Maryland Prescription Drug Affordability Stakeholder Council: Supply Chain Report

June 27, 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

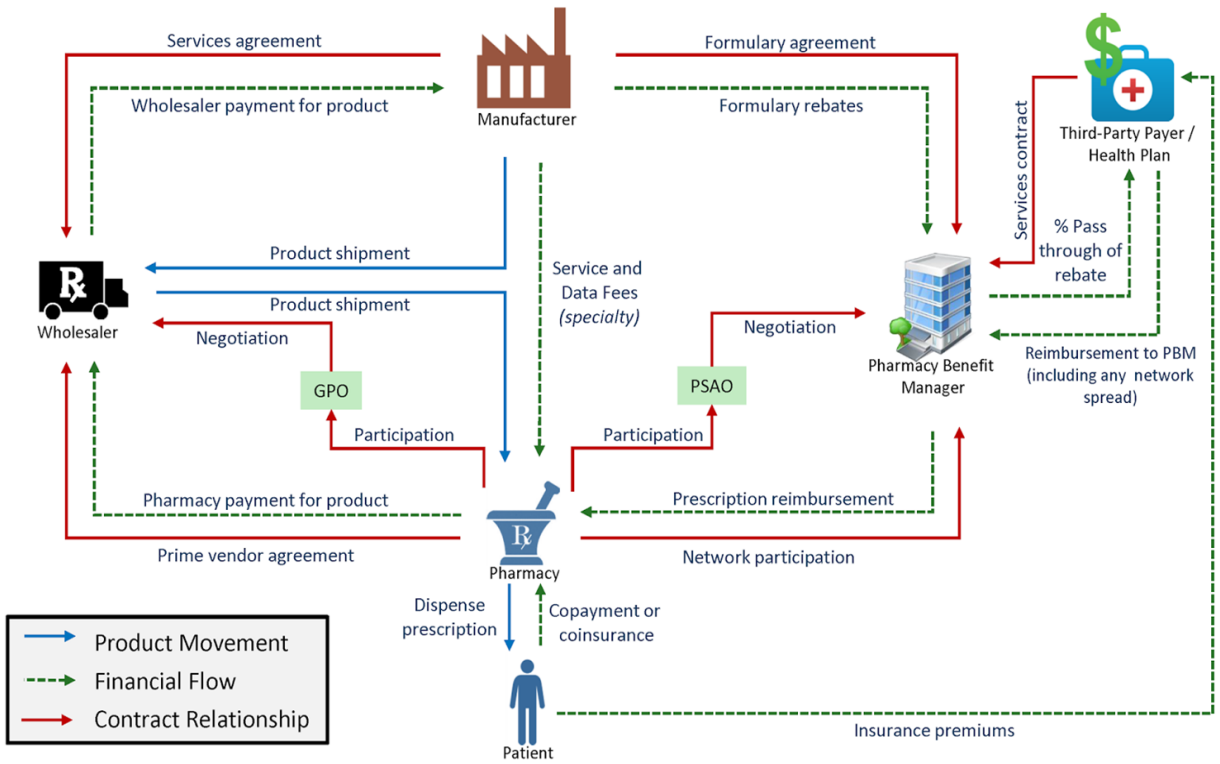
Overview - National Trends

- 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

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

DRUG CHANNELS INSTITUTE

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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 industry 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" often does not pay the full price of 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 Review

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

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 is currently in the process of trying to administer the reverse auction

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$ and MMCAP

Bulk Purchasing: Background

Cooperative purchasing for health insurance:

- In 2018, Maryland convened the Task Force to Study Cooperative Purchasing for Health Insurance
- 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

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
- No Surprises Act

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

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

Federal Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act

- $35 monthly copay cap for insured

Both help insured patients, but do 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

