Maryland Prescription Drug Affordability Board: Supply Chain Report

May 23, 2022

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

§ 21-2C-07. Study of aspects of pharmaceutical distribution and payment

The Board, in consultation with the Stakeholder Council, shall:

(1) Study:

(i) The entire pharmaceutical distribution and payment system in the State; and

(ii) Policy options being used in other states and countries to lower the list price of pharmaceuticals, including:

1. Setting upper payment limits;
2. Using a reverse auction marketplace; and
3. Implementing a bulk purchasing process; and

§ 21-2C-07. (Continued)

(2) Report its findings and recommendations, including findings for each option studied under item (1)(ii) of this section and any legislation required to implement the recommendations, to the Senate Finance Committee and the House Health and Government Operations Committee in accordance with § 2-1257 of the State Government Article.

Study of aspects of pharmaceutical distribution and payment: Overview

Overview of Supply Chain and Issues of Prescription Drug Affordability

1. Introduction
2. Drug Spending and Trends: Nationally and Maryland
3. Pharmaceutical Supply Chain
4. Pharmaceutical Market

Overview- National Spending

National Prescription Drug Spending $574 billion in net payer spending[1]

- $420 billion on retail spending
- $154 billion on physician administered drug spending

1. IQVIA The Use of Medicines in the U.S. 2022

Overview- Maryland Spending

Maryland Prescription Drug Spend

- MCDB Gross Spend approximately $2 billion in 2018[1]
  - MCDB represents approximately 55% of fully insured Marylanders
- Maryland State Employees approximately $390 million in 2020[2]

1. MHCC Spending and Use Among Maryland's Privately Insured Annual Report, 2019
2. Maryland DBM. Quarterly Prescription Drug Performance

