Evaluation of Federal Drug Pricing Proposals:
A Series of Short Essays

Executive Summary

Positioned between plan sponsors and patients, pharmacy benefit managers (PBMs) receive compensation from multiple drug supply chain stakeholders, including pharmaceutical manufacturers, pharmacy providers, health insurers, and employers. In negotiating with drug manufacturers, PBMs charge administrative fees for services such as administering, collecting, invoicing, and allocating rebates. These fees, which have grown significantly in recent years, are typically calculated as a percentage of a medicine's list price, estimated at between 3.5% to 5%.[1] Administrative fees are far from the only way that current PBM compensation is linked to drug prices as PBMs can also generate pricing differentials (i.e., spread pricing) as a percentage of drug list prices based upon the differences in their contracted rate guarantees with plan sponsors and pharmacy providers.[2]

This relationship between PBM compensation and the list price of a medicine creates an incentive for PBMs to prefer higher list prices. Therefore, it stands to reason that PBMs may oppose activities that would lower the list prices of medicines because of the financial incentives being derived from those list prices. If PBMs are instead compensated based on fixed fees (even if such fixed fees were to produce the same revenues for PBMs as the current model achieves), PBMs may have more motivation to secure lower drug prices, resulting in reduced drug costs.[3]

Federal policies that broadly and effectively prohibit PBMs from profiting from manufacturer list prices are expected to lower drug spending and generate savings for plan sponsors and patients. This policy change would alter PBM incentives. Instead of attempting to maximize their compensation by focusing on higher list prices with retrospective price concessions, PBMs would be best served to prioritize negotiating lower up-front costs and designing formularies that consistently favor the lowest cost medicines, including generics and biosimilars.

Changing PBM incentives to prioritize the most cost-effective treatments is expected to generate savings for employers and Medicare Part D plan sponsors. Patients would also directly benefit from expanded coverage of medicines with lower list prices in the form of lower out-of-pocket costs. Because patient out-of-pocket spending is strongly associated with better adherence to medicines, reductions in the use of costly hospital and emergency care could generate additional downstream savings for plan sponsors and the health care system.[4]

Delinking PBM compensation from the list prices of prescription drugs could have substantial impacts on U.S. prescription drug spending. Although various factors – including market dynamics, policy changes, and the behavior of different stakeholders – will ultimately shape the actual outcomes, we estimate total savings could range from $39.9 billion to $273.6 billion over 10 years [see Methods]. Netting out anticipated savings resulting from the Inflation Reduction Act could reduce our estimates by up to 42%.

[1] Law Insider. (n.d.-a). *Manufacturer administrative fees definition*. https://www.lawinsider.com/dictionary/manufacturer-administrative-fees
[2] 3 Axis Advisors. (2019, December 15). *Analysis of PBM spread pricing in New York Medicaid managed care*. https://www.3axisadvisors.com/projects/2019/1/17/analysis-of-pbm-spread-pricing-in-new-york-medicaid-managed-care
[3] 3 Axis Advisors. (2022, October 22). *Understanding Pharmacy reimbursement trends in Oregon.* https://www.3axisadvisors.com/projects/2022/10/27/understanding-pharmacy-reimbursement-trends-in-oregon
[4] Iuga, A. O., & McGuire, M. J. (2014, February 20). *Adherence and Health Care Costs*. Risk management and healthcare policy. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/

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Background on Series:

In 2021, gross prescription drug spending in the U.S. totaled $577 billion, with significant drug costs incurred under the federal programs of Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the individual marketplace of the Affordable Care Act.[5] At the same time, federal projections for retail prescription drug spending estimate that spending will increase at a rate of 5% from 2021 to 2030.[6] As such, developing thoughtful approaches for managing drug costs will be critical to the long-term viability of these federal programs.

Numerous legislative inquiries and federal investigations have been undertaken to analyze U.S. drug pricing over the last decade. The federal government is a major purchaser of prescription medications, incurring over $295 billion on gross prescription drug expenditures (estimated $134 billion net) in the Medicare and Medicaid programs in 2021 alone.[7] [8] This is more than half of all gross drug spending during that year (see above).

Recent legislative investigations have identified the following four key challenges facing federal policy makers related to prescription drug prices:

- Misaligned incentives that drive up prices and costs
- Insufficient transparency that distorts the market
- Hurdles to pharmacy access
- Behind-the-scenes practices that impede competition and increase costs

PBMS ARE ENTITIES THAT INTERACT WITH PLAN SPONSORS, DRUG MANUFACTURERS, AND PHARMACY PROVIDERS TO FACILITATE THE PROCESSING OF PRESCRIPTION DRUG CLAIMS, NEGOTIATE DRUG PRICES WITH PHARMACIES AND PHARMACEUTICAL MANUFACTURERS, AND IMPLEMENT COST-CONTROL MEASURES.

Policy proposals to address these challenges have begun to take shape in both the U.S. Senate and the U.S. House of Representatives. Common themes being explored in policy appear to focus on the role of prescription drug intermediaries known as pharmacy benefit managers (PBMs) and their impact on market access and drug prices. More specifically, the focus appears on targeting the following areas of PBM-related activities:

1. Delinking PBM compensation from drug list prices
2. Addressing patient steering to PBM affiliated pharmacies
3. Increasing transparency around PBM compensation

The PBM Accountability Project hired 3 Axis Advisors, LLC, to provide an overview of our opinions on these proposals based on our understanding of the U.S. drug supply chain. They also requested we attempt to quantify the potential financial impact of the proposals. As a

[5] The United States Senate Committee on Finance. (2021, January 14). *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf

[6] Centers for Medicare and Medicaid Services. (2022, March 28) *CMS Office of the Actuary Releases 2021-2030 Projections of National Health Expenditures*. https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2021-2030-projections-national-health-expenditures

[7] Medicaid and CHIP Payment and Access Commission. (2022, October 26). *Trends in Medicaid drug spending and rebates*. https://www.macpac.gov/publication/trends-in-medicaid-drug-spending-and-rebates/

[8] Medicare Payment Advisory Commission. (2023, March). *Medicare Payment Policy*. https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf

result of our engagement, we elected to address these proposals through a series of short essays with each addressing one of the policy targets.

