

CONCERNS REGARDING THE PHARMACY BENEFIT MANAGEMENT INDUSTRY

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INTRODUCTION

The purpose of this report is to provide an overview of three legislative and regulatory concerns that legislators, policymakers, customers, and pharmacies have raised regarding the pharmacy benefit management (PBM) industry:

1. The importance of accuracy and transparency in PBM revenue streams;
2. Potential conflicts of interest with PBM-owned mail-order and specialty pharmacies; and
3. Unclear generic drug pricing and maximum allowable cost payment calculations.

These issues are critical for policymakers and legislators to understand as they consider whether additional oversight of the PBM industry is warranted. Over the past decade, the role of PBMs in the delivery of health care has increased, due to a confluence of factors: coverage expansions under both the Medicare Part D prescription drug benefit and the Affordable Care Act, combined with an increase in prescription drug spending that has motivated commercial health plans and self-insured employers to outsource the management of their spending on outpatient prescription drugs. Adding to that, PBMs now offer customers entire suites of services, moving beyond claims processing to administering policies that affect the clinical management of patients. As the profile of the PBM industry has risen over the past decade, it has become increasingly important that policymakers fully understand the role that PBMs play in the prescription drug supply chain.

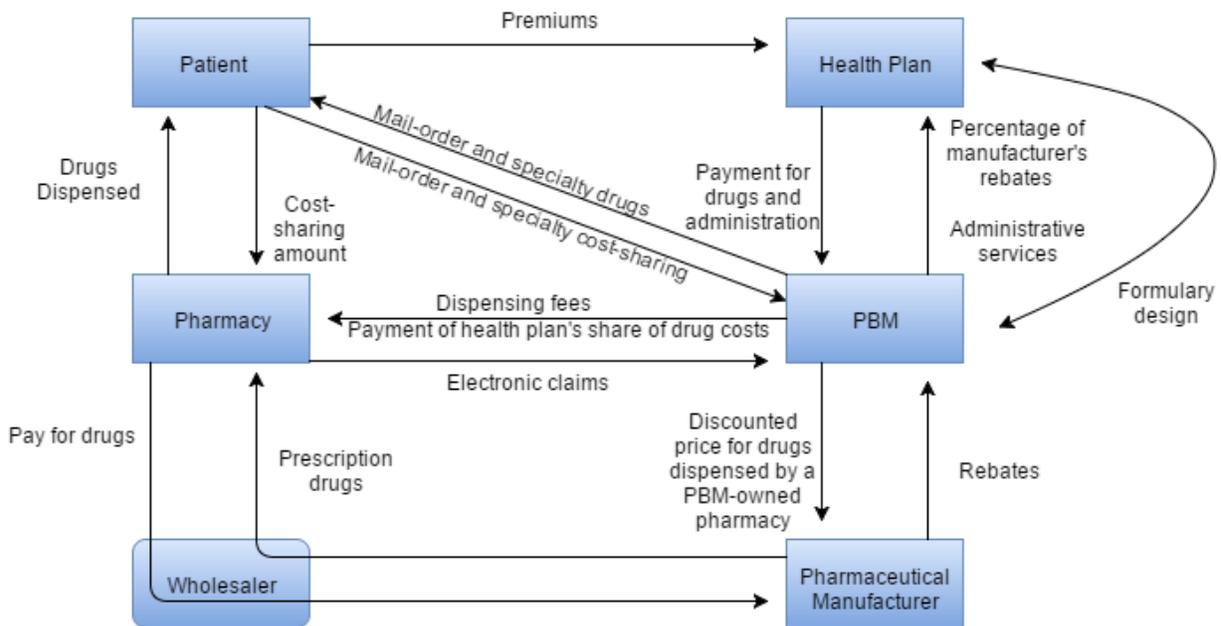
OVERVIEW OF PHARMACY BENEFIT MANAGERS

A PBM is an administrator of prescription drug programs. PBMs are responsible for developing and maintaining formularies and other clinical management programs, processing prescription drug claims for insurance companies or corporations, and negotiating contracts with pharmacies and pharmaceutical manufacturers.¹ Other responsibilities of PBMs include performing drug

utilization reviews, managing clinical programs targeted to specific disease states, and operating pharmacies, including mail-order and specialty pharmacies. PBM customers, which are called “plan sponsors,” include commercial health plans, federal government programs such as Medicare, Tricare, and the Federal Employees Health Benefits Program (FEHBP), self-insured companies, unions, and public health programs.

