The Price of Insulin: Who Gets to Decide?

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

According to the Commonwealth Fund, the U.S. ranks as the worst in critical areas of healthcare among 10 developed countries. These areas include preventing deaths, access to quality treatment, and consistent treatment among gender, income, and location (Blumenthal, 2024). Many people in the U.S. are deterred from insurance based on cost, barricading them from receiving vital treatments. According to Rakshit et al. (2024), 28 percent of people reported delaying healthcare based on cost in 2022. With out-of-pocket prices for drugs also soaring, people are unable to take care of their essential health needs. Policy and technology are at the forefront of improving healthcare accessibility. By effectively involving the government in drug sales and enacting more inclusive policies, crucial drugs can be more accessible for both the insured and uninsured.

For people with diabetes, inaccessibility to vital drugs often causes delay of treatment and rationing. Diabetes affects roughly 38.4 million people of all ages in the United States, accounting for 11.6 percent of the population (CDC, 2021). Specifically, around 1.7 million adults aged 20 or older are diagnosed with type 1 diabetes. Type 1 diabetes mellitus (T1DM) is an autoimmune disease that halts insulin production in the body, a hormone that is vital for food digestion and glucose intake (De Meyts, 2000). Without insulin secretion in the body, glucose is unable to enter cells, leading to a buildup of ketones in the bloodstream, also known as ketoacidosis. This can lead to side effects such as increased urination, weakness, vomiting, and stomach pain. When untreated, ketoacidosis can lead to loss of consciousness and death (Bullard, 2018).

To counteract the lack of production of insulin, the management of T1DM primarily relies on insulin replacement therapy, administered through insulin injections or pumps up to 4 or

5 times per day. However, vital insulin usage is often unattainable to patients, especially those in vulnerable populations. According to the Health Care Cost Institute, there has been a 184% increase in insulin prices in the United States from 2012 to 2021, with a 30-day supply increasing from $271 to $499. This pattern was shown in both long acting and fast acting types of insulin (Gordon, 2023). This increase in price makes it harder for insurances to cover the whole cost, resulting in high out-of-pocket costs for patients. In 2019, the out-of-pocket price for a month of insulin for people with insurance was $63 per fill (Schwarz, 2023). T1International found that one in four diabetics in the US reported intentional underuse and rationing of insulin in order to mitigate the cost of the hormone. USA respondents reported the highest percentage of insulin rationing of all high income countries surveyed, with only 6.5% of patients rationing insulin among the other high income countries (T1International, 2018).

The US government has tried to counteract the increase in prices through policy changes that aim to place checks on drug manufacturers and protect those under Medicare insurance. However, these attempts have historically failed and the newer policies being enacted, specifically the Inflation Reduction Act of 2022, have not done much to remedy past issues. The Inflation Reduction Act fails to make insulin accessible for type 1 diabetics by not holding pharmaceutical business managements (PBMs) accountable for their role in increasing the price of insulin. In this paper, I will first provide an overview of the drug distribution process and the role of PBMs, literature on different insurance coverages used in the US, the failure of Medicare Part B and D in lowering insulin prices, and the introduction of the Inflation Reduction Act as a solution to high insulin prices. Then, I will analyze the current IRA policy to show the omission of equitable coverage and proper accountability of those driving insulin prices up. Through this analysis, I find that those uninsured by Medicare are consistently excluded from the language of

the IRA and that PBMs are not being monitored thoroughly. Finally, I will end with a discussion of why the IRA contains these oversights and what can be done to counteract the high insulin prices we continue to experience.

