Upper Payment Limit Action Plan

Legislative Policy Committee Hearing

October 22, 2024

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

PDAB Overview

- During the 2019 Session, the General Assembly enacted HB768/SB759 creating the Maryland Prescription Drug Affordability Board as an independent agency

- Structure:
  - 5 Member Board
  - 26 Member Stakeholder Council

- Purpose:
  - "…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- Board Members

Van Mitchell, Chair (Appointed by the Senate President and Speaker)

Joe Levy, PhD (Appointed by the Governor)

Stephen Rockower, MD, FAAOS (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)

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Prescription Drug Affordability Board

PDAB Overview

Priority Projects:

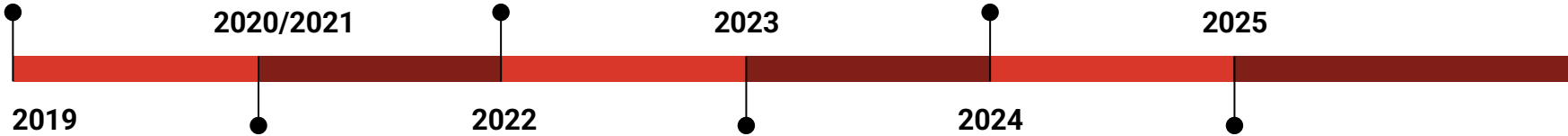
- **Cost Reviews**
  - **In-depth review of select drugs to determine if they cause affordability challenges**

- **Upper Payment Limits**
  - **Policy tool to address drugs that cause affordability challenges implemented through Upper Payment Limit Action Plan**

- **Recommend Additional Policies**
  - **Annual report that summarizes price trends and recommends policies**

MARYLAND
Prescription Drug Affordability Board

Timeline of Board Work



PDAB Created

- Board appointed in July 2019

PDAB Funding Legislation Passed
- Executive Director hired
- Implementation of Fee Assessment
- Adopted By Laws
- Began Research for PDAB Work

Initial work
- Supply Chain Report Research Began
- Generics Report
- Research for Cost Review Study Process

Cost Review Study Process
- Developed and Approved Regulations and Process for Cost Review Study Process
- Began Discussion on UPL Action Plan
- Fully Staffed

Cost Review Study Process/UPL Action Plan
- Board selected 6 drugs for the Cost Review Study Process
- Board Approved the UPL Action Plan
- Supply Chain Report Approved

Future
- Continue to work through the Cost Review Study Process
- Finalize UPL Regulations
- Explore other Prescription Drug Affordability Issues

Cost Review Study Process

COMAR 14.01.04

Identify

Select

Collect

Analyze

Results

MARYLAND
Prescription Drug Affordability Board

Cost Review Study Process Timeline

Identify → **Select**

PDAB Meeting	PDAB Meeting	Stakeholder Council Meeting	Interim	PDAB Meeting
Public Reporting of Drug Affordability Issues Board has opportunity to add prescription drug products for inclusion on the list of eligible drugs for cost review	Identifying prescription drug products to consider for cost review- this is a subset from eligibility list Refer prescription drug products to the Stakeholder Council for input	PDASC will review and discuss the referred prescription drug products at an open meeting	Public comment Listening sessions	Board selects prescription drug product(s) for cost review Next Steps: → Collect → Analyze → Results

Timeline

Drug(s) in Cost Review	Data Collection	Analyze	PDAB Preliminary Determination of Affordability	Cost Review Study Report
Drug(s) selected for Cost Review Study will be posted on the Board's Website. - 60 day written comment period begins with posting	PDAB may request information from, and post request: 1. Manufacturers 2. Carrier, HMO and MCO 3. Pharmacy Benefits Managers 4. Wholesale Distributor	Board Staff may assemble a dossier of data and analyses for consideration in cost review study as outlined in COMAR 14.01.04.05.	Board may determine whether the prescription drug has led or will lead to: - Affordability challenges to the State health care system or - High out of pocket costs for patients	Board creates and adopts a report of the cost review study that summarizes the information considered by the Board in conducting the cost review study, and the Board's determination.

Drugs Selected for Cost Review Study Process

- Farxiga (dapagliflozin)
- Jardiance (empagliflozin)
- Ozempic (semaglutide)
- Trulicity (dulaglutide)
- Dupixent (dupilumab)
- Skyrizi (risankizumab)

UPL Status

Previous Actions:

- Stakeholder Council reviewed UPL draft and provided feedback at 8/26/24 meeting
- Public comments were accepted on the UPL draft until 8/26/24
    - 22 Comment Letters Received, posted on the website and shared with the Board
- Comments were reviewed by staff and changes were made for Board meeting on 9/10/2024
- Board approved UPL Action Plan on 9/10/2024

Prior UPL work:

- Board meeting July 24, 2023
- PDASC meeting August 28, 2023
- Board meeting September 18, 2023
- PDASC meeting October 23, 2023
- Supply Chain Report January 29, 2024
- Board meeting July 22, 2024

Overview-
UPL Action Plan

- Board develops “plan of action for implementing the process that includes the criteria the Board shall use to set upper payment limits (“UPL Action Plan”)”

- Because setting a UPL is a quasi-legislative action, the procedures in this action plan provide for the setting of a UPL by adopting a regulation through the notice and comment rulemaking provisions of the Maryland Administrative Procedure Act

- The cost review study and the policy review process are part of this quasi-legislative process that enables the Board to acquire relevant data and information to inform the development and promulgation of public policy

Overview-
Policy Review Process and UPL Development

1. Optional Information Gathering
2. Staff Recommends Policy Options
    - Drivers of Affordability Challenges
    - Policy Options to Address Identified Drivers
        - Non-UPL Policy
        - UPL Policy
3. Final Actions

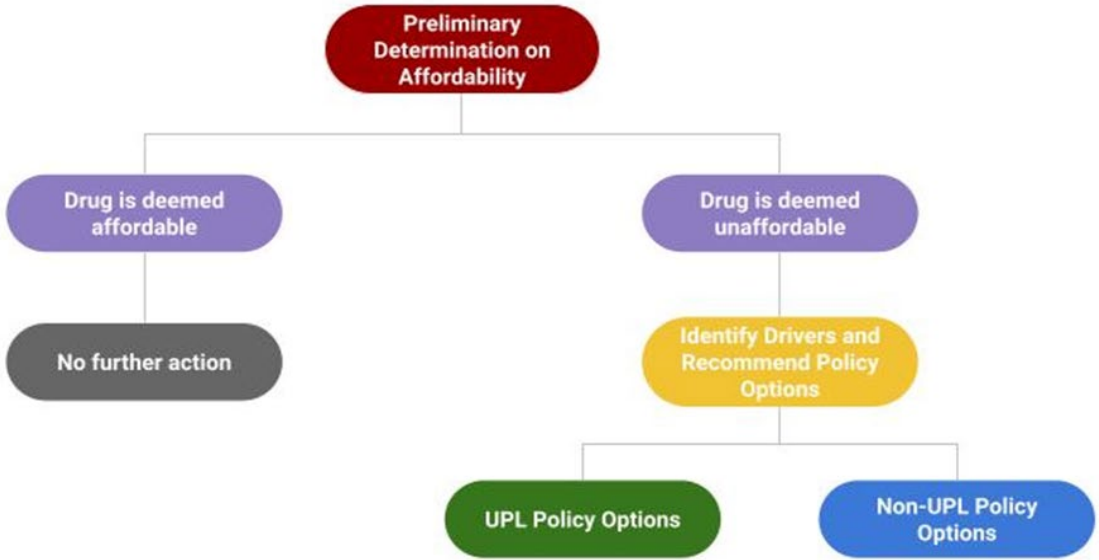
    Adopt Final Determination Concerning Affordability Challenge

    Adopt (a) other (non-UPL) policy recommendations; (b) proposed regulations setting the UPL at the specified amount; or (c) both.

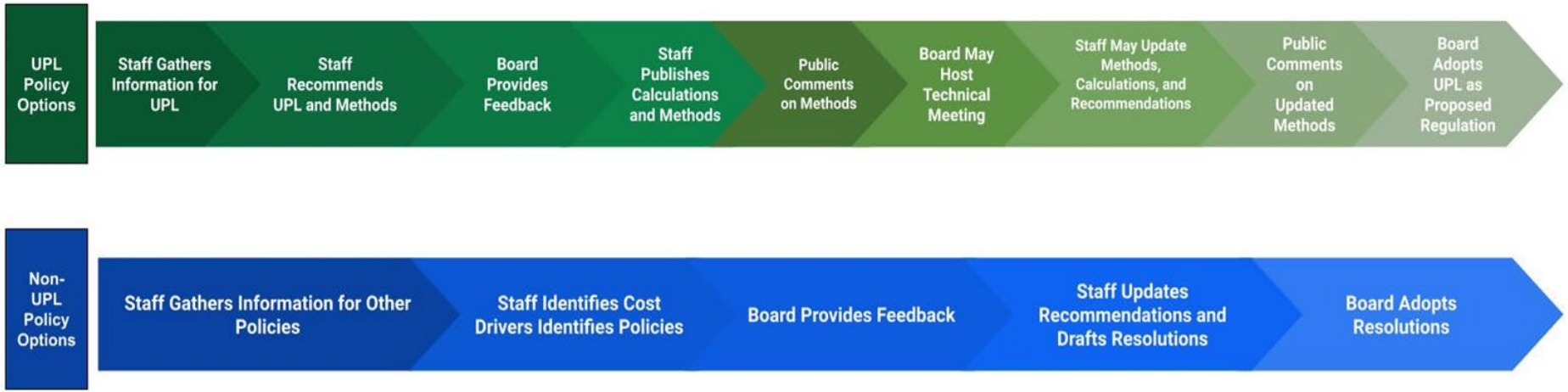
Cost and Policy Review Process

Drug(s) in Cost Review	Data Collection	Analyze	Preliminary Determination	Policy Review Process	Final Results
Drug(s) selected for Cost Review Study will be posted on the Board's Website. - 60 day written comment period begins with posting	PDAB may request information from, and post request: - Manufacturers - Carrier, HMO and MCO - Pharmacy Benefits Managers - Wholesale Distributor	Board Staff may assemble a dossier of data and analyses for consideration in cost review study as outlined in COMAR 14.01.04.05.	Board may preliminarily determine whether the prescription drug has led or will lead to: - Affordability challenges to the State health care system or - High out of pocket costs for patients	Board may perform the policy review process to identify and recommend policies to address affordability challenges: - Process for setting upper payment limits - Process for all other policies that are not upper payment limits	Board takes final action: - Board Finalizes Determination and Adopts Final Cost Review Study Report - Board Adopts Policy Recommendations - Board Adopts Proposed UPL Regulation

Process after Board Makes Preliminary Determination on Affordability



Policy Options- Drug Deemed Unaffordable



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Prescription Drug Affordability Board

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Appendix

Steps for Policy Review and UPL Process

Criteria for Setting an Upper Payment Limit

The Board shall apply the following criteria (as applicable) when determining whether to set a UPL and when setting a UPL amount:

- The Board shall consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs
- The Board shall determine that a UPL is an appropriate tool to address the driver(s) of the affordability challenge identified for the prescription drug product
- The Board shall not set a UPL for the prescription drug product if utilization of the product by Eligible Governmental Entities is minimal
- The Board shall set a UPL in a way to minimize adverse outcomes and minimize the risk of unintended consequences
- The Board shall prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug
- The Board shall not set a UPL for generic prescription drug products that have nine (9) or more marketed therapeutic equivalents
- The Board shall not set a UPL amount that impacts statutory or regulatory amounts, such as Medicaid Best Price
- The Board shall not set a UPL that is lower than the Medicare Maximum Fair Prices

1. Optional Information Gathering-
Policy Review Process and UPL Development

1. Optional Information Gathering

- **Staff assesses if additional information is needed.**
- **If additional information is needed, the Board may use the following tools:**
  - **Informational Hearings**
  - **Stakeholder Council Input**
  - **Expert Testimony Hearings**
  - **Board Staff Research and Analysis**
  - **Input from Eligible Governmental Entities**

2. Staff Recommends Policy Options
Policy Review Process and UPL Development

2. Staff Recommends Policy Options

- **Drivers of Affordability Challenges– the factors which cause the phenomenon of an affordability challenge**
- **Policy Options to Address Identified Drivers**
  - **Non-UPL Policy**
  - **UPL**

Staff Recommends Policy Options
Non- UPL Policy Review Process

Preliminary Policy Recommendations

- Staff identifies drivers of affordability challenges
- Staff proposes policy options to address identified drivers which may include:
  - how a particular policy addresses a driver
  - the strengths and weaknesses of such a policy
  - information regarding possible implementation of such a policy
  - the potential impacts of the policy option.

Staff Recommends Policy Options
UPL Development Process

Preliminary Policy Recommendations

- Staff identifies drivers of affordability challenges
- Staff proposes UPL option which may include analysis of:
  - contextual issues related to the driver(s) of the affordability challenge
  - the ability of a UPL to address these issues
  - the relevant regulatory criteria
  - the use of the drugs by Eligible Governmental Entities

Overview-
Upper Payment Limit (UPL) Development

After staff recommends a UPL as a policy option:

A. **Staff Recommends Methodologies and Contextual Information to Establish a UPL (opportunity for public comment)**
B. **Staff Performs Calculations and Analyses to Develop a Collection of Potential UPL Values (opportunity for public comment)**
C. **Board May Convene Technical Hearing**
D. **Staff May Update Calculation of UPL Amount (opportunity for public comment)**

A. Staff Recommends Methodologies & Contextual Information to Establish a UPL

Preliminary Recommendations for UPL Methodologies and Contextual Information

- **Staff recommends methodologies and contextual information to establish a UPL**
- **Staff posts the recommendations on the Board's website prior to the Board meeting and requests public comment**
- **Staff presents recommendations to the Board**
- **Board directs staff to calculate preliminary UPL amount(s)**

Sample Methodologies

- Cost Effectiveness Analysis
- Therapeutic Class Reference Upper Payment Limit
- Launch Price-Based Upper Payment Limit
- Same Molecule Reference Upper Payment Limit
- Domestic Reference Upper Payment Limit
- International Reference Upper Payment Limit
- Budget Impact-Based Upper Payment Limits
- Blend of Multiple Methodologies

Contextual Information for Setting UPL

The Board may consider the following contextual information when setting a UPL amount:

- Any information contained in the Cost Review dossier
- Utilization in the state health plan in terms of patients and prescriptions
- Utilization in county, bicounty, and municipal health plans in terms of patients and prescriptions
- Amount of direct government purchases in terms of units and patients served
- Utilization in Medicaid in terms of patients and prescriptions
- Net prices for the state health plan
- Net prices for county, bicounty, and municipal health plans
- Net prices for direct government purchases
- Net prices for Medicaid
- Total out-of-pocket costs in the state health plan
- Total out-of-pocket costs in county, bicounty, and municipal health plans
- Total out-of-pocket costs in Medicaid
- Current coverage status of the drug in the state health plan
- Current coverage status in Medicaid
- Current coverage status in the county, bicounty, and municipal health plans
- The number of prescriptions paid through the Maryland State Medical Assistance Program
- The number of patients for the drug helped through the Maryland State Medical Assistance Program
- The total amount paid for the drug through the Maryland State Medical Assistance Program
- Information submitted as part of a request for information
- Information provided based on public testimony
- Information derived from listening sessions hosted by board staff
- Any information provided by entities potentially subject to UPLs
- Information derived from feedback from the stakeholder council
- Information derived from public comments on board meetings
- Any information that can be derived from the manipulation, aggregation, calculation, and comparison of the information listed above
- Information on the potential impact setting a UPL (e.g., savings, impacts on access, behavioral changes)

B. Staff Performs Calculations and Analyses to Develop a Collection of Potential UPL Values

Board staff shall post a public version of:

- **The collected potential UPL values**
- **Staff's recommendation for a proposed UPL amount**
- **A description of the calculation and analyses**
- **A request for public written comment**

C. Board May Convene Technical Hearing

- The Board may convene a technical hearing to receive additional technical input and information
- The Board may request that persons who submitted technical written comments, or comments that raised additional issues the Board wishes to explore, attend the hearing and provide testimony
- The Board shall adopt regulations governing these quasi-legislative hearings

D. Staff May Update Calculation of UPL Amount

- **Board staff may modify or amend the public version of the collection of potential UPL values, and staff's recommendations for a proposed UPL amount**
- **If Board staff modifies or amends the collection of potential UPL values and staff's recommendations, staff shall post the amendments to the Board's website, and request public written comment by a specified date**

3. Final Policy Action and Final Cost Review

The adoption of a final policy recommendation shall occur after the final determination and adoption of the final cost review study report.

