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2022

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Gabrielle Landes

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Pharmacy Benefit Managers: What Are The Real Costs Behind-The-Counter?

Dr. Gabrielle Landes

I. Introduction

Picking up a prescription is an experience most all Americans will have in their lifetime. For many people, visiting the pharmacy is painless—your doctor sends a prescription, the pharmacist fills it, and your insurance pays most or all of the bill. But what does it *actually* cost to fill that prescription? More importantly—what does it *actually* cost the pharmacy and the patient?

For Jeff Olson, these questions are answered daily. Jeff graduated from the University of Iowa School of Pharmacy in 1993 when the pharmacy landscape looked much different than it does today. After graduation, Jeff, a native Iowan, returned to his hometown to pursue a career in independent community pharmacy. Upon returning, he became the co-owner and operator of Montross Pharmacy in small-town Winterset, Iowa. Montross Pharmacy is a pillar of the community in Winterset; in fact, it will be celebrating its 100th anniversary in 2021.

When Jeff became a partner in Montross in 1995, retail and community-based pharmacy was a different endeavor than it is today. At the time, pharmacies and pharmacists served patients primarily by filling prescriptions and providing counseling services. While these activities remain Jeff's primary focus, the situation has become more complicated. In the late 1990s, most patients paid for their prescriptions in cash; however, as drug prices began to rise, prescription drug coverage became increasingly common through private insurance companies and Medicare Part D plans. This huge change in the pharmacy payment structure has created what Jeff calls the "Low Pay-Slow Pay-No Pay" cycle.

First: Low Pay. The low pay portion stems from low reimbursement rates. Because pharmacies must spend money up-front to keep stock on the shelves, they must be reimbursed by the insurance company for the cost of the medication and the cost to dispense it. This system is primarily how pharmacies generate revenue. Over time, however, pharmacy reimbursement rates have decreased drastically. Jeff accounts that he loses an average of $120,000 per year attributable to low reimbursement costs.

Next: Slow Pay. Slow pay revolves around the Direct and Indirect Remuneration (DIR) Fees that claw back additional money on prescriptions after the point of sale. These fees are not applied, however, until months after the initial sale. Thus, pharmacy owners such as Jeff cannot adequately prepare for the amount of money they will owe any given month. Jeff estimates that about 3-6% of his yearly net profits, about $240,000 total, goes towards DIR Fees.

Lastly: No Pay. Audits performed on filled prescriptions claw back even more money from the pharmacy. For example, money can be clawed back for something as simple as failure of the pharmacist to strike through a hard-copy prescription or for calculating an inaccurate day supply for a topical product, which is a difficult task to do precisely. Jeff has fallen victim to predatory audits several times, citing that they are incredibly expensive and unpredictable, making it hard to plan the pharmacy's finances any given month or year.

Jeff loses approximately half a million dollars in revenue each year to the "Low Pay-Slow Pay-No Pay" cycle. Jeff sees the effects of the losses as twofold: (1) decreased pharmacist job availability and satisfaction and (2) lower value patient care. The monetary losses of pharmacies across the country have detrimental effects on the pharmacy, patients, and overall health. For many pharmacy owners across the country, Jeff's story is a familiar one. Unfortunately, he is the

rule and not the exception. This begs the question: why is this happening? Three words: Pharmacy Benefit Managers (PBMs).

Most Americans have neither heard of PBMs nor have any idea what they have to do with prescription drug costs. They are even less likely to be familiar with the dark, secretive side of PBMs. This Comment will explore the terrifying truth of PBMs: the history of PBMs, insight into the secretive practices of PBMs, and the ends to which PBMs are willing to go to make a profit. Lastly, this Comment will prove that PBM money making schemes are closing pharmacy doors for good, costing pharmacists jobs, and negatively impacting patient safety and access to quality health care and affordable medications.

Part II of this Comment will explore what pharmacists do and why they are vital to health care. Part III will take a deep dive into the depths of PBM business practices. Part IV will aim to prove that PBMs historically and continuously skim money off the top of every pharmacy transaction, which lowers pharmacy reimbursement rates, affects pharmacist job security and satisfaction, and, ultimately, affects patient access to adequate and affordable health care. Finally, Part V will discuss past, current, and future PBM regulation. Specifically, it will discuss former President Trump's eleventh-hour executive orders and regulations; President Biden's proposed regulations on drug prices; and future regulation and legislation.

II. Pharmacists: What Do They Do and Why Are They Vital to Health Care?

A familiar question most pharmacists receive at some point in their career is an iteration of the following: "Why do you have Dr. before your name? You are not a *real* doctor, right?"[1] In

[1] *See* Joseph Epstein, *Is There a Doctor in the White House? Not if You Need and M.D.*, WALL ST. J. (Dec. 11, 2020), https://www.wsj.com/articles/is-there-a-doctor-in-the-white-house-not-if-you-need-an-m-d-11607727380 (urging First Lady Dr. Jill Biden to "drop the 'Dr.'" from her title because she is not a physician). *But see* Michael Levenson, *An Opinion Writer Argued Jill Biden Should Drop the 'Dr.' (Few Were Swayed.)*, N.Y. TIMES (Dec. 12, 2020),

fact, I have received this question several times. So, what exactly *are* pharmacists? And what can they do? The answer: it depends.

A. Pharmacy Education Throughout the Years

A pharmacist who graduated before 2000 likely has a Bachelor of Pharmacy (B.Pharm), rather than a Doctorate of Pharmacy. This is because in July 2000 the Accreditation Council for Pharmacy Education (ACPE) mandated that all pharmacy schools offer a PharmD program to receive accreditation.[2] This was not precisely when PharmD programs came on the scene, however. In fact, the first earliest PharmD–like programs began in the 1940s after World War II.[3] By the late eighties, only 56% of pharmacy schools exclusively offered bachelor's degrees, while 14% offered only PharmD programs.[4]

The switch to PharmD programs meant a few things for students and faculty: (1) the program of study was extended from five to six years; (2) experiential learning was introduced; and (3) emphasis shifted to clinically-driven, patient-focused curricula. Original B.Pharm programs were only five years of coursework. The common approaches were a two-year undergrad, three years of formal pharmacy education; one-year undergrad, four years of formal pharmacy education; or admittance into formal pharmacy education from high school.[5] As PharmD programs were adopted, these structures remained largely unchanged. The most common structure seen today is a two-year pre-pharmacy program, with four years of formal pharmacy

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https://www.nytimes.com/2020/12/12/us/jill-biden-doctor-wsj.html ("'If you have a doctorate in pharmacy or education or biology, it doesn't matter: Call yourself doctor . . . .'").

[2] Teeraporn Supapaan et al., *A Transition from the BPharm to the PharmD Degree in Five Selected Countries*, 17 PHARMACY PRAC. 1611, 1613 (2019).

[3] *See generally* Joseph Fink, *Pharmacy: A Brief History of the Profession*, STUDENT DR. NETWORK (Jan. 11, 2012, 9:10 AM) https://www.studentdoctor.net/2012/01/11/pharmacy-a-brief-history-of-the-profession/; Supapapaan, *supra* note 2.

[4] Supapapaan, *supra* note 2.

[5] Fink, *supra* note 3.

education. The additional year of the formal pharmacy education was added to require experiential learning, called Advanced Pharmacy Practice Experience (APPE).[6]

The largest change was within the curriculum. The traditional B.Pharm curriculum focused heavily on medicinal chemistry, pharmacology, and compounding. After the switch, the curriculum kept aspects of these elements but focused much more on a patient-centered approach.[7] Another large change that arose from the advent of PharmD programs was post-doctoral pharmacist specialization with the introduction of Post-Graduate Year 1 and 2 (PGY-1 and PGY-2) and Pharmaceutical Industry Fellowship programs. A recent study found that on average over five years, about 47.2% of PharmD graduates apply for PGY-1 residencies, with about 33% accepting positions.[8] Moreover, the American College of Clinical Pharmacy (ACCP) and the American Society of Health-System Pharmacists (ASHP) recommend that all pharmacists involved in "direct patient care [should] be required to complete a residency prior to entering practice by 2020."[9] This switch reflects the profession's leaders overall agenda of involving pharmacists throughout the patient-care process and not solely at the end.

B. Types of Pharmacy Practices

Whether it is an insignificant role in a TV show or a commercial featuring gummy vitamins that are "Pharmacist Approved," retail pharmacists are the most well recognized of the profession. In fact, a recent study showed that about 65% of pharmacists practice in community–based settings while 25% practice in hospital-based settings in the U.S.[10] But pharmacists, and the profession as

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[6] Supapapaan, *supra* note 2.

[7] *See* Fink, *supra* note 3.

[8] Katherine A. Kelley et al., *Employment Trends for Doctor of Pharmacy Graduates of Research-Intensive Institutions, 2013–2017*, 83 AM. J. PHARMACEUTICAL ED. 148, 150 (2019).

[9] Supapapaan, *supra* note 2, at 1614 (while many hospital system employers prefer residency-trained pharmacists, it has not been formally required by accreditation standards).

[10] Supapapaan, *supra* note 2.

a whole, have drastically changed throughout the years. This change is due to several circumstances: advocacy by leaders, the switch from BPharm to PharmD, and the assessed need in other clinical areas.

Pharmacists are now involved in a multitude of clinical practices, including Medication Therapy Management (MTM),[11] ambulatory care practices, Managed Care Organizations (MCOs), pharmaceutical industry, public policy, and association management.[12] Through these professional advancements, pharmacists have earned the ability to be "supplementary or independent prescribers via [C]ollaborative [P]ractice [A]greements."[13] The most common example of this is the ability to administer vaccinations at the pharmacy, a more recent advancement of the profession. Lesser known Collaborative Practice Agreements permit pharmacists to provide anticoagulation, diabetes, HIV, and contraceptive management services.[14]

C. Future of the Pharmacy Profession

Although the scope of professional pharmacist services has increased recently, there is still room for improvement and expansion of practice. Pharmacists continue to fight to be recognized

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[11] *Medication Therapy Management (MTM) Services*, AM. PHARMACISTS ASS'N, https://www.pharmacist.com/medication-therapy-management-services?is_sso_called=1 (last visited Nov. 11, 2020) ("[MTM] is a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them.").

[12] *See generally* Jon C. Schommer et al., *Career Pathways for Pharmacists*, 47 J. AM. PHARMACISTS ASS'N 563 (2007).

[13] Supapapaan, *supra* note 2, at 1612; *see* National Center for Chronic Disease Prevention and Health Promotion, *Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists* (2013), https://www.cdc.gov/dhdsp/pubs/docs/Translational_Tools_Pharmacists.pdf (a Pharmacist Collaborative Practice Agreement (CPA) is "[a] formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions").

