Bringing TRANSPARENCY & ACCOUNTABILITY to Drug Pricing

Are rebates inflating the price of your prescription?
A special report by Auditor General Eugene DePasquale

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Dear fellow Pennsylvanians,

You could be paying too much for your medications and losing access to lower-cost drugs because of complex, behind-the-scenes rebate deals that take place every time you fill a prescription.

You probably know that a rebate is a repayment designed to reduce the cost of something you have purchased, and you most likely have redeemed some retail rebates in your life.

When it comes to your prescription drug plan, the standard definition of "rebate" still loosely applies: It is the return of part of a payment. But instead of returning money to you, the patient, the rebate process is a behind-the-scenes exchange among a drug manufacturer, your insurer and your pharmacy benefit manager, or PBM.

As I explained in my December 2018 special report, [“Bringing Accountability and Transparency to Prescription Drug Pricing,”] PBMs are the middlemen who administer your prescription drug benefits. Ever been told you need a prior authorization to take a newly prescribed drug? Or that you may not get a medication filled because it's not on your insurer's preferred drug list? Then you've encountered your PBM.

PBMs today serve a variety of functions within the pharmacy industry. Some argue that they exert undue influence on the prescription drug marketplace, affecting patients' wallets and, ultimately, their health; others say they fulfill a critical need for claims administration and, at the end of the day, save taxpayers money. Among the roles PBMs fill is negotiating with drug manufacturers to secure rebates for prescription drugs.

I have serious concerns about whether rebates should be used at all, as they may artificially inflate drug prices for everyone. Since they are used, though, this special report focuses solely on that rebate process and how it affects you as a patient and as a Pennsylvania taxpayer.

Here's what my review found:

- Because of federal oversight, rebates are generally working the way they should for Medicaid: by returning about $1.8 billion per year to state coffers, thereby offsetting the amount taxpayers pitch in to help Medicaid recipients afford their medications.
- However, drug manufacturers say, a lack of federal or state oversight of PBMs for those with private health insurance has led to higher drug prices and higher health care premiums.

If this issue strikes a chord with you, contact your state and federal legislators and let them know you want them to advocate for not only the three recommendations I make in this special report, but also the recommendations I made in my December 2018 special report. It's time to rein in the companies that are raking in tens of billions of dollars in profit each year as millions of hard-working people struggle to afford their medications.

Thank you for the opportunity to serve you.

Eugene A. DePasquale

Glossary

PBMs: Pharmacy benefit managers

Medicaid: Pennsylvania's medical assistance program

Third-party payer: The entity responsible for paying the drug manufacturer for a prescription medication; often either the state Office of Medical Assistance Programs (Medicaid office) or a private health insurer

Rebate: The repayment of a portion of the cost of a prescription medication from the drug manufacturer to the third-party payer

Minimum required rebate: The percentage drug manufacturers are statutorily required to pay back to states for Medicaid prescriptions. For brand-name drugs, it's 23.1 percent.

Consumer Price Index (CPI) penalty rebate: The percentage above the rate of inflation that drug manufacturers must pay back to states for all Medicaid-paid prescription medications whose prices have risen faster than the rate of inflation

Supplemental rebate: Any rebate offered to a state beyond the minimum required rebate and the CPI penalty rebate, up to 99 percent of a drug's cost

Best price: Medicare and Medicaid programs must statutorily be charged the lowest possible price that a drug manufacturer can charge for all prescription drugs

Intro

Why should you care about a complex rebate transaction that takes place behind the scenes of many prescriptions you have filled?

The main question here is why does it matter?

Because rebates and other discounts actually drive up the price of your prescription drugs by as much as 30 percent — meaning your brand-name heart medication, for instance, may be almost a third more expensive than it needs to be.

And because, without federally mandated rebates, you as a taxpayer could be spending nearly twice as much to help Pennsylvania's 2.8 million Medicaid clients get their medications.