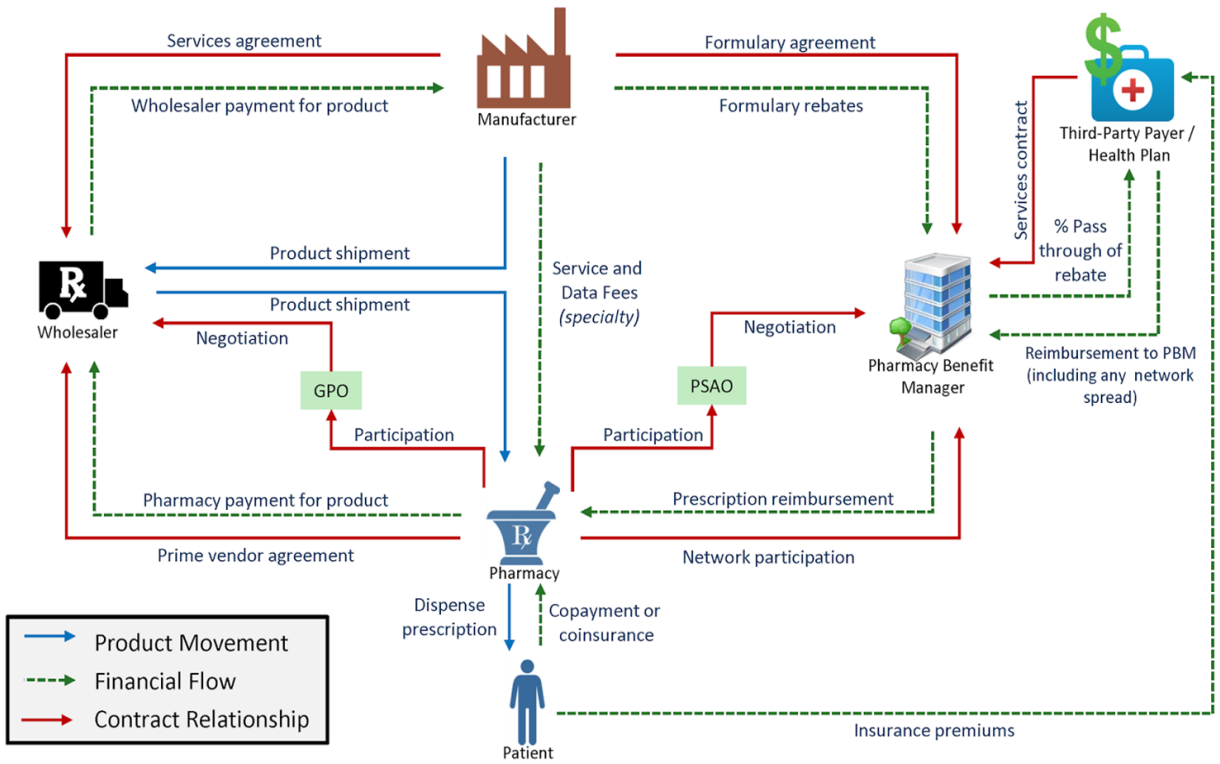
Overview- National Trends

- Spending on medicines rose sharply in 2021, up 12% to $407 billion due to availability (increases largely due to COVID vaccines; 5% increase for the overall market)
- Differences between list price (WAC) spending and payer net spending reached $190 billion in 2021 as negotiated discounts and rebates to payers and providers
  - Up from $118 billion in 2016
- Patient out-of-pocket costs rose to a total of $79 billion in 2021
  - Up from $74 billion in 2020

1. IQVIA The Use of Medicines in the U.S. 2022

Pharmaceutical Supply Chain-Distribution

U.S. Distribution and Reimbursement System: Patient-Administered, Outpatient Drugs



Source: Fein, Adam J., *The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, 2017. Chart illustrates flows for **Patient-Administered, Outpatient Drugs**. Please note that this chart is illustrative. It not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
GPO = Group Purchasing Organization; PSAO = Pharmacy Services Administrative Organization

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Pharmaceutical Supply Chain- Distribution

- Active Pharmaceutical Ingredient Manufacturer (API)
- Manufacturer
- Wholesaler
- Pharmacy
- Hospital
- Patient

Pharmaceutical Supply Chain-Reimbursement

- Insurer
- Pharmacy Benefit Manager
- Pharmacy services administrative organizations (PSAOs)
- Group Purchasing Organizations (GPOs)
- Medical claims clearinghouses

Pharmaceutical Market

- Prescription drugs is one of the most highly regulated industries in the world
- Drugs receive a government granted monopoly to recoup investment
- Drugs require a prescription (i.e., patients generally don't select the product)
- Drugs are extremely expensive to bring to market
  - Estimates range from $314M to $2.8B
- Complex and opaque market that makes it easy to shift costs between stakeholders and difficult identify the source and drivers of costs

Pharmaceutical Market- Drivers of Affordability Issues

- Competitive market forces often do not drive prices down
  - No publicly available, market clearing prices
  - “Customer” does not often does not pay for the drug
  - “Customer” does not choose the drug
  - Inelastic demand

Pharmaceutical Market- Impact on Drug Affordability

- High launch prices
- Increase of list prices with unclear trends in net prices
- High out-of-pocket costs for patients
  - Coinsurance and cash prices based on the list price
- Important area of the health care spend that is causing affordability issues for Marylanders