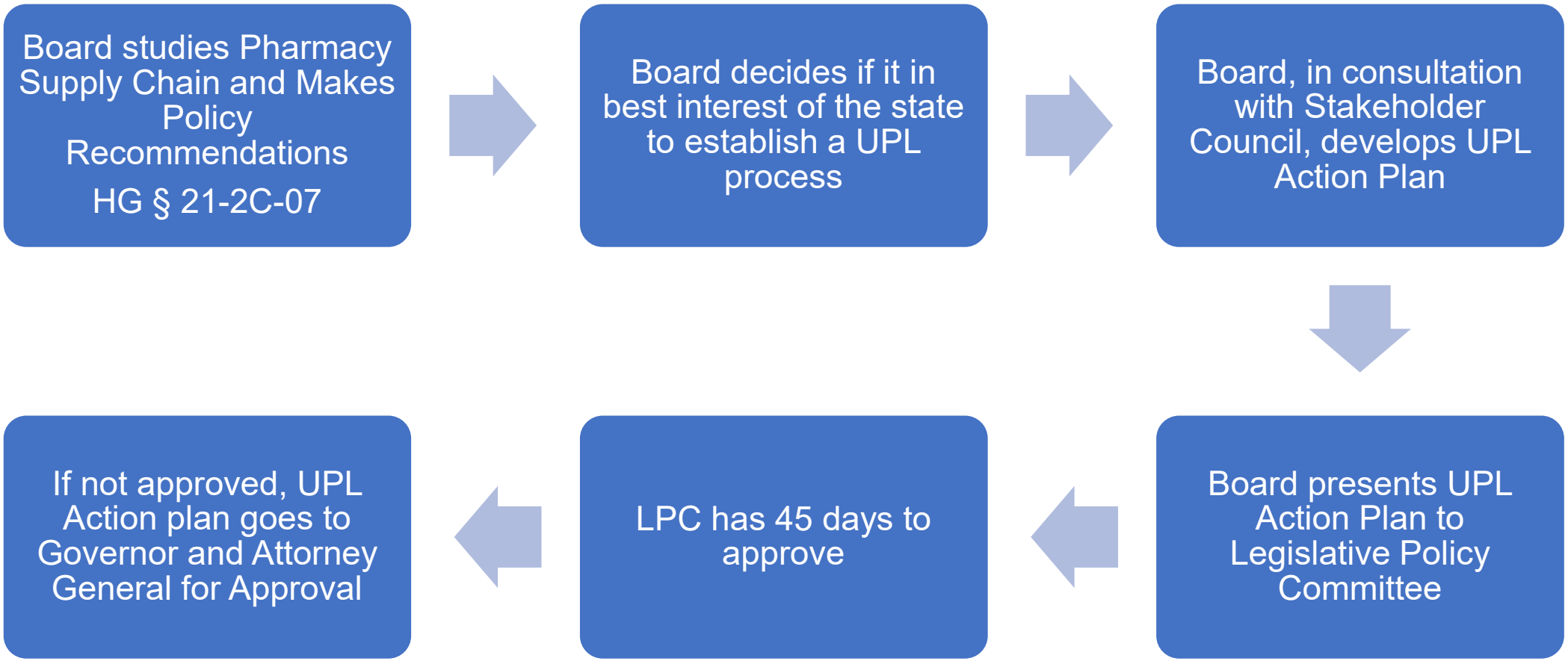
Affordability Program: Risks

- Limited patient population/impact
- Voluntary partnerships without legislation

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 led 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



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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