The policy review process culminates in the adoption of: (1) other (non-UPL) policy recommendation(s) as Board resolutions; (2) proposed regulations setting the UPL at the specified amount; or (3) both.

The adoption of the final cost review report, adoption of policy recommendations (non-UPL) by resolution and the adoption of proposed regulations setting a UPL amount shall be performed sequentially, where applicable. These actions may be taken at the same Board meeting.

Establishing and Implementing a UPL

- The UPL is the maximum final net ingredient cost paid by Eligible Governmental Entities
- Each UPL will be established by a regulation that specifies:
  - UPL amount
  - Specified Eligible Governmental Entities
  - Prospective effective date that provides sufficient time for implementation
- The Board and staff shall work with Eligible Governmental Entities to develop the best method for implementing the UPL for the entity

Monitoring, Suspending, and Rescinding a UPL

- The Board shall develop a program for monitoring the availability of any prescription drug product for which it sets a UPL
- The Board shall adopt regulations providing for the suspension, modification, and rescission of a UPL
    - If monitoring discloses a shortage of the prescription drug product in the State, the Board may suspend or modify the UPL
    - The Board shall provide for the automatic suspension of the UPL for the time that the prescription drug product is on the federal Food and Drug Administration prescription drug shortage list

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AARP Maryland

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October 16, 2024

The Honorable Bill Ferguson
President of the Senate
State House, H-107
100 State Circle
State Circle
Annapolis, MD 21401

RE: Testimony in Support of the Prescription Drug Affordability Board's Upper Payment Limit Action Plan

Dear President Ferguson and Members of the Legislative Policy Committee,

AARP, the nation's largest nonprofit, nonpartisan organization, is dedicated to empowering Americans aged 50 and older. With over 850,000 members in Maryland, we focus on health security, financial stability, and personal fulfillment for families across the state. One key aspect of our advocacy is addressing the transparency and containment of prescription drug costs for consumers.

I am writing on behalf of AARP Maryland to voice our strong support for the Maryland Prescription Drug Affordability Board's Upper Payment Limit (UPL) Action Plan. Rising prescription drug costs continue to burden Maryland's senior population, and this plan offers a critical framework for addressing the issue by reviewing certain high-cost medications. As mandated by the 2019 legislation, this proposal now requires approval from the Legislative Policy Committee within 45 days.

The Prescription Drug Affordability Board, with its knowledgeable staff and five appointed members, has worked diligently to develop a well-considered process. Their proposed upper payment limit process is among the most comprehensive to date, covering the entire supply chain and offering greater transparency. The Board's unanimous vote to adopt the UPL Action Plan is timely, especially considering federal developments, such as Medicare's new drug pricing negotiations under the Inflation Reduction Act.

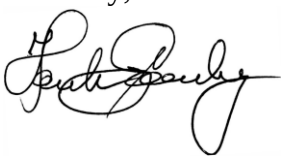
Currently, two drugs under Medicare's Maximum Fair Price program are being reviewed by the Maryland Prescription Drug Affordability Board. With the approval of the UPL Action Plan, Maryland could align state upper payment limits with federal rates, potentially influencing prescription drug negotiations for state and local governments.

The UPL Action Plan, formed through a fair and thorough public discussion process, aims to efficiently establish upper payment limits while ensuring all stakeholders have ample opportunity to participate. Additionally, the plan includes safeguards to ensure that drugs under review for upper payment limits remain available to Maryland consumers.

We respectfully urge the Legislative Policy Committee to approve this vital plan. Swift approval will empower the Board to implement upper payment limits, benefiting countless Marylanders affected by rising prescription drug prices.

Thank you for your leadership on this critical issue. Should you have any questions or need further information, please feel free to contact Director of Advocacy Tammy Bresnahan at tbresnahan@aarp.org or 410-302-8451.

Sincerely,



Hank Greenberg
State Director
AARP Maryland

AARP Maryland

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October 16, 2024

The Honorable Adrienne A. Jones
Speaker of the House of Delegates
State House, H-101
100 State Circle
Annapolis, MD 21401

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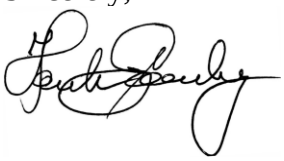

Hank Greenberg
State Director
AARP Maryland

abbvie

August 26, 2024

VIA ELECTRONIC MAIL TO COMMENTS.PDAB@MARYLAND.GOV

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Comments on Draft Upper Payment Limit Action Plan

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. ("AbbVie" or "the Company") is submitting comments in response to the "Maryland Prescription Drug Affordability Board Plan of Action for Implementing the Process for Setting Upper Payment Limits" ("Draft UPL Action Plan") that the Maryland Prescription Drug Affordability Board ("PDAB" or "the Board") published on August 9, 2024.[1]

AbbVie is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, neuroscience, and eye care. AbbVie also is a leader in precision medicine, using genetic and molecular data, as well as companion diagnostic tests, to help target medicines to patients who are most likely to respond to and benefit from them. AbbVie focuses on these areas to accelerate the development of innovative approaches to treat disease and to respond to unmet patient needs. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives.

As a threshold matter, AbbVie believes that the Maryland PDAB statute is bad public policy that will not result in improving patient affordability. Moreover, we believe that the Board's implementation of the PDAB statute is unconstitutional, potentially implicating the Dormant Commerce Clause, the Supremacy Clause, the Takings Clause, and the Due Process Clause. Additionally, as expressed in our prior comment letters, the Board's implementation and administration of the Maryland PDAB statute is inconsistent with Maryland's Administrative Procedure Act ("APA"). Among other examples, the Board's lack of transparency regarding its decision-making is contrary to the public interest and has deprived AbbVie of the ability to effectively and predictably participate in the PDAB's drug selection process.

The Draft UPL Action Plan further compounds our concerns regarding the legality of the Board's activities for, but not limited to, the following reasons:

[1] Maryland Prescription Drug Affordability Board, "Maryland Prescription Drug Affordability Board Plan of Action for Implementing the Process for Setting Upper Payment Limits" (August 9, 2024), at https://pdab.maryland.gov/Documents/comments/Draft%20Outline%20UPL%20Action%20Plan.2024.08.09.1700.pdf.

abbvie

- **The Board incorrectly characterizes the UPL setting process as a quasi-legislative action.** The Board states several times in the Draft UPL Action Plan that "setting a UPL is a quasi-legislative action," and that the cost review study and setting of a UPL are part of a "quasi-legislative process."[2] First, the PDAB's repeated, out-of-context references to a key aspect of Maryland's judicial standard applicable to the review of agency action is unusual and suggests the Board recognizes that the deficiencies of its flawed PDAB policies and processes will be challenged by impacted stakeholders in court. Second, characterizing its cost review study and setting of a UPL as "quasi-legislative" is wholly inconsistent with the highly drug- and fact-specific nature of those activities (including, among other things, that both are determined with respect to a particular drug following a deliberative fact-finding process that weighs data and information that pertains specifically to such product),[3] inconsistent with Maryland legal precedent,[4] and appears to be designed to discourage judicial review of those activities.

- **The Board fails to explain how it will ensure that a UPL would not "impact[] statutory or regulatory amounts, such as Medicaid Best Price."[5]** AbbVie supports the Board's position that a UPL "shall not . . . impact statutory or regulatory amounts, such as Best Price."[6] Indeed, if a UPL were to affect any federal pricing metrics, it would raise significant Constitutional concerns, including under the Dormant Commerce Clause. It is therefore critically important that the PDAB develop adequate procedures to ensure that any UPL set by the Board does not have such effect. The Board must identify specifically which statutory or regulatory amounts a UPL shall not impact and explain how the Board will overcome significant implementation challenges to comply with this requirement in practice, the costs of which could reasonably exceed any perceived savings generated by setting a UPL. For example, statutory and regulatory pricing metrics like Medicaid Average Manufacturer Price and Best Price and Medicare Part B Average Sales Price continually change, and the Board's standard would therefore require constant monitoring. Also, to ensure there is no impact, the Board would need to obtain confidential information which the PDAB and, more broadly, the State of Maryland, may not possess just to know whether and how a particular UPL might affect "statutory or regulatory amounts." In many cases such information is protected from disclosure to a state or other third party by federal

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2 Draft UPL Action Plan at 2.

3 *See, e.g.,* COMAR 14.01.04.02 ("Identifying Drugs Eligible for Cost Review"); COMAR 14.01.04.03 ("Selecting Drugs for Cost Review"); COMAR 14.01.04.04 ("Request for Information for Cost Review"); COMAR 14.01.04.05 ("Cost Review Study"); MD Code, Health - General, § 21-2C-08 ("Identifying prescription drug products that create affordability challenges for State health care system and patients"); MD Code, Health - General, § 21-2C-09 ("Cost review of prescription drug products identified in § 21-2C-08"); MD Code, Health - General, § 21-2C-13 ("Process for setting upper payment limits for prescription drug products that lead to affordability challenges"); MD Code, Health - General, § 21-2C-14 ("Upper payment limits"); Maryland Prescription Drug Affordability Board, "Requests for Information," at https://pdab.maryland.gov/Pages/Request-for-Information.aspx.

4 *See, e.g.*, *Md. Bd. of Pub. Works v. K. Hovnanian's Four Seasons at Kent Island, LLC*, 425 Md. 482, 514, 42 A.3d 40, 59 (2012); *Talbot Cnty. v. Miles Point Prop., LLC*, 415 Md. 372, 387, 2 A.3d 344, 353 (2010); Md. Overpak Corp. v. Mayor of Baltimore, 395 Md. 16, 33 (2006) (citations omitted).

5 Draft UPL Action Plan at 3.

6 *Id.*

law,[7] and the Board lacks authority to compel disclosure of the information in contravention of such federal protections.

- **The Draft UPL Action Plan lacks clear and meaningful standards and procedures to adequately guard against the risk of inconsistent and arbitrary decision-making.** Under Maryland law, "[a]n agency's decisions must . . . not be so fluid as to become arbitrary or capricious," as occurs if "similarly situated individuals are treated differently without a rational basis for such a deviation."[8] The Draft UPL Action Plan, however, merely reiterates the categories of potential information that it may consider, as already identified in statute and regulation. Significantly, none of the "key decisions" for a UPL action plan the Board itself previously identified—*i.e.*, when UPLs should apply, how the Board will set a UPL, and how the Board will apply a UPL—are meaningfully addressed in the Draft UPL Action Plan.[9] The lack of clear and concrete standards prevents stakeholders from meaningfully participating in and commenting on the PDAB's processes, and the vagueness of the applicable standards raises inherent concerns about whether the policy review and/or UPL setting processes will be appropriately grounded in statutorily relevant factors and consistently applied. AbbVie has identified below several such areas for which the Board has failed to provide clear and meaningful standards:

    - The Draft UPL Action Plan incorporates extensive lists and categories of information and data sources that the Board "may" consider as part of its policy review and UPL setting processes.[10] However, the Draft UPL Action Plan lacks any specific, concrete, and meaningful procedures and standards that explain how the Board intends to make use of the information it obtains from these disparate sources, including how information will be weighed, compared, and considered both independently and relative to other information and factors considered by the Board.

    - The Draft UPL Action Plan fails to provide specific procedures and standards that will govern the Board's determination of whether a UPL is an "appropriate policy solution" or an "appropriate tool."[11] The Draft UPL Action Plan instead merely provides that Board staff "may" analyze "contextual issues" related to the identified affordability challenge. These vague and ambiguous statements fail to establish an ascertainable standard for the Board's decision-making.

    - The Draft UPL Action Plan fails to establish a specific methodology or sufficiently concrete criteria for establishing a UPL. Instead, the Draft UPL Action Plan sets forth an extensive list of disparate methodologies that the Board staff "may"

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7 *See, e.g.*, 42 U.S.C. § 1396r-8(b)(3)(D) (protecting from disclosure pricing information, including Best Price and Non-FAMP, submitted by a manufacturer to the Centers for Medicare & Medicaid Services and the U.S. Department of Veterans Affairs).

8 *Harvey v. Marshall*, 389 Md. 243, 303, 884 A.2d 1171, 1207 (2005).

9 *See* Maryland Prescription Drug Affordability Board, Upper Payment Limits (July 24, 2023), available at: https://pdab.maryland.gov/documents/meetings/2023/pdab_upper_pymt_limits_prst.pdf.

10 Draft UPL Action Plan at 6-7.

11 Draft UPL Action Plan at 3, 8.

recommend and asserts that Board staff "may" recommend the Board consider "certain factors" that provide "additional context" to the listed methodologies.[12] The Board states it "may select or prioritize one or more of the methodologies and factors" without clarifying how the Board will select a methodology or how one methodology may be "prioritize[d]" over another.[13] The following are examples of the myriad deficiencies in the PDAB's proposed methodologies:

- The Board proposes a "Therapeutic Class Reference Upper Payment Limit" that would consider "competitor products that have similar chemical structures and act through similar pathways to treat the same conditions" but has not established clear standards to ensure that only appropriate alternatives are considered, leaving the Board free to identify therapeutic alternatives in a standardless vacuum. This ambiguity and lack of transparency can only serve to make the process more arbitrary and inconsistent by obscuring the Board's process and leaving unfettered discretion for the Board to group whatever drugs it wishes as therapeutic alternatives, with no standards and no accountability. Any consideration of therapeutic alternatives should be based exclusively on clinical appropriateness within the same class and mechanism of action and should not consider the costs of therapy of other drugs. The Board should consider whether a potential therapeutic alternative is medically appropriate for the same group of patients as the selected drug, as supported by widely accepted and updated clinical guidelines, real-world practice, and evidence-based medicine. Likewise, the Board should clarify, and be transparent about, the data, information, and resources it uses to select therapeutic alternatives, which it should do from within appropriate drug classes.

- The Board proposes a "Cost Effectiveness Analysis" as another potential methodology for setting a UPL but acknowledges not only that it has not developed any clear and consistent standards for this methodology, but that such analysis will vary significantly by product "[g]iven the variety of drugs" that could undergo review. The PDAB states only "that the policy review process will help guide the determination of the appropriate health outcome for the drug, and thus, the appropriate threshold." Again, this vague principle of a methodology seems to allow the Board unfettered discretion to design and conduct such analyses in a standardless vacuum with inconsistent principles applied on a drug-by-drug basis.

- The Board proposes a "Budget Impact-Based Upper Payment Limit" methodology for setting a UPL, but merely describes the principle of a methodology in a single sentence and provides no further details or standards for any such approach.

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12 Draft UPL Action Plan at 8-11.

13 Draft UPL Action Plan at 8.

- **<u>The Board should determine "affordability" solely as to state and local government entities to which a UPL would apply and should not consider "affordability" as to commercial payors and other entities to which a UPL would not apply</u>.** A substantial number of the criteria for setting a UPL identified in the Draft UPL Action Plan are derived from drug price and cost metrics associated with commercial utilization of the products the Board will have deemed unaffordable. The Board exceeds the scope of its statutory authority and violates Maryland's APA by determining affordability based on data that clearly, erroneously, unreasonably, and disproportionately skews the Board's findings against manufacturers. For example, relative out-of-pocket costs, payor costs, co-pay and cost-sharing amounts, and various spending metrics, among other data elements, are generally higher for a drug in the commercial context as compared to those entities to and contexts in which a UPL will apply in practice.

- **<u>The Board should not use an "International Reference Upper Payment Limit" as a potential methodology to set a UPL</u>.** The Board proposes an "International Reference Upper Payment Limit" as a potential methodology to set a UPL for a drug it determines to be unaffordable.[14] The Board states in the Draft UPL Action Plan that if it "uses the international reference UPL as the method for setting the UPL, the Board may set the UPL to be the lowest price among those paid in the United Kingdom, Germany, France, and Canada, converted to U.S. dollars."[15] Other countries have pricing and reimbursement regimes that are not market-based or governed by U.S. healthcare laws, and their healthcare systems and policies do not match those found in the U.S. or any individual state or territory. These prices are not a relevant consideration for pricing in the U.S. and using them to set a UPL would raise Constitutional concerns. For example, Canadian and many other countries' prices are governed by price controls that are based on the use of quality-adjusted life years ("QALYs"). The U.S. federal government recognizes that QALYs are inherently discriminatory to patients with chronic disease and disability.[16] Indeed, a bill that would prohibit the use of QALYs and other similar discriminatory measures in all federal programs passed in the U.S. House of Representatives earlier this year and is now being considered by the Senate.[17]

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[14] Draft UPL Action Plan at 10.

[15] Draft UPL Action Plan at 10.