Literature Review

The manufacturing and distribution process for insulin is not highly regularized, with middlemen called pharmaceutical business managements determining the price that patients pay for drugs at the end of the production line. PBMs operate at the center of the distribution chain, acting as middlemen between manufacturers and patients and receiving a percentage of the payments made for prescription drugs (Van Nuys, 2022). An overview of the drug distribution structure is detailed in **Figure 1.**

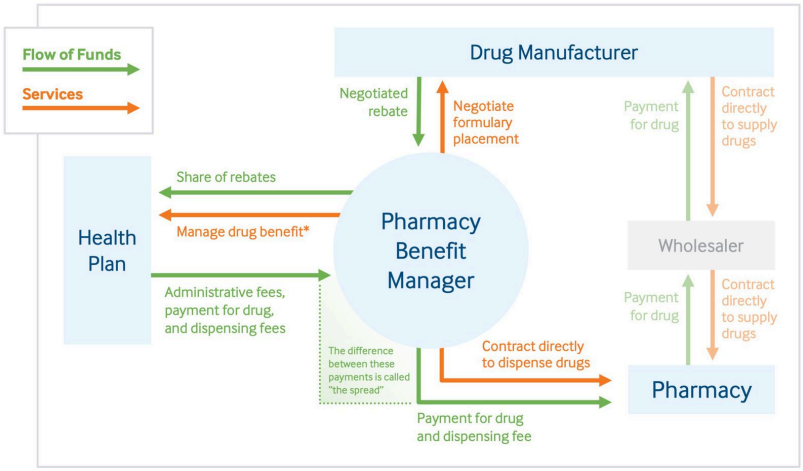

Figure 1: Interaction Scheme of Drug Distribution Process (Martin, 2025)

PBMs negotiate with drug manufacturers to set prices and determine patients' access to certain medications, all while contracting with pharmacies to participate in networks (Martin, 2025). The financial incentives of PBMs are based on a drug's average wholesale price (AWP), which is the suggested "list price" given by drug manufacturers for retail before any of the negotiations between PBMs and pharmacies are applied ("Glossary of Drug Pricing Terms", 2024). PBMs

negotiate rebate and fee rates through their group purchasing organizations (GPOs), which are entities that combine the purchasing power of multiple PBMs in negotiations involving drug sales (FTC, 2024). These negotiations typically involve the private companies operating Medicare Part B plans and PBMs negotiating rebates in exchange for favorable formulary placement or for waiving utilization management tools, such as prior authorization. In this process PBMs collect part of these rebates and decide how much savings are passed to insurers, pharmacies, or patients. The three dominant PBMs are Express Scripts (owned by insurer Cigna), CVS Caremark (part of CVS Health, also owns insurer Aetna), and OptumRx (a subsidiary of insurer UnitedHealth Group) (Van Nuys, 2022). In both the GPOs and the contracting of pharmacies, PBMs are able to extend their influence and power over drug distribution using vertical integration, having control and connections to pharmacies and insurers involved in negotiations. This presents a particular concern for smaller pharmacies and insurers, as PBMs are more likely to contract the pharmacies and insurers they are owned by or connected to. Figure 2 shows the vertical integration taking place between PBMs, insurers, and pharmacies in 2024.

Figure 2: Vertical Integration of Insurers, PBMs, and Pharmacies in 2024 (Fein, 2024)

Both enacted in 1965, Medicare and Medicaid have been the U.S. government's main response to gaps in healthcare coverage. Medicare is a health insurance program exclusively to those 65+ years of age and those with certain disabilities, permanent kidney failure, and ALS. The standard coverage plan is Original Medicare (Part A and Part B) with the option to buy Medicare Supplemental Insurance, also known as Medigap, from a private insurance company. Medigap helps with a client's out-of-pocket payments, including copayments, coinsurance, and deductibles. Part A and B cover hospital insurance and medical insurance, including coverage of hospital stays, hospice care, preventative treatment, and doctor's visits (Medicare, n.d.). Medicaid is a joint federal and state program to cover medical costs for people with low income. The federal government determines the general rules of the program, while each state runs the program, with eligibility and benefits varying from state to state (*What's the difference between Medicare and Medicaid?*, 2022). There are several terms to know when discussing insurance that will be mentioned further in the paper: premiums, coinsurance, copayment, and deductibles. A premium is the monthly amount the client pays for coverage. Coinsurance is the percentage of costs the client pays for covered services, which, for Medicare Part B, constitutes 20 percent (French & De Pietro, 2024). A copayment is a fixed fee the client pays for a covered medical expense. A deductible is the amount the client pays for covered healthcare services before Medicare starts to cover the costs (How Much Does Medicare Cost?, n.d.). Compared to Medicare and Medicaid, private insurances have higher premiums and deductibles, but much of the plan is covered by employment, which can offset the costs. A monthly premium for Medicare Part B is usually around $185, whereas the premium for private insurance can range from $364 to $488 depending on the plan purchased (Plemons, 2024).

