBMs or other contract affiliates.[5]

Formularies

PBMs create "formularies," which are preferred lists of generic and brand name drugs. Clinical efficacy, cost, and competition with other drugs are some of the factors PBMs weigh in determining a drug's inclusion in a formulary. PBMs use formularies to incentivize health-plan participants to choose preferred products in treating their medical conditions and diseases. Preferred status means a relatively lower price for plan members, which then results in greater demand and higher sales volume for the manufacturer.

The most common formulary structure is the three-tier plan, in which the highest tier allows plan participants to purchase non-preferred, brand-name drugs with the highest copays; the middle tier allows for the purchase of brand-name drugs from a preferred brand with moderate copays; and the lowest tier allows for the purchase of generics and preferred brand-name drugs (for which there are numerous substitutes) with only nominal copays.

PBMs generally develop a standard, national formulary that can be tailored by individual clients. Because copays increase or decrease according to their tier, prescribers tend to select drugs from manufacturers who obtain preferred status (and a lower tier) for their products. This incentivizes drug manufacturers to negotiate with PBMs to attain preferred status.

[5] Government Accountability Office, *The Number, Role, and Ownership of Pharmacy Services Administrative Organizations*, GAO-13-176: Published: Jan 29, 2013. Publicly Released: Feb 28, 2013. Available at http://www.gao.gov/products/GAO-13-176

Rebates

PBMs claim to leverage their clients' buying power to negotiate lower prices, in the form of rebates, with drug manufacturers. However, price negotiation between PBMs and drug manufacturers is a complicated and controversial topic, particularly because the actual costs of drugs are virtually never disclosed to the clients.[6] Actual costs include such factors as ingredient prices, research and development, marketing, packaging, and other expenses of production. Wholesalers sell drugs to pharmacies, who then sell the drugs to consumers, and the pharmacies are reimbursed by the PBM based on the PBM's contract with the client.

Actual costs are considered trade secrets, so they are rarely ever seen by outsiders to purchasing contracts. An industry has grown in this void to compile drug price indices and benchmarks based on self-reported data from drug companies, distributors, and other suppliers. One such index is the Average Wholesale Price (AWP). A drug's benchmark, or index, price may be thought of as a manufacturer's suggested retail price or sticker price.

A PBM-negotiated rebate is presented as the index price minus a discount. This rebate information, which is readily available to health plan auditors and others, usually appears simply as a percentage of AWP. For example, if AWP for drug A is $100 per unit, and a PBM negotiates a 20 percent rebate (i.e., AWP-20%), the amount the benefit plan will reimburse the pharmacy is $80 per unit. Remember that $80 per unit is not how much drug A actually costs; it is likely substantially less.

Revenue streams

Pharmacies purchase their drugs from wholesalers at a rate below AWP – in the example above, perhaps $75 for drug A. The price at which wholesalers acquire drugs is negotiated separately and is accounted for in another index – the Wholesale Acquisition Cost, which takes into account volume, prompt payment history, and other factors.

Pharmacies also charge consumers a nominal dispensing fee, usually around two to five dollars per prescription. This fee, together with the above stated example of the $80 PBM reimbursement, plus a copay, adds up to a pharmacy's revenue for drug A.

The manufacturer of drug A profits from the spread between the rebated price and the actual cost to make the drug.

PBMs profit from fees charged to clients for services like financial performance guarantees, disease management, routine claims processing, fees from pharmacies, and mail-order services,[7] and may profit from a portion of the manufacturer rebates.[8]

---

[6] "Actual costs" in this context is meant to be the actual dollar amount of the drug. PBM-payer contracts spell out the terms of rebate sharing or pass-through.

[7] Testimony of Randy DeFrehn on behalf of the National Coordinating Committee for Multiemployer Plans, presented to 2014 ERISA Advisory Council Study Group Regarding PBM Compensation and Fee Disclosure (2014). Available at https://www.dol.gov/sites/default/files/ebsa/about-ebsa/about-us/erisa-advisory-council/ACDefrehn061914.pdf.

