

Maryland Prescription Drug Affordability Board: Orientation

Prescription Drug Affordability Stakeholder Council
Member Orientation

February 23, 2022

PDAB Staff



MARYLAND
Prescription Drug Affordability Board

Introduction and Opening Remarks

MD PDAB: Overview

House Bill 768 / Senate Bill 759

- During the 2019 Session, the General Assembly introduced and enacted HB768/SB759, “Health - Prescription Drug Affordability Board”
- The Maryland Prescription Drug Affordability Board came into effect in July 2019, as an independent agency
- Its purpose is to protect 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 drug products



PDAB Overview

- Membership: Five members appointed by the Governor, Senate President, Speaker, and Attorney General, and three alternate members appointed by the Governor, Senate President, and the Speaker
- Term: Five years (Sitting & Alternate)
- Board members must possess expertise in health care economics and/or clinical medicine

PDAB Overview

Current Roster:

- **Van Mitchell, Chair** (Appointed by the Senate President and Speaker)
- **Joe Levy, PhD** (Appointed by the Governor)
- **Renee Bovellet, MD** (Appointed by the Senate President)
- **Ebere Onukwugha, PhD** (Appointed by the Speaker of the House of Delegates)
- **Jerry Anderson, PhD** (Appointed by the Attorney General)



PDAB Overview

Board Meetings:

- The Board regularly meets every other month on the fourth Monday, but it can schedule additional meetings as necessary to advance the Board's work
- Presentations from a variety of stakeholders in the pharmaceutical market and supply chain, including peer states, trade associations, and consumer/patient support groups
- All of the Board's meetings, including presentation materials, agendas, and minutes can be found on the Board Meetings page at pdab.maryland.gov



Board Authority and Required Reports

Under its enabling statute, the Board is authorized to:

- Assess an annual fee to fund the work of the Board;
- One-time study and report on:
 - the entire pharmaceutical distribution and payment system in MD;
 - policy options used in other states to lower Rx costs, including upper payment limits, reverse auction marketplace, and bulk purchasing;
- Collect and review data on drug utilization and pricing data, from public sources or directly from stakeholders;



Board Authority and Required Reports (cont'd)

- Provide annual report to the General Assembly on price trends and legislation;
- Identify drug products that meet certain statutorily-defined pricing thresholds;
- Identify circumstances where a cost review of a prescription drug product is warranted; and
- Determine whether it is in the best interest of the State to establish a process for setting upper payment limits for drug products that create affordability challenges, and, if so, an action plan to implement it.

Many of these tasks are to be performed in consultation with the Stakeholder Council.

Reporting Timelines

- Two reports are due by June 30, 2022
 - Study of pharmaceutical distribution and payment system; and
 - Identification and cost review of drugs (if any) that cause affordability issues.
- One report is due on June 1, 2022
 - Study of the operation of the generic drug market in the United States that includes a review of physician–administered drugs
- Annual report (price trends/cost reviews/recommendations) due on Dec. 31 each year
- Determine whether to implement upper payment limits, and (if adopted) an action plan for implementation



Pharmaceutical Distribution and Payment System & Affordability Reports

- In consultation with the Stakeholder Council:
 - Study the entire pharmaceutical distribution and payment system in the State; and
 - Identify policy options being used in other states and countries to lower the list price of pharmaceuticals, including:
 - Setting upper payment limits;
 - Using a reverse auction marketplace; and
 - Implementing a bulk purchasing process; and
- Report findings and recommendations to Senate Finance and House Health & Government Operations Committees.



Upper Payment Limits

- If the Board determines that it is in the best interest of the State to establish upper payment limits (UPL), then in conjunction with the Stakeholder Council, it shall draft an action plan to implement UPLs
- On or before December 1, 2023, the Board, in consultation with the Stakeholder Council, shall report to SFC and HGO the legality, obstacles, and benefits of UPLs on all purchases and reimbursements of prescription drug products in MD, and any recommendations on additional legislation.



