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I. EXECUTIVE SUMMARY

TBD

II. INTRODUCTION

A. Study of the Pharmaceutical Distribution and Payment System

Established in 2019, the Maryland Prescription Drug Affordability Board (Board) is an independent agency charged with protecting State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drugs. The five-member Board is supported by staff and a 26-member advisory Stakeholder Council composed of experts across the supply chain and stakeholder representatives.

Section 21-2C-07 of the Health General Article, Annotated Code of Maryland, directs the Board to study the pharmaceutical distribution and payment system in the State as well as the policy options used in other states and countries to lower the price of pharmaceuticals, by considering a range of options including upper payment limits, reverse auctions, and bulk purchasing. This work underpins the Board's development of a process for setting upper payment limits, including drafting an upper payment action plan for approval by the General Assembly, Health-Gen. 21-2C-13. The development of the upper payment limit action plan runs parallel to the Board's cost review work—identifying drugs causing affordability issues, conducting a cost review of selected drugs, and determining whether the drug has or will lead to an affordability challenge—which is a prerequisite to establishing an upper payment limit, Health-Gen. 21-2C-09.

The Cost Review Report (Md. Code Ann., Health-Gen. 21-2C-09(c)) is a statutorily-mandated annual report identifying (1) prescription drug price trends, (2) the drugs for which the Board conducted a cost review, and (3) recommendations for additional legislation to make prescription drug products more affordable in the state. Please refer to the 2022[1] and 2023 Cost Review Reports[2] for a brief summary in drug pricing trends that show the need and importance of the work of the Prescription Drug Affordability Board.

The Board has undertaken the study of the prescription drug supply chain and payment system, as well as explored myriad policy options, through robust literature reviews, data analysis, presentations at public Board meetings, presentations at public Stakeholder Council meetings, written comments from members of the Stakeholder Council and the

[1] 2022 Health General Article § 21-2C-09- Cost Review Report. December 31, 2022. https://pdab.maryland.gov/documents/Health_gen_article_cost_review_rpt.pdf
[2] 2023 Health General Article § 21-2C-09- Cost Review Report. https://pdab.maryland.gov/documents/meetings/2023/pdab_2023_hlth_gen_article_21_2C_09.pdf

public, and opportunities for public comment at Board and Stakeholder Council Meetings.

B. Scope of the Report

The prescription drug market is complex, opaque, and subject to manipulation and anticompetitive practices.

The purpose of this report is to provide an overview of the prescription drug supply chain and market, identify reasons that prescription drugs may be unaffordable to people in Maryland, and propose recommendations to make prescription drugs more affordable for people in Maryland—including patients, employers, and taxpayers.

The target audience for this report is for individuals from Maryland who can assist in turning the Board's recommendations into action. These include: policy makers, advocates, patients, and stakeholders in the pharmaceutical supply chain. The Board hopes that this report will aid these individuals in understanding the issues affecting prescription drug affordability and how to address those issues, and serve as an effective tool for action.

III. PHARMACEUTICAL INDUSTRY AND SUPPLY CHAIN

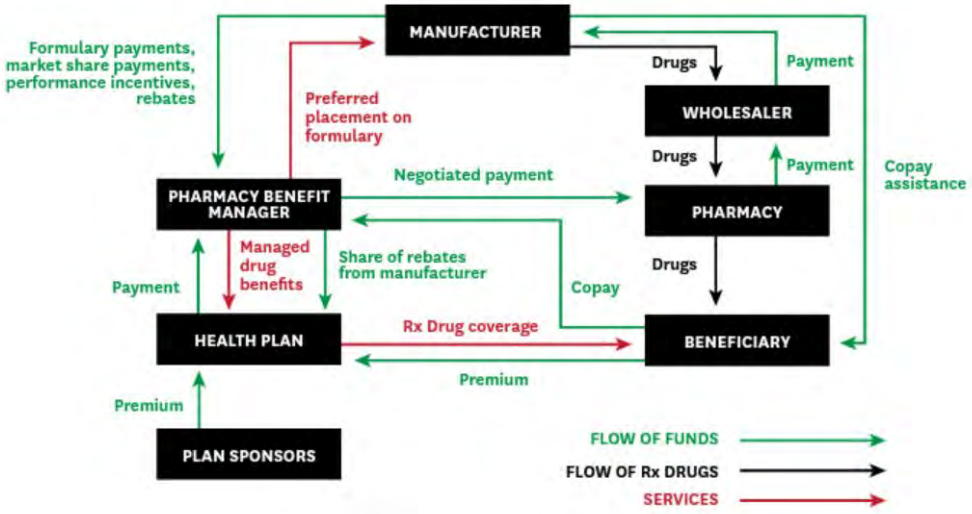
A. Introduction to the Supply Chain

The pharmaceutical supply chain involves a complex set of transactions. Each transaction differs depending on the type of drug—brand and generic, biologic and biosimilar—and how it is provided to patients, whether dispensed by a pharmacy, through mail order, or administered by a physician. In fact, each drug is unique in some way.

This section provides a brief overview of the entities in the pharmaceutical supply chain, how the entities interact with each other, how money flows through the supply chain, and introduces financial incentives within the system.[3] The summary does not include all the participants in the drug supply chain; it emphasizes the main participants. The incentives and resulting behaviors in this system will be explored in the next section. The diagram below provides an overview of the participants and how they are connected.

Figure 1. The Pharmaceutical Supply Chain through Retail Pharmacies

[3] For a more detailed look at the pharmaceutical supply chain, see Mulcahy, A. & Kareddy, V. (2021). *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*. Assistant Secretary for Planning and Evaluation, U.S. Dep't of Health and Human Services. https://aspe.hhs.gov/reports/prescription-drug-supply-chains



Adapted From: Flow of Money Through the Pharmaceutical Distribution System[4]

B. Overview of Pharmaceutical Supply Chain Entities and Pricing Terms

The manufacture, distribution, and reimbursement for prescription drugs involves a multitude of transactions and multiple entities. At the highest level, the primary participants include those in the supply chain and those involved in reimbursement/payment Those involved in the supply chain take physical control of the drug and get the drugs from the manufacturers to the patients. Those involved in reimbursement/payment are responsible for the financing of the drug market.

Supply Chain:

- **Manufacturers** are authorized by the U.S. Food and Drug Administration (FDA) to market and sell a finished prescription drug product. The manufacturer creates the finished drug product from raw active pharmaceutical ingredients (APIs) and other ingredients that can be sourced from other entities. Generally, the manufacturer establishes the list price of the drug. Brand manufacturers conduct the research and development to develop the drug. Generic manufacturers conduct the studies to demonstrate bioequivalence
- **Wholesalers** (i.e., distributors or wholesale distributors) operate nationally or regionally by purchasing finished drug products from the manufacturer and

[4] Sood, N., Shih, T. Van Nuys, K. & Goldman, D. (2017). *The Flow of Money Through the Pharmaceutical Distribution System* [White paper]. University of Southern California Schaeffer Center for Health Policy & Economics. https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/

shipping drugs to the pharmacy, physician, or hospital.[5] The three major health care distributors in the United States—AmerisourceBergen, Cardinal Health, and McKesson—account for about 90 percent of the overall market.[6,7,8] Wholesalers that do business in Maryland are required to be permitted by the Maryland Board of Pharmacy.

- **Pharmacies** purchase drugs from the wholesaler and dispense the drugs to patients. Pharmacies operate under the permitting authority of the Maryland Board of Pharmacy.
    - **Retail pharmacies** dispense drugs to the general public once they receive a prescription from the physician, and include independent pharmacies, chain pharmacies, supermarket pharmacies, or mass merchandiser pharmacies.
    - **Specialty Pharmacies** are pharmacies that dispense medications not typically found in a retail pharmacy. These medications are usually high in cost, tend to treat complex and rare diseases, and may require specific handling or management.
    - **Mail Order Pharmacies** are pharmacies that provide prescription drugs to patients by mail. The largest mail-order pharmacies are associated with pharmacy benefit managers, or PBMs (e.g., CVS Caremark, Express Scripts Pharmacy, and OptumRx) (See below).
- **Hospitals/Physician Offices** provide physician-administered drugs to patients. These drugs are paid under the patient's medical coverage through the buy-and-bill model in which the hospitals/physician offices purchase and take ownership of the drug as part of their budget and bill for the drug and additional services including the administration of the drug. Patients can also purchase the drugs themselves and bring them to the facility in some cases.
- **Patients** are prescribed the drug by clinicians and receive the drug from the pharmacy. Patients and clinicians work together to pick the best drug for the patient with cost often a factor in drug selection.

Reimbursement/Repayment:

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[5] Mulcahy, A. & Kareddy, V. (2021). *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*. Assistant Secretary for Planning and Evaluation, U.S. Dep't of Health and Human Services. https://aspe.hhs.gov/reports/prescription-drug-supply-chains

[6] Deloitte, *The Role of Distributors in the U.S. Health Care Industry: 2019 Report*, at p. 8, 2019. https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/the-role-of-distributors-in-the-us-health-care-industry.html

[7] Fein AJ. The 2023-24 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors.Accessed: December 8, 2023. https://www.drugchannelsinstitute.com/files/2023-24-PharmaWholesalers-Overview.pdf

[8] Seely E. The Impact of Pharmaceutical Wholesalers on U.S. Drug Spending. The Commonwealth Fund. July 20, 2022. https://www.commonwealthfund.org/publications/issue-briefs/2022/jul/impact-pharmaceutical-wholesalers-drug-spending

- **Pharmacy benefit managers (PBMs)** pay the pharmacy/provider for the drug dispensed to the patient on behalf of the health plan. PBMs manage the pharmacy network and pharmacy payment. PBMs design and manage drug formularies and utilization management tools (*e.g.*, prior authorization), which they use to negotiate discounts from manufacturers paid in the form of rebates and other types of discounts. Some, though not always all, of the rebates may be passed on to the health plan and can be used as the plan or sponsor see fit, such as to lower premiums, lower out-of-pocket costs to the patient, or higher profits by the PBM. PBMs are subject to regulation in Maryland and must register with the Maryland Insurance Administration. Three PBMs–CVS Caremark (a segment of CVS Health, which also owns Aetna), Express Scripts (owned by Cigna), and OptumRx (owned by UntitedHealth Group)–handle over 75% of the prescription drug market, with estimates of their market share ranging from 80% to 89% of the market.[9,10]
- **Payors** can be the government, through Medicare and Medicaid, or commercial insurers. Under commercial, large employers self-fund plans for employees or commercial insurers sell health and prescription benefits to individuals or employees (through their employer).
- **Health plans** manage and pay for health benefits for patients. In addition to their role in allocating risk, health plans help control costs through insurance design and price negotiation for medical services. Insurance design determines what medical services are covered and the potential out-of-pocket responsibility of the patient.[11] A health plan often uses a pharmacy benefit manager (PBM) to develop and manage the pharmacy benefit, including the formulary and the patient's financial responsibility.
- **Patients** often pay some portion of the cost of the prescription drug in the form of copays (a flat payment amount for a tier of drugs) or coinsurance (a percentage of the list price or paid amount). Some health plans also have a deductible (the amount a patient pays before insurance coverage begins) and out-of-pocket maximums (the amount above which patients no longer have to pay). Uninsured patients may pay the full list price of the drug, which is often much more than the negotiated rates paid by a PBM or health plan.

Pricing Terms:

[9] Drug Channels. The Top Pharmacy Benefit Managers of 2022: Market Share and Trends for the Biggest Companies. May 23, 2023. https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html

[10] Pharmacy Benefit Manager.. National Association of Insurance Commissioners. April 11, 2022. https://content.naic.org/cipr-topics/pharmacy-benefit-managers

[11]Delbanco SF, Murray R, et. al. A Typology of Benefit Designs. Urban Institute. April 2016. https://www.urban.org/sites/default/files/publication/80321/2000780-A-Typology-of-Benefit-Designs.pdf

The terminology employed to describe the price at which the drug is offered, purchased, rebated, and paid depends on where in the supply chain the transaction occurs. There are close to a dozen different "prices" that can be associated with a drug, and almost none of them represent the final actual price paid or the cost of a drug. The role of insurance and other entrants in the supply chain dramatically increases the complexity and variation of these transactions. The main different prices are:

- **Wholesale Acquisition Cost (WAC)**:[12] A federally defined price representing what the wholesaler pays the manufacturer. Generally considered the "list" price, this price is set by the manufacturer and rarely reflects the actual amount since the amount is adjusted periodically based on a series of factors such as total volume purchased rebates, or market share obtained by the drug company. WAC often serves as a starting point for negotiations between manufacturers and PBMs, and is comparable to the manufacturer-suggested retail price (MSRP) in other markets (e.g., car lot sticker price). The WAC is commercially published through proprietary databases, so it is not technically a publicly available price. It is, however, defined in federal statute. The information from these databases must be licensed, but it is widely available and accessible. The WAC is generally correlated with the actual wholesale costs for brand-name drugs. However, the WAC has been shown to be extremely inflated compared to actual wholesale costs especially for generic drugs.[13]
- **Average Wholesale Price (AWP)**: The price at which a wholesaler sells a product to others in the supply chain (e.g., cost to the pharmacy from the wholesaler). Often referred to "Ain't What's Paid," there is no federal definition of AWP and it is not based on any sales data or actual prices paid. AWP is estimated by companies that provide "pricing files" to insurers or PBMs and is rarely reflective of the actual amount paid. It is generally a percentage of the WAC (AWP is usually 120% of WAC). Federal studies and audits have continually found that the AWP is an often-inflated price compared to ASP (see below), with the biggest differences in the generics market.[14] AWP used to be commercially published by wholesalers but is rarely published by wholesalers because of fraud claims. Despite the fact that the AWP is a price that has no definition written in regulations, is not based on any actual sales data or prices paid, and is generally agreed to be highly inflated, it is still generally the price metric that anchors many transactions in the pharmaceutical supply chain. It can be used to determine the

[12] 42 U.S. Code § 1395w–3a(c)(6). Wholesale Acquisition Cost
[13] Lieberman, Ginsberg. Would Transparency for Generic Drugs Lower Costs for Payers and Patients? USC- Brookings Schaeffer Initiative for Innovation in Health Policy. June 2017. https://www.brookings.edu/wp-content/uploads/2017/06/es_20170613_genericdrugpricing.pdf
[14] US Office of the Inspector General (OIG). Medicaid PRice Comparison: Average Sales Price to Average Wholesale Price. June 2005. https://oig.hhs.gov/oei/reports/oei-03-05-00200.pdf

amount a person pays out-of-pocket. It is also used by some insurers, including some Medicaid plans to determine payment rates.

- **Average Sales Price (ASP)**:[15] A federally defined price that is reported to the federal government and represents the quarterly average of the manufacturer's sales, net of rebates, discounts, and other price concessions of a drug to all purchasers included in best price, divided by the total number of units of the drug sold to those purchasers in that same quarter. The ASP is generally used to reimburse physician-administered drugs covered under the medical benefit, especially in Medicare Part B. This is the metric that is closest to the actual price paid in the market, though there are certain nominal sales excluded from the calculation. It is not generally available or used for pharmacy benefit drugs and does not impact the amounts paid by patients or insurers in the pharmacy benefit.
- **Average Manufacturer Price (AMP**): A federally-defined price that is the average of the prices paid to manufacturers for drugs distributed or sold directly to retail community pharmacies. This includes discounts and rebates to wholesalers and retail community pharmacies, but not to any other entities, including insurers, pharmacy benefit managers, hospitals, governmental bodies, and outpatient clinics. This price does not include all discounts that the manufacturer is offering to the wholesaler. AMP is not a publicly available price, and it is used to calculate the rebates for the Medicaid Drug Rebate Program (MDRP) and prices for the federal 340B program.
- **Estimated Acquisition Cost (EAC):**[16] An estimated amount that states must pay pharmacies in the Medicaid program. It is defined in federal law. However, most states have transitioned to actual acquisition costs, such as AAC, SAAC and other methods.
- **National Average Drug Acquisition Cost (NADAC)**: A federally administered voluntary survey that captures the average price pharmacies pay to acquire a drug from a wholesaler or manufacturer. NADAC includes only the discounts received by pharmacies at a drug's acquisition; it does not include subsequent discounts or rebates from manufacturers to wholesalers or pharmacies. NADAC is derived from a voluntary survey based on wholesaler invoices. For chain pharmacies this may not include significant volume-based discounts if they accrue off-invoice at the corporate level rather than the pharmacy level. Also, not all drugs have a NADAC price. Despite its weaknesses, NADAC is an important pricing metric because it represents actual amounts paid within the supply chain. It is commonly used by Medicaid programs.
- **Actual Acquisition Cost (AAC) or State Actual Acquisition Cost (SAAC):** A metric that is comparable to the NADAC, but is often derived from a state-administered survey to capture actual acquisition costs for pharmacies. Since it is

[15] 42 CFR § 414.904 - Average sales price as the basis for payment.
[16] Previously defined in 42 CFR 447.502. The February 2016 final Medicaid drug rule [CMS-2345-FC] replaced estimated acquisition cost with actual acquisition cost.

state specific, and sometimes based on a mandatory survey, this term can be a more accurate price point than NADAC in that state. AAC and SAAC are often used for reimbursement from state Medicaid programs. Maryland has a SAAC, though it is not a mandatory survey.[17].

- **Usual and Customary Price (U&C):** An amount that pharmacies charge for a particular drug for cash paying patients. This amount is not defined and is set by the pharmacy, which explains why a cash customer can be quoted different prices for the same drug across different pharmacies. There is an incentive for pharmacies to charge very high U&Cs because payments from PBMs are usually based on a "lesser of" model in which they pay the lesser of the pharmacies' U&C or the PBMs' maximum allowable cost (MAC). This incentivizes pharmacies to set U&C prices that are high enough that they always trigger the MAC.
- **Maximum Allowable Cost (MAC)**: The maximum amount that a PBM will pay a pharmacy for a particular drug. This is based on a contractual agreement, but the pharmacy often does not know what the MAC is for each PBM, so the pharmacy generally submits inflated U&C prices to the PBM to ensure that it is reimbursed at the MAC. States set MACs for their Medicaid programs in some cases. Private insurers also have MACs
- **Federal Upper Limit (FUL)**: A maximum price that Medicaid programs will pay for certain generic drugs, usually 175% of AMP. This is a term of art for the Medicaid program, but it is included because it sounds similar to the policy of upper payment limits.
- **Net Cost:** The cost of a prescription drug after all rebates and discounts. There is no formal definition, statutory requirement, or formula for the net cost of a drug. Depending on the size of the rebates and other discounts, the net cost of the drug to the health care system can be significantly lower than the gross spend on the drug-based payment at the pharmacy, available in claims data. The example in Section XX demonstrates the concept of net price.

C. Flow of Funds Through the Pharmaceutical Supply Chain

1. Overview of the Supply Chain Transactions

In theory, manufacturers sell drugs to wholesalers at the Wholesale Acquisition Cost (WAC) minus some predetermined discount based on a formula. Wholesalers, in turn, sell the drugs to pharmacies at some percentage of the Average Wholesale Price (AWP). When the drug is dispensed, the patient pays any co-pays, coinsurance, or applicable deductible. Those amounts are determined by the design of the insurance plan. Furthermore, the pharmacy's payment involves a series of negotiations and contractual arrangements between the health plan/insurer, the insurer's pharmacy benefits manager

[17] Myers and Stauffer. Maryland Department of Health Pharmacy Reimbursement. https://myersandstauffer.com/client-portal/maryland/maryland-pharmacy

(PBM), the pharmacy, and the manufacturer. In short, the system is complex, with multiple inputs and variables, and following the money can be difficult. There is not any price transparency along the supply chain.

This section traces the circuitous flow of funds and describes the interactions and transactions between the different entities in the supply chain. The flow of funds, incentives, and distortions in the supply chain vary based on the type of drug in the transaction—brand name, generic drugs, biologics, or biosimilars—and whether it is dispensed by a retail pharmacy, mail order pharmacy or administered by a physician. These differences will be explored further in the next chapter.

a) Insulin Quick-Pen Supply Chain Example

The first simplified example comes from the insulin market because that market clearly demonstrates the distortions caused by the existing incentives, including the difference between the gross and net price of the drug.[18] There have been some recent substantial changes in the insulin market, including interchangeable biosimilar competition[19] and inflation penalties that have incentivized insulin manufacturers to substantially reduce their list prices. While some of these issues have been addressed in the insulin market, it still provides a helpful example to see some of the distortions in the supply chain.

Example 1 (Figure 2, Tables 1 and 2) concerns an insulin quick-pen product.

Product Supply Side Sales

- The product costs $5 for the manufacturer to produce.
- The manufacturer sells the product at the WAC of $100 to the wholesaler.
- The wholesaler sells it to the pharmacy for $102, which is AWP-15% (AWP=120% of WAC=$120; AWP-15%=$120-$18=$102). The typical markup for the wholesaler is around 2 percent.
- The pharmacy dispenses the product to the patient for a total negotiated rate of $108, which is AWP-10% (AWP=120% of WAC=$120; AWP-10%=$120-

[18] A few factors explain why the insulin market was such an extreme example of the prescription drug market and the natural result of existing incentives: (1) Insulins have been on the market for a long time with no "generic" competition, so this market is the result of decades of these trends; (2) there are a limited number of direct brand name competitors that require manufacturers to compete aggressively for preferred placement on formularies; and (3) there are few enough competitors that they can shadow price each other. This is addressed further in the next chapter.
[19] US Food and Drug Administration (FDA). FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes. July 28, 2021. https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes

$12=$108). Payment for this total negotiated rate is split between the patient and the pharmacy benefit manager (PBM). This does not include the pharmacy's dispensing fee which can be in the $10-12 range for Medicaid Fee for Service, or as low as less than $1 in the managed care and commercial market.

Based on the Produce Supply Side sales, the gross and net revenue to each member of the supply chain is:

- Gross revenue to the manufacturer is $100 and the net revenue is $95 (gross revenue minus cost of production=$100-$5=$95). However, as shown below the manufacturer probably does not receive the full $95.
- Gross revenue to the wholesaler is $102 and the net revenue to the wholesaler is $2 (gross revenue minus acquisition costs=$102-$100=$2).
- Gross revenue to the pharmacy is $108 and the net revenue to the pharmacy is $6 (gross revenue minus acquisition costs= 108-$102=$6). This example does not does not include the dispensing fee.

Reimbursement Side Sales- Where it gets complicated:

- The pharmacy dispenses the product to the patient, who pays coinsurance of $21.60, which is 20% of the total negotiated rate that the PBM pays to the pharmacy (PBM total negotiated rate=AWP-10%= $120-$12= $108; 20% of negotiated rate=$108*.20= $21.60).
- The PBM pays the pharmacy $86.40, which is the balance of the negotiated rate (negotiated rate=$108; 80% of negotiated rate= $108*.80= $86.40).
- On the back end, the PBM, acting on behalf of the health plan/insurer, negotiates with the manufacturer for a rebate of $75 that the manufacturer pays to the PBM for being the preferred insulin quick-pen on the PBM formulary.

Based on the additional discounts and payments, the gross and net cost to each member on the payment side is:

- The total gross cost of the drug to the PBM is $86.40 (paid amount to the pharmacy) and the net price of the product for the PBM after patient coinsurance is $11.40 (PBM paid amount-rebate=$86.40-$75=$11.40).
- The final cost to the patient is $21.60.
- The final net revenue to the manufacturer after rebates is $20 ($95-$75).