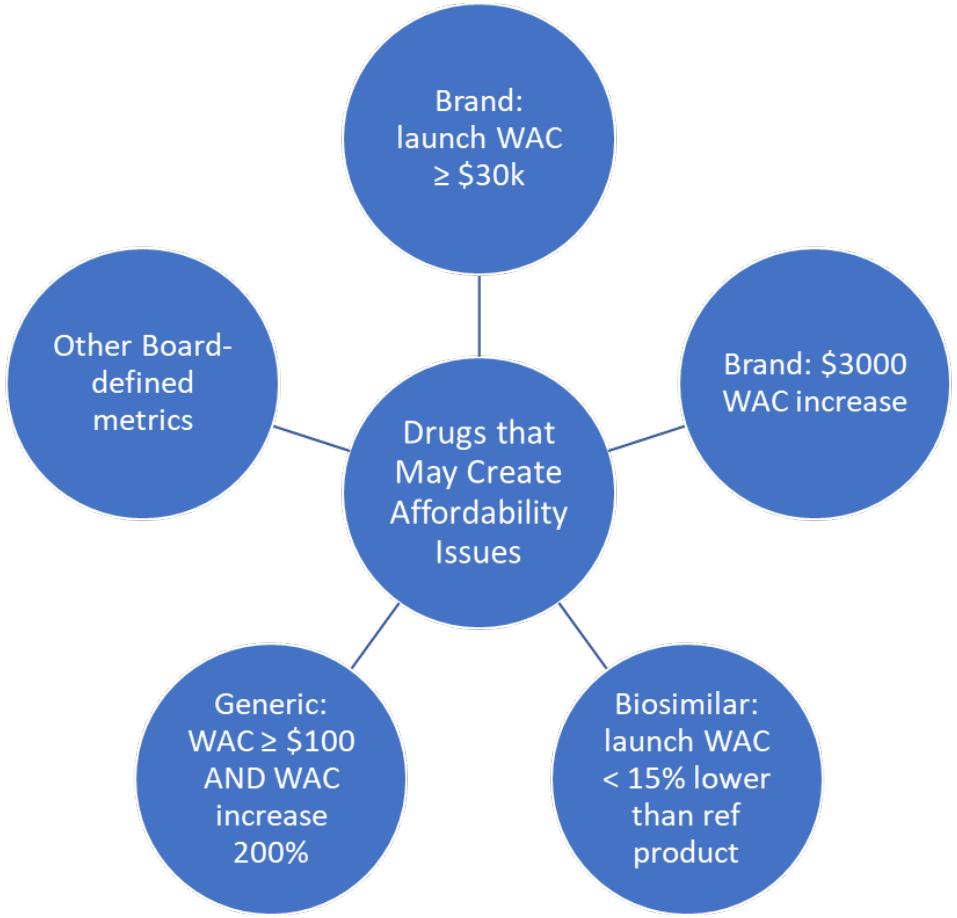
Upper Payment Limit: Risks

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

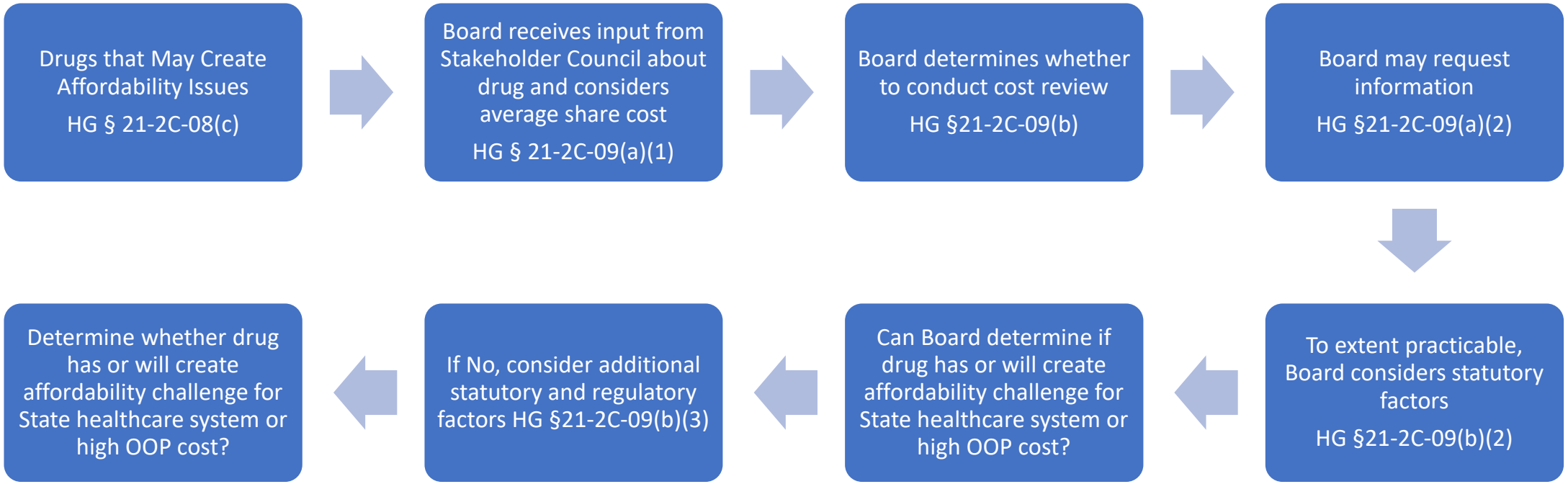
Questions

- How does the Board determine whether a drug has or will create affordability issues?
- How does the UPL process relate to the cost review process?

