To order reprints or e-prints of JDD articles please contact sales@jddonline.com

doi:10.36849/JDD.2020.5241

Copyright © 2020

The Impact of Pharmacy Benefit Managers on Drug Pricing

Dillon J. Patel BS,[a] Neal Bhatia MD,[b] Mark D. Kaufmann MD[c]
[a]Biochemistry and Cell Biology, University of California, San Diego, La Jolla, CA
[b]Therapeutics Clinical Research, San Diego, CA
[c]Icahn School of Medicine at Mount Sinai, New York, NY

INTRODUCTION

What is behind the price of a medication that we see today? Who is responsible for the obstacles that prevent patients from getting on life changing medications? In other words, who is the man behind the curtain?

An analysis from 2012–2017 pharmacy claims data from Blue Cross Blue Shield Axis found that 78% of the available drugs analyzed have seen a greater than 50% increase in insurer and out-of-pocket cost. Moreover, over 44% of those analyzed, nearly 49 common brand-name drugs, had more than doubled in price.[1] As demonstrated in patient testimonials, social and mainstream media reports, and the growing negativity towards healthcare, the increase in the cost of drugs is pinned on pharmaceutical companies who are blamed for stuffing their pockets. In reality, the price determination is much more convoluted. There is little transparency between pharmaceutical companies, pharmacy benefit managers (PBMs), insurance companies, and pharmacies. By law, transparency is not required, and patients are left to suffer either without treatment or as victims of high prices.

Meet the Pharmacy Benefit Managers

Most insurance companies utilize outside companies, such as pharmacy benefit managers (PBMs), to decide what drugs should be on formulary, which ones to force patients to pay a larger share for, and especially to negotiate lower pharmaceutical prices. Like brokers and agents, PBMs are assumed to navigate between the insurer and pharmaceutical companies and often function under similar incentives. The original goal of the PBM was "to simplify the administration of benefits for health plan members and to provide some cost-management services," but those goals soon shifted due to their incentivized revenue "from claim processing to other sources, including manufacturer rebates, selling data to manufacturers, and selling mail order and retail drugs."[2] The role of the PBMs were thought to be crucial in determining how much pharmacies get paid, the cost for insurers, and ultimately the cost for patients. In reality, they are responsible for putting their hands in the pockets of patients. PBMs are suspected of utilizing strategies to gouge pricing, which include copay clawbacks, spread pricing, rebates, copay accumulator cards, and step edits. In direct opposition to the Sunshine Act for physicians, PBMs have no obligation to be transparent to the public or the healthcare system.

Copay Clawbacks

By example, PBMs have arms like an octopus – they intercalate into every transaction, supposedly meant to navigate between insurer and pharmaceutical company. However, they also intercalate with the pharmacy. In the past, a transaction used to work as follows: a pharmacy used to buy a bottle of medication for $1.50, they would charge the patient $4.00, and the pharmacy would pocket a profit of $2.50. Today with the PBM acting as a middleman, the pharmacy still buys the bottle of medication for $1.50, but now the pharmacy has to sell the bottle at a copay cost of $11.00 because the PBM will take $9.00, leaving the pharmacy a profit of $2.00, less than the amount from the previous interaction. That $9.00 is considered the copay clawback. In other words, if the negotiated price is less than the copay, the difference is passed back from the pharmacy to the PBM, which is known as a clawback.[3,4]

Prior to October 10th, 2018 pharmacies had gag clauses with the PBMs that prevented them from sharing the cost of medication without using insurance to patients – the pharmacist could not disclose to the patient the cost of the medication would have been $4.00, not $11.00 with insurance. In October 2018, Trump signed the *Patient Right to Know Drug Prices Act.* This act prohibits insurers and PBMs from restricting a pharmacy's ability to provide drug price information to a plan enrollee when there is a difference between the cost of the drug under the plan and the cost of the drug when purchased without insurance. The *Know the Lowest Price Act* provides the same protection for individuals who are covered by Medicare Advantage and Medicare Part D plans.

Spread Pricing

Imagine this scenario: A drugstore buys a hypothetical bottle of pills for $6. When someone uses employer-provided insurance to fill a prescription, their pharmacy benefit manager pays the pharmacy to cover the cost ($8) in this example, allowing the pharmacy to pocket $2. The PBM will then charge the employer $16 for the pills. The spread is the "difference between the drug ingredient cost billed to the employer by the PBM and the drug

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD. If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com

To order reprints or e-prints of JDD articles please contact sales@jddonline.com

ingredient cost the PBM pays to the dispensing pharmacy for that line item."[5-7] In other words, the spread pricing is difference between the product acquisition cost for the PBM and what they're telling the insurance company what they have to pay them.