Figure 2: Insulin Quick-Pen Payment with Diagram with Payment Values

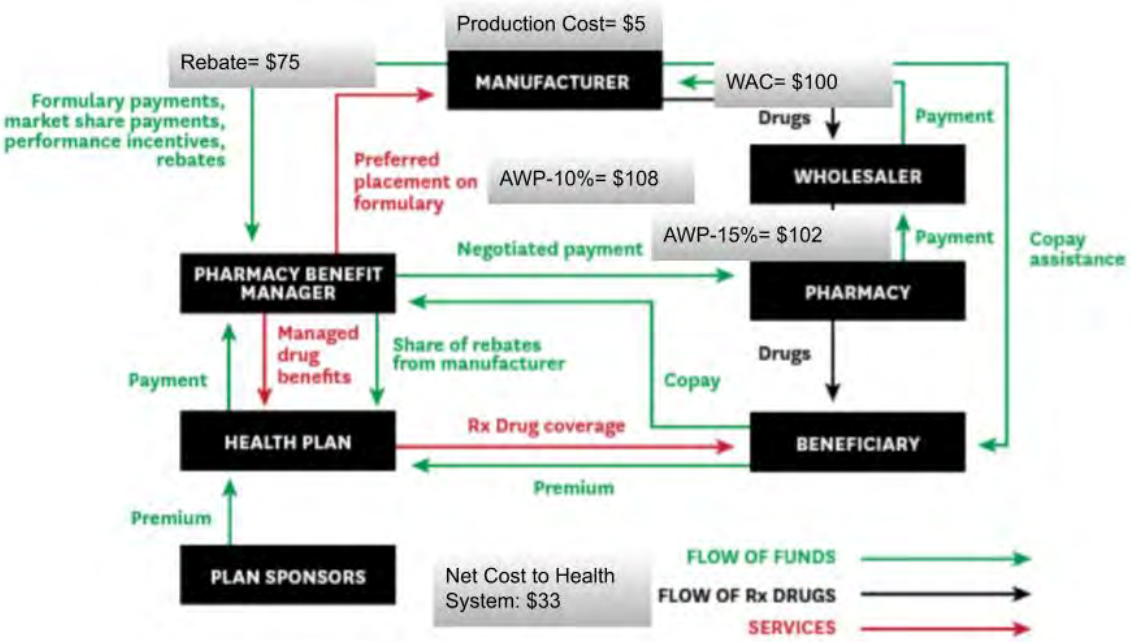


Table X1. Insulin Quick-Pen Payment Supply Chain Transactions

Stakeholder	Transaction	Cost (Description)	Cost (Amount)	Symbols and Equations to Represent Transactions
Manufacturer	Production of drug		($5)	(-A)
	Wholesaler purchases from Manufacturer	WAC	$100	(B)
	Gross revenue to manufacturer		$100	(B)
Wholesaler	Wholesaler purchases from Manufacturer	WAC	($100)	(-B)
	Pharmacy Purchases from Manufacturer	AWP-15%	$102	(C)
	Net margin to		$2	(D)=(C)+(-B)

	wholesaler			
Pharmacy	Pharmacy Purchases from Manufacturer	AWP-15%	($102)	-(C)
	PBM pays the pharmacy on behalf of the insurer	AWP-10%	$108	(E)
	Net margin to pharmacy		$6	(F)=(E)+(-C)

Table X2. Insulin Quick-Pen Reimbursement System Transactions (with rebates)

Stakeholder	**Transaction**	**Cost (Description)**	**Cost (Amount)**	**Symbols and Equations to Represent Transactions**
Pharmacy Benefit Manager	PBM negotiated payment to pharmacy (Gross Cost to PBM)	AWP-10%	($108)	(-E)
	Coinsurance collected from patient	20% of negotiated rate (AWP-10%)	$21.60	(I)
	PBM payment of the balance of the negotiated rate to the pharmacy	80% of negotiated rate (	$86.40	
	Rebates collected from manufacturer	75% of WAC	$75	(G)

	Net Cost of Drug to PBM before coinsurance from patient		($33)	(H)=(-E)+(G)
	Net Cost to PBM after patient coinsurance		($11.40)	(J)= (-H)+(I)
	Share of Net Cost of Drug to PBM		34.5%	(K)=(J)/(H)
Manufacturer	Gross revenue from Wholesaler	WAC	$100	(B)
	Rebate to PBM	75% of WAC	($75)	(-G)
	Net Revenues to Manufacturer		$25	(L)=(B)=(-G)
	Net Margin to Manufacturer		$20	(M)=(J)+(-A)
Patient	Coinsurance collected from patient	20% of amount paid (AWP-10%)	($21.60)	(-I)
	Net Cost to Patient		($21.60)	(-I)
	Share of Gross Negotiated Rate for Drug		20%	(N)= (I)/(E)
	Share of Net Negotiated Rate for Drug		65.5%	(O)= (I)/(H)

Notes about the example:

1. The example for insulin includes a 75% rebate, which was representative of the difference between the list price and net prices of insulin.[20] The amount of rebates varies widely per drug, and a limited number of highly-rebated drugs may make up the majority of rebates. In 2021, manufacturers paid plan sponsors $48.6 billion in rebates, which accounted for 23% of the $210.6 billion in Part D gross expenditures.[21] This example uses a higher-than-average rebate to emphasize the difference between gross and net prices.
2. This example uses values that are generally representative of real transactions. It is a reasonable assumption to say that wholesalers purchase a drug for something comparable to the wholesale acquisition cost (WAC), while the pharmacy cost and reimbursement are some percentage of average wholesale price (AWP), which can be estimated to be 120% of WAC. While reasonable estimates, these are highly variable based on the specific contracts between parties, though most PBM contracts are based on percentages of AWP.
3. This is a highly simplified example. It does not include entities such as group purchasing organizations (GPOs) that help pharmacies negotiate with wholesalers or pharmacy service administrative organizations (PSAOs) that help pharmacies negotiate with PBMs. The example also treats PBMs and insurers as the same entity with the same interests. In reality, the PBM administers the pharmacy benefit for the insurer and is compensated through fees and sometimes a percentage of rebates and/or spread pricing, so there are issues in that relationship that can be explored separately. This example also does not parse different types of fees. The example does not include pharmacy dispensing fees, direct and indirect remuneration (DIR) between the pharmacy and PBM, volume and performance discounts available to wholesalers and pharmacies, and does not mention the impact on premiums. All of these issues can be explored in-depth in the future.

b) Summary and Key Findings

Product Supply Side and Reimbursement Side Different Entities Have Different Incentives That Affect Drug Affordability:

[20] U.S. Senate Finance Committee. Staff Report. *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*. January 14, 2022. https://www.finance.senate.gov/download/grassley-wyden-insulin-report

[21] Government Accountability Office (GAO). Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending. GAO-23-105270. September 2023. www.gao.gov/assets/gao-23-105270.pdf

Working through the example, it important to differentiate between the payments and flow of money on the product side (manufacturer to wholesaler to pharmacy, paid by the pharmacy benefit manager and patient copay), which results in the gross spend on the drug, and on the payment side (PBM payment to the pharmacy, manufacturer rebates to PBM), which results in the net cost of the drug to the health system and patient. Each side of the supply chain (supply vs payment) has its own incentives that impact drug affordability. These issues will be addressed in the next chapter.

Net Price is Often not Passed on to the Patient:

When patients pays cash, or payment is part of their deductible phase, copay or coinsurance (percentage of the cost of the drug), the amount the person pays is often based on the WAC or the total negotiated paid amount and does not account for any off-invoice discounts and rebates. That means that the patient is often actually paying a much higher percentage of the net cost of the drug, while rebates stay with the PBM and health plan. The health plan can use these funds to do things such as reduce premiums, lower out-of-pocket costs, or increase profits. This means that patients taking high-cost, highly-rebated drugs can pay a large percentage of the cost of the drug. Functionally, this also means that patients taking high-cost, highly-rebated drugs subsidize lower premiums for other beneficiaries on the health plan.

Higher List Prices Benefit Everyone in the Supply Chain Except for the Patient:

A higher list price with negotiated off-invoice discounts, such as rebates, benefit all entities in the supply chain except for the patient. It allows manufacturers to set a higher list price and argue that the list price does not matter because the net price of the drug is significantly lower. It potentially allows larger margins for wholesalers and pharmacies, because they generally receive margins that are a percentage derived from the list price, the higher the list price, the higher their margin. Finally, it benefits PBMs and health plans because it provides a selling point for PBMs to tell health plans and self-insured companies that they are getting a huge discount and savings, and it gives health plans and self-insured companies discretionary funds that they can use as they see fit, such as for reducing premiums or increasing profits. Most importantly, it creates a black box of prices where everyone in the supply chain can blame each other for the high costs of prescription drugs for patients, while not needing to take any responsibility for their own actions..

2. Additional Examples of Following the Dollars

All examples trying to demonstrate the flow of funds through the supply chain are going to be simplified from the extremely complex and intertwined actual transactions in the supply chain. Specific examples often try to demonstrate particular features or characteristics of the supply chain. There are a few examples worth reviewing to see the

different ways that this information can be conveyed.[22,23,24] While these examples can be illustrative, actual transactions provide different margins and profits to the different entities through the supply chain. For example, it is now common for pharmacies to be paid for certain drugs below their acquisition costs (i.e., they lose money on some drugs), while making substantial margins on other drugs. They earn profits on the entire book of business.

It is worth noting that it may be difficult, if not impossible, to track the exact net cost of a specific drug across the supply chain because of the complexity of the contracts; many of the discounts, fees, and rebates may be negotiated in aggregate and depend on things like volume and different performance metrics that can span across multiple drugs. This means that while different stakeholders may be able to state overall gross revenue and net revenue related to specific contracts and state that certain drugs may provide higher and lower margins, they may not be able to state the "net cost" of any specific drug.

In terms of where the dollars land in the supply chain in aggregate, one report (Figure 3) estimates that for every $100 from consumers (out-of-pocket costs and insurer payments), roughly $17 goes to drug production costs, $41 goes to the manufacturers (a third of which is net profit), and $19 goes to insurers ($3 of which is net profit). PBMs keep about $5 ($2 net profit), pharmacies keep about $15 ($3 net profit), and wholesalers keep about $2 (30 cents net profit). Total net profit on a $100 expenditure is $23, of which $15 is captured by manufacturers and the remaining $8 by intermediaries.[25] However, different reports have different estimates and there is huge variability for different products. Finally, very blunt estimates are used for this information because all of these transactions live in a black box that prevents the public from understanding where the money lands and what are the true costs of prescription drugs.

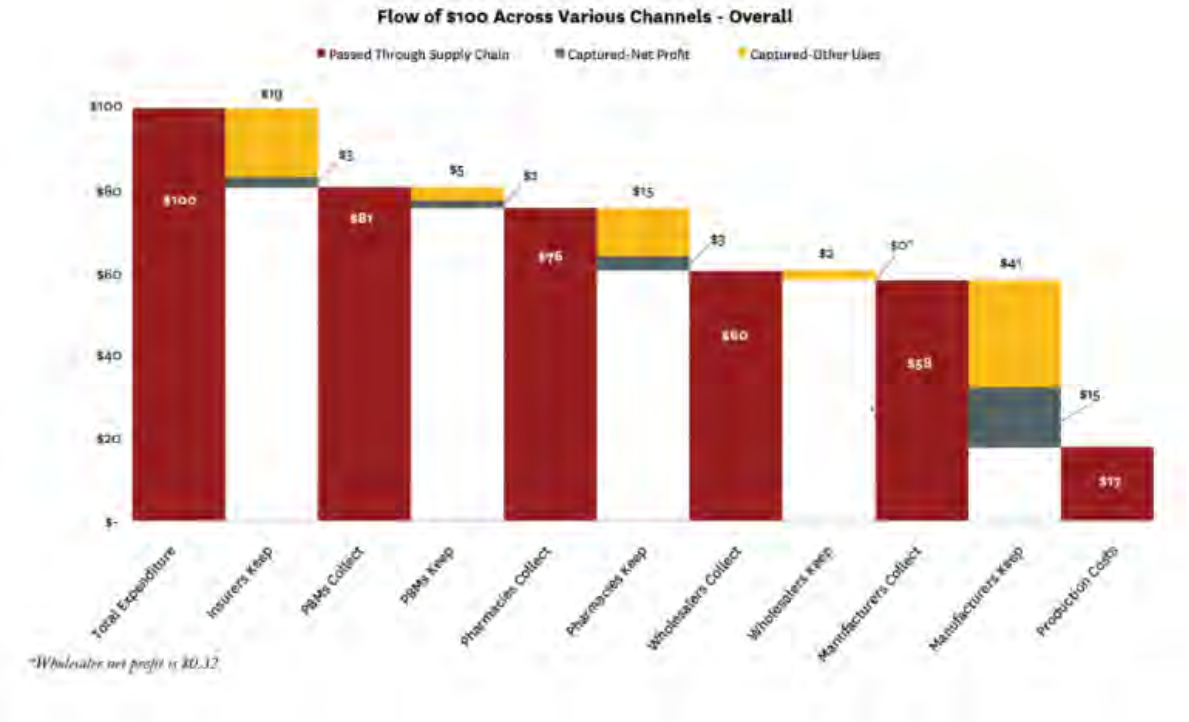
[22] Rockoff J. Behind the Push to Keep Higher-Priced EpiPen in Consumers' Hands. WSJ. Aug. 6, 2017. This Wall Street Journal article attempts to trace the funds and profits throughout the supply chain for Epipen. Similar to insulin, Epipen shows the extreme example of where the incentives in the supply chain can lead.

[23] Fein A. Follow the Dollar Math: How Much Do Pharmacies, Wholesalers, and PBMs Make From a Prescription? Drug Channels. August 08, 2017. https://www.drugchannels.net/2017/08/follow-dollar-math-how-much-do.html. This article shows the work behind the assumptions that are built into the WSJ Epipen example.

[24] Alston A, Dieguez G, Tomicki S. A primer on prescription drug rebates: Insights into why rebates are a target for reducing prices. Milliman. May 21, 2018. https://www.milliman.com/en/insight/a-primer-on-prescription-drug-rebates-insights-into-why-rebates-are-a-target-for-reducing. This article shows another example of the flow of funds behind rebates.

[25] Sood N, Shih T, Van Nuys K, and Goldman D. The Flow of Money Through the Pharmaceutical Distribution System. USC Schaeffer Center White Paper Series. June 2017. https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/

Figure 3. Flow of a Hypothetical $100 expenditure on prescription drugs covered under private insurance through the US distribution system.[26]



3. Features of the Generics Supply Chain

There are some important features that are specific to the generic supply chain and generic market that are worth noting. First, the profit margins are different for the different stakeholders in the supply chain. Where most of the profits likely accrue to the manufacturer in the brand name market, the other supply chain entities make a larger percentage of the profit in the generic market. While manufacturers make about three times the gross profits on branded vs. generic drugs ($58 vs. $18, consistent with the market exclusivity granted to patented drugs), other segments make much more on generic expenditures: PBMs make four times as much on generic drugs compared to brand, while wholesalers make eleven times as much, and pharmacies almost twelve times as much ($32 compared to $3).[27] An analysis in Medicare Part D demonstrated that PBMs represent 40.8% of gross profits, pharmacies represent 17.2% of gross profits, wholesalers represent 12.0% of gross profits, and manufacturers represent 30.0% of gross profits.[28]

[26] *Id.*

[27] Sood N, Shih T, Van Nuys K, and Goldman D. The Flow of Money Through the Pharmaceutical Distribution System. USC Schaeffer Center White Paper Series. June 2017. https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/

[28] Mattingly, T. Joseph, et al. "Pharmacy Benefit Manager Pricing and Spread Pricing for High-Utilization Generic Drugs." JAMA Health Forum. Vol. 4. No. 10. American Medical Association, 2023.

The generic market also allows for different distortions in the supply chain payments than what are seen in the brand name market. Generic drugs often have the largest difference between their WAC and the national average drug acquisition cost (NADAC), meaning that there is a lot of flexibility for different margins for different stakeholders in the supply chain. Generic companies are often competing with other generic companies selling the therapeutically equivalent products and use the combination of list and actual sales price to get favorable procurement decisions.

The relatively new and more transparent business model of cost-plus pricing has shown some of the distortions in the generics market. Companies like the Mark Cuban Cost Plus Drug Company[29] and Blueberry Pharmacy[30] have been using this model, but the other pharmacies have stated their intent to use this model.[31] The firm, 46 Brooklyn, described observations related to the Mark Cuban Cost Plus Drug Company's experience with the drug albendazole.[32] The Mark Cuban Cost Plus Drug company is focusing on selling generic drugs, and using a cost-plus model where they acquire the drug and use a fixed mark-up in its labeling and sale. For the initial drugs it sells, the Mark Cuban Cost Plus Drug Company purchases the drug from a generic manufacturer and sells it under its own label and NDC but uses the same Abbreviated New Drug Application (ANDA) as the actual manufacturer.[33]

- Cost to Manufacture the Drug and Sell to the Wholesaler: The Mark Cuban Cost Plus Drug Company identified its cost to produce albendazole as $13 per pill, and with the 15% mark-up, it could set the WAC at $15 per pill. This is multiples lower than the existing prices from the multiple manufacturer labels selling the drug from the same ANDA.
- Cost to the Pharmacy from the Wholesaler: the firm,46 Brooklyn, reports that the NADAC (which is the estimated price sold to pharmacies) of albendazole was $132.19 per pill in December of 2020. This is almost 10 times higher than the reported cost to manufacture the drug. This suggests that the wholesalers should be able to negotiate comparable deals to what the Mark Cuban Cost Plus Drug Company was able to negotiate; it also suggests that there is over a $100 mark-up at the wholesaler-to-pharmacy point for that drug.
- Reimbursement to the Pharmacy for the Drug: the firm, 46 Brooklyn, reports that the average pharmacy was reimbursed $76 dollars ($14 copay from the patient and

[29] https://costplusdrugs.com/
[30] https://blueberrypharmacy.com/
[31] Mathews AW. CVS Plans to Overhaul How Much Drugs Cost. WSJ. December 5, 2023. https://www.wsj.com/health/healthcare/prescription-drug-costs-cvs-pharmacy-56acb623
[32] 46 Brooklyn Podcast. Episode 9: What can Mark Cuban teach us about over-inflated drug prices? July 4, 2022. https://www.46brooklyn.com/podcast
[33] The Mark Cuban Cost Plus Drug Company sells their drug manufactured under the ANDA A211117, which belongs to Edenbridge Pharmaceuticals.

$62 from the PBM). This suggests that pharmacies fill albendazole at a loss or receive other off-invoice discounts from the wholesaler. Also, NADAC overrepresents small and/or independent pharmacies, so there is a chance that chain pharmacies are able to acquire the drugs at an even lowest cost.

- Cost to the Payer for the Drug: the firm, 46 Brooklyn, reports that the average cost to a Medicare plan, according to the Medicare Part D Dashboard, is approximately $130. This suggests that the PBM makes a margin of about $50 on each pill.

These observations are based on available data sources (NADAC data, pharmacy sales data, and Medicare Part D Dashboard), so stakeholders may suggest that these observations do not represent true margins or values for these transactions. However, if that is the case, it just reinforces that there is a need for transparency throughout the supply chain to understand exactly how we get from a cost of $13 per pill to the health plan and patients paying closer to $130 per pill.

IV. DISTORTIONS IN THE PHARMACEUTICAL MARKET

A. Introduction to the Pharmaceutical Market

The pharmaceutical industry has factors that result in high prices to the health plan and patient. In this section, we explore these different issues. Distortions in the pharmaceutical industry fall into three broad categories—issues with imperfect competition, imperfect information, and perverse incentives.

Imperfect competition exists when markets do not meet the requirements of a competitive market. When markets are imperfect, prices may be too high or too low (depending on who has market power) and as a result, entities produce or consume lower quantities of a product than what would be provided in a competitive market at a higher or lower cost.

The first source of imperfect competition is the monopoly power of drug manufacturers. Branded drug companies receive monopoly power when they obtain patents from the US patent office or market exclusivities from the Food and Drug Administration. When there are competing branded companies, there is oligopsony power.

Imperfect information exists when one entity cannot fully observe the actions (including potential actions) of another entity. As noted earlier, the prices in the supply chain are not transparent. This issue is particularly important when one entity is supposed to act as an agent of the other entity. When the principal to this agent cannot observe the first agent's actions (e.g. prices), incentives exist for the agent to act in their interest at the expense of the principal. The complexity of the supply chain results in several such relationships. It can be unclear whose interest several entities are working for.

Finally, there are segments of the pharmaceutical supply chain where the incentives encourage the use of higher-priced drugs. This is especially apparent for physicians administered drugs where the Medicare program pays the physician a fee that is dependent on the price of the drug and is higher with more expensive drugs. These incentives may cause manufacturers to increase the price of their drugs to respond to the financial incentive.

In this section, we split the issues into the three types of issues outlined above.

B. Issues with Imperfect Competition: Manufacturers

The prescription drug market often does not adhere to the principles of perfect competition. These issues begin with the fundamental tradeoff between innovation and access.

The US prescription drug market is built on the framework created in 1984 by the Price Competition and Patent Term Restoration Action (the Hatch-Waxman Act).[34] The general social contract created under the Hatch-Waxman Act is that the federal government gives the manufacturer of a new drug a monopoly for a certain amount of time to allow the manufacturer to recoup the substantial investment necessary to bring a drug to market, and allow them to earn a return on that drug to fund and incentivize future innovation. In exchange, the Hatch-Waxman Act creates an abbreviated approval process to bring substantial generic competition to market shortly after the government-granted monopolies expire, quickly reducing the cost of the drug to almost commodity pricing.

This framework has proven effective, with generics making up over 90% of the the prescriptions dispensed and only making up about 17.5% of the total spend.[35] The United States has the highest proportion of generic drugs dispensed and generally has lower generic drug prices than other industrialized countries.[36]

This framework has also created challenges. Americans pay higher prices for prescription drugs than any other country in the world, with prescription drug prices in the U.S. that are more than 2.5 times as high as those in other similar high-income nations.[37] This

[34] Drug Price Competition and Patent Term Restoration Act. Public Law 98-417. www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf
[35] Association for Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report. September 2023. https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf
[36] Mulcahy, AW, Whaley C, et. al. International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies. RAND Corporation. 2021. https://www.rand.org/pubs/research_reports/RR2956.html
[37] *Id.*

framework also creates incredibly strong incentives for manufacturers to extend their government granted monopolies as long as possible (arguably longer than what was originally intended when the Hatch Waxman Act was created). For blockbuster drugs, evening a few months of monopoly extension can result in hundreds of millions of dollars of additional revenue, sometimes resulting in total increases of tens of billions of additional revenue.[38]

In this section, we introduce the background related to the incentives created to develop new drugs. We also discuss how these incentives have also encouraged manufacturers to engage in behaviors to extend their monopolies without always providing meaningful innovation.

In addition to these issues with manufacturers, other parts of the supply chain have issues with imperfect competition. In response to the exercise of market power by manufacturers, consolidated entities have arisen to partially counteract the market power of the manufacturers. However, since these entities are consolidated, they can exert market power on those vying for their services

1. Introduction to FDA Approval Process

The manufacturing and sale of prescription drugs is regulated at the state and federal level. At the federal level, the U.S. Food and Drug Administration ("FDA") "is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices."[39] In discharging this responsibility, the FDA has approved more than 20,000 drugs for marketing and sale in the United States. Because the approval pathway and associated costs vary depending on the kind of drug that is brought to market—brand name, generic, biologic, or biosimilar—the pricing for those drugs likewise varies.

a) FDA Approval Process for New Drugs (Small-Molecule Brand Name)

Small-molecule drugs are compounds with low molecular weights that are capable of modulating biochemical processes to diagnose, treat, or prevent diseases. Small-molecule drugs include the drugs typically found in patients' medicine cabinets. Before a new small-molecule drug may be legally sold in the United States, the drug manufacturer must submit a New Drug Application ("NDA"), with supporting information, to the FDA. The manufacturer conducts clinical trials to demonstrate the safety and efficacy of the new

[38] Robbins R. How a Drug Company Made $114 Billion by Gaming the U.S. Patent System. New York Times. January 28, 2023. https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html

[39] https://www.fda.gov/about-fda/what-we-do (last checked September 14, 2022).

drug and submits that information to the FDA along with information about whether the benefits of the drug outweigh the risks, the appropriateness of the drug's proposed labeling, and whether the methods and controls used to manufacture the drug are sufficient to preserve the drug's strength, quality, and purity.[40]

Bringing a new drug to market can be a risky and costly process—estimates range from $300 million to $3 billion from research and development through FDA approval.[41] Once approved, name-brand drugs receive market exclusivities and the manufacturer sets the "list price" of the drug known as the wholesale acquisition cost (WAC). While this number is not tied to a real sales price, it does provide a benchmark for other supply chain transactions.

b) FDA Approval Process for New Drugs (Biologic)

Biologics are medicines derived from living cells or biological processes; they may be living entities such as cells and tissues, or complex molecules composed of sugars, proteins, or nucleic acids, or a complex combination of these substances.[42] Biologics include things such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

To obtain FDA approval for a biologic drug product, a biologic manufacturer files a biologic license application demonstrating through laboratory and clinical studies that the product satisfies safety, purity, and potency requirements.[43]

The fragility of biological macromolecules and the sensitivity of the living cells that produce biologics impose complex manufacturing requirements for fermentation, aseptic processing, storage, and testing. Thus, manufacturing, storing, and distributing it is expensive.

c) FDA Approval Process for Small-Molecule Generic Drugs

[40] *See generally* 21 U.S.C. § 355 (small molecule new drug application); FDA. New Drug Application (NDA). January 2022. Link Verified: November 15, 2022. https://www.fda.gov/drugs/types-applications/new-drug-application-nda

[41] Wouters, OJ, McKee, Luten J. *Estimated Research and Development Investment Needed to Bring a New Medicine to Market*, 2009-2018. JAMA. 2020 Mar 3;323(9):844-853. doi: 10.1001/jama.2020.1166.

[42] Morrow, T, Felcone, LH. *Defining the difference: What Makes Biologics Unique.* Biotechnol Healthc. 2004 Sep;1(4):24-9. PMID: 23393437; PMCID: PMC3564302.

[43] 21 C.F.R. § 601.2, subd. (a). *See also* (last checked November 23, 2022) https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products

Generic drugs are approved by the FDA through the Abbreviated New Drug Application (ANDA) approval pathway.[44] Under this pathway, the FDA relies upon its prior safety and efficacy determination of the original drug, and a manufacturer must only demonstrate bioequivalence to the brand name reference product, instead of the full preclinical and clinical trials to bring a drug to market under an NDA. In addition, the generic drug manufacturer must certify either (1) that the brand name drug's patent has expired or is invalid, or (2) that the generic manufacturer's sale of the drug will not infringe on any of the brand name drug's patents.[45]

This allows generic drug manufacturers to bring drugs to market more quickly and at a lower cost. Because a generic drug may be substituted for brand-name and other generic drugs, robust competition incentivizes manufacturers to produce and sell the drug at the lowest possible price—that is, at an amount that approaches the marginal cost of production.

d) FDA Approval Process for Generic "Biosimilar" and "Interchangeable" Biologics

A biosimilar drug is a biological product that is similar to a previously-licensed, branded biologic drug. Because the active component of a biologic is often a portion of a large complex macromolecule, the "new" drug will never be the exact molecule as the reference biologic, and, due to the complexity of the molecule, it is difficult to develop. For this reason, generic versions of biological drugs are not approved through the same process as generic small-molecule drugs.

Instead, biosimilars are approved under the abbreviated 351(k) approval pathway. The manufacturer must show that the biosimilar is highly similar to, and has no clinically meaningful difference in safety, purity, and potency from an existing FDA-approved reference product.[46]

The 351(k) licensure process can be very costly and biosimilars have the same high manufacturing costs as reference biologic products. Drugs that are approved as a biosimilar under the 351(k) pathway may not be substituted for the reference biologic in the same way that a generic small molecule drug may be substituted for the reference brand name drug.

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[44] FDA. Abbreviated New Drug Application (ANDA). January 2022. Link Verified: November 15 2022. https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda#:~:text=An%20abbreviated%20new%20drug%20application,brand%2Dname%20drug%20it%20references.

[45] 21 U.S.C. § 355, subd. (j)(2)(A).

[46] 42 U.S.C. § 262, subd. (k); *see also* FDA. *Biosimilar Development, Review, and Approval*. October 17, 2017. https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval

"Interchangeable" biologic drugs are biosimilar drugs that have received an "interchangeable" designation upon satisfactorily demonstrating that they can be expected to produce the same clinical results as the original biologic in any given patient.[47] The interchangeability issue prevents direct competition between the biologic and biosimilar since unlike small molecules and generics they cannot be substituted at the pharmacy counter.