[14] *See generally* Patti Gasdek Manolakis et al., *Pharmacists' Contribution to Primary Care in the United States Collaborating to Address Unmet Patient Care Needs: The Emerging Role for Pharmacists to Address the Shortage of Primary Care Providers*, 74 AM. J. PHARMACEUTICAL EDUC. 1, 2 (2010) (discussing the roles of the pharmacists at VA hospitals and clinics).

as healthcare providers as a matter of law.[15] The main purpose for seeking provider status through federal legislation is to obtain reimbursement for services pharmacists currently provide. The proposed legislation would "amend Title XVIII of the Social Security Act to provide for coverage under Medicare program of pharmacist services."[16] Although the full scope of the services pharmacists are permitted to provide are individually mandated by each state, the proposed regulation would formally classify pharmacists as healthcare providers and require reimbursement for clinical services.[17]

The call for pharmacist provider status from industry leaders and professionals has gained strength amid the COVID-19 pandemic. With a national physician shortage, and health care systems and hospitals overwhelmed, pharmacists are ready and able to take over primary health care concerns.[18] For example, although pharmacists are permitted to administer vaccines in all fifty states, some states limit the types of vaccines pharmacists may administer.[19] Conferring provider status would allow pharmacists to administer all vaccines without Collaborative Practice Agreements or state approval, which could increase access to the COVID-19 vaccine and other vaccines in the future. Provider status could also guarantee pharmacists adequate payment for the

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[15] *See* Pharmacy and Medically Underserved Areas Enhancement Act, S. 109, 115th Cong. (2017). The bill has not yet been introduced during the current session; *see also* Patrick C. Harper, *Pharmacist Provider Status Legislation: Projections and Prospects*, 55 J. AM. PHARMACISTS ASS'N 203 (2015).

[16] Pharmacy and Medically Unserved Areas Enhancement Act, *supra* note 15.

[17] *See infra* Part IV.A for a discussion on pharmacist-based clinical services.

[18] Debbie Weitzman, *Provider Status for Pharmacists: It's About Time*, PHARMACYTIMES (Oct. 7, 2020), https://www.pharmacytimes.com/news/provider-status-for-pharmacists-its-about-time; *see also* Pharmacy Organizations Executive Summary, *Pharmacists As Front-Line Responders For COVID-19 Patient Care* 1, 2 (2020), https://www.pharmacist.com/sites/default/files/files/APHA%20Meeting%20Update/PHARMACISTS_COVID19-Final-3-20-20.pdf.

[19] Weitzman, *supra* note 18; *see also* Richard Hughes IV et al., *The Pharmacist's Role in COVID-19 Response Efforts*, HEALTHAFFAIRS.ORG (Jul. 23, 2020), https://www.pharmacytimes.com/news/provider-status-for-pharmacists-its-about-time (explaining that "state laws frequently place limitations on pharmacist-vaccinations based on age, type of immunization, and other requirements, such as parent or guardian consent or physician authorization").

provision of acute access to COVID-19, flu, and strep testing, and other treatments for minor ailments.[20]

D. Pharmacists' Vitality to Healthcare

Why is provider status for pharmacists necessary to the health care system? Because pharmacists are uniquely qualified to provide primary care and are the most accessible health care providers.[21] There is currently a shortage of primary care physicians in the U.S. The number of new physician graduates that choose primary care as a career has fallen by 50% since 1997, and only about 2% of all physician graduates plan to work in primary care settings.[22] In fact, it is estimated that "over 56 million Americans lack adequate access to primary health care . . . ."[23] With the baby boomer population reaching sixty-five years of age, and more people suffering from chronic conditions, primary care services are needed now more than ever. In older populations in particular, studies show that "28 percent of patients . . . take five or more chronic medications each month."[24] The problems permeating the healthcare system require a shift by all professions to improve patient access to care. Because pharmacists have a deep understanding of medication management, adverse events, and diagnostic criteria, they are perfectly positioned to assume roles within the primary care system.[25]

Pharmacists are also the most accessible health care providers to patients.[26] The lack of access to a health care provider is specifically exacerbated in rural areas of the country. In fact, about "20% of the US population—more than 50 million people—live in rural areas, but only 9%

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[20] Weitzman, *supra* note 18; Pharmacy Organizations, *supra* note 18.
[21] *See* Pharmacy Organizations, *supra* note 18.
[22] Manolakis, *supra* note 14, at 1.
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *See* Pharmacy Organizations, *supra* note 18.

of the nation's physicians practice" in those communities.[27] Conversely, 90% of Americans live within five miles of a community pharmacy, thereby making pharmacists the most accessible health care provider to all American communities.[28] Ensuring pharmacists and essential services remain accessible to Americans requires proper pharmacist reimbursement, provider status, and an expansion of pharmacists' scope of practice.

III. PBMs: Who Are They and How Do They Fit Into Healthcare?

Most Americans have likely never heard of Pharmacy Benefit Managers (PBMs). Whenever an American fills a prescription, however, they are utilizing PBM services. This is because PBMs are the silent middlemen in all pharmacy transactions; they are perfectly positioned between the manufacturers, health plans, and retail pharmacies.[29]

PBMs were originally primarily responsible for what is called claims adjudication.[30] The typical claims adjudication process goes as follows. A patient arrives at a pharmacy with two things in hand: a prescription and an insurance card. The pharmacy then uses special coding provided on the insurance card to bill the patient's insurance for the prescription. This is actually accomplished through a series of complicated computer transactions with the PBM. First, the patient's insurance information is transmitted to the PBM, which decides whether the patient's insurance covers the particular drug. If it does, the claim goes through; if not, it is rejected back to the pharmacy. Assuming the prescription is covered, the PBM then transmits two pieces of information back to the pharmacy: (1) the patient's copayment, if any, and (2) the pharmacy

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[27] Roger A. Rosenblatt, *Physicians and Rural America*, 173 WESTERN J. MED. 348 (2000).
[28] Pharmacy Organizations, *supra* note 18.
[29] *See* Alan Lyles, *Pharmacy Benefit Management Companies: Do They Create Value in the US Healthcare System?*, 35 PHARMACOECONOMICS 493, 494 (2017).
[30] *See* Kwanghuyuk Yoo, *Pharmacy Benefit Managers and Generic Pharmaceuticals Pricing Conspiracy: Unveiling Lock-In Mechanisms, Structural Shortcomings and Antitrust Evidence*, 64 S.D. L. REV. 43, 56 (2019) (discussing the process of claims adjudication).

reimbursement information. Lastly, the PBM determines how much to bill the health plan for the transaction. Although claims adjudication was the primary impetus for PBMs, they have now positioned themselves as the middlemen between many different actors.[31]

A. History of PBMs

The first-generation PBMs came on the scene in the late 1960s as insurance companies began covering prescription medications.[32] Health plans needed to outsource claims adjudication for efficiency reasons, which gave rise to an entirely new health care business. As PBMs became more popular, the model began to change. In the early 1990s, top pharmaceutical companies, such as Eli Lilly, Merck, and SmithKline, purchased large PBMs to create formulary synergy.[33] This new model allowed pharmaceutical companies to list their drugs as "preferred" through the PBMs they respectively owned.[34] Eventually this practice was challenged in a breach of fiduciary duty class-action lawsuit, which provoked the Federal Trade Commission (FTC) to "crack down on the PBM/drug company alliance."[35] Although each pharmaceutical company sold their interest in PBMs in the early 2000s, the evolution of the PBM business model had lasting effects.[36]

Today, there are three major, publicly-traded PBMs: ExpressScripts, OptumRx, and CVS-Caremark. These PBMs are responsible for administering prescription drug benefits to over 180 million people—about 80% of the market.[37] They have, essentially, utilized the formulary-based

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[31] *See generally* Lyles, *supra* note 29.
[32] *See, e.g.*, Lyles, *supra* note 29; Comments of David A. Balto to the Federal Trade Commission (Dec. 6, 2017).
[33] Lyles, *supra* note 29.
[34] *See* David Dayen, *The Hidden Monopolies That Raise Drug Prices: How Pharmacy Benefit Managers Morphed From Processors to Predators*, AMERICAN PROSPECT (Mar. 28, 2017), https://prospect.org/health/hidden-monopolies-raise-drug-prices/ ("[Merck, Eli Lilly, and SmithKline] could then view competitors' pricing information and place their own drugs over their rivals' on PBM formularies.").
[35] *Id.*
[36] *See* Lyles, *supra* note 29.
[37] Yoo, *supra* note 30, at 55.

model that was projected in the original PBM/drug company alliances without triggering the FTC antitrust regulation. The idea of consolidating into three major PBMs, instead of separate, smaller health plans or PBMs, was for one effect: bargaining power—they are stronger together than apart.[38]

PBMs' current business model is best described as a wagon wheel: PBMs are the hub, while the pharmacies, health plans, wholesalers, and manufacturers are the spokes that are all interconnected themselves.[39] First, PBMs contract with several health plans to create a patient network. For example, according to their website, CVS-Caremark serves as the PBM for thirty-nine different health plans, which amounts to about eighty million members.[40] Large patient networks give PBMs sufficient bargaining power with the drug manufacturers to negotiate for lower drug prices. Manufacturers will provide PBMs rebates in exchange for preferred spots on their formulary.[41] A PBMs' formulary is a tiered system: the top tier consists of the most preferred medications—typically, drugs from manufacturers with whom they have negotiated the highest rebates. For example, a tiering system may commonly look like the following: "Tier 1—preferred generic, Tier 2—non-preferred generic, Tier 3—preferred brand, Tier 4—non-preferred drug, and Tier 5—specialty medicines."[42] As you get higher in the tiers, the more expensive the drug is to

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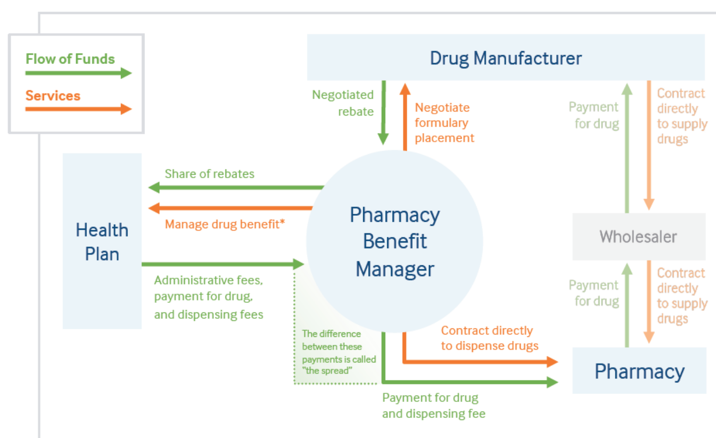
[38] *See generally id.* at 56.
[39] Seeley, *infra* note 45.
[40] CVS Health Plan Partners, https://www.cvs.com/health-insurance/medicare/health-plan-partners?icid=medicare-tab-partners; *see also* Lyles, *supra* note 29, at 495.
[41] Abigail Gore, *Exposing the Middlemen in Rising Drug Costs: Modifying Safe Harbor Protections for Pharmacy Benefit Manager Rebates Under Federal Anti-Kickback Statutes*, 98 OR. L. REV. 297, 301 (2020); *see also* Balto, *supra* note 32; *infra* Part III.B.1 discussing PBM rebate practices.
[42] Lyles, *supra* note 29, at 495.

the PBM, health plan, and, ultimately, the patient.[43] This formulary serves as the backbone for the PBM claims adjudication and pharmacy reimbursement.[44]

B. PBMs' Pricing Scheme

So, how exactly do PBMs make money? And why has this business model disrupted the prescription drug market? In order to understand how the system has been exploited, it is important to understand how the PBM business model was initially designed to work. There are three primary ways in which PBMs make their money: (1) manufacturer rebates, (2) discounts on pharmacy reimbursement rates, and (3) DIR fees. An overview of the PBM—health plan—pharmacy interaction is shown in Figure I. A breakdown of each component will be explored in the sections below.