Initial Statutory Screen for Drugs Creating Affordability Challenges under HG § 21-2C-08



Overview of Statutory Cost Review Process Under HG § 21-2C-09



In-depth Cost Review

Drugs that May Create Affordability Issues

HG § 21-2C-08(c)

- Pool obtained from statutory metrics and any Board metrics

Should Board conduct cost review? HG § 21-2C-09(a)(1)

- Receives input from Stakeholder Council about drug and considers average share cost

If yes, Board may obtain additional information and considers statutory factors

- 10 statutory factors and any factors adopted by Board in regulation

Board may request additional information to conduct a cost review (HG § 21-2C-09(a)(2))

- The Board may request information from:
  - The manufacturer of the prescription drug product; and
  - As appropriate, a wholesale distributor, pharmacy benefits manager, health insurance carrier, health maintenance organization, or managed care organization with relevant information on setting the cost of the prescription drug product in the State.
- The information to conduct a cost review may include:
  - any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including life cycle management, net average price in the State, market competition and context, projected revenue, and the estimated value or cost-effectiveness of the prescription drug product.

To the extent practicable, the Board shall consider the following factors under HG § 21-2C-09(b)(2):

- Wholesale acquisition cost (WAC) . . . ;
- The average monetary price concession, discount, or rebate the manufacturer provides to health plans in the State. . .expressed as a percent of the WAC for the prescription drug product under review;
- The total amount of the price concession, discount, or rebate the manufacturer provides to each pharmacy benefits manager operating in the State for the prescription drug product under review. . . expressed as a percent of the WAC;
- The price at which therapeutic alternatives have been sold in the State;
- The average monetary concession, discount, or rebate the manufacturer provides. . .to health plan payors and pharmacy benefits managers in the State for therapeutic alternatives;
- The costs to health plans based on patient access consistent with US FDA labeled indications;
- The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;
- The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer;
- The relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;
- The average patient copay or other cost-sharing for the prescription drug product in the State; and
- Any other factors as determined by the Board in regulation.

In-Depth Cost Review Continued. . .

Can Board determine if drug has or will create affordability challenges

- Affordability challenge for State healthcare system or high out-of-pocket costs? HG 21-2C-09(b)(1)

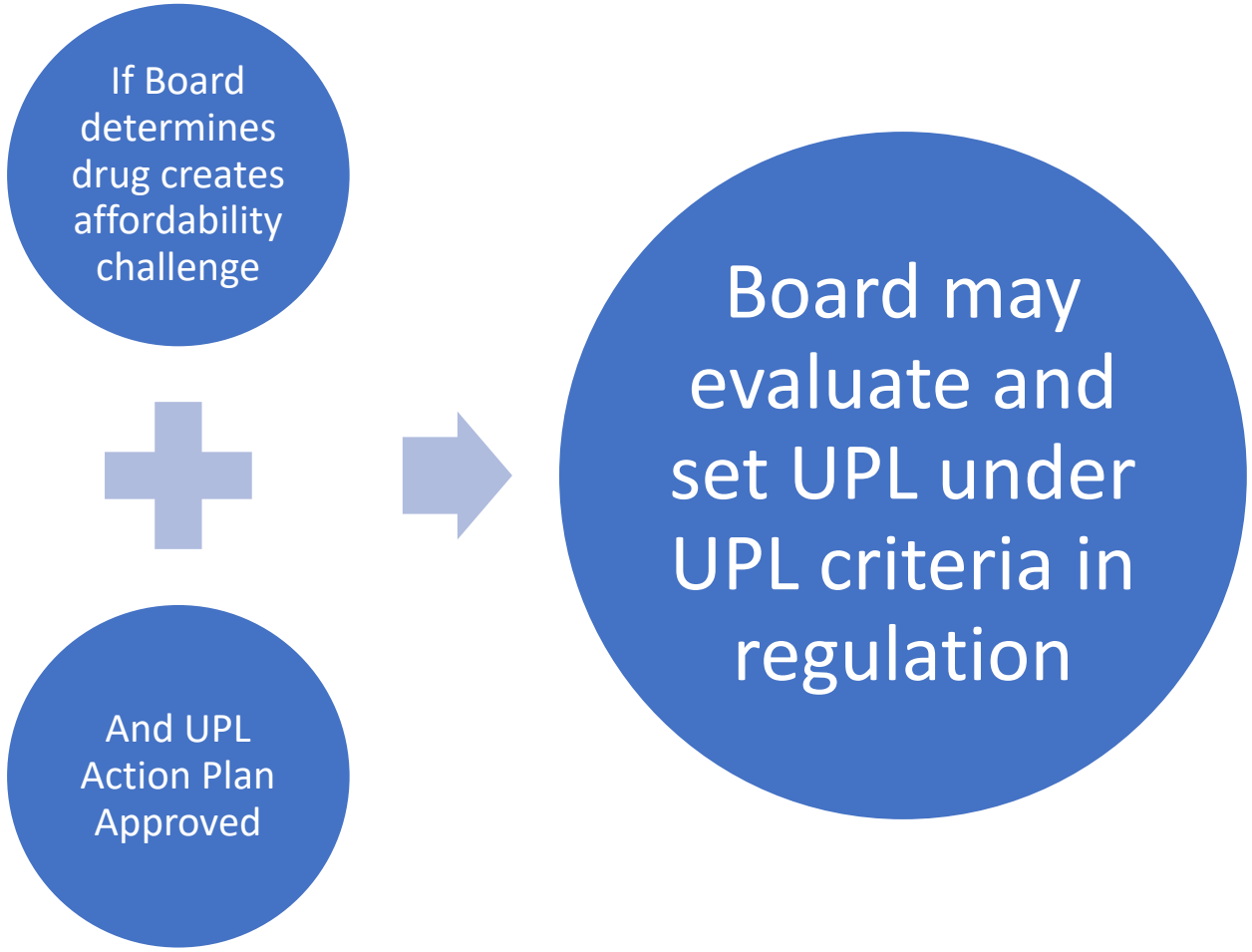
If No, may consider additional factors per HG §21-2C-09(b)(3)