[16] In its November 2019 report on QALYs, the National Council on Disability (NCD) "found sufficient evidence of QALYs being discriminatory (or potentially discriminatory) to warrant concern." National Council on Disability, "Quality-Adjusted Life Years and the Devaluation of Life with Disability" (November 6, 2019), at https://ncd.gov/newsroom/2019/federal-study-finds-certain-health-care-cost-effectiveness-measuresdiscriminate.

[17] H.R. 485 would prohibit the use of QALYs and other similar discriminatory measures in all federal programs, an expansion from the current prohibition that only applies in a limited fashion to the Medicare program. *See* H.R.485, "Protecting Health Care for All Patients Act of 2023," at https://www.congress.gov/bill/118th-congress/house-bill/485. Note also that the Inflation Reduction Act of 2022, which established the Medicare Drug Price Negotiation Program ("DPNP"), explicitly prohibits use of QALYs as factors for consideration in determining the offers and counteroffers in the DPNP. Social Security Act § 1194(e)(2) ("the Secretary shall not use evidence from comparative clinical

- **The Board should focus on identifying drugs with high out-of-pocket costs for patients and work with *insurers* to lower those out-of-pocket costs.** As part of its proposed criteria for setting a UPL, the Board seeks to prioritize drugs that have a high proportion of out-of-pocket costs for patients compared to the net cost of the drug.[18] If that is the case, we urge the Board to instead consider insurance benefit design as the mechanism to achieve lower out-of-pocket costs. Insurance plans, not manufacturers, control patient deductibles, copays, and coinsurance. The Board must also consider the utilization management practices used by pharmacy benefit managers and insurers (e.g., prior authorization requirements, step therapy requirements, non-medical switching) that can create barriers to patient access to treatment, beyond a singular focus on out-of-pocket costs alone.

- **The Board should clarify several aspects of the UPL setting process, including, without limitation, the term of a UPL, whether a UPL will be set through a formal rulemaking process, and the expert testimony process.** First, other than stating that a UPL should be suspended if it leads to a drug shortage, the Draft UPL Action Plan does not provide any indication of the term of a UPL. Given the highly dynamic nature of drug pricing, there must be, at minimum, adjustment for inflation, which is standard in government pricing, but also, for example and not limited to, consideration of changed circumstances and a process for terminating a UPL. AbbVie requests that the Board clarify how long a drug's UPL will apply and provide its justification for a currently indefinite price control. Second, the Draft UPL Action Plan states that "the procedures in this plan provide for the setting of a UPL by adopting a regulation through notice and comment rulemaking provisions of the Maryland Administrative Procedure Act.[19] The Board has given no indication of whether it intends to pursue notice and comment rulemaking to codify the UPL process proposed in the Draft UPL Action Plan. We urge the Board to clarify whether it intends to initiate formal rulemaking now or in the future. Third, as part of the policy review process, the Board proposes to convene expert testimony hearings. Specifically, the Draft UPL Action Plan states "the Board may convene a hearing for the purpose of receiving expert testimony and soliciting testimony from persons with specific knowledge, skills or expertise."[20] While AbbVie supports the Board's interest in seeking expert input, we are concerned the Board will not be providing sufficient transparency with respect to the feedback it collects and how such feedback will be considered in its approach. The PDAB must provide further information on this opaque proposed expert testimony process. Specifically, among other things, the Board must clarify how experts will be selected for testimony and who will lead this selection process, the criteria for their presentations, how often these hearings will be convened, the process for stakeholder input, and opportunities for manufacturers to select their own experts. The PDAB should also consider seeking testimony, in a transparent manner, from healthcare provider advisory boards that fairly reflect the treating community and can provide input as to what drugs

effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.").

18 Draft UPL Action Plan at 3.

19 Draft UPL Action Plan at 2.

20 Draft UPL Action Plan at 7.

truly should be considered as therapeutic alternatives. It should also identify the sources it is relying on and allow manufacturers a meaningful opportunity to engage in discussion on the input.

- **We continue to have, and reiterate, our concerns regarding the reliability of information sources used by the Board.** The Draft UPL Action Plan contemplates the Board considering and using data and information from a variety of sources.[21] The PDAB also proposes that it may consider additional information beyond those sources identified in the Draft UPL Action Plan.[22] However, the Board fails to articulate how it will appropriately consider and weigh the accuracy, reliability, and validity of these varied sources and how the Board will limit its consideration of data and information from such sources to the factors listed in statute and implementing regulations. The PDAB's decision-making can be only as accurate as the data and information the Board relies upon, so we request that the Board identify with greater specificity the processes it will implement to help reduce the risk that the Board's analyses may rely on erroneous, incomplete, dated, or otherwise misleading and/or deficient datasets or analyses.

- **We continue to have, and reiterate, our concerns about the adequacy of the Board's safeguards for ensuring the confidentiality of all trade secret, confidential, or proprietary information used in association with the activities of the Board, and for preventing the unlawful and unconstitutional disclosure of such information.** Regulations promulgated by the Board state the Board "may . . . determine that information it has received is confidential, trade secret, or proprietary."[23] We believe this is inconsistent with the plain reading of the PDAB statute, which states that "all information and data obtained by the Board under the subtitle, that is not otherwise publicly available: (1) Is considered to be a trade secret and confidential and proprietary information; and (2) Is not subject to disclosure under the Public Information Act."[24] The statute thus does not grant the Board authority to "determine" whether information is confidential, and thus, protected. That authority rests with those submitting data to the Board and the individual certifying that information is designated as protected information. If data is not otherwise publicly available, then its status under the statute is unambiguously protected information and the Board should recognize it as so. Those making decisions as to what data they will submit, and in what format, should have transparency as the procedures and protection for such statutorily protected trade secret and confidential and proprietary information so that they are able to meaningfully participate in the requested data submission process.

- **We continue to have, and reiterate, our concerns regarding deficiencies in the Board's drug selection process.** As the manufacturer of a drug selected for cost review, AbbVie has serious concerns about the Board's drug selection process and as noted above, the quality of available data to the Board. Selecting drugs for cost review requires a transparent and consistent process, but the Board has not publicly adopted or applied such a process.

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21 Draft UPL Action Plan at 6-7.

22 *Id.*

23 Md. Code Regs. 14.01.01.04.

24 Md. Code Ann., Health-Gen. § 21-2C-10 (emphasis added).

Among other things, we are concerned that the Board's selections may not reflect drugs that pose actual affordability challenges to Maryland patients. With respect to data the Board considered during the drug selection process, the Board has only provided a limited subset of data in a public dashboard[25] which lacks context and complete source information. Moreover, as discussed above, such data considered by the PDAB largely pertains to commercial utilization of SKYRIZI®. If the Board had obtained and evaluated more complete and accurate data during the selection process, it would have been found that SKYRIZI results in overall savings compared to other medicines and greatly improves patient outcomes, and that the vast majority of patients, whether or not insured, can access SKYRIZI for little or no cost. The lack of consistency and transparency regarding the Board's decision-making in selecting drugs for cost review is contrary to the public interest, raises questions under Maryland's APA, and has critically deprived AbbVie of the ability to effectively participate in the Board's selection process.

* * * *

Thank you for this opportunity to provide our comments on the Draft UPL Action Plan. Please contact Helen Fitzpatrick at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Fitzpatrick

Helen Kim Fitpatrick
Vice President, State Government Affairs
Government Affairs
On behalf of AbbVie Inc

[25] *See* Maryland PDAB, "Drugs Referred to the Stakeholder Council- Dashboard," at https://pdab.maryland.gov/documents/comments/drugs_referred_stakeholder_council_dashboard_2024.xlsx.

October 18, 2024

VIA ELECTRONIC MAIL TO RYANE.NECESSARY@MLIS.STATE.MD.US AND DANA.TAGALICOD@MLIS.STATE.MD.US

The Honorable Bill Ferguson, Co-Chair
The Honorable Adrienne A. Jones, Co-Chair
Members of the Legislative Policy Committee
Department of Legislative Services
Legislative Services Building, Room 200B
90 State Circle, Annapolis, MD 21401

Re: Written Testimony Explaining Why the Legislative Policy Committee Cannot Approve the Maryland Prescription Drug Affordability Board's Upper Payment Limit Action Plan

Dear Hon. Ferguson, Hon. Jones, and Members of the Legislative Policy Committee:

AbbVie Inc. ("AbbVie" or "the Company") is pleased to submit this written testimony in advance of the Legislative Policy Committee's ("LPC's") October 22, 2024 hearing on the "Health General Article § 21-2C-13(d) Prescription Drug Affordability Board Upper Payment Limit Action Plan" ("UPL Action Plan") that the Maryland Prescription Drug Affordability Board ("PDAB" or "the Board") approved on September 10, 2024. ***For the reasons discussed herein, the LPC cannot approve the UPL Action Plan.***

AbbVie is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, neuroscience, and eye care. AbbVie also is a leader in precision medicine, using genetic and molecular data, as well as companion diagnostic tests, to help target medicines to patients who are most likely to respond to and benefit from them. AbbVie focuses on these areas to accelerate the development of innovative approaches to treat disease and to respond to unmet patient needs. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives.

AbbVie manufactures and markets SKYRIZI®, one of the products selected by the Board for a "cost review" (or "affordability review"), a critical step towards the potential future establishment of a UPL by the PDAB. Accordingly, AbbVie has a significant interest in the Board's activities generally, and the UPL Action Plan specifically. Since the Board's formation, AbbVie has actively participated in the PDAB's administrative processes — that is, when the Board has presented opportunities to do so. As a directly impacted stakeholder, we have attempted to meaningfully engage with the Board through, among other things, our submission of numerous public comments on various topics, as well as multiple requests to the Board under Maryland's

Public Information Act seeking basic but critical information the Board — in stark contrast to other state PDABs — has not made publicly available.[1]

SKYRIZI® is approved by the U.S. Food and Drug Administration for the treatment of three (3) different conditions: (1) moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy; (2) active psoriatic arthritis in adults; and (3) moderately to severely active Crohn's disease in adults.[2] The product has clear and well-defined clinical and economic value to patients and payors alike supported by an extensive body of data, information, and health care provider and patient accounts, among other relevant information we have provided directly to the Board during its PDAB review and selection processes. Of particular concern to AbbVie, the Board has never even explained how or why SKYRIZI® was chosen for affordability review, notwithstanding all the compelling information to the contrary.

As a threshold matter, AbbVie has significant concerns with the Maryland PDAB statute and the Board's implementation of the law, including but not limited to its adoption of the UPL Action Plan. The Maryland PDAB statute is flawed public policy that will not result in improving patient affordability. Moreover, the Board's implementation of the law is unconstitutional, potentially implicating the U.S. Constitution's Dormant Commerce Clause, Supremacy Clause, Takings Clause, and Due Process Clause, among other issues. Additionally, the Board's implementation and administration of the Maryland PDAB statute is inconsistent with Maryland's Administrative Procedure Act. Among other examples, the Board's lack of transparency regarding its decision-making is contrary to the public interest and has deprived AbbVie and all other impacted stakeholders, including Maryland resident patients, of the ability to effectively and predictably participate in the PDAB's drug selection and review processes.

The Board's development of its UPL Action Plan has been rushed, with only a superficial focus on critical issues of substance, as evidenced by the final product now before the LPC for review. Indeed, we seriously question whether the Board actually considered any of the feedback in the **twenty-two** public comments it received on the initial draft UPL action plan from providers, pharmacies, trade associations, advocates, and manufacturers (including AbbVie) given the following timeline, and the few revisions made to the final version adopted by the PDAB now before the LPC:

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[1] *See, e.g.*, AbbVie's Comments on SKYRIZI®'s Selection for Cost Review (July 22, 2024), at https://pdab.maryland.gov/Documents/comments/Board%20selected%20Drugs%20Comments.pdf; AbbVie's Comments on SKYRIZI®'s Referral to the Stakeholder Council (May 10, 2024), at https://pdab.maryland.gov/Documents/comments/AbbVie_MD%20PDAB%20Comment%20Letter_May%209%2024-FINAL.pdf; AbbVie's Comments on the Board's List of "Therapeutic Alternatives" for SKYRIZI® (May 13, 2024), at https://pdab.maryland.gov/Documents/comments/MD%20PDAB%20Therapeutic%20Alternatives%20Comments%20-%20SKYRIZI.pdf; AbbVie's Comments on SKYRIZI®'s Selection and Referral to the Stakeholder Council (April 23, 2024)," at https://pdab.maryland.gov/Documents/comments/4.29.2024%20PDASC%20Comments%20combined.pdf.

[2] SKYRIZI®, Full Prescribing Information, at https://www.rxabbvie.com/pdf/skyrizi_pi.pdf.

- **Friday, August 9, 2024:** Board publishes initial draft of UPL Action Plan.
- **Monday, August 26, 2024:** Deadline to submit public comments on draft UPL Action Plan.
- **Monday, August 26, 2024:** Date of the Maryland Prescription Drug Affordability Stakeholder Council ("PDASC" or "Stakeholder Council") meeting during which the PDASC — the purpose of which is to represent impacted stakeholders[3] — provided feedback to the Board on the draft UPL Action Plan. It seems inconceivable that before it met that day, the Stakeholder Council could have read and considered each and every one of the twenty-two comments submitted by that **same day**, betraying a lack of any intent by the PDAB to provide an opportunity for meaningful public engagement.
- **Friday, August 30, 2024:** Board issues revised draft UPL Action Plan on the Friday of Labor Day Weekend.[4]
- **Tuesday, September 10, 2024:** PDAB meeting during which the Board approves the minimally revised draft UPL Action Plan.[5]

Maryland courts have consistently held that the state's Administrative Procedure Act requires government entities like the PDAB to provide a "reasoned analysis" that shows the "basis of the agency's action" and adequate "factual findings ... to support the agency's conclusions."[6] Under this reasoned analysis standard, such "[f]indings of fact must [also] be meaningful and cannot simply repeat statutory criteria, broad conclusory statements, or boilerplate resolutions."[7] This is exactly what we see in the UPL Action Plan, however. The timing of the Board's approval of the UPL Action Plan relative to the number of comments the PDAB received from the public, together with the lack of quality of the final document, unequivocally demonstrate the Board's efforts fail to satisfy applicable standards and compounds our concerns regarding the legality and propriety of the Board's activities. **We respectfully request that the LPC consider the enclosed comment letter, which summarizes AbbVie's main objections to an earlier draft of the UPL Action Plan (which, as noted above, was largely unchanged in the final version now before the LPC).** Because the Board failed to address our concerns in the current draft, the UPL Action Plan that the LPC is considering suffers from the same flaws and cannot be approved.

Beyond the aforementioned failures in proper conduct by the Board, we bring to your attention a critical constitutional concern that the Board has publicly acknowledged but has

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[3] Maryland Prescription Drug Affordability Board, "Prescription Drug Affordability Stakeholder Council, 2022 Stakeholder Council Meeting," at https://pdab.maryland.gov/pdab_stakeholder_2022.html ("The purpose of the Prescription Drug Affordability Stakeholder Council is to provide stakeholder input to assist the PDAB in making decisions to protect the State, its residents, and other stakeholders in the Maryland health care system").

[4] Maryland Prescription Drug Affordability Board, "Maryland Prescription Drug Affordability Board Upper Payment Limit Action Plan (August 30, 2024)," at https://pdab.maryland.gov/Documents/UPL%20Action%20Plan.2024.08.30.1745.pdf.

[5] Maryland Prescription Drug Affordability Board, "PDAB Meeting: Upper Payment Limit Action Plan (September 10, 2024)," at https://pdab.maryland.gov/Documents/meetings/2024/FINAL%202024.09.10%20Presentation%20UPL%20.pdf.

[6] *Elbert v. Charles Cnty. Plan. Comm'n*, 259 Md. App. 499, 509 (2023); *see also, e.g.*, *Mortimer v. Howard Research and Development Corp.*, 83 Md. App. 432, 442 (1990).

[7] *Bucktail, L.L.C. v. County Council of Talbot County*, 352 Md. 530, 553 (1999).

not addressed in the UPL Action Plan or other work product — that a Maryland UPL could reasonably have far-reaching impacts on federal pricing metrics that determine drug reimbursement amounts across the United States, including purchases under *federal* and other healthcare programs that occur entirely outside of Maryland. This legal and practical reality cannot be ignored.