2. U.S. Patent System

The monopoly that exists in drug markets is partially the result of government-issued patents. The government issues patents to 1) give companies incentives to engage in research and development and 2) encourage companies to disclose knowledge.[48]

There are many types of patents that a drug product can receive. The most basic type is a primary or drug substance patent. These patents cover the active pharmaceutical ingredient and are considered the strongest patent for small molecule products because there is only one molecule and it cannot be copied . For biological products, this patent is still a primary patent but is considered weaker because a biosimilar does not need to have the same chemical structure, and the size of the molecules makes it easy to make small changes. The next strongest patents are drug product patents, which patent the active ingredient in a particular formulation. In addition, pharmaceuticals may receive many other types of patents such as patents on delivery mechanisms and patents on manufacturing technologies and processes.[49] These are often referred to as secondary patents.

3. The Patent and Approval Process Provide Opportunities for Drug Companies to Extend the Patents In Several Ways

a) Intellectual Property Right Challenges Can Extend Monopoly Exclusivities Preventing Competitive Market Pricing

As described above, the patents and market exclusivity rights are given to manufacturers of new drugs. During this time, they can act as monopolists or oligopolists and charge prices above the competitive market rate. The expectation behind the Drug Price Competition and Patent Term Restoration Act (often known as the Hatch-Waxman Act) is that established the rules governing the FDA's process is that these patents and market

[47] 42 U.S.C. § 262, subd. (k)(4).
[48] https://www.wipo.int/patents/en/#:~:text=in%20patent%20documents.-,Patents%2C%20technology%20and%20development,information%20and%20promote%20technology%20transfer
[49] https://sgp.fas.org/crs/misc/R46679.pdf

exclusivities will eventually expire and generic and biosimilar competitors can enter the market and prices will decline.

Pharmaceutical companies have found ways to extend their potential exclusivities by filing more patents. Often these are not for the main components of the drug but involve secondary patents of how the drug is administered. One study found that 78% of patents for pharmaceutical products involved drugs already on the market rather than new drugs between 2005 and 2015.[50] The practice of obtaining new patents for old products is called "evergreening" and typically involves secondary patents.

Second, pharmaceutical companies appear to be increasing the number of patents covering their products in practice known as creating "patent thickets". These patent thickets make it harder for generics and biosimilar products to enter the market and have disrupted the traditional view that these secondary patents are weak. For instance, Enrbel, a drug approved in 1999, won a patent case that ensures no biosimilar entry until 2029.[51] That means the patent preventing the marketing of biosimilars until 2029. These kinds of practices increase the prices to health plans and patients, while not requiring additional research and development for new drugs.

An analysis of the patenting pattern for new drugs suggests that patenting after approval is common.[52] Forty percent of all newly approved drugs from 2004-2015 had patents added after approval. Among blockbuster drugs, drug manufacturers added patents after approval at least once 70 percent of the time, and for these drugs manufacturers added patents more than once 50 percent of the time.

The exact impact of these patents on generic entry is not known. While the advocacy group that studies patents - I-Mak - highlighted the number of patents for certain blockbuster drugs, deeper analysis shows that generics are set to enter prior to the expiration date of the last patents.[53]

b) Pay for Delay

One of the assumptions of the Drug Price Competition and Patent Term Restoration Act was incentives for generic firms to engineer around and challenge patents would lead to rapid entry once the patent protection was lost. The goal was to ensure that the weak patents listed above did not prevent generic competition. This incentive gives the first-to-file generic manufacturer 180 days on the market before FDA can improve another

[50] https://academic.oup.com/jlb/article/5/3/590/5232981
[51] https://www.amgen.com/newsroom/press-releases/2019/08/amgen-wins-patent-case-on-enbrel-etanercept
[52] https://aspe.hhs.gov/reports/cost-generic-drugs
[53] https://aspe.hhs.gov/reports/cost-generic-drugs

generic. This is an opportunity to earn substantial profit because the generic company can set the price at a small discount off the branded price without any generic competition.

Branded drug companies want to keep the generic drug companies from entering the market. This has led to an increasingly complex system of settlements where the generic first waits to enter the market because of the possibility of settlements between the brand and generic company. The branded company makes a cash or other type of financial arrangement with the generic company to delay entry. This increases the value of the first generic to file an application but prevents patients from seeing the savings from generic competition because of the financial settlement.

Research has shown that patent litigation is expensive and risky for generic manufacturers.[54] As a result, each year hundreds of generic manufacturers settle cases with the brand manufacturer, increasing the cost to the patient.

c) Issues Bringing Complex Generics to Market

Policy makers have paid attention to the increasing price of EpiPens and other products where it is not the drug but the means of administration that leads to higher prices because of patents or market exclusivities on the means of administration.[55]

EpiPens help people administer epinephrine to somebody experiencing anaphylaxis. The drug compound itself - epinephrine- was not the reason for the lack of generic competition. It is a generic. Instead, generic competitors had difficulties copying the device to administer the drug.

Issues in the Hatch-Waxman Act make it hard to bring generic versions of drug-device combinations products to the market. The law currently limits the information FDA can require that may help generic products get approved with slightly different devices. In the absence of easier ways to get these competitors approved, markets for complex generic products will continue to be uncompetitive. FDA has tried to remedy this by issuing Product Specific Guidance (PSGs). These PSG provide information on FDA's thinking about the data needed to support the approval for generic versions of a particular product. PSGs do not set requirements, so sponsors can submit packages that do not follow the PSGs. An analysis of PSG suggests it can bring these drugs to market 18 months sooner and increase the expected net present cost of drug development by $25 million.[56]

d) Lack of Biosimilar Approval and Utilization

[54] https://aspe.hhs.gov/reports/cost-generic-drugs
[55] https://www.statnews.com/2016/08/26/epipen-recipe-price-controversy
[56] https://aspe.hhs.gov/reports/cost-generic-drugs

Biosimilar and interchangeable biological products have the potential to help save patients and health plans substantial amounts of money. Even when not using biosimilar products, the introduction of biosimilars helps bring down reference product costs.[57]

Unfortunately, fewer biosimilar products are on the market in the U.S. than in Europe. There are several reasons for this. First, in some U.S. markets, biosimilars have not been approved even when the drug company patent and market exclusivity has expired. For example, Lucentis lost exclusivity in 2018 but the first biosimilar was not approved until 2021. Second, even with approved biosimilars, some take years to reach the market. For example, Humira settled with biosimilar manufacturers to delay the launch until 2023 despite approvals starting in 2016 (https://www.biopharmadive.com/news/abbvie-boehringer-ingelheim-settle-humira-patent-biosimilar/554729/). A third issue that will be discussed below is interchangeability of biologics and biosimilars.

e) Product Hopping

When a blockbuster drug loses its patent status, drug manufacturers sometimes create new versions of products , with new patent protection, in order to retain market share. These new products may include some innovation that increases the convenience of use (such as a long-acting version of a product). Such innovation may prove to have some value to patients and having patients decide if they want to pay extra for that convenience is a personal decision. However, at times pharmaceutical companies takes this decision away from patients and physicians by removing the older versions from the market before generic entry and forcing patients to switch to the new version of the product. This practice is known as product hopping.[58]

One study found that reformulation was less likely to occur after generic entry, which suggests that manufacturers are strategically reformulating to enable product switching prior to generic entry.[59] Product hopping has the potential to cut into the revenue of potential generic manufacturers of the original formulation. One study found that past product hops reduced first generic revenue on average by 29%.[60]

Without proper insight into when generics for such products will be available, it makes sense for consumers to switch to a similarly priced reformulation product if it has any (even if marginal) value.

f) Accelerated approval

[57] https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025
[58] https://sgp.fas.org/crs/misc/R46679.pdf
[59] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2792644
[60] https://aspe.hhs.gov/reports/cost-generic-drugs

If a drug is approved under accelerated approval, the drug does not go through a full clinical trial but instead the drug is approved on a surrogate endpoint and can be sold waiting a final confirmatory trial. In other words, the standard of evidence is lower.[61]

Under the accelerated approval pathway, drugs are approved by off surrogate rather than clinical endpoints. These surrogate endpoints are markers that are supposed to predict clinical endpoints. An example is the reduction in the size of the tumor instead of longer life expectancy. By using the surrogate endpoint, drug manufacturers can complete studies sooner in cases where the clinical endpoint takes a long time to develop. After receiving accelerated approval, drug companies must complete confirmatory studies to demonstrate the actual clinical benefit.

Recently the accelerated approval program has come under scrutiny. Companies have often delayed the completion of confirmatory studies because they can still sell the drug while they are completing the confirmatory trial. At the same time, the FDA has been reluctant to take action to remove the drugs from the market. Some of the drugs have been shown to have important side effects. By keeping them on the market, companies can earn money on the product without ever completing the confirmatory studies.

The pricing of accelerated approval drugs raises important questions. Since the accelerated approval is intended for drugs that treat serious and life-threatening diseases with unmet needs, the drugs approved under the pathway often are given a high price. However, the actual value of the drugs is not known without confirmatory studies.

With unrestricted pricing and lags in FDA action, companies might not have the incentives to complete the studies.

g) Issues with Skinny Labeling

Another issue is the use of skinny labels. Skinny labeling refers to the practice of generic and biosimilar products seeking approval with labels that do not include all the indications of the reference product. Labels that do not include all uses and patient populations that are included on the reference product label.[62]

These types of labels can occur when the manufacturer of the reference product has patents or exclusivity over a particular indication, use, or patient population on the label. Recent court cases have challenged the ability of generic and biosimilar manufacturers to market products with skinny labels. If brand manufacturers win in court, some drugs will have additional delays before generic and biosimilar products can enter.

[61] https://www.fda.gov/drugs/nda-and-bla-approvals/accelerated-approval-program
[62] https://www.commonwealthfund.org/blog/2021/skinny-labeling-pathway-timely-generic-drug-competition

One study examined the frequency of generic approvals with skinny labels.[63] They found 43% of first generics from 2015 to 2019 had skinny labels. Without skinny label approval, the average approval would have been delayed over three years. In another study, authors found that 62% of marketed biosimilar products were approved with skinny labels.[64]

If the practice of skinny labels is eliminated, there will be major delays in the approval of generics and biosimilar drugs. The current estimates do not consider the potential incentives to add new patient populations, indications, or methods of use to the label. Manufacturers would have the incentive to add more and delay the addition of indications so that they can maximize the length of the monopoly.

4. Lack of Competition Along the Supply Chain

The large three PBMs–CVS Caremark, Express Scripts, and OptumRx--represent over 75% of the prescription drug market and are all affiliated with health plans. Three large wholesalers–AmerisourceBergen, Cardinal Health, and McKesson Corporation–help distribute over 90% of the prescriptions in the United States. Through the pharmaceutical supply chain, we find very concentrated environments. Because each player interacts with more components of the supply chain, high market concentration allows them to leverage their power and increase profits.

PBMs negotiate with manufacturers to get rebates on drugs. By consolidating multiple insurers together, PBMs can potentially get lower prices for a drug than the plan would be able to get themselves. This allows PBMs to provide countervailing market power to drug manufacturers. However, they also have market power over the health plans and can extract some of the savings on reduced prices. Similarly, PBMs negotiate with pharmacies. This may allow them to get lower dispensing fees and smaller markups on ingredient costs. However, the PBMs may not fully pass on these savings to their health plans.

In terms of wholesalers, they negotiate with drug manufacturers (particularly generic manufacturers) to get lower prices for pharmacies. However, since the wholesaler market is highly concentrated, they may have market power over pharmacies. In response, buying alliances between chain pharmacies and wholesalers are forming and buying collaboratives with independent pharmacies. This can add to the cost to the health plan and patients.

[63] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2777965

[64] https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2798552?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamainternmed.2022.5419

An individual patient has virtually no market power and interacts with only a small number of potential health plans and pharmacies. That gives health plans market power over patients. One way in which patients counteract market power is through employer-sponsored plans or union sponsored-plans. In addition, government regulations (such as Medical Loss Ratio regulations) exist to limit (but not eliminate) insurer market power.

Since some entities are engaged in transactions on both sides of the market (e.g. health plans and PBMs), it is often difficult to know what an entity is doing on the other side of the market. As a result, it is hard to hold them accountable. Even if one does eventually figure out potential issues and violations, the lack of competition means few alternatives exist to increase competition. Also , they can change the behavior and replace it with another behavior.

C. Issues of Imperfect Information

Imperfect information is an economics term that describes the fact that all sides of the transaction may not have the same information. It can enable agents (those acting on behalf of another) to act in their own best interest and not in the best interest of their client. Throughout the supply chain, several entities act as agents of other entities. For instance, wholesalers act as agents for pharmacies. PBMs act as agents for health plans. In this section, we highlight the issues that result in imperfect information and the problems that can arise from imperfect information.

1. Lack of Transparency

Because the pharmaceutical supply chain involves many players, with different interactions, that occur at different points in time, the supply chain lacks transparency. Each player in the supply chain has several interactions that they may manipulate to increase profits. For instance, if a health plan tries to eliminate spread pricing for the ingredient cost to the PBM, the PBM can potentially work with pharmacies to increase the ingredient cost and make instead have pharmacies pay higher fees later. It can become a game of “whack a mole.”

The exact distribution of market power along the supply chain varies within the context of a particular drug. As a result, it is hard to understand how much money a particular entity is making on a particular drug. One study found that for a $100 brand name drug, manufacturers received $58 in profit, wholesalers received $1 in profit, pharmacies received $3 in profit, PBMs received $2 in profit, and health plans received $19 in profit. In contrast, for $100 in generic drugs, manufacturers received $18 in profit, wholesalers

received $8 in profit, pharmacies received $32 in profit, PBMs received $7 in profit, and insurers received $17 in profit.[65]

The profit margins for each entity vary by drug and drug category. These numbers described in the previous paragraph represent averages, but there is great variability between drugs. The lack of transparency along the supply chain means that for certain drugs some entities in the supply chain receive even more profit at the expense of others in the supply chain. On the one hand, the lack of transparency at times can help entities in the supply chain do their jobs in lowering costs since they have a financial incentive. On the other hand, the lack of transparency also makes it less likely that those additional savings flow along the supply chain and to the consumer.

Various federal and state laws already require public disclosure of limited pricing information and price reporting by companies or payers. For example, the 2021 Consolidated Appropriations Act requires manufacturers to report (quarterly) average sales price information to the Centers for Medicare & Medicaid Services (CMS) for medications covered under Medicare Part B.[66] Reporting of the cost of drugs in the pharmacy is not complete.

2. Vertical Integration Along the Supply Chain

One possible solution to the principal-agent problem is vertical integration. However, vertical integration along the supply chain raises other concerns. Since the early 2000s, various entities in the supply chain have integrated with one another. While the supply chain sketched out above delineates the different roles, it is not an accurate depiction of the differences in organizations. Instead, we have a patchwork of organizations that own various parts of the supply chain. This means a company may be negotiating with its subsidiary or a competitor on behalf of itself or a competitor.

For instance, CVS Health has expanded its role throughout the supply chain. In 2006, CVS acquired MinuteClinic, a chain of primary care clinics run by nurse practitioners In 2007, they merged with Caremark. In 2017, CVS Health acquired Aetna, a large insurer, but was required to divest Aetna's Medicare drug plans as part of the deal. OptumRx is a subsidiary of UnitedHealth Group and was founded by UnitedHealth Group in 2011. Since then, OptumRx became part of a larger Optum (still owned by UnitedHealth Group) that has expanded to include data analytics, consulting, and medical services.

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[65] Sood, N., Shih, T. Van Nuys, K. & Goldman, D. (2017). *The Flow of Money Through the Pharmaceutical Distribution System* [White paper]. University of Southern California Schaeffer Center for Health Policy & Economics. https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/

[66] United States, Congress. Public Law 116-260, Consolidated Appropriations Act, govinfo.gov, 2021. https://www.govinfo.gov/app/details/CPRT-117HPRT43749/CPRT-117HPRT43749.

ExpressScripts became the largest PBM after acquiring Medco (another PBM) in 2012. Then in 2018, Cigna (a large health insurer) bought ExpressScripts. Outside of the PBM space, Walgreens purchased a 30% stake (making it the largest single shareholder) in wholesaler AmerisourceBergen.

This type of vertical integration raises important questions. As this section shows, the pharmaceutical supply chain involves many interactions. Vertical integration often means an entity gets to negotiate with its competitors – e.g. Walgreens – a pharmacy owns part of a wholesaler, AmerisourceBergen, that sells to other pharmacies. These interactions could result in anti-competitive practices if the integrated firm gives itself preferential treatment or abuses privileged information from competitors. In addition, the different roles of the same entity raise the possibility of self-dealing.

The first PBM originated in 1968 as Pharmaceutical Card System, Inc, which later changed its name to AdvancePCS. Their original purpose was to allow medication purchases to occur at certain pharmacies. As the years progressed, their purpose evolved to integrate electronic adjudication of real-time claims of medications which allowed them to take more control over the pharmaceutical industry in the1980s. After the merging of PBMs and insurers began, their roles continued to evolve from just processing prescription transitions and claims to being more involved with negotiating drug discounts with manufacturers and assisting with drug utilization reviews (DURs). In collaboration with insurers, PBMs began to assist in creating drug formularies that insurance companies would require their patients to pick from when it came to medication drug coverage.

3. Few Incentives Exist for Entities to Act as Fiduciaries of the Patient

Patients are trapped by this system because there is little incentive for entities along the supply chain to consider the cost to the patient. In this section, we explain the system ultimately ends up resulting in the passing of more out-of-pocket responsibility to patients. We then explain issues arising related to out-of-pocket costs. Patents find themselves stuck in an arms race between manufacturers pushing high-cost drugs and insurers/PBMs attempting to influence the patient's medical decision-making.

a) The supply chain encourages higher prices and passing more responsibility to patients.

One main concern with the pharmaceutical supply chain is that it encourages higher list prices for brand drugs. Each participant in the supply chain (aside from patients) experiences higher profitability with higher list prices.

Wholesalers make more if the list price is higher. Even if the margins are small, profit increases with the price since it is the same small percentage of a larger number. From the manufacturer's perspective, the increased price either makes more money by increasing the price or allows them to give larger rebates to PBMs. Even if the list price remains the same, if multiple competitors have high list prices, it increases the wedge between preferred and non-preferred brands and thus helps drive volume to them when preferred. For the PBM, higher prices and higher rebates may mean more money if they are paid in ways that allow them to retain rebates.[67]

For health plans, this strategy allows them to retain the same actuarial value of insurance while creating a scheme that transfers rebates to lower premiums or higher profits . Since the price increases for cash customers when the list price increases, patients can pay the same percentage of that price without changing the actuarial value of insurance. However, since net prices are the same, insurers earn higher profits. This allows them to either cut premiums or earn more profit (subject to MLR limits). Both may generate more money if the lower premium allows the insurer to attract more customers (and potentially more health customers which reduces the risk in their risk pool).

For pharmacies and wholesalers, higher priced brand name drugs might mean larger profits. For wholesalers, higher prices increase revenues and profit because they make a similar percentage of the cost of the drug regardless of price. Pharmacies might make larger profits if the change in the benchmark payment by the PBM is slightly different from their acquisition cost. For instance, a pharmacy that purchased drugs right before a price increase can suddenly make more profit by selling them after the benchmark payment changes in response to the price increase.

Ultimately, everybody in the supply chain earns higher profits in this situation except for patients that need access to drugs, particularly those without insurance. There is fundamentally a lack of incentive to adequately consider the well-being of the patient.

b) Patients find themselves caught in a war between manufacturers and insurers/PBMs over out-of-pocket costs

Plans and PBMs want to control spending by directing patients to the drugs that provide higher profits to the health plan and/or PBM. More important; however, there has been an increasing war between manufacturers and Plans/PBMs over ways that reduce out-of-pocket costs. Manufacturers have developed new ways to "help" patients with their out-of-pocket costs. While PBMs/Plans have attempted to create new ways to prevent manufacturers from circumventing negotiations. While these systems (described below)

[67] Shepherd, J., *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs* (January 1, 2019). Yale Law & Policy Review, Vol. 38, 2019, Available at SSRN: https://ssrn.com/abstract=3313828 or http://dx.doi.org/10.2139/ssrn.3313828

lower the out-of-pocket cost to patients, the interfere with the attempt to have the patient use the drug with the greatest value.

(1) Co-Pay Coupons and Free Samples

Manufacturer copay cards for commercially insured patients are provided to a pharmacy at the point of sale to reduce a patient's out-of-pocket costs. Publicly insured patients are prohibited from using them for reasons that will be described below.

To encourage the use of brand-name drugs, drug companies provide copay coupons and free samples of drugs. The goal of these programs is to get patients to start using their drugs and thus prevent them from using a competing product instead.

In one sense, copay coupons and samples help lower the net price of drugs to patients. It lowers their out-of-pocket costs and makes them more easily able to afford copays and deductibles. Copay coupons also count against the net revenue received by manufacturers.

However, co-pay coupons are mainly a way to undermine the ability of PBMs to select the drugs with the greatest value. When patients use copay coupons the effectiveness of tiered formularies for selecting the drug with the highest value is undermined. The concern that co-pay coupons are mainly used to circumvent formularies comes from the fact that coupons are more likely to be offered if there is a brand-name competitor.[68]

(2) Independent Charity Patient Assistance Programs

Besides the copay cards and coupons, drug manufacturers provide financial support to charities to create patient assistance programs. These charities help provide support to patients to cover their copays. These are primarily to assist publicly insured patients which cannot get coupons. Amazingly, these charities seldom provide assistance to the uninsured.

In theory, these charities are supposed to be independent. However, at times the pharmaceutical companies and the charities have structured arrangements that have been found to violate federal law.[69] Research has shown that patient assistance programs help pharmaceutical companies make money while being able to deduct donations from taxes.[70]

[68] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2783127
[69] https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid
[70] https://www.nejm.org/doi/full/10.1056/NEJMp1401658

(3) Accumulator Programs Shift Drug Costs to Patients

The use of coupons has led some PBMs and health plans to establish copay accumulator and maximizer programs. Copay maximizers take the value of the coupon and ensure they don't count against the deductible.[71] Both these programs have the effect of shifting the cost back to patients. States have been reviewing these copay accumulators.

(4) Patient Cost-Sharing Impacts Adherence

A recent analysis of branded prescription drug trends found that if patient out-of-pocket costs totaled between $50 and $74.99 per month, 30 percent of patients would not fill their medications. If that amount were increased to $250 or more, over 70 percent of patients would forego critical prescription drugs.[72]

Another study highlighted the negative impact of copay accumulator programs finding that patients who are subject to the programs fill prescriptions 1.5 times less than patients in high deductible health plans. Additionally, patients subject to these programs experience a 13 percent drop in persistence between months 3 and 4 as they reach the cap in their annual benefits and terminate their therapies.[73]

D. Incentives for Perverse Behavior

Throughout the supply chain, some incentives exist that reduce affordability. These incentives exist because of insurance system design, complex supply chain relationships, and payment practices.

1. Issues with Different Drug Payment Systems

Different types of insurance use different mechanisms for pricing drugs. These create different incentives, and this impacts the prices of drugs. The main types of insurance are Medicare, Medicaid, and commercial insurance.

a) Medicare

Medicare is the federally administered health benefit for Americans over 65 years old and Americans with disabilities and end stage renal disease. Medicare is largely separated

[71] https://www.drugchannels.net/2022/02/four-reasons-why-pbms-gain-as.html
[72] IQVIA National Prescription Audit, Formulary Impact Analyzer, January 2019.

[73] Steve Mink and Arran Standring, "Driving persistence among patients affected by copay accumulators with patient-centric support," American Journal of Managed Care, October 18, 2020.

into four main benefit categories. In Maryland, there are about 800,000 people covered by Medicare.

Medicare Part A largely covers inpatient hospital services. In future papers, we may explore drug costs in the hospital.

Medicare Part B covers outpatient benefits, including physician-administered drugs (Part B drugs). Part B has specific rules for reimbursing physician-administered drugs. Specifically, Part B is a fee-for-service (FFS) structure that reimburses Part B based on the Medicare average sales price (ASP) plus 6 percent. As a result, physicians have a financial incentive to select the more expensive drug.

Most commercial payers follow Medicare's lead on this policy and pay for Part B drugs in the "buy and bill" model out of the medical benefit. Commercial payment amounts are often based on Medicare's payment amounts (usually some percentage higher than ASP), but this is not universally true. This payment structure may create an incentive for providers to select higher-cost drugs to administer to patients because the percentage-based payment to the physician is higher for drugs with a higher ASP.

Medicare Advantage (Part C) is the private plan alternative to traditional Medicare fee-for-service. In Medicare Advantage, the Medicare beneficiary enrolls in a private health plan that covers inpatient (Part A), outpatient (Part B), and usually prescription drugs (Part D). Medicare Advantage plans must follow rules set by Medicare, and are subsidized by Medicare, but they have some flexibility in the benefit design that allows them to provide benefits and have a different benefit design than traditional fee-for-service Medicare. Medicare Advantage functions much like the commercial market. approximately half of all Medicare beneficiaries are enrolled in Medicare Part C

Medicare Part D is the standalone prescription drug benefit that covers prescription drugs. Similar to Medicare Advantage, Part D is provided through private prescription drug plans that are subsidized by Medicare. Medicare Part D has a very specific plan design, but the Part D plan has the flexibility to design its own formulary and certain design elements that are different from the standard Part D plan design as long as they follow certain rules and meet certain tests of actuarial equivalence. The Inflation Reduction Act included some substantial updates to the Medicare Part D program, including most importantly an annual out-of-pocket cost maximum. One of the major issues with the initial plan design was that there was no out-of-pocket cost maximum and Medicare does not allow for the use of copay coupons, so there were some Medicare beneficiaries with substantial out-of-pocket costs. In 2022, 49 million Medicare beneficiaries enrolled in Part D plans. Of that total, 53% were enrolled in Medicare Advantage Part D plans (MA-PD) and 47% were enrolled in standalone prescription drug plans.