PBMs generate revenue from pharmaceutical manufacturers through two main types of payments: formulary payments to obtain preferred formulary status, and market-share payments to encourage utilization of their drugs relative to competitors.² These payments are typically referred to as “rebates.” PBMs negotiate rebates directly with pharmaceutical manufacturers, and they can be based on preferred placement on a formulary tier (e.g. placement on a “preferred brand” tier with more favorable cost-sharing amounts relative to products on a higher tier) or based on utilization (e.g. if the manufacturer is able to achieve a certain percentage of the PBM’s utilization for a particular therapeutic class of drugs).² In addition, PBMs generate revenue through administration and service fees charged to plan sponsors for processing prescriptions; through operation of their own mail-order and specialty pharmacies; and on the margin between the amount charged to customers and the amount paid out to pharmacies for a prescription (also referred to as “spread pricing”).

THE ROLE OF PBMS IN THE PRESCRIPTION DRUG SUPPLY CHAIN



The graphic above provides a high level illustration of some of the major players in the prescription drug supply chain, including PBMs:



- **Pharmaceutical manufacturers** negotiate rebates and other concessions with PBMs. They also supply pharmaceutical **wholesalers** with prescription drugs.
- **PBMs** contract with commercial health plans or self-funded insured groups to administer the plan’s pharmacy benefit, including development of a formulary and terms for payment, including agreements to pass-through manufacturer rebates. PBMs contract with a network of retail and community pharmacies, and also are responsible for setting patient cost-sharing amounts and establishing clinical policies, such as prior authorization requirements. Finally, many PBMs also own mail-order and specialty pharmacies, which directly supply prescription drugs to patients.
- **Health plans** are responsible for paying PBMs for prescription drugs dispensed to plan members and collecting premiums from patients.
- **Pharmacies** contract directly with PBMs to dispense prescription drugs to patients. This includes negotiating a payment rate for each prescription, plus a dispensing fee. Pharmacies are also responsible for collecting patient cost-sharing payments and sending those to the PBM. Separately, pharmacies negotiate with **wholesalers** to purchase prescription drugs.
- **Patients** are responsible for paying cost-sharing to either a retail or community pharmacy, or to a mail-order or specialty pharmacy. They are also responsible for paying premiums to their health plan.

THE ROLE OF PBMS IN MEDICARE PART D

The Medicare Part D program was established by the Medicare Modernization Act of 2003 (MMA), and implemented in 2006. Medicare beneficiaries have coverage through either stand-alone prescription drug plans (PDPs) or Medicare Advantage Prescription Drug plans (MA-PDs).³ In 2015, more than 39 million beneficiaries are enrolled in Part D plans, including 24 million PDPs, and 15 million MA-PD plans.⁴ Part D plans receive payments from the government to provide subsidized drug coverage to beneficiaries. The Part D benefit is financed through general revenues (74%), beneficiary premiums (15%), and state payments (11%).⁵ Spending on Part D has grown from \$44.3 billion in 2006 to approximately \$88.6 billion in 2015, and is expected to grow to \$858 billion in 2024.^{6,7} In 2015, approximately 50% of beneficiaries are enrolled in a PDP or MA-PD plan sponsored by UnitedHealth, Humana, or CVSHealth.⁸

The Medicare statute (Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.)) requires Part D plan sponsors to offer either a defined standard benefit or an alternative equal in value, and have the option of offering enhanced benefits. In reality, very few Part D plans offer the “standard” benefit, which includes a deductible and flat co-insurance after the deductible is met, a period of reduced coverage (i.e. the “doughnut hole”) and then a catastrophic benefit. Instead, Part D plan sponsors offer “actuarially equivalent” plan designs that include a formulary with tiered cost-sharing, similar to those seen in commercial health plans, though most Part D plans use more tiers.⁹ Decisions on formulary design, beneficiary cost-sharing requirements, and pharmacy networks (including determinations of pharmacy reimbursement) are made by PBMs



under contract with a plan sponsor; therefore, PBMs wield a great deal of influence in how beneficiaries access their needed medications in the Part D program as a whole.