As background, drugs that are dispensed or administered in federal healthcare programs – such as Medicaid and Medicare Part B – may be reimbursed based on metrics that consider a manufacturer's sales outside of that federal program. For example, in the Medicaid Drug Rebate Program, manufacturers of covered outpatient drugs are required to pay rebates to state Medicaid programs that generally are based on a drug's "Best Price" to an eligible entity.[8] In enacting this provision, Congress intended that the Medicaid program would get the "Best Price" offered to other commercial customers.[9] Thus, a manufacturer's sale of a drug to an eligible customer is excluded from Best Price *only* if it falls under an exclusion that is explicitly enumerated in the federal Medicaid statute. For example, prices offered under certain federal healthcare programs are excluded (e.g., Indian Health Service, Department of Veterans Affairs, Medicare Part D), as well as prices used in a State pharmaceutical assistance program.[10] However, there is no exclusion from Best Price that appears to exclude a future Maryland UPL – which would apply to certain purchases and reimbursements under Maryland state programs.[11]

If a UPL were to affect any federal pricing metrics, it would raise significant Constitutional infirmities, including under the Dormant Commerce Clause. It is therefore critically important that the PDAB develop adequate procedures to ensure that any UPL set by the Board does not have such effect. In recognition of this serious legal obstacle, the UPL Action Plan states that a UPL "shall not . . . impact statutory or regulatory amounts, such as Best Price."[12] In our enclosed comments to the Board, we supported the Board's statement that any UPL should not impact Best Price or any other federal pricing metrics, for the reasons summarized above, but asked the Board to explain how it would effectuate this position in practice in light of significant implementation challenges which we outlined. We are troubled that the Board has not further addressed this issue.

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8 42 U.S.C. § 1396r-8(c)(1)(C)(i) ("The term 'best price' means, with respect to a single source drug or innovator multiple source drug of a manufacturer . . . the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States," subject to enumerated exclusions.).

9 136 Cong. Rec. E2813 (1990) (Sep. 12, 1990) (statement of Senator Ron Wyden) ("There is simply no logical reason why the Medicaid Program . . . should have to pay prices for drugs which average 40 to 70 percent more than those prices paid by other large purchasers.").

10 42 U.S.C. § 1396r-8(c)(1)(C)(i)(I-VI).

11 Md. Health Gen. § 21-2C-14(a) ("If [the UPL Action Plan] is approved . . . the Board may set upper payment limits for prescription drug products that are: (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, including: (i) State or county correctional facilities; (ii) State hospitals; and (iii) Health clinics at State institutions of higher education; (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.").

12 UPL Action Plan at 3.

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Fundamentally, a state administrative body (such as the Maryland PDAB) cannot unilaterally exclude a given purchase from Best Price. Only the U.S. Congress can add exclusions to the federal Best Price statute. Additionally, statutory and regulatory pricing metrics like Best Price (and Medicaid Average Manufacturer Price and Medicare Part B Average Sales Price) are calculated on a quarterly basis and continually change;[13] therefore, the Board's standard would therefore require constant monitoring. Also, to ensure there is no impact, the Board would need to obtain confidential information which the PDAB and, more broadly, the State of Maryland, may not possess just to know whether and how a particular UPL might affect "statutory or regulatory amounts." In many cases such information is protected from disclosure to a state or other third party by federal law,[14] and the Board lacks authority to compel disclosure of the information in contravention of such federal protections.

The intent of Maryland's PDAB law 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."[15] If the Board does not provide meaningful information regarding how it determines whether a drug will lead to an affordability challenge, or how it will develop a UPL if the Bord determines a drug is "unaffordable," AbbVie and the broader public have no way to determine whether the Board is acting consistently with its charge. Given that the UPL Action Plan not only fails to meet this statutory threshold, but further, also raises significant constitutional concerns, the LPC cannot approve the UPL Action Plan.

* * * *

Thank you for this opportunity to provide written testimony on the LPC's consideration of the UPL Action Plan. Please contact Helen Fitzpatrick at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Fitzpatrick

Helen Kim Fitpatrick
Vice President, State Government Affairs
Government Affairs
On behalf of AbbVie Inc

Enclosure

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[13] 42 U.S.C. § 1396r-8(b)(3)(A) (requiring manufacturers to report to the Centers for Medicare & Medicaid Services their Best Price and Average Manufacturer Price every calendar quarter); 42 U.S.C. § 1395w-3a (Average Sales Price is calculated each calendar quarter).

[14] *See, e.g.*, 42 U.S.C. § 1396r-8(b)(3)(D) (protecting from disclosure pricing information, including Best Price and Non-FAMP, submitted by a manufacturer to the Centers for Medicare & Medicaid Services and the U.S. Department of Veterans Affairs).

[15] Md. Code Ann., Health-Gen. § 21-2C-02(b).

October 18, 2024

The Honorable Adrienne Jones
The Honorable Bill Ferguson
Maryland Legislative Policy Committee
Department of Legislative Services
Annapolis, Maryland 21401

Dear Speaker Jones, President Ferguson, and Members of the Legislative Policy Committee:

AstraZeneca is writing this letter to express our concern with the request made by the Prescription Drug Affordability Board (PDAB) to the Legislative Policy Committee to approve an Upper Payment Limit (UPL) Plan (Plan). The work done to date by the PDAB is not comprehensive enough to satisfy the needs of the patient, the state or to those business entities that will be impacted by a UPL. Any consideration of the Plan is premature, and more work should be completed to provide appropriate specificity to everyone involved. The PDAB also needs to develop a deeper understanding of unintended consequences to the patient and pharmaceutical supply chain.

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas: Oncology, Cardiovascular, Renal and Metabolism, and Respiratory. Based in Cambridge, UK, AstraZeneca is committed to developing innovative, lifesaving medicines and making these medicines accessible to patients.

Throughout the PDAB's existence, the manufacturing industry has continually voiced concerns with the design and construction of the PDAB, and with the Board's focus on UPLs as the main tool to control costs for state-funded programs. While the statute allows for any number of policy recommendations to offset a finding of "unaffordability," the Board's laser-like focus on UPLs misconstrues the mechanics and economics of the drug supply chain, and the impact that other players in the supply chain have on the cost of drugs. Instead of considering flaws across the system, the Board has instead focused on a very narrow and inappropriate set of supposed cost drivers (namely, WAC price) that demonstrates a fundamental lack of understanding about how rebates and other cost calculations are used by actors within the supply chain to manipulate the cost to the patient. According to a report by

BRG[1], in reality, less than 50 percent of the total cost of a drug ends up with the manufacturer. This significant portion of spend on brand medications goes to other non-manufacturer entities like insurers, Pharmacy Benefit Managers (PBMs), hospitals, pharmacies, governments, and others. The disproportionate focus on list price fails to recognize that a patient's final out-of-pocket costs for a medicine are primarily a function of their health benefit plan design. The actual amount paid by the patient is typically set by the PBM or plan sponsor, entities that receive significant rebates from the manufacturer but do not fully pass those rebates on when it charges patients for out-of-pocket costs. This dynamic is also true for commercial plans that provide services to State employees and Maryland Medicaid Managed Care plans.

AstraZeneca has concerns over the lack of detail currently included in the Plan. The lack of specificity creates uncertainty for patients and other stakeholders who will be directly and significantly impacted by a potential UPL. This approach could be burdensome for Maryland patients who could face higher prices or restricted access to a drug that has a UPL placed on it. **The Committee should refuse to approve the UPL Plan under these circumstances and encourage the PDAB to be more thorough in its approach by sending the Plan back to the PDAB for further consideration and detail.**

The PDAB should include clear processes, methodologies, and contextual information that will be used in the UPL process. This clarity will allow manufacturers to engage in a meaningful way to ensure all aspects of the supply chain, as well as the effect on the patient, are considered in the setting of a UPL. This will allow everyone involved to provide the most applicable and helpful insights and information for the PDAB to consider. Specifically, the Plan should include details on the following criteria that are currently not included:

- Clearly define the criteria for what it means for a drug to have, or lead to, "affordability challenges".
- Establish what criteria needs to be met to establish that a UPL is in the best interest of the state.
- Establish clear criteria to use in order to determine if it is appropriate to apply a UPL for a drug subject to a cost review.
- Set out a clearly defined process on how a UPL is set with appropriate timelines.
- Establish what other policy recommendations should be considered before a UPL is applied with an explanation of why those policies would not adequately address affordability concerns.

[1] https://www.thinkbrg.com/news/more-than-half-brand-medicine-spending-goes-to-supply-chain-middlemen-other-stakeholders/

- Determine how the Board will determine the effect of a UPL on Medicaid Best Price and other statutory and regulatory calculations, with a clear explanation of how the Board will avoid impact to those calculations.
- Define what "minimal utilization" by Eligible Governmental Entities means that would result in a UPL not being appropriate.
- Establish the Board's methodology on how they plan to limit or minimize adverse outcomes and the risk of unintended consequences in the UPL setting process on an individual drug.
- Clearly state how a UPL will be implemented within the supply chain considering current statutory and legal limitations.
- Provide specificity on the type of methodology the PDAB intends to implement. Currently, the Plan list seven options or a mix of multiple methodologies. The purpose of the Plan should be to provide this level of thinking and detail.

Each of these issues is particularly important to understand because of the potential harm to each patient who is on or will be prescribed a drug subjected to a UPL. The unintended impacts of a UPL on the supply chain, the patient, and to the state should be understood prior to the approval of a UPL plan. These steps are also important before the legislature considers the broadening of the UPL authority to other lines of business outside of those currently established in the statute.

The Legislative Policy Committee also deserves to have full insight into what the PDAB is doing to ensure that the intent of the UPL is followed. This will ensure that the impacts are understood by all impacted stakeholders before a UPL is set. We encourage the Committee to reject the proposed Plan and require the Board to establish criteria that will allow everyone involved to be comfortable with the outcome.

Please let us know if you have any questions or require further information.

Sincerely,

Geoffrey A Gallo
Head of Corporate & State Government Affairs

October 9, 2024

Legislative Policy Committee (LPC)
Department of Legislative Services
Annapolis, Maryland 21401

Submitted electronically: ryane.necessary@mlis.state.md.us

Re: Review of the Upper Payment Limit Action Plan approved by the Prescription Drug Affordability Board

Dear Members of the Legislative Policy Committee:

On behalf of the Association of Women in Rheumatology (AWIR), I am writing to offer our comments regarding the Maryland's Prescription Drug Affordability Review Boards' *Plan of Action for Implementing the Process for Setting Upper Payment Limits (UPLs)* on prescription medications.

As an organization committed to advocating for accessible and affordable prescription medications for patients, we acknowledge the need for reforms in our current drug pricing system. The specialty of rheumatology frequently involves high-cost medications, particularly biologics, which are often not initial treatment options. Rheumatologists frequently guide patients through a complex trial-and-error process—chronicling several months to a year—before identifying the most effective medication. Maintaining continuity of this treatment is critical not only to prevent disease flares but also to ensure that patients can perform their daily activities without interruption.

The AWIR supports the objective of the Maryland Prescription Affordability Board to lower medication costs and increase accessibility. However, we urge the LPC to carefully consider the implications of implementing UPLs on an already fragile drug pricing system. The present framework of prescription pricing is heavily influenced by the rebates that pharmaceutical manufacturers provide to Pharmacy Benefit Managers (PBMs). This 'backwards bidding' system incentivizes manufacturers to inflate the list prices of drugs, leaving patients to pay out-of-pocket costs based on these inflated prices—rather than the actual discounted rates that PBMs receive.

In the context of rheumatology, many of our physicians utilize a buy-and-bill model to provide medications directly in their offices. This approach allows healthcare providers to tailor dosages according to real-time vitals and laboratory results, ensuring safety and effectiveness. It is noteworthy that providing medications through the office setting is often significantly more cost-effective compared to hospital settings or insurer-owned specialty pharmacies. For instance, one recently analyzed drug, Stelara, was 22% less expensive in the provider care setting and 34% more costly when administered via hospital services.[1]

While setting UPLs might seem well-intentioned, it poses a risk. If reimbursement caps set by the board lead to financial shortfalls for providers, it may jeopardize the sustainability of the buy-and-bill process. Providers may find themselves covering costs for medications that exceed the UPL they receive for

[1] https://www.mass.gov/doc/review-of-third-party-specialty-pharmacy-use-for-clinician-administered-drugs/download

reimbursement, which could force them to reconsider the delivery of care models that are currently more economical for patients. This shift has the potential to unintentionally channel patients towards more expensive healthcare environments, counteracting the goal of increasing affordability.

AWIR strongly supports the Board's mission to enhance the affordability of medications, but we advocate for a holistic perspective that considers the repercussions of UPLs on specialty providers and their patients. The delicate balance between setting manageable limits and ensuring patient access to effective treatment must be upheld.

AWIR's Suggested Solutions:

- **Ensure that the UPL setting process incorporates patient access considerations as a key criterion. Strategies should be put in place to evaluate how proposed limits may impact patient availability to necessary medications and treatment options.**

- **Create exceptions criteria for specialty providers who buy-and-bill their drugs and administer in-office. By including guardrails to account for drug acquisition costs and drug administration reimbursement, you protect the site of care that delivers the most cost-effective way of treating patients who need specialty medications. It also protects patients from being shifted to a hospital setting where administration costs are substantially higher.**

- **Ensure that stakeholder input and expert testimony hearings take into consideration that providers are seeing patients during regular work hours. AWIR strongly suggests that these meetings take place in the early morning or late evening hours of the day so that both providers and patients can provide essential input.**

We appreciate your consideration of these concerns and look forward to working collaboratively to find solutions that truly promote affordability and access for all patients, particularly in the specialty of rheumatology.

Thank you for your attention to this critical matter.

Sincerely,

Gwenesta Melton, MD
VP, Co-Chair of Advocacy
AWIR

Stephanie Ott, MD
Co-Chair, Co-Chair of Advocacy
AWIR

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VIA Electronic Delivery October 18, 2024

Re: Plan of Action for Implementing the Process for Setting Upper Payment Limits

Dear Maryland Legislative Policy Committee:

The Biotechnology Innovation Organization (BIO) urges the Legislative Policy Committee (LPC) to not move forward with Maryland's Draft Plan of Action for Implementing the Process for Setting Upper Payment Limits (Draft Plan). BIO strenuously disagrees with Maryland's approach to effectuating a UPL system, which will have profound negative repercussions for patient access. BIO also opposes future legislation aimed at expanding the scope of Maryland's Prescription Drug Affordability Board (PDAB).

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life- saving medicines and vaccines for all individuals.

BIO and our members have long argued that the underlying structure and utilization of an upper payment limit (UPL) is flawed and should not be enacted. UPLs will harm patient access to lifesaving medication while failing to protect patients from harmful plan designs, and other restrictive coverage strategies and barriers imposed by plans and PBMs. It is evident that setting UPLs without consideration for the drug coverage ecosystem and supply chain could have profound negative repercussions for patient access. Unfortunately, the Draft Plan provides no specificity on how the impact on patient access will be measured and puts emphasis on arbitrary cost factors rather than providing a holistic assessment of drug value, including clinical and non-clinical benefits. Maryland's stated goals of transparency and engagement require immediate reconsideration of the Draft Plan.

Please note our recommendations below do not resolve the more fundamental issues of UPL effectuation and BIO's positioning remains that UPLs should not be enacted.

Inadequate Opportunities for Stakeholder Input

BIO remains extremely concerned that the Draft Plan gives the PDAB carte blanche to move decisions forward without public comment. It is evident that the Draft Plan must properly consider the policy's impact on patients and offer specific opportunities for the patient community, including rare disease patients/Rare Disease Advisory Councils (RDACs), to be a part of the process early on and at all levels of review.

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No Clear Definitions for "Affordability Challenge" While Disregarding True Drivers of Patient Affordability

As BIO has stated in previous comments, UPLs do not address affordability concerns for patients because it does not address barriers to access imposed by plans and PBMs, including formulary tiering, cost sharing, and utilization management. Nearly 90% of patients[1] pay a given price based on what their health insurer determines. A May 2021 Congressional Research Service report found that insurers are imposing higher levels of cost sharing and forcing some patients, i.e., the chronically ill, to pay a greater financial burden than others.[2] Nonetheless, Maryland's Draft Plan fails to consider the true drivers of patient affordability and access that are determined by plans and PBMs. Without information on formulary tiering, cost-sharing, and utilization management, it is impossible to discern the UPL's impact on patient affordability. The Draft Plan also disregards manufacturer assistance, which significantly helps patients with their out-of-pocket costs. While high out-of-pocket costs relative to a drug's net price is mentioned as a consideration factor when evaluating affordability, a UPL would not be a solution to this problem and the Draft Plan offers no examples of affordability solutions that may be better suited to the underlying concern.

BIO is strongly concerned by the Draft Plan's lack of consistent and clear information on how affordability will be defined. This clarity is critical to avoid an arbitrary process where assessments could change over time and not reflect patient values. It is critical that this process is transparent and repeatable and allows for sufficient stakeholder input to aid in the efficient collection/provision of information to support the UPL process.