- Three statutory factors and any additional factors in regulation

Can Board determine if drug has or will create affordability challenges

- Affordability challenge for State healthcare system or high out-of-pocket costs? HG 21-2C-09(b)(1)

Through the parallel cost review process and UPL Action Plan development:



Public Comment: Overview

- Received Comments from 5 Commenters so far
- All 5 represented views on the Stakeholder Council
- Comments topics include:
  - Overall Comments
  - Transparency
  - Insulin Affordability Program
  - Upper Payment Limits

Public Comments: Overall Comments

- Continue to do more stratified research
  - E.g., Spending on drugs with no generics available; spending on drugs with large promotional support spending; % of prescriptions of heavily promoted drugs vs older, less promoted options; and drivers of the increases in OOP spending
- Make sure to consider all policies that are available that can make drugs affordable for Marylanders
- Ensure that the report considers the role of all stakeholders, such as pharmacy benefit managers, in driving affordability issues
- Data collected and trade secrets collected as part of the Board's work must remain confidential

Public Comments: Transparency

- Transparency throughout the supply chain is necessary.
  - Many of the rebates do not make their way to helping patient at the pharmacy counter
- Horizontal and vertical integration in the payer/PBM side of the market may be harming patients and driving up list prices

Public Comments: Insulin Affordability Program

- Make sure to outline the details of the Maryland Insulin Cost Reduction Act
  - What patients are protected? Are any patients not protected?

- Make Sure to Consider Other Policies:
  - Drug benefit for essential drugs, such as insulin, should receive coverage before the deductible
  - Patient assistance programs should count toward patients' deductibles
  - Rebates and savings to payers/PBMs should be passed on to the patient
  - Public/non-profit insulin manufacturers

Public Comments: Upper Payment Limits

Additional Risks/Unintended Consequences:

- Risk of driving up prices as the parties in the supply chain raise prices to reach the UPL
- Manufacturers may try to increase prices in other states for entities that negotiate multi-state contracts for prescription drugs
- Capping prices within the drug supply chain could result in stifled innovation, fewer jobs, and the lack of availability of life-saving therapies for patients in Maryland; limit medications that a patient can access
  - Example: A pharmacy or dispensing provider may not be able to stock the drug because it cannot meet the UPL and/or cannot incorporate a dispensing fee into the transaction for the medicine

Legal Issues:

- Upper payment limits on patented medicines raise constitutional concerns under the Supremacy Clause because they would restrict the goal of federal patent law

For Consideration:
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-14
- Develop Transparency Program
- Develop Insulin Affordability Program