Evaluation of Federal Drug Pricing Proposals:
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The following is the first in our three-part essay series on the common themes of federal policy proposals in 2023 that address pharmacy benefit managers (PBMs) in the U.S. drug supply chain.

Part I: Delinking PBM Compensation from Drug List Prices

According to IQVIA, manufacturer list prices (as measured by Wholesale Acquisition Cost [WAC]) have grown 88% over the last 10 years. Over the same time frame, payer net prices have grown 61%, manufacturer net prices have grown 55%, and patient out-of-pocket (OOP) costs have grown 4%.[9] Regardless of where you find yourself in the drug supply chain, costs have gone up over the last decade. This is because all levels of the drug supply chain include financial incentives that encourage higher list prices.[10] [11] [12]

PBM compensation models can generally be described as either linked or delinked to drug prices. The PBMs with the largest market share, namely OptumRx (a division of United Healthcare), Express Scripts (a division of Evernorth), and Caremark (a division of CVS Health), have compensation models that are generally linked to drug list prices. These PBMs are generally referred to as the "Big 3" and have over 80% of the current PBM market share (based upon claim volume).[13] However, smaller PBMs like AffirmedRx, Capital Rx, Gainwell (formerly DXC Technologies), Navitus, Ventegra, and others have compensation models not dependent or linked to drug prices.[14]

The gap between drug manufacturer list price growth (88%) and net price growth (55%) is largely explained by retrospective price concessions provided by manufacturers to drug channel participants. Prescription drug rebates and fees are generally paid by drug manufacturers to a PBM, who then shares a portion with the health insurer.[15] Drug Channels Institute estimates that the gap between sales at manufacturer list price and net price for brand medications has grown 230% from 2011 to 2021 ($61 billion to $204 billion).[16] [17] The average net brand discount is estimated to exceed 12% of the list price for specialty drugs and 47% for

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[9] IQVIA. (2022, April). *The Use of Medicines in the U.S. 2022*. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022

[10] Fein, A. J. (2018, July 24). *Building a new drug wholesaler compensation model: What happens as brand inflation slows?* Drug Channels Institute. https://www.drugchannels.net/2018/07/building-new-drug-wholesaler.html

[11] Feldman, R. (2018, April, 18). *Perverse Incentives: Why Everyone Prefers High Drug Prices -- Except for Those Who Pay the Bills.* SSRN – Elsevier. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3162432.

[12] Sood, Neeraj & Mulligan, Karen & Zhong, Kimberly. (2021). *Do companies in the pharmaceutical supply chain earn excess returns?.* International Journal of Health Economics and Management. 21. 1-16. 10.1007/s10754-020-09291-1. https://pubmed.ncbi.nlm.nih.gov/33394339/

[13] Bean, M. (2022, March 8). *PBMs ranked by market share: CVS Caremark is no. 1*. Becker's Hospital Review. https://www.beckershospitalreview.com/pharmacy/pbms-ranked-by-market-share-cvs-caremark-is-no-1.html

[14] Candisky, C., Sullivan, L. (2018, June 28). *Drug Middlemen's charges called "obscene."* The Columbus Dispatch. https://www.dispatch.com/story/news/politics/government/2018/06/27/drug-middlemen-s-charges-called/11641169007/

[15] California Department of Managed Health Care/Department of Insurance. (2020, July 29). *SB 17 - Prescription Drug Cost Reporting Form for Commercial Plans Instructions.* https://www.dmhc.ca.gov/Portals/0/Docs/OFR/SB%2017%20Instructions%20for%20Prescription%20Drug%20Cost%20Reporting%20Form%20for%20Commercial%20Plans%20Revision%207_29_20%20-%20Final.pdf?ver=2020-08-05-101404-393

[16] Fein, A. J. (2017, June 14). *New data show the Gross-to-net rebate bubble growing even bigger*. Drug Channels Institute. https://www.drugchannels.net/2017/06/new-data-show-gross-to-net-rebate.html

[17] Fein, A. J. (2022, May 10). *Gross-to-net bubble update: 2021 pricing realities at 10 top drugmakers*. Drug Channels Institute. https://www.drugchannels.net/2022/05/gross-to-net-bubble-update-pricing.html

non-specialty brands, although there are some drugs whose rebate is known to exceed 75% of the list price, such as insulins like Lantus.[18] [19] [20]

EXAMPLES OF FEE TYPES

DRUG PULL-THROUGH PROGRAMS

IMPLEMENTATION ALLOWANCES

REBATE SUBMISSION FEES

FORMULARY PLACEMENT FEES

DATA FEES

HEALTH MANAGEMENT FEES

EDUCATIONAL FEES

How PBM Compensation is Linked to List Prices Today

In adjudicating pharmacy claims, PBMs negotiate discounts with drug channel participants. These include rebates from drug manufacturers and network discounts with pharmacy providers. We know from investigations by federal agencies and legislative bodies that both forms of discounts are linked to drug list prices, with PBMs positioned to derive compensation from their negotiations in either arena in relation to the drug's list price. For example, in negotiating for drug pricing rebates with manufacturers, PBMs secure administrative fees. These fees may be directly collected by the PBM or collected via a PBM-owned or affiliated rebate aggregator. Generally, administrative fees are collected for administering, invoicing, allocating and collecting the rebates PBMs negotiated on behalf of the plan sponsor. However, other rationales for administrative fees have been proposed and are in existence on select therapies (see side panel). Similarly, PBMs can generate pricing differentials (i.e., spread pricing) as a percentage of drug list prices based upon the differences in their contracted rates with plan sponsors and pharmacy providers. Private research has demonstrated that PBM compensation is linked to drug list prices, even as PBM compensation places a greater emphasis on fees and fulfillment than traditional rebate withhold amounts or pharmacy network spread pricing.[21] [22]