BIO also notes our strong disappointment in the Draft Plan's inability to follow its own stated goals to "determine whether a UPL is an appropriate policy solution to redress the driver(s) of the affordability challenge." The Draft Plan contradicts its own stated intent by assuming that the UPL is the primary or only solution to address affordability challenges. The Draft Plan fails to focus on any other policy tools that the Board can consider to address affordability, such as changes to plan benefit designs or transparency measures aimed at PBMs and plans. It is evident that, given the operational costs to set up, administer, and maintain an UPL, other policy tools may be more fiscally reasonable for the state. BIO strongly urges the LPC to give equal consideration to other policy tools other than a UPL, including those that require additional legislative authority.

Lack of Clarity and Consistency in Setting the UPL

The Draft Plan does not address to whom or how a UPL may be set and provides no clarity on how the UPL, if established, would be effectuated. This lack of clarity and consistency could lead to different approaches used for each drug, which presents challenges in ensuring efficient stakeholder engagement, data collection and decision-making. It is essential that the entire UPL process should be applied consistently to reflect the value of each drug and to minimize potential bias and ensure equity and fairness.

[1] Kaiser Family Foundation. https://www.kff.org/uninsured/state-indicator/nonelderly-uninsured-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[2] "Frequently Asked Questions About Prescription Drug Pricing and Policy," Congressional Research Service Report, Updated May 6, 2021.

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It is also critical that the Draft Plan clearly explain and set forth a detailed plan for how it will minimize adverse outcomes and minimize the risk of unintended consequences. This is essential because, depending on the level at which a potential UPL is established or how MD envisions it being implemented, the result could create product access barriers or could even increase costs for patients.

Problematic Assumptions within the Cost Review Study Process and Cost Effectiveness Analysis

BIO also urges the LPC to not move forward with the Draft Plan given the widely inappropriate and discriminatory nature of the proposed use of cost effectiveness analysis. As the Draft Plan itself states, the cost-effectiveness analysis would "estimat(e) how much it costs to gain a unit of a health outcome, like a life year gained or a death prevented." Cost-effectiveness analysis anchors to composite health metrics - such as the quality-adjusted life year (QALY) - that have been proven to have discriminatory properties. Due to issues of discrimination, cost-effectiveness and the QALY have been banned from use in price setting decisions at the federal (i.e., IRA) and State level - with Colorado, Oregon and Washington including QALY bans and other provisions in their PDAB legislation that helps to ensure equal valuation of drugs. Stakeholders, including disability advocates and bioethicists, continue to express concern that evidence that uses these discriminatory approaches would devalue the lives of the disabled, the chronically ill, seniors, and communities of color. Indeed, the Federal government has found the use of QALYs or similar measures to be inherently discriminatory to patients with chronic disease and disability.[3] BIO urges MD to ban the use of QALYs in their PDAB processes, thereby removing the use of cost-effectiveness analysis anchored to the QALY from their proposed methods for determining the UPL.

The Draft Plan also contains problematic assumptions within the Cost Review Study Process. The Draft Plan states that the Board will consider different factors including various drug prices at different points in the supply chain. This fails to consider the significant complexity of the pharmaceutical supply chain and all the price concessions given to all entities that purchase or cover a given drug across the supply chain. Considering price concessions in a supply chain would entail information from potentially hundreds of different stakeholders and require entities to divulge their own proprietary data, and possibly even protected health information (PHI).

Inadequate Consideration for the Manufacturing Complexity Needed to Develop Valuable Innovative Therapies

The proposed Draft Plan does not adequately account for drugs with complex manufacturing processes. Many innovative therapies require sophisticated, costly, and often bespoke manufacturing processes. These can include specialized facilities, highly trained personnel, and rigorous quality control measures. The costs associated with these complex manufacturing processes are ongoing and can be substantial, extending well

[3] "Quality-Adjusted Life Years and the Devaluation of Life with Disability," National Council on Disability, November 6, 2019.

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beyond the initial R&D phase.

For rare disease treatments, manufacturing complexity is often even more pronounced. Many rare disease therapies require highly specialized production processes, such as personalized cell therapies that must be manufactured individually for each patient, gene therapies that require complex viral vector production, and plasma-derived therapies that require extensive plasma collection, complex fractionation processes, and stringent safety measures.

The pharmaceutical industry is rapidly evolving, with new types of therapies constantly emerging. The proposed UPL process may not be agile enough to adapt to novel treatment modalities, such as cell and gene therapies, or innovative pricing models like value-based contracts. In the rare disease space, flexibility is particularly crucial. Many rare disease treatments have very different development pathways, manufacturing processes, and value propositions compared to traditional drugs. A rigid UPL process could struggle to appropriately assess and price these innovative therapies, potentially discouraging their development or limiting patient access.

Potential Disclosure of Confidential, Proprietary, and Sensitive Information

As BIO has stated in previous comments, we continue to be concerned by the extensive amount of information that will be collected as a part of the Draft Plan, including potentially confidential, proprietary, and sensitive information. Despite this significant concern, the Draft Plan does not provide any mention of how such information shared with the Board will be treated. It is essential that the Draft Plan needs to stipulate that the document being shared with the public would not include any confidential and proprietary information shared by manufacturers or other stakeholders.

Lack of Clear Guidelines Around Proposed Information Gathering Process

BIO remains concerned that the Draft Plan does not provide any reasonable limits to the Board's authority to gather information. As it stands, the unrestricted ability of the Board to collect information could lead to inappropriate or excessive attempts to gather information at any point throughout the process. It is essential that the Draft Plan include guardrails around the information that can be considered and how it can be utilized to establish a UPL. Throughout the process, it is critical that stakeholders are always informed about what information is being collected and why, and that the Board provide stakeholders with a meaningful opportunity to object or provide input.

Lack of Appeals Process and Other Safeguards

BIO is also concerned that the Draft Plan does not contain any mention of an appeals process. As stated in previous comments, Section 21–2C–14 of the statute clearly requires there to be an appeals process for Board decisions. Given the complexity of drug pricing and the potential for misunderstandings or overlooked factors in the UPL setting process, a robust appeals mechanism is crucial to ensure fair and accurate pricing decisions. For rare disease treatments, an appeals process is even more critical. These drugs often have unique development stories, complex manufacturing processes, and nuanced value propositions

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that may not be fully captured in standardized assessment processes. An appeals process would allow rare disease drug manufacturers to present detailed, case-specific information that might be overlooked in the initial UPL setting process.

For these reasons, BIO urges the LPC not to move forward with the Draft Plan. We also encourage the LPC to not move forward with any expansion of the PDAB in future legislation, and look forward to continuing to work with the LPC to ensure Marylanders can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact me at 202-962-9200.

Sincerely,

/s/

Melody Calkins
Director,
Healthcare Policy and Reimbursement

COMMUNITY ACCESS NATIONAL NETWORK

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October 18, 2024

Maryland General Assembly
Legislative Services Building
90 State Circle
Annapolis, MD 21401

RE: OPPOSE: Proposed UPL Action Plan

Honorable Members of the Maryland Legislative Policy Committee,

The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions.

Today, we write with comments regarding the proposed Upper Payment Limit Action Plan.

The Cost-Benefit of a UPL Does Not Serve Maryland Patients

The Oregon Prescription Drug Advisory Board recently contracted with Myers and Stauffer, independent consultants, to analyze the potential cost savings of implementing a UPL. While Maryland and Oregon are two different states, both have large numbers of citizens dependent upon Medicaid and safety net entities.

The consultants noted a few concerns that are particularly important to under-served and marginalized communities highly impacted by health disparities. The most noted is that the imposition of a UPL on a best-case basis may produce less than half a million dollars in “savings” to Oregon’s Medicaid program due to reductions in rebate values applied to the program. The UPL does not consider the negative fiscal impact of potentially reducing federal matching dollars (FMAP) in assisting the state of Oregon in meeting its Medicaid population’s needs. This mirrors the concern we further detailed in this letter regarding Maryland’s Medicaid shortfalls.

Moreover, their report indicated that Medicaid rebate reductions as a result of a UPL would be mirrored by a similar reduction in 340B discount values. For 340B covered entities serving marginalized populations and otherwise operating as safety net entities, such a reduction would likely prove damaging to patient affordability and access and harmful to the financial sustainability of these entities, particularly federally qualified health centers.

Simply put, a UPL does not serve either the "health system" as a whole or patients living in Maryland. CANN continues to urge the Maryland Legislature and the PDAB to weigh the potential of minor benefits relative to significant concerns in these regards.

Should the Board or Legislature seek to impose a UPL, the Legislature must be prepared to seek additional appropriations to support the state's Medicaid program, AIDS Drugs Assistance Program, and safety net providers, like FQHC's, or risk reducing meaningful access to care for the state's most vulnerable populations.

Draft Plan Lacks Specificity of Definitions, Stakeholders, and Goals

The first page of the document states that the Board may conduct cost review studies to determine whether the use of a medication "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients ("affordability challenges"). There is further explanation that if a medication is deemed to pose an "affordability challenge", the Board can use remedies such as a UPL in response to the challenge.

Our concern with the opening sentiments is we do not perceive that the Board currently has a definition of what is or is not "affordable". With a lack of consensus on what defines "affordability", one cannot feasibly go one step further and delineate a drug as presenting an "affordability challenge". This is a matter of defining goals and endpoints of what will be achieved by enacting something such as an "upper payment limit" (UPL, alternatively "reimbursement cap"). Without having a consensus on what affordability looks like for various stakeholders and why the subsequently selected parameters of affordability best meet all parties' needs, one cannot move forward.

Similarly, the Draft Plan does not specify to which stakeholders a UPL should be "benefiting". Lacking a definition of "affordability" also means lacking a definition of "affordability for whom?" – Failing to specify these definitions, several states, including Maryland, already engaged in PDAB work have quite readily conflated "patient affordability" with "PBM profitability", which results in perverse incentives and perspectives, usurping any potential patient impacts with the priorities of for-profit companies. If the goal of a UPL is to serve patient-consumer needs, a reimbursement cap may not directly affect a patient-consumer's premium payments, co-pays, or other plan design concerns. If the goal of a UPL is meant to serve the plan sponsor's budgetary concerns, fiduciary duty requires the Board to consider potential unintended consequences relative to state-based payor programs like Medicaid, AIDS Drug Assistance Programs, and broader funding considerations for public health partners like hospitals and federally qualified health centers.

We detail these concerns with more specificity below.

Medication Shortages

On page two, the draft document states: "A UPL may not be applied to a prescription drug product that is on the federal Food and Drug Administration prescription drug shortage list. HG § 21-2C-13(c)(1). The Board shall

also "[m]onitor the availability of any prescription drug product for which it sets an upper payment limit," and "[i]f there becomes a shortage of the prescription drug product in the State, reconsider or suspend the upper payment limit."

As of the time of this letter, certain formulations of two of the Board's selected medications are in "shortage", according to the FDA.

- Dulaglutide, injection (3mg/0.5ml and 4.5mg/0.5ml), representing two (2) of four (4) dose formulations.

- Semaglutide injection (0.25mg/0.5ml), representing one (1) of eight (8) dose formulations.

While CANN has no means of estimating the market share of these dose formulations, the Board must make a diligent effort to understand the dynamics of these shortages, including the role and danger of "compounding" and other counterfeit drugs currently being marketed to patients who would benefit from semaglutide. Counterfeits pose an exceptional threat to patient-consumer safety and the United States drug supply chain. Specifically, the Board should consider consulting expertise on how a UPL might further counterfeit medication sales by creating an artificial and unsustainable business model for retail pharmacies. Maryland patients deserve to enjoy the supply chain security the rest of the country experiences, and this Board must also consider how its actions may undermine that security.

Additionally, we want to highlight that this emphasis on shortages as described in the Draft Action Plan, in itself, is an acknowledgment that instituting a UPL can potentially cause access problems for patients. While a UPL may not create a nationwide "shortage" as would be identified by the FDA's shortage database, insufficient reimbursement can create "medication deserts" by harming the sustainability of retail pharmacies as a business.

At this point, most of the Board's deliberations and energies seem to be focused on arriving at UPLs without equal consideration for the exploration of other options or consideration of confounding, factual information which might lead the Board to alternative conclusions. The Board must not decide on actions and then seek to justify them; instead, they should identify appropriate information prior to determining any particular action.

Criteria for a UPL do not Address Patient Experiences and are Insufficient

On page 3, under the section, 'Criteria for Setting an Upper Payment Limit,' several bullet points deserve consideration.

Bullet two: The Board shall determine that an upper payment limit is an appropriate tool to address the driver(s) of the affordability challenge identified for the prescription drug product

This bullet directly mirrors our concern that presently, without consensus on affordability or affordability challenges, it is not possible to conclude that a UPL is an appropriate solution.

Bullet five: The Board shall prioritize drugs with a high proportion of out-of-pocket costs compared to the net cost of the drug.

Out-of-pocket costs to patients are controlled by plan design, which includes formulary placements and cost share. A proposed UPL will not necessarily benefit patients' out-of-pocket costs, particularly for patient-

consumers participating in Medicaid, as most medications utilized by Medicaid beneficiaries do not have any out-of-pocket cost in which to consider Moreover, the assumption that a UPL may help with system costs is also not guaranteed, given the opaque nature of pricing in the drug supply chain. Furthermore, should the imposition of a reimbursement cap manifest in "medication deserts" or otherwise harm tangible access to these medications, "system" costs will increase as patients experience poorer health outcomes commonly associated with lack of access to medications.

Coincidentally, a UPL could increase Maryland' s state out of pocket costs by adversely affecting its Medicaid spending. More than one-quarter of the state's population is enrolled in Medicaid. Recent reporting indicates that Maryland is facing almost one billion dollars in projected budget deficits, with an estimated eight hundred million dollars of that as projected Medicaid shortfalls. The amount of federal dollars allocated to the state to help pay for Medicaid services is based on Federal Medical Assistance Percentages (FMAPs). FMAPs determine the matching federal funds based on the state expenditure. If UPLs drastically affect Medicaid expenditures, Maryland would receive fewer federal matching dollars, thus requiring increased state spending on Medicaid services. Conversely, instead of increasing state spending, a response to less funding could be cutting Medicaid services which would be deleterious to the health outcomes of the 1.7 million Maryland residents who depend on Medicaid.

Prior to any action by the Board, the Board must appropriately inquire with Maryland's Medicaid program to better understand any unintended budgetary consequences of imposing a UPL. The Board must consider Maryland's fiduciary duty to Medicaid and its intended beneficiaries as part of information gathering.

Cost Review Study Process is Opaque and otherwise Unspecified

Under the section labeled 'Cost Review Study Process,' the draft document states a cost review study involves: **"Board staff compiling and analyzing quantitative data, qualitative data, and public input for the Board to consider and determine whether use of the drug has led or will lead to affordability challenges. This study process informs subsequent policy action."**

Presently, we do not perceive much qualitative data gathering pursued or any robust pursuit of patient input or engagement. If the Board's purpose is to address patient-consumer experiences and concerns, the Board and its staff must take more meaningful action to engage patients. Failure to do so proves the unfortunate concern that the Board has already determined a conclusion and is merely seeking to justify that pre-determined conclusion rather than engaging in a good-faith exploration of data and experiences.

The section also specifies that **"the Board may request that manufacturers submit documents explaining the relationship between the price of a prescription drug product and the cost of development and therapeutic benefit…".** We inquire as to how comparing a manufacturer's price of a drug to what they spent on the research and development costs of the drug affects the Board's determination of the affordability of a drug for patients and the system and how a UPL factors into the results of said comparison. Furthermore, manufacturers, not the FDA, are largely tasked with continuous monitoring of drug supply chain safety and security, dedicating whole teams of employees and contractors to manage, investigate, and address bad actors exploiting the lack of government involvement in supply chain security. These are continuous costs which must be considered as equally important as current costs of manufacturing and development.

Methodologies for Establishing a UPL Open the Door to Discriminatory Selection

We have multiple concerns regarding the section discussing possible methodologies to be used to establish a UPL on pages nine and ten.

Cost Effective Analysis – This section, in essence, describes the theory of utilizing QALYs. QALY theory and practice puts a price tag on the value of a year of life. QALYs arbitrarily define a monetary value on what is defined as a full year of life in perfect health. Any drug whose utilization does not offer a full year of life or provides less than a full quality of life is considered less of a priority for usage or reimbursement and is scored lower.