THE “BIG THREE” PBMS

According to the Pharmaceutical Care Management Association, the trade group that represents the PBM industry, PBMs manage pharmacy benefits for over 253 million Americans.¹⁰ Three large companies lead the PBM market: Express Scripts®, CVSHealth®, and OptumRx®. In total, they cover more than 180 million lives in the United States, or roughly 78% of Americans whose pharmacy benefits are managed by a PBM.¹¹ Annual revenues for Express Scripts in 2014 were approximately \$100.887 billion while CVSHealth had the highest revenues of the big three coming in at \$139.367 billion in 2014.^{12,13} Finally, OptumRx reported \$31.97 billion annual revenues in 2014 (In 2015, OptumRx acquired Catamaran, which reported annual revenues of \$21.6 billion in 2014).^{14,15,16}

Express Scripts processes more than one billion prescriptions each year and covers approximately 85 million lives, making it the largest PBM in the country.^{17,18} Express Scripts maintains network contracts with more than 69,000 retail pharmacies as well offering home delivery services of prescriptions. Express Scripts offers its PBM services to managed care organizations, government health plans, health insurers, employers and a host of other organizations. In addition to contracting with retail pharmacies which comprises 98.4% of their business, Express Scripts also receives revenue from their specialty drug pharmacies.¹⁹

CVSHealth works with almost 68,000 retail pharmacies which includes their own CVS stores as well as 27,000 independent pharmacies.²⁰ CVSHealth covers approximately 65 million lives and processed more than 930 million prescriptions in 2014.²¹ CVSHealth clients include health plans, government payers and employers. CVSHealth also operates a mail order pharmacy.²²

UnitedHealthcare® operates its PBM business under OptumRx, which covered more than 30 million lives and processed more than 600 million prescriptions in 2014.²³ In 2015, OptumRx acquired Catamaran, another PBM that has more than 35 million covered lives and processed over 400 million prescriptions in 2014.²⁴ OptumRx’s network consists of more than 67,000 retail pharmacies and includes two home delivery pharmacies.²⁵ Catamaran has a pharmacy network that covers all 50 states, including mail order and specialty pharmacies.²⁶

LEGISLATIVE AND REGULATORY CHALLENGES WITH THE PBM INDUSTRY

Several market dynamics have raised the profile of PBMs in recent years: the growth in prescription drug costs, the implementation of the Medicare Part D prescription drug benefit, and consolidation within the PBM industry itself. Below is a brief overview of three legislative and regulatory issues that legislators, policymakers, PBM customers, and pharmacies have raised regarding the PBM industry.