Prescription Drug Affordability Stakeholder Council: Overview

Stakeholder Council Overview

- Membership: Twenty-six members appointed by the Governor, Senate President, and Speaker of the House
- Term: Three years (Staggered for initial terms)
- Meetings: TBD
- Leadership: The Chair will select two members of the Stakeholder Council to serve as co-Chairs
- Board staff works with the PDAB Chair and Stakeholder Council co-Chairs to create agendas, administer meetings, coordinate with presenters, etc.



Council Current Membership (1/3)

Name	Representation
Mandi Poplawski, Pharm.D.	Nonprofit Insurance Carriers
Glenn Schneider, MPH	Statewide Health Care Advocacy Coalition
Allison Ciborowski	Statewide Advocacy Organization for Seniors
Jacqueline Allsup	Statewide Organization for Diverse Communities
Shaun O'Brien	Labor Union
Sean Tunis, MD, MSc	Health Services Researcher Specializing in Prescription Drugs
Shawn Brown	Generic Drug Corporations
Thea Williams	Public Member



Council Current Membership (2/3)

Name	Representation
Deron Johnson	Brand Name Drug Corporations
Stephen Rockower, MD	Physicians
Lorraine Diana	Nurses
Nicole Stallings	Hospitals
Eric Morse, DDS	Dentists
-	Managed Care Organizations
Marc Nicole	Department of Budget and Management
Sherita Hill Golden, MD, MHS	Clinical Researchers
James Gutman	Public Member



Council Current Membership (3/3)

Name	Representation
-	Brand Name Drug Corporations
John Elliott	Generic Drug Corporations
Martin Rosendale	Biotechnology Companies
-	For-Profit Health Insurance Carriers
-	Employers
-	Pharmacy Benefit Managers
Babette Edgar, Pharm.D.	Pharmacies
-	Pharmacologists
Barry N. Lipsy	Public Member



Council Purpose

- Provide input that will assist the Board in making decisions to protect the State, its residents, and other stakeholders in the Maryland health care system
- Serves in an advisory role including
 - Consults with Board as Board prepares certain studies and reports, adopts certain regulations, recommends certain statutory changes, and, possibly, identifies drug products that may create affordability challenges
 - The Board may request that the Stakeholder Council to review and discuss certain issues or policies on an ad hoc basis



Advisory Body

Council is:

- statutorily-created public body that functions in an advisory capacity only;
- subject to the Open Meetings Act;
- its business requires a quorum; and
- its members are subject to the Public Ethics Laws.
 - Public Ethics Training to be held at a later date
 - Existing conflicts of interest are disclosed to the Appointing Authority on/as part of appointment



Requirements of the Council

The following topics are deferred to future meetings:

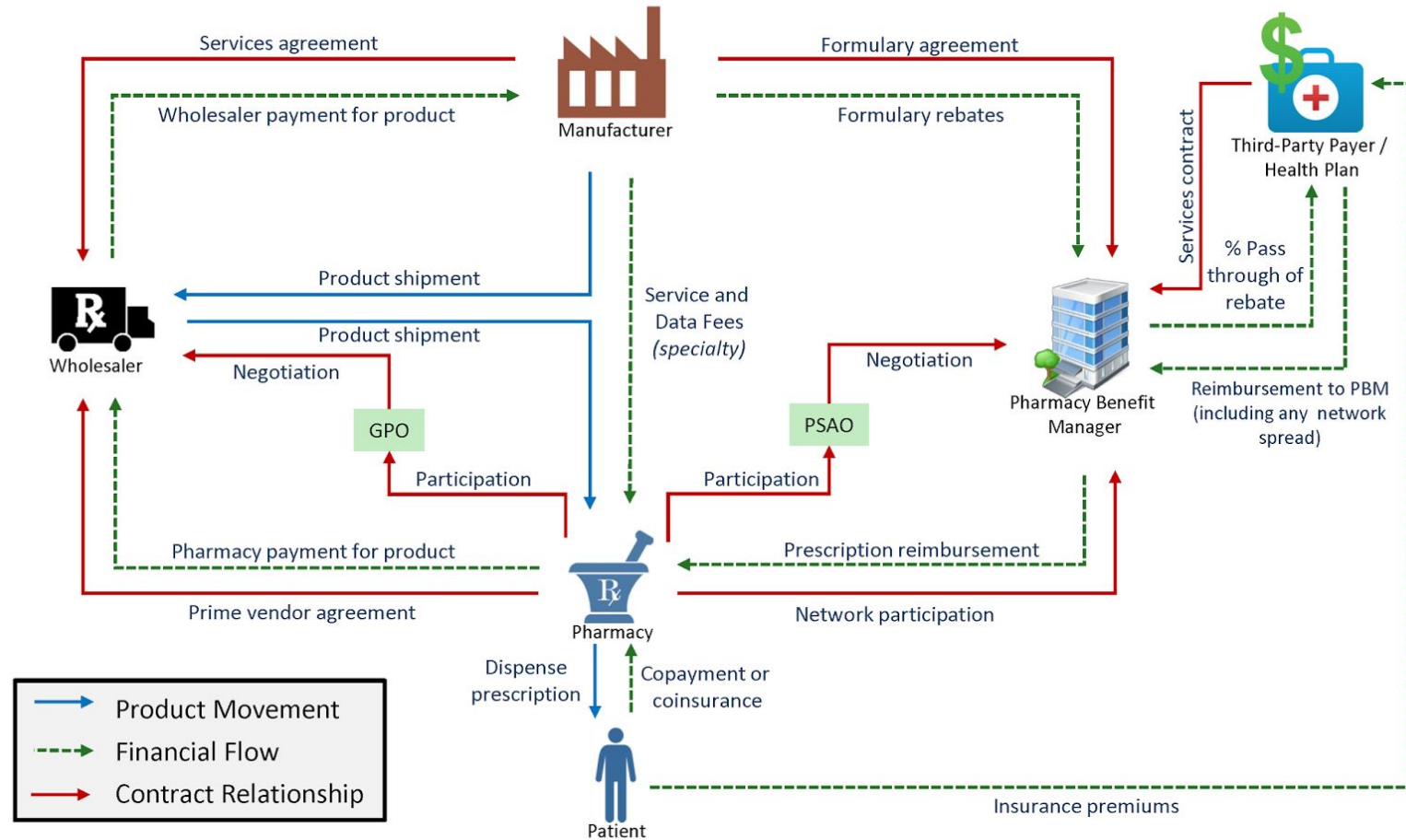
- Meeting policies (*i.e.*, frequency, attendance, in-person/virtual, timing, location, public participation);
- Council Orientation;
- Conflicts of Interest/State Ethics provisions;
- Review of Open Meetings Act; and
- Other Issues Identified by the Stakeholder Council



Issues in Drug Pricing & Policies Available to States to Promote Affordability

Overview of Supply Chain

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

Overview of Issues in Drug Pricing

- For the patient:
 - About of 1/2 of Americans regularly take prescription drugs
 - Of those Americans, 1/4 have trouble affording their drugs
 - Americans spend almost 2X as much as other countries on brand name drugs
- For the health system:
 - 14% of spending is on prescription drugs, and growing
 - Almost \$500 billion spent on prescription drugs in 2018
 - \$355 billion on retail drugs
 - \$165 billion on non-retail (physician administered)



Features in the Prescription Drug 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



Impact on Prescription 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 spending that is causing affordability issues for Marylanders



Options Available to States

State Options for Addressing Prescription Drug Affordability

National Academy for State Health Policy (NASHP) State Legislative Action Tracker

Drug Pricing Laws 2017-2020					
Year	2017	2018	2019	2020	Total
Number of States Enacting Laws	13	28	37	17	48
Total Laws Enacted	18	45	62	35*	160*
PBM	8	32	33	19	92
Transparency	3	4	7	4	18
Importation	0	1	3	2	6
Affordability Review**	1	0	3	1	5
Volume Purchasing	0	0	2	0	2
Coupons/Cost Sharing	1	0	4	9	14
Study	0	1	5	1	7
Other	5	7	5	0	17

*Totals laws enacted are lower than column totals because a New Hampshire law contains multiple provisions.