Initially, Part D design had the Medicare beneficiary paying a large portion of the cost of the drug. At the beginning Part D benefit design included a deductible phase, an initial coverage phase, a coverage gap phase, and a catastrophic phase.[74] In the deductible or first phase, patients were completely responsible for the cost of drugs. In 2023, the standard deductible was $505. After the deductible phase, plans paid 75 percent and patients paid 25% percent during the initial coverage phase. In 2023, the initial coverage period lasted until $4,660 in spending. After that, patients were still responsible for 25 percent and plans were responsible for 5 percent of spending during the coverage gap phase. During this phase, manufacturers made up the other 70 percent as part of the "coverage gap discount" program. This phase lasts until $11,206 in spending. Finally, in the catastrophic phase, the government pays 80% of the spending while patients pay 5 percent and Part D plans pay 15 percent. Some worried that this plan design encouraged Part D plans to favor high-price, high-rebate drugs. High prices and rebates resulted in patients moving through the benefit design more quickly, resulting in patients reaching the catastrophic phase, where the government is responsible for the majority of the spending.

The IRA passed in 2022 changes the Medicare plan design. After 2025 there is only the deductible phase, the initial coverage period, and the catastrophic phase. The deductible phase remains the same. In the initial coverage period, patients cover 25 percent of the cost, plans cover 65 percent, and manufacturers cover 10 percent. This phase lasts until a $2,000 Out-of-pocket threshold. After that threshold, plans are responsible for 60 percent, manufacturers are responsible for 20 percent, and the government is responsible for the last 20 percent. The Medicare beneficiary pays nothing. The hope is that this design prevents Part D plans and manufacturers from jointly having incentives to reach the catastrophic phase. In addition to all of these changes, the IRA also allows Medicare patients to spread their deductible out over the year.

b) Medicaid

Medicaid is a joint federal-state program that provides healthcare to economically disadvantaged populations, including low-income children and their families, low-income seniors, and low-income people with disabilities. Within federal guidelines, states establish their own eligibility standards, benefit packages, provider payment policies, and administrative structures, so each Medicaid program is state specific. Medicaid is the largest health program, covering an estimated 70.2 million people in fiscal year 2019. In 2021, there were about 1.2 million people covered by Medicaid in Maryland.

Medicaid can be administered through traditional fee-for-service design, or now more commonly, through managed care organizations (MCOs). In Maryland, most coverage is provided through Medicaid MCOs, with some specific services and categories being

[74] https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/

covered under FFS. MCOs have many of the plan design elements of the commercial sector while following strict rules associated with the Medicaid program.

Drugs paid by Medicaid participate in the Medicaid Drug Rebate Program.[75] As part of this program, manufacturers enter into national drug rebate agreements. These rebate agreements entitle Medicaid programs to get rebates from manufacturers related to the drugs using a formula determined by federal statute. The base rebate is 23.1 percent of AMP for most brand-name prescription drugs, 17.1 percent of AMP for brand-name pediatric drugs and clotting factors, and 13 percent of AMP for generic and over-the-counter drugs. Brand name drugs are subject to "best price" discounts and inflation-based discounts as well. Generic drugs are subject to inflation-based discounts. In addition, states can negotiate supplemental rebates.

This discount program results in Medicaid getting some of the lowest prices in the United States.

c) Commercial

Most Americans are covered by commercial, or private, health insurance. About 170 million Americans are covered by commercial plans. This is most commonly provided through employer-sponsored health plans, covering 156 million Americans, though about 20 million Americans are covered through the direct purchase of health insurance, such as through the state health benefit exchanges. In Maryland, about 3,175,000 citizens had employer-sponsored insurance, and about 336,000 purchase commercial insurance on their own in 202X.

Commercial insurance can take several different forms and plan designs. For our purposes, the most important element to note is that physician-administered drugs are often covered and managed under the medical benefit. The pharmacy benefit is often a separate benefit and health plans often outsource the work of developing and managing the prescription drug benefit to a pharmacy benefit manager.

2. Drug rebates to PBMs impact plan design and contribute to overall increased spending through rebate walls and market share.

Drug company rebates to PBMs can contribute to increasing medical costs.

Drug company rebates are negotiated between manufacturers and providers or health plans. PBMs use "formularies" and health plans use medical benefit policies to determine the prescription medications the plan will cover. A drug may be "preferred" or "on

[75] https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html

formulary," and there may be "tiers" of preferred medications. Payers may also use a process called "step therapy," "step edits," or "fail first," where a patient prescribed a certain drug must first try and fail a drug in a higher formulary or benefit tier before the plan will cover the cost of the originally prescribed drug.5

Drug companies use rebates as an incentive to have their products included on a formulary or place in more favorable tiers of the formulary.6 These rebates are after-the-fact discounts calculated as a percentage of the drug's list price. They are commonly based on the share of the market that the PBM or physician group purchases or total sales. For drugs that are covered by pharmacy benefits under a plan, drug companies most often pay rebates to PBMs, who may pass through some or all of the rebates to the payers.7 While their precise form may vary, rebate payments are often conditioned on the drug's continuing to hold a preferred or exclusive position on a PBM's formulary.

Some industry analysts and academics have observed that rebates can become a "trap" for health plans and providers, causing them to make decisions about coverage and utilization for their beneficiaries due to the financial incentives created by the rebate structure.8 The rebate "trap" occurs because the rebate is conditioned on formulary access or a market share requirement. If a rival drug is granted formulary access, the manufacturer may stop paying rebates (or even "claw back" previously paid rebates), thus forcing the third-party payer to face the full list price of the manufacturer's drug for any purchases of that manufacturer's drug. If the third-party payer is unable to switch a sufficient proportion of its covered patients to the lower-priced alternative, then granting a rival drug formulary access it may not be worth losing the original rebates. Thus payers who wish to make the lower-cost medication available may have to continue paying for the original product, without the benefit of rebates, for some portion of covered patients in the short term. This "rebate wall" may give payers strong incentives to block patient access to lower-priced medicines, whereas absent rebates a lower-priced equally effective product would tend to take sales from the higher-priced incumbent product.9

In this way, some rebates can operate to increase overall drug spending. The cost implications are particularly significant for biologics, given their generally higher costs relative to small-molecule drugs. In addition, rebate walls such as those described above may reduce incentives for biotechnology companies to develop new medicines and/or invest in biosimilars, harming competition and the quality of care available to patients.10 One study found a nearly equal correlation between increases in PBM rebates and list prices.[76]

[76] Neeraj Sood et al., USC Leonard D. Schaeffer Ctr. for Health Pol'y & Econ., The Association Between Drug Rebates and List Prices (Feb. 11, 2020), https://perma.cc/L7GA-SA86.

PBM market consolidation is leading manufacturers to offer increasingly attractive rebates: with three PBMs controlling an estimated 80-90% of the market if one PBM excludes a drug then the manufacturer loses access to a relatively large market share.23

3. The 340B Drug Discount Program Distorts Incentives

a) Overview of the Program

The 340B drug pricing program is intended to help "covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[77] To do this, the 340B drug pricing program gives certain safety net hospitals access to discounts on prescription drugs. The program is administered by Health Resources and Services Administration (HRSA). Eligible entities include Health Center Program Award Recipients, Health Center Program Look-Alikes, Native Hawaiian Health Centers, Tribal / Urban Indian Health Centers, Ryan White HIV/AIDS Program Grantees, Children's Hospitals, Critical Access Hospitals, Disproportionate Share Hospitals, Free Standing Cancer Hospitals, Rural Referral Centers, Sole Community Hospitals, Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Title X Family Planning Clinics, Sexually Transmitted Disease Clinics, and Tuberculosis Clinics. Disproportionate Share Hospitals (DSHs) make up over 40% of the entities ever registered as covered entities. Meanwhile, DSHs make up over 70% of the 340B purchases.[78] A particular hospital is a DSH if they serve a large percentage of Medicaid or low-income Medicare patients.

Once eligible, a hospital can purchase outpatient drugs for an eligible patient at a discount. According to federal regulations, "an individual is a ''patient'' of a covered entity (except for State-operated or funded AIDS drug purchasing assistance programs) only if: 1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care, and 2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and 3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement. An individual will not be considered a ''patient'' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the

[77] https://www.hrsa.gov/opa

[78] https://www.commonwealthfund.org/publications/explainer/2022/sep/federal-340b-drug-pricing-program-what-it-is-why-its-facing-legal-challenges

dispensing of a drug or drugs for subsequent self-administration or administration in the home setting."[79]

The 340B program has become a growing part of the drug supply chain. In 2012, the program represented an estimated $12.1 billion in spending. By 2021, that number increased to $44 billion.[80]

The pricing of 340B drugs is complicated. The 340B drug pricing program first sets a ceiling price. This ceiling price is equal to the AMP minus a unit rebate amount (URA). The URA is at minimum equal to 23.1 percent of AMP for most brand-name prescription drugs, 17.1 percent of AMP for brand-name pediatric drugs and clotting factor, and 13 percent of AMP for generic and over-the-counter drugs. Brand name drugs are subject to "best price" discounts and inflation-based discounts as well. Generic drugs are subject to inflation-based discounts. Finally, the program maintains a "prime vendor" to negotiate additional discounts.

b) Incentives Created by the Program

The 340B program creates incentives for hospitals to purchase different drugs.

First, the program creates incentives to serve sufficient number of Medicaid patients to ensure program eligibility. Imagine a hospital just below the threshold. This hospital has an incentive to serve more Medicaid patients, so they reach the threshold and get access to the program. Now imagine a hospital just above the threshold. Serving an additional Medicaid patient does not give them access to more discounts, but results in lost profits from providing drugs (which will be eligible for 340B discounts) to patients with commercial and private insurance. Previous research shows that there is an abnormal amount of bunching of the Medicaid patient population around the eligibility threshold.[81] This suggests that the program is resulting in strategic behavior to reach the threshold.

Second, the program creates incentives to use higher cost drugs. Researchers have theorized about this incentive. Because of the interaction between payment policy and the 340B drug discount, 340B providers make more money on more expensive drugs. Pharmacies are reimbursed WAC and a margin for brand drugs. Meanwhile, the 340B price is set based on AMP minus a certain percentage. As a result, higher-priced drugs would have larger dollar profits.

Finally, the program creates incentives for consolidation. A "child" facility is eligible for 340B if the "parent" facility is a 340B facility. Since the 340B provider can make more

[79] https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf
[80] https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html?m=1
[81]

profit for the same product compared to a non-340B provider, there is an incentive to move the patients to a 340B provider. Facilities can do this by consolidating via merger or acquisition.

4. Incentives Exist for High Launch Prices

Besides issues with price increases, some worry about the incentives to establish high list prices. First, the use of inflation-based penalties included in the Inflation Reduction Act there are incentives for drug companies to begin with high list prices. Inflation penalties punish manufacturers for increasing prices at rates exceeding inflation. In response to such regulation, manufacturers may simply increase their initial price. A higher initial price allows drug companies to also have larger nominal increases later while not triggering the inflation penalty.

Second, some payment practices encourage competing products to launch at prices higher than the competitors. Consider the market for physician-administered drugs. In Medicare, the physicians are paid based on the ASP. However, the collection of the ASP has a two-quarter lag. In the first two quarters, Medicare pays the physician based on the WAC instead. Imagine a drug that is the second product in the class to market. By launching at a higher price than the first-in-class product, physicians get paid more. The second manufacturer can also give larger discounts from WAC to further incentivize physicians to use their product.

5. Treatment of biosimilar drugs as brand name drugs not as generics provides fewer incentives for wholesalers and pharmacies to negotiate prices.

The treatment of biosimilars as brand drugs may inadvertently incentivize the preference for brand-name drugs. As previously stated, wholesalers earn markups on brand-name drugs by taking a small percentage markup on the WAC. Generally speaking, the WAC for a biosimilar product is less than that of the reference product. As a result, a wholesaler earns less money on the biosimilar. These incentives may be particularly strong for the pharmacy-dispensed market, where no entity is negotiating discounts on the acquisition cost.

V. POLICY OPTIONS

A. Introduction

As shown earlier in this report the pharmaceutical market is not a functioning competitive market and this results in affordability challenges throughout the supply chain, and ultimately, many patients being unable to afford their drugs. This section of the paper

lays out the existing and potential policy options that have been implemented or considered that are available to Maryland to make prescription drugs more affordable. The purpose of this section is to be a resource for Maryland to understand the available policies, and the potential impacts of those policies.

One of the key takeaways of this section is that there is no one single approach that will address the problems. Maryland will likely need to implement several policies to address specific prescription drug affordability issues. It is important to strategically select and implement policies to make sure that they are synergistic and complement and build on each other. Some policies use opposing mechanisms to address affordability challenges, or address different issues in prescription drug affordability, and may directly work or counteract other policies. The purpose of this section of the report is to provide a review of available policies and ensure that the framework and policies that the Board recommends build on each other and work together to make prescription drugs more affordable for residents of Maryland.

Our categorization largely overlaps with the NASHP policy tracker and the NCSL policy tracker, with some differences The order of these sections is based on the policies that are specifically mentioned in the Maryland legislation, and then policies in order of timeline and feasibility for implementation.

The general categories of policies are:

1. Upper Payment Limits- This chapter includes policies that directly affect the amount that is paid for a drug, including rates set by Boards, index pricing, inflation penalties, or unsupported price hikes.
2. Bulk Purchasing- This chapter includes policies that are related to maximizing purchase volume and lives covered to increase leverage to negotiate better rates and discounts. Some contracting tools overlap with this section that we've included in the Novel Contracting section.
3. Reverse Auctions- This section includes policies that promote the use of the reverse auction contracting tool to select pharmacy benefit management services.
4. PBM Reform- This section includes policies to all policies related to addressing existing PBM practices. This includes policies such as gag clauses, rebate policies, direct and indirect remuneration policies, formulary rules, copay, and coinsurance rules, copay aggregators and maximizers, white bagging and brown bagging, and point of sale discounts.
5. Price Transparency- This chapter includes policies related to bringing transparency to different parts of the prescription drug supply chain.
6. Medicaid Reform- This chapter includes policies that are specific to Medicaid. Medicaid makes up a significant portion of the state's prescription drug spending and is also highly regulated by a web of complex rules that make any policies

specific to Medicaid. Even policies that are addressed in other sections would likely be implemented fundamentally differently for Medicaid than other markets.

7. Out-of-Pocket Costs- This chapter includes policies that directly target reducing patient out-of-pocket costs, such as copay caps and out-of-pocket maximums. These policies address a very specific part of the cost of drugs, but may not impact, or could adversely impact, the cost of drugs to the overall system.
8. Novel Contracting- This chapter includes policies that look at novel mechanisms to transition away from traditional fee-for-service reimbursement of drugs, such as subscription models, value-based contracting, or reimbursement structures for high-cost drugs.
9. Importation- This chapter includes policies related to the importation of prescription drugs from other countries.
10. Additional Policy Options- This section includes other policies that don't neatly fit into other categories, such as efforts to promote biosimilar interchangeability and promoting waste-free formularies.

B. Upper Payment Limits (UPLs)

1. Introduction to UPLs

The idea of setting an upper payment limit (UPL)—a maximum amount paid for a product—is a standard practice in Maryland. It is commonly used in Maryland and the United States to set the amounts paid for various goods and services. However, applying upper payment limits to prescription drug products in Maryland is a new development that became available when the Prescription Drug Affordability Board was established in 2019.

Establishing UPLs for prescription drugs is comparable to state rate setting, a practice Maryland has been using to set hospital payments and is common throughout the healthcare and public utility industries: it is a practice long established in Maryland.[82] Since 1971, the Maryland Health Services Cost Review Commission (HSCRC) has set maximum hospital rates for inpatient, outpatient, and emergency services provided at Maryland hospitals.[83] Today, Maryland continues to administer an active all-payer rate-setting system but has shifted its hospital rate-setting system to global budgets.[84]

[82] In Maryland, the Public Service Commission regulates public utilities and sets public utility rates.

[83] HSCRC negotiated a waiver of federal law to allow Medicare and Medicaid to pay HSCRC-approved hospital rates beginning July 1, 1977. Md. Code Ann., Health-Gen. § 19-211

[84] The all-payer approach refers to a hospital payment system in which all payers (both public and private) pay the same rates. https://hscrc.maryland.gov/Pages/tcocmodel.aspx (explaining total cost of care model) (last checked Dec. 2, 2022).

Governmental programs also establish maximum payment and payment rates for services and prescription drug products. Since its inception, Medicare has set fee-for-service payment rates it will pay for health services. Both the Department of Defense and the Department of Veterans Affairs set payment rates for prescription drugs. Medicaid, a federally funded program administered by each state, provides a federal upper limit (FUL) for reimbursement for some generic drugs,[85] and states may develop their own Maximum Allowable Cost (MAC) programs and set their own MAC reimbursement rates for multiple-source (generic) drugs.[86] Maryland follows this practice.

The concept of establishing a maximum rate at which certain prescription drugs are paid or reimbursed has long been adopted by PBMs through contracting and "maximum allowable cost" lists for multisource generic drugs. In Maryland, PBMs are required to provide pharmacies with updated lists of drugs for which a "maximum allowable cost"—the maximum amount that a pharmacy benefits manager or a purchaser will reimburse a contracted pharmacy for the cost of a multisource generic drug—has been established.[87] Maryland contracts with a PBM to determine the rates the state will pay for state employees.

Thus, while the concept of an upper payment limit is not new, deciding precisely how it can be implemented to make prescription drugs affordable is the responsibility of the Prescription Drug Affordability Board.

2. Market Failures Solved by UPLs

Upper payment limits will address the market failures in the drug supply chain described earlier. When markets are not perfectly competitive, different parts of the drug supply chain can charge higher prices, allowing them to earn higher profits while producing smaller quantities compared to a perfectly competitive market. In economics this is known as being allocatively inefficient.

UPLs represent an attempt to approximate the perfectly competitive equilibrium. If the UPL is set at the perfectly competitive price level, suppliers have the incentive to produce the perfectly competitive quantity. As a result, UPLs can address potential market failures. As previously discussed, the pharmaceutical supply chain is complex and imperfect competition exists at multiple levels. As a result, UPLs, in theory, can apply to different levels of the supply chain in order to address the imperfectly competitive nature

[85] Because prices can vary widely between generic drugs, the FUL program is designed to base payments on market prices by calculating an FUL amount for specific dosage forms and strengths for each multiple-source drug that meets the established criteria.
[86] Despite using the same terminology, the MAC set by a State Medicare program is different from the MAC lists established and managed by PBMs.

[87] Md. Code Ann., Ins. § 15-1628.1(a)(3)(i).

of the market at that level. It will be necessary to consider a number of factors including the value of the drug and the cost of research and development among other factors.

3. Potential Approaches to Set UPLs

One of the core challenges when setting an upper payment limit is how to determine the precise amount. A review of peer-reviewed literature and experience with rate setting programs have identified several theories that can guide the development of a upper payment limit for drugs. Rate-setting structures are designed based on four primary concepts: (1) value assessment; (2) affordability/budget assessment; (3) index pricing; and (4) rate of return. This section is intended as an introduction and overview of the current theories informing the development of rate-setting systems.

a) Value Assessment

Value assessment reflects the principle that the amount paid for a drug should be based on the benefit it provides (value). This analytical framework includes comparative effectiveness research, cost-effectiveness research, and health technology assessments. Each approach endeavors to answer two main questions, "How well does a drug work?" and, "Is it worth what we are paying for it?"

Comparative effectiveness research involves a systematic review of existing research on the effectiveness and outcomes of certain medicines compared to other similar treatments or the standard of care.[88] The comparison of treatments for the same condition can suggest whether certain treatments provide better or worse outcomes compared to competing treatments based on their costs or the costs of alternatives. Under the comparative effectiveness view, comparable drugs could have the same price and new drugs with similar effectiveness should be priced to match or be lower than the existing therapy.

Cost-effectiveness research builds on comparative effectiveness research and incorporates a standardized effectiveness measure with standardized costs. It provides a mechanism for valuing drugs that are better or worse than existing therapies. This research often produces a value of the benefits provided that can be used to suggest a reasonable cost for a specific treatment.

[88] NSCL. *Comparative Effectiveness to Evaluate Prescription Drugs*. https://www.ncsl.org/research/health/comparative-effectiveness-and-academic-detailing-to-evaluate-prescription-drugs.aspx (last checked Dec. 2, 2022).

Health technology assessment (HTA) provides a framework for determining the value of health technology.[89] HTA usually contains an assessment of scientific evidence, including clinical outcomes and economic costs, and an appraisal that guides the price or coverage decisions.[90]

Many developed countries have centralized HTA programs that are used in formulating drug coverage decisions and prices. The United States does not have a central HTA program. Instead, the U.S. market-based system largely based on the complex and problematic supply chain discussed earlier in this report.

The problem with the United States and Maryland supply chain is that for many drugs, there is limited or no competition; this may be one reason why the U.S. often pays over twice as much as other developed countries for many brand-name prescription drugs.[91] U.S. insurers and PBMs increasingly using HTA in their coverage decisions and negotiations.[92] However, where there is only one drug in a therapeutic category or limited competition, the ability of PBMs and insurers to negotiate coverage and pricing rebates is limited.

The Institute of Clinical Effectiveness and Research (ICER) is a non-governmental organization that produces cost effectiveness research and value assessment reports. The Patient-Centered Outcomes Research Institute (PCORI) and the Agency for Healthcare Research and Quality (AHRQ)—both government entities—focus on clinical and comparative effectiveness research, and generally do not address value-assessment.

b) Affordability/Budget Assessment

Affordability and budget assessment policies suggest that the amount paid should be based on the amount that the health plan and/or patient is able to pay. This is different from a value assessment (the benefit of the drug) because it also accounts for the insurer and/or patient's ability to pay. Under a strict value framework, a prescription drug can have a high price that is fully supported by the value it provides yet simply remain unaffordable.[93]

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[89] https://pubmed.ncbi.nlm.nih.gov/32398176/

[90] Mulligan K, Lakdawalla D, Goldman D, *et. al*. *Health Technology Assessment for the U.S. Healthcare System.* USC Schaeffer Center for Health Policy & Economics. February 26, 2020. https://healthpolicy.usc.edu/research/health-technology-assessment-for-the-u-s-healthcare-system

[91] Mulcahy, A., Whaley, C., Gizaw, M., Schwam, D., Edenfield, N., Becerra-Ornelas, A. July 1, 2022. *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*. ASPE.

[92] https://www.healthaffairs.org/content/forefront/inclusion-health-technology-assessments-first-step-toward-equity

[93] https://pubmed.ncbi.nlm.nih.gov/24438712/

For example, in 2014, the price of $84,000 per round of therapy for hepatitis C treatment was deemed to be of value compared to the price of alternative maintenance therapy and the effect of the natural course of the disease over the life of the patient by some organizations . However, the cost was deemed to be so substantial that it would be difficult for state Medicaid programs to treat all qualifying patients.[94] Ten Medicaid programs submitted letters to the U.S. Senate Committee on Finance noting that while the treatments may be effective, they were unaffordable with existing Medicaid budgets.[95] The Senate Committee on Finance found that Medicaid programs spent over $1.3 billion on hepatitis C treatment in 2014, while treating only about 2.4% of eligible Medicaid patients.[96] Louisiana and other states developed an alternative payment methodology that allowed them to pay one price for the drug regardless of the quantity purchased One thing to note in this case is that since 2014, as new competitors have entered the market, the net price of the new hepatitis C products have decreased substantially. However, other drugs with even higher prices have entered the market since 2014.

Payment systems based exclusively on affordability are usually based on a global budget and are rare. The Maryland HSCRC global budget hospital rate-setting system is an example of a state-level program with a global budget. There are other substate programs for rural hospitals in other states and the federal government has recently authorized more states to apply for waivers. In practice, affordability assessments are often paired with value-based assessments in which a budget cap triggers an affordability review. An example are outcome-based payments for gene therapies that many states have adopted.

c) Index Pricing

Index, or reference, pricing links the amounts paid for a drug to prices paid in other markets such as: (1) domestic market; (2) therapeutic class market; and (3) international markets.

Domestic reference pricing uses benchmarks based on prices paid by other domestic payers and purchasers. For example, the Federal Supply Schedule (FSS) for Pharmaceuticals Program establishes prices available to all direct federal purchasers—

[94] ICER. *The Comparative Clinical Effectiveness and Value of Novel Combination Therapies for the Treatment of Patients with Genotype 1 Chronic Hepatitis C Infection*. Final Report. January 30, 2015 (last checked Dec. 3, 2022).
[95] U.S. Senate Committee on Finance. *Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy Behind $84,000 Hepatitis Drug: Letters from state Medicaid programs*. December 1, 2015. http://www.finance.senate.gov/newsroom/ranking/download/?id=5f59aeab-94a7-4099-b9cb-3c2622a2a62d
[96] U.S. Senate Committee on Finance. *The Price of Sivaldi and Its Impact on the U.S. Health Care System*. Final Report. December 1, 2015. https://www.finance.senate.gov/download/the-price-of-sovaldi-and-its-impact-on-the-us-health-care-system-full-report

federal agencies that buy drugs directly from wholesalers or manufacturers and provide their own dispensing services.[97] The prices listed on the FSS are publicly reported prices determined by negotiation between the VA (on behalf of all direct federal purchasers) and drug manufacturers. Under the program, direct federal purchasers can buy brand-name drugs at prices equal to or below the lowest prices negotiated between manufacturers and their most-favored commercial customers—that is, the customers that receive the best discount or price agreement.[98] These firm, fixed-pricing schedules provide a reference benchmark.

Similarly, pricing in other federal programs provides other possible benchmarks. In 2021, the Congressional Budget Office (CBO) studied the prescription drug prices paid by various federal agencies when purchased directly (e.g., FFS, "Big Four" agencies, etc.) and indirectly through federal health insurance programs (e.g., Medicare Part D, Medicaid).[99] This study provides insight into what public agencies obtain the lowest price for prescription drugs and the mechanisms by which those prices are obtained.

