White Paper

Pharmacy Benefit Manager Transparency Act of 2023

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Overview

On February 16, 2023, the United States Senate held a hearing to discuss S. 127, Pharmacy Benefit Manager Transparency Act of 2023, a new bill introduced earlier this year that aims to shine light on the behaviors and practices of pharmacy benefit managers (PBMs) and the dollar amounts involved.

A panel of witnesses consisting of industry experts across the American healthcare landscape provided testimony to the Committee of Commerce, Science, and Transportation. They included an independent pharmacy owner, an oncologist, a health policy expert and researcher, and a professor of economics. Each brought a unique perspective to the conversation as senators grapple with the big question: *How can PBMs be regulated to drive transparency and eliminate predatory practices without crippling their ability to negotiate better drug prices for patients*? Although the issues are clear, the practices and mechanisms that drive them are opaque and complex.

The issues at hand

Pharmacy benefit managers have been around for decades, originally created by insurers as a mechanism to help fight rising drug costs by pushing more affordable generics through group buying power. Over time, through waves of consolidation and vertical integration into the pharmaceutical supply chain, PBMs now have substantial leverage in the marketplace, with the top three – Express Scripts, CVS Caremark, and Optum Rx -- holding 80% market share, and the top six holding 96%. In total, PBMs cover 275 million American lives.

The immense power they hold is not problematic if used to drive prescription costs lower for Americans, however, drug prices continue to rise with little transparency into how they are determined. Consequently, the practices of these PBMs have been brought under scrutiny and labeled predatory, with a focus on maximizing profits as opposed to passing savings along to patients. The criticism extends beyond monetary impact. It is argued that PBMs stifle medical innovation and stand in the way of patients' ability to receive the highest level of care possible. The following is a breakdown of the major issues discussed in the hearing:

PROFITING OFF REBATES AND HIGH LIST PRICES

Manufacturers establish a list price for each drug. When contracting with these manufacturers, PBMs use their size and formulary placement to negotiate rebate percentages off this list price. Often, these rebates are substantial, equating to 50% or greater. This leads to inflated drug prices which are in the best interest of the PBM, as it allows for greater rebates. The lack of transparency makes it impossible to discern whether, or how much of these rebates PBMs then pass along to patients. The list below illustrates a simplified example:

- Rebate Percentage - **50%**
- Manufacturer Original List Price - **$100**
  - » Rebate Amount Earned by PBM = **$50**
- Manufacturer Increased List Price - **$150**
  - » Rebate Amount Earned by PBM = **$75**
- Rebate Amount Passed Down to the Patient = **???**

COPAY CLAWBACK

A 2018 Schaeffer Center study found that 23% of prescriptions involved a copay paid by a patient which exceeded the cost paid by the PBM. The patient overpaid and the PBM kept the difference.

CONTROL OF TREATMENT

The vertical integration that has brought specialty and mail-order pharmacies under the purview of PBMs has been to the detriment of patients, resulting in higher costs and less effective treatment of their conditions.

- **Delays** - PBMs often drive prescription fulfillment away from provider pharmacies to their own affiliated pharmacies, which can cause delays in getting patients their medication. The example provided in the hearing centered around a cancer patient who was prescribed an oral pill for treatment. This pill is proven to be effective and a less toxic alternative to chemotherapy, allowing for a better quality of life as the patient undergoes treatment. There was a delay in the PBMs fulfillment of the prescription, and as the provider continued to monitor the patient's cancer and saw it getting worse, they had no choice but to defer to the more toxic alternative of chemotherapy, an inferior treatment option that is much more harmful to the patient's everyday life. Additionally, PBMs may require mandatory mail-order fulfillment of a prescription drug, which if not delivered on time, may compound the problems and expenses incurred by patients, as they may need to repeat lab work or other tests.
- **Waste** - The treatment of complex diseases such as cancer are tailored to each individual patient's needs. For example, providers may prescribe a weeks-worth of a drug, after which they will monitor the patient's toxicity and tweak the dosage accordingly going forward. Mail-order pharmacies may not always allow for this flexibility, requiring a minimum 90-day supply. The patient ends up paying for more prescription drugs than they need, and the excess goes to waste.
- **Denials** – There may be multiple prescription drugs on the market to treat a disease. Providers may prescribe one over another based on its efficacy to treat a particular area of a patient's disease. The best drug for one patient may not be the best choice for another with the same illness, and it may not be the drug on formulary, resulting in the prescription being denied and replaced with an alternative drug that was not recommended by the care provider. Although it may be more affordable, it may not be as effective. When this occurs, PBMs are in control of the administration of care, not the physician.

PRESSURE ON LOCAL INDEPENDENT PHARMACIES

Across America, especially in the more rural parts of the country, local independent pharmacies are pillars of the community and may be the only access to healthcare people have. Their impact extends beyond filling prescriptions, as they run essential programs such as HIV awareness, and blood pressure and glucose monitoring, and provide treatment education. IQVIA estimates that between December 2017 and December 2020 almost 2,200 pharmacies closed nationwide. This is largely due to the following pressures they face from PBMs, crippling their ability to do business.

- **Direct and Indirect Remuneration (DIR) Fees** - PBMs claw back DIR fees from pharmacies sometimes months after a prescription has been filled. These fees, meant to be based on quality measures, are convoluted, unpredictable, and ineffective. One example provided in the hearing focused on a pharmacy at an Oncology center that had to pay DIR fees based on hypertension and cholesterol metrics, conditions they do not treat. These fees do not provide value, and the inconsistency in which they are applied make it difficult for pharmacies to plan accordingly. Small independent pharmacies are left with no choice but to lay off staff, reducing their ability to provide patient care. Additionally, these fees are not factored in when payers calculate the cost of the drug, resulting in patients paying more than the plan pays.