Under the current legislative proposals, PBMs would be prohibited from collecting compensation based on a drug's list price. As a result, it is reasonable to assume that PBM compensation would move to a flat "fee-for-service" structure. Many existing channel contracts include "economic parity clauses" which require the contract be re-negotiated to maintain both parties' relative economics in the event of industry changes (note these clauses have previously been employed with other industry changes).[23] This suggests that the total value of PBM compensation would be kept whole regardless of these policy changes. Nevertheless, the

[18] Center for Improving Value in Health Care. (2021, August 13). *Drug rebates impact rising prescription drug spending and continue to increase for high cost drugs like brand and specialty*. https://civhc.org/2021/08/13/prescription-drug-rebates/
[19] The United States Senate Committee on Finance. (2021, January 14). *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf
[20] Medicare Payment Advisory Commission. (2023, March). *Medicare Payment Policy*. https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf
[21] Nephron Research LLC. (2020, January 10). *Nephron Research 2020 Outlook: New Year, new data, more slides, more insights*. https://nephronresearch.com/nephron-research-2020-outlook-new-year-new-data-more-slides-more-insights/
[22] PBM Accountability Project. (2021, December 1). *Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers*. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true
[23] Deloitte. (2009, April 6). AWP settlement and the implications for the healthcare industry. https://benefitslink.com/articles/guests/washbull090406a.html

change in incentives for PBMs are likely to result in savings for plan sponsors and patients. As Charlie Munger once said, "Show me the incentive, and I'll show you the outcome."

Impact of Delinking

Delinking PBM compensation from the list price of prescription drugs could potentially have several impacts on prescription drug spending in the U.S. However, various factors, including market dynamics, policy changes, and the behavior of different stakeholders, will ultimately shape the actual outcomes on prescription drug spending. In general, we believe that federal policies that broadly and effectively prohibit PBMs from profiting from manufacturer list prices would have the following impacts:

1. **Altered PBM Incentives**: Changing the way PBMs are compensated would change their financial incentives. PBMs would likely prioritize negotiating lower up-front costs instead of focusing on higher list prices (which currently may better maximize their compensation). This would likely encourage more cost-effective drug choices and formulary designs (e.g., less incentive to prefer brands over generics, preference for older therapeutic options in comparison to newer, etc.). This in turn may change the incentives of other drug channel participants that PBMs operate with today, particularly if existing interactions are currently tied to list prices.
2. **Lower Drug Costs**: Delinking PBM compensation from list prices may incentivize lower drug list prices. The degree to which lower list prices are incentivized are likely dependent upon other factors (such as rebate reform). The ability of federal policy to encourage lower list prices has recently been observed with insulin (which was in part due to rebate form changes) and may serve as a guide for what future incentives might look like.[24] Currently, PBMs are often compensated based on the list price of drugs, which can create an incentive for higher list prices. If PBMs are instead compensated based on fixed fees, they may have more motivation to secure lower prices, resulting in reduced drug costs. The degree of changes in drug costs are likely dependent on factors beyond delinked PBM compensation.
3. **Lower Utilization of High-Priced Medicines**: It stands to reason that increased PBM margins derived from high-priced medicines erodes certain incentives to appropriately control utilization of those products. Most compensation for PBMs will not occur unless utilization is present. By creating a more agnostic method of compensation, PBMs will be better incentivized to encourage more efficient utilization of high-priced medicines. Based on current observations of preferences to high-priced therapies over their low-cost alternatives, we estimate if PBM compensation was delinked from list prices, gross drug spending could be reduced by up to $8 billion annually in Medicare with an estimated equivalent amount ($8 billion) saved in the private insurance market from these altered incentives around formulary design [see Methods].
4. **Payer and Patient Savings**: Preference for lower cost medicines from delinking PBM compensation could translate into savings for end payers of prescription medications (such as health insurance companies, employers, and patients). Many plan designs factor list prices in determining cost sharing amounts. Patients would directly benefit if delinked compensation resulted in PBMs preferring to cover more drugs with lower list prices. Similarly, the financial risk required to be managed by drug insurance would be less if the underlying service being insured (i.e., drugs) were of lower cost. Therefore, plan sponsors (health insurance companies and

[24] Wilkerson, J. (2023, March 5). *By cutting insulin prices, Eli Lilly avoids paying Big Medicaid rebates*. STAT News. https://www.statnews.com/2023/03/06/eli-lilly-insulin-medicaid-rebates/

employers) would benefit. The degree of these savings is likely predicated on factors beyond just lower utilization of high-priced medicines (above).

5. **Downstream Savings from Better Medication Adherence:** It is well established within clinical research that higher patient cost sharing amounts are associated with reductions in patient adherence to therapy and ultimately worse healthcare outcomes. Historical estimates have identified that billions in avoidable health care costs are attributed to nonadherence; however, other studies have found less clear relationships.[25] [26] To be clear, high drug costs are not the sole rationale for medication nonadherence, but based on the proportion of patient response for the rationale for nonmedication adherence tied to drug cost, we estimate that there is likely a modest opportunity to reduce overall healthcare expenditures through current policy proposals [see Methods].
6. **Increased Transparency**: Separating PBM compensation from list prices could improve transparency in the pharmaceutical supply chain. Currently, the complex system of rebates and discounts can make it difficult to understand the net prices paid for drugs. In turn, the profitability of drug supply chain participants and segments can be unclear. Delinking compensation may make it easier for plan sponsors to track the flow of money and identify the true costs of prescription medications, potentially leading to a more informed decision-making process, improved ability to perform value-based assessments of care, and ultimately lead to higher quality healthcare. Based on information regarding compensation for public programs, the Big 3 PBMs receive greater fees on average than smaller, delinked PBMs. The potential value in transparency is estimated at $7.8 billion annually [see Methods].
7. **A More Robust Generic Marketplace**: When compensation to PBMs by drugmakers increases, the purpose is to encourage favoritism in formulary design and thus improve utilization of their products. While this can help manufacturers pull market share from brand competitors, it can also pull market share from generic and biosimilar manufacturers (if they exist). The ability for brand companies to entice PBMs to forego generic and biosimilar alternatives shrinks the size of the market opportunity for the manufacturers of those alternative products, thus undermining desired competitive forces that could drive costs down even further. Furthermore, the previously mentioned lack of transparency can make it difficult for manufacturers to properly compete in the market, potentially creating barriers for a more resilient market.[27]
8. **Increased Plan Spending on Medical Services and Less Spending on Administrative Costs**: Inflated drug prices can distort plan medical loss ratio (MLR) requirements, which aim to prioritize plan spending on healthcare services rather than administrative costs and profits. By incentivizing utilization of lower priced medicines, it can remove any degree of padding that those inflated prices have on health plan MLR calculations and thus put pressure on plans to either lower administrative costs or proportionally spend more on medical services.
9. **Potential Impact to Premiums**: The net impact on premiums is unclear because premium calculations reflect more than just a drug product's cost. Plan sponsor design, such as amount of cost sharing borne by members, retrospective rebates, provider payments, medication adherence, and other factors ultimately influence premium costs. Delinking PBM compensation from drug list prices reflects a small portion of the overall drug marketplace; however, it seems