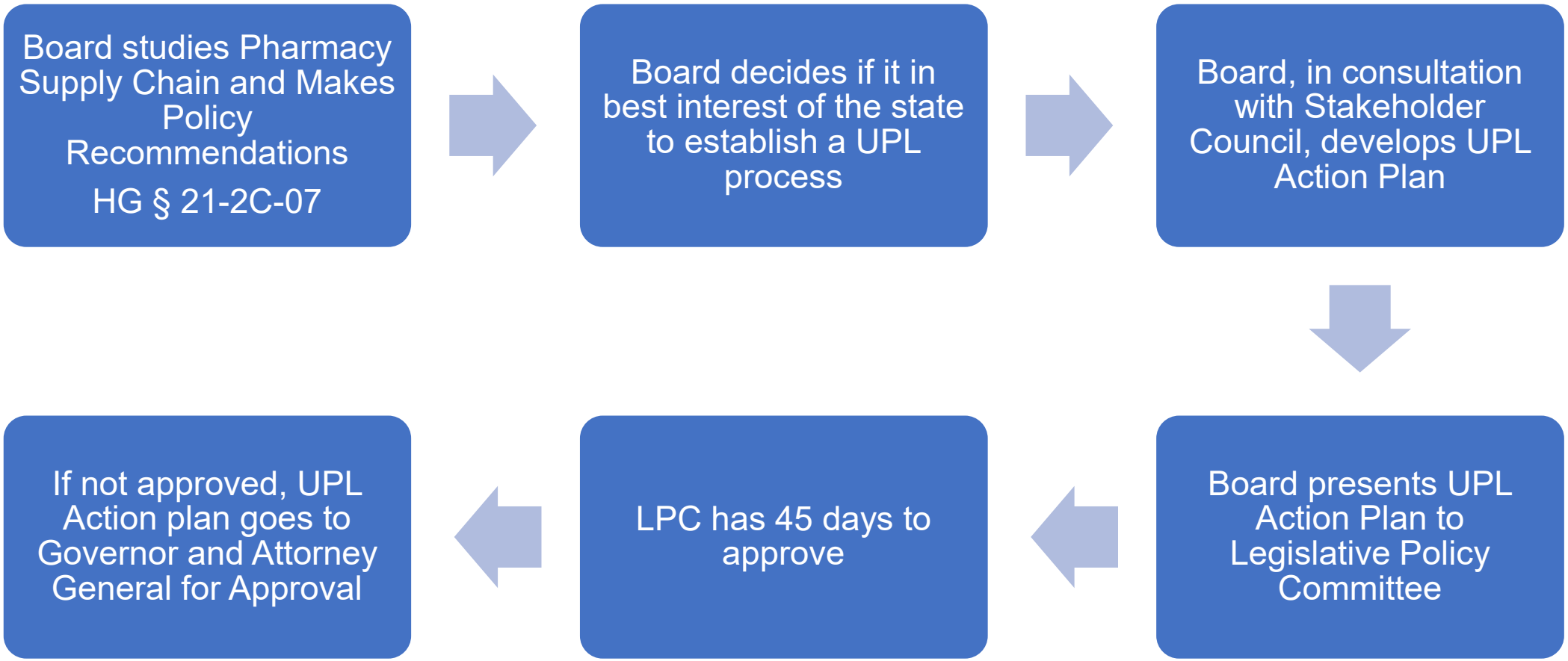
Policy Options

- Upper Payment Limits
- Reverse Auctions
- Bulk Purchasing
- Transparency Program
- Insulin Affordability Program

Upper Payment Limit: Background

- The General Assembly tasked the Board with studying and recommending policy options to address high costs. Health-Gen. § 21-2C-07.
- If the Board determines it is in the best interest of the State to establish a process for setting upper payment limits for prescription drug products that have lead or will lead to affordability challenges, the Board, in conjunction with the Stakeholder Council, shall draft a plan of action for implementing the process.
- That Action Plan is then submitted to the General Assembly for approval.

Upper Payment Limit: Process to Develop UPL Action Plan



Upper Payment Limit: Background

What is an Upper Payment Limit?

- Maryland Code does not define "upper payment limit"
- For our purposes, UPL means the maximum amount paid or reimbursed for a prescription drug product

UPL: Implementation Scope Health-Gen. § 21-2c-14

In compliance with any approved UPL Action Plan, the Board is authorized to set UPLs for prescription drug products:

1. Purchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government;
2. Paid for through a health benefit plan on behalf of a unit of State or local government, including a county, bicounty, or municipal employee health benefit plan; or,
3. Purchased for or paid for by the Maryland State Medical Assistance Program.

Upper Payment Limit: Benefits

- Cost savings for state and local government and taxpayers
- Reduced out-of-pocket costs for state and local government employees
- Lower premiums for state and local government employees
- Increase access to care for state and local employees
- UPL process is transparent which promotes participation from patients and community

Upper Payment Limit: Risks

- May have unintended consequences:
  - Adversely impact access
    - Market access
    - Shortages
- May not achieve anticipated savings

Bulk Purchasing: Background

- Bulk purchasing is a tool that uses volume and purchasing power as leverage to negotiate for better prices
- Relevant for:
  - Reimbursement for drugs
  - Cooperative purchasing for health insurance