What we find is the spread changes over time. In the Ohio state Medicaid program, when Imatinib 400 mg (generic Gleevec) first came out in 2016, it cost around $9,500 to the state Medicaid program. At the time, the PBM could acquire Gleevec for $9,017 and charged a $482-dollar spread. As Gleevec became less expensive over the next 18 months, the PBMs told the Medicaid insurance companies that this $9,500 drug is now going to cost them $7,200. However, the PBMs were only paying $3,800 – the spread widening greatly. Ohio Attorney General Dave Yost is suing one of the PBMs for these overcharges and other states have been following suit.[8] A similar scenario occurred with aripiprazole 5 mg (generic Abilify) in New York. For New York state Medicaid in 2015, it cost $431 and cost $382 for PBMs. As time went on, it cost New York state Medicaid $163, and $21 for PBMs.[9] On a broader scale, in 2017, it is estimated that New York state Medicaid spent 7.5 million dollars on aripiprazole 5 mg, while the ingredient cost was 1.4 million dollars, the pharmacy was estimated to be paid 1.2 million dollars, leaving 4.9 million in spread margin for the PBMs.[10] The PBMs are also suspected of doing the same for entecavir 0.5 mg (generic Baraclude) in Indiana. In 2015, the cost to Indiana Medicaid program was $1,011, the cost to the pharmacy was $889. In 2017, the cost to Medicaid was $846 and the cost to the pharmacy was $138, leading to a PBM spread of $709 for the PBMs.[9,11]

Rebates

To determine where a pharmaceutical medication will be on a formulary, it depends on the amount of rebate that PBMs receive. Rebates are, "a form of price concession paid by the pharmaceutical manufacturer to the health plan sponsor or to the pharmacy benefit manager working on the plan's behalf… the terms of rebates are generally confidential, rebates are typically offered in exchange for improved market access."[12] In some cases, pharmaceutical companies have tried to provide low prices and were faced with a situation that if they did not raise the cost of the drug, therefore giving a larger rebate to the PBMs, they did not appear on the formulary.[13] In other words, the PBMs can force the pharmaceutical companies to raise their prices to appear on the formulary.

The PBMs claim that rebates go back to the insurers so they can lower the premium for the patients, which there is no evidence for. Due to the 1987 *Medicare Anti-Kickback Safe Harbor* act, which was extended to PBMs in 2003, PBMs are exempt from penalties for taking kickbacks/rebates from supplier and are protected from having to release any of this information. They are not mandated to disclose how much they charge a company, how much they are keeping for themselves, and how much they are giving back to the insurance companies.

Alex Azar, the former president of Eli Lilly and Secretary of Health and Human Services during the Trump Administration, tried to implement change to lower drug prices. In May 2018, a Trump administration blueprint, *The American Patients First*, aimed to lower drug prices and reduce out of pocket costs based on USC article about the "copay clawback" phenomenon. Alex Azar came up with plan to "protect discounts offered to patients at the pharmacy counter" and to "create new safe harbor for fixed fee services arrangements between manufacturers and PBMs."[14] This would take protection away from PBMs and give it to the patients, so the patients would get the kickback.[15] Unfortunately, this fell through because it had the potential to increase premiums for Medicare beneficiaries. The decision drew praise from PBMs, who had lobbied members of the Domestic Policy Council and top health officials to drop it.[16]

The Copay Accumulator

Pharmaceutical companies may provide patients with copay assistance programs, such as copay assistance cards or coupons. In theory, these programs are meant to help patients pay for their out-of-pocket costs for prescriptions until their pharmaceutical deductible is reached, which could be very useful for patients who have high deductible plans. These cards typically have a maximum, likely providing a few months of coverage. After the patient's deductible would have been met, the insurance would kick-in to start full coverage for the drug. The insurance companies with the PBMs decided to double dip from the deductible with copay accumulator programs. The money is taken from the cards, but the patient's deductible is not credited. The PBMs and insurance companies have the ability to take a few thousand dollars from the cards and patients have to start from scratch from their $5,000 deductible. This effectively can allow the insurance companies and PBMs to collect twice the amount of a patient's deductible.[17]

Step Edits and Prior Authorizations

Most medical offices and physicians know of the obstacles that prior authorizations present. Utilizing step edits or step therapy may delay access to life changing medicine by having patients try and fail therapy, step by step. The PBMs can make the process of putting patients on life-changing medications quite cumbersome with repeated denials and tedious paperwork. The story of oncology patients having treatment denied for months by PBMs is not unique and happens to patients with all indications.[18] At the same time, PBMs hire physician reviewers who may not practice actively and not all states require the reviewing physician to have a similar specialty as the prescriber.[19] As PBMs are responsible for the development and maintenance of the formularies, they determine the tiers for coverage. Evzio, which is one of the brand name medications for naloxone on

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD. If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com

To order reprints or e-prints of JDD articles please contact sales@jddonline.com

TABLE 1.