[25] Iuga, A. O., & McGuire, M. J. (2014, February 20). *Adherence and Health Care Costs*. Risk management and healthcare policy. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/

[26] Ho, P. M., Bryson, C. L., Rumsfeld, J. S.. (2009, June 16). *Medication Adherence: Its Importance in Cardiovascular Outcomes.* Circulation. https://www.ahajournals.org/doi/full/10.1161/circulationaha.108.768986#d1e283

[27] Swetlitz, I. (2023, May 18). *Teva to cut back generic drug production amid shortages*. Bloomberg. https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages#xj4y7vzkg

reasonable that in the face of business risk, PBMs may seek higher base compensation (ultimately reflected in premium increases). At the same time, we have noted that most of the marketplace actions we anticipate would produce savings (and therefore decrease pressure on premiums). While it is reasonable to assume that PBM compensation would move to a flat "fee-for-service" structure and recoup much of the existing revenues, some revenue is likely to be lost (for example, PBMs would unlikely be able to claim an administrative fee if the formulary moves the existing brand-preferred product to the alternative generic [generics do not provide administrative fees]).

There is clearly an opportunity to re-align market incentives within prescription drug benefits with the current policy proposals. It has been well documented that all aspects of the U.S. drug supply chain have distorted incentives to prefer higher prices, and historic policy approaches have not altered these fundamentals in decades. While our savings estimate uses recent data and transparent assumptions to arrive at an impact of no more than 3% of gross drug expenditures [see Methods], we caution that actual savings will hinge on the policy actually enacted, industry reaction to the actual policy, and any regulatory decisions made to govern the enacted policy.

Part I Methods:

Because it informs our methods, an understanding of the history of drug price concessions can provide key insights into why the drug supply chain appears to prefer and value retrospective price discounts as opposed to lower upfront prices. In turn, this history will help us understand what might happen if the incentives of the drug supply chain were delinked from manufacturer list prices.

Historical Rationale for List Price Linkage

Almost 30 years ago, in 1996, fifteen major drug manufacturers agreed to pay $408 million to settle a class action lawsuit by retail pharmacies. The pharmacies' lawsuit alleged that drug makers violated U.S. antitrust laws by conspiring to charge independent and chain pharmacies more money for brand-name prescription drugs than they charged to managed health plans, such as Health Maintenance Organizations (HMOs), even when both groups were acquiring drugs via bulk purchases.[28] The Sherman Antitrust Act and the Robinson-Patman Act prevent actions such as competitors conspiring to reduce competition, fix prices, and stop suppliers from offering better prices to large retailers at the expense of their smaller competitors.[29]

In the early 1990s, drug manufacturers offered significant price discounts to health plans, but not necessarily to pharmacies, based upon who manufacturers believed were best positioned to influence what medicines were prescribed and dispensed. Health plans and PBMs create formularies which restrict access to medications in ways most pharmacies do not. Said differently, most pharmacies will stock or buy whatever medication is needed to fill the prescription order; however, health plan formularies might restrict which drugs can be used to treat a given medical condition (i.e., one brand of insulin for people with diabetes). Retail pharmacies alleged that the two-tier system of pricing kept prices artificially high for pharmacies and that they were entitled to the same price concessions as their competitors.[30]

The legal settlement reached helped ensure that post hoc rebates, and not upfront discounts, became commonplace in the pharmaceutical market. Drug manufacturers continued to have an interest in ensuring their products gain market share, particularly relative to their competitors, and health plans remained interested in securing discounts on drug purchases. As a result, rebate formulas were developed based in no small part on the ability to move market share of prescription products and were structured in ways that pharmacies were unable to provide the evidence to prove qualification for the rebates. Furthermore, since the percentage of the market share that a drug represents could only be calculated retrospectively, the differences in the realized net price has been generally accepted to avoid the historic pharmacy antitrust concerns.

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[28] Freudenheim, M. (1996, February 10). *Drug makers settle suit on price fixing*. The New York Times. https://www.nytimes.com/1996/02/10/business/drug-makers-settle-suit-on-price-fixing.html

[29] Ritchie, J. N. & A., & Staff in the Bureau of Competition & Office of Technology. (2022, March 4). *The antitrust laws*. Federal Trade Commission. https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/antitrust-laws

[30] In re Brand Name Prescription Drugs Antitrust Litigation, United States Court of Appeals, Seventh Circuit August 15, 1997 123 F.3d 599.

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Part I:

Drug Spending in 2021

To begin, we must first have a base understanding of the existing drug insurance marketplace. In 2021, gross prescription drug spending in the U.S. totaled $577 billion.[i] According to the Medicaid and CHIP Payment and Access Commission (MACPAC), the federal Medicaid program spent approximately $80.6 billion on outpatient prescription drugs and collected $42.5 billion in rebates, bringing net drug spending to $38.1 billon, in fiscal year 2021.[ii] According to the Centers for Medicare and Medicaid Services (CMS), gross Medicare Part D expenditures in 2021 were $215.7 billion.[iii] The Medicare Payment Advisory Commission (MedPAC) identified that Medicare spent approximately $95.9 billion on Part D drugs in the net. This amount was arrived at after a reduction of gross expenditures through[iv]:

$49.3 billion from manufacturer collected rebates on Part D plans

$22.4 billion that Part D plan enrollees paid for premiums (both baseline and those that paid for enhanced benefits ($14.9 billion in premiums + $7.5 billion for enhanced benefits)

$17.9 billion that Part D plan enrollees paid in cost sharing

$12.6 billion in post-sale performance payments made by pharmacies to Part D plan sponsors

$17.6 billion from other sources (Other sources include "State transfers" payments from the states to Medicare, required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, for assuming primary responsibility for prescription drug spending as well as "Drug fees" imposed by the Affordable Care Act of 2010 on manufacturers and importers of brand- name prescription drugs; these fees are deposited in the Part B account of the Supplementary Medical Insurance Trust Fund.)