Therapeutic class reference pricing groups drugs by therapeutic class and limits payment for all drugs in the class to the price of one of the cheapest drugs in that class. By setting the same price for all prescription drug products in the therapeutic class, this structure fosters competition within the class. This principle may be applied in different ways to limit high drug prices. For example, new drugs that are not more clinically beneficial than existing drugs should not be priced higher than the existing drug.[100] When the new drug is in the same therapeutic class, the reference price in the class is what is paid. Many programs outside the United States use this approach. Congress has mandated that the Centers for Medicare and Medicaid Services use this methodology when they negotiate drug prices under provisions of the Inflation Reduction Act.

External or international reference pricing uses international drug pricing data or other benchmarks to determine prices. Used both formally and informally throughout Europe, countries make different decisions in structuring their external reference pricing

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[97] The General Services Administration delegated authority to the Federal Supply Schedule (FSS) Service, Veterans Administration, to award multi-year, multiple award federal contracts for medical equipment, supplies, pharmaceutical, and certain services for use by the VA and eligible federal agencies. https://www.fss.va.gov/ (Last checked Dec. 4, 2022).
[98] VA Federal Supply Schedule Service. https://www.fss.va.gov/ (Last checked Dec. 4, 2022)
[99] CBO. *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs*. February 18, 2021. https://www.cbo.gov/publication/56978
[100] Dickson S, Hernandez I, Gabriel N, Kirby M, Newman T, and Berenbrok LA. *Estimated Savings from Application of a Domestic Reference Price Model for Pricing Drugs at Launch*, 2015-2019 Westhealth, the University of Pittsburgh, and the University of San Diego. September 20, 2021. https://uploads-ssl.webflow.com/5e59d7f99e288f91abe20b9f/614b9d62474b3e0b4e89ec57_Estimated%20Medicare%20Savings%20from%20Domestic%20Reference%20Pricing.pdf

policies.[101] Given the significant differences in healthcare delivery and payment around the world, the selection of comparator countries and the identification of useful data sets will require additional investigation. It was the basis of the Build Back Better legislation that passed in the U.S. House of Representatives.

The markets upon which index pricing is based often use some kind of value or affordability assessment in establishing the payment rate. For this reason, index pricing effectively incorporates the value assessments and negotiations forming the benchmark.

d) Rate of Return

Rate of return pricing sets payment rates to ensure a pre-specified rate of return for manufacturers, after covering the costs of developing and marketing the product. This rate-setting approach has been used widely in regulating public utility monopolies where public utility commissions seek "to balance consumers' interest in affordable prices against the need to set rates at a level sufficient to motivate production and allow utilities to attract investment" and "in a manner that gives utilities incentives to operate efficiently."[102] There is growing interest in applying rate of return rate setting to the prescription drug market for ultra-rare diseases that are not "cost effective" under a value framework or may be unaffordable under an affordability framework because of the small patient population or when the value of a drug is unaffordable because it cures a previously untreatable disease.[103]

4. Examples of Setting UPLs or Cost Caps

Several states have experience implementing UPLs in this manner. A survey of states and a review of peer-reviewed literature disclosed several approaches to formulating and applying UPLs, rate setting, and supplemental rebates to redress the high cost of prescription drugs and its effect on patient access.

To date, six states have created Prescription Drug Affordability Boards: Maryland, Colorado, Oregon, New Hampshire, Maine, and Washington.[104] Three of the six states have authorized these boards to conduct affordability reviews and set UPLs: Maryland (subject to approval of UPL action plan), Colorado, and Washington. One state (Oregon)

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[101] Remuzat, C et. al, Overview of External Reference Pricing Systems in Europe. Journal of Market Access and Policy. Vol. 2015:3. September 10, 2015.
[102] Michelle M. Mello, Rebecca E. Wolitz, *Legal Strategies for Reining in "Unconscionable" Prices for Prescription Drugs*, 114 Nw. U. L. Rev. 859, 937 (2020) (citations omitted).
[103] Drummond M, Towse A. *Is rate of return pricing a useful approach when value-based pricing is not appropriate?* Eur J Health Econ. 2019 Sep;20(7):945-948.
[104] *See* Md. Code Ann, Health-Gen. § 21-2C-01, *et seq.*; Colo. Rev. Stat. § 10-16-1401, *et seq.*; Or. Rev. Stat. § 646A.693, *et seq.*; N.H. Rev. Stat. Ann. § 126-BB:1, *et seq.*; Me. Rev. Stat. tit. 5, § 2041, *et seq.*; Wash. Rev. Code Ann. § 70.405.010, *et seq.*

was directed to conduct affordability reviews and study policy options designed to lower prices, including UPLs, and submit its findings by the close of 2022.[105] The Maine and New Hampshire Boards have the authority to determine spending targets for specific drugs and recommend policies to meet the targets. Nationally, efforts to create PDABs and establish UPLs have been ongoing.[106] For example, in the most recent legislative sessions, legislation creating PDABs and authorizing UPLs was proposed in eight additional states. Of the boards presently evaluating and implementing UPLs, only Colorado has proposed regulations outlining how a UPL would be determined.

a) Colorado All Payers UPLs[107]

The work of the Colorado Prescription Drug Affordability Board (Colorado PDAB) differs from the Maryland PDAB in several fundamental ways. First, the primary purpose of the Colorado PDAB is to set upper payment limits; the Maryland PDAB was charged with surveying and studying policies to make prescription drugs more affordable and determining if UPLs are appropriate policy tools for Maryland.[108] Second, the Colorado PDAB has the authority to set UPLs for all payers in the state, whereas the Maryland PDAB is authorized to establish UPLs for state and local government payers and study whether to recommend expansion of the policy to all payers.[109]

Maryland and Colorado law both contemplate (1) identifying drugs based on certain statutory criteria and (2) conducting cost or affordability reviews of selected drugs.[110] If

[105] Or. Rev. Stat. § 646A.696 (board to submit "[r]ecommendations, if any, for legislative changes necessary to make prescription drug products more affordable in this state"). See also Or. Rev. Stat. § 646A.694 (affordability reviews).
[106] *See generally* Michelle M. Mello, Rebecca E. Wolitz, *Legal Strategies for Reining in "Unconscionable" Prices for Prescription Drugs*, 114 Nw. U. L. Rev. 859, 884 (2020).
[107] Colorado Prescription Drug Affordability Review Board & Advisory Council https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board
[108] Colo. Rev. Stat. Ann. § 10-16-1403(1)(c) (board shall "[e]stablish upper payment limits for prescription drugs") and Md. Code Ann., Health-Gen. §§ 21-2C-07(1)(ii) and 21-2C-13(d)(1) (board shall study policy options including UPLs and if Board determines developing a UPL plan is in the best interest of State it shall submit the draft UPL action plan to the Legislative Policy Committee for approval).
[109] Colo. Rev. Stat. Ann. § 10-16-1407(5) ("upper payment limit applies to all purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state") and Md. Code Ann., Health-Gen. § 21-2C-14 (upper payment limit applies to prescription drugs purchased or paid for by a unit of State or local government, health benefit plan, or Maryland Medical Assistance Program). In Colorado, self-funded health benefit plans (ERISA plans) may elect to "subject its purchases of or payer reimbursements for prescription drugs for its members in Colorado to the requirements of" the PDAB. Colo. Rev. Stat. Ann. § 10-16-1401.
[110] Colo. Rev. Stat. Ann. § 10-16-1406 and Md. Code Ann., Health-Gen. § 21-2C-08.

the Colorado PDAB performs an affordability review on a drug and determines "that the use of the prescription drug is unaffordable for Colorado consumers," it may establish an upper payment limit for that drug.[111]

The Colorado PDAB-proposed UPL methodology authorizes the Colorado PDAB to consider a variety of pricing or cost information in establishing a UPL, including the following: out-of-pocket costs, whether the drug is on the drug shortage list, certain metrics concerning the impact on elderly and disabled residents, and Stakeholder input.

By statute, a UPL established by the Colorado PDAB "applies to all purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state in person, by mail, or by other means."[112] By proposed rule, the upper payment limit "applies to the Colorado consumer's purchase from a pharmacy or provider of a prescription drug that is dispensed or administered to the Colorado consumer in person, by mail, or by other means," and "[i]f the Colorado consumer is insured, the consumer's portion of the payment together with the reimbursement to the pharmacy and provider by the carrier, state entity, or optional participating plan should not exceed the upper payment limit."[113]

The proposed methodology contemplates that each UPL will be established through rulemaking under the Colorado State Administrative Procedure Act.[114] There are no current savings estimates associated with the Colorado PDAB UPL methodology.

b) Washington PDAB UPLs

Like Maryland and Colorado, the Washington PDAB must identify prescription drugs that meet certain statutory pricing metrics and may conduct affordability reviews of up to 24 prescription drugs per year.[115] To be eligible for selection for an affordability review, "the board must determine whether the prescription drug has led or will lead to excess costs to patients."[116] As part of the affordability review, a "manufacturer must submit all requested information to the board within 30 days of the request."[117]

The Washington PDAB is vested with authority to "adopt rules setting forth a methodology…for setting upper payment limits for prescription drugs the board has

[111] Colo. Rev. Stat. Ann. § 10-16-1407(1).
[112] Colo. Rev. Stat. Ann. § 10-16-1407(5).
[113] Proposed Rule Part 4 - UPL Methodology(last checked Dec. 4, 2022). Colorado PDAB.
[114] Colo. Rev. Stat. Ann. § 24-4-103 (procedure for agency rulemaking requiring notice and other procedures).
[115] Wash. Rev. Code Ann. §§ 70.405.030 and 70.405.040(1).
[116] Wash. Rev. Code Ann. § 70.405.040(2).
[117] Wash. Rev. Code Ann. § 70.405.040(3).

determined have led or will lead to excess costs based on its affordability review."[118] The rules do not go into effect until at least 90 days after the next regular legislative session. Each year, the board may set an upper payment limit for up to 12 prescription drugs, but no upper payment limit may be established for any prescription drug before January 1, 2027.[119]

The UPL methodology must "take into consideration" the following: "(a) the cost of administering the drug; (b) the cost of delivering the drug to patients; (c) the status of the drug on the drug shortage list published by the United States food and drug administration; and (d) other relevant administrative costs related to the production and delivery of the drug."[120]

Like Colorado, an upper payment limit established by the board "applies to all purchases of the drug by any entity and reimbursements for a claim for the drug by a health carrier, or a health plan . . . when the drug is dispensed or administered to an individual in the state in person, by mail, or by other means."[121] Self-funded, employer-sponsored plans may elect to be subject to the upper payment limits.

c) Maine International Reference Pricing Projected Savings Reporting

In 2021, Maine enacted laws directing the Maine Health Data Organization to identify the 100 most costly prescription drugs and the 100 most frequently prescribed prescription drugs in the State, the manufacturers of those drugs, and the average WAC for each drug for the most current 12-month period.[122] In conjunction with the Maine Prescription Drug Affordability Board, the Maine Health Data Organization determines the "referenced rate" for each drug by "comparing the wholesale acquisition cost to the cost in official publications of the governments of the Canadian provinces of Ontario, Quebec, British Columbia and Alberta"[123] and using the lowest cost. The organization then determines the potential savings that could be achieved by subjecting those drugs to the referenced rate as calculated "based on the payments reported in the organization's claims database for the most current 12-month period."[124] This information is then reported annually.

[118] Wash. Rev. Code Ann. § 70.405.050(1).
[119] Wash. Rev. Code Ann. § 70.405.050(1) and (12).
[120] Wash. Rev. Code Ann. § 70.405.050(2).
[121] Wash. Rev. Code Ann. § 70.405.050(6).
[122] Me. Rev. Stat. tit. 22, § 8741.2.A.

[123] Me. Rev. Stat. tit. 22, § 8741.2.B.
[124] Me. Rev. Stat. tit. 22, § 8741.2.C.

d) NASHP State-Based International Reference Pricing for Prescription Drugs[125]

The National Academy of State Health Policy (NASHP) developed model legislation entitled "An Act to Reduce Prescription Drug Costs Using International Pricing"[126] that would prohibit state entities, health plans and participating ERISA plans from purchasing "referenced drugs" to be dispensed or delivered to a consumer in the state, whether directly or through a distributor, for a cost higher than the "referenced rate." It would also prohibit retail pharmacies from purchasing "referenced drugs" for a cost that exceeds the "referenced rate" for sale or distribution to a person whose health care is provided by a state entity or health plan or participating ERISA plan.

Under the model legislation, 250 referenced drugs would be subject to the referenced rate, which is determined "by comparing the Wholesale Acquisition Cost to the cost from the: 1) Ontario Ministry of Health and Long Term Care and most recently published on the Ontario Drug Benefit Formulary; 2) Régie de l'Assurance Maladie du Québec and most recently published on the Quebec Public Drug Programs List of Medications; 3) British Columbia Ministry of Health and most recently published on the BC Pharmacare Formulary; and 4) Alberta Ministry of Health and most recently published on the Alberta Drug Benefit List."[127]
The cost reductions would be implemented through the amounts paid by the payer to pharmacies and hospitals.

e) New York Medicaid Drug Cap Program[128]

In 2017, New York created a program designed to cap drug spending in the state Medicaid program as part of the existing Medicaid global spending cap.[129] The program limits drug spending growth to the 10–year rolling average of the medical component of

[125] NASHP. *An Act to Reduce Prescription Drug Costs Using International Pricing.* November 20, 2020 (last checked Dec. 4, 2022). https://www.nashp.org/an-act-to-reduce-prescription-drug-costs-using-international-pricing/
[126] Sachs R. *The National Academy for State Health Policy's Proposal for State-Based International Reference Pricing for Prescription Drugs.* August 10, 2020. https://www.nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs/
[127] NASHP. *An Act to Reduce Prescription Drug Costs Using International Pricing*, section 5(b). November 20, 2022 (last checked Dec. 4, 2022). https://www.nashp.org/an-act-to-reduce-prescription-drug-costs-using-international-pricing/
[128] New York Medicaid Drug Cap Program. https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/docs/general_faqs.pdf (last checked Dec. 3, 2022).
[129] N.Y. Pub. Health Law § 280 (McKinney).

the Consumer Price Index (CPI).[130] Under this program, New York established a prescription drug spending cap. If that cap is exceeded, the New York Department of Health identifies the drugs that were most responsible for exceeding the cap, notifies the relevant manufacturers, and seeks additional supplemental rebates from the manufacturers.[131] If the Department is not able to reach agreements with the relevant manufacturers, it refers the drug to the New York Drug Utilization Review Board (DURB), a 23-member entity that reviews and authorizes prescription drugs and prescribing practices for the state's Medicaid program.

Prior to seeking an additional rebate, the Department determines if a drug's actual cost to the state, net of current rebate amounts, is greater than $5 million.[132] The Department then considers how the rebates for this drug compare to other drugs in the therapeutic class and if increasing the rebate would help prevent the state from surpassing its spending cap.

In determining whether to recommend a target supplemental rebate for a drug, the DURB must consider the actual cost of the drug to the Medicaid program, including federal and state rebates, and may consider:

> "(a) the drug's impact on the Medicaid drug spending growth target and the adequacy of capitation rates of participating Medicaid managed care plans, and the drug's affordability and value to the Medicaid program; or
> (b) significant and unjustified increases in the price of the drug; or
> (c) whether the drug may be priced disproportionately to its therapeutic benefits."[133]

In formulating a recommendation concerning the target rebate, the DURB may consider: (1) publicly available and Department supplied pricing information and information related to value–based pricing; (2) the seriousness and prevalence of the disease or condition being treated; (3) Medicaid utilization and the drug's effectiveness or impact on improving health, quality of life, or outcomes; (4) the likelihood that the drug will reduce the need for other medical care, including hospitalization; (5) the average wholesale

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[130] SFY 2021-22 Medicaid Drug Cap Stakeholder Webinar (last checked Dec. 5, 2022) https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/docs/2021-12-15_medicaid_drug_cap.pdf

[131] "Such rebate may be based on evidence-based research, including, but not limited to, such research operated or conducted by or for other state governments, the federal government, the governments of other nations, and third party payers or multi-state coalitions, provided however that the department shall account for the effectiveness of the drug in treating the conditions for which it is prescribed or in improving a patient's health, quality of life, or overall health outcomes, and the likelihood that use of the drug will reduce the need for other medical care, including hospitalization." N.Y. Pub. Health Law § 280(b) (McKinney).

[132] N.Y. Pub. Health Law § 280(d) (McKinney).

[133] N.Y. Pub. Health Law § 280(e)(4) (McKinney).

price, wholesale acquisition cost, retail price, and cost of the drug to Medicaid minus rebates; (6) whether there are pharmaceutical equivalents to the drug; and (7) information provided by the manufacturer, if any, regarding pricing and development costs, therapeutic benefits, and/or other information pertinent to pricing decisions, which shall be considered confidential.[134]

Since 2017, the New York Department of Health has identified 30 potential drugs in 2017-18, 42 drugs in 2018-19, 29 drugs in 2019-20, zero drugs in 2020-21 (did not reach the cap), and 39 drugs in 2021-22.[135] Only one drug (Spinraza) proceeded to the DURB for review.

The New York Medicaid Drug Caps are implemented through supplemental rebates to the Medicaid program. New York Medicaid estimates that it has been able to negotiate over $300 million in additional supplemental rebates since 2017 as a result of the leverage provided by this process.[136]

f) Massachusetts Health Commission Drug Pricing Review (Medicaid)[137]

Starting in 2020, MassHealth (the Massachusetts Medicaid program) was given additional authority to control the cost of drugs in the Medicaid program through a drug pricing review.[138]

As a first step, MassHealth negotiates supplemental rebates with manufacturers for certain high-cost drugs. If MassHealth and the manufacturer fail to reach an agreement, MassHealth may publicly propose a value for the drug for public comment. MassHealth and the manufacturer then return to the negotiating table to see if they can agree on supplemental rebates. If they do not reach an agreement, the drug is referred to the Massachusetts Health Policy Commission (HPC).

The HPC conducts a drug pricing review based on information submitted by the manufacturer.[139] The HPC may identify a proposed value for the drug, propose a supplemental rebate for the drug, and determine if the manufacturer's pricing is

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[134] N.Y. Pub. Health Law § 280(5)(e) (McKinney).
[135] CITE
[136] CITE
[137] Drug Pricing Review. https://www.mass.gov/service-details/drug-pricing-review#:~:text=The%20HPC%20helps%20manage%20pharmaceutical,in%20relation%20to%20the%20value.
[138] Mass. Gen. Laws Ann. ch. 6D, § 8A.

[139] CITATION

potentially unreasonable or excessive. The manufacturer can then submit additional information before the HPC finalizes its recommendation.

The cost reductions through the Drug Pricing Review process are implemented through additional supplemental rebates to MassHealth. As of November 2021, MassHealth has active agreements on supplemental rebate contracts with 17 manufacturers for 50 drugs with a total annual incremental savings of approximately $171 million as a result of the leverage provided by this process.[140]

g) Inflation Reduction Act of 2022: Medicare Drug Price Negotiation

The Inflation Reduction Act of 2022 includes provisions to require Medicare to negotiate prices for certain Part D drugs in 2026 and certain Part B drugs starting in 2028. As part of this process, Medicare will set a maximum fair price, which will be the upper limit for the negotiated price. The maximum fair price is the lower of the drug's enrollment-weighted negotiated price (net of all price concessions) for a Part D drug, the average sales price for a Part B drug, or a percentage of a drug's non-federal average manufacturer price. For small-molecule drugs and vaccines more than 9 years but less than 12 years beyond approval, the percentage is 75%; for drugs between 12 and 16 years beyond approval or licensure, the percentage is 65%; and for drugs more than 16 years beyond approval or licensure, the percentage is 40%.[141]

Medicare will be able to negotiate additional concessions below this maximum fair price, and like most negotiations between payers and manufacturers, will likely incorporate elements of value assessments and affordability assessments. Medicare has not announced how the cost reductions through Medicare negotiation will be implemented—whether through reductions in payments to the pharmacy, negotiation of rebates with the manufacturer, or both.

The CBO estimates $98.5 billion in Medicare savings over 10 years (2022-2031) from the drug negotiation provisions in the Inflation Reduction Act.

h) Center for Medicare and Medicaid Innovation (CMMI) Most Favored Nation Model

In 2020, the Center for Medicare and Medicaid Innovation (CMMI) considered implementing a mandatory international index pricing model. Under this model,

[140] CITATION

[141] Cubanski J, Neuman T, Freed M. *Explaining the Prescription Drug Provisions in the Inflation Reduction Act.* KFF. September 22, 2022. https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/

Medicare pays for certain Part B (physician-administered) drugs based on a blending formula that includes the lowest adjusted international price (the Most Favored Nation Price, or "MFN Price") and the average sales price (ASP), with a flat add-on payment instead of a percentage of ASP. The MFN Price would be based on the lowest GDP-adjusted price paid by an Organisation for Economic Corporation and Development (OECD) member country with a GDP per capita (based on purchasing power parity) that is at least 60 percent of the U.S. GDP per capita.
The Most Favored Nation Model cost reductions would have been implemented through the paid amount to hospitals and physician practices. However, on December 27, 2021, CMS rescinded the rule and it was never implemented.

5. Potential Savings from UPLs

Until the methodology to be employed in establishing an upper payment limit is fully developed in the Upper Payment Limit action plan and specific drugs are chosen, it is difficult to quantify the potential savings to be realized by implementing a UPL. For that reason, and for the purpose of this projection only, this estimate is modeled on setting UPLs similar to the "maximum fair price" established under the Inflation Reduction Act (IRA).[142] According to the CBO, Medicare negotiation under the IRA would save $4.844 billion in 2026 compared to the CBO estimate of a projected $157 billion spending in Medicare Part D at baseline.[143,144] Thus, the CBO estimates a 3.1% savings through setting a maximum fair price and negotiation.

With the limitation that a state UPL and the Medicare "maximum fair price" model may not deliver identical savings, by applying the anticipated 3.1% savings to the drug spending by Maryland state employees, one can approximate the potential savings in Maryland for that program. For example, in 2020, the net spend for prescription drugs for state employees was $270.5 million. Applying a 3.1% savings rate, a similar program would save $8.3 million. The Medicare program initially applies to 10 drugs.

This estimate represents savings for prescription drugs paid for by one class of payer, the State government health benefit plans, but the Maryland PDAB may also establish UPLs for prescription drugs purchased by state and local governments for the following: state or county correctional facilities, State hospitals, and health clinics at State institutions of higher education; county, bi-county, and municipal employee health benefit plans; and

[142] Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 1194, 136 Stat. 1843-48 (2022).
[143] Congressional Budget Office. Baseline Budget Projections. July 2021. https://www.cbo.gov/system/files/2021-07/51302-2021-07-medicare.pdf (last checked Dec. 9, 2022).
[144]The IRA states that Medicare Part D drugs, but not Medicare Part B should be set in 2026.

the Maryland State Medical Assistance Program.[145] As a result the savings would be larger.

Overall, upper payment limits have the potential to result in substantial savings for state government and government employees.

Two publicly available savings estimates for comparable work with Medicaid programs are the New York Medicaid program and the Massachusetts HPC program. The New York Price Cap has been credited with achieving an additional $300 million in supplemental rebates for the NY Medicaid Program. As of November 1, 2021, MassHealth has active agreements on supplemental rebate contracts with 17 manufacturers for 50 drugs with a total annual incremental savings of approximately $171 million. As a result of state experiences, the estimates based on Medicare program might be conservative.

6. Recommendations

Upper payment limits provide an important tool to reduce drug spending and address affordability challenges where market competition and other interventions have failed. UPLs do not discriminate between payers and can be focused on drugs sold within the state. Further exploration of how a UPL might be developed to achieve desired objectives is warranted. The desired objectives are to balance the many competing interests attendant to every drug pricing policy component and make prescription drugs more affordable to Maryland residents. Because the effectiveness of a UPL is a function of its design, the thoughtful development of the UPL methodology is critical.

For this reason, the Board recommends pursuing the development of an Upper Payment Limit Action Plan that will establish a process for setting and implementing upper payment limits.

C. Bulk Purchasing

1. Overview of Bulk Purchasing

Bulk purchasing is the consolidation of purchasing power to negotiate lower unit costs. This policy has been applied in the pharmaceutical and healthcare markets in a variety of ways— across multiple agencies within a single state (intrastate), in multi-state

[145] Md. Code Ann., Health-Gen. § 12-2C-14.

arrangements that consolidate purchasing power across states (interstate), and in federal bulk purchasing initiatives.[146,147,148]

The design of intrastate and interstate bulk purchasing programs is informed by whether participants are purchasers or payers. Purchasers—such as a department of correction, state hospital, or public health agency—buy, own, stock, and dispense prescription drugs directly. In contrast, payers do not take possession of a prescription drug but instead pay the retail pharmacy or physician's office after the drug has been dispensed to the consumer.

2. Market Failures Solved by Bulk Purchasing

Bulk purchasing attempts to solve the problem created by imperfect competition. When markets are not perfectly competitive, suppliers can charge higher prices, allowing them to earn more money while producing smaller quantities compared to a perfectly competitive market. These deviations are economically and allocatively inefficient. Bulk purchasing represents an attempt to restore the perfectly competitive equilibrium.

The idea with bulk purchasing is to develop countervailing market power. The impact of imperfect competition may be reduced when both sides of the market have similar levels of power. In a way, the current pharmaceutical supply chain offers a countervailing market power to the drug companies. However, this situation can just result in shifting the inefficiencies to other transactions in the supply chain. It also creates principal-agent issues throughout the supply chain. Principal-agent issues occur when an entity hired to act as an agent of another entity acts in their own (the agent's) self-interest even though it is counter to the interest of the other (the principal's). By implementing Bulk purchasing, the state can limit the amount of principal-agent issues throughout the supply chain.

2. Theoretical Ways of Creating Bulk Purchasing Arrangements

A. Consolidated Direct Purchase

Through the bulk purchasing of prescription drugs, states and local agencies increase negotiating power with manufacturers and wholesalers. The savings from lower unit prices can be transferred to consumers or taxpayers, making drugs more affordable.