Figure I[45]



1. Rebates

[43] *See infra* Part IV.C for a discussion on patient cost-sharing initiatives by health plans.
[44] *See supra* Part III for an explanation of PBM claims adjudication; *see also infra* Part III.B.2 for a discussion on pharmacy reimbursement.
[45] Elizabeth Seeley, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead*, COMMONWEALTH FUND 1, 2 (2019) https://www.commonwealthfund.org/publications/issue-briefs/2019/mar/pharmacy-benefit-managers-practices-controversies-what-lies-ahead.

PBMs first negotiate with the drug manufacturer for rebates on generic and brand-name medications and then list these medications on their preferred formulary.[46] Manufacturer rebates serve two purposes: (1) to provide payment to the PBM for the service of negotiating and (2) to pass savings on to the health plan, overall lowering the price for prescription medications.[47] Over time, however, the manufacturers have utilized rebate negotiations in exchange for better formulary placement and increase market share for their products.[48]

PBMs negotiate up to a 40% discount off of the list price of the drug. It is estimated, however, that the average rebate price is around 14%, which is to be paid to the PBM by the insurance company after the point of sale at the pharmacy.[49] A 2015 study found that the rebates manufacturers offered to PBMs "totaled about $58 billion of the $350 billion in total gross expenditures for brand name drugs . . . ."[50] PBMs are then supposed to pass on 90% of the rebate to the health plan, which should ideally pass savings to patients in the form of lower premiums and copayments.[51]

For example, Lipitor® (produced by Pfizer) and Zocor® (produced by Merck) are both used to treat hyperlipidemia or high cholesterol. If Lipitor®'s list price is $150 and Pfizer offers a 40% rebate, the cost of the drug to the health plan is $90 post-rebate. If Zocor®'s list price is $100 and Merck offers a 30% rebate, the cost of the drug to the health plan is $70 post-rebate. Barring all other considerations and assuming the medications have equivalent efficacy profiles, the PBM should pick Zocor® as the preferred medication because the drug price and rebate

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[46] *See supra* Part III.B for a discussion on PBMs' preferred formulary model.
[47] *See generally* Seeley, *supra* note 45; *see also* Gore, *supra* note 41, at 302.
[48] Gore, *supra* note 41, at 302.
[49] Yoo, *supra* note 30, at 73.
[50] *Id.* at 75.
[51] Seeley, *supra* note 45, at 3.

combination offer the lowest price. Under that scenario, the PBM would pass $27 dollars in rebates to the health plan and make a profit of $3 on each Zocor® prescription filled by a patient. This, however, is not what often occurs.

In fact, there are three distinct problems that have emerged from PBMs' rebating system: (1) decreased rebate savings passed through to insurance companies, (2) increased manufacturer drug prices, and (3) increased cost-saving and cost-sharing mechanisms for patients. First, because of lack of regulation and transparency, PBMs are not required to disclose the rebates they obtain from manufacturers on each drug.[52] Thus, PBMs are not incentivized to choose the lowest priced drug, but instead the drug with the highest rebate regardless of overall cost. Moreover, many speculate, and there is evidence that PBMs do not pass the full 90% of the rebate to the health plans.[53] This has detrimental effects on prescription drug costs to the health plan.

Revisiting the earlier example: even though Zocor® was the lower post-rebate cost medication, in reality, the PBM would likely choose Lipitor®. This would allow the PBM to instead pass $54 in rebates to the health plan and make a profit of $6 on each Lipitor® prescription filled, yielding twice the profit for the PBM on each prescription filled than it would earn on Zocor®. Further, PBMs are unlikely to pass the full 90% rebate through to the health plan. Assume the PBM in this scenario only passes 85% of the rebate to the health plan. The health plan would only receive $51 in rebates and the PBM would then profit $9 on each Lipitor® prescription filled. The health plan would now have to pay $93 dollars for the prescription, as compared to the original $90. While a $3 loss per prescription may seem negligible in the long run, it has the

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[52] *See generally* Lyles, *supra* note 29 at 497; Balto, *supra* note 32.
[53] Gore, *supra* note 41, at 302; *see* Seeley, *supra* note 45, at 3 ("[S]mall payers and employers have reported that they did not receive this share (i.e., 90%) of savings.").

potential to have a huge impact on health care spending when extrapolated to encompass every drug paid for by the health plan.

Second, aggressive negotiating by PBMs for higher rebates from manufacturers results in an inverse increase in drug pricing. Industry professionals and thought leaders often blame investment in innovation and Research and Development (R&D), and other considerations, such as patent and regulatory exclusivity, as responsible for increased drug prices.[54] The cost of R&D, however, only accounts for 15.2% of the ten largest pharmaceutical companies' total annual revenue.[55] If innovation costs are so low compared to annual revenues, then what is the justification for such high drug prices? The answer is that the United States is the only country that allows manufacturers to set their own drug prices.[56] Therefore, drug manufacturers set drug prices "primarily on . . . what the market will bear."[57] For example, Lantus® is a popular long-acting synthetic insulin sold world-wide for the treatment of Type I and Type II diabetes. In 2015, the average cost of Lantus® in the U.S. at fifty units per day pre–rebate was $372.75. In contrast, the price of Lantus® at fifty units a day in Canada, France, and Germany was $67.00, $46.60, and $60.90, respectively.[58] This means, at best, America's price for the same prescription drug from the same manufacturer is 5.6 times higher than other countries.

This independent pricing model is further complicated by PBMs' use of market power to pressure manufacturers into providing higher rebates each year. In a perfect world, the rebates are supposed to keep drug prices low; in reality, however, to make up for costs manufacturers provide

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[54] *See* Kesselheim, *supra* note 62, at 863.
[55] *See id.* (discussing results in Table 4 from a 2014 study of Sales and R&D Costs).
[56] *Id.* at 860.
[57] *Id.* at 863.
[58] *Id.* at 859.

in discounts in one year, they send drug prices soaring the next.[59] For example, in 2016, Eli Lilly's Humalog®, a popular short-acting insulin for the treatment of diabetes, was more than double its price in 2011.[60] When reporters from the *Wall Street Journal* inquired about the stark price increase, Lilly reported that they were actually making less on Humalog® in 2016 than in 2009.[61] The reason? PBMs' continuous demand for higher rebates in exchange for preferred placement on formulary lists.

Lastly, because rebate savings often are less than anticipated by the health plans, they are required to employ several other strategies to keep premiums and escalating drug costs down. These tactics usually take form in patient cost-sharing initiatives, such as copayments or high deductible plans.[62] These tactics will be discussed in further detail in Part IV-C.

2. Pharmacy Reimbursement Rates: "The Pricing Horribles"

PBMs continually make a profit from discounts and claw-backs on pharmacy reimbursement rates. A pharmacy's reimbursement consists of two components: ingredient costs and the dispensing fee.[63] First, because the pharmacy must front most of the cost to keep medications in stock, they must be reimbursed by the PBM for the cost of obtaining the medication from the wholesaler.[64] Second, the dispensing fee pays for materials required for filling

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[59] Gore, *supra* note 41, at 302; *see also* Denise Roland and Peter Loftus, *Insulin Prices Soar While Drugmakers' Share Stays Flat; Role of Health-Care Middlemen Fuel Market with Higher List Prices; Deep Discounts are Available to Some*, WALL ST. J. (Oct. 7, 2016) https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764.

[60] Roland & Loftus, *supra* note 59.

[61] *Id.*

[62] *See* Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 864 (2016); *see also infra* Part IV.C for a discussion on how cost-sharing and cost-saving measures affect patients.

[63] Yoo, *supra* note 30, at 81.

[64] Lisa L. Causey, Nuts and Bolts of Pharmacy Reimbursement: Why It Should Matter To You (June 2009) (unpublished note, University of Houston Law School) (on file with Houston Journal of Health Law and Policy at https://www.law.uh.edu/healthlaw/perspectives/2009/(LC)%20Pharmacy.pdf).

prescriptions (e.g., amber vials and bags) and labor costs (e.g., pharmacists and pharmacy technicians).[65] Dispensing fees and patient copayments are the primary ways pharmacies make a profit from filling prescriptions.[66]

In order to understand pharmacy reimbursement, it is important to understand the complex pricing system and flow of money between health plans, PBMs, and pharmacies. The price paid to the wholesalers is called the Wholesale Acquisition Cost (WAC).[67] This is the price at which manufacturers sell drugs to wholesalers and pharmacies.[68] This is not, however, the price used in the pharmacy reimbursement calculation.