Currently, neither you, as the patient, nor your pharmacist directly receives money to pocket from these behind-the-scenes exchanges.

What are rebates?

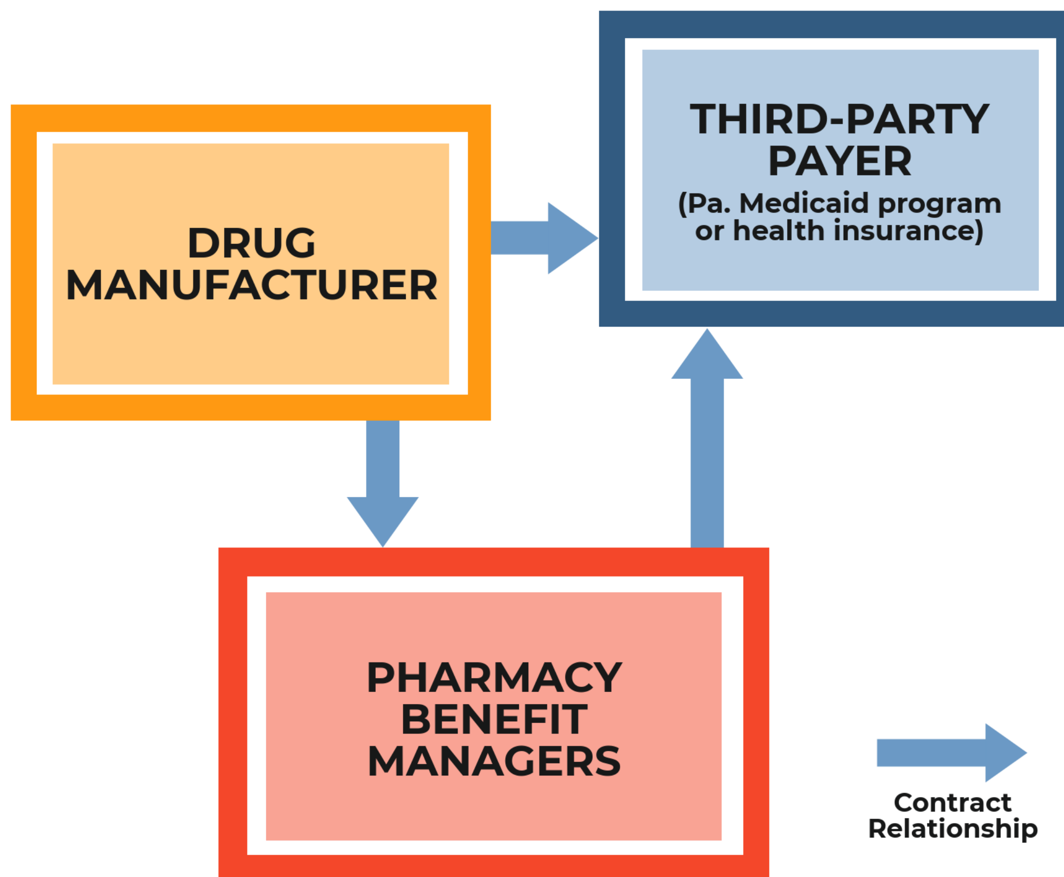
Let's start with the basics: The ultimate purpose of rebates is to lower the cost of prescription drugs.

But rebates are not paid directly to you, the consumer. Instead, rebates are paid to your health insurer — whether that's the government, through Medicaid, or your health insurance provider — to help lower your health care costs.

Rebates are also not paid to your independent community or retail pharmacy, which dispenses your medications to you. They do not receive a cut of the rebate, nor should they, necessarily.

Rebates are paid from a drug manufacturer either directly to government-funded programs, such as Pennsylvania's Medicaid program, or through pharmacy benefit managers (PBMs) to third-party payers such as Pennsylvania's Medicaid program or private insurers.