As a result of these figures, we calculate gross and net payments for these programs as follows:

$$Total\ Medicare\ \&\ Medicaid\ Gross\ Payments$$
$$= Medicaid\ Payment\ before\ Rebates + Medciare\ Part\ D\ Gross\ Expenditures$$
$$= \$80.6\ billion + \$215.7\ billion$$
$$= \$296.3\ billion$$

$$Total\ Net\ Medicare\ \&\ Medicaid\ Payments$$
$$= Medicaid\ Payments\ Net\ of\ Rebates + Medicare\ Net\ Payment$$
$$= \$38.1\ billion\ + \$95.9\ billion$$
$$= \$134\ billion$$

Lower Utilization of High-Price Therapies Savings

PBMs provide numerous services to plan sponsors including, but not limited to, negotiating rebates with drug manufacturers, adjudicating pharmacy claims, creating pharmacy networks, reviewing drug utilization patterns, managing mail order prescriptions and creating

formularies.[v] According to the Academy of Managed Care Pharmacy (AMCP), "A drug formulary, or preferred drug list, is a continually updated list of medications and related products supported by current evidence-based medicine, judgment of physicians, pharmacists and other experts in the diagnosis and treatment of disease and preservation of health. The primary purpose of the formulary is to encourage the use of safe, effective and most affordable medications."[vi]

In practical terms, a PBM formulary designates which medications can be filled at a pharmacy counter routinely and which medications will require additional steps in order to be filled. Examples of these other steps include completing a prior authorization request, modifying the dosage, or increasing the interval between fills. Formularies often balance the cost of a therapy against its clinical value.[vii] If a drug has superior clinical evidence to the alternative therapies and lower cost, it would be relatively easy to identify it as the most cost-effective option and to give it preferred formulary coverage.[viii] However, the secretive nature of drug's costs, combined with often unclear superiority data between therapies, makes drug coverage decisions challenging; hence the role of PBM formularies.

Currently, many incentives, for example administrative fees linked to a percentage of list price, encourage PBMs to prefer higher list price medications over lower list price therapeutic alternatives. The most recognizable of these types of coverage decisions are "brand preferred over generic" decisions. Brands and their generic alternatives are products that are identified by the FDA as equivalent in all clinical practices, but brands have significantly higher gross drug costs than their generic alternatives.[ix] Furthermore, brands have the potential to produce administrative fees for PBMs, whereas generics do not. Prior estimates have found that generic drugs have savings of 30% to 90% relative to the brands they replace.[x] Historically, PBMs would move aggressively to prefer generic alternatives as soon as they hit the market (referred to as the "golden rule" of drug benefit design); however, recent trends suggest PBMs are not as aggressive in moving off brand therapies.[xi] This is generally attributed to warped incentives where PBM compensation is derived from drug list prices. If PBM compensation was delinked from list prices, the rationale for these practices would likely quickly disappear, resulting in potential savings to plan sponsors and savings to patients whose cost sharing is tied to the list price of a medicine.

To evaluate the potential savings associated with this practice, we analyzed 2021 Medicare Part D data for existing "brand preferred over generic" medications. Because not all "brand preferred over generic" decisions will be made at the behest of the PBM, we limited our analysis to only active ingredients where 50% or more of the total claim count was attributed to the brand product (suggesting deliberate plan design). Once these drug products were identified, we calculated the average gross cost difference between brand and generic product expenditures in Medicare and calculated savings based upon the assumption that existing brand claims would be converted to the lower cost generic alternative. The specific drugs, along with the dollar estimates, are identified in the **Appendix to Part I** at the end of our methodology. The total gross value of the identified products was $8,122,243,356 in annual Medicare savings. To be clear, the existing brand utilization is likely associated with rebates which reduces their net costs. According to averages, these drugs are largely not specialty therapies and so the brands' upfront cost may be reduced by 47% of the gross cost.

This would reduce the value of savings to approximately $4 billion annually (reducing the existing brand cost by the assumed rebate and comparing those cost to the generic).

Because Medicare prescription drug coverage relies on partnerships with private health plans, we believe that their coverage decisions are generally representative of the coverage decisions made by private insurers. The Kaiser Family Foundation has previously identified that the size of private health insurance is roughly equivalent to that of federal programs (at least as a portion of total retail prescription drug spending in their slightly dated 2017 analysis [we know public sources of coverage have gone up since then with increased qualifications of Medicare by retiring baby boomers and swollen Medicaid rolls during the pandemic]).[xii] Therefore, lacking a public data source of aggregate private payer claims data, we assume that the Medicare impact would be representative of the potential savings available to the private market. We have additional confidence in our estimate here due to our experience analyzing commercial pharmacy claims data, where we have identified similar formulary decisions and pricing practices that we have also seen in Medicare data.