Instead, pharmacy reimbursement is calculated using one of three other price benchmarks: Average Wholesale Price (AWP), Maximum Allowable Cost (MAC), or Average Manufacturers Price (AMP).[69] The AWP is not the actual price of the medication; instead, it is "an artificial benchmark set by the drug manufacturer."[70] Manufacturers and PBMs also use AWP during rebate negotiations.[71] AWP is the WAC plus a 12–20% markup.[72] Conversely, MAC is the "upper limits that PBMs or health insurers pay retail pharmacies for generic . . . and . . . brand drugs."[73] This rate is determined by using the average published AWP or WAC prices. Generally, MAC prices are 50–60% lower than AWP prices.[74] Different from WAC or AWP, AMP is the actual sales

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[65] *See id.*
[66] Yoo, *supra* note 30, at 81.
[67] *Id.* at 60–61.
[68] *Id.*
[69] *See id.* at 61; Causey, *supra* note 64.
[70] Yoo, *supra* note 30, at 60.
[71] *Id.* at 61.
[72] *Id.*
[73] *Id.* at 62
[74] *Id.* at 84.

price reported by manufacturers.[75] Therefore, AMP prices are usually lower than WAC or AWP prices, but higher than the actual acquisition cost to the pharmacy.

How exactly does "the pricing horribles" scheme fit into pharmacy reimbursement rates? To keep copayment and reimbursement rates lower, PBMs will contract with certain retail pharmacies to create pharmacy "networks." Large, corporate chain retail pharmacies, such as Walgreens and CVS, will then offer discounts on different price points (AWP, AMP, and MAC) to negotiate for a better position within the PBMs' preferred network.[76] For brand medications, PBMs typically calculate a pharmacy's reimbursement based on AWP, less any pharmacy discounts, plus a dispensing fee.[77] Pharmacies typically purchase medications based on WAC, but will offer a discount of about 12–15% of AWP (recall that AWP is WAC plus a 12-20% markup).[78] Thus, pharmacies are generally reimbursed the exact amount it costs to acquire brand named medications from the wholesaler.

For generic medications, PBMs typically reimburse pharmacies based on MAC prices.[79] PBMs keep MAC list prices private, however, and do not allow health plans to see the actual reimbursement to pharmacies.[80] Thus, PBMs charge the health plan a higher amount for the drug while reimbursing the pharmacy at the listed MAC price, creating what is known as spread pricing.[81] For example, a PBM in Ohio "reimbursed pharmacies 2.3 billion and billed Medicaid 2.5 billion . . . , resulting in a spread of $200 million" in profit to the PBM.[82] Not only do PBMs

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[75] *Id.* at 64.
[76] Yoo, *supra* note 30, at 70; *see also* Lyles, *supra* note 29, at 496.
[77] Yoo, *supra* note 30 at 84.
[78] *Id.*
[79] Seeley, *supra* note 45, at 5.
[80] *Id.*; *see also* Yoo, *supra* note 30, at 70–71.
[81] *See, e.g.*, Yoo, *supra* note 30, at 80; Balto, *supra* note 32.
[82] Seeley, *supra* note 45, at 5.

profit from the spread, they also profit from slowly updating MAC lists. Ideally, MAC is typically on par with WAC, meaning the pharmacy is reimbursed at or slightly above cost for generic medications. This is to induce pharmacies to fill for lower cost generics instead of brand medications. When manufacturers raise the prices on generics, however, PBMs are slow to correct MAC pricing.[83] This means that WAC is now substantially higher than MAC, which results in pharmacies being reimbursed less than acquisition cost. Conversely, if the manufacturer drops the generic price, PBMs quickly update the MAC list, ensuring pharmacies are not reimbursed more than their acquisition cost.[84] Because of the need to compete for the PBMs' business, pharmacies are not able to be reimbursed at a markup like a typical business. Instead, they are reimbursed at or below cost, which lowers their overall profit on each prescription.

Moreover, the payment for dispensing the medication does not reflect its actual cost. A study conducted in 2007 noted that while it typically costs around $10.50 to dispense a prescription, most pharmacies were only reimbursed a dispensing fee around $4.50 on average.[85] A more recent study calculated the average cost of filling a prescription at $12.40, with $7.22 of that cost directly attributed to payroll expenses.[86] Thus, pharmacies are reimbursed at or below what it costs to purchase the medication and cost to dispense the medication, which leads to an overall net loss on each prescription filled. "The Pricing Horribles" stands as a barrier to pharmacies making a profit from their main business model: selling prescriptions.

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[83] Michael Matalavage, *Navigating the Complexities of Pharmacy Reimbursement: Will We Ever Reach Transparency?*, PHARMACY TIMES (Mar. 23, 2016), https://www.pharmacytimes.com/publications/issue/2016/march2016/navigating-the-complexities-of-pharmacy-reimbursement-will-we-ever-reach-transparency.
[84] *Id.*
[85] Causey, *supra* note 64 (citing to Sandra Levy, *Dispensing Fees Woefully Inadequate, Says Study,* (Feb. 19, 2007), available at http://drugtopics.modernmedicine.com/drugtopics/article/articleDetail.jsp?id-404988).
[86] Sarah Shoemaker-Hunt et al., *Cost of Dispensing Study*, ABT ASSOCIATES (Jan. 2020), https://www.nacds.org/pdfs/pharmacy/2020/NACDS-NASP-NCPA-COD-Report-01-31-2020-Final.pdf.

3. Direct and Indirect Remuneration (DIR) Fees

The final piece of the PBM profit scheme is Direct and Indirect Remuneration (DIR) Fees. DIR Fees were initially implemented by the Centers for Medicare and Medicaid (CMS) upon the enactment of the Medicare Modernization Act of 2003.[87] The statute requires PBMs to send an annual report to CMS encapsulating the gross cost of prescription drugs that were not captured at the point of sale.[88] For example, PBMs are often provided additional discounts from the manufacturers after the point of sale in the form of supplemental rebates or patient co-pay assistance programs, such as manufacturer coupons.[89] Because the federal government aims to keep drug costs low for taxpayers, CMS intended DIR reports to provide them with the accurate costs of medications to reimburse at the lowest cost possible.[90] In theory, this retrospective analysis should provide pharmacies with a more accurate reimbursement rate; however, PBMs have vastly expanded the scope of DIR Fees.

PBMs use DIR Fees for many different fees, such as, "costs for pharmacies to participate in a Part D preferred network, price reconciliations based on contractual rates, compliance fees for contract-based performance metrics, or a combination of these fees."[91] In reality, PBMs are using DIR Fees as a way to claw back additional money from the pharmacy after the point of sale.[92] In

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[87] Michael Gabay, *Direct and Indirect Remuneration Fees: The Controversy Continues*, 52 HOSPITAL PHARMACY 740 (2017).

[88] *See* National Community Pharmacists Association, *Frequently Asked Questions (FAQs) About Pharmacy "DIR" Fees*, http://www.ncpa.co/pdf/dir-faq.pdf.

[89] *White Paper: PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues*, FRIER LEVITT: PHARMACY L. (Feb. 2, 2017), https://www.frierlevitt.com/articles/service/pharmacylaw/white-paper-pbm-dir-fees-costing-medicare-beneficiaries-investigative-white-paper-background-cost-impact-legal-issues/.

[90] *See* Gabay, *supra* note 87.

[91] *Id.*

[92] *Id.*

fact, most pharmacies report that PBMs are applying DIR Fees months after the initial sale, making it nearly impossible to predict how much money a pharmacy will owe to a PBM any given month.[93]

One example of DIR Fees is tied to CMS's "5-Star" ratings.[94] CMS puts forth patient quality metrics and standards, such as medication adherence to regimens for chronic conditions like diabetes, hypertension, and hyperlipidemia.[95] PBMs with better patient quality metrics will receive a higher 5-Star rating from CMS.[96] This 5-Star rating then directly correlates to how much a PBM is reimbursed on Medicare Part D claims.[97] To ensure that patients who utilize the PBMs services meet these metrics, PBMs perform audits on pharmacies. For example, PBMs will measure how often and likely patients are to refill their prescriptions on time as a way to measure the patient's adherence to the medication regimen—a measure over which a pharmacy has little control.[98] Then, based on the adherence data, the PBM will assign a performance rating to that particular pharmacy.[99] The lower the performance rating, the higher the DIR Fees that are imposed on that pharmacy.[100] This is a way for the PBM to make up the difference in cost from CMS for a lower 5-Star rating. The average amount of these DIR Fees can be anywhere from $2 to $12 on each claim.[101] Further, if a pharmacy's performance rating continues to remain low, the PBM will

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[93] *Id.*; *see also supra* Part I for a real-world explanation of DIR Fees within the "low pay-slow pay-no pay" cycle.
[94] *See generally* Kate Traynor, *DIR Fees Pose a 5-Star Problem for Pharmacies*, 74 AM. J. HEALTH-SYS. PHARMACY 546 (2017).
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] *See* Traynor, *supra* note 94, at 548 (adverse events, a change in medical status, and even the use of product samples obtained from a patient's physician might also affect an assessment of adherence on the basis of pharmacy claims data."); *see also* Dayen, *supra* note 34 (quoting a local pharmacy owner as saying, "I can't stop by your house and say take your pill every day. . . . We have strategies, but we're at the mercy of the customers."); Matalavage, *supra* note 83.
[99] *See* Traynor, *supra* note 94.
[100] *See* Dayen, *supra* note 34.
[101] Gabay, *supra* note 87.

use it as a way to negotiate lower reimbursement to the pharmacy through continual DIR Fees or lower preferred network placement.[102] Failure to pay the fees will result in the pharmacy being removed from the preferred network list entirely, leaving patients to find a new pharmacy altogether.[103]

Initially, the fees were only for Medicare Part D claims, however, there is evidence that most PBMs have started using these fees on private insurance claims as well, clawing back even more money from pharmacies.[104] The PBMs argue that the savings from DIR Fees are passed onto health plans, which subsequently lowers premium and copayment costs to patients.[105] There is no evidence, however, that PBMs actually pass any revenue of DIR Fees to the health plans.[106] In fact, the evidence indicates that PBMs' DIR Fees actually increase patient costs.[107] Because PBMs are not required to report DIR Fees, they obscure the actual cost of the medication, keep MAC prices higher, and retain the profits from lower reimbursement rates to pharmacies.[108] This particularly affects patients who use Medicare Part D by forcing them into the "donut hole" faster and requiring them to pay for their medications out-of-pocket.[109] Higher drug costs also require CMS to allocate additional taxpayer dollars to fund Medicare Part D.[110]

IV. How PBM Pricing Schemes Affect Pharmacies, Pharmacists, and Patients.

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[102] Matalavage, *supra* note 83.
[103] *Id.*
[104] *See* National Community Pharmacists Association, *supra* note 88.
[105] Gabay, *supra* note 87.
[106] *See* Dayen, *supra* note 34 ("[R]etroactive DIR fees are routinely not reported to Medicare, as PBMs call them "network variable rates" or "pharmacy performance payments" and keep them for themselves.").
[107] Dayen, *supra* note 34; National Community Pharmacists Association, *supra* note 88; *see also* Gabay, *supra* note 87.
[108] *Id.*
[109] Dayen, *supra* note 34; Gabay, *supra* note 87; *see also infra* Part IV.C for a discussion on Medicare Part D cost-sharing initiatives and the Medicare donut-hole.
[110] *See* Gabay, *supra* note 87.