It looks like this:



The exact route a rebate payment takes is based on a variety of factors, including what kind of rebate is being applied (there are multiple definitions of the word "rebate" in the pharmacy industry).

Let's take a more in-depth look at this in the next section.

What We Heard 1:

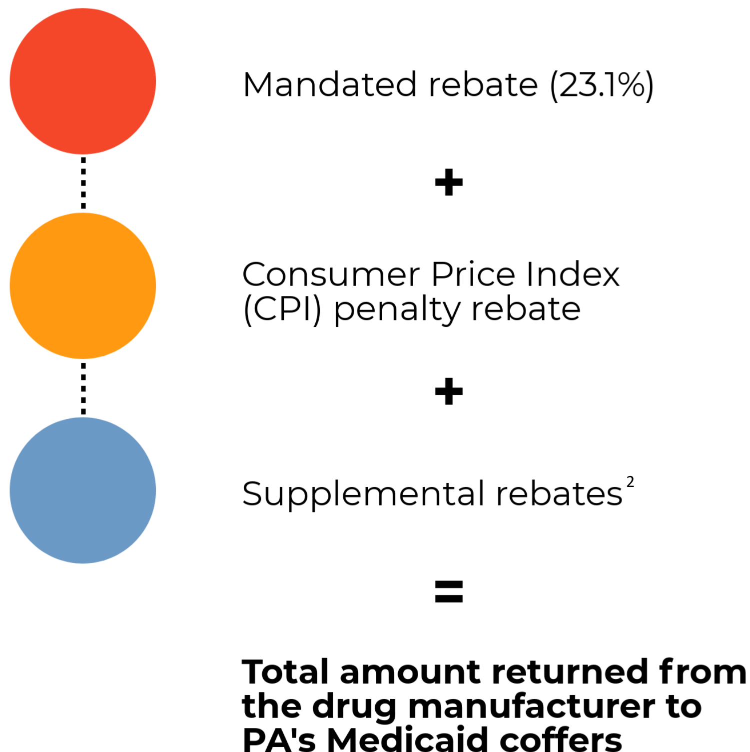
Rebates can do some good ...

Because of federal oversight, the rebate process for prescription drugs filled through Pennsylvania's Medicaid program is functioning largely as it should.

Federal regulation mandates that states must always get the lowest price available on prescription drugs. This means that, for each Medicaid prescription filled, the state must chose which of these two formulas gets it the lowest price:

- The drug manufacturer's "best price" offer, or
- A specified portion of the cost being returned to the state (a "rebate"). For brand-name drugs, it's 23.1 percent.[1]

If the rebate choice is the lowest amount, then the formula for each prescription is as follows:



[1] 42 U.S. Code § 1396r–8 (related to Payment for covered outpatient drugs), Title XIX of the Social Security Act, Section 1927

[2] Note that supplemental rebates are any rebate amount that a PBM negotiates above and beyond the federally mandated 23.1 percent and CPI penalty rebate. For ease of understanding, this report does not delve into supplemental rebates.

All of that rebate money flows directly between the drug manufacturer and the state.[3]

To understand how this process works, let's use a hypothetical example.

Sarah is a Pennsylvania Medicaid recipient whose doctor has prescribed for her a brand-name cholesterol medication for which there is no generic equivalent. Sarah pays the pharmacist a $3 Medicaid co-pay[4] and goes on with her day.

Behind the scenes, let's say the list price of the drug is $150 and the lowest price the manufacturer can offer the state for that drug is $100.

By federal statute, Pennsylvania must pay the lesser of the lowest price offered (the $100) or the list price ($150) minus 23.1 percent[5] and any inflation penalty.

For this example, let's say that the drug price has not risen faster than the rate of inflation for the last year, so no CPI penalty rebate applies.

Pennsylvania could pay either $100 (the lowest price offered) or $115 ($150 minus the federally required 23.1 percent).

Since the $100 best price is less than $115, Pennsylvania pays $100 to the drug manufacturer for Sarah's cholesterol medication.