- **Contract Negotiation** – PBMs can use their influence to strong-arm small independent pharmacies into signing contracts that result in significantly less reimbursement for the same drug under the current agreement. One mechanism to do this is by reclassifying a drug under a more expensive specialty market category. The pharmacy has no negotiating power and is forced to accept these terms to their own detriment.
- **Spread Pricing** - PBMs charge health plans and payers more for a transaction than what they reimburse for the pharmacy, keeping the difference (the spread) for themselves. Statistics from the Schaeffer Center cited in the hearing include:
  - » 2018 - PBMs charged the state of Ohio a spread of 31% for generic drugs for Medicaid plans
  - » 2020 - PBMs extracted $9.5 billion in price concessions from pharmacies on Medicare Part D transactions alone, up more than 1000% from a decade prior

Although these issues ripple throughout the American healthcare system, impacting the various players — from manufacturers, to providers, to pharmacies — it ultimately all funnels down to the patient. In the end, they are the ones who bear the brunt of these practices on their wallets, on their health, and in their overall lifestyle.

What the proposed bill means for PBMs

The proposed bill is the latest in a trend of increased transparency and regulation that has been prevalent in the pharmaceutical and life sciences industry for over a decade. The Physician Payments Sunshine Act, signed into law in 2010, required drug and medical device manufacturers to comply with specific transparency and reporting requirements to shed light on the nature of relationships between manufacturers and healthcare practitioners. When enacted into law, manufacturers faced immense pressure as they built out corporate policies and internal interpretations of the law. They struggled as they worked through how to extract all the necessary data points from various source systems and aggregate it all in a concise manner that adhered to the reporting requirements, all under tight deadlines. Additionally, some states came out with their own specific requirements, adding to the complexity and amount of work required. There was significant financial impact, as companies hired additional headcount or third-party advisors to build out their transparency program, or faced absorbing the work into their current compliance and legal departments with existing resources. PBMs will face similar hurdles around requirement vagueness, data aggregation, financial burden, and increased resources if the Pharmacy Benefit Manager Transparency Act of 2023 becomes law.

SUMMARY OF THE BILL

Enactment of the proposed bill would result in the following:

- Eliminate the practice of spread pricing
- Prohibit arbitrary DIR fees from being clawed back from pharmacies
- Prohibit increasing fees or lowering reimbursement to a pharmacy to offset reimbursement changes required by the federal government

PBMs shall not be found in violation of bullets 1-3 if they meet the following criteria:

- Return 100% of price concessions to the health plan or payer
- Disclose the cost, price, and reimbursement of a prescription to each health plan, payer, and pharmacy with which a PBM contracts
- Disclose the fee, markup, and discount charged to each health plan, payer, and pharmacy with which a PBM contracts
- Disclose the aggregate number of rebates, discounts, and administrative fees received from manufacturers for each prescription drug

The bill presents the following mandatory transparency requirements that must be reported on an annual basis:

- The aggregate differential between the amount paid by a health plan and the amount paid to each pharmacy for prescription drugs
- The aggregate amount of the generic effective rate charged to each pharmacy
- The aggregate amount of remuneration fees charged or other price concessions to each pharmacy
- The aggregate amount of DIR fees and any other clawbacks from reimbursement made against each pharmacy
- List of prescription drugs that were moved to a formulary tier associated with a higher cost, copayment, coinsurance, or deductible to patients, or a lower reimbursement to pharmacies, along with rationale for the decision

Conclusion

The bill must strike a balance of addressing the pain points without taking away the power of PBMs to continue to negotiate lower prices for patients. Opponents of the bill criticize it as being a win for Big Pharma, burdening PBMs and undermining their ability to negotiate with manufacturers by leveraging their buying power. The pharmaceutical supply chain has become so confusing and increasingly shadowed over the past few decades that no one, even those operating within it, have a clear understanding of the price of a drug as it moves from manufacturing to order fulfillment. Pricing is not provided to patients in an easy-to-understand format. It varies from place to place and plan to plan. Imagine going to a supermarket and not knowing the price of your groceries until you check out. Imagine going to a gas station and having no idea of the price per gallon. Americans do not face pricing obscurity in other aspects of their lives, yet this is the status quo in the modern healthcare system, a system that has the largest impact on peoples' quality of life and can mean the difference between life and death.

The success of the proposed bill ultimately lies in whether it can lower drug prices for patients and improve the quality of care throughout the healthcare continuum. Increased transparency, in and of itself, does not equate to improvement unless actionable change can be derived from it in the form of considerate and impactful legislation. The challenge lies in defining what level is necessary to achieve these means in the years to come.

Sources

The full senate hearing recording and witness testimonies can be found here:
https://www.commerce.senate.gov/2023/2/bringing-transparency-and-accountability-to-pharmacy-benefit-managers

Bill Abstract/main page
https://www.congress.gov/bill/118th-congress/senate-bill/127?q=%7B%22search%22%3A%5B%22S.+127%22%5D%7D&s=1&r=4

PCMA – Pharmaceutical Care Management Association
https://www.pcmanet.org/value-of-pbms/#:~:text=PBMs%20administer%20prescription%20drug%20plans,)%2C%20state%20government%20employee%20plans%2C

NACDS - National Association of Chain Drug Stores - DIR Fees
https://www.nacds.org/dir-fees/

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Michael has been an advisor in the pharmaceutical and medical device industry for over 10 years, the past six spent assisting manufacturers with their revenue management challenges. Specializing in business process redesign, institutional contracting, and rebate and fee processing, he has supported large-scale revenue management system implementations, harmonization, and upgrades for manufacturers throughout the industry. Prior to joining IQVIA, Michael worked for a global consulting and accounting firm, providing advisory services to manufacturers in the areas of risk management and compliance.

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