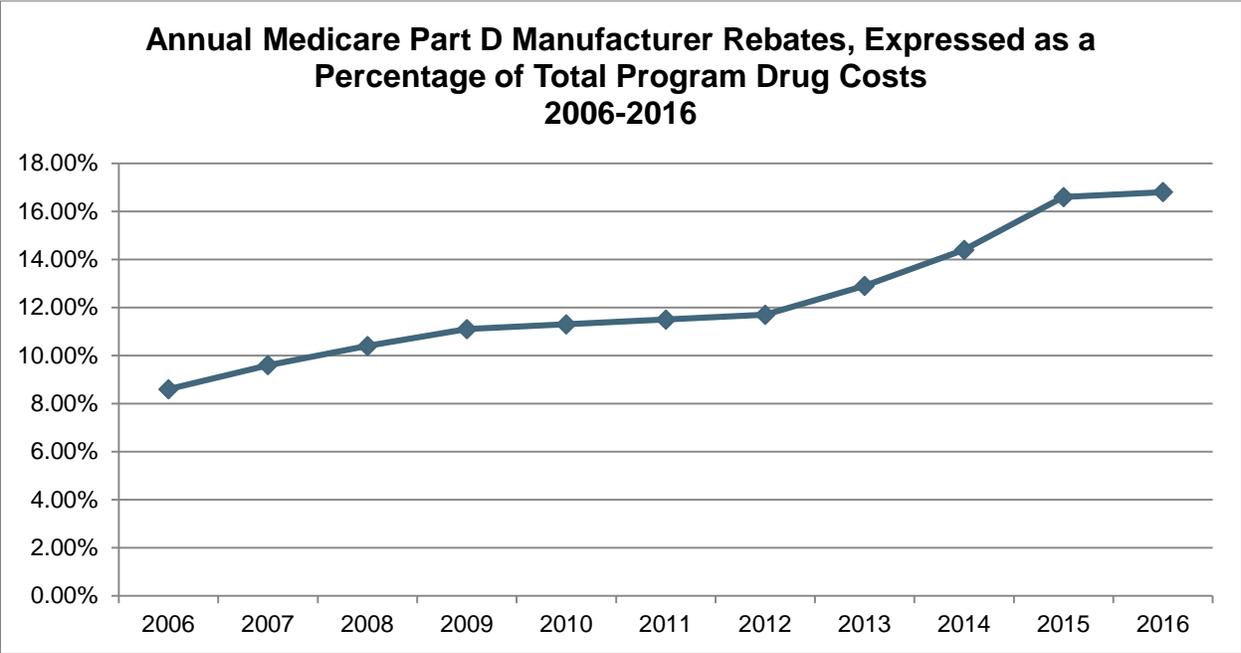


INCREASING ACCURACY AND TRANSPARENCY IN PBM REVENUES

PBMs generate revenues through rebates, or payments negotiated directly with pharmaceutical manufacturers, and from the margin, or difference, between what a PBM charges a customer for a prescription and what the PBM pays a pharmacy to fill that prescription. PBM contracts with customers often include revenue sharing provisions. However, PBM customers and pharmacy owners have complained that there is a lack of transparency in these revenue streams that make it difficult to know exactly how much revenue a PBM is generating, and whether or not that revenue is being shared in accordance with contract terms.²⁷ PBMs maintain that efforts to regulate disclosure and transparency requirements will lead to increased prices though reduced competition (between PBMs and drug manufacturers and PBMs and pharmacies) and increased administrative costs due to calculating and analyzing data that are not currently required.²⁸

However, experience with the Medicare Part D benefit indicates that concerns regarding increased transparency of rebates and other price concessions leading to reduced competition and preventing PBMs from negotiating the largest rebates possible, may be unfounded. Since the inception of the Medicare Part D benefit in 2006, all Part D plan sponsors have been required to disclose rebates and other price concessions to CMS. This, in turn, impacts the payments CMS makes to sponsors for providing the benefit.²⁹ An analysis of reported rebate amounts by plan sponsors, expressed as a percentage of overall Part D drug costs, shows rebates have increased or held steady each year, and are estimated to grow from 8.6% of overall Part D drug costs in 2006 to 16.8% of overall Part D drug costs in 2016.³⁰ This indicates that disclosure requirements, when properly protected with confidentiality clauses, do not necessarily hinder a PBM's ability to negotiate competitive rebates with manufacturers.





**2014 – 2016 denote estimates. Rebates are projected to increase for 2015 due to the high competition in the hepatitis C drug market. Source: Annual Reports of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2008 – 2015.*

The PBM industry also asserts that many customers are successful at negotiating “pass-through pricing,” in which a PBM passes through rebates and other concessions to the customer, or other disclosure provisions that have essentially created a transparent system.³¹ While this may be true in theory, in practice, there are examples of the difficulties that even large, sophisticated purchasers face when trying to analyze PBM contracts:

- Medicare Part D.** Both the U.S. Department of Health and Human Services’ Office of the Inspector General and the Government Accountability Office recommend requiring additional disclosures and reporting from the PBMs that serve the Part D program. These government agencies have found potential problems with both the way that Part D plan sponsors were calculating and reporting rebates, also known as “direct and indirect remuneration” (DIR), to CMS.³² In 2009, CMS required plan sponsors that contract with a PBM to report to CMS both the price the PBM charges a plan for a prescription, and the price that the PBM pays a pharmacy for the same prescription. Any difference between the two prices must be calculated as an “administrative cost” on behalf of the PBM. This change was made in an effort to achieve more accurate reporting of drug costs.³³ In proposed regulation released in January 2014, CMS expressed concerns that the existing calculation and reporting requirements may offer too much flexibility for plans to report price concessions separately, thereby artificially inflating the negotiated price, leading to higher costs for beneficiaries, the Medicare program, and manufacturers. Therefore, CMS proposed to revise the definition to better clarify how plan sponsors must report fees.³⁴ CMS finalized this revised definition in May