Medicare attempts to lower drug prices and bring about more accessible healthcare through Medicare Part B and D. However, Medicare frequently underestimated the coverage necessary for increasing insulin costs, leading to the underpayment to pharmacies to provide insulin to patients. This oversight increased the out-of-pocket costs for Medicare enrollees and further embedded inequity into insulin sales. Medicare Part B changed the reimbursement process for 20 infused drugs, including pump-delivered insulin. The reimbursement process was flawed, with Medicare overpaying pharmacies for some infused drugs while underpaying for insulin consistently, as shown in Table 1 (Brown-Georgi, 2020). With a lack of coverage of pump-delivered insulin, large suppliers stopped providing it to beneficiaries, making it difficult for patients to fill their prescription.

Table 1: Medicare Reimbursement in Q4 2015 (Adapted from Brown-Georgi, 2020)

	Infused insulin (per 50 units)	Infused milrinone lactate (per 5 mg)
Average cost to pharmacies	$7.91	$2.53
Medicare payment to pharmacies	$2.80	$51.58
Impact on pharmacies	65% underpayment	1939% overpayment

Medicare Part D is part of Medigap and provides prescription drug coverage. Under Medicare Part D, Medicare subsidizes premium costs and provides additional premiums and subsidies for low-income enrollees. Part D also established five drug tiers, providing lower copays or coinsurance for preferred generics and brand-name drugs (Cubanski et al., 2018). In the 2023 original plan, there are four stages of drug coverage: the deductible phase, initial coverage phase, coverage gap phase, and catastrophic phase. With increasing cost of total prescription drug costs, the enrollee pays for less of the drug costs, with Part D and

manufacturers covering the rest of the prices at certain cost thresholds. These four phases and their thresholds are detailed in Figure 3.