PBM Strategies		
	Concept	**Scenario**
Copay Clawbacks	If the negotiated price is less than the copay, the difference is passed back from the pharmacy to the PBM is coined the copay clawback.	The pharmacy buys a bottle of medication for $1.50. The pharmacy has to sell the bottle to a patient using insurance at a copay cost of $11.00 because the PBM will take $9.00, leaving the pharmacy a profit of $2.00. If the patient was to pay without insurance, the cost would be $4.00.
Spread Pricing	Spread Pricing is difference between the product acquisition cost for the PBM and what they're telling the insurance company that they have to pay them	Gleevec cost in 2016 was $9,500, and the cost to the pharmacy was $9017. The combined pharmacy and PBM spread and fees were $482. As the cost of the medication decreased to $3,859, the PBMs charged Ohio Medicaid $7,201, increasing their spread to $3,342.
Rebates	To determine whether the pharmaceutical companies will be on a formulary, it depends on the amount of rebate they get. The PBMs claim that the rebates go back to the insurers so they can lower the premium for the patients, but there is no evidence of this.	The cost of Humalog more than doubled from 2011 to 2016 per vial. After rebates and discounts, Eli Lilly collected less than they did in 2009. PBMs, who negotiate these rebates, who "keep a portion of the rebates off list that they negotiate,"[23] Without transparency, there is no evidence to demonstrate that the increase in price is passed back to the consumers.
Copay Accumulator	Pharmaceutical companies may provide patients with copay assistance programs, such as copay assistance cards or coupons. The money is taken from the cards, but the patient's deductible is not credited.	A patient has a deductible of $5,000 and is prescribed a biologic medication. The drug manufacturer offers to cover the first $3,000. However, with the copay accumulator program, now the patient's deductible is not credited, and they still have to spend $5,000 out of pocket, instead of $2,000.
Step Edits/Prior Authorizations	Step therapy, a method that often delay access to life changing medicine by having patients try and fail therapy, step by step. As PBMs are responsible for the development and maintenance of the formularies, they determine the tiers for coverage.	A Dermatologist prescribes a biologic, knowing well that this is the best course of action for the patient. The prior authorization is submitted, and the insurance companies/ PBMs sends a denial, and requests that the patient uses a different medication, requiring patients needing to have failed another medication – one that may be fiscally superior for the PBMs, but not necessarily medically superior.

the market currently costs around $4,000. When the medication was originally priced at $575, the medication was largely unable to be covered. Per Spencer Williamson, the CEO of Kaleo at the time, the company raised the price to $4,000 based on roadblocks set by PBMs. The PBMs discouraged physicians from prescribing Evzio at the $575 price tag and said that patients had to try and fail another form of naloxone (despite the fact that it would be fatal if patients failed another form of naloxone). Once the price was raised more than 550%, patients began to have access to this medication, jumping from 5,000 filled prescriptions in the first 12 months to 65,000 prescriptions filled over the next 12 months.[13] The bottom line for PBMs may not correlate with positive patient outcomes.

Legislation

It is clear that change needs to occur to lower drug prices for our patients. To make the change and impact, a grassroots effort needs to be made by prescribers and patients alike. To make some of these changes, advocating for legislative fixes should be a priority. In 2018, promising proposals such as H.R. 1316 – Prescription Drug Price Transparency Act and S. 637 – Creating Transparency to Have Drug Rebates Unlocked did not get anywhere. Those proposals had to be re-proposed as the H.R.1035 – Prescription Drug Price Transparency Act 116th Congress and S.476 – Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2019. However, it is troublesome to see that, according to opensecrets.org, high campaign contributions to political parties are from PBMs, including UnitedHealth group, Aetna (which CVS merged with), and formerly Express Scripts.[20-21] The contributions are nearly split down the middle between Democrats and Republicans, indicating their influence regardless of who is elected. In addition, in April 2019, Pharmacy Benefit Managers were set to testify in front of the U.S. Senate Committee on Finance to answer how PBMs impact the cost of prescriptions. It's disconcerting to find that 27 of the 28 senators had accepted money from the PBMs, some even receiving personal donations.[22]

CONCLUSIONS

PBMs are intertwined with every step of a patient's journey to get treatment. From the highest level, PBMs have influence legislatively. On the patient level, the majority of PBMs are now part of insurance companies and are even in local pharmacies. Exposing the suspected price gouging techniques – copay clawbacks, spread pricing, rebates, copay accumulator cards, and step edits – can be key to familiarizing ourselves with the complicated high cost of a prescription. As patients and prescribers, we must make a grassroots effort to demand greater price transparency and change from our government.