Medication Adherence Savings

It is well established within clinical research that higher patient cost sharing amounts are associated with reductions in patient adherence to therapy and ultimately worse healthcare outcomes. The reasons for nonadherence are varied and include patient concerns about safety and patient beliefs that their condition can be managed without adhering to taking medication as prescribed (e.g., skipping doses when symptoms are low/absent). However, most research seems to identify patient concerns over drug costs and affordability as the major reason for failing to take medication as prescribed.[xiii] [xiv] [xv] [xvi]

As former Surgeon General C. Everett Koop said, "Drugs don't work if patients don't take them." The Centers for Disease Control and Prevention (CDC) has identified that historic trends of medication nonadherence account for 125,000 deaths, 11% of hospitalizations, and $100–$300 billion in annual spending with an estimated 20%–30% of prescriptions being never dispensed and, on average, 50% of medications for chronic disease (including hypertension) not taken as prescribed.[xvii] In the CBO's estimated Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act, drug cost savings of $31 billion (attributable to price negotiation, inflation rebates in Medicare, and Part D redesign provisions) were associated with $5 billion in savings in Medicare Part A & B (i.e., medical insurance) through the increased use of (i.e., adherence to) prescription drugs.[xviii] Whether the proportion was intentional, this suggests a 6-to-1 relationship between drug costs savings and savings through other areas of healthcare.[xix]

In order to generate savings through increased adherence, underlying drug expenditures may increase and so there may be a nominal impact to the aggregate effect. For this reason, we are inclined to rely upon the CBO estimate as opposed to prior research by CDC or others on the impact of poor adherence. It should also be noted that the CBO estimate appears limited to Medicare; however, we can see no reason why commercial and other payers would not benefit from the same degree from increased adherence as Medicare members do. This assumption may be off-the-mark a bit, given the slightly sicker population Medicare may represent due to

their advanced age, but we are unaware of any research that would support an estimate of the difference.

We will rely on these values in calculating our overall estimate of savings. To be clear, much of the research regarding adherence is five to ten years old. The drug marketplace and benefit offerings look significantly different today than they did in 2013 to 2017. Hence, we feel a conservative approach to estimating the value of increased adherence is warranted.

Increased Transparency Savings

The pricing models of PBMs are heavily guarded trade secrets. To evaluate the differences, we are relying upon the known differences in cost per claims in public programs between Big 3 PBM operations and delinked PBMs (e.g., Navitus, MagellanRx, DXC Technologies). According to bids to public programs like Ohio Medicaid by CVS Caremark and OptumRx, per prescription fees ranged from $5.60 to $6.50 per script.[xx] Bids by Navitus, MagellanRx, and DXC ranged from as little as $0.26 to as much as $1.70 per script to manage the same program currently incurring these much higher fees.[xxi] Note our channel checks suggest that smaller groups may incur fees of up to $4 per script from delinked PBMs, but we could not find public sources to confirm those statements.

The maximum difference in these public figures equates to $6.24 per claim whereas the minimum difference is $3.90 per claim. In a given year, there are more than four billion prescriptions dispensed in the United States, meaning the value of transparency could be worth $15.6 to $25 billion per year.[xxii] Our prior work with the PBM Accountability Project informs us that competitively bid PBM contracts can produce 20% savings to current models for select clients.[xxiii] Out of gross drug expenditures of $557 billion, the above calculation is approximately 5% of the overall value and therefore seems to meet the threshold of reasonableness. If delinked PBM models were to be half as efficient as they are today, due to this scaling, the number could be as low as $7.8 billion annually.

Various factors, including market dynamics, policy changes, and the behavior of different stakeholders will play a role in any potential policy change to delink PBM compensation. Many existing channel contracts include "economic parity clauses" which require the contract be re-negotiated to maintain both parties' relative economics in the event of policy changes such as those being proposed. We are assuming that the likely fee structure that would replace existing PBM compensation models would be equivalent to their existing compensation. At the same time, given the high impact of these policies on the PBM business model, there is potential for some lost PBM revenue, which could ultimately result in higher costs to plan sponsors for PBM services. Competitive market forces would likely offset such potential increases, but how these countervailing impacts net out is unclear.

Total Estimated Savings

To arrive at our aggregate estimate of savings from potential proposals to delink PBM compensation from drug list prices, we begin with a review of our individual assessments on savings. Our overall estimates are therefore outlined on the table on the next page:

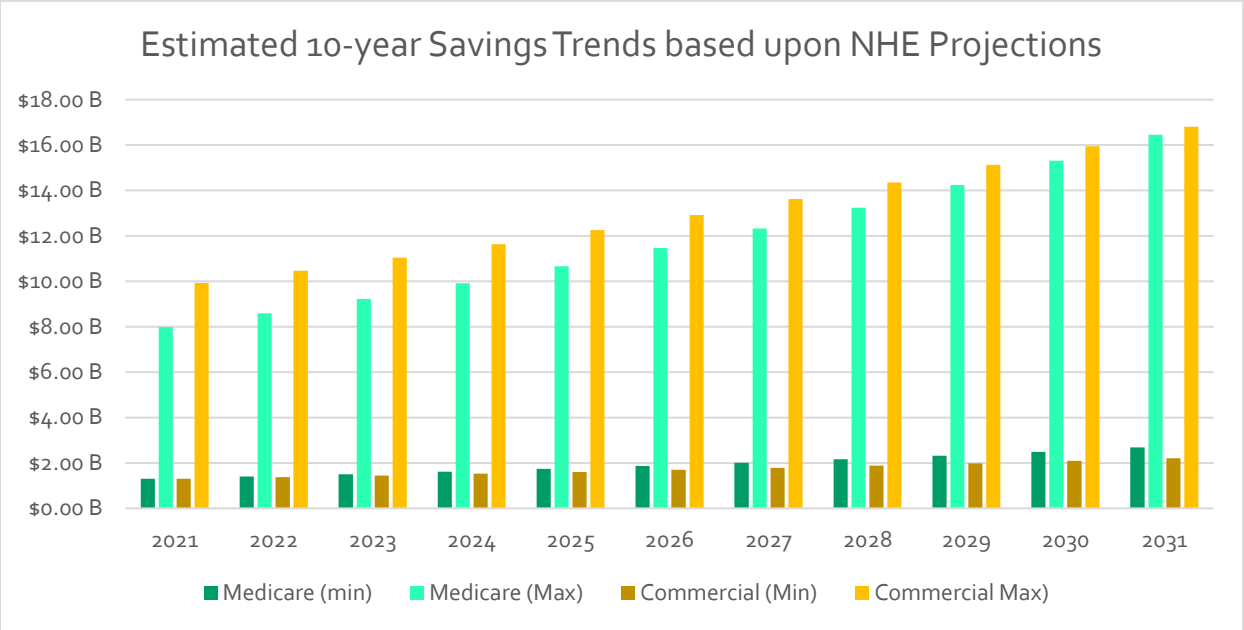
	Medicare	All Others	Overall
Total Gross Drug Expenditures	$216,000,000,000	$361,000,000,000	$577,000,000,000
Lower Utilization of High-Price Therapies†	-$3,760,000,000 (Net Impact)	-$3,760,000,000 (Net Impact)	$7,520,000,000 (Net Impact)
Medication Adherence Savings×	-$1,300,000,000	-$1,300,000,000	-$2,600,000,000
Transparency Savings※	-$2,925,000,000	-$4,875,000,000	-$7,800,000,000
Total Impact	$1,300,000,000 to $7,985,000,000	$1,300,000,000 to $9,935,000,000	$2,600,000,000 to $17,920,000,000