** Includes New York's Medicaid drug cap and Massachusetts' enhanced negotiating authority.

NASHP Legislative Tracker:
<https://www.nashp.org/rx-laws>

NASHP MD PDAB Presentation:
https://pdab.maryland.gov/documents/presentations/NASHP_Overview_of_State_Policies_03222021.pdf



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Federal vs State Action

Federal

Legislation

- H.R. 3
- Reconciliation package
 - Medicare Negotiation
 - Part D Reform (OOP price caps)
 - Inflation Penalties

Administrative Action

- Model tests (Part B, Part D, and TCOC)
- Data collection/transparency
- Continued biosimilar and generics approval

State

- Since 2017, legislation to address prescription drug costs has been **introduced** in all 50 states
- Since 2017, 48 states have **enacted** 160 laws to address prescription drug costs



Federal vs State Scope

Federal

- Medicare reform
- Drug approval and regulation
- Patent reform/market exclusivity
- Data reporting/transparency

State

- Medicaid reform (within federal parameters)
- Insurance and pharmacy benefit manager licensing and regulation (within federal parameters)
- Hospital and provider regulation
- State as employer/purchaser
- Data reporting/transparency



Options Available to Maryland

- Upper Payment Limits
- Reverse Auction Marketplace
- Implementing a Bulk Purchasing Process
- Price Transparency
- Novel Contracting
- PBM Reform
- Medicaid Reform
- Importation
- Out of Pocket Costs



Upper Payment Limits

- The Board has the authority to set upper payment limits for drugs that cause affordability issues for Marylanders
- May reduce prescription drug costs by setting an upper payment limit to promote access and affordability
- The Board must determine the process for setting and the mechanisms for implementing upper payment limits



Reverse Auction Marketplace

- Reduces costs for states by increasing competition among PBMs across objective, measurable designs to aid in negotiating high-value contracts, without sacrificing drug benefits
 - New Jersey was the first state to implement this model, resulting in projected savings of \$2.5 - \$3 billion from 2017-2022
- Maryland passed legislation authorizing a reverse auction marketplace in 2020



Bulk Purchasing

- Leverages market forces and increases purchasing/negotiating power by purchasing pharmaceuticals in bulk or joining a purchasing pool
 - 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\$



Drug Price Transparency

- Collect data to understand issues in prescription drug affordability and promote market competition to reduce prescription costs
 - A number of states and the federal government are promoting transparency in health care
- Build on existing Maryland infrastructure, such as the Medical Care Data Base



Out-of-Pocket Costs

- Limit the risk to patients by limiting the total out of pocket costs
 - Many states, including Maryland, developing policies limit out-of-pocket costs on essential drugs, such as copay caps on insulin
- Maryland can explore opportunities around copay caps, out-of-pocket maximums, and policies around copay coupons, maximizers, and accumulators



Novel Reimbursement Models

- Engage in novel contracting to transition away from volume-based reimbursement
 - States have engaged in payment arrangement such as the “Netflix Model” and there are opportunities to test value-based contracting
- Maryland can explore opportunities to promote novel contracting strategies to pay high-value drugs to promote innovation



PBM Reform

- Promote reform and regulation of the pharmaceutical benefit manager sector to promote market competition and drug affordability
 - States, including Maryland, have proposed policies to regulate and improve the PBM sector
- Maryland can explore opportunities to improve the PBM sector to promote market competition, prescription drug affordability, and address unintended consequences of existing practices



Medicaid Reform

- Medicaid is generally the largest state spend on prescription drugs
 - States have taken steps to try to control their Medicaid drug spend
- Maryland can explore opportunities to address state affordability issues related Medicaid prescription drug spend



Importation

- There is a mechanism to import prescription drugs to the United States
 - Federal guidelines were published in 2019, and Requests for Proposals to import drugs were published in 2020 (and rescinded in 2021)
- Maryland can explore importation as an option to promote access to affordable prescription drugs



Questions?



Next Steps

- Future Meeting Dates
 - Every other month- April, June, August, October, December
- Future Meeting Topics
 - Ethics
 - Drug Pricing 101
 - Topics/Policies