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[146] Horvath J. *State Initiatives Using Purchasing Power to Achieve Drug Cost Containment*. NASHP. https://nashp.org/wp-content/uploads/2019/04/Rx-Purchasing-Paper-Jane-Horvath-FINAL-4_9_2019.pdf

[147] National Conference of State Legislators. *Bulk Purchasing of Prescription Drugs*. August 26, 2021. https://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx

[148] Thomas Waldrop. *Using Bulk Purchasing to Lower Prescription Drug Prices*. Centers for American Progress. May 2021. https://americanprogress.org/wp-content/uploads/2021/05/BulkDrugPurchasing-report11.pdf

1. Single-State Direct Bulk Purchasing

A state can consolidate direct drug purchasing across several existing state programs, which leverages the volume of drugs to negotiate lower unit prices. For example, bulk purchasing of prescription drugs by state public health agencies that directly purchase and distribute prescription drugs such as health departments, state correctional facilities, and state hospitals, produces lower unit prices because of the increased market leverage generated by aggregating the number of persons covered (and volume of drugs subject to negotiation) across multiple programs.

There are multiple states that have consolidated their direct purchasing power across state agencies.

2. Multi-State Direct Bulk Purchasing

Working collaboratively states can establish purchasing groups for the direct purchase of drugs. These groups are comparable to the commercial sector group purchasing organizations (GPOs)—entities that help healthcare providers, such as hospitals, nursing homes, and home health agencies aggregate purchasing volume to negotiate discounts with manufacturers, distributors, and other vendors.

B. Bulk Purchase of Prescription Drug Services as a Payer

In the same way that purchasing power can be consolidated for the direct purchase of prescription drugs, the number of lives covered by a health plan can be consolidated to negotiate more favorable terms. In Maryland, state employees are covered under one prescription drug contract, but local employees and other public sector employees may be covered under separate contracts. Consolidating the pool of covered employees would enable health plans to negotiate better rates and prices. These can be set in ways that are within a single state and across multiple states.

C. Medicaid Supplemental Rebate Pools

Under the Medicaid Prescription Drug Rebate Program (MDRP), a manufacturer who wants its drug covered under Medicare or Medicaid must enter into a rebate agreement with the Secretary of U.S. Department of Health and Human Services (HHS) that it provide rebates to Medicaid programs through the Medicaid Drug Rebate Program.[149] In addition to federal statutory rebates, most states negotiate with manufacturers for supplemental rebates.

[149] Kaiser Family Foundation. https://www.kff.org/report-section/understanding-the-medicare-prescription-drug-rebate-issue-brief/#endnote_link_438418-16 (last checked Dec, 8, 2022).

To increase their negotiating power, states have formed multi-state purchasing pools when negotiating supplemental Medicaid rebates. More than half of all states participate in a multi-state supplemental rebate pool.[150] Three purchasing pools specialize in negotiating supplemental rebates for Medicaid. Because each program has its own drug lists and various strengths and weaknesses, when selecting a purchasing pool each state seeks to identify the pool that most aligns with their program design and needs.

3. Examples of Bulk Purchasing

Massachusetts State Office for Pharmacy Services (SOPS)[151]

Created in 1992, the Massachusetts State Office for Pharmacy Services (SOPS) provides an integrated and consolidated system for the direct purchase of pharmaceuticals for approximately 50 state facilities across the Department of Health, Department of Mental Health, Department of Developmental Services, Department of Corrections, Sheriff's Department, and Soldier's Homes. SOPS also manages a naloxone bulk purchasing program for the state.

Washington State Prescription Drug Project[152]

In 2001, Washington convened an inter-agency workgroup to study the ways Washington state procured prescription drugs and explore opportunities to consolidate purchasing power. The workgroup included representatives of the state's Health Care Authority (Medicaid), Department of Corrections, Department of General Administration, Department of Health, Department of Labor and Industries, Department of Social and Health Services, Department of Veterans Affairs, Office of the Attorney General, Office of the Insurance Commissioner, and the State Board of Health. In 2001, the taskforce completed its comprehensive assessment and published its findings and recommendations in the Prescription Drug Project report.

The report recommended: (1) establishing a statewide Pharmacy and Therapeutics (P&T) Committee to develop, implement, and maintain Washington State Preferred Drug List; (2) establishing a statewide Drug Utilization Review to develop treatment guidelines and criteria for appropriate drug use; (3) exploring the feasibility of consolidating claims processing, claims adjudication, and other pharmacy management and information services; and (4) exploring the feasibility of implementing and maintaining a consolidated rebate program. Due to feasibility and operational issues, the recommendations were not implemented as proposed.

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[150] Richard Cauchi, Pharmaceutical Bulk Purchasing (National Council of State Legislatures, May 2019), http://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx.

[151] Massachusetts State Office for Pharmacy Services (SOPS). https://www.mass.gov/service-details/state-office-for-pharmacy-services-sops-facilities

[152] Washington State. Prescription Drug Project- Phase 1 Final Report. June 29, 2001. https://drive.google.com/file/d/1HjdDfprloMSQ6EQuvy5JGsH-tadmTwAE/view

This study led to the 2006 creation of the Northwest Prescription Drug Consortium, a joint effort of Washington and Oregon states to pool prescription drug purchasing to lower drug costs.

California Statewide Pharmaceutical Program (SPP)[153]

Created in 2003, the California Statewide Pharmaceutical Program (SPP) coordinates the purchase of prescription drugs for the Department of State Hospitals, Department of Corrections and Rehabilitation (CDCR), Correctional Health Care Services, Division of Juvenile Justice, and the Department of Developmental Services. In 2019, Governor Newsome issued an Executive Order[154] directing state agencies to review opportunities to expand existing bulk purchasing efforts for state, local, and private sector entities and transition Medi-Cal pharmacy services from managed care into the fee-for-service delivery system to create significant negotiating leverage and substantial savings for the state.[155] Many of these initiatives are still under development.

1. Single-State Payer

New Mexico Interagency Pharmaceuticals Purchasing Council[156]

Created in 2019, the New Mexico Interagency Pharmaceuticals Purchasing Council operates under the Department of General Services and is comprised of the secretaries[157] of the Departments of Human Services, health children, youth and families, and corrections, the director of the risk management division of the general services department, the executive directors of the retiree health care authority and the public school insurance authority, the superintendent of the Albuquerque public school district, the president of the university of New Mexico, and two members who are officers or representative of organizations that represent, county, municipal or local government entities that participate in consolidated purchasing of pharmaceuticals or pharmacy benefits.[158]

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[153] California Statewide Pharmaceutical Program (SPP). https://www.dgs.ca.gov/PD/About/Page-Content/PD-Branch-Intro-Accordion-List/Acquisitions/Statewide-Pharmaceutical-Program

[154] https://www.gov.ca.gov/wp-content/uploads/2019/01/EO-N-01-19-Attested-01.07.19.pdf?emrc=c6276b

[155] Office of Governor Gavin Newsome. California Moves One Step Closer Toward Creating A Prescription Drug Single-Purchaser System. Jul 22, 2019. https://www.gov.ca.gov/2019/07/22/california-moves-one-step-closer-toward-creating-a-prescription-drug-single-purchaser-system/

[156] New Mexico. Interagency Pharmaceuticals Purchasing Council. https://www.generalservices.state.nm.us/ippc/

[157] Or designees.

[158] N.M. Stat. Ann. § 9-17-9.C.

The Council is tasked with: (1) reviewing and coordinating cost-containment strategies for the procurement of pharmaceuticals and pharmacy benefits and the pooling of risk for pharmacy services by the constituent agencies; (2) identifying ways to leverage constituent agencies' pharmaceutical and pharmacy benefits procurement to maximize the purchasing power; and (3) identifying other cost-saving opportunities for New Mexico residents purchasing pharmaceuticals or pharmacy benefits in the private sector.[159]

Maryland Task Force to Study Cooperative Purchasing for Health Insurance[160]

In 2018, the General Assembly convened the Task Force to Study Cooperative Purchasing for Health Insurance.[161] The task force was charged with studying models of cooperative purchasing of health insurance, and determining what health insurance benefit options can be consolidated and offered to satellite organizations, such as nonprofit organizations, county governments, municipal corporations, and retirees. On December 23, 2019, the Task Force issued its report recommending increased outreach to eligible local governments, and coordination and information sharing across state and local entities. Despite recognizing that pooling resources and procuring health care cooperatively may lead to cost savings and increased efficiencies for participants, no action plan for integrating local entities into the State's health insurance was recommended.

Maryland should reconstituted the task force to examine potential savings.

2. Multi-State Payers

There are many examples of multistate bulk purchasing cooperatives.

Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) Infuse[162]

Established in 1985, MMCAP Infuse operates under the State of Minnesota Office of State Procurement. With over 13,000 members across all 50 states, MMCAP obtains competitively bid contracts that can be used by its members to procure healthcare services including pharmaceuticals. Two-thirds of the administrative fees collected from suppliers are returned to the members in the form of a wholesaler credit.

[159] N.M. Stat. Ann. § 9-17-9.A.
[160] Maryland Task Force to Study Cooperative Purchasing for Health Insurance. State of Maryland Task Force Report to the Governor and General Assembly on Cooperative Purchasing of Health Insurance. December 23, 2019. https://msa.maryland.gov/msa/mdmanual/26excom/html/20healinscoop.html
[161] 2018 Maryland Laws Ch. 307 (H.B. 1400); 2019 Maryland Laws Ch. 110 (S.B. 49).
[162] MMCAP Infuse. https://infuse-mn.gov/

For member facilities, including state agencies, counties, cities, and school districts responsible for providing healthcare, this national cooperative group purchasing organization (GPO) negotiates contracts that leverage aggregated member volume to obtain deeper discounts.[163]

ArrayRx (formerly The Northwest Prescription Drug Consortium (NPDC))[164]

The Consortium was created in 2006 as a partnership between Washington and Oregon to pool prescription drug purchasing for the states' public sector programs. Over the years, it has expanded to provide a full suite of prescription drug services, including pharmacy benefit management (PBM) services, workers compensation services, discount card programs, and voucher programs.

In 2021, the Consortium changed its name to ArrayRx to reflect this full complement of available pharmacy services. ArrayRx serves a variety of participating programs within the member states of Washington, Oregon and Nevada.[165] Participating Programs include: (1) large public-sector programs such as state employee benefit plans, school districts, workers' compensation programs, state hospitals and corrections institutions, as well as managed Medicaid plans; (2) private-sector groups such as large employer groups with both carve-in and carve-out PBM services; and (3) Taft-Hartley programs such as union plans.[166]

ArrayRx leverages the purchasing power of over 1 million covered lives to obtain the best price on medications facilitating in excess of $800 million in annual drug purchases in the member states. ArrayRx contracts with Moda Health and Navitus Health Solutions to provide these services.[167] Moda Health provides pharmacy benefits and is the administrator for ArrayRx programs. Navitus Health Solutions is a full pass-through pharmacy benefit manager (PBM). As a subcontractor to Moda Health, Navitus combines a pass-through approach to PBM services that returns 100% of rebates and discounts from manufacturers, and on drug costs from participating pharmacies.

3. International Payers

Beneluxa Initiative on Pharmaceutical Policy[168]

[163] https://infuse-mn.gov/about/missionandvision/index.jsp
[164] ArrayRx. https://www.arrayrxsolutions.com/
[165] https://dhhs.nv.gov/Reports/Press_Releases/2022/Nevada_joins_Northwest_Prescription_Drug_Consortium/

[166] https://www.arrayrxsolutions.com/Frequently-Asked-Questions
[167] https://www.arrayrxsolutions.com/Frequently-Asked-Questions
[168] https://beneluxa.org/

The Beneluxa Initiative is a joint collaboration between Belgium, the Netherlands, Luxembourg, Austria, and Ireland. The Beneluxa initiative was originally conceived as a project between Belgium and the Netherlands in April 2015. In September 2015, Luxembourg joined. Austria joined in 2016, and Ireland joined in 2018. The goal is to enable collaboration on a range of pharmaceutical policies including horizontal scanning, health technology assessment, and pricing and reimbursement. To date the group has enabled the countries to share and recognize each other's HTA assessments, allowing them to pool resources and stretch workload. The goal is eventually to use their joint purchasing power to negotiate the price of new drugs, with a focus on drugs that may require Managed Entry Agreements. To date the initiative has reached an agreement of pricing on one drug–Zolgensma.[169]

1. **The National Medicaid Pooling Initiative (NMPI)**[170]

Created in 2003, NMPI is a multi-state purchasing pool administered by Magellan Medicaid Administration to negotiate Medicaid Supplemental Rebates.

2. **Top Dollar Program (TOP$)**[171]

Created in 2005, TOP$ is a multi-state purchasing pool that uses preferred drug lists administered by Magellan Management to negotiate Medicaid Supplemental Rebates. Maryland participates in the TOP$ program.

3. **The Sovereign States Drug Consortium (SSDC)**[172]

Created in 2006, the SSDC is a multi-state purchasing pool that is managed by the participating states.

4. Savings Estimates for Bulk Purchasing

Estimating overall cost savings for different bulk purchasing models is complex, and highly dependent on the specific detail of the program. Administrators of the Medicaid purchasing pools (NMPI, TOP$, and SSDC) estimate that states using a purchasing pool saved between 3-5% on pharmaceutical procurement.[173] Between 2016 and 2019, the

[169] https://beneluxa.org/statements

[170] National Medicaid Pooling Initiative. https://www1.magellanrx.com/preferred-drug-list-programs/manufacturer-hub/nmpi-national-medicaid-pooling-initiative/#:~:text=The%20NMPI%20was%20the%20first,with%20over%20100%20pharmaceutical%20manufacturers.

[171] TOP$ — The Optimal PDL $olution. https://www1.magellanrx.com/preferred-drug-list-programs/manufacturer-hub/top-the-optimal-pdl-solution/

[172] Sovereign States Drug Consortium. https://rxssdc.org/

[173] National Conference of State Legislators. Bulk Purchasing of Prescription Drugs. August 26, 2021. https://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx

Northwest Prescription Drug Consortium, estimates it saved over $99.4 million through network over-performance.[174] The California Legislative Analyst's Office estimates that the potential savings of California's intrastate agency pool, including carving prescription drugs back into Medicaid fee-for-service for state-wide negotiation, could be hundreds of millions of dollars. However, these savings are yet to be realized.[175]

As these estimates demonstrate, the potential for savings is significant; realizing these savings is complex.

5. Recommendations

The Board recommends continuing to explore opportunities for consolidated direct purchasing of prescription drugs across state agencies and purchasing power as a payer by continuing to study and implement the recommendations of the Maryland Task Force to Study Cooperative Purchasing for Health Insurance and move forward with greater bulk purchasing.

D. Reverse Auctions

1. Overview of Reverse Auctions

A reverse auction refers to a competitive bidding process for procurement. Unlike a traditional auction, a "reverse auction" involves sellers competing to provide a good or service rather than buyers competing to buy a good or service. As such, rather than the price going up over the course of the auction, the price goes down over the course of the auction. The most common current examples related to prescription drugs are reverse auctions for states to procure the services of a pharmacy benefit manager (PBM) for their employee health plan, though the general structure can be applied to other procurements.[176] The Board heard a presentation by the State of New Jersey that implemented a reverse auction.

To implement a "reverse auction" there is an initial round of bids, and then the blinded results of the first bid are shared so that bidders can use them for a second round of bidding (i.e., the lowest bid of the first round effectively becomes the ceiling price for the second round of bids). Another key feature of the PBM reverse auction is that they use a platform to manage the reverse auction that ensures that there is a direct comparison of

[174] Oregon Health Authority. The Northwest Prescription Drug Consortium. https://www.oregon.gov/oha/HPA/DSI-Pharmacy/Pages/Northwest-Prescription-Drug-Consortium.aspx

[175] California Legislative Analyst's Office. The 2019-20 Budget. Analysis of the Carve Out of Medi-Cal Pharmacy Services From Managed Care. April 5, 2019. https://lao.ca.gov/Publications/Report/3997#top

[176] Montgomery County Office of Legislative Oversight. Report 2018-4. Reverse Auction Purchasing. https://www.montgomerycountymd.gov/OLO/Resources/Files/2018%20Reports/ReverseAuctionPurchasing2018-4.pdf

the benefits provided by the plans. This is important in the PBM market because PBM contracts currently have different formularies and different contract terms that can make direct comparisons of products and services nearly impossible.

2. Market Failures Solved by Reverse Auctions

Given that there are only three major PBMs in the US, the potential market for PBM services is relatively uncompetitive. This may give PBMs market power over their potential customers, resulting in higher prices for PBM services. The extent of the market power that PBMs have depends on the market design. Designed properly, reverse auctions can mitigate the ability of PBMs to tacitly collude and behave strategically in order to obtain more profits in an uncompetitive manner.

3. Theoretical Ways to Set Up Reverse Auctions

Auction design is an important field that guides the way in which governments structure the procurement of services. When designing a reverse auction for PBM services, the state should determine exactly what services they want covered, the terms of the contract, and process beforehand. As noted above, PBMs can be differentiated from each other and as a result, comparing PBMs based solely on price is usually not possible because they do not offer a standard service. The reverse auction can used in ways to standardize the offerings, so price is the main mechanism of competition. To what extent offerings are standardized is up to the entity running the auction.

4. Examples of Reverse Auctions for State Benefit Pharmacy Benefit Managers

Most reverse auctions for state employee health PBMs are based on the same model legislation, so the policies and implementation across states is often very similar.

New Jersey Reverse Auction for Employee Health Plan PBM Services:

In 2016, New Jersey passed SB2949 to become the first state in the nation to implement a reverse auction to procurement for their state employee PBM.[177] Their experience has served as a model for other state legislation. The legislation required the use of a digital platform to conduct a reverse auction to procure their state employee PBM.

[177] New Jersey Legislature. Session 2016-2017. S2749- Provides for procurement by State of pharmacy benefits manager, automated reverse auction services, and claims adjudication services. https://www.njleg.state.nj.us/bill-search/2016/S2749

New Hampshire, Colorado, Louisiana, and Minnesota[178]:

There have been multiple states that have also passed reverse auction legislation. They can all be described together because they are all closely modeled after the initial New Jersey legislation.

Maryland:

In 2020, Maryland passed the Maryland Competitive Pharmacy Benefits Manager Marketplace Act (HB1150) to implement a reverse auction to procure a PBM for January 1, 2023.[179] This required the Department of Budget and Management (DBM) to use a reverse auction, to select a pharmacy benefits manager or other entity to administer the state employee prescription drug benefits. This included procuring the platform that is necessary to conduct a reverse auction.

DBM is currently in the process of trying to implement the reverse auction. The first step is to procure the platform to implement the reverse auction, which includes updating procurement rules and procedures to accommodate the procurement of the platform. DBM posted a Request for Proposals for Pharmacy Benefit Management (PBM) Reverse Auction Platform and Professional Services in the spring of 2021 with proposals due on July 1, 2021.[180] DBM made a selection, but that award was contested. Currently, DBM is working through the contestation process, with no updated timelines for when they will conduct the reverse auction or when the new PBM implementation date will be.

5. Impact of Reverse Auctions

Proponents of reverse auctions suggest that this tool can create significant savings for a state. NASHP reports that New Jersey anticipated it saved $2.5 billion in drug spending for its 800,000 public employees and retirees from 2017 to 2022.[181] A study suggests that New Hampshire could save $17.8 million to $22.2 million annually.[182] However, the savings accrued from this process are not necessarily attributable to the reverse auction process. Additionally, it is important to ensure that the reverse auction process is comprehensive in addressing all of the issues that can make PBM services more costly.

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[178] Amanda Attiya. Three More States Enact Reverse Auction Laws to Reduce Prescription Drug Spending.NASHP. August 16, 2021. https://nashp.org/three-more-states-enact-reverse-auction-laws-to-reduce-prescription-drug-spending/

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6. Recommendations

The Board supports the continued implementation of Maryland's reverse auction process. As part of this process, the Board recommends the state take additional steps to procure high quality, cost effective pharmacy benefit management services. This includes using strong contracting language and ensuring that the reverse auction process accommodates submissions from alternative PBM models, such as cost-plus administrative fee models. Other states have provided strong examples of the process and the savings.

E. Price Transparency

1. Introduction to Price Transparency

As discussed earlier, one of the key issues in the prescription drug supply chain is that there is no single, meaningful, publicly available price for a drug. Instead, there are almost a dozen "prices", and each represents a different price paid in the supply chain. Given the opacity and complexity of the system it almost impossible for patients to easily and meaningfully "shop" for lower cost options or alternatives: the most fundamental force that allows market competition to drive prices down. Additionally, and potentially more importantly, this allows different members of the supply chain to point fingers and blame each other for affordability challenges, with no way for the public and policy makers to validate any claims, understand the true drivers and issues, or come up with policy solutions to address those issues.

2. Market Failures Addressed by Price Transparency

Price transparency is tied to market failures related to imperfect information. Transparency programs may not be effective if they do not collect useful information, do not allow policymakers to use the data in a meaningful way, or put a high reporting burden on the industry.

Information regarding previously unknown aspects of the cost picture alone does not lead to greater use of high-value services: the goal of price transparency will only be reached through changes in incentives and infrastructure, not simply additional patient knowledge.

First, let's consider issues that arise when patients have access to imperfect information. Patients (nor their physicians) have perfect information on the potential costs and coverage of drugs at the time of prescribing. Patients have different insurance plans with different benefits designs, patients and physicians are not fully informed of the price at the time of prescribing. The goal is that transparency would allow consumers to make more efficient choices, helping lower the cost of drugs.

Next let's consider the imperfect information along other parts of the supply chain. Throughout the supply chain, different entities negotiate prices on behalf of other entities. This creates principal-agent relationships. In face of imperfect information, there is potential for perverse incentives in each of these relationships

Transparency plays an important part in the regulatory process. Without transparency policymakers cannot assess and determine the source of market failures. Since there are many transactions in the supply chain, it is difficult to gain insight into issues. In addition, the complexity of the supply chain allows the industry to develop new strategies to evade regulations. As a result, transparency can help policymakers make effective policy.

3. Theoretical Frameworks of Price Transparency

When establishing price transparency policies, policy makers must consider who is reporting, what they are reporting, and who has access to the report.

a) Who is reporting?

One of the key questions when deciding on price transparency reporting is who is doing the reporting. Different entities in the supply chain have access to different information. As a result, the "price" information that is received is different depending on which entity is answering. For instance, the "net price" reported by the manufacturer would represent the net amount they received for a drug product. Meanwhile, the "net price" reported by the PBM would be the net price they pay. The difference between those two prices would represent the mark up along the supply chain.

When considering who does the reporting, it is worth considering what information they have. Manufacturers would have information on their sales to pharmacies and wholesalers, coupons given to patients, payments to physicians, and rebates given to PBMs. Wholesalers would have information on purchases from manufacturers and sales to pharmacies. Pharmacies would have information about purchases from wholesalers and manufacturers, payments from and fee paid to PBMs, and coupons processed. PBMs would have information on rebates collected from manufacturers, payments paid to and fees collected from pharmacies, out of pocket payments by patients, and payments from health plans. Health plans would have information on payments made to PBMs and premiums collected from patients, their employers, or government programs.

Another consideration would be if the state would prefer two sources or one source for the same information. Since both sides of the transaction have access to information, it may make sense to get the same information for one source to reduce burden or from both sources to help increase data quality.

The state should consider the number of reporting entities. As previously described, there are a limited number of PBMs and wholesalers, with three large players dominating each market. Limiting the number of reporting entities may reduce burden on industry and the government.

b) What are they reporting?

As part of price transparency, one should consider what data they are reporting. Many entities in the supply chain participate as intermediaries and as such operate on two sides of the market. Meanwhile, manufacturers engage in interactions with multiple intermediaries. As a result, price transparency initiatives need to consider which transactions are reported and included. In addition, one must consider if the entity should report the "gross price/cost," the "net price/cost," or both. In addition, one must consider which "discounts," "rebates," or "price concessions" are included in the reporting. Including all potential ways that the price may be reduced might result in prices that are not meaningful and not representatives. On the other hand, excluding some transactions may result in new ways to evade the regulations. Finally, the policy should consider how aggregated the reporting is. The policy could report various rebates, discounts, and price concessions separately or in aggregate.

c) Who has access to reported information?

One thing to consider is who gets access to the reports. Publicly available reporting can help inform the public and help individuals make informed decisions.

Providing patient access to information on health care costs has not demonstrated a decrease in health care spending, and little to no benefit has been demonstrated associated with patient-centered price transparency initiatives. For example, a 2021 study of eligible New Hampshire residents found that within the first 3 years of the state's price transparency website becoming available, only 1% used the resource; furthermore, advertising increased patient use of the website without lowering use of low-cost health care practitioners.

Another potential regulation would be to require reporting by agents to their principles. By requiring reporting, the intermediaries may have a harder time engaging in actions not in the best interest of the principal.

Finally, the reporting could simply be required to be made to regulators. Reporting to regulators would allow policymakers to make decisions based on the data, but not allow the public or private entities to make their own individual decisions.

4. Examples of Price Transparency

a) Data Collected by Maryland

The state of Maryland operates an All Payer Claims database . This database reports all claims for insurance companies operating in Maryland except for ERISA plans and since 2018 federal employee health benefit plans. Using this information, we can understand the average amount paid to pharmacies for different drugs and the patient out of pocket payments.

The state of Maryland collects pharmacy average acquisition costs.

The state insurance commissioner collects information premiums charged by insurance companies.

b) Data Collected by the Federal Government

The federal government collects a variety of data. The Average Sales Price (ASP) is reported by manufacturers for physician-administered drugs. It represents the price net of all rebates and discounts (besides 340B and Medicare Part D discounts). The Average Manufacturer Price (AMP) is collected from manufacturers and represents the price for sales to wholesalers and pharmacies. The government also collects the "Best Price" which represents the lowest price to commercial plans net of rebates.

The federal government also collects the National Average Drug Acquisition Cost (NADAC) by surveying pharmacies.

The federal government has administrative data for government programs. This includes information on payments for pharmacies, rebates, and DIR fees for the Medicare Part D program.