† We relied upon our estimate of net impact, as if brands convert to generic, rebates on the historical brands will be lost (as well as any other fees).

× We relied upon the 6-to-1 ratio of prior work to estimate adherence savings.

※ Transparency savings were initially accounted in the aggregate. We proportioned them according to the number of Medicare scripts in 2021 relative to the overall estimated count in 2021.

Note that in estimating a total impact of delinking policy, our range reflects the value of the smallest bucket (the idea that only one assumption [the smallest] transpires) to the total value of all estimates. As a result, less than 1% of gross drug costs ($2.6 billion) may be saved annually with the proposal to as much as 3% overall impact ($17.9 billion) annually. We believe the range from the smallest likely event to the cumulative impact appropriately reflects the limitations of the unknown that may result from changes to the marketplace with these policy proposals. Relying upon the 2022-2031 National Health Expenditure Projections for future prescription drug growth over the next 10 years, we would estimate that over 10 years would range from $39.93 B to $273.6 B (assuming the percentage of gross drug cost reductions is durable)[xxiv]



*Medicare growth was pegged to NHE 7.5% projection; Commercial was pegged to NHE 5.4% projection

Evaluation of Federal Drug Pricing Proposals:
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In August 2022, Congress passed the Inflation Reduction Act, which made several significant reforms to the prescription drug market.[xxv] These include allowing Medicare to negotiate prices for selected medicines, requiring companies to pay a rebate to Medicare if the price of a medicine rises faster than inflation, and a redesign of the Part D benefit. These provisions, specifically the inflation rebate and Part D redesign, are expected to alter the incentives of PBMs and Part D plan sponsors in a similar manner as we expect under delinking. For example, in their analysis of the IRA, CBO attributed savings to slower growth in drug prices and increased incentives for PBMs and Part D plan sponsors to control costs, along with savings from improved medication adherence.[xxvi] A policy that would delink PBM compensation from the list price of a medicine is expected to generate further incremental savings, but it is difficult to quantify exactly what additive effects delinking would have to IRA estimated savings, particularly given that much of the IRA has yet to go into effect (and therefore actual market impacts remain unknown).

The CBO estimated IRA would produce $159 billion in health savings over two years related to drug price negotiation and rebate inflationary caps. These savings would be offset by an incurred cost of $44 billion related to Part D re-design (netting $115 billion). If our savings analysis is double counting any of these savings, our estimate may be that no additional savings will be produced, to a reduction to our top line number by approximately 42% or $158.7 billion over 10 years.

Appendix to Part I:

Active Ingredient (As Labeled in Part D Dashboard by CMS)	Total Brand Spending (2021) [A]	Total Brand Claim Count (2021) [B]	Total Generic Spending (2021) [C]	Total Generic Claim Count (2021) [D]	Avg Generic Gross Drug Cost Savings (2021) [E] (A/B) – (C/D)	Total Generic Savings Attributed with Brand to Generic Conversion [E]*[B]
Insulin Aspart	$ 2,373.9 M	2,842,954	$ 80.2 M	268,499	$536.38	$1,524,905,649.52
Budesonide/Formoterol Fumarate	$ 1,952.2 M	3,735,932	$ 176.9 M	505,355	$172.54	$644,581,120.44
Fluticasone Propion/Salmeterol	$ 1,721.4 M	3,536,880	$ 250.4 M	1,024,098	$242.19	$856,612,154.69
Insulin Lispro	$ 1,705.9 M	2,041,510	$ 261.3 M	791,885	$505.65	$1,032,282,310.41
Cyclosporine	$ 1,746.2 M	1,831,673	$ 7.4 M	13,281	$394.13	$721,917,984.60
Sofosbuvir/Velpatasvir	$ 938.7 M	37,195	$ 95.4 M	11,329	$16,810.99	$625,284,745.17
Icosapent Ethyl	$ 832.0 M	1,698,206	$ 68.4 M	186,322	$122.70	$208,369,685.45
Glatiramer Acetate	$ 648.6 M	111,227	$ 178.7 M	48,618	$2,155.98	$239,802,806.51
Dimethyl Fumarate	$ 569.2 M	63,761	$ 164.2 M	45,810	$5,341.78	$340,596,994.28
Bimatoprost	$ 668.9 M	1,674,888	$ 5.8 M	34,469	$232.52	$389,450,306.03
Ipratropium/Albuterol Sulfate	$ 520.3 M	838,701	$ 8.8 M	390,648	$597.84	$501,405,301.60
Nebivolol HCl	$ 415.4 M	1,282,818	$ 30.1 M	188,423	$163.86	$210,202,746.40
Teriparatide	$ 371.3 M	90,142	$ 24.6 M	8,478	$1,215.48	$109,566,018.65
Insulin Lispro Protamin/Lispro	$ 362.3 M	329,019	$ 19.3 M	38,351	$598.07	$196,775,192.78
Varenicline Tartrate	$ 153.5 M	295,619	$ 33.3 M	76,472	$83.82	$24,777,870.74
Ledipasvir/Sofosbuvir	$ 143.2 M	4,307	$ 14.3 M	1,132	$20,601.79	$88,731,915.83
Brinzolamide	$ 82.8 M	180,138	$ 35.6 M	97,493	$94.21	$16,970,508.00
Sunitinib Malate	$ 97.0 M	7,602	$ 15.6 M	1,600	$3,033.15	$23,058,000.08
Tolvaptan	$ 84.8 M	5,884	$ 26.9 M	2,762	$4,660.28	$27,421,107.47
Rufinamide	$ 79.9 M	20,377	$ 20.1 M	9,202	$1,739.55	$35,446,901.18
Bromfenac Sodium	$ 86.6 M	269,887	$ 5.8 M	29,792	$125.67	$33,916,234.42