While rebates, reimbursement rates, and DIR Fees may seem negligible in isolation, together they create catastrophic effects on the health care system and most notably on retail pharmacies, pharmacists' wages, and patient's pocketbooks.

A. Retail Pharmacies: A Dying Breed?

Retail pharmacies are hit the hardest by PBMs in two distinct areas: (1) reimbursement rates and (2) DIR Fees. As explained above, a pharmacy's reimbursement consists of both acquisition and dispensing costs. Because of MAC and AWP price gouging, pharmacies are being reimbursed at or below acquisition costs for medications.[111] Additionally, pharmacies' dispensing fees are often reimbursed below the actual cost to fill a medication.[112] Together, low reimbursement rates hinder a pharmacy's ability to make a profit. Next, PBMs employ large DIR Fees on pharmacies, which claw back additional revenue.[113]

The combination of these two factors create an unsustainable business model, making it difficult for pharmacies to keep their lights on and doors open. For example, Cleveland Clinic has eighteen retail pharmacy locations and one specialty pharmacy. In 2017, it reported over $250,000 in DIR Fees alone, doubling the amount it paid in those fees in 2015.[114] Don Carroll, Associate Chief of Pharmacy at Cleveland Clinic noted that as the number of prescriptions its pharmacies filled increased, the DIR fees increased as well, "but . . . declining to participate in pharmacy networks of large national PBMs would cut off Cleveland Clinic's pharmacies from a large portion of its customers . . . ."[115]

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[111] *See supra* Part III.B.2 for a discussion on pharmacy reimbursement rates and MAC/AWP pricing.
[112] *See supra* Part III.B.2 for a discussion on dispensing fees.
[113] *See supra* Part III.B.3.
[114] Traynor, *supra* note 94, at 546.
[115] *Id.*

This presents a large, gaping hole in the PBM–Retail Pharmacy relationship: bargaining power. Large, corporate retail pharmacies can bargain for better placement on preferred network lists by providing higher discounts on acquisition costs (i.e., AWP/MAC prices).[116] Additionally, corporate pharmacies attached to large grocery store chains are often able to make up margins lost in pharmacy DIR Fees and low reimbursement rates through grocery or other sales.[117] This problem is further exacerbated by the fact that two of the largest corporate retail pharmacies, CVS and Walgreens, own two out of the five largest PBMs, CVS/Caremark and Envision, respectively.[118] This reinforces large-scale "vertical integration in the supply distribution chain" and allows pharmacy-owned PBMs to set their own pricing and force others to follow suit.[119]

Those "others" left out in the cold are often independent and rural retail pharmacies. Independent pharmacies lack sufficient bargaining power against PBMs.[120] This means independent pharmacies face "take-it-or-leave-it" deals; if they turn down the PBMs, they are required to turn away patients that utilize the PBMs' services.[121] But if the pharmacy accepts the deal, they're subject to huge profit losses.[122] The lack of profit from filling prescriptions sends independent pharmacies, and even large retailers, into a financial tailspin. A study in 2019 found

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[116] *See* Yoo, *supra* note 30, at 81; *see also* Aina Abell & Rachel Balick, *Behind Closed Doors: What Happens When Pharmacies Close?*, 26 PHARMACY TODAY: INNOVATIONS 23, 25 (2020) ("Pharmacies who are forced to accept contracts that pay them less per prescription than they received in the past, and also experience DIR fees and other claw backs from revenue . . . , are seeing their overall revenue from dispensing decrease, despite continuing to fill large numbers of prescriptions[.]").
[117] *See* Abell & Balick, *supra* note 116, at 24–25 ("Pharmacies, especially retailers like grocery and discount stores that operate pharmacy departments . . . depend on nonprescription revenue . . . .").
[118] Thomas A. Hemphill, *The "Troubles" With Pharmacy Benefit Managers*, REG: HEALTH & MED. 16 (Spring 2017), https://www.cato.org/sites/cato.org/files/serials/files/regulation/2017/3/regulation-v40n1-5.pdf.
[119] *See id.*
[120] *See id.* ("[I]ndependent pharmacies are looking to acquire a larger share of the PBM's "spread" to enhance their profit margins.").
[121] Causey, *supra* note 64.
[122] *See Id.*

that, from 2009 to 2015, about 9,564 (12.8%) pharmacies closed their doors.[123] The study showed that independent pharmacies suffered most of the blow. Approximately 27% of the pharmacies that closed in urban areas and 23% of the pharmacies that closed in rural areas were independent pharmacies.[124]

Even local, grocery store-backed retail pharmacies, however, are having to shutter operations. For example, California-based Raley's Supermarkets shut down twenty-seven of their nearly one-hundred locations, citing "high operating and drug costs, and low reimbursement rates from Medicare, [California State Medicaid], and private health insurers."[125] With drug prices steadily increasing, reimbursement rates remaining low, and DIR Fees at an all-time high, independent pharmacies are struggling to come up with ways to make ends meet.

To increase and diversify revenue streams, many pharmacies have begun offering different types of clinical services. These services include Medication Therapy Management (MTM) and Comprehensive Medication Reviews (CMRs), Medication Synchronization, immunizations, and adherence measures.[126] Although these services are great ideas in theory, there are several barriers to execution. First, it remains an open question whether pharmacies are properly reimbursed by PBMs for these services. One study found that most payers recognized the potential cost-saving of allowing community pharmacies to provide additional services, but had concerns about financial and legal risks. Payers recognized that if "pharmacists ha[d] the regulatory ability to provide services, then the payer organization could have negotiations as they would with a physician's

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[123] Jenny S. Guadamuz et al., *Assessment of Pharmacy Closures in the United States from 2009 through 2015*, 180 JAMA INTERNAL MED. 157 (2019).
[124] *Id.*; *see also* Abell & Balick, *supra* note 116, at 24.
[125] Abell & Balick, *supra* note 116116, at 23, 25.
[126] *See generally* Abell & Balick, *supra* note 116116, at 27; Tom Kosty, *Retail Pharmacy Clinical Services: Influence of ACOs & Healthcare Financing Model*, (June 25–27, 2015), presented at American Society for Automation In Pharmacy 2015 Midyear Conference.

practice."[127] Lack of federal provider status obstructs the pharmacy profession from providing vital services to the community and realizing additional revenue streams that would allow pharmacies to keep their doors open.[128]

Pharmacies closings often have negative implications on patient health. In rural areas in particular, pharmacists may be the only accessible health care provider for patients, which makes pharmacists absolutely vital to primary care functions.[129] Pharmacists provide several primary care functions for patients, such as counseling on adverse drug events, drug interactions, medication therapy management, adherence, and over-the-counter remedies.[130] Moreover, pharmacists often serve as the first line of triage for patients, instructing them to seek further physician consultation in an office visit, urgent care, or emergency room. These patient interactions with pharmacists can make the difference between detrimental disease progression and remission or cure.

B. Pharmacists: The Wage Wars

In order to lower overall costs associated with running a pharmacy, many pharmacies have begun a series of layoffs, hiring freezes, and decreased wages.[131] For example, in 2019, Walmart laid off about 3% of its pharmacy staff, in which about half was senior staff.[132] This has led not only to a lot of pharmacists being out of work, but increased burdens on the pharmacists that

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[127] Bradley S. Merrill et al., *Payers' Perspectives on Pharmacist-Directed Care in a Community Pharmacy Setting*, 53 ANNALS OF PHARMACOTHERAPY 916, 920 (2019).
[128] *See supra* Part II.C discussing pharmacist provider status.
[129] *See infra* Part II.D discussing pharmacists' vitality to health care and access for patients.
[130] *See infra* Part II.C discussing the importance of patient access to affordable medications and pharmacists.
[131] *See* Abell & Balick, *supra* note 116, at 27.
[132] Christine Blank, *Walmart Layoffs Impact Senior Staff*, DRUG TOPICS (July 9, 2019), https://www.drugtopics.com/view/walmart-layoffs-impact-senior-staff.

remain.[133] For example, a high-volume store that normally requires two pharmacists working simultaneously, may now only have one pharmacist working the full twelve-hour shift.[134] Similarly, a 2016 study reported that 61% of responding pharmacists found their workload to be high or excessively high and that it had increased or greatly increased over the past year.[135] The burdens and demands of the fast-paced workflow do not allow pharmacists to provide clinical benefits to patients. In fact, the above 2016 study found that increased workload infringed on the ability of pharmacists to adequately solve drug therapy problems, prevent or reduce potential errors, and spend adequate time counseling patients—all vital functions to effectively serving patients.[136]

Pharmacists wages have also been significantly cut over the years. In the late 1990s and early 2000s, the demand for pharmacists was high and the number of pharmacy schools and graduates increased rapidly.[137] Although necessary at the time, it has now led to market saturation. Rumblings across pharmacy blogs, Reddit pages, and inner circles offer proof that oversupply and lack of demand for pharmacist services has created a wage crisis for many. One Reddit user claims that, in 2016, they were offered a staff position with a corporate chain pharmacy at $58 per hour.[138] In 2017, however, that same corporate chain pharmacy was offering new graduates only $56 per

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[133] *See generally* Alexia Elejalde-Ruiz, *Union Alleges Overwork and Understaffing at CVS Pharmacies*, CHI. TRIBUNE (May 10, 2016), https://www.chicagotribune.com/business/ct-cvs-pharmacists-contract-0511-biz-20160510-story.html ("[W]hen pharmacists are constantly given more work with less help and little downtime during their long demanding shifts, this affects their performance and well-being – and it also can impact customer safety . . . .").
[134] *See id.*
[135] Fadi M. Alkhateeb et al., *Workload Perceptions of Pharmacists: Part of Changing a National Trend*, 1 SOC PHARMACY J. 104, 106 (2016).
[136] *Id.* at 107–08.
[137] Kelley, *supra* note 8, at 148; *see also* Alex Barker, *Why Pharmacists' Salaries Are Decrease: A Conspiracy Theory*, HAPPY PHARMD (Apr. 27, 2017), https://www.thehappypharmd.com/why-pharmacists-salaries-are-decreasing-a-conspiracy-theory/.
[138] *Decrease in Walgreens Pharmacist Salary?*, REDDIT (2018), https://www.reddit.com/r/pharmacy/comments/9acnfz/decrease_in_walgreens_pharmacist_salary/

hour.[139] While that example may only be a modest decrease, with pharmacy school tuition rates rapidly increasing and potential wages lowering, pharmacy education is becoming a bad investment. For example, most pharmacists graduate with an average student loan debt of $213,000.[140] While approximately 15,000 pharmacists graduate each year, the Bureau of Labor Statistics projects a negative 3% job growth for pharmacists over the next ten years.[141] What exactly are new graduates with mounting student loan debt expected to do for an adequate return-on-investment?