Why does it matter? Because Americans spent $333.4 billion on prescription drug costs alone in 2017.

Now, imagine that transaction must be determined for every single Medicaid prescription filled for every single Medicaid recipient in Pennsylvania for every quarter of every year — and manufacturers have fewer than 40 days to do the math and decide if they agree with every transaction the state bills them for. (There is an appeals process, which isn't necessary to understand for this discussion.)

Overwhelmed? You're not alone. Even some drug manufacturers' Medicaid rebate experts have told us it's a jumble for them to figure out.

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[3] States work directly with drug manufacturers to receive rebates in Medicaid, so no rebate transaction passes through PBMs.

[4] To understand how the pharmacist gets paid, please see the 2018 "Bringing Greater Transparency and Accountability to Drug Pricing" special report.

[5] The 23.1 percent rebate is actually split between the federal government and Pennsylvania through a pre-determined Federal Medical Assistance Percentage (FMAP) formula, but for this discussion that delineation is not imperative.

Each quarter, Pennsylvania is repaid roughly $450 million in rebates from drug manufacturers. Here is a look at how much Pennsylvania has been paid in rebates for each of the last 8 quarters:

Rebate Quarter	Federal Rebate Collected for Fee-For-Service Utilization±	Federal Rebate Collected for MCO Utilization±	Total Federal Rebate Collected
2018 Q3	$18,912,863	$265,340,352	$284,253,215*
2018 Q2	$19,085,387	$439,736,539	$458,821,926
2018 Q1	$19,441,675	$453,778,368	$473,220,043
2017 Q4	$19,604,040	$412,861,984	$432,466,024
2017 Q3	$19,146,987	$414,679,962	$433,826,949
2017 Q2	$20,485,574	$599,912,981	$620,398,555
201 7Q1	$19,643,420	$402,108,717	$421,752,137
2016 Q4	$18,511,225	$387,257,539	$405,768,764

± These numbers reflect federally required rebates that Pennsylvania received directly from drug manufacturers for Medicaid prescriptions.

* This quarter shows a reduced amount of rebates compared with other quarters because drug manufacturers and the state are still in the collections process for all of the 2018 Q3 prescriptions filled, according to the Dept. of Human Services.

The money collected through rebates is placed back into the state's Medicaid coffers, according to the Department of Human Services, which oversees the Office of Medical Assistance Programs.

Pennsylvania paid almost $3.5 billion for outpatient Medicaid prescriptions in 2017, and it received just over $2 billion back from drug manufacturers for rebates, according to the Department of Human Services. That equals a total spend of about $1.5 billion on Medicaid prescription drugs in the 2017 calendar year — and it shows that Pennsylvania taxpayers would spend at least 50 percent more on Medicaid recipients' medications without the rebates.

Let's get back to the main question: Why does all this matter?

Drug manufacturers told us they know they'll have to pay these rebates, so sometimes they raise the initial cost of a medication (remember the $150?) to maintain their profit. Manufacturers know that they'll be paying at least 23.1 percent of the cost of a drug back to the government, so they increase the "best price" they offer the government for each medication — which means that, ultimately, it costs you, the taxpayer, more behind the scenes for Sarah's cholesterol prescription.

Note that the rebate process does not affect how much Pennsylvania Medicaid recipients themselves pay for their medications; that means Sarah always pays either $1 or $3 per prescription regardless of the behind-the-scenes rebate transaction.

But for people not covered by Medicaid, the rebate process does affect how much patients might pay for their own prescriptions.

Pennsylvania paid almost $3.5 billion for outpatient Medicaid prescriptions in 2017 and received just over $2 billion back through rebates.

What We Heard 2:

… But they raise drug list prices

Because of a lack of state or federal oversight of PBMs, the rebate process is not working to lower costs for patients not covered by Medicaid.

Without a state or federal mandate for PBMs to return at least of portion of rebates to other health insurers, PBMs can claim whatever rebate percentage they can negotiate with health insurers.