The entire QALY methodology (i.e., Cost Effective Analysis) is built upon subjective value judgments. It is detrimental to public health to arbitrarily attribute a value to a perfect year of health and use that for universal efficacy cost comparisons.

QALYs disadvantage people with disabilities as well as those with chronic health conditions because these populations will never be able to achieve what is defined as the "highest quality of life." Drugs treating these populations would be considered of lower priority and value because their potential of returning patients to perfect health is much lower than the potential of ideal health offered by medications utilized by younger people and those in better health states.

Moreover, Congress has already banned the use of QALY theory in cost effectiveness reviews in the Medicare program. The following link directs to a study from the Pioneer Institute discussing the need for extreme caution in this line of cost-effective analysis. (LINK)

Therapeutic Class Reference Upper Payment Limit – This section discusses limiting drugs within the same therapeutic class to be included in reference baskets for setting UPLs by therapeutic class. We urge caution in any therapeutic equivalency comparative effectiveness dialogue as many nuanced factors are involved. Two crucial factors are the differences in the way different patients respond to the same drug as well as the potential to undermine the doctor-patient relationship by possibly interfering with the physician's recommended treatment priority.

Domestic Reference Upper Payment Limit – We urge caution in making decisions based on prices paid by other purchasers. Due to the opacity of the drug supply chain and pricing process, it isn't possible to gain robust details on how a particular purchaser arrived at their net price. Using another payer's situation could have unforeseen negative consequences on the best interests of the Maryland system.

International Reference Upper Payment Limit – Drug prices paid in other countries should not be considered. Seeking drug pricing information from other countries would be comparing apples to oranges, providing no translatable correlation. Other countries' markets are very different from those in the U.S., including those with a single-payer system and vastly different means of price control. Additionally, other countries' pricing methodologies include QALYs and other discriminatory designs. Thus, utilizing drug pricing information from other countries is a 'backdooring' of prohibited metrics.

Conflict of Interests in Consultants Must be Addressed

The Board must consider conflicts of interests in pursuing any consulting agreements for data analysis. Particularly, the Board should consider those entities funded by the same funding interests that presented authorizing legislation as necessarily conflicted and prohibit any contracting with those entities. Similarly,

Board members with these same conflicts should be prohibited from serving; at this time, at least one Board member has received exceptional funding from Arnold Ventures, the fiduciary sponsor of NASHP's model PDAB legislation.

Policy Conclusions are Nonspecific

Under the Final Policy Action section on page 12, the draft document states: "The policy review process culminates in the adoption of: (1) other (non-UPL) policy recommendations; (2) proposed regulations setting the UPL at the specified amount; or (3) both.

Our concern is that this section and other places throughout the draft document allude to the possible utilization of non-UPL policy recommendations. Yet, there is no high-level nor detailed discussion of what those are or how they are being investigated. Additionally, potential non-UPL policy recommendations may require the Board to seek and obtain additional legislative authority to enable enforcement. The draft document does not indicate how this possibility would manifest and be executed. Nor does it specify how such a process would fit into and alter policy implementation timelines, including the necessary feedback from all stakeholders, including patients.

Continuous Monitoring for Patient Access is Unaddressed

The PDAB's enabling statute requires the Board to monitor impacts on patient access to care upon imposition of a UPL. However, the Draft Action Plan does not offer any specificity of establishing a monitoring system *prior* to establishing a UPL – failing it statutory obligation. A UPL must not be imposed prior to establishing both a monitoring system and baseline data.

We thank you for the opportunity to provide feedback on the proposed Upper Payment Limit Action Plan. We respectfully ask that you consider all the concerns raised.

Respectfully submitted,

Sincerely,

Ranier Simons
Director of State Policy
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network

HealthHIV

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Dear Members of the Legislative Policy Committee,

HealthHIV remains committed to advocating for the health and well-being of Persons Living with HIV (PWH) and individuals vulnerable to HIV transmission. We appreciate the Maryland Prescription Drug Affordability Board's (PDAB) efforts to address the affordability of prescription drugs for Marylanders. However, we wish to express to the Committee our long-standing, unresolved (but remediable) concerns regarding the Upper Payment Limits (UPLs) plan set for review.

The UPLs aim to allow the state to negotiate through the establishment of upper payment limits on selected drugs–often essential lifelong (and with HIV lifesaving) medications. However, we are apprehensive about the potential impact these limits may have on the comprehensive care continuum that HIV service providers already offer, particularly its effect on the AIDS Drug Assistance Program in Maryland (MADAP) and aligned 340B providers (*both FQHCs and community-based organizations*).

Implementing UPLs without fully considering the rebate and discount structures of ADAPs and 340B programs could severely limit the resources available for patient care. Any disruptions in access to necessary medications due to UPLs could increase HIV transmission rates and overall healthcare costs, undermining public health progress.

We urge the Committee to carefully consider the following:

1. **Exempt HIV Medications from UPLs:** Exempting these medications would help safeguard the financial stability of ADAPs and 340B providers, ensuring uninterrupted access to essential treatments.
2. **Engage with HIV Service Providers:** Actively engage with MADAP and ADAPs—and 340B covered entities (FQHCs and Community-Based) to understand the full implications of UPLs on HIV care.
3. **Consider Long-Term Impact:** Evaluate the potential long-term public health consequences of UPLs, including the risk of increased infections and healthcare costs due to reduced access to medications.

We are prepared to collaborate with the PDAB to ensure that any policies implemented protect the interests of PWH and maintain the integrity of the HIV care continuum.

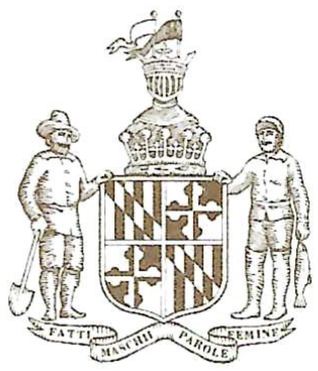
Thank you for your attention to this critical issue.

Scott D Bertani, MNM PgMP

Director of Advocacy for HealthHIV

Bonnie Cullison
Legislative District 19
Montgomery County

Health and Government Operations
Committee



The Maryland House of Delegates
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THE MARYLAND HOUSE OF DELEGATES

Annapolis, Maryland 21401

Madam Speaker, Mister President, and Members of the Legislative Policy Committee;

I write to you today to ask for your favorable consideration and approval of the Upper Payment Limit Action Plan that has been presented to you by the Prescription Drug Affordability Board.

As leaders of the Maryland General Assembly, you are acutely aware of the impact that the skyrocketing cost of prescription drugs has on our constituents and our state's health care system. Whether it's through our out-of-pocket costs, our insurance premiums, or our taxpayer dollars, we are all hurt by the high cost of prescription drugs. Thankfully, under your guidance, Maryland has led the nation in innovative solutions to this issue, particularly with the 2019 establishment of the landmark Prescription Drug Affordability Board. Today offers an important opportunity to advance the Board's work by approving the Upper Payment Limit Action Plan presented, which is designed to address prescription drug costs for state and local government entities. I urge your support for this measure.

I have been involved in efforts to support the Board since 2019, when I led the floor discussion of Chair Peña-Melnyk's bill.[i] Since then, the Maryland General Assembly has established a funding mechanism,[ii] and the Board has delivered reports on the supply chain[iii] and shared their expertise on prescription drug affordability issues before the body. The diverse Stakeholder Council has been actively involved in providing and analyzing data to ensure that the Board makes informed decisions and recommendations. I am confident that the Board members and its staff are well-equipped to do this work thoughtfully in ways that balance the need for consumer affordability with the revenue needs of suppliers.

While I ultimately hope that we can soon expand the authority of the Board to address the high cost of prescription drugs for *all* Marylanders, this initial step presented before you today will mark significant progress for our state. Over the years, we have heard from several local leaders that prescription drug costs present a significant challenge to their budgets, with the cost of employees' prescription drug coverage limiting the other public services that can be provided.[iv] I urge your swift approval of this plan so that the Board may begin this work and establish select upper payment limits that could be included in future state and local government contract negotiations, helping to alleviate burdens on our government budgets.

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[i] https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/hb0768/?ys=2019rs
[ii] https://mgaleg.maryland.gov/2020RS/bills/hb/hb1095T.pdf
[iii] https://pdab.maryland.gov/Documents/reports/Health%20General%20Article%20§%2021-2C-07-%20Prescription%20Drug%20Affordability%20%20Board-%20Supply%20Chain%20Report.pdf
[iv] https://pdab.maryland.gov/documents/stakeholders/CEs_memo_to_pdab_complete.pdf

DCAN
DERMA CARE ACCESS NETWORK

10/2/24

Legislative Policy Committee
Maryland General Assembly
90 State Circle
Annapolis, MD 21401

Dear Members of the Legislative Policy Committee,

On behalf of the Derma Care Access Network, I am writing to express concerns regarding the Maryland Prescription Drug Affordability Board's (PDAB) Upper Payment Limit (UPL) Action Plan. We respectfully request that the Legislative Policy Committee reject the plan as it currently stands, as it fails to adequately address the complexities of the healthcare ecosystem and instead presents an oversimplified approach to drug pricing.

The Derma Care Access Network is a coalition of more than two dozen advocacy organization representing patients, health providers, and other skin health stakeholders working to raise awareness and inform polices impacting patient-centered care.

While we recognize the importance of addressing affordability challenges within Maryland's health care system, the UPL proposal places sole emphasis on list price and fails to account for the broader systemic issues driving high drug costs. Notably, the plan neglects the roles played by pharmacy benefit managers (PBMs) and insurance companies, both of which are critical to understanding the full picture of prescription drug pricing and patient access.

PBMs, in particular, have been scrutinized by the FTC for their opaque pricing practices and powerful influence. These practices often lead to inflated costs to consumers, providers, and payers alike. Without requiring steps to address the influence of PBMs and their control over drug formularies, rebates, and out-of-pocket costs, any attempt to regulate drug prices through UPLs will miss a significant portion of the problem.

Similarly, the plan does not tackle the increasing use of practices by insurance companies that frequently shift the burden of drug costs onto patients. High deductibles, copayments, and formulary exclusions are just a few ways in which insurers can exacerbate the cost burden, regardless of the initial price set by manufacturers.

Moreover, we believe that the UPL Action Plan's current process lacks sufficient input from those who will be most affected by these policies: patients and clinicians. It is crucial that the Maryland PDAB has a clear and transparent process that incorporates testimony from healthcare providers, patients, caregivers, and other relevant parties. These individuals bring valuable firsthand insights into how these decisions will impact patient care and access to medications.

The Derma Care Access Network believes that the UPL Action Plan lacks the necessary depth and insight to meaningfully lower healthcare costs for Maryland residents. We urge the Committee to reconsider this approach and instead recommend a comprehensive analysis of the healthcare system, one that scrutinizes the roles of PBMs, insurers, and all other stakeholders in the pricing chain.

Thank you for considering our perspective, and we look forward to further discussions on how we can work together to ensure affordable healthcare solutions that address the root causes of high drug prices.

Sincerely,

Killian Lozach
Director of Policy and Advocacy
Derma Care Access Network

Written Testimony of Dr. Klint Peebles, MD, Before the Maryland Legislative Policy Committee Regarding the Upper Payment Limit Action Plan

October 22, 2024

Legislative Policy Committee
Department of Legislative Services
Annapolis, Maryland 21401

RE: Concerns regarding the Upper Payment Limit (UPL) Action Plan proposed by the MD Prescription Drug Affordability Board

Dear Chair and Members of the Legislative Policy Committee,

My name is Dr. Klint Peebles, and I am a board-certified dermatologist with Kaiser Permanente, serving both Washington, D.C., and suburban Maryland, the latter constituting more than 75% of my current practice. In addition to my clinical practice, I serve as the Chair of the American Academy of Dermatology's Access to Dermatologic Care Committee and sit on the Academy's Council on Government Affairs and Health Policy. I also serve on the editorial board of the Journal of the American Academy of Dermatology and co-chair the journal's diversity, equity, and inclusion workgroup. Additionally, I sit on the board of directors for the Medical Society of the District of Columbia and am Chair of the society's advocacy committee. Importantly, I also serve on the board of the Derma Care Access Network, where I help lead advocacy initiatives that increase timely and affordable access to patients living with skin conditions. My experiences and diverse skillset allow me to understand the intricacies of healthcare access, especially for vulnerable populations and patients with complex medical needs.

I am here today to voice my concerns regarding the Upper Payment Limit (UPL) Action Plan, recently approved by the Prescription Drug Affordability Board. While the plan seeks to address the growing burden of prescription drug costs, its current form may inadvertently pose serious risks to patient health and access to necessary medications, especially those who rely on complex treatments.

1. **Specificity on Upper Payment Limits**

The current UPL-setting process lacks sufficient specificity in defining the adverse outcomes and unintended consequences it aims to avoid. During the Board's September meeting, there was considerable ambiguity around these concerns, which should not be

overlooked when dealing with essential medications. Metrics such as QALY (Quality-Adjusted Life Year) pose a significant risk of being biased against certain patient groups, especially those with chronic or rare conditions, both of which I encounter every day in my practice.

2. Adverse Outcomes for Patients

The UPL Action Plan does not sufficiently address the risks to patient access, particularly for those with chronic conditions that require long-term, stable medication regimens. A forced switch due to pricing changes could have detrimental health consequences, leading to symptom flare-ups, side effects, or more severe adverse health outcomes. Physicians like myself who prescribe complex biologics such as dupilumab (Dupixent) and risankizumab (Skyrizi) have seen the adverse outcomes of non-medical switching, which poses a real risk under the current plan. If UPLs force price-driven medication changes, patients reliant on these treatments may suffer worsening health, ultimately increasing the burden on healthcare resources.

3. Addressing Patient Savings

The Action Plan does not outline mechanisms to ensure that cost savings from UPLs will translate into lower out-of-pocket expenses for patients. While cost-containment for insurers and pharmaceutical companies is important, it is vital that these savings directly benefit patients. Without provisions for reducing deductibles, co-pays, and co-insurance, Marylanders may not see any financial relief, even if drug prices are regulated.

Additionally, it has been well documented by the FTC that utilization management tools imposed by Pharmacy Benefit Managers lead to delays in accessing treatment and patient care. This drives negative health outcomes and increased cost associated with emergency room visits for your state. We encourage the Legislative Policy Committee to direct the Maryland Prescription Drug Affordability Board to investigate how these supposed 'cost-containment' tools are increasing costs for the larger Maryland healthcare system.

Conclusion

While the goal of reducing healthcare costs is commendable, it is critical that the UPL Action Plan be revised to prioritize patient health, maintain access to necessary medications, and ensure that cost savings are passed on to patients.

I respectfully urge the Committee to oppose this plan as it currently stands, and to re-direct the Maryland Prescription Drug Affordability Board to consider these concerns and

ensure the UPL Action Plan is refined to better serve the people of Maryland, particularly those who rely on complex, life-saving treatments.

Thank you for your time and consideration. I am happy to provide further insights or answer any questions you may have.

Sincerely,
Dr. Klint Peebles, MD

October 18, 2024

VIA ELECTRONIC FILING

Senator Bill Ferguson, Chair
Delegate Adrienne A. Jones, Chair
Maryland Legislative Policy Committee
Annapolis, MD 21041

RE: GSK's Response to Maryland's Upper Payment Limit Setting Process

Dear Senator Ferguson and Delegate Jones:

GSK appreciates the opportunity to submit testimony to the Committee regarding the Maryland Prescription Drug Affordability Board's (Board) Plan of Action (Plan) for Implementing the Process for Setting Upper Payment Limits (UPLs) ahead of its hearing on October 22, 2024. GSK is a science-led global healthcare company with a special purpose to unite science, technology, and talent to get ahead of disease together. We focus on science of the immune system, human genetics, and advanced technologies to impact health at scale. We prevent and treat disease with vaccines, as well as specialty and general medicines. GSK supports policy solutions that transform our healthcare system into one that rewards innovation, improves patient outcomes, and achieves higher value care.

Below, GSK highlights several concerns regarding the Board's proposed Plan and recommends alternative strategies to ensure patient access to life-saving medications. Overall, we object to UPLs, as they may impact provider and health plan net costs if medications subject to a UPL no longer qualify for multi-product discounts. Additionally, the Board's proposed Plan does not address how a UPL would interact with existing pricing and reimbursement mechanisms.

Monitoring, Suspending, and Rescinding a UPL
The Plan requires that the Board establish a process for monitoring drug availability and adopting regulations for suspending, modifying, and rescinding a UPL. The Plan does not, however, provide a timeline for adopting these regulations. As we state above, it is likely that the UPL setting process will impact provider and health plan net costs, resulting in service disruptions and patient access challenges. As such, it is important that the Board implement its process for monitoring, suspending, and rescinding a UPL in a timely manner.