PBMs may or may not share in a rebate depending on the type of contract it has negotiated with its client. There are two types of contracts: traditional or "spread-pricing" and the increasingly more popular "transparent" or "pass-through pricing." In a traditional contract, the PBM shares a portion of the difference, or spread, between the actual drug cost and the rebated price charged to the plan. This amount is shown only as a percentage to the client, not the dollar amount. Conversely, pass-through pricing allots the rebate entirely to the client and the PBM is paid for administrative fees.[9]

PBMs also benefit from fees assessed on pharmacies for participation in preferred networks and payments based on pharmacies' performance metrics on certain activities such as generic dispensing, cost-effective dispensing, improving medication adherence, and reducing inappropriate drug use.[10] PBMs may also assess "clawbacks," the practice of recovering money already disbursed.[11]

A clawback can occur when a PBM recoups the difference between a consumer's co-pay and the PBM's reimbursement to the pharmacy. In certain circumstances, a consumer may be charged their flat co-pay, for example, $20, when the cost of the drug is less than that, for example, $10. While it would be in a consumer's best interest to skip the co-pay and purchase the drug at full cost, the consumer may not know unless the pharmacist tells them. Pharmacists may not want or be able to tell a consumer because they may be prohibited by the terms of their PBM contract, or they may be hesitant to alert the consumer to the cost savings for fear of losing further PBM business.

Conflicts in the system

There are significant potentials for conflicts in the PBM ecosystem because of the asymmetry of pricing information and reach of PBM businesses. Part of the problem is that prescription drug costs are hidden in premiums, copays, reimbursements, fees, coupons, and rebates. "It's such a complicated web of intermediaries that stand between consumers and the prices they pay," said Erin Fuse Brown, an assistant professor of law at Georgia State University College of Law. "As a result, no one knows if they're getting ripped off."[12]

As previously noted, PBMs often operate their own mail-order and retail pharmacies, establishing a climate ripe for self-dealing and unfair advantages. Walmart, for example,

---

[8] *Two Largest PBMs' Profits Enhanced by Large Rebates from Drug Companies, Report Says*, Kaiser Health News, June 11, 2009. Available at http://khn.org/morning-breakout/dr00015447/.

[9] Thomas D. Snook and Troy M. Filipek, Pharmacy benefit management: Pros and cons of various approaches. Milliman White Paper, May 2011. Available at http://valuedpharmacyservices.com/wp-content/uploads/2013/10/pharmacy-benefit-management-pros-white-paper.pdf

[10] PCMA Fact Sheet, "Direct and Indirect Remuneration."

[11] Jared S. Hopkins, *You're Overpaying for Drugs and Your Pharmacist Can't Tell You*, Bloomberg, February 24, 2017. Available at https://www.bloomberg.com/news/articles/2017-02-24/sworn-to-secrecy-drugstores-stay-silent-as-customers-overpay

[12] Julie Appleby, *Anthem, Express Scripts Face Legal Challenge Over Prescription Drug Prices*, Kaiser Health News, July 1, 2016. Available at http://khn.org/news/anthem-express-scripts-face-legal-challenge-over-prescription-drug-prices/

reported in 2015 that reduced reimbursement rates from PBMs has reduced profits from its pharmacy business and Target has simply decided to sell its pharmacy business to CVS.[13] Under the guise of promoting efficiency, PBMs leverage their access to health-plan members to push consumers towards their own pharmacies by offering price incentives, coupons, and fee waivers. Or, as several retail pharmacies allege in a recent class-action complaint, they just take the customers outright.[14] Independent pharmacies are especially vulnerable to abuse by these substantially larger players due to their unequal bargaining power. There is a pending lawsuit by several independent pharmacies against Catamaran Corporation, a PBM now part of UnitedHealth (which operates Optum Rx), alleging that the PBM routinely paid less than it cost the pharmacies to fill prescriptions, jeopardizing their survival.[15]

While confidential price negotiation is not, on its own, problematic or confined to the healthcare industry, the negotiations between drug manufacturers and PBMs raises some concerns. PBMs are supposed to extract the best prices from drug manufacturers on behalf of their clients, but PBMs don't want to completely alienate them, either, because both parties derive benefit from the rebate system. Critics claim that the lack of transparency provides an opportunity for PBMs and manufacturers (as well as wholesalers and chain pharmacies) to collude rather than to compete. Moreover, critics also claim that there is no way of knowing whether PBMs are acting in their clients' best interests because auditors are only privy to rebate and general index-price information, and not actual costs.