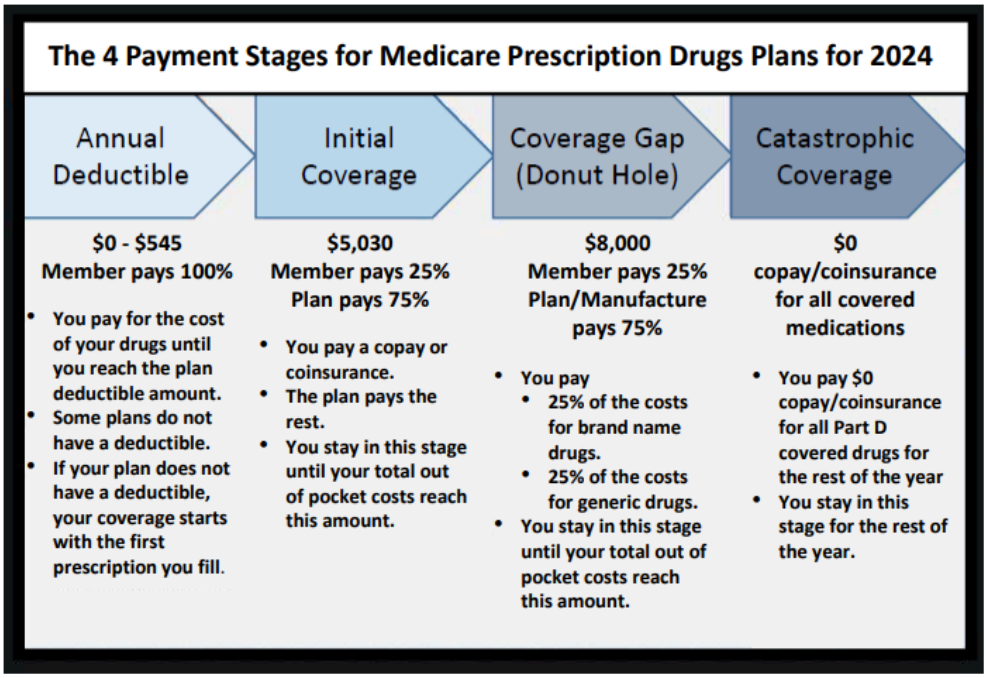

Figure 3: The Four Payment Stages of Medicare Part D ("Medicare Part D Coverage Stages", 2023)

Without an out-of-pocket cost cap, the cost of insulin products drastically rises among the different phases. During the initial coverage phase, the cost for enrollees was usually a $47 copayment per prescription as a preferred Tier 3 drug. As the enrollee quickly progresses through the initial coverage phase, the coverage gap phase increases the out-of-pocket payment substantially through the 25% coinsurance, which leads to enrollees paying $100 or more out-of-pocket per monthly prescription (Cubanski et al., 2020).

The Inflation Reflection Act of 2022 was introduced by the Biden-Harris administration to remedy Medicare Part B and D. The IRA promises to "lower prescription drug costs, make health insurance more affordable, and make the economy work for working families" (HHS, 2023). The notable benefits include an out-of-pocket insulin cap at $35/month per covered

prescription, access to recommended adult vaccines without cost-sharing, a yearly cap on out-of-pocket prescription drug costs in Medicare, and expansion of the low-income subsidy program under Medicare Part D (CDC, 2024).

Methods

My chosen framework for this project is policy analysis. I will analyze the failures of the Inflation Reduction Act. I will couple this policy analysis with trends of insulin prices before and after pharmacy acquisition and for the insured vs. uninsured. I will use policy language to point out the populations that are covered coupled with demographic statistics of who is affected. I will cite the policy texts for their language, academic journals that analyze social and economic effects of policies, news articles that portray social effects, advertisements and lobbying efforts, and pharmaceutical industry statements.

Analysis

The Inflation Reduction Act of 2022 aims to fix the mistakes of Medicare Part B and D and place checks on manufacturers and PBMs. However, the IRA fails to protect those not uninsured by Medicare. Multiple sources of cost analysis shows that the IRA counteracted the pricing debacles that resulted in the underpaying of insulin. Specifically, the IRA's insulin cap, where they set coinsurances and copays for insulin up to $35 a month provided the most economic relief. A study by Sayed et. al (2023) contends that if the IRA insulin cap had been in effect before 2020, Medicare beneficiaries could have saved $761 million from 2020 to 2023. The changes to Medicare Part B and D are restricted solely to those insured with Medicare, excluding those with Medicaid, private insurance, or no insurance at all. This caveat opens up the ability for pharmacies to drive up prices for out-of-pocket payments, knowing that Medicare will cover an increase in price to accommodate the $35 a month cap. The people who are left most

vulnerable to this out-of-pocket cap are the uninsured and those covered by Medicaid. Among insulin users, those covered by Medicare constitute a majority of 52 percent, whereas 33% are privately insured, 12% are on Medicaid, and 2% are uninsured. All three of these populations are vulnerable to high out-of-pocket costs, with uninsured patients being the most exposed (Finnegold & Sayed, 2022). Because Medicaid regulations are run on the state-level, it varies from state to state whether an insulin cap is required. There are 26 states, along with the District of Columbia, that have capped insulin copayments for insurance plans. These caps range from $25 to $100, averaging out at a cap of $47. The states with insulin caps above this mean value are Virginia, Vermont, Louisiana, Illinois, Delaware, Colorado, and Alabama (*State Insulin Copay Caps*, n.d.). The lack of consistency among Medicaid policies and the exclusion of those uninsured in the IRA insulin cap policy sets up vulnerable populations to experience increasingly more expensive out-of-pocket payments with little protection on a federal level. In this way, the insulin cap seems to benefit Medicare by ways of "anti-competition". By making one of the cheapest prices exclusive to only those with Medicare, it excludes others and puts more vulnerable patients at a disadvantage.