UPL Effectuation
While the Plan considers methodologies for establishing a UPL, the Plan does not consider nor characterize how the process would be effectuated. Without this necessary analysis and review, UPLs could create access barriers to essential medications and potentially increase costs for patients.

The Plan also does not clarify whether UPLs will be reimbursed at the purchaser (e.g., pharmacy) level, the health plan level, or both. If both, the Plan fails to propose any safeguards to mitigate

unintended adverse impacts to manufacturers, such as duplicate discounting. Duplicate discounting occurs when a manufacturer sells a drug at a statutory discount (e.g., UPL) to a purchaser and the manufacturer subsequently pays a rebate on that same drug to a health plan, which could result in the drug being sold below cost. Additionally, UPLs may adversely impact provider and health plan net costs if medications subject to a UPL no longer qualify for multi-product discounts, leading to instances where the savings from a UPL are less than the previous savings with muti-product or bundled discounts. Furthermore, the Plan does not address how a UPL would interact with existing pricing and reimbursement mechanisms. Insurance providers retain control over cost-sharing requirements, and this Plan does not consider that insurers are not required to pass along savings to patients, with or without the imposition of a UPL.

If a UPL is implemented at the purchaser level, the Plan does not identify any processes, including data needs, for how manufacturers will distinguish between UPL and non-UPL transactions. For example, the Plan does not include procedures for how manufacturers may distinguish between purchases made by entities (e.g., pharmacies, wholesalers) for whom a UPL is and is not required. For discount transactions, manufacturers can generally offer upfront discounts or provide the discount after the sale in the form of a rebate. In both cases, manufacturers require certain data to verify UPL transactions, where appropriate.

UPL Criteria and Data Considerations

The language and criteria explaining how a UPL will be determined and evaluated is vague and missing key details. Without pharmacy benefit manager (PBM)/plan transparency concerning rebates and fees, neither a manufacturer nor the State has visibility to actual plan net cost for a particular drug. For example, the Plan does not account for administrative costs such as PBM/plan retained rebates. It is not clear if the Board has visibility to PBM or health plan transactions such that unrelated administrative fees, spread pricing, and pharmacy claw backs end up benefiting the PBM or health plan more than the State and its employees.

While it seems simple enough for a manufacturer to offer rebates on a UPL medicine from wholesale acquisition cost (WAC) to the UPL, the Plan does not explain how the Board will ensure PBMs and health plans base State beneficiary cost-sharing on a UPL rather than the WAC price, which is the current practice. High out-of-pocket costs relative to a drug's net price are mentioned as a consideration when evaluating affordability, but a UPL would not be a solution to this problem and the Plan offers no examples of alternative affordability solutions that may be better suited to the underlying concern despite requiring the Board to consider them.

The Plan also fails to require consideration of the value that various therapeutic approaches can provide to patients. While it is likely that a therapy's impact on patient health outcomes and clinician input will surface during public meetings, it is not guaranteed nor required for Board consideration in determining affordability or the maximum value of a prescription medication. This appears to be a critical oversight in what the Board must evaluate in a UPL process.

Finally, the criteria listed for consideration when setting a UPL are not clear. The Plan says, "the Board shall not set a UPL for generic prescription drug products that have nine or more marketed therapeutic equivalents." However, this threshold is not explained or justified in any way. The Plan

also notes that the Board cannot set a UPL if usage is "minimal," but “minimal” is also not defined. Finally, the Plan does not define the term “affordability challenge.” Lack of formal definitions leaves room for inconsistent interpretation.

Furthermore, the listed methodologies for establishing the UPLs are not ranked or prioritized against one another, or against referenced cost offsets. This lack of order may lead to inconsistent criteria and considerations when applying UPLs to different drugs. The Plan also only alludes to cost offsets in passing; however, they are an essential part of the review process and should not be overlooked. This is particularly important in the case of vaccines and preventative medicines, for which an analysis of estimated costs avoided or averted by the preventative medicine is essential.

Many data elements are also missing from the Plan and the Plan fails to explain how the Board will validate data from various sources. The gaps in the required data could lead to incorrect conclusions which, in turn, may cause unintended harm to prescription drug access, research, and innovation in Maryland.

Transparency, Communication, & Stakeholder Engagement
The Board has a duty to ensure the most transparent, consistent, and public process possible. The methodology outlined in the Plan does not provide a clear timeline for stakeholder engagement, including the length of comment periods, frequency of hearings, and deadline for a final determination. Additionally, the process for collecting and incorporating public and stakeholder feedback is not outlined, and stakeholder input appears secondary to data and calculations.

International Reference Pricing (IRP)
While GSK disagrees with many of the UPL setting methodologies in the Plan, IRP uses fundamentally flawed reasoning and should not be included. Using IRP overlooks variations in drug pricing due to local market conditions, such as competition or negotiation practices. The use of IRP fails to account for variations in purchasing power, healthcare expenditures, cost of living, currency exchange rate fluctuations, and the fundamental differences among national health systems across the world.

The language in the Plan around which countries would be used for IRP leaves significant room for interpretation and potential bias within an already broken methodological approach. While the Plan lists the United Kingdom, France, Germany, and Canada, it only stipulates the Board may use the prices in the countries to set a UPL. The use of open-ended language leaves the opportunity for the Board to use data from other nations, which could lead to biases or inconsistent application of the Plan.

The language around IRP does not detail how the Board or Board staff plan to access pricing data from specific sources, nor does it explain how prices will be compared to data collected for prices in Maryland in instances where dosages or methods of administration may vary. This operational mechanism is key for this analysis and is notably absent.

The Plan also does not consider how using IRP might impact global trade practices and international availability of drugs, nor does it include a comparison of international pricing with local

health outcomes and treatment effectiveness data. Currently, the United States typically receives access to newly approved medicines more quickly than foreign countries with price controls, something that the Plan does not consider through its use of IRP.

Cost-Effectiveness Analysis and Value Assessment
The Plan suggests that the Board may utilize cost-effectiveness analysis (CEA) in UPL determination without providing much detail on the type of CEA that would be considered. CEA typically relies on use of Quality-Adjusted Life Years (QALY), which use is expressly prohibited for certain government programs in the United States, such as the Affordable Care Act and the Inflation Reduction Act. Multiple organizations, including the National Disability Council, have deemed this metric discriminatory for undervaluing health improvements among the sick, disabled, elderly, and other populations.[1] In other words, this approach may favor interventions used in healthier populations.

Similarly, any use of IRP as described above would inherently involve the use of CEA. The countries mentioned as references or benchmarks for the IRP all use value assessment, namely QALY-based CEA, to set prices. The value assessments used in these countries are specific to their own patient populations, which may look considerably different in terms of race/ethnicity, age, disease severity, and other characteristics. This fact, combined with the potential for discriminatory conclusions on product value, raises even more concerns about the use of IRP.

Recommendations
GSK welcomes the opportunity to provide specific recommendations for how the Plan may be amended to ensure patients maintain access to important medications:

1. **Define "Affordability Challenges":** The Plan should include a standard definition of "affordability challenges" that includes clear thresholds that must be met in order to establish a UPL.
2. **Reduce the List of Possible UPLs:** The current list of UPLs may lead to inconsistencies in the evaluation and application of UPLs. Applying different standards to different policy reviews will complicate deliberations and lead to an unintended reduction in access.
3. **Outline the Implementation Process:** Without clear structure in how a UPL will be implemented (including effective dates and applications), the result could create medication access barriers and increase costs patients pay at the pharmacy counter.
4. **Require Holistic Data Review:** The Board should require safeguards to mitigate unintended impacts, such as duplicate discounting, and potential interactions with existing pricing mechanisms.
5. **Require Insurers to Pass on Savings to Patients:** The Plan should require health insurers to pass on any savings from a UPL directly to patients. The Plan should also require that cost-sharing requirements are based on the UPL alone, and not on the WAC or other price benchmarks.

[1] Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series (ncd.gov)

6. **Establish a Clear Timeline:** The Plan should specify the timeline for implementing UPL effectuation processes and include clear deadlines for public comment that are enshrined in regulations to allow for effective engagement.
7. **Remove IRP from the Price Setting Methodology:** A UPL set through IRP overlooks key differences between the United States and the international market and would import the use of potentially discriminatory QALY-based methodologies. It fails to account for different pricing mechanisms and legal structures that will not translate to an American market.
8. **Remove Domestic Reference Pricing**: For many of the same reasons IRP should be removed from consideration, the Board should remove domestic reference pricing from consideration when establishing a UPL. Assuming equivalency between other negotiation programs, such as Medicare Maximum Fair Price or negotiations in other states, erases important nuances that may or may not exist in an evaluation of Maryland's spending.
9. **Consider Alternative Policy Solutions:** The Board should consider other policy solutions as alternatives to the establishment of a UPL, including requiring PBMs to pass along manufacturer rebates to patients at the pharmacy counter and closing policy loopholes in health insurer coverage that allow copay accumulator adjustment programs, copay maximizer programs, and alternative funding programs to interfere with patient cost savings.
10. **Impact on Pharmacies:** The Board and Legislative Policy Committee should fully investigate and research the implications of a UPL due to unintended consequences it may have on pharmacies.

Thank you again for your consideration of our testimony and for the opportunity to engage with the Committee. Please feel free to contact me at Christopher.J.Bryce@gsk.com with any questions.

Sincerely,

Chris Bryce
Director, State Government Affairs
GSK

TESTIMONY IN SUPPORT OF THE UPPER PAYMENT LIMIT ACTION PLAN

Before the Legislative Policy Committee

By Vincent DeMarco, President of the Maryland Health Care for All! Coalition

October 22, 2024

President Ferguson, Speaker Jones, and Members of the Legislative Policy Committee, on behalf of the over 450 faith, community, business, and labor organizations that comprise the Maryland Prescription Drug Affordability Coalition, we write today to strongly urge your support of the Upper Payment Limit Action Plan submitted for this committee's approval. Since 2019, Maryland's first-in-the-nation Prescription Drug Affordability Board has been working to address expensive medications and the impact these costs have on our state's residents, health care system, and government budgets. We are thrilled to see the Board moving forward with its work to take action to make prescription drugs more affordable for state and local government entities. We respectfully request that you approve the plan presented before you today.

We applaud Maryland's Prescription Drug Affordability Board, its Stakeholder Council, and its Staff for the thoughtful work they have accomplished thus far. Designed to examine the entirety of the supply chain, the upper payment limit processes established by the Board are the most comprehensive approach to prescription drug affordability to-date. While we hope that the Board's authority can ultimately be expanded to make prescription drugs more affordable for all Marylanders, the ability to establish upper payment limits for state and local government entities is a critical first step. We have heard from many local leaders from across the state that prescription drug costs are a significant burden, with the cost of employees' prescription drug coverage limiting the ability to provide other services. At a time when many government budgets are stretched thin, adopting the Upper Payment Limit Action plan would equip our state with the tools to bring meaningful relief.

Additionally, we would like to thank the members of the Legislative Policy Committee for your continued leadership, which has allowed Maryland to become an established trailblazer in prescription drug affordability efforts. While several states have followed suit in establishing Prescription Drug Affordability Boards, the approval of the Upper Payment Limit Action Plan would make Maryland poised to be the first state to enact an upper payment limit of some kind. We urge swift approval of this plan so that the Board can move forward with its important work.

Thank you for your consideration and for all the work the Maryland General Assembly has done to make this state a leader in health care access and affordability.

HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

October 18, 2024

Senator Bill Ferguson, Chair
Delegate Adrienne A. Jones, Chair
CC: Maryland Legislative Policy Committee
Department of Legislative Services
Annapolis, Maryland 21401

Healthcare Distribution Alliance
Testimony Opposing Upper Payment Limit Action Plan

Dear Senator Ferguson, Delegate Jones, and Honorable Members of the LPC:

On behalf of our member companies, the Healthcare Distribution Alliance (HDA) appreciates this opportunity to share our concerns with the Maryland Prescription Drug Affordability Board's Plan of Action for Implementing the Process for Setting Upper Payment Limits.

HDA is the national trade association representing pharmaceutical wholesale distributors, the vital link between roughly 1,400 pharmaceutical manufacturers and more than 180,000 pharmacies and other healthcare settings nationwide, including over 4,600 sites of care in Maryland. As background, **distributors do not set list prices or determine the amount patients pay for medicines, but rather are the logistical experts in the supply chain**. Distributors do not play a role in determining the amount patients pay for medicines, which medicines are included on formularies, benefit design decisions, or reimbursement rates for dispensing pharmacies. Their core business does not involve manufacturing, marketing, prescribing or dispensing medicines, nor do they set the Wholesale Acquisition Cost (WAC) or list price of prescription drugs, influence prescribing patterns, determine patient-benefit design, or impact what patients pay at the counter. Rather, our members serve as the logistical experts within the physical supply chain who ensure products are physically on pharmacy shelves where and when patients need them by executing manufacturer contracts and physically fulfilling pharmacy orders.

As a representative of such logistical experts, HDA would like to share our concerns that certain included proposals could have on the physical supply chain:

- **Domestic or International Reference Upper Payment Limits Would Have Adverse Outcomes and Unintended Consequences.** HDA appreciates language in the plan stating that the Board should consider the cost of administering the drug and delivering drugs to consumers; however, we would like to share our view that state-level UPLs on the purchases and reimbursement of drugs do not adequately reflect the fact that prescription drugs are bought and paid for in the United States.

The committee should be aware that establishing a state-level UPL would place a cap on in-state purchases but not out-of-state purchases. Even when allowing for a nominal fee, a healthcare provider may be unable to recoup costs for administering a product, and there would be little incentive or ability for them to continue to stock these medications. It is also important to note that many independent pharmacies are already struggling to maintain their businesses and reducing their ability to maintain overhead when dealing with specific medications would undoubtedly lead to further consolidation in the pharmacy and provider community.

Further, the federal Inflation Reduction Act of 2021 created the Medicare Drug Price Negotiation Program. Under this program, CMS will set a Maximum Fair Price (MFP) for certain prescription drugs. However, it is important to note that while the MFP represents the most that Medicare will pay for a drug, it does not change the "list price" of drugs, as set by manufacturers. Reductions in price to CMS will likely be achieved through a number of actions, such as rebates paid to Medicare. With very limited exceptions, a provider such as a pharmacy, hospital, or clinic that dispenses or administers drugs to patients must first purchase the physical product and then receive reimbursement to cover the cost of that product. The complex system in which prescription drugs are purchased and distributed from a manufacturer to a wholesaler, then to a healthcare provider, and finally to a patient involves numerous transactions between each entity and with insurance companies, pharmacy benefit managers, and government payers. At each step along the way, these transactions are subject to private negotiations and often involve complicated discount and rebate arrangements which often take place nationally, and cannot be adequately achieved at the state level. An international reference price also does not adequately take into account the way the nation's supply chain operates, and utilizing either MFP or international reference prices as a state-level UPL may result in some products being unavailable in Maryland. HDA therefore respectfully opposes the use of UPLs modeled on Medicare MFP or on international reference rates.

- **For supply chain stability, UPLs should not apply to drugs that have been in shortage anytime within the past 2 years.** Distributors work hard every day to help support a resilient supply chain; however, drug shortages are a serious issue facing the nation, and ultimately distributors cannot deliver products that are not available from manufacturers. HDA appreciates that this draft plan states that a UPL may not be applied to a prescription drug product that is on the federal Food and Drug Administration prescription drug shortage list, and that the Board will also monitor the availability of any prescription drug product for which it sets an upper payment limit, and reconsider or suspend the upper payment limit in cases of shortage. HDA would further recommend that the any final approved plan apply such policies to any drug that has been on the FDA's drug shortage list at any point within the past two years. This would further support the stability of the physical supply chain by ensuring that the manufacturing and supply of a drug recently in shortage can continue to stabilize, without undue hindrances. Additionally, HDA would like to raise that the UPL Action Plan does not instruct the PDAB to take into consideration drug shortages caused by consider supply disruptions from events such as hurricanes.