The Health insurer, Anthem, Inc. is currently suing its PBM, Express Scripts, for allegedly failing to negotiate sufficiently low drug prices, resulting in "an obscene profit windfall" for Express Scripts.[16] Anthem is seeking $15 billion in damages for breach of contract.[17] In August 2016, the United States Attorney's Office for the Southern District of New York requested information regarding Express Scripts' relationships with pharmaceutical manufacturers and prescription drug plan clients, and payments made to and from those entities.[18]

Another feared adverse effect of undisclosed price negotiation is that PBMs may be encouraged to add or maintain certain drugs on their formularies based upon business considerations.[19] Drug companies on the losing end of a formulary battle often argue that their drugs are "competitively

---

[13] Nathan Layne, *Wal-Mart's Drug Problem: Pharmacy Business Drags on Profit*, Reuters, August 18, 2015. Available at http://www.reuters.com/article/us-wal-mart-stores-results-pharmacy-idUSKCN0QO01V20150819

[14] Erica Teichert, *Retail pharmacies say Express Scripts stole prescriptions and profits*, Modern Healthcare, August 2, 2016. Available at http://www.modernhealthcare.com/article/20160802/NEWS/160809973, referencing *Trone Health Services, Inc. et al v. Express Scripts Holding Company et al.*

[15] *Lakeview Pharmacy of Racine, Inc. v. Catamaran Corporation, U.S. District Court for the Middle District of Pennsylvania, Civ. No. 3:15-cv-00290-MEM*

[16] Anna Wilde Mathews, *Anthem Sues Express Scripts Over Drug Pricing*, Wall Street Journal, March 21, 2016 http://www.wsj.com/articles/anthem-sues-express-scripts-over-pricing-1458578830

[17] *Anthem, Inc. v. Express Scripts, Inc*., case number 1:16-cv-02048, United States District Court for the Southern District of New York, filed March 21, 2016.

[18] United States Security and Exchange Commission, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year ended December 31, 2016.

[19] *See* Calabrese *supra* note 12.

priced and that patients and doctors should have the right to choose the drugs they want instead of being directed to only limited range of drugs as set by the PBMs." [20]

Proponents of maintaining the status quo with regard to price negotiation note that bargaining must be done out of public view in order to preserve competition. For example, if a manufacturer disclosed the actual costs of making a particular drug, manufacturers of similar/substitute drugs might refuse to lower their prices below that number, eliminating competition from the market. The effect, proponents claim, would be tantamount to price setting. Whether this logic holds true certainly merits further discussion.

Proponents also posit that there are already effective safeguards to ensure that PBMs are selecting efficacious drugs and not merely profitable ones. Foremost are the use of Pharmacy and Therapeutics ("P&T") committees, entities comprised primarily of physicians and pharmacists who make formulary recommendations based on a number of purely clinical factors. P&T Committees do not have the only say in formularies, however; each PBM may have business considerations that are overlaid on these clinical appraisals. For example, CVS Caremark's internal Formulary Review Committee (FRC) may evaluate the following factors for similarly positioned drugs:

- Utilization trends
- Impact of generic drugs or drugs designed to become available over-the-counter
- Brand and generic pipeline
- Line of business
- Plan sponsor cost
- Applicable manufacturer agreement
- Potential impact on members[21]

CVS Caremark notes that their P&T committee has final say on any FRC recommendations before they are implemented.[22]

Competition

The entire pharmaceutical market suffers from a dearth of major players. For example, there are only three major PBMs, [23] only fifteen to twenty major drug manufacturers, and only three major

---

[20] Joseph Walker and Paul Ziobro, *CVS Drops Coverage of Two Branded Biotech Drugs in Favor of Copies*, Wall Street Journal, August 2, 2016. Available at http://www.wsj.com/articles/cvs-drops-coverage-of-2-branded-biotech-drugs-in-favor-of-copies-1470176277

[21] *Formulary Development and Management at CVS Caremark*, January 4, 2017, available at https://www.caremark.com/portal/asset/FormDevMgmt.pdf

[22] Ibid

[23] Table of PBM integration and consolidation, 1968 – Present:

- Pharmaceutical Firms Acquire PBMs
  - 1968: First PBM – *Pharmaceutical Card Systems (PCS)*
  - 1993: Merck buys *Medco* for $6 billion
  - 1994: Eli Lilly buys *PCS Health Systems* for $4 billion; SmithKline Beecham buys *Diversified Pharmaceutical Services* (from insurer UnitedHealth) for $2.3 billion

drug wholesalers.[24] While generics inject some competition into the market at the upper levels, barriers to entry like patents, FDA approvals, and high capital costs limit the number of substitute options.

However, when reviewing the proposed acquisition of one major PBM by another in 2012, the Federal Trade Commission (FTC) did not see the consolidation, resulting in 40% market share for Express Scripts, as a threat to competition in the overall PBM market. In explaining this conclusion, the FTC stated that while the industry itself would be concentrated, the effects of the consolidation would not be harmful.