2014, but delayed implementation until 2016.³⁵ In September 2014, CMS issued a request for comments,³⁶ but the agency has yet to publically release final guidance. In October 2015, 11 members of the U.S. House of Representatives sent a letter to CMS in support of the revision, as well as an update on plans to finalize the definition.³⁷

- **Large Employers.** The ERISA Advisory Council, established under the Employee Retirement Income Security Act of 1974 (ERISA), is responsible for advising the Secretary of Labor on issues surrounding employee welfare and pension benefit plans, including health benefits provided under ERISA.³⁸ In response to concerns about large, self-insured health plans' ability to negotiate competitive, transparent PBM contracts, the Council held a hearing in August 2014.

At the hearing, representatives of two large employers testified regarding difficulties they have faced in negotiating transparent contracts with PBMs. Testimony delivered on behalf of Honeywell International Inc., emphasized that, due to the complexity inherent in the PBM business model, it was essential that all contract terms are fully defined and that all agreements between the PBM and other third-party service providers are transparent.

The HR Policy Association's (HRPA) Pharmaceutical Coalition testified about experiences that the Coalition had in trying to negotiate transparent contract language with PBMs. In 2004, the Coalition established a set of transparency standards with the goal of certifying PBMs that agreed to the standards. Coalition members were then free to make certification a requirement before accepting bids from a PBM. The certification process was moderately successful; at the highest point, 15 of 30 PBMs were certified (though certification did not guarantee that all contracts offered by the PBM met the certification standards). The Coalition continued to innovate and established the PharmaDirect program, which essentially disaggregates PBM services to allow customers to select PBMs to deliver a specific set of services, instead of a complete suite of services. Under this paradigm, a PBM's revenue is mainly limited to administrative fees charged to the customer. However, the Coalition has struggled to increase adoption of the PharmaDirect program, even though participants reported savings of between 10% and 15%.³⁹ This example illustrates that even large employers, who ostensibly should be in a position to negotiate favorable contracting terms, can have trouble negotiating transparent contracts with PBMs.

The experiences of both CMS and large employers illustrate the difficulties that even large purchasers, including the federal government, can have in fully evaluating PBM contracts, even those contracts that are supposed to be transparent. Furthermore, the ERISA Advisory Council supports expanding regulations that require certain levels of transparency from PBMs contracting with health plans covered under the statute, in a similar manner that the financial services industry is now required to disclose direct and indirect disclosure to pension plans. In making the recommendation, the Advisory Council noted that the enhanced reporting



requirements would “greatly enhance the ability of [PBM customers] to provide prescription drug benefits to participants and beneficiaries, with minimal or no adverse impact on PBMs.”⁴⁰

POTENTIAL CONFLICTS OF INTEREST WITH PBM-OWNED MAIL ORDER AND SPECIALTY PHARMACIES

Many PBMs own and operate their own mail-order and specialty pharmacies, and PBM customers, community pharmacies, and patients have raised concerns that the relationship introduces conflicts of interest. PBMs offer mail order pharmacy benefits to patients with chronic conditions who require daily (or regular) use of certain medications as a way to reduce costs. Generally, mail order pharmacies fill prescriptions in 90-day supplies, necessitating a refill once every three months instead of once a month. PBMs offer incentives to patients to use mail order via lower cost-sharing requirements. Some commercial plans require patients needing chronic medications to use mail order services. However, Medicare Part D prohibits mandatory mail order requirements.⁴¹ The research is inconclusive regarding the effect of mail order access on patient adherence. Some studies indicate that patient adherence may increase when prescriptions are filled through mail order, yet other studies indicate that mandatory mail order policies may actually discourage adherence.⁴² What is agreed upon is that face-to-face pharmacist counseling is valuable in improving adherence. CVSHealth has reported that face-to-face counseling can be “two to three times as effective as other forms of communication in driving adherence to prescription drug regimens.”⁴³

Critics charge that PBM ownership of mail order pharmacies creates several conflicts of interest. A PBM may be incentivized to:

- Perform fewer generic substitutions;
- Switch patients to higher-cost therapeutic alternatives (“therapeutic interchange”); or
- Repackage drugs in a manner that could lead to increased costs to plan sponsors, while maximizing revenue for the PBM (“package size pricing”).