This means there is no required 23.1 percent that must be paid from the drug manufacturer back to patients' health insurance companies. Manufacturers and PBMs can negotiate any kind of rebate they want, in any amount, and the PBM can take whatever cut of the rebate it works out during the contracting process.

For the record, officials with CVS Health — which owns CVS Caremark, one of the three largest PBMs in the nation — said their company keeps only 2 percent of all rebates, with the rest being passed along to third-party payers. The Pharmaceutical Care Management Association, which represents PBMs, said that, on average, PBMs keep about 10 percent of the rebates they help negotiate (which means they pass along 90 percent to insurance companies).

However, because the process lacks transparency, there is no way to independently verify that information.

Let's look at Sarah's hypothetical friend Janice, who has private health insurance for the same doctor-prescribed, brand-name cholesterol medication.

Janice takes the new prescription to her pharmacy, which checks with her PBM to make sure the drug is covered by her plan's formulary (its list of covered drugs). It is covered, and the pharmacy fills the 30-day prescription for her.

Behind the scenes, the drug manufacturer has said the list price of that medication is $200, which is the amount, minus a small discount, that the wholesaler would pay the manufacturer. However, Janice's PBM has worked out a deal with the drug manufacturer to include the medication on her insurance company's formulary — a rebate — for 50 percent of the drug cost.

So the wholesaler buys it for just under $200, then sells it to a pharmacy with a small mark-up. When Janice picks up the prescription, she pays $40 (20 percent co-insurance of the $200 list price), and the pharmacy bills the PBM for the balance of what it paid for the drug, plus a small markup and any fees. Let's say the PBM is billed $160.

Remember that the PBM has negotiated a 50 percent rebate, so it collects $100 from the manufacturer.

What happens next is completely controlled by the PBM.

The PBM can deduct the $100 rebate from the bill they send to Janice's insurer, which would bring the amount they owe down to $60. Or they could keep the rebate and send the insurer a bill for $160.

Today, we have no idea what happens. PBMs say they pass on about 90 percent of the rebate, but the percentage probably depends on the sophistication of the insurer or employer contracting with them. It also depends on the contract language and how “rebate” is actually defined.

Under this system, the manufacturer earns just under $100 on the prescription, and the remaining difference goes primarily to the PBM.

And the person who loses the most is Janice.

Remember, she paid 20 percent of the list price. However, at a minimum that price was actually $100 lower because of the rebate. Therefore, she should not have paid more than $20 (20 percent of $100). Instead, she paid $40 – or 100 percent more than she should have.

Note that, in the first example using Sarah’s prescription via Medicaid, the drug manufacturer made $100 on the Medicaid prescription, but a PBM did not profit.

However, note that, in the second example using Janice’s prescription, the manufacturer made $100 and the PBM potentially pocketed up to $100 that would otherwise be returned to the health insurer.

The system monetarily rewards PBMs for placing higher-priced medications on formularies.

Here’s where it twists even more.

PBMs should, of course, be entitled to a share of the rebates they help negotiate — but instead of getting a flat fee per prescription, they get a percentage of the total cost of the drug. This means that the more expensive the medication, the more profit the PBM gets to keep. This is called a “perverse incentive,” because the PBM benefits by placing more-expensive medications instead of lower-cost alternatives on formularies.

This “perverse incentive” means that, instead of rewarding the PBM for including lower-cost medications on a preferred drug list, the system monetarily rewards the PBM for placing higher-priced medications on formularies.

For example, a drug that's been proven to cure Hepatitis C cost about $84,000 per treatment regimen when it was released in 2013.[6] When another version of the drug became available for only about $24,000 per treatment regimen,[7] the manufacturer struggled to have it placed on preferred drug lists because, drug manufacturers say, PBMs didn't want to lose their hefty percentage rebates on the brand-name drug — even though it was a cheaper drug that can cure patients suffering from Hepatitis C.