The IRA falsely places the blame of high prices on drug manufacturers and targets them through their regulations, failing to regulate the PBMs that have been negotiating higher prices. Under the Medicare Drug Price Negotiations policy, Medicare earns the ability to "negotiate directly with drug manufacturers to lower the price of some of the costliest single-source brand-name Medicare Part B and Part D drugs" (CDC, 2024). This policy is futile, as it incorrectly places drug manufacturers as the targets of their regulations, even though trends have shown that, while insulin prices have been rising, drug manufacturers have actually decreased their prices and shares for insulin drugs. A study done by Van Nuys in 2021 disproves the idea of

mainly holding drug manufacturers accountable. They tracked the list price (manufacturers' price to wholesalers or direct purchasers), net price (revenue per unit of product after manufacturer concessions are accounted for), and net expenditure (total cost to healthcare system) per 100 units of insulin from 2014 to 2018 ("Glossary of Drug Pricing Terms", 2024). From this, they found that the list price increased from $19.60 to $27.45, a 40.1% increase over 5 years. The net price actually decreased 30.8% from $10.53 to $7.29. Net expenditure stayed relatively constant, increasing slightly by 3.2 percent. During this time the proceeds from insulin sales flowing to PBMs, pharmacies, and wholesalers have only increased, accounting for 42.9% of all expenditures compared to 16.5% in 2014 (Van Nuys, 2021). In putting more restrictions on manufacturers, the proceeds going to insulin manufacturers will decrease, but the IRA does nothing to stop the proceeds going to those manipulating the prices. Presently, PBMs are still found to be manipulating the list prices of insulin, artificially inflating them for their own gain. On September 20, 2024, the FTC sued three of the largest PBMs for "engaging in anti-competitive and unfair rebating practices that have artificial inflated the list price of insulin drugs, impaired patients' access to lower list price products, and shifted the cost of high insulin prices to vulnerable patients" (FTC, 2024). The complaint accuses these PBMs of intentionally excluding lower priced insulin drugs for the highly rebated, higher list price insulin drugs, rejecting the choice to put forth an affordable option for vulnerable patients. Patients with deductibles and coinsurance often end up paying more out-of-pocket than the net price paid by the commercial payer. As of April 2025, the case is still active, with the PBMs filing for preliminary injunction, in hopes of delaying the case (Morse, 2025). Even with the Part B and D updates put in place, PBMs are still able to find ways to manipulate insulin list prices for their personal profit.

The IRA's oversight of PBMs driving up insulin prices is a political move to gain bipartisan support against "Big Pharma," all while knowingly ignoring the real problems within the pharmaceutical system. In an attempt to shift incoming focus off of themselves, PBMs add to the target on drug manufacturers through ad campaigns and lobbying. The IRA made the move to target drug manufacturers specifically because of political visibility. Through their lack of transparency, PBMs have mostly gone undetected by the general public, only recently becoming a main topic of political discussion. With increasing drug prices, the finger is being pointed at "Big Pharma" within the public eye. PBMs have only contributed to this public blaming of drug manufacturers through targeted ads to the public and to policymakers. One of these efforts includes a seven-figure advertising campaign spearheaded by the Pharmaceutical Care Management Association (PCMA), the national association representing America's PBMs. This campaign was broadcasted inside Washington DC and surrounding areas along with target states. The aim of the campaign was to "remind policymakers and the public that Big Pharma's egregious pricing and anti-competitive practices are the root cause of high prescription drug prices and encourage lawmakers to reject Big Pharma's blame game designed to keep drug prices high by targeting cost-saving pharmacy benefits" (Baldyga, 2023). Figure 4 contains some snapshots from the commercials aired, showing heavy claims against pharmaceutical companies.