Finally, the federal government recently received authority to collect more rebate information. The government requires insurers to submit information on, the 50 most frequently dispensed brand prescription drugs, the 50 costliest prescription drugs by total annual spending, the 50 prescription drugs with the greatest increase in plan or coverage expenditures from the previous year, prescription drug rebates, fees, and other remuneration paid by drug manufacturers to the plan or issuer in each therapeutic class of drugs, as well as for each of the 25 drugs that yielded the highest amount of rebates, and the impact of prescription drug rebates, fees, and other remuneration on premiums and out-of-pocket costs.[183]

[183] https://www.cms.gov/newsroom/fact-sheets/prescription-drug-and-health-care-spending-interim-final-rule-request-comments

TIC data

c) Commercially Available Datasets

Commercially available datasets offer a way to get all kinds of pharmaceutical data.

(1) Pharmaceutical Dispensing and Sales Data

IQVIA and Symphony Health sell pharmaceutical sales data. In particular they receive data from pharmacy claims processors and wholesalers to monitor the pharmaceutical market. This data is curated with the pharmaceutical industry in mind and used by the industry for market research.

The companies offer a variety of datasets that can include various data points including sales, prescriptions, out of pocket costs, pharmacy revenue, and coupon use.

(2) List Price Data

As previously stated, WAC and AWP represent different versions of list prices. To keep track of these prices several Drug Knowledge Databases exist. The primary use of these Databases is for pharmacies. Available datasets include Analysource, Gold Standard Database, and RedBook.

(3) Net Sales Data

Most of the databases represent gross or list price based sales figures. Generally rebate data is confidential. However, public companies are required to report information on important profit drivers of a company. As a result, these companies report the net sales (sales minis rebates) for the top drugs sold by the company. This information can be found in quarterly reports. SSR Health is a private company that combines these reports with volume data to determine the net price of drugs.

(4) Commercial Claims Data

Several companies provide access to databases that give commercial claims data. The datasets normally focus on all the lines of business of select health insurance companies. Some of these databases include Optum and MarketScan.

These Databases work similarly to the Maryland All Payer Claims Database, but may include employer plans.

d) Data Being Collected by States

A variety of states have begun to collect different drug pricing data. Below is a list of recent attempts by states to collect additional drug pricing data.

(1) Maine

Maine enacted Public Law 2019, Chapter 470, An Act to Further Expand Drug Price Transparency. This act required Manufacturers report to the state certain WAC based price increases. In addition, the manufacturers reported factors that contributed to the price increase.

(2) Oregon

Oregon Health insurance companies are required by state law to report the 25 most prescribed drugs, the 25 most costly drugs, and the 25 drugs that caused the biggest increases in yearly health plan spending. Oregon requires manufacturers to report new high cost drugs, annual price increases, and information on patient assistance programs.

(3) Colorado

Colorado as part of their All Payer Claims Database began requiring insurers to report rebate information.[184]

(4) California

California requires that drug manufacturers submit information on new drugs and drug price increases.

(5) Washington

Washington requires issuers of health insurance, pharmacy benefit managers (PBMs), manufacturers, and pharmacy service administrative organizations (PSAOs) to submit data on drug costs and pricing.[185] In addition, Drug manufacturers must submit information on new drugs,

e) Key Considerations with Other Data Sources

Since other sources of data exist, it provides two different, but conflicting opportunities for Maryland. First, in some cases Maryland has the potential to access this data rather

[184] https://www.civhc.org/wp-content/uploads/2022/08/Drug-Rebates-Issue-Brief_FINAL.pdf
[185] https://www.hca.wa.gov/about-hca/programs-and-initiatives/clinical-collaboration-and-initiatives/prescription-drug-price-transparency#background

than collecting it. However, data access may cost additional money or may not be available for some confidential sources. The data sources may even limit the ability to share the data or analysis of the data publicly.

On the other hand, the existence of certain datasets implies certain entities already have a pre-existing method of collecting and reporting such data. Maryland can leverage this infrastructure to reduce the administrative burden of new data collections.

5. Recommendations for Price Transparency

There are many different sources of data and the PDAB should take advantage of them. However, there are certain data that are confidential.

The current recommendation is to have those in the pharmaceutical supply chain voluntarily provide information to Maryland Prescription Drug Affordability Board as requested. The PDAB should keep this information confidential and use it to make policy recommendations. This is what is discussed in the PDAB regulations and was part of the discussion with the various stakeholders. However, if the data is not provided the state should mandate its disclosure.

F. Pharmacy Benefit Management

1. Introduction

As previously discussed, PBMs hold a variety of responsibilities and engage in various transactions impacting different parts of the supply chain. Recent court rulings have clarified the ability of states to regulate PBMs. As a result, policymakers have considered regulating PBMs. Regulating PBMs involves considering which transactions to regulate and what types of regulations to enact.

2. Market Failures Addressed by PBM Reform

PBMs are an intermediary in the pharmaceutical supply chain. They operate in the space with a complex set of contracts with health plans, pharmacies, and manufacturers. PBM reform attempts to address two potential issues. First, since the PBM market is highly concentrated, it is possible for PBMs to extract surplus from other parts of the market (namely health plans and pharmacies). Next, PBMs are in theory agents of health plans. However, due to the complex nature of the contracts, it is possible that PBMs could hide information from the health plans and as a result work in their own best interest at the expense of the client's best interest. This concern is even more heightened given the vertically integrated nature of the main large PBMs. They may operate in ways that help their other lines of business, even if they are not in the best interest of the health plans.

3. Potential Ways to Regulate PBMs

Given their role in the supply chain, regulations of the PBMs can focus on the various interactions the PBMs have with other elements of the supply chain.

a) Regulating PBM Interactions with Plans

First, regulation can attempt to define the guidelines for interacting with health plans. Health plans are the ones that contract with the PBMs. There are several ways to improve the contracting arrangements.

(1) Limits On and the Disclosure of Conflicts of Interest

Conflicts of interest can arise out of a variety of behaviors and relationships between PBMs and health plans. These include:: ownership (PBM ownership of mail-order and specialty pharmacies), vertical integration (patient steering or increased volume incentives), contractual language (gag clauses), conduct (price spreading), and lack of transparency (sharing of rebates). State efforts to prevent or manage these conflicts have address these issues in various states.

Conflicts of interest often arise out of the extensive vertical integration of PBMs and their partners or affiliates. For example, CVS Health has combined CVS Pharmacy, CVS Caremark (PBM), MinuteClinic, CVS HealthHub, and the health insurer Aetna under a single company. Where the PBM's corporate affiliate operates a primary care health clinic, the prescriber/provider may be incentivized to write more prescriptions (volume) for more expensive prescription drugs.

Moreover, some PBMs require contracted health plan enrollees to visit affiliated pharmacies, or pharmacies in which the PBM has an ownership interest. Ownership of mail-order and specialty pharmacies, as well as retail pharmacies, gives PBMs an incentive to channel plan members to their own pharmacies. Many states, including Maryland, prohibit a PBM from requiring the beneficiary to use a pharmacy in which the PBM or corporate affiliate has an ownership interest. Such bans prevent the most overt means to steer patients to affiliated pharmacies but does not necessarily prevent other means of patient steering, such as differential cost-sharing.

The Maryland PDAB will monitor the need to conflict of interest

(2) Banning Spread Pricing

When pharmacies bill for a drug, the PBM may directly pay the pharmacy for the agreed-upon amount. The PBM then gets paid by the health plan for this payment. Spread pricing is the practice of charging the health plan more than the PBM actually paid. The ability to engage in this practice results from the opacity of the contracts. The health plan may not know what the negotiated rate for the pharmacy is and how it might change over time. Meanwhile, the contract with the health plan may have a different basis for the reimbursement. Bans on spread pricing essentially require PBMs to charge only what they actually reimbursed pharmacies.

Bans on spread pricing may have unanticipated consequences. Spread pricing targets specific transactions. As a result, bans on spread pricing may simply shift PBM transactions such that they receive more revenue from other non-regulated transactions. For instance, a ban on spread pricing may simply lead PBMs to pay pharmacies more per transaction (which is passed on to the insurer) and then collect more in fees from pharmacies that cannot be tied to a specific prescription. States have passed spread pricing bans and the Congress is considering doing the same. It could be prudent for the state of Maryland to wait to see how this actually changes behavior.

(3) Require PBMs to Have Fiduciary Responsibility

Another set of policy reforms would require that PBMs have a fiduciary responsibility to their clients. A fiduciary is required to put the interests of the clients ahead of the profits for the PBM. Current policy and court decisions suggest that PBMs do not have a fiduciary responsibility to the plans they serve. Meanwhile, pre-Rutledge court cases have ruled ERISA preempts state fiduciary responsibility requirements.
In addition to the legal questions about fiduciary responsibility, the potential impacts of such a policy are not known. Fiduciary requirements in theory create a broad approach to limit potential actions of PBMs. On the other hand, enforcement of a fiduciary responsibility regulation can be complex. Finally, having a fiduciary responsibility to the insurer may not limit actions that harm patients. As previously stated, high pricing-high rebate strategies may help the insurer lower premiums and attract more enrollees but shift more cost to the patients. While this may be a good idea the problems of enforcement are huge.

(4) Rebate Pass Through

Rebate passthrough laws are an attempt to disrupt the business model where PBMs are paid based on the proportion of the rebate they negotiate. If PBMs no longer receive a percentage of the rebate, they no longer have the incentive to prefer more expensive but higher rebate drugs. A preference for higher rebate drugs may result in PBMs preferring drugs with higher net prices, but more rebates simply because they would be more profitable for the PBM. On the other hand, such arrangements may encourage PBMs to

vigorously negotiate for rebates. Without these incentives, PBMs may not try as hard to negotiate rebates, resulting in higher net prices for the insurers.

Some PBMs are doing away with rebates and the state should monitor this behavior and do everything it can to have PBMs eliminate rebates since they tend to result in higher list prices which harm patients. The Maryland PDAB will examine the issue of rebates

b) Regulating PBM Interactions with Pharmacies

Other potential regulations target the relationship between PBMs and pharmacies. These regulations attempt to ensure PBMs treat pharmacies fairly and do not discriminate against pharmacies not affiliated with the PBM.

This is becoming a significant issue because companies like CVS operate PBMs and pharmacies. They can use this power to make competitor pharmacies at a disadvantage by making them pay higher prices. This is a large issue in rural and standalone pharmacies.

The Maryland PDAB will examine if the large PBMs discriminate against standalone pharmacies.

(1) Network Adequacy

Network adequacy reforms ensure patient access to prescription drugs. Network adequacy is often defined as the distance between a patient's residence and where services can be physically accessed. The pharmacy network is the list of pharmacies or pharmacists that a health plan or PBM has contracted with to provide prescription drug services to their members. Related measures prohibit PBMs from requiring the use of mail-order pharmacies.

Network adequacy ensures that patients have access to pharmacy services that are convenient. Research has shown that minority communities in major cities often live in pharmacy deserts. While not directly addressing all the causes of pharmacy deserts, network adequacy requirements can help ensure that a pharmacy located in a pharmacy desert would be covered.

The Maryland PDAB will examine network adequacy.

(2) Adjudication of Claims and Appeals/MAC Lists

One way in which PBMs reimburse pharmacies is through the maximum allowable cost (MAC). The MAC for a drug may change over time and may or may not be responsive to

changing market conditions. The MAC procedures are generally set for a range of drugs, so many are not responsive to a particular circumstance.

One possible approach for the state to consider is to provide reasonable administrative appeals procedures to allow pharmacies to challenge maximum allowable cost (MAC) pricing. Another option is to require PBM to update their cost schedules with pharmacies to reflect drug price increases and disclose the maximum amount they will reimburse a pharmacy for a generic or multisource drug.

The Maryland PDAB will examine claims adjudication.

(3) Gag Clauses

Gag Clauses were contractual provisions that prevent pharmacies from informing patients they could save money by paying cash rather than the copay of the insurer. This can occur for certain low-cost drugs.

A ban on gag clauses is an attempt to address issues in which a patient's copayment was larger than the cash price of a drug. These situations arise when the insurer has a set copayment for preferred generic drugs. As a result, an inexpensive prescription can be less than the cost of the copayment. In these situations, the pharmacy would collect the copayment and return the difference between the copayment and MAC to the insurer.

Gag clauses prevented pharmacies from telling patients they could pay the lower cash price. However, it is not necessarily true that paying the lower cash price is necessarily better for patients. For instance, without other regulations paying cash for drugs results in that transaction not counting against the deductible or out-of-pocket maximum. As a result, without additional regulations, patients have to consider if they should pay more now to save more later.

The federal government has passed legislation prohibiting gag clauses. The Maryland PDAB will monitor if additional legislation is needed in Maryland.

(4) Pharmacy Reimbursement Price Transparency

As previously stated, PBMs operate in a space with several complex contracts. As a result, they can mask financial transactions in multiple ways. This complex maneuvering makes it hard for the health plan to monitor the behavior of the PBM. One way to deal with this is to require PBMs to disclose certain pricing and cost information, such as data on rebates, payments, and fees collected from drug manufacturers, insurers, and pharmacies.

This is data that could be considered proprietary and part of commerce.

(5) Banning Clawbacks

These provisions prohibit a PBM from denying or reducing the amount they pay a pharmacy or pharmacist for a claim. Clawbacks occur when a health plan enrollee's copayment exceeds the total cost of the drug to their insurer, and the PBM "claws back" some, or all, of the overpayment from the pharmacy.

Such regulations aim to ensure that pharmacies receive a predictable stream of revenue for a claim. Clawback bans prevent PBMs from creating a separate revenue stream based on these clawbacks. However, as a result of such bans, PBMs may shift their strategies to other types of behavior.

This is a primarily a business decision. The Maryland PDAB will monitor if additional legislation is needed.

(6) DIR Reform

Direct and Indirect Remuneration fees represent an additional way for PBMs to generate revenue. DIR fees represent fees paid (or in theory bonuses given to) pharmacies for meeting certain quality measures. DIR represents a term of art established by Medicare but is used in all types of insurance. In recent years, the DIR fees paid to Medicare have increased rapidly, growing by 107,400 percent between 2010 and 2020.

DIR fees have the potential to increase drug costs for patients because they are not included when calculating patient cost-sharing. As a result, patients end up paying a larger percentage of the net cost of a drug when accounting for DIR fees.
Pharmacies have also complained that DIR fees are enforced and calculated inconsistently between brands and often are based on measures outside the control of the pharmacy. Pharmacy groups have asked for reforms including limits on the scope and size of such fees.

While there are reasons to limit DIR fees, there is the likelihood that they will reappear in other forms. These are business to business transactions. The Maryland PDAB will monitor if additional legislation is needed .

(7) Establishing Reimbursement Floors

Reimbursement floors are attempts to ensure pharmacies are properly reimbursed for the cost of the drug. These floors limit the ability of PBMs to pay pharmacies less than this floor. The goal is to ensure pharmacies can recoup their costs. This may be particularly

important in terms of rapid changes in drug prices. However, it also represents an opportunity for pharmacies to potentially make money if the floor is not representative of the actual cost of buying a drug.

The Maryland PDAB will monitor the viability of pharmacies

4. Recent Attempts to Regulate PBMs

Several recent court cases have helped clarify the ability of states to regulate PBMs in more context. As a result, Maryland has a broad set of policies they can consider to reform the PBM market.

a) ERISA Does Not Preempt State Laws Regulating PBMs

In Rutledge v. Pharmaceutical Care Management Association, 141 S.Ct. 474 (2020), the Supreme Court held that the Employee Retirement Income Security Act ("ERISA") did not preempt an Arkansas law requiring PBMs to reimburse pharmacies at a price equal to or higher than the pharmacy's acquisition cost.[186] The law (1) imposed requirements on PBMs regarding their maximum allowable cost ("MAC") lists, which set the reimbursement rates for pharmacies; (2) prescribed administrative appeal procedures for pharmacies; and (3) enabled pharmacies to decline to dispense if the transaction would result in a loss. Id. at 479.

The Court confirmed that ERISA does not preempt state laws that merely "alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." 141 S. Ct. at 480. In rejecting the argument that federal law preempted state regulation of pharmacy reimbursement rates, the Court noted that mandating PBM pricing methodologies does not "require plans to provide any particular benefit to any particular beneficiary in any particular way." Id. at 482.

In upholding the law requiring PBMs to update MAC lists the Court explained:
[t]he amount a PBM "reimburses" a pharmacy for a drug is not necessarily tied to how much the pharmacy paid to purchase that drug from a wholesaler. Instead, PBMs' contracts with pharmacies typically set reimbursement rates according to a list specifying the maximum allowable cost (MAC) for each drug. PBMs normally develop and administer their own unique MAC lists. Likewise, the amount that prescription-drug plans reimburse PBMs is a matter of contract between a given plan and a PBM. A PBM's

[186] ERISA "supersede[s] any and all State laws insofar as they may now or hereafter relate to any" ERISA plan. 29 U.S.C. § 1144(a). A law "relate[s] to" an ERISA plan if and only if it "has a connection with or reference to such a plan." *Rutledge*, 141 S. Ct. at 479.

reimbursement from a plan often differs from and exceeds a PBM's reimbursement to a pharmacy. That difference generates a profit for PBMs.[187]

Courts applying Rutledge have likewise found no federal preemption of state law. In November 2021, the Eight Circuit Court of Appeals considered more comprehensive PBM regulations—authorizing pharmacies to provide information to a patient and prohibiting PBMs from having an ownership interest in a patient assistance program—and held that ERISA preemption did not apply. Pharm. Care Mgmt. Ass'n v. Wehbi, 18 F.4th 956 (8th Cir. 2021). In concluding that ERISA did not preempt laws such as anti-gag provisions, the Eighth Circuit rejected the argument that Rutledge is limited to reimbursement laws, and analyzed the impact of each law on the ERISA plan finding that "none of the challenged provisions meets the connection-with standard" required to prove preemption.[188]

b) After *Rutledge*, Maryland Enacted Laws Regulating PBMs That Serve ERISA Plans

Since the Rutledge decision, many states including Maryland have enacted legislation regulating PBMs. In 2021, the General Assembly passed legislation making the statutory provisions governing certain regulated activities including PBM registration, financial and market conduct exams, contracts between pharmacies and PBMs, required disclosures by PBMs to pharmacies, and requirements for MAC pricing and other reimbursement practices apply to PBMs performing services on behalf of an ERISA plan. Md. Laws, Ch. 358, Acts of 2021 (HB 601).

In 2022, two bills relating to PBMs were enacted: House Bill 97 (Chapter 307) which requires PBMs, rather than pharmacy services administrative organizations (PSAO), to submit contracts to the Maryland Insurance Administration and prohibits a PSAO that had not registered with the Insurance Commissioner from entering into an agreement or contract with an independent pharmacy, and House Bill 1274 (Chapter 365) which

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[187] Id. at 478. As the Supreme Court noted, "spread pricing" is a pricing model in which a PBM charges a health benefit plan a contracted price for prescription drugs, but pays the pharmacy a different price. The PBM keeps the difference between the amount charged to the health benefit plan and the amount paid to the pharmacy.

[188] Id. at 968. *See also Pharm. Care Mgmt. Ass'n v. Mulready*, 5:19-CV-00977-J, 2022 WL 1438659 (W.D. Okla. Apr. 4, 2022) (upholding Oklahoma's Patient's Right to Pharmacy Choice Act finding no connection with an ERISA plan and no basis for preemption), *appeal docketed*, 22-6074 (10th Cir. 2022); *ACS Primary Care Physicians Sw., P.A. v. UnitedHealthcare Ins. Co.*, 514 F. Supp. 3d 927, 941 (S.D. Tex. 2021), *supplemented,* 2021 WL 6617719 (S.D. Tex. Feb. 10, 2021) (applying *Rutledge* and holding that the Texas emergency care statutes, which regulate the rate at which insurers and insurance plan administrators reimburse emergency care physicians, are not preempted by ERISA).

prohibits discrimination and differential treatment by PBMs of pharmacies and pharmacists that participate in the federal 340B program.

The Maryland PDAB will continue to monitor the need for additional reforms

c) Other States are Exploring PBM Reform

Between 2017 and 2021, states enacted over 100 laws to regulate PBMs, improve transparency and protect consumers' rights.[189] As of August 2022, 135 bills involving PBM legislation had been introduced in thirty-four states.[190] These reforms fall into several broad categories.[191] Some are designed to address or alleviate the high cost of prescription drugs, some to regulate conduct and anti-competitive behavior, and some to protect consumers.

The Maryland PDAB will monitor these.

(1) Conflicts of Interest Disclosure

Many states, including Maryland, prohibit a PBM from requiring the beneficiary to use a pharmacy in which the PBM or corporate affiliate has an ownership interest.
A few states also require the express disclosure of conflicts of interest. For example, New York requires the PBM to disclose to the health plan "any activity, policy, practice, contract or arrangement of the pharmacy benefit manager that directly or indirectly presents any conflict of interest with the pharmacy benefit manager's relationship with or obligation to the health plan."[192]

(2) Ban Spread Pricing

Some states have enacted legislation prohibiting a PBM from utilizing a spread pricing model. As the Supreme Court discussed in Rutledge, under that model the PBM keeps a portion of the amount, or spread, between what the payer pays the PBM and the amount that the PBM reimburses the pharmacy.

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[189] Lanford, S. & Reck, J., Nat'l Acad. State Health Pol'y, *Legislative Approaches to Curbing Drug Costs Targeted at PBMs: 2017-2021* (June 14, 2021), https://perma.cc/8D57-DBLL

[190] Nat'l Acad. State Health Pol'y, *2022 State Legislative Action to Lower Pharmaceutical Costs (Pharmacy Benefit Mgr Topic Selected)* (Aug. 23, 2022), https://perma.cc/2MCC-LDE7.

[191] Nat'l Conf. of State Legislatures, *State Policy Options and Pharmacy Benefits Managers (PBMs)* (March 23, 2022). https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx#/ (last checked November 21, 2022).

[192] N.Y. Pub. Health Law § 280a.2(e) (McKinney).

In 2021, the National Academy for State Health Policy (NASHP) reported that audits of state Medicaid pharmacy services disclosed over $100 million in spread pricing per year retained by their PBMs. For example, the audit of Ohio's Medicaid Managed Care Pharmacy Services disclosed that PBMs retained more than $200 million in spread over the 2018 year.[193] For a similar program, Kentucky found that PBMs retained $123 million in spread in 2017.[194]

Some states have enacted laws to limit the ability to use spread pricing in PBMs' contracts. For example, as of 2021, Louisiana, Kentucky, New York, Pennsylvania, Virginia, Georgia, Vermont, Maine, Delaware, Alabama, Arkansas, Minnesota, and the District of Columbia have prohibited spread pricing by restricting what can be collected from the insurer (eliminate spread), or enacted other restrictions and limitations on price spreading. Georgia prohibits a PBM from "charging or collecting from an insured a copayment that exceeds the total submitted charges by the network pharmacy or other dispenser practice for which the pharmacy or dispenser practice is paid."[195] New York, however, directs that all funds received by a PBM for PBM services, including administrative fees and funds received through spread pricing, "shall be used or distributed only pursuant to the pharmacy benefit manager's contract with the health plan or applicable law."[196]

Maryland should consider banning spread pricing although it might be moot if the Congress passes legislation banning spread pricing.

(3) Rebate Pass Through

In 2022, Rhode Island considered a bill that would require PBMs to pass through to payers 100% of manufacturer-derived PBM revenues including rebates and other manufacturer revenues.[197] The bill is pending before the Rhode Island Senate Health and Human Services Committee.

This provision would effectively eliminate rebates in Maryland and would probably reduce incentives to increase list prices which would benefit consumers.

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[193] Lanford, S. & Reck, J., Nat'l Acad. State Health Pol'y, *Legislative Approaches to Curbing Drug Costs Targeted at PBMs: 2017-2021* (June 14, 2021), https://perma.cc/8D57-DBLL

[194] Lanford, S. & Reck, J., Nat'l Acad. State Health Pol'y, *Legislative Approaches to Curbing Drug Costs Targeted at PBMs: 2017-2021* (June 14, 2021), https://perma.cc/8D57-DBLL

[195] Ga. Code Ann. § 33-64-11(a)(3).

[196] N.Y. Pub. Health Law § 280a.2(b) (McKinney).

[197] *See, e.g.*, S. 2619, 2022 Gen. Assembl., Reg. Sess. (R.I. 2022) (Pending - Senate Health and Human Services Committee).

(4) Network Adequacy

Twenty-nine states, including Maryland, have enacted legislation regulating how PBMs establish or manage pharmacy networks.[198]

For example, § 15–1611.1 of the Maryland Insurance Article prohibits a PBM from requiring a beneficiary to use a specific pharmacy if the PBM or corporate affiliate has an ownership interest in the pharmacy, or the pharmacy has an ownership interest in the PBM or corporate affiliate. Specialty drugs are not subject to this restriction.

Section 15-1628 requires PBMs to disclose terms, conditions, and reimbursement rates to pharmacies at least 30 days before any contract change, provide notice of a dispute resolution and audit appeal process, and the process for verifying which drugs are on the formulary. The statute also prohibits a PBM, as a condition to membership in the pharmacy network, from requiring a pharmacy to renew credentialing more than once every three years, and from charging a fee for credentialing. PBMs are also required to file a contract form or amendment with the Insurance Commissioner at least 30 days before its effective date.

Maryland also requires reimbursement parity between PBM-affiliated pharmacies and non-affiliated pharmacies—a PBM may not reimburse a pharmacy or pharmacist for a pharmaceutical product or pharmacist service in an amount less than the amount that the PBM reimburses itself or an affiliate for providing the same product or service.[199] This does not apply to mail order, specialty, and chain pharmacies.

At the present time, the PDAB does not have any further suggestion to make regarding network adequacy.

(5) Adjudication of Claims and Appeals/MAC Lists

States acting in this area have enacted legislation requiring PBMs to provide reasonable administrative appeals procedures to allow pharmacies to challenge maximum allowable cost (MAC) pricing. Other legislation mandates that PBMs update their cost schedules with pharmacies to reflect drug price increases and disclose the maximum amount they will reimburse a pharmacy for a generic or multisource drug.

[198] Nat'l Conf. of State Legislatures, *State Policy Options and Pharmacy Benefits Managers (PBMs)* (March 23, 2022) https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx#/ (last checked November 21, 2022).
[199] Md. Code Ann., Insur. § 15–1612(c) (2022).