Again, let's get back to the main question: Why does this transaction matter?

It matters because Americans spent $333.4 billion on prescription drug costs in 2017 alone.[8] Without rebates, the list price of all drugs would drop by about 30 percent, drug manufacturers told us, because they would no longer have to build the cost of rebates into their prices.

Alternatively, if PBMs gave 100 percent of rebates back to third-party payers (the private insurance companies), then many people might see a decrease in their health insurance premiums.

The effect of this practice is that patients with private health insurance have difficulty predicting what they'll pay at the pharmacy counter because of the complex nature of co-insurance and deductibles.

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[6] Kliff, Sarah. Vox. "Each of these Hepatitis C pills cost $1,000. That's actually a great deal." https://www.vox.com/2014/7/16/5902271/hepatitis-c-drug-sovaldi-price. Accessed Feb. 11, 2019.

[7] Ryan, Benjamin. Hep Magazine. "Gilead to Release Authorized Generics of Hep C Drugs Epclusa and Harvoni." https://www.hepmag.com/article/gilead-release-authorized-generics-hep-c-drugs-epclusa-harvoni. Accessed Feb. 11, 2019.

[8] U.S. Centers for Medicare & Medicaid Services. "National Health Expenditures 2017 Highlights." https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf. Accessed Feb. 6, 2019.

Recommendations on rebates

1. **The Pennsylvania General Assembly** should mandate that pharmacy benefit managers receive a flat fee for service for providing administration of each prescription drug claim, regardless of the drug price, rather than being paid a percentage of the drug price as a rebate.

2. **Congress** should mandate that 100 percent of all rebates should go back to the third-party payer, whether that is a government program such as Medicaid or a private health insurer, and mandate that health insurers pass along the savings to patients.

3. **Congress** should consider revising the Social Security Act after determining whether the rebate percentages required for all medications should be altered or increased because the last mandated increase went into effect 10 years ago, in 2009.

Recommendations from the 2018 report on pharmacy benefit managers

1. **The General Assembly** should immediately pass legislation banning all "gag rules" and allow pharmacists to tell all patients if they could be paying less for a medication.
2. To ensure taxpayer dollars are being handled effectively and efficiently, **the General Assembly** should immediately pass legislation allowing the state to perform a full-scale annual review or audit of subcontracts with pharmacy benefit managers.
3. To better control costs, **Pennsylvania** should consider directly managing its Medicaid prescription drug benefits instead of contracting with managed care organizations to do so.
4. **The General Assembly** should pass legislation that increases transparency into PBM pricing practices.
5. **The General Assembly** should pass legislation to use the federal Centers for Medicare & Medicaid Services' National Average Drug Acquisition Cost (NADAC) for pricing prescription drugs filled through Medicaid.
6. **The General Assembly** should grant state oversight of contracts signed between PBMs and pharmacies or pharmacy services administration organizations, which are currently shielded from oversight because they are subcontracts.
7. So the state pays only for services PBMs render, **the General Assembly** should pass legislation requiring a flat-fee pricing model for compensating PBMs.
8. **Pennsylvania's Department of Human Services** should use Texas' Vendor Drug Program as a model to create Pennsylvania's own universal preferred drug list for Medicaid clients.
9. **Pennsylvania's Department of Human Services** should add "good steward" language to all Medicaid-related contracts.
10. **The Federal Trade Commission** should investigate whether separation truly exists between the PBM and pharmacy acquisition segments of major companies that operate both.
    - If the FTC does not investigate, then **the General Assembly** should consider legislation that prevents managed care organizations from using a PBM for Medicaid if the PBM is part of a larger company that also owns retail pharmacies.

3 QUESTIONS YOU SHOULD ASK

To help consumers take an active role in getting the best price possible for their prescriptions, Auditor General DePasquale released a short informational video with **three questions everyone should ask their pharmacist**.

Watch online here.

www.PaAuditor.gov