The culmination of these burdens leads to pharmacist burnout and patient safety concerns. One study found that 53.2% of pharmacists experience high levels of burnout.[142] Most pharmacists in the study cited emotional exhaustion, reduced personal accomplishment, and depersonalization as reasons for professional burnout.[143] Another study across all healthcare professions found that burnout can result in increased medical errors and patient safety risks.[144]

C. Patients: Hitting 'Em Where It Hurts—Their Pocketbooks

One of the most prominent consequences of PBM pricing schemes was the implementation of patient cost-sharing initiatives, particularly for older adults on Medicare. In order to make up for the costs insurance companies are losing in rebates to the PBMs, payers initiated four types of

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139 *Id.*

140 Rob Bertman, *Pharmacist Job Outlook: It's Worse Than You Thought*, STUDENT LOAN PLANNER (2020), https://www.studentloanplanner.com/pharmacist-job-outlook-growth/.

141 U.S. Bureau of Labor Statistics, Occupational Outlook Handbook: Pharmacists (2020), https://www.bls.gov/ooh/healthcare/pharmacists.htm; Bertman, *supra* note 140.

142 Mary E. Durham et al., *Evidence of Burnout in Health-System Pharmacists*, 75 AM. J. HEALTH-SYS. PHARMACY S93, S95 (2018).

143 *Id.*

144 *See id.* (citing to Louise H. Hall et al., *Healthcare Staff Wellbeing, Burnout, and Patient Safety: A Systematic Review*, 11 PLOS ONE 1 (2016)).

cost-sharing programs: premiums, copayments, deductibles, and the "donut-hole."[145] While only premiums and copayments are utilized by private insurers, Medicare Part D programs often employ all four cost-sharing strategies.[146]

The earliest two strategies employed in cost-sharing initiatives were premiums and copayments. Premiums, which have been employed for the longest, require that the patient essentially "pays-to-play." The premium is the amount the patient pays monthly or yearly in exchange for prescription and medical insurance coverage.[147] Although premiums are not unfamiliar among other types of insurance coverage, health insurance premiums have significantly risen over time. In fact, from 1999 to 2016, private health insurance premiums rose by 213%, compared to an increase in employee's wages and overall inflation at 60% and 44%, respectively.[148]

Due to patient dissatisfaction over premium increases, health plans initiated copayments to offset some of the costs. Copayments are what the patient pays out-of-pocket at the pharmacy to supplement the insurance coverage of the prescription.[149] The pricing of copayments varies dramatically and many factors influence a patient's copay. The biggest influences on copayments are a patient's premium payment, preferred or non-preferred medication, PBM tier lists, and the

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[145] Kenneth E. Thorpe, *Out-Of-Pocket Prescription Costs Under A Typical Silver Plan are Twice as High as They are in the Average Employer Plan*, 34 HEALTH AFFAIRS 1695, 1696 (2015); *see also infra* Part III.B.1 for a discussion on rebates and how they affect patient cost-sharing initiatives.
[146] *See* Thorpe, *supra* note 145.
[147] *Premium*, HEALTHCARE.GOV: GLOSSARY, https://www.healthcare.gov/glossary/premium/.
[148] Lyles, *supra* note 29, at 494.
[149] *Copayment*, HEALTHCARE.GOV: GLOSSARY, https://www.healthcare.gov/glossary/co-payment/.

patient-selected plan.[150] While a patient's copayment can be as little as a few cents, patients can also experience copayments that are thousands of dollars.[151]

Two large influences on a patient's copayment are whether they have selected a high deductible plan or are in the "donut-hole." High Deductible Health Plans (HDHPs) and the "donut-hole" are two of the newest types of cost-sharing initiatives.[152] HDHPs allow patients to exchange lower premiums for higher out-of-pocket costs up front.[153] Therefore, there is no coverage on the cost of medications until the patient pays the requisite amount for their insurance to "kick-in." HDHPs have become increasingly more popular over the years, growing from 4% in 2006 to 29% in 2016.[154] Further, high deductibles have become even higher over the years. From 2006 to 2016, the average deductible "grew from $584 to $1,478 . . . , with 51% of workers at large employers in 2016 having insurance with an annual deductible of [greater than] $1,000."[155]

HDHPs are ideal for patients who are healthy and only utilize the health plan's services seldomly or not at all.[156] This allows healthy patients to have low monthly premiums and only pay high out-of-pocket costs if they have a catastrophic health care event. Therefore, it is theoretically possible that a healthy patient would never have to pay more than the low monthly premium. Due to the favorable premium prices, however, many patients that are not healthy also

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[150] *See, e.g.*, Jess Roubal, *Deciphering Your Copay -- What Your Pharmacy isn't Telling You*, ALTO BLOG (Mar. 6, 2017), https://blog.alto.com/deciphering-your-copay-what-your-pharmacy-isnt-telling-you-aad2220787aa (discussing the different influences on patient copayments).

[151] *See also* Roland & Loftus, *supra* note 59 (discussing a patient who pays $1,250 out-of-pocket for a three-month supply of insulin).

[152] Lyles, *supra* note 29, at 494.

[153] *High Deductible Health Plan (HDHP)*, HEALTHCARE.GOV: GLOSSARY, https://www.healthcare.gov/glossary/high-deductible-health-plan/; *see also* Lyles, *supra* note 29.

[154] Lyles, *supra* note 29, at 494.

[155] *Id.*

[156] *See, e.g.*, Adam Caltado, *Think Carefully Before Signing Up for a High Deductible Health Plan*, WEALTHFRONT BLOGS (May 28, 2014).

select high deductible–high copayment hybrid plans, which leaves them with unaffordable medication prices.[157]

The last cost-sharing initiative is potentially the most confusing and unexpected to patients: the "donut-hole." The "donut-hole" is a colloquial term for a coverage gap.[158] Essentially, throughout a patient's year of coverage, they begin on one side of the donut, traveling to the other side and, when they hit the hole in the center, they lose prescription drug coverage. Patients enter the donut-hole once the health plan has paid a certain amount of money towards cost-sharing.[159] To get out of the donut-hole, however, the patient must spend a certain amount of money out-of-pocket.[160] Once the patient has reached the requisite total out-of-pocket expenditure, the Catastrophic Benefit Coverage will set in and coverage resumes.[161]

There are several major problems with the donut-hole. First, patients' biggest complaints about the donut-hole center around not knowing when they will reach it. Most patients have no idea how much their insurance has paid throughout the year; further, they have no idea how much they have to spend to get out of the donut-hole. Absent spending several hours on hold waiting for a customer service representation to assist, many patients struggle to obtain this critical information. To add more confusion, in 2019 Medicare promised to eliminate the donut-hole by 2020. Instead, Medicare began calling it the "coverage-gap" and merely supplemented donut-hole coverage slightly.[162]

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[157] Lyles, *supra* note 29, at 494.
[158] *Donut Hole, Medicare Prescription Drug*, HEALTHCARE.GOV: GLOSSARY, https://www.healthcare.gov/glossary/donut-hole-medicare-prescription-drug/.
[159] *Costs in the Coverage Gap*, MEDICARE.GOV, https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap.
[160] *See id.*
[161] *See 2021 Part D Standard Plan Cost-Sharing*, CENTER FOR BENEFITS ACCESS – NATIONAL COUNCIL ON AGING (Aug. 2020), https://d2mkcg26uvg1cz.cloudfront.net/wp-content/uploads/part-d-cost-sharing-chart-2021.pdf [Hereinafter *2021 Part D Standard Plan Cost-Sharing*].
[162] *Id.*

Second, to add insult to injury, the price that health plans use to determine if the patient has met the upper limits to send them into the donut hole is based on the drug's list price.[163] In reality, however, the insurance company is receiving heavy subsidies in rebates from the PBM and manufacturers on each prescription. Thus, the price that is calculated to push the patient into the donut hole is higher than what the insurance company has actually paid.[164] A study conducted in 2020 found that if health plans based beneficiary cost-sharing initiatives on the rebate price, rather than the list price, annual patient out-of-pocket costs would reduce, on average, by $91.[165] The study also found that "[t]wenty percent of beneficiaries would see annual out-of-pocket savings of more than $100, . . . five percent would see annual savings of more than $500, and nearly one percent would see annual savings of more than $1,000."[166]

Lastly, donut-hole plans are often combined with high deductible and copayment plans in the name of lowering patient premiums.[167] This means that throughout the year of coverage, a patient could theoretically pay a high deductible, high copayments based on non-preferred or brand name medications, out-of-pocket costs towards the donut hole, and then continue to pay copayments after reaching the Catastrophic Benefit Period. Over a coverage year, many patients pay thousands of dollars in cost-sharing pricing schemes. For example, the 2021 Medicare Part D Proposed Standard Cost-Sharing Plan includes all three initiatives. The patient has an initial deductible of up to $445; a coverage period that includes a 25% copayment on all prescriptions and a payer upper limit of $3,097.50. Once the payer reaches the upper limit, the patient is in the

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[163] Erin Trish et al., *How Would Sharing Rebates at the Point-of-Sale Affect Beneficiary Cost-Sharing in Medicare Part D?*, U.S.C. LEONARD D SCHAEFFER CTR. HEALTH POL'Y ECON. 1–2 (Mar. 17, 2020), https://healthpolicy.usc.edu/research/how-would-sharing-rebates-at-the-point-of-sale-affect-beneficiary-cost-sharing-in-medicare-part-d/.
[164] *Id.*
[165] *Id.* at 5.
[166] *Id.*
[167] *See 2021 Part D Standard Plan Cost-Sharing*, *supra* note 161.

coverage gap, during which they will pay up to $5,183.75 in copayments. Finally, once a patient reaches a total out-of-pocket cost of $6,550, the Catastrophic Benefit Period takes effect and coverage resumes.[168]