Maryland regulates MAC lists and requires PBMs to provide a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing.[200]

At the present time, the PDAB does not have any further suggestion to make regarding claims and appeal processes.

(6) Gag Clauses

To date, 45 states, including Maryland, and the District of Columbia have enacted cost disclosure and gag clause provisions. In 2018, the federal government also banned gag clauses.[201]

Under § 15-1611 of the Maryland Insurance Article, a PBM may not prohibit a pharmacy from (1) providing a beneficiary with information regarding the retail price or the amount of the cost share for which the beneficiary is responsible; (2) discussing with a beneficiary the retail price for a prescription drug or the amount of the cost share for which the beneficiary is responsible; or (3) selling a more affordable alternative if a more affordable drug is available than one on the purchaser's formulary and the requirements for a therapeutic interchange are met.

At the present time, the PDAB does not have any further suggestion to make regarding gag clauses.

(7) Pharmacy Reimbursement Price Transparency

One trend in recent legislation is to require PBMs to disclose certain pricing and cost information, such as data on rebates, payments, and fees collected from drug manufacturers, insurers, and pharmacies. For example, in New York, the PBM must account annually or more frequently to the health plan "for any pricing discounts, rebates of any kind, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other benefits received by" the PBM.[202]
Other states require that aggregated rebate and other payment information be reported directly to state agencies.[203]

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[200] Md. Code Ann., Ins. § 15-1628.1 (2019).

[201]

[202] N.Y. Pub. Health Law § 280a.2(c) (McKinney).

[203] *See e.g.*, Iowa Code Ann. § 510C.21.a (requiring the reporting of "[t]he aggregate dollar amount of all rebates received by the pharmacy benefits manager."); Wis. Stat. Ann. § 632.865(7) (requiring PBM to "submit to the commissioner a report that contains, from the previous calendar year, the aggregate rebate amount that the pharmacy benefit manager received from all pharmaceutical manufacturers but retained and did not pass through to health benefit plan sponsors").

Maryland requires PBMs, prior to entering into a contract with a purchaser, to offer to provide the purchaser with a report that contains (1) net revenue of the PBM from sales of prescription drugs to purchasers made through the PBM's network with respect to the PBM's entire client base of purchasers, and (2) the amount of all manufacturer payments earned by the PBM.[204] Maryland also permits the PBM to defer providing this report until after the purchaser executes a nondisclosure agreement, if requested to do so by the PBM.[205]

At the present time, the PDAB does not have any further suggestion to make regarding price transparency.

(8) Banning Clawbacks

Some states, including Maryland, have chosen to prohibit these types of retroactive payments and at least 22 states have enacted some form of clawback legislation.[206]

Except for an overpayment, in Maryland, a PBM "may not retroactively deny or modify reimbursement to a pharmacy or pharmacist" unless: (1) the claim was fraudulent, (2) the pharmacy or pharmacist had been reimbursed for the claim previously, or (3) the services reimbursed were not rendered by the pharmacy or pharmacist.[207]

Maryland also prohibits a PBM or carrier from making or allowing any reduction in payment for pharmacy services or directly or indirectly reducing payment for a pharmacy service "under a reconciliation process to an effective rate of reimbursement, including generic effective rates, brand effective rates, direct and indirect remuneration fees, or any other reduction or aggregate reduction of payments."[208]

At the present time, the PDAB does not have any further suggestion to make regarding revising the clawback provisions.

(9) Establish Reimbursement Floor

[204] Md. Code Ann., Insur. § 15–1623(a) (2008).
[205] Md. Code Ann., Insur. § 15–1623(b)(2) (2008).
[206] Nat'l Conf. of State Legislatures, *State Policy Options and Pharmacy Benefits Managers (PBMs)* (March 23, 2022) https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx#/ (last checked November 21, 2022).
[207] Md. Code Ann., Insur. § 15–1631 (2019).
[208] Md. Code Ann., Insur. § 15–1628.3 (2022).

State laws may provide reimbursement standards for pharmacies with which the PBM contracts. For example, a state might establish a minimum amount that the PBM must pay pharmacies. For example, West Virginia requires PBMs to reimburse a pharmacy an amount no "less than the national average drug acquisition cost for the prescription drug or pharmacy service at the time the drug is administered or dispensed, plus a professional dispensing fee of $10.49."[209]

At the present time, the PDAB does not have any further suggestion to make regarding a reimbursement floor.

5. Recommendations

Maryland has enacted significant and robust legislation in PBM reform. Because of the unique role PBMs play in the distribution and payment chain, further exploration of PBM reform as a means of redressing high prescription drug costs is necessary. Maryland PDAB, therefore, recommends that it work collaboratively with the Maryland Insurance Administration and Department of Health to identify and explore additional areas where additional regulation may redress high prescription drug costs.

G. Out-of-Pocket Costs

1. Introduction

The patient's out-of-pocket costs are an important part of understanding the pharmaceutical supply chain. Out-of-pocket costs influence the behavior of patients and are a main reason for challenges of affordability. Health plans introduce deductibles, copays, and coinsurance to make patients aware of the cost of the drugs they are taking. A concern is that these deductibles, copays, and coinsurance will make it more difficult for patients to access the drugs that they need. This is a special concern for low-income patients who must choose between spending dollars on drugs or other necessities. Getting the appropriate balance between making sure that patients are aware of the cost of the drugs and have access to the drugs that they need is a challenge for economists, insurance executives and public policy makers. It is something that the Maryland PDAB monitors closely. Nationally there are statistics showing that between 25% and 40% of Americans are not filling prescriptions because of the out-of-pocket costs (Commonwealth Fund and KFF) There are several policies that may reduce out-pocket-costs and increase affordability that the Maryland PDAB is monitoring.

[209] W. Va. Code Ann. § 33-51-9(e) (2022).

The Maryland PDAB will continue to monitor if out-of-pocket spending is making drugs unaffordable in Maryland.

2. Policy Options to Revise Out-of-Pocket Costs

a) Value-Based Insurance Design

Value-based insurance design (VBID) is an attempt to align cost-sharing to emphasize the clinical benefit of health services. The challenge is determining the clinical benefit of a drug for a specific person. It is well known that some drugs are more effective in some people than others. This is known a personalized medicine.

Traditional tiered formularies do not differentiate between patients that find the drug effective and those where it is not effective. Traditional tiered formularies place the same cost-sharing requirements (same deductible, copayment or coinsurance percentage) for every drug on the tier for every person. However, that blunt approach does not necessarily consider the clinical benefits of the drugs overall or for the specific person. VBID approaches attempt to differentiate the drug based on its clinical efficacy – either overall or for that individual person.

In VBID, some drugs with high value would be covered with zero cost-sharing under VBID. High-priced drugs with a high value might have lower out-of-pocket costs than under a traditional tiered formulary that uses co-insurance. This drug-specific approach could lower out-pocket costs for more useful drugs and increase patient adherence.

Medicare, the Veterans Administration, TRICARE (military health plans) and several states are using VBID in their benefit design The Office of Inspector General and CMS issued rules on value-based purchasing.[210]

b) Formulary design

PBMs have multiple methods to manage and steer drug utilization. These methods include drug exclusion, tiered formularies, requiring step therapy, and requiring prior authorization. All of these are designed to give the health plan the ability to steer the patient and the physicians to drugs they believe have the greatest value. However, they

[210] https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the

interfere with the doctor patient relationship and add to the cost of the system because the physician and the patient have to appeal the decisions which takes time and money.

The Maryland PDAB will continue to monitor the data to determine the benefits and challenges of these efforts to steer drug utilizations.

c) Copay Coupons

Copay coupons are vouchers or cards produced by manufacturers or third parties to reduce the out-of-pocket costs of drugs.

The federal government does not allow Medicare, Medicaid, and other publicly insured patients to use copay coupons. The concern is that they interfere with the benefit design by having a drug with higher cost sharing to be less expensive to the patient because of the coupon. Drug companies use the coupons to get patients to use their drugs if their drug is placed on a tier with more cost sharing. It is a battle between the health plans and the drug companies over how to provide incentives to use certain drugs.

Two states—Massachusetts and California have limited bans on copay coupons. Massachusetts bans coupons for prescription drugs with drugs generic equivalents. California bans the use of coupons when a prescription drug product has a lower-cost generic on the patient's formulary. California also prohibits coupons for drugs with lower-cost, non-prescription generic equivalents. Neither policy attempts to address coupons with lower costs biosimilars or lower-cost drugs in the same class.

The Maryland PDAB will continue to monitor state legislation to regulate the use of copay coupons.

d. Rebates at the Point of Sale

It has been proposed that rebates be applied at the point of sale. This is similar to the coupons discussed earlier but instead of the dollar amount being determined by the drug company it is based on the amount of the rebate the PBM and the drug company negotiate. This proposal may give patients even more incentive to use the drugs with more rebates because not only of the lower formulary placement but because they also realize the lower negotiated price. Such a policy would impact patients subject to coinsurance, deductibles, and copayments (when the copayment is more than the net price).

The Maryland PDAB will continue to monitor state legislation and the literature to regulate the use of rebates at point of sale.

e) Bans on Copay Maximizers and Accumulators

Copay maximizers are designed to prevent copay coupons from counting against the deductible and out-of-pocket maximums. It is a response by the health plans to discourage the use of copay coupons.

Copay maximizers still allow patients to use the coupons to reduce the price of the drug when they fill a prescription (they reduce amount paid at the point of sale). However, the amount of the coupon does not count towards payment towards the deductible. As a result, patients may simply shift the costs to later prescriptions.

Currently, 19 states ban copay accumulators or maximizers. Despite this increase in policies, there is little evidence of how these policies impact patients and their out-of-pocket costs. The impact of copay maximizers is theoretically complex and the impacts have not been well studied because of a lack of data. The impact of copay maximizers depends on how patients respond to the desire to get a lower price now or pay a lower price in the future .

The Maryland PDAB will continue to monitor state legislation and the literature to regulate the use of copay maximizers and accumulators.

e. Reducing Copayments When the Cost of the Drug is Less than Copayments

There are two circumstances where the patient may pay more than the cost of the drug.

Drugs with high rebates mean that cost of the drug is actually much less than the list price. It is not uncommon to have rebates in the 80%-90% range. As a result a drug with a list ;price of $100 may cost only $10 or $20. However, if the cost sharing on that drug is 20% then the patient is either paying all of the cost of the drug if the cost is $20 or $10 more than the cost of the drug if the rebate about is 90%.

A second instance involves low-cost drugs. For some low-cost drugs, the cost to health plan is less than that of a flat copayment. As a result, their copayment is greater than the cost of the drug and they end up paying more than if they purchased the drug in cash.

Policy options include requiring plans to lower the copayments in these cases. One policy would require plans to reduce copayments to the cash price.. Another would limit the copay to the actual cost of the drug. Other policies just require cash payments paid by the patient for such drugs to count against deductibles and out-of-pocket maximums.

The Maryland PDAB will continue to monitor the data to determine the relationship between the cost of the drug and level of copay.

g) Deductible Stretching

Another potential policy is to require PBMs to allow for deductible stretching. Deductible stretching allows a patient to pay for the deductible over time instead of when they fill a prescription.
The impact of deductible stretching is not known. According to economic theory, patients making decisions based on marginal end-of-year prices should not be impacted by deductible stretching. However, deductible stretching may help patients with low income afford drugs.

As part of the Inflation Reduction Act, Medicare Part D plans will implement deductible stretching starting in 2025.

The Maryland PDAB will continue to monitor the data to determine the benefits of deductible stretching.

f. Real-Time Benefit Tools

Real-time benefit tools allow patients and their doctors to compare the out-of-pocket costs for different drugs before sending a prescription to pharmacies. Research has suggested that real-time benefit tools reduce medication abandonment.[211] However, the study did not assess the impact on drug selection.

g. Importation

Drug importation is the practice of outsourcing prescription drugs/medications manufactured overseas with the intent to sell to another country. Prescription drug prices in the United States average 2.56 times more than other countries;[212] Canadian drug prices have been noted to be cheaper than United States drug prices, ranging from 28% to 46%.[213] This suggests that the United States could potentially save money by importing drugs from other countries. Importation from Canada would provide savings because Canada regulates drug prices and therefore pays less than the U.S.

[211] https://www.amjmed.com/article/S0002-9343(22)00528-9/fulltext
[212] https://www.rand.org/news/press/2021/01/28.html
[213] https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/

Under current law, the United States can only import prescription drugs from Canada. Section 804 of the Food, Drug, and Cosmetic Act lays out the framework for importation of unapproved drugs for use in the United States.[214] The Secretary of Health and Human Services (HHS) has the authority to establish drug importation programs that allow imported drugs to enter into the United States with subsequent regulations and guidance. According to the legislation, the drug should cause no harm to the public's safety and should provide a significant reduction in drug costs to consumers. For states that want to implement an importation plan, there are two options: Plans must be either sponsored (1) by the states and tribal governments, or (2) by wholesalers and pharmacists while being cosponsored by a state or tribal government.

T Department of Health and Human Services has promulgated a final rule to implement Section 804.[215] The final rule will allow States and Indian Tribes the opportunity to submit importation program proposals to the FDA for review and authorization.[216] A key parameter is that the importation program may be cosponsored by a State, Indian Tribe, pharmacist, or wholesaler. Proposals must be submitted to the FDA for approval.[217] The purpose of the final rule is to "achieve a significant reduction in the cost of covered products to the American consumer while posing no additional risk to the public's health and safety."[218] The drug industry filed a lawsuit in 2021 that challenged the rule based on safety concerns.[219]

In August 2022, President Biden issued an executive order[220] calling for Congress to lower prescription drug prices. The executive order states that the federal government will work with the "Food and Drug Administration to work with states and tribes to safely import prescription drugs from Canada, pursuant to the Medicare Modernization Act of 2003."[221] They will attempt to accelerate "the development and uptake of generic and biosimilar drugs that give patients the same clinical benefit but at a fraction of the price."[222] Importation has received bipartisan support thus far, therefore charging states with implementing these policies is now necessary. [223]

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[214] https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim)
[215]https://crsreports.congress.gov/product/pdf/IF/IF11056#:~:text=Under%20current%20law%2C%20the%20importation,outside%20of%20the%20United%20States.
[216] www.hhs.gov/sites/default/files/importation-final-rule.pdf
[217] www.hhs.gov/sites/default/files/importation-final-rule.pdf
[218] https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs
[219] https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/
[220]https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/
[221]https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/
[222]https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/12/fact-sheet-president-biden-calls-on-congress-to-lower-prescription-drug-prices/
[223] https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/

To import drugs states must decide which drug to import, which importation partners to engage with (in the US and in Canada), and if the state should sponsor or simply co-sponsor (where a state-licensed wholesaler or pharmacist is the sponsor), how to regulate and monitor the importation partners, and determine the price charged for each product.

Examples of State Importation Programs

1. Florida

Florida has submitted a Section 804 importation program proposal, CS/HB 19: Prescription Drug Importation Programs and is currently waiting for approval from the FDA. The state is still waiting for importation approval and is now suing the FDA for allegedly delaying their approval on a Freedom of Information Act request that is linked to their pending drug importation program.[224] The lawsuit is under Case No. 8:22-cv-1981-TPB-JSS, to establish and administer the Canadian Prescription Drug Importation Program.[225] Governor DeSantis states this is an unreasonable delay of more that 630 days[226] and that the state submitted approval for their Canadian Prescription Drug program nearly 21 months ago and that the main issue is receiving approval from the federal government. The Governor has estimated that the importation program could save local taxpayers up to $150 millions dollars in a year.[227]

2. Colorado

Colorado passed Senate Bill 19-005 in 2019 to develop a Canadian prescription drug importation program which went into effect in November 2020.[228] An Invitation to Negotiate (ITN) was sent out in January 2021 to find potential vendors for the program.[229] When the application closed, the Department embarked on negotiations with supply chain partners and the identification of program consultants and certifiers to ensure compliance with program requirements. The Department announced all program partners in August 2022 and on December 5, 2022, they announced the submission of a Section 804 Importation Program (SIP) application to the federal Food and Drug Administration (FDA) for federal review and approval.[230] Once submitted, FDA has

[224]https://www.fiercepharma.com/pharma/florida-tees-legal-showdown-fda-over-stalled-information-act-request-canada-drug-import-plan
[225] https://www.flgov.com/wp-content/uploads/2022/08/FILE_3187.pdf
[226]https://www.flgov.com/2022/08/31/governor-ron-desantis-announces-lawsuit-against-biden-administrations-reckless-delay-of-canadian-prescription-drug-importation-program/
[227]https://www.fiercepharma.com/pharma/florida-tees-legal-showdown-fda-over-stalled-information-act-request-canada-drug-import-plan
[228] https://hcpf.colorado.gov/drug-importation
[229] https://hcpf.colorado.gov/drug-importation
[230] https://hcpf.colorado.gov/drug-importation

suggested a six-month SIP review timeline.[231] The Department estimates that the Colorado Importation Program will be operational by mid-2023, at the earliest.[232]

The manufacturers that have been approved by the FDA will have an opportunity to sell their eligible prescription drugs to AdiraMedica, Colorado's Foreign Seller which is located in Canada.[233] Once imported into the United States, the eligible prescriptions will have to be sent to laboratories for tests to make sure they are properly approved by the FDA. After the eligible prescription drugs are relabeled and shipped back to Premier Pharmaceuticals, (which is located in the United States) and they will be distributed to Colorado pharmacies where they can be dispensed to Colorado patients.[234] Colorado has named 112 drugs that it wishes to import to help with cost savings in their state.[235] Colorado's Department of Health Care Policy and Financing estimates that their importation program could save Coloradans $53 million to $88 million annually on prescription drug spending.[236]

The Maryland PDAB will continue to evaluate the plans of other states and determine if importation could be a viable policy for reducing drug costs for Maryland residents.

h. Contracting Models

Under the current prescription drug payment policy have incentives to optimize volume . Alternative contracting approaches attempt to re-align incentives away from volume.

1. Outcome-Based Pricing

Outcome-based pricing is paying for outcomes rather than volume. Under outcome-based pricing, payors would pay manufacturers a flat amount based on a clinical outcome. If a patient is not responsive to the drug, they would not receive payment or must refund prior payments related to outcomes.

The utility of outcome-based pricing depends on the knowledge base that exists for a particular drug. For drugs with well-established clinical information on their efficacy, outcome-based pricing may be helpful. However, in most cases the outcomes cannot be

[231] https://hcpf.colorado.gov/drug-importation
[232] https://hcpf.colorado.gov/drug-importation
[233] https://hcpf.colorado.gov/drug-importation
[234] https://hcpf.colorado.gov/drug-importation
[235] https://coloradosun.com/2022/12/06/colorado-import-prescription-drugs-canada/
[236] https://coloradosun.com/2022/12/06/colorado-import-prescription-drugs-canada/

well defined because so many different factors can influence the outcome or the drug has not been on the market long enough to measure long term benefits.

The Maryland PDAB will continue to evaluate the plans of other states and determine if outcome-based pricing will benefit Maryland residents.

2. Subscription Models

Under the subscription model, payors pay a flat amount each year regardless of use. The subscription model provides payors incentives to identify and treat every patient that has the disease.
As a result, there is no fixed or guaranteed price per unit sold . Instead, the effective price can vary based on how much is used; however, the total amount the state will pay is determined.
Manufacturers benefit from such models because they don't have to invest in things like advertising to drive volume and they no longer have the financial risk of performance. In exchange, they are trading off the extra revenues that would be associated with high volumes.
Subscription models are most useful in the context of infectious diseases. The subscription incentives diagnosing and treating patients earlier, limiting new infections.

One of the most highly discussed novel contacts was Louisiana's subscription model for Hepatitis C drugs. Under this model, Louisiana could purchase a certain amount of the drugs and pay the same cost regardless of the number of patients treated

The Maryland PDAB will continue to evaluate the plans of other states and determine if subscription model pricing will benefit Maryland residents.

3. Indication-Specific Pricing

Many drugs have multiple indications. They may treat different diseases, different severities of the same disease, or different subpopulations. Within these different uses, the drug may have different evidence of efficacy and effectiveness.
The current system typically has one price across all indications. However, the drug may have different values for different indications.

Indication-specific pricing allows manufacturers to charge different prices for different indications. The goal of such pricing is to incentivize evidence development across indications and ensure the drug gets a value-based price for each indication.
Without indication-specific pricing, drugs are often priced based on the most common or first indication. PBMs stake this into account in determine the rates they will pay.

In some cases, switching to indication-specific pricing will result in manufacturers being able to get charge higher prices for rarer but highly effective indications. On the other hand, indication-specific pricing will result in lower prices for indications with little evidence of effectiveness, such as off-label use.

From a societal standpoint, this may be beneficial because it encourages companies to develop evidence to support highly valuable uses and discourages companies from promoting unsupported and ineffective use. However, lower prices for these ineffective indications may encourage consumers to use the drugs more, since they are now cheaper.

The Maryland PDAB will continue to evaluate the plans of other states and determine if indication based pricing will benefit Maryland residents.

i. Biosimilar Substitutability

Compared to small molecule products, biological products are large and complex. As a result, generic versions of them were not approvable under current law. In 2010, Congress created a pathway for follow-on products called biosimilars. In addition, they created an interchangeability pathway that requires additional testing. Biologics make up an increasing percentage of drug costs. Humira, the highest grossing drug in the United States, is a biological product. A study said by 2025, the U.S will save $34 billion because of biosimilars (https://www.rand.org/pubs/external_publications/EP68829.html) . Getting even more cost savings from biosimilar competition is an approach to reduce drug prices.

The environment has changed since the biosimilar pathway was first developed. Studies from other countries show that there is little harm associated with switching from the originator biologic to a bioimsilar product (https://pubmed.ncbi.nlm.nih.gov/28502609/). A recent meta-analysis demonstrated that biosimilar-to-similar switching is also safe (https://link.springer.com/content/pdf/10.1007/s40259-022-00546-6.pdf).

In the United States, the control of the scope of practice for pharmacist's rest in the states. As a result, Maryland has the opportunity to decide how much authority pharmacists should have when switching non-interchangeable biologics. The following are key considerations for the legislature to consider:

Frequency and number of switches: Maryland can consider to what exact and how often a pharmacist can switch biosimilar products without interchangeability designations. This includes the time period between switches and the number of switches in a particular year. This requirement would involve the establishment of a mechanism to track patients in Maryland to ensure compliance.

Informed consent requirements: Maryland can decide the extent and when the pharmacist must inform the patient about the switch. Maryland can decide what is

included in such disclosure. This includes the possibility of different rules for new patients compared to existing patients.
Prescriber Disclosure: Maryland can decide the extent and when a prescriber is informed about a substitution. This includes the possibility of different rules for new patients compared to existing patients.
The role of PBMs: Maryland should consider whether PBM formulary placement should be considered when pharmacists make a substitution.

The Maryland PDAB will continue to evaluate the plans of other states and determine if biosimilar substitution will benefit Maryland residents.

SUMMARY AND RECOMMENDATIONS

Maryland will play an important role in making prescription drugs affordable. While many policies and issues must be addressed at the federal level, there are a number of policies that Maryland can implement..

The initial set of recommendations of this report focus on getting the information necessary to fully understand the different issues around prescription drug affordability, and maximizing market forces and resources within the existing prescription drug market to provide accessible, affordable drugs for residents of Maryland.

1) Draft the Upper Payment Limit Action Plan

The Maryland Prescription Drug Affordability Board has the authority to set upper payment limits for state and local government.[237] To do this, the Board is drafting a plan of action. The plan includes the criteria the Board will use to set an upper payment limit. This plan will outline what drugs may be subject to upper payment limits, the criteria that will be used to set the upper payment limit amount, and how the upper payment limit will be implemented for state and local governments.

The Board has already discussed that: (1) for drugs that it has determined have led or will lead to an affordability challenge as a result of the Cost Review process, they will affirmatively determine that an upper payment limit is the appropriate policy tool to improve access to, and the affordability of, the prescription drug; (2) the Board will want to consider a full range of data points and criteria when selecting the upper payment limit

[237] § 21-2C-14. Upper payment limits

for the prescription drug; and, (3) the upper payment limit for state and local government may be implemented through the existing rebate structure to maximize the likelihood of implementation and minimize unintended consequences associated with setting upper payment limits for a specific prescription drug market. The Board will receive advice from the Stakeholder council.

The Board will submit the upper payment limit action plan to the Legislative Policy Committee (LPC) for approval in early 2024.

The Board will draft a report, in consultation with the Stakeholder Council, on the legality, obstacles, and benefits of setting upper payment limits on all purchases and payor reimbursements of prescription drug products in the state. This report will include recommendations on whether the General Assembly should pass legislation to expand the authority to expand the authority of the Board to set upper payment limits to all purchases and payor reimbursements of prescription drug products in the State.

2) Study and Make Recommendations for a Prescription Drug Transparency Program

For all of the information that the state has on the prescription drug market, there are substantial gaps in available information that makes it impossible to answer some of the most basic questions about the Maryland prescription drug market or understand the affordability challenges facing Maryland patients.

The Board will work with state partners and stakeholders across the supply chain to understand what information is available and what information could be reported in a form and manner that provides the most value in understanding the supply chain and different affordability challenges, while minimizing reporting burden.

3) Insulin Affordability Program

Insulins have become an example of an essential drug that can be inaccessible and unaffordable leading to serious, and potentially deadly, consequences. A $35 copay cap that was implemented for Medicare beneficiaries and the $30 copay cap that was implemented for Maryland patients. Additionally, many insulin manufacturers have announced dramatic list price cuts effective January 1, 2024.[238] Finally, manufacturers

[238] https://www.novonordisk.com/news-and-media/latest-news/lowering-us-list-prices-of-several-products-.html

provide generous patient-assistance programs for uninsured or underinsured patients to access affordable insulin.

The Board evaluate if there is need for a program to help Marylanders access affordable insulin. If a need exists, the Board, in partnership with manufacturers may develop a program to help Marylanders access affordable insulins. The program infrastructure will be developed to expand this service into other drug classes, potentially resulting in a full patient navigator program to help patients access affordable prescription drugs