Employers have specifically highlighted the issue of package-size pricing with PBM-owned mail order pharmacies as a challenge. Generally, PBMs charge customers a set discount off of a product’s average wholesale price (AWP) (e.g. AWP minus 15%). However, the AWP may be set to a package size commonly purchased by a retail pharmacy (e.g. 100 tablets), whereas a mail-order pharmacy may be purchasing the drug in much larger package sizes (e.g. 50,000 tablets) at a much lower price. When a PBM owns a mail-order pharmacy, they may continue to charge the customer based on the AWP set to the smaller package size, while not passing on the savings associated with large-volume purchasing.⁴⁴

Finally, when a PBM both owns a mail order pharmacy, and is responsible for building a retail pharmacy network, the PBM is responsible for negotiating contracts with entities that are competitors to the PBM’s mail order pharmacy.



As the utilization of specialty drugs has increased, the use of specialty pharmacies, which generally deliver medications directly to a patient's home, has likewise increased. Because the specialty pharmacy model is similar to the mail-order pharmacy model, concerns over conflicts of interest also apply. In addition, concerns have also been raised with how PBMs categorize particular drugs as "specialty" drugs.

Specialty drugs are generally subject to higher cost-sharing, as well as special handling requirements. There is no single agreed-upon definition of what classifies a drug as a "specialty" drug in the commercial health insurance market. While drugs that require specialized handling (such as refrigeration) or are subject to additional safety requirements as mandated by the U.S. Food and Drug Administration (FDA) clearly qualify as specialty drugs, PBMs also use high cost as a qualifying factor.⁴⁵ Cost of these therapies is a valid concern; spending on specialty drugs currently represents about one-third of all prescription drug spending, and PBMs contend that specialty pharmacies help ensure that patients are taking the drugs correctly and appropriately. However, because many large PBMs also own specialty pharmacies, and therefore generate direct revenue from filling patient prescriptions, it is essential for PBM customers to understand the methodology behind a PBM's classification of a product as a "specialty" product, especially if the PBM also owns a specialty pharmacy.⁴⁶ CMS establishes a specialty tier minimum threshold each year (currently \$600 per month) and only allows Part D plan sponsors to place drugs with costs exceeding that amount on the plan's specialty tier.⁴⁷ There is no such cost threshold in place for non-Medicare Part D health plans.

GENERIC DRUG PRICING, MAXIMUM ALLOWABLE COST, AND INDEPENDENT PHARMACIES

Independent pharmacies are important members of the U.S. healthcare system. Almost 23,000 independent pharmacies dispense close to 1.4 billion prescriptions annually, with over 80% of those prescriptions filled using a generic drug.⁴⁸ In recent years, volatility in the generic drug pricing marketplace has caused issues for pharmacists, physicians, patients, and payers alike.⁴⁹ A survey of members of the National Community Pharmacists Association (NCPA) in January 2014 showed that over 75% of respondents reported instances of a large price increase in at least 26 generic drugs over the last six months of 2013.⁵⁰

Commercial payers, including PBMs, as well as government payers, such as state Medicaid programs, can link reimbursement for a particular drug to a "maximum allowable cost" (MAC). This reimbursement method is intended to promote generic substitution, since reimbursement for a brand-name drug is set at reimbursement for a generic equivalent, as well as encourage pharmacies to purchase drugs from wholesalers at competitive prices.⁵¹ However, issues can arise when a payer's MAC price for a specific drug is not updated frequently enough to account for sudden increases in prices. In the same NCPA survey cited above, over 85% of survey respondents reported that it could take a PBM or other payer between two to six months to update their reimbursement rates for generic drugs.⁵²