While increased cost-sharing schemes have huge impacts on a patient's purse strings, they can also significantly affect patient health. A 2015 poll found that about 25% of 648 respondents "reported that they or another family member did not fill a prescription in the last year because of cost[s]."[169] Further, patients prescribed brand-named medication were less likely to adhere to their regimen compared to those prescribed a less costly generic medication.[170] Lack of adherence to medication regimens has been shown to lead to worse health outcomes and increased health care costs overall. In fact, it is estimated that nonadherence contributes to "$105 billion in avoidable health care costs annually."[171]

V. Resolutions

A. Previous Federal Action on PBMs

In recent years, Congress, the public, and former President Trump have focused increasing attention on PBM unethical practices. In the late 1990s and early 2000s, the Department of Justice (DOJ) first attempted to regulate PBM practices. The DOJ accused PBMs of violating the Federal Anti-Kickback Statute (AKS) and the False Claims Act while negotiating rebate agreements with manufacturers and failing to disclose such agreements to the government.[172] The AKS makes it a criminal offense to "'knowingly and willfully' offer, pay, solicit, or receive any 'remuneration' to

[168] *Id.*
[169] Kesselheim., *supra* note 62, at 864.
[170] *Id.*
[171] *Id.*
[172] Gore, *supra* note 41, at 306.

induce referrals of items or services . . . under the federal health care programs."[173] The alleged violation stemmed from the PBM practice of placing certain medications higher on formulary lists based on the negotiated rebate instead of considerations such as the safety and efficacy of the medication.[174]

These actions against PBMs, however, mostly resulted in private settlements with the government.[175] This is because the federal government concluded that PBMs' rebate practices are seemingly covered under the discount safe harbor provision of the AKS.[176] The discount safe harbor protects a federal health care program provider (i.e., manufacturer, physician or pharmacist) from anti-kickback liability when providing a discount or reduction in price for an item or service.[177] Discounts are defined to include rebates "whose terms are 'fixed and disclosed in writing to the buyer at the time of initial purchase to which the discount applies, but which is not given at the time of sale.'"[178] While PBMs are not explicitly listed as covered providers under the safe harbor provisions, it has become clear over the years that the federal government views PBM rebates as falling within the statutory exemption.[179]

A. Recent Presidential Proposals

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[173] Greg Radinsky, *The Spotlight on PBMs: Federal Enforcement of the Anti-Kickback Statute on the Pharmaceutical Benefit Management Industry*, 36 J. HEALTH L. 213, 221 (2003).
[174] *Id.*
[175] *See* Press Release, U.S. Dep't of Justice*, AstraZeneca to Pay $7.9 Million to Resolve Kickback Allegations* (Feb. 11, 2015), https://www.justice.gov/opa/pr/astrazeneca-pay-79-million-resolve-kickback-allegations ("AstraZeneca agreed to provide remuneration to Medco Health Solutions . . . in exchange for Medco maintaining Nexium's 'sole and exclusive' status on certain Medco formularies . . . . The United States alleged that AstraZeneca provided some or all of the remuneration to Medco through price concessions on [other medications] . . . .").
[176] *See* Gore, *supra* note 41, at 307.
[177] Regina S. Johnson, *PBMs: Ripe for Regulation*, 57 FOOD & DRUG L.J. 323, 360 (2002); *see also* Gore, *supra* note 41, at 308.
[178] Gore, *supra* note 41, at 308 (quoting 42. C.F.R. § 1001.952(h)(4) (2018)).
[179] *See* Johnson, *supra* note 177.

Before the 2016 election, focus shifted towards skyrocketing drug prices when pharmaceutical companies such as Valeant raised drug prices by forty-eight times overnight.[180] If there was one thing the Democrats and Republicans could agree on, it was that drug prices were too high. Throughout much of his campaign, President Trump promised future legislation on drug pricing and in 2018, he began zeroing in on PBMs. Trump proposed permitting PBMs and manufacturers to continue to negotiate rebates freely while mandating that one-third of those rebates be directly passed onto the patients at the point-of-sale.[181] Trump also proposed revising the current AKS to include restrictions on rebate practices.[182] The Trump solution, however, also proposed two new safe harbors: (1) point-of-sale reductions in price offered by drug manufacturers directly to patients and (2) PBM service fees for claims adjudication.[183]

The proposed regulations were intended to encourage up-front discounts for patients, rather than cost-saving strategies that may or may not trickle down into lowered premiums.[184] The White House formally proposed the plan in February 2019. Trump, however, rescinded the proposal in its entirety in July 2019.[185] While White House officials pointed to pending legislation as the excuse, many speculate that aggressive lobbying campaigns from two of the largest PBMs—CVS and OptumRx—were ultimately responsible for the plan's demise.[186]

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[180] *See generally* Melody Petersen, *How 4 Drug Companies Rapidly Raised Prices on Life-Saving Drugs*, L.A. TIMES (Dec. 21, 2016), https://www.latimes.com/business/la-fi-senate-drug-price-study-20161221-story.html
[181] Seeley, *supra* note 45, at 4.
[182] Gore, *supra* note 41, at 310.
[183] *Id.* at 311.
[184] *See id.* at 312.
[185] *Id.* at 311–12.
[186] *Id.* at 312; *see also* Stephanie Armour & Joseph Walker, *Trump Administration Moves to Curb Drug Rebates in Medicare, Medicaid*, WALL ST. J. (Jan. 31, 2019), https://www.wsj.com/articles/u-s-proposes-curbing-drug-rebates-in-some-medicare-medicaid-plans-11548971322; Stephanie Armour, *Trump Administration Drops Plan to Curb Drug Rebates*, WALL ST. J. (July 11, 2019), https://www.wsj.com/articles/trump-administration-drops-plan-to-curb-drug-rebates-11562845155.

As the 2020 election etched eerily closer, and the COVID-19 pandemic mandated a hard look at our country's health care system, there was renewed hope that legislative efforts on drug pricing would be revitalized. On July 24, 2020, President Trump issued three executive orders regarding drug pricing practices.[187] Those orders took aim at high drug prices by: (1) lowering the cost of insulin, (2) allowing the international importation of medications, and (3) eliminating kickbacks to middlemen (PBMs). First, Trump ordered Medicare and Medicaid to purchase insulin at Federally Qualified Health Centers (FQHCs) 340B prices, which permits insulin and other medications to be purchased at wholesale prices.[188] Second, Trump ordered that patients be permitted to import safe prescription medication from Canada or European countries at a lower price.[189] Lastly, Trump ordered that rebates be passed onto patients at the point of sale, the elimination of discount safe harbor protection in the AKS, and for new point-of-sale discount safe harbors.[190]

On September 13, 2020, President Trump issued a fourth executive order addressing manufacturer drug pricing.[191] That proposal aimed to lower drug prices based on "The Most-Favored Nation Price." The order defines the most-favored nation price to mean

> the lowest price, after adjusting for volume and differences in national gross domestic product, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product.[192]

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[187] Exec. Order No. 13,937, 85 Fed. Reg. 45,755 (July 24, 2020); Exec. Order No. 13,938, 85 Fed. Reg. 45,757 (July 24, 2020); Exec. Order No. 13,939, 85 Fed. Reg. 45,759 (July 24, 2020).
[188] Exec. Order No. 13,937, 85 Fed. Reg. 45,755 (July 24, 2020).
[189] Exec. Order No. 13,938, 85 Fed. Reg. 45,757 (July 24, 2020).
[190] Exec. Order No. 13,939, 85 Fed. Reg. 45,759 (July 24, 2020).
[191] Exec. Order No. 13,948, 85 Fed. Reg. 59,649 (Sept. 13, 2020).
[192] *Id.*

In effect, the executive order prevents Medicare Part D patients from paying more out-of-pocket than the most-favored-nation price for that particular medication.[193]

There are several issues with and rebuttals to this executive action. In December 2019, the House Democrats proposed similar legislation based on international pricing, which Trump vetoed.[194] Many industry leaders, and even Republican supporters, have criticized the action for predicating prices on international standards. For industry leaders, such as Stephen Ubl, the chief executive of PhRMA, the concern is that the policy is "unworkable" and "will give foreign governments a say in how America provides access to treatments . . . ."[195] In contrast, many Republicans are concerned that adopting drug prices from other countries is "effectively importing socialism."[196]

The rule was quickly challenged in December 2020 in a Maryland District Court by PhRMA.[197] While the rule was set to go into effect on January 1, 2021, the District Court judge temporarily restrained the order.[198] The court held that the executive order was in violation of federal law because it bypassed the notice and comment rule-making procedures without good cause.[199]

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193 *Id.*
194 Sheryl Gay Stolberg, *Trump Issues Expansive Order Aimed at Lowering Drug Prices*, N.Y. TIMES (Sep. 13, 2020), https://www.nytimes.com/2020/09/13/us/politics/trump-executive-order-drug-prices.html.
195 *Id.*
196 *Id.*
197 Joshua Cohen, *Court Injunction Temporarily Upends Most Favored Nation Policy to Lower Prices of Medicare Part B Drugs*, FORBES (Jan. 2 2021), https://www.forbes.com/sites/joshuacohen/2021/01/02/court-injunction-temporarily-upends-most-favored-nation-policy-to-lower-prices-of-medicare-part-b-drugs/?sh=70fbafa7505b.
198 Ass'n of Cmty. Cancer Ctr. v. Azar, No. CCB-20-3531, 2020 U.S. Dist. LEXIS 241732, at *40–41 (D. Md. Dec. 23, 2020).
199 *Id.*

At the same time, the Office of Inspector General (OIG) began working on regulatory efforts to amend the AKS rebate safe harbor protections.[200] The final rule first excluded PBMs from the safe harbor provisions regarding reductions in price to Medicare Part D plan sponsors.[201] Notably, however, the final rule did not include the same action for Medicaid plan sponsors.[202] Next, the rule created new safe harbors that exempted point-of-sale reductions in price. The rule states that reductions in price from manufacturers to plan sponsors under Medicare Part D or Medicaid do not violate the AKS if (1) the reduction in price was set in advance; (2) the "full value of the . . . price is provided to the dispensing pharmacy by the manufacturer . . . through point-of-sale chargeback[s]"; and (3) "the reduction in price [is] completely reflected in the price of the . . . product at the time the pharmacy dispenses it to the beneficiary."[203]

Ideally, this rule should protect pharmacies from receiving low reimbursement rates from either the plan sponsor or patient copayments. The rule recognizes, however, that this is unlikely to happen.[204] Thus, HHS promulgates that the pharmacies will need to be "'made whole' through the chargeback process," but offers no formal process for ensuring pharmacies receive the chargebacks from the wholesalers, manufacturers, or PBMs.[205]

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[200] *See generally* Andrew D. Ruskin & Margaret L. Power, *OIG Finalizes Rebate Rules: Removal of Safe Harbor Protections for Rebates and Creation of New Safe Harbors for Other Discounts and Service Fees*, NAT'L L. R. (Dec. 2, 2020).
[201] *Id.*
[202] *Id.*
[203] Department of Health and Human Services, Office of Inspector General, HHS, Fraud And Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals And Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 85 Fed. Reg. 76,666, 76,731 (Nov. 30, 2020) (to be codified at 42 C.F.R. 1001.952(cc)) [hereinafter OIG Final Rule].
[204] Ruskin, *supra* note 200.
[205] *Id.*

Lastly, the rule created a fixed fee safe harbor that allows PBMs to set a flat, fixed fee for claims adjudication and service fees.[206] The final rule was to take effect on January 29, 2021, which would have required PBMs to negotiate these prices for contracts to take effect in 2022.[207]

The fate of Trump's executive orders and regulatory action became unknown, however, when newly-elected President Joe Biden took office on January 20, 2021. Within hours of ascending the Presidency, President Biden executed a flurry of executive orders and memorandums—many aimed specifically at reversing Trump-era actions.[208] Among these orders, President Biden required a regulatory freeze pending review on all agency actions that were (1) issued after noon on January 20, 2021; (2) not yet published in the *Federal Register*; and (3) had been published in the *Federal Register*, but had not yet taken effect.[209] President Biden effectively halted all regulatory action, including the final OIG rules, from taking effect until properly reviewed and approved by the new administration.