Bulk Purchasing: Background

- Currently, five operational multi-state bulk purchasing pools negotiate deeper discounts on behalf of state and local agencies: NMPI, TOP$, SSDC, MMCAP, & NPDC
- Maryland has studied this issue recently, and is currently a participant in TOP$

Bulk Purchasing: Background

Cooperative purchasing for health insurance:

- In 2018, Maryland convened the Task Force to Study Cooperative Purchasing for Health Insurance was formed by the General Assembly
- Goal: “pool public employee health care purchasing by the State, counties, municipal corporations, and county boards to maximize value while maintaining a broad package of benefits and reasonable premiums
- Recommendations:
  - Continue to study the issue to work through the technical challenges associated with implementation

Reverse Auction: Background

- Reverse Auctions are a contracting tool to promote competitive contracting of pharmaceutical benefit management (PBM) services
- In 2020, Maryland passed HB1150-Maryland Competitive Pharmacy Benefits Manager Marketplace Act to promote using a reverse auction process to select the PBM for Maryland employee benefits
- Maryland currently in the process of trying to administer the reverse auction

Transparency Program: Background

- Key problem in the pharmaceutical supply chain is that there are no meaningful publicly available, mutually agreed to, market clearing prices
  - Allows for market arbitrage for stakeholders with more information
  - Prevents policy makers from identifying the causes of affordability issues
- Growing issue—difference between list price (WAC) spending and payer net spending reached $190 billion in 2021 compared to $118 in 2016

Transparency Program: Background

Federal Policies

- CMS Transparency in Coverage Rule

State Policies

- Over 17 States have Developed Transparency Programs
  - Oregon The Prescription Drug Price Transparency Act (ORS 646A.689)
  - Colorado HB19-1131 Prescription Drug Cost Education and

Transparency: Background

Maryland All Payers Claims Database (APCD) (aka MCDB)

- Privately insured data (claims and membership) collected in the Medical Care Data Base (MCDB)
- Collected on a quarterly basis from life and health insurance carriers, health maintenance organizations (HMOs), third party administrators (TPAs), and pharmacy benefits managers (PBMs), licensed to do business in Maryland
- MCDB comprises 90 - 95% of the private fully-insured market and about 25 - 30% of the self-insured market
- Represents gross expenditures in claims data

Transparency: Background

- APCD does not capture rebate data or allow to approximate net prices
- Opportunity to collect additional data from stakeholders in the supply chain to identify drug affordability issues and promote policies to promote drug affordability

Transparency: Benefits

- Transparency efforts likely will not have a direct impact on drug affordability
  - Evidence is limited that transparency will produce the necessary market forces to reduce costs through market competition
- However, transparency data will provide essential data to the public and to policy makers to identify the drivers of affordability issues and inform potential policy solutions

Transparency: Risks

- Costs
- Reporting burden on stakeholders
- May not get the information that we need

Insulin Affordability Program: Background

Insulin affordability is a top priority at federal and state level:

- Essential, life saving drug
- Generally affordable for insured patients
- Likely one of the drug classes that has the largest gross to net differences
- Certain patient populations can have serious affordability challenges:
  - Uninsured
  - Patients with high deductible health plans
  - Patients that require a non-preferred insulin

Affordability Program: Background

Maryland passed HB1397: Insulin Cost Reduction Act

- Limits the monthly copay or coinsurance for insulin to no more than $30 for a 30 days supply
- Helps insured patients, but does not address uninsured patients

Affordability Program: Options

Opportunity to implement a program to support the uninsured:

1. Funded benefit
2. Partnership with manufacturers
   e.g., Minnesota Insulin Safety Net Program
3. Partnership with 340B entities
   e.g., University of Vermont Health Network Health Assistance Program

Affordability Program: Benefits

- Promotes access to insulin for patients in need
- Supplements the work that the state has already done to promote insulin affordability

Affordability Program: Risk

- Limited patient population/impact
- Voluntary partnerships without legislation

For Consideration and Vote: Board Policy Recommendations for Report

- Determine Best Interest of State to Establish Process for Setting UPL
- Develop UPL Action Plan
  - Health-Gen. § 21-2C-13 and § 21-2C-13
- Develop Transparency Program
- Develop Insulin Affordability Program