Unlike commercial health plans, Medicare Part D plan sponsors are required to update their prescription drug pricing lists at least once a week for network pharmacies.⁵³ In May 2014, CMS finalized a regulation that clarified that this requirement applied to MAC listings and also required Part D plan sponsors, beginning January 1, 2016, to update reimbursement amounts, including MAC listings, in advance of their use for claim reimbursement. In proposing and subsequently finalizing this change, CMS noted the impact that inaccurate MAC prices have not only on pharmacies attempting to validate accurate payments, but also on beneficiaries who rely upon pricing information available via the Medicare Plan Finder tool. The majority of commenters on the proposal were supportive, according to CMS.⁵⁴

In recent years, 24 states have implemented legislation similar to CMS requirements for Medicare Part D.⁵⁵ While MAC list pricing is not the genesis of, nor the solution to, price volatility in the generic market, providing updated MAC prices in advance of reimbursement, in a timely manner, can help to avoid situations in which a pharmacy is under-reimbursed for a prescription due to large fluctuations in price.

CURRENT EFFORTS TO REGULATE PBMS

At the federal level, commercial health insurers that offer employer-sponsored health plans are regulated under the Employee Retirement Income Security Act (ERISA), as well as the Health Insurance Portability and Accountability Act (HIPAA) and the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA).⁵⁶ The Affordable Care Act further expanded the federal government's regulation of the commercial insurance industry.⁵⁷ Finally, Medicare Advantage and Part D prescription drug plans are regulated by CMS,⁵⁸ and health plans offered to federal employees, which cover over 8 million Americans, must meet requirements established by the Office of Personnel Management.⁵⁹ However, the bulk of insurance regulation resides at the state level, where insurer solvency and underwriting requirements, coverage mandates, and access requirements are typically regulated.⁶⁰ The majority of states also have effective rate review programs that enable state regulators to review premium rate increases for approval or rejection.⁶¹

In spite of the fact that PBMs play such an integral role in how patients access their prescription drug benefit in both commercial health insurance and Medicare Part D, PBMs are not subject to industry-wide regulation similar to what is generally required of large commercial health insurers. Instead, PBMs face a patchwork of regulations at the state level: 33 states have passed legislation governing PBM audits of pharmacies, and 17 states have passed laws requiring PBMs to register with, or obtain a license from, the state department of insurance (though these requirements generally require only the payment of a nominal fee).⁶² There are no federal laws or regulations specific to the PBM industry (though commercial health plans are required to meet the prescription drug coverage requirements under the Affordable Care Act).⁶³



CONCLUSION

The U.S. healthcare system is in the midst of a large transformation. Research in the pharmaceutical sector continues to deliver innovative pharmacological treatments for many challenging and complex medical conditions. Likewise, the PBM industry has evolved beyond simply processing pharmacy claims and managing a formulary. Expansions of prescription drug coverage over the past 10 years mean that PBMs are involved in a majority of prescription drug transactions today. In light of that fact, transparency regarding the PBM industry is needed so that purchasers of these services in both in the commercial and government sectors can make well-informed decisions. Likewise, it is important for legislators and policymakers to better understand the complex PBM industry, and the role PBMs play in the pharmaceutical supply chain

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ABOUT APPLIED POLICY

Applied Policy, L.L.C., is a health policy and reimbursement consulting firm strategically located minutes from Washington, D.C. At Applied Policy, our governing principle is transforming intention into action. Our tactics are to identify new opportunities, reframe challenges, empower people with information and create long-term stakeholder relationships. These tactics facilitate our clients' desired outcomes by enabling effective navigation of the complex Medicare and commercial reimbursement landscape within the U.S.

We have consulted for hospitals and other health care providers, specialty societies and trade associations, device, diagnostic and drug manufacturers, group purchasing organizations and other health care supplier's health care policy and reimbursement issues. We are recognized health policy leaders, having been called upon to testify before the U.S. Senate Health, Education, Labor and Pensions Committee regarding the implementation of the Affordable Care Act; commissioned by the U.S. Senate Special Committee on Aging to conduct an analysis of Medicare reform options and being regularly invited to speak at international conferences regarding health policy and reimbursement issues. Applied Policy has an unmatched reputation in Washington for thoughtful analysis, reliability and credibility.

For more information about Applied Policy, please contact Jim Scott, President & CEO, at 202-558-5272. You may also visit our website at <http://www.appliedpolicy.com/>.



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