Although we will have to wait to see what President Biden ultimately will choose to do with Trump's executive orders, his campaign website offers some insights concerning actions he may take to address high drug prices. According to the website, Biden intends to propose that Congress repeal the law that bars CMS from directly negotiating drug prices with the manufacturers for Medicare patients. This would effectively allow the federal government to bypass PBMs for rebate negotiations and formulary management.[210] Biden also suggests limiting

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206 *Id.*
207 OIG Final Rule, *supra* note 203.
208 Elizabeth Janowski, *Here's the Full List of Biden's Executive Actions So Far*, NBC NEWS (Jan 25, 2021), https://www.nbcnews.com/politics/white-house/here-s-full-list-biden-s-executive-actions-so-far-n1255564 (last visited Feb. 16, 2021).
209 Memorandum for the Heads of Executive Department Agencies, 86 Fed. Reg. 7424 (Jan. 28, 2021); *see also* Ronald A. Klain, *Regulatory Freeze Pending Review*, WHITEHOUSE: PRESIDENTIAL ACTIONS (Jan. 20, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/.
210 BIDEN HARRIS CAMPAIGN WEBSITE: HEALTHCARE, https://joebiden.com/healthcare/ (last visited Nov. 6, 2020).

aggressive pricing for newly launched products. He proposes that the Department of Health and Human Services (HHS) establish an independent review board to assess the value of the drug and recommend a reasonable price.[211] Lastly, Biden intends to allow Americans to purchase prescription drugs from other countries.

While these efforts will be a good first step to lowering drug prices, they will not control PBMs' aggressive pricing schemes or lack of reimbursement to pharmacies. Thus, while many Americans on Medicare may benefit from lower copays and drug prices, Americans utilizing private insurers and Medicaid will likely be left to pick up the tab in cost-shifting measures from PBMs and manufacturers. Moreover, pharmacies will continue to face large DIR fees and low reimbursement rates through PBM claim adjudication.

A. Future Regulatory and Legislative Efforts

While enhanced price regulation of the pharmaceutical industry is a good start, the federal government needs to regulate the PBMs as well to create a system that will permanently shrink drug costs. The failure to regulate the PBMs permits them to lie, cheat, and steal from the manufacturers, pharmacies, insurance companies, and, ultimately, patients. The incoming administration has an opportunity to mold a new regulatory and legislative scheme to effectively control drug pricing.

The quickest way to remedy PBMs' predatory price gouging is for the executive branch to regulate rebate practices with rule-making. First, President Biden should absolutely approve the final OIG rule regarding AKS safe harbors. While the rule may not be the perfect solution, it's a step in the right direction. By carving out PBMs from the discount safe harbors, the existing AKS rules prohibit PBMs from leveraging formulary placement based on the rebate. Formulary

[211] *Id.*

management would, instead, be based on therapeutic considerations, such as safety, efficacy, and cost-benefit analyses. The OIG rules also allow for PBMs to negotiate rebates so long as there is adequate transparency. This would ensure that cost savings through rebate negotiations are actually passed on to patients and health plans. A huge pitfall of the OIG rules, however, is that pharmacy reimbursement is still not guaranteed.

Next, CMS must remove the provisions that allow PBMs to implement DIR Fees. As mentioned in Part III, CMS adopted DIR Fees to obtain a better understanding of the actual costs of prescription drugs post-sale.[212] DIR Fees have been utilized, however, to claw back additional money from pharmacies on filled prescriptions. Thus, in conjunction with Congressional action against PBM formulary management as discussed below, DIR Fees will no longer be necessary for obtaining the actual costs of prescription drugs. Eliminating DIR Fees is essential to stopping PBMs from clawing back additional money from the pharmacy after the point of sale.

While executive branch regulatory reform is needed to control PBM practices, Congressional action is also required. First, President Biden has proposed that Congress repeal the law that bars the federal government from negotiating rebates with the manufacturers directly. This is an absolutely necessary step to decrease PBM power. Not only would such reform leave formulary management to the federal government, it would provide greater prescription drug cost transparency. Allowing the federal government to negotiate drug prices will increase top-down transparency and create a predictable financial landscape for pharmacies.

Congress also should expand upon the executive branch's regulatory efforts to eliminate DIR Fees. While DIR Fees were initially created by CMS to obtain accurate pricing information, PBMs have since utilized DIR Fees to apply hidden fees to pharmacies and engage in predatory

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[212] *See supra* Part III.B.3 discussing the history and background of DIR Fees.

audits.[213] While some audits are necessary to ensure accurate claims adjudication and dispensing, most PBM auditing practices are schemes to realize larger PBM profits. Congress, therefore, should enact legislation concerning current auditing practices that carefully balances the PBM interest in ensuring correct claims adjudication with the pharmacy interest in retaining profits from selling prescriptions. For example, providing pharmacies a way to appeal DIR Fees or limiting the types of audits PBMs can perform may yield the best results for both parties.

Next, Congress should require that PBMs pass 90–100% of any rebate through to insurance companies and ensure the enforcement of that law by enaction legislation that demands strict transparency rules between PBMs and their clients. Such laws would allow insurance companies to realize the full benefits of the rebates provided by manufacturers. Thus, patient cost-sharing measures, such as premiums, copayments, and high deductible plans, would be reduced or obsolete in some cases. Deemphasizing rebates and negotiation as a means for competition between manufacturers will drive competition through scientific innovation and, therefore, yielding optimal clinical results for patients.

Fourth, Congress needs to attack PBMs predatory reimbursement rates to keep pharmacies afloat. As a first step in that endeavor, Congress should eliminate preferred pharmacy network negotiations. Preferred pharmacy networks leave pharmacies at a disadvantage by requiring a discount on acquisition costs at about 12–15%.[214] Thus, elimination of these take-or-leave-it deals would allow pharmacies to sell their products at a traditional mark-up. Some may argue that this will result in increased premium payments to patients. This is exactly why the 90% rebate pass

[213] *See supra* Part III.B.3 discussing the history and background of DIR Fees.
[214] *See supra* Part III.B.2 discussing pharmacy reimbursement rates.

through requirement is absolutely necessary to create a workable system. So long as payers fail to receive adequate rebates from PBMs, they will short pharmacies on their reimbursement rates.

To ensure that pharmacies are guaranteed their mark-up price, Congress also needs to implement a system in which PBMs are required to update their MAC lists for generic medications in real time. Recall from Part III that PBMs are slow to correct MAC pricing when manufacturers raise the prices on generics.[215] This causes the pharmacy's acquisition costs to become substantially higher than MAC and, therefore, the pharmacy loses money on each generic prescription filled. Requiring that PBMs provide transparent, updated MAC lists will allow pharmacies to fill generic medications from manufacturers that yield the highest profits.

Lastly, Congress should grant pharmacists federal provider status under Medicare and Medicaid. Provider status will ensure that pharmacists are able to provide more immunizations, POC testing (COVID-19, rapid flu test, rapid strep test), disease management services, streamlined refills, contraceptives, and additional primary health care services. Pharmacists ought to be properly reimbursed from Medicare for the clinical services they provide. This change would also allow PBMs and insurance companies to shift cost-burdens associated with physician office visits to the pharmacies. Most importantly, this will provide patients with increased access to health care providers.

VI. Conclusion

As drug costs continue to rise and people continue to get sicker, America can no longer stand idly by and watch the system crash. As for Jeff Olson, he hopes to get off the "Low Pay-Slow Pay-No Pay" ride as soon as possible. His biggest worry if the Ferris Wheel keeps spinning? The patients and pharmacists. When asked about the future of community pharmacy, Jeff replied:

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[215] *See supra* Part III.B.2 discussing PBMs MAC lists.

> The PBMs are not here for patient care—they're here for profit. This model only benefits one group—the PBM. If this system doesn't end . . . we're going to see [an increase] of another 2,000–4,000 rural [community] pharmacies closing. Patients will be forced to either use mail order or travel up to 40 miles to an urban area to find a pharmacy. . . . The only pharmacies that will survive this are those that use enhanced [clinical] services.

Jeff realizes that if things do not change with the current PBM structure, health care access for many patients will be extremely limited. In the meantime, Jeff plans to continue to offer high level and innovative clinical services to bring in additional revenue to keep his doors open for as long as possible. He hopes that these clinical services will provide meaningful and exciting work to pharmacists.

In thinking about the effect PBMs have on the pharmacy profession landscape, Jeff questions where all the new pharmacy graduates will go: "[Pharmacy] students are graduating with huge amounts of debt and no way to pay for it—it's an incredible disservice to new pharmacists." Even in his own pharmacy he has seen these limitations play out. For example, Jeff explains his lack of ability to keep up with providing enhanced services due to low pharmacist staff numbers. Jeff recognizes, however, that he also cannot afford to pay additional pharmacists due to the money he loses from PBMs.

Even though the system seems to be working against him, Jeff says he will continue to keep fighting for patients, pharmacists, and pharmacy owners. While Jeff's story is the reality for many other pharmacy owners, it does not have to continue to be. Implementing regulatory and legislative reform against PBMs in three key areas—rebates, reimbursement rates, and DIR Fees—will create meaningful change in the life of pharmacies, pharmacists, and patients.