Figure 4: Screen Captures from "Big Power" Ad Funded by PMCA (Baldya, 2023)

This campaign was just one instance in a never-ending lobbying war between pharmaceutical companies and PBMs, both paying higher and higher amounts to shift the blame on the other for drug price surges. Historically, the pharmaceutical and health products industry outspent all other industries on campaign contributions and lobbying (Chen, 2024). Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group that represents pharmaceutical companies, has consistently been the highest lobbying source within the pharmaceutical industry, paying nearly $30 million in 2023. Compared to PhRMA, PCMA pays much less, but they nearly doubled their lobbying funds within the same year, paying $15 million in 2023 as opposed to the $8.6 million in 2022. In lobbying, PBMs aim to prevent new laws asking for transparency and continue the scrutiny that pharmaceutical companies find themselves under. The increase in lobbying the year after the IRA was passed adds as a reminder that businesses can urge policies through their money, which clearly PBMs are trying to do.

Conclusion

Within this finger-pointing game, there is not a clear person to blame. As the public, we are not given all the information we need to understand why insulin prices are soaring. We are painted a picture that is easy to digest of an evil “Big Pharma” that hikes up prices although the price of production stays the same. The public is not told the whole truth; one could blame it on lobbying but I believe that it is also the responsibility of those that represent the people to be fully transparent about the factors affecting drug prices. According to a poll taken by the National Community Pharmacists Association (NCPA), voters know little to nothing about PBMs, with 49% knowing nothing at all and 24% knowing not much. In being informed, around 80% of voters found the power of PBMs concerning, and multiple proposed sanctions to address PBM business practices were overwhelmingly supported by voters. On receiving these results,

NCPA CEO B. Douglas Hoey explained, "When you explain to voters the dominant role that PBMs play in the prescription drug market, and the outsized control they have over patients and their health care providers, they are very concerned. The data makes that crystal clear, and it cuts across every political and demographic group. If ever there was an opportunity for Congress to pass bipartisan reform, that time is right now," (NCPA, 2025). In giving voters the opportunity to transparency within the drug distribution, they can decide among themselves how they best need to be supported.

It is clear that political visibility was a driving factor behind the choice to target pharmaceutical companies. Assisting those with Medicare was also a more convenient option, because the IRA would run the risk of controversy in delivering federal mandates on state-run Medicaid programs. Now that checks have been placed upon Big Pharma and there have been no significant changes in price, it is about time that PBMs receive the regulations needed to ensure fair and equitable distribution of insulin.

There are promising policies that are being proposed with potential for bipartisan support. One of these being introduced is the Patients Before Monopolies (PBM) Act, proposed by Senators Elizabeth Warren (D-Mass.) and Josh Hawley (R-Mo.) with Representatives Diana Harshbarger (R-Tenn.) and Jake Auchincloss (D-Mass.). This act will prohibit joint ownership of PBMs and pharmacies, tackling the vertical integration that is threatening small pharmacies and other businesses. This act also gives power to the FTC, Department of Health and Human Services, and the Antitrust Division of the Department of Justice to regulate PBMs and their investment in pharmacies ("Warren, Hawley, Harshbarg…", 2024). This act would act as a first step of many in truly holding PBMs accountable, and would, in turn, allow for more regulations to follow.

There are harms in adding more sanctions against pharmaceutical companies, as has been shown by lobbying patterns in response to new laws. For example, since the IRA passed in 2022 and put sanctions on the negotiation of drug prices, early-stage funding for small-molecule drugs has dropped 70 percent (Lokuwithana, 2025). The power pharmaceutical companies achieve through lobbying places lawmakers in a very difficult dilemma. With a shifting social and political climate, it is more important than ever to protect the vulnerable and ensure accessible healthcare. In a time where “money talks”, it is up to those in charge to determine whether being funded by “Big Pharma” and PBMs is more important than providing accessible healthcare.

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