> While this transaction appears to result in a significant increase in industry concentration, nearly every other consideration weighs against an enforcement action to block the transaction. Our investigation revealed a competitive market for PBM services characterized by numerous, vigorous competitors who are expanding and winning business from traditional market leaders. The acquisition of Medco by Express Scripts will likely not change these dynamics: the merging parties are not particularly close competitors, the market today is not conducive to coordinated interaction, and there is little risk of the merged company exercising monopsony power.[25]

Interestingly, the FTC Commissioners noted that they heard more concerns from pharmacies and pharmacists about the merger than those who would be literally paying the cost of consolidation, potential PBM clients. After reviewing their concerns, FTC concluded that there was no data to suggest that pharmacy reimbursement rates would go down as a result, and even if it did, pharmacies would still be able to function. Further,

---

- Pharmaceutical Firms Sell PBMs as a Result of 1990s FTC Antitrust Actions
  - 1998: Eli Lilly sells *PCS Health Systems* for $1.5 billion
  - 1999: SmithKline Beecham sells *Diversified Pharmaceutical Services* to *Express Scripts* for $700 million
  - 2003: Merck sells *Medco*
- PBM Consolidation and Mergers between PBMs and Pharmacy Chains
  - 2000: *Advance Paradigm* buys *PCS* for $1 billion and becomes *AdvancePCS*
  - 2003: *Caremark* buys *AdvancePCS* for $5.6 billion
  - 2007: CVS buys *Caremark* for $26.5 billion
  - 2012: *Express Scripts* and its CuraScript pharmacy merges with *Medco* and its Accredo specialty pharmacy for $29 billion – merger of largest and second-largest PBMs
  - 2015: Rite Aid buys *EnvisionRx* for $2 billion – *EnvisionRx* owned *MedTrak*, *Connect Health Solutions*, and *Smith Premier Services; OptumRx* buys *Catamaran* for $12.8 billion – merger of third and fourth-largest PBMs; and CVS buys *Omnicare* for $12.7 billion

[24] "Three companies account for about 85% to 90% of all revenues from drug distribution in the United States: AmerisourceBergen Corporation (NYSE:ABC), Cardinal Health, Inc. (NYSE:CAH) and McKesson Corporation (NYSE:MCK)." Adam Fein, *Market Leaders*, adapted from "2016-17 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors" for Modern Distribution Management, 2016 MDM Market Leaders. Available at https://www.mdm.com/2016-top-pharmaceuticals-distributors

[25] Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc., April 2, 2012. Available at https://www.ftc.gov/sites/default/files/documents/closing_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf

the FTC stated that greater vertical integration (further squeezing independent specialty pharmacies) was unlikely because both merging entities already had their own specialty pharmacies, and no new incentives were created by the combination.[26]

State and Federal Regulation

While PBMs are regulated generally as third party administrators (organizations that processes claims and perform other administrative services in accordance with a service contract; PBMs must abide by the terms required of health insurance plans, to the extent PBMs are authorized to effectuate those plans), they are not regulated specifically at a national level. Twenty one states, however, regulate them specifically to varying degrees. While the majority of laws relate to standardizing audit practices (including California's), many focus on regulating other aspects of their business practices such as requiring a PBM to attest to any conflicts of interest,[27] disclose all financial arrangements between themselves and insurers,[28] and prohibiting a PBM from contacting a covered individual without express written permission of the covered entity.[29]

States are increasingly requiring PBMs to license or register with their Department of Insurance or Board of Pharmacy, as well. Addendums to this report detail California and other states' PBM statutes and regulations.

Conclusion

Drug prices are rising beyond reach for many consumers, and health plan participants alone cannot affect real change in the pharmaceutical world – a complex market that bears numerous players, complicated relationships, and opaque practices. Moreover, independent pharmacies are struggling to operate in a crowded business environment, resulting in fewer choices and higher prices for consumers. It is incumbent upon the Legislature to fulfill its role as a market-failure corrector and address some of the myriad problems endemic to the prescription drug system. And because PBMs are so integral to that system, they merit the Legislature's substantial consideration.

---

[26] "The Commission also investigated whether the merger would lead to greater vertical integration by the merged firm, which could lead to fewer sales by independent pharmacies. We concluded that the merger is unlikely to affect the incentive of the merged firm to offer plans designed to increase the business of its own specialty pharmacy. Both Express Scripts and Medco already operate specialty pharmacies that offer discounts for restrictive networks, so the transaction does not create incentives that did not exist before. In addition, greater vertical integration may benefit consumers by lowering prices." Ibid, page 8.

[27] District of Columbia, Title 48, Subtitle II, Chapter 8A, Subchapter II

[28] Rhode Island, 27-29.1

[29] South Dakota, Chapter 58-29E