Active Ingredient (As Labeled in Part D Dashboard by CMS)	Total Brand Spending (2021) [A]	Total Brand Claim Count (2021) [B]	Total Generic Spending (2021) [C]	Total Generic Claim Count (2021) [D]	Avg Generic Gross Drug Cost Savings (2021) [E] (A/B) – (C/D)	Total Generic Savings Attributed with Brand to Generic Conversion [E]*[B]
Leuprolide Acetate	$ 90.8 M	25,532	$ 0.1 M	75	$2,451.24	$62,585,099.75
Loteprednol Etabonate	$ 56.4 M	197,200	$ 26.4 M	128,834	$80.92	$15,956,580.87
Naloxone HCl	$ 63.7 M	481,037	$ 0.6 M	22,839	$104.73	$50,378,920.94
Etravirine	$ 46.9 M	30,054	$ 8.8 M	6,722	$246.18	$7,398,636.88
Difluprednate	$ 49.8 M	213,631	$ 2.3 M	13,733	$62.78	$13,412,620.82
Azacitidine	$ 42.6 M	1,964	$ 3.1 M	944	$18,399.42	$36,136,468.67
Zonisamide	$ 22.3 M	6,484	$ 18.0 M	384,362	$3,395.40	$22,015,759.07
Hydrocodone Bitartrate	$ 30.3 M	53,038	$ 4.3 M	10,268	$152.35	$8,080,205.53
Deferiprone	$ 30.6 M	1,635	$ 3.1 M	294	$8,265.04	$13,513,336.92
Sapropterin Dihydrochloride	$ 19.5 M	1,231	$ 9.6 M	975	$6,026.73	$7,418,902.50
Bepotastine Besilate	$ 18.3 M	53,216	$ 5.4 M	19,581	$68.23	$3,630,727.04
Timolol Maleate/PF	$ 8.3 M	11,489	$ 5.9 M	11,111	$191.65	$2,201,919.35
Testosterone Enanthate	$ 10.8 M	15,810	$ 0.8 M	9,471	$604.85	$9,562,694.09
Lopinavir/Ritonavir	$ 9.1 M	8,232	$ 1.8 M	2,188	$269.31	$2,216,955.44
PEG3350/Sod Sul/NaCl/KCl/Asb/C	$ 7.8 M	62,139	$ 2.2 M	23,336	$31.24	$1,941,239.33
Treprostinil Sodium	$ 6.9 M	495	$ 0.7 M	115	$7,615.03	$3,769,439.45
Formoterol Fumarate	$ 5.7 M	7,076	$ 1.8 M	2,941	$190.96	$1,351,206.23
Arformoterol Tartrate	$ 5.0 M	7,208	$ 1.6 M	3,655	$269.52	$1,942,720.29
Flurandrenolide	$ 3.9 M	4,186	$ 1.1 M	1,686	$270.11	$1,130,696.79
Fluoride (Sodium)	$ 3.5 M	250,110	$ 1.0 M	80,225	$2.06	$515,456.87
Norethindrone-E.Estradiol-Iron	$ 3.0 M	59,592	$ 0.2 M	5,742	$14.75	$878,998.32
Efavirenz/Lamivu/Tenofov Disop	$ 2.4 M	972	$ 0.6 M	400	$1,001.46	$973,418.51
Norgestimate-Ethinyl Estradiol	$ 2.6 M	99,962	$ 0.3 M	13,538	$0.89	$89,324.21
Hydrocortisone/Pramoxine	$ 2.2 M	10,314	$ 0.5 M	3,490	$83.58	$862,023.29
Prochlorperazine	$ 1.2 M	8,558	$ 1.0 M	8,249	$10.38	$88,814.57

Active Ingredient (As Labeled in Part D Dashboard by CMS)	Total Brand Spending (2021) [A]	Total Brand Claim Count (2021) [B]	Total Generic Spending (2021) [C]	Total Generic Claim Count (2021) [D]	Avg Generic Gross Drug Cost Savings (2021) [E] (A/B) – (C/D)	Total Generic Savings Attributed with Brand to Generic Conversion [E]*[B]
Hydroxyprogesterone Caproat/PF	$ 1.3 M	394	$ 0.5 M	230	$1,143.26	$450,443.65
Abacavir/Lamivudine/Zidovudine	$ 1.3 M	762	$ 0.1 M	118	$440.97	$336,018.65
L-Norgest/E.Estradiol-E.Estrad	$ 0.7 M	6,613	$ 0.2 M	2,541	$25.83	$170,801.42
Sodium Fluoride/Potassium Nit	$ 0.5 M	27,863	$ 0.3 M	19,150	$4.07	$113,306.62
Desogestrel-Ethinyl Estradiol	$ 0.6 M	19,345	$ 0.0 M	22	$5.70	$110,178.61
Epoprostenol Sodium	$ 0.5 M	200	$ 0.0 M	21	$1,097.12	$219,423.98
Mesna	$ 0.5 M	535	$ 0.0 M	55	$960.75	$514,002.51
Methenam/Sod Phos/Mblue/Hyoscy	$ 0.2 M	664	$ 0.1 M	458	$134.37	$89,224.45
Noreth-Ethinyl Estradiol/Iron	$ 0.1 M	852	$ 0.0 M	268	$48.37	$41,214.01
PNV No.163/Iron/Folate No.10	$ 0.1 M	26	$ 0.0 M	14	$758.04	$19,708.97
Fosphenytoin Sodium	$ 0.1 M	87	$ 0.0 M	42	$589.81	$51,313.24

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