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD. If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com

To order reprints or e-prints of JDD articles please contact sales@jddonline.com

DISCLOSURES

The authors have no relevant conflicts of interest to report.

REFERENCES

1. Wineinger NE, et al. Trends in prices of popular brand-name prescription drugs in the United States. *JAMA Network Open.* 2(5 e194791);3 May. 2019. doi:10.1001/jamanetworkopen.2019.4791
2. Martin SS. PBM industry today: who's managing drug costs? *Manag Care.* 2001;10(12):36–38
3. Hiltzik M. Column: The 'clawback': another hidden scam driving up your prescription prices. *Los Angeles Times, Los Angeles Times.* 9 Aug 2017
4. Van Nuys K, et al. Overpaying for prescription drugs: the copay clawback phenomenon. 2018. USC Schaeffer Center for Health Policy & Economics.
5. Garis RI, Clark BE. The spread: pilot study of an undocumented source of pharmacy benefit manager revenue. *J Am Pharmacists Assoc.* 2004;44(1):15-21.
6. Garis, RI, Clark BE, Mark V. Siracuse. Shining the light on non-transparent PBM cash flows. *America's Pharm.* 2004;126:20-25.
7. Silverman E. Spread pricing: from largely unknown to much scrutinized and criticized. *Managed Care Magazine.* 20 Sept 2019.
8. Candisky C. OptumRx overcharged Ohio on more than 1.3 million prescription claims, attorney general says. *The Columbus Dispatch.* 8 Feb 2020.
9. Attorney General. Attorney general seeks to recover nearly $16M in prescription overcharge. Ohio.gov. 19 Feb 2019.
10. 3 Axis Advisors. Analysis of spread pricing in New York Medicaid Managed Care. *National Community Pharmacy Association,* Pharmacist's Society of the State of New York, Inc., 24 Jan 2019.
11. Langreth R, et al. The Secret drug pricing system middlemen use to rake in millions. *Bloomberg.* 11 Sept 2018.
12. Dusetzina S, et al. Association of prescription drug price rebates in Medicare Part D with patient out-of-pocket and federal spending. *JAMA Intern Med.* 2017;177(8):1185–1118.
13. Stahl L. Evzio: the overdose-reversal drug with a $4000+ price tag. *CBS News,* CBS Interactive, 18 Nov. 2018.
14. U.S. Department of Health and Human Services. Fact sheet: Trump administration proposes to lower drug costs by targeting backdoor rebates and encouraging direct discounts to patients. *HHS.gov.* 31 Jan 2019.
15. U.S. Department of Health and Human Services. Trump administration proposes to lower drug costs by targeting backdoor rebates and encouraging direct discounts to patients. *HHS.gov,* US Department of Health and Human Services, 31 Jan. 2019
16. Alonso-zaldivar R. Setbacks for Trump's drive to lower prescription drug costs. *AP NEWS,* Associated Press. 11 July 2019
17. Feldman M. Copay accumulator adjustment policies impede treatment access for patients with rheumatoid arthritis. *Rheumatology Practice Management.* 2018;6(6).
18. Vacirca J. Pharmacy benefit managers: stop 'treating' my cancer patients. *STAT,* STAT News, 9 May 2019.
19. American Medical Association. 2018 prior authorization state law chart. Available at https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/pa-state-chart.pdf. Accessed Nov 16, 2019.
20. Open Secrets. Health services/HMOs top contributors, 2019-2020. Available at https://www.opensecrets.org/industries/indus.php?ind=H03. Accessed Jan 05, 2020.
21. Open Secrets. Health Services/HMOs: Top contributors to federal candidates, parties, and outside groups. Available at https://www.opensecrets.org/industries/contrib.php?cycle=2018&ind=H03. Accessed Jan 05, 2020.
22. Tindera M. These senators received the biggest checks from CVS, Humana and other drug middlemen testifying tuesday. Forbes, 10 Apr 2019.
23. Roland D, Loftus P. Insulin prices soar while drugmakers' share stays flat. WSJ. 7 Oct 2016.

AUTHOR CORRESPONDENCE

Mark D. Kaufmann MD

E-mail:..... Mark.Kaufmann@mountsinai.org

This document contains proprietary information, images and marks of Journal of Drugs in Dermatology (JDD).
No reproduction or use of any portion of the contents of these materials may be made without the express written consent of JDD. If you feel you have obtained this copy illegally, please contact JDD immediately at support@jddonline.com