In summary, HDA is concerned with the overall disruption that establishing UPLs could have on the supply chain. UPLs may result in manufacturers choosing to no longer allow products with an established UPL to be sold into the state, or being forced to simply cease production of certain drug products. This could lead to a disruption in patient care, the need to identify new drugs to offset the product being removed from market, and potential shortages of products given the instability in the marketplace. With more states considering PDAB legislation and UPL policies, the resulting patchwork of state policies and pricing metrics for a variety of

pharmaceutical products will ultimately exacerbate the overall cost in the supply chain and create unpredictability in the marketplace as a whole- often without even impacting the out-of-pocket price that patients pay. These concerns have been echoed in other states considering establishing a UPL, most recently outlined in the Oregon PDAB Constituent Group Engagement Draft Report developed by Myers and Stauffer LC which noted that "an analysis of qualitative survey data found that more than half of respondents did not believe a UPL would result in cost savings, with many expressing concerns regarding loss of revenue, decreased patient access, and increased patient costs. A number of respondents also expressed concern that implementation of a UPL would result in increased administrative burden, infrastructure costs, and operational challenges." HDA is further concerned that these UPLs would be based on data collections that are currently underway by the PDAB without there being clear processes in place to protect the "consideration and discussion of proprietary, confidential, and trade secret information and that the board will have a closed session".

Thank you for the opportunity to share our concerns with the establishment of a UPL on drug products in Maryland and to further highlight the unique and critical role that wholesale distributors play in the supply chain. HDA is available to serve as further resource at any time- please contact kmemphis@hda.org .

Sincerely,

Kelly Memphis
Director, State Government Affairs
Healthcare Distribution Alliance

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COMMITTEE TO PROTECT HEALTH CARE

October 22, 2024

RE: Testimony in Support of the Prescription Drug Affordability Board's Upper Payment Limit Action Plan

Speaker Jones, President Ferguson, and Members of the Legislative Policy Committee,

Thank you for the opportunity to express our support for the Upper Payment Limit Action Plan under consideration today.

As a mobilization of physicians and health care professionals advocating for pro-patient policies to lower health care costs and expand access, the Committee to Protect Health Care strongly supports these efforts to tackle the skyrocketing costs of prescription medications. We know firsthand the burden these costs place on patients and families, and state governments, and are encouraged to see the Board moving forward with a decisive action plan that aims to make prescription drugs more affordable for state and local governments.

As physicians, we regularly see how unaffordable prescription drug prices force many patients to make impossible decisions between putting food on the table and paying high costs for the medications they need. We applaud the Prescription Drug Affordability Board's efforts to change this reality for patients across Maryland.

The Upper Payment Limit Action Plan offers a landmark step forward in Maryland's ongoing leadership on prescription drug affordability, and we believe this measure will provide real relief to government budgets, allowing for the reallocation of resources where they are needed most. We strongly urge your support of this plan.

Maryland's PDAB is uniquely positioned to drive this initiative. The Board's experienced staff and its five appointed members have taken a thoughtful and comprehensive approach to addressing the entire pharmaceutical supply chain. The proposed upper payment limit process, the most robust of its kind, would not only set fair prices for prescription drugs but also increase transparency in the system, benefiting patients and taxpayers alike. Moreover, the Board's unanimous vote to adopt the Upper Payment Limit Action Plan aligns well with recent federal action through Medicare negotiations enabled by the Inflation Reduction Act. With two prescription drugs identified for Medicare's Maximum Fair Price also being considered by this Board, there is an exciting opportunity to extend those savings to Marylanders.

Your leadership in establishing the Prescription Drug Affordability Board has already positioned Maryland as a pioneer in addressing prescription drug costs. By swiftly approving the Upper Payment Limit Action Plan, you will empower the Board to continue this vital work, ensuring Maryland remains a leader in protecting patients and taxpayers from exorbitant drug costs.

Thank you again for your commitment to health care affordability, and we urge you to move forward with approving this critical plan.

Sincerely,

Rob Davidson, MD, MPH
Executive Director

MARYLAND ASSOCIATION
OF CHAIN DRUG STORES

171 CONDUIT STREET, ANNAPOLIS, MD 21401 | 410-269-1440

Upper Payment Limit Action Plan
Maryland Legislative Policy Committee
October 22, 2024

On behalf of the chain pharmacy industry in Maryland, the Maryland Association of Chain Drug Stores (MACDS), which operates under the umbrella of the Maryland Retailers Alliance, is committed to supporting pharmacy providers, improving patient access, and lowering healthcare costs across the care continuum. With those priorities in mind, MACDS believes that the Upper Payment Limit provision must be considered and effectuated in a manner that ensures fair and adequate reimbursement levels for pharmacies. A failure to do so could have unintended consequences of restricting patient access, exacerbating pharmacy closures, and further decreasing pharmacy reimbursement to unsustainable levels.

Pharmacy Reimbursement Overview as Developed by the National Association of Chain Drug Stores

Pharmacy reimbursement should be comprised of two parts: 1) the product cost; and 2) a professional dispensing fee across payer markets (e.g., Medicaid, Medicare, commercial) to help ensure reasonable reimbursement and sustainable pharmacy services for beneficiaries. The dispensing fee is typically calculated to incorporate the costs of a pharmacist's time reviewing the patient's medication history/coverage, filling the container, performing a drug utilization review, overhead expenses (rent, heat, etc.), labor expenses, patient counseling, and more to provide quality patient care.[1] For example, under the 2016 Covered Outpatient Drug Final rule, in Medicaid, the Centers for Medicare and Medicaid Services (CMS) requires all states to adopt a more transparent reimbursement model.[2] CMS' final rule utilizes actual acquisition costs and a professional dispensing fee as a benchmark to balance the importance of both the need for affordable solutions and adequate reimbursement for actual costs incurred by pharmacies. In fact, to illustrate further, *Maryland Medicaid* performed a cost of dispensing (COD) study in 2020 that found on average, Maryland pharmacies, including specialty, spent $13.72 to dispense most medications. In the Maryland PDAB plan of action, Board staff are directed to consider the "cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs" when setting a UPL. Additionally, for non-specialty pharmacies only, the average cost of dispensing was $12.03 per prescription.[3] In order to maintain availability and access to certain prescription drugs for Marylanders, it is imperative that these cost considerations include *both* the product costs of the drug and a professional dispensing fee. Said differently, pharmacy reimbursement for prescription drugs subject to the Maryland PDAB's UPL should at a minimum cover pharmacy's cost to acquire and dispense or administer each drug.

Without necessary guardrails to ensure reasonable and sufficient reimbursement for community pharmacies, UPLs could inadvertently result in inadequate or below-cost reimbursement to pharmacy providers and pharmacies by failing to reconcile the difference between the UPL and the pharmacy's acquisition cost and cost to dispense the prescribed drug. This outcome could force pharmacies to either operate at a loss, be unable to stock certain medications that a UPL applies to, or worse, potentially close

[1] CMS defines the professional dispensing fee at 42 CFR § 447.502 https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-I/section- 447.502

[2] Medicaid Program; Covered Outpatient Drugs, 81 FR 5169 https://www.federalregister.gov/documents/2016/02/01/2016-01274/medicaid-program-covered- outpatient-drugs

[3] Maryland Department of Health Survey of the Average Cost of Dispensing a Prescription to Fee-For-Service Maryland Medicaid Participants https://health.maryland.gov/mmcp/pap/docs/MD_2018_COD_Report_final_report%20Jan%202020.pdf

their doors permanently—negatively impacting Marylanders by ultimately worsening patient outcomes, reducing medication adherence, and increasing prescription abandonment and hospitalizations. Careful consideration of the impact on pharmacies and the communities they serve is both necessary and invaluable to help avoid preventable adverse downstream consequences on patient access to essential medications and overall health outcomes.

Proposed Solutions to Ensure Marylanders' Continued Access to Affordable Medications

Members of MACDS, along with our partners at the National Association of Chain Drug Stores (NACDS), are concerned that UPLs have the potential to further exacerbate inadequate and unreasonable pharmacy reimbursement if they do not incorporate reasonable reimbursement methodologies and practices to help preserve patient access. When an affordability challenge is identified, Maryland PDAB should direct Board staff to ensure that any recommendations concerning the methodologies and criteria factors used to set a UPL must include a pharmacy's actual drug acquisition cost as well as a requirement for applicable payers to provide professional dispensing fees or administration fees aligned with the state's Medicaid's professional dispensing fee rates (discussed above) on any prescription claim subject to a UPL. This will ensure that UPLs do not further strain the already strained finances of pharmacies across Maryland. The Colorado PDAB has already set a precedent of incorporating a pharmacy dispensing fee in its UPL methodology. Furthermore, the Maryland PDAB should consider adjusting the UPL in a timely manner, similar to CMS, for selected drugs that fall below the aforementioned acquisition and dispensing costs so that Maryland pharmacies are not subject to underwater reimbursement from PBMs.

We appreciate the Maryland PDAB's sincere efforts to account for the impact of the Inflation Reduction Act's Maximum Fair Price under the new Medicare Negotiation Program and work to reduce prescription drug costs and enhance affordability for patients in the state. We welcome the opportunity to collaborate on the draft working document titled, "*Maryland Prescription Drug Affordability Board Plan of Action for Implementing the Process for Setting Upper Payment Limits*" to address these serious concerns, as all members of the pharmaceutical supply chain will likely be affected, including pharmacies. We strongly encourage the incorporation of adequate reimbursement safeguards for all pharmacies, as mentioned above, in all recommendations concerning the methodologies and factors used to set a UPL. We and NACDS will continue to recommend that the Maryland legislature and the Maryland PDAB ensure increased patient access and fair and adequate reimbursement for pharmacists, pharmacies of all sizes, and the Marylanders they serve.

Tagalicod, Dana

From: MD Legislative Coalition <mdlegislativecoalition@gmail.com>
Sent: Wednesday, October 16, 2024 9:14 PM
To: Necessary, Ryane; Tagalicod, Dana
Subject: Testimony in Support of the Prescription Drug Affordability Board's Upper Payment Limit Action Plan

Testimony in Support of the Prescription Drug Affordability Board's Upper Payment Limit Action Plan

Aileen Alex, Co-Lead
Maryland Legislative Coalition

October 22, 2024

Speaker Jones, President Ferguson, and Members of the Legislative Policy Committee, we thank you for the opportunity to express our support for the Upper Payment Limit Action Plan being considered for approval today. Since 2019, Maryland's first-in-the-nation Prescription Drug Affordability Board has been working to address the issue of high-cost medications, and the Maryland Legislative Coalition has been working to support these efforts.

The Maryland Legislative Coalition is composed of NGOs, individuals, and grassroots groups in every district in the state. We are unpaid citizen lobbyists supporting well over 30,000 activists. Since our inception in 2017, we have been conducting email campaigns and writing testimony in support of PDAB because Marylanders have no use for drugs that are too expensive. Almost all of our Coalition members struggle with high drug prices. They can't afford the copays. They can't afford to take medications that they need because those medications are priced out of reach. We want to see the Board fulfill its promise to all.

We are thrilled to see the Board moving forward with their work to take initial actions to address this issue in Maryland. The plan presented before you offers the opportunity to take the landmark step in making prescription drugs more affordable for our state and local government entities, bringing real relief to strained government budgets, and we urge your support of this measure.

The Prescription Drug Affordability Board is uniquely equipped to do this work. Both its staff and the five appointed Members have worked diligently to ensure that a thoughtful process was developed. Designed to include the entirety of the supply chain, the Board's upper payment limit processes are the most comprehensive approach to prescription drug affordability to-date, and these reviews could provide additional transparency across the system. The Board's unanimous vote to adopt the Upper Payment Limit Action plan is timely, as well, as we have recently seen federal action on prescription drug affordability through the Medicare negotiations made possible by the Inflation Reduction Act. Two of the prescription drug products with a newly determined Medicare Maximum Fair Price are also being considered by our Prescription Drug Affordability Board. Should the Upper Payment Limit Action Plan be approved, the Board could implement these federal rates as a state upper payment limit in time to impact upcoming prescription drug plan negotiations for state and local governments.

We thank you for the work that you have done as the legislative leaders of the Maryland General Assembly to make this state a leader in addressing the skyrocketing cost of prescription drugs. We urge swift approval of the Upper Payment Limit Action Plan so that the Prescription Drug Affordability Board can move forward with its important work.

MARYLAND TECH COUNCIL
ADVANCING LIFE SCIENCES AND TECHNOLOGY

October 18, 2024

Maryland General Assembly
Legislative Policy Committee Staff
Ryane.Necessary@mlis.state.md.us
Dana.Tagalicod@mlis.state.md.us

Re: Written comment on the Prescription Drug Affordability Board – Upper Payment Limit (UPL) Action Plan

Dear Legislative Policy Committee,

I write today as both the CEO of the Maryland Tech Council (the "Tech Council") and as the biotechnology representative on the Prescription Drug Affordability Board ("PDAB" or "Board") Stakeholder Council to comment on the *Prescription Drug Affordability Board – Upper Payment Limit Action Plan* (the "Plan"). The Tech Council is a community of nearly 800 Maryland member companies that span the full range of the technology sector. Our vision is to propel Maryland to become the number one innovation economy for life sciences and technology in the nation.

Maryland is one of the leading states in the nation for the concentration of life sciences companies and jobs. The State is rich in assets that make life sciences innovation possible – with 54,000 life sciences jobs, 2,700 life sciences and biotechnology companies, world class universities, and government agencies. These companies are a critical asset to Maryland's economy. We consistently urge policymakers to bear this in mind when considering new policies that could harm our life sciences ecosystem. To that end, the following are a number of concerns and observations on the Plan and how it impacts the life sciences community.

1. *We encourage patient out-of-pocket costs to be a primary consideration in the "cost review study process".*

The Plan states "In the cost review study, the Board may consider many different factors, including but not limited to the following: various drug prices at different points in the supply chain; price concessions, discounts and rebates; therapeutic alternatives; patient access; cost and comparative effectiveness analysis; cost sharing; clinical information; disease burden; gross spending and utilization data; shortage status; industry entity responses to requests for information; and public input."

We appreciate that the Board is attempting to look at the full picture and all of the factors that contribute to the price of a given medication, including discounts and rebates. However, the Plan does not specifically call out patient out-of-pocket costs as part of this analysis. If the primary goal of the PDAB is to reduce the cost burden for Maryland patients and families, then the amount of money a patient is paying out-of-pocket for a medication should be a primary consideration.

2. *The Plan does not specifically mention an analysis of the impact that Pharmacy Benefit Managers (PBM's) have on the price of a given drug.*

The Federal Trade Commission released a report in July 2024 titled "*Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies.*"[1] In relevant part, the report states that "PBMs serve as middlemen, negotiating the terms and conditions for access to prescription drugs for hundreds of millions of Americans. Due to decades of mergers and acquisitions, the three largest PBMs now manage nearly 80 percent of all prescriptions filled in the United States. They are also vertically integrated, serving as health plans and pharmacists, and playing other roles in the drug supply chain as well. **As a result, they wield enormous power and influence over patients' access to drugs and the prices they pay**."

One of the primary focuses of the Plan is the manufacturer's pricing for a given drug. However, that price is often artificially influenced by policies and practices of PBM's. Again, we appreciate that the Cost Review Study Process will examine "various drug prices at different points in the supply chain", but this language is not specific enough to give confidence that the Board will take a serious look at the influence of PBM's in drug pricing and ultimately on patient access and affordability. Any analysis that does not include the role of PBM's is insufficient to understand what drives the price of a given drug.

3. *The Plan is light on details about what alternatives to UPL's would be considered by the Board as part of the Policy Review Process.*

The Plan states that "If the Board determines that a prescription drug product has led or will lead to affordability challenges, the Board may consider, recommend, and implement policies to address those affordability challenges, including establishing an upper payment limit that applies to state and local governments and units." The Plan goes on to say, "because a UPL may not be the preferred policy solution for every affordability challenge, the Board may recommend other policy actions." The Plan states that the Board will conduct a "policy review process to study and assess what, if any, policy tools are best suited to redress the identified affordability challenges."

The Plan contains a fair amount of detail on how the Board will ultimately arrive at recommending a UPL. However, there is little to no information about what "other policy actions" could be recommended by the Board. It is difficult for manufacturers to prepare for other policy actions if the Board does not state what types of actions would be considered. The report seems to contemplate that the Board may not have the authority to pursue such other policy actions, stating that such actions "may include seeking additional legislative authority to implement a policy solution and providing policy recommendations to the legislature, state and local government partners, and others." It is difficult for the life sciences community to weigh the outcome of a possible UPL, which the Board does have the authority to implement, to other potential recommendations that the Board does not have the authority to implement. Given the potentially enormous ramifications of Board-imposed policy actions, we urge the Board to provide additional details on what else could be considered.

[1] Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies (ftc.gov)

4. *Once the Board determines that a UPL is necessary, the Plan does not contain sufficient detail on how the UPL will be implemented.*

The Plan does not contain specific information on how a UPL would be implemented if the Board determines that a UPL is an appropriate policy solution. Rather, the Plan states that "Board staff shall develop and present to the Board recommendations concerning the methodologies used to set a UPL for the subject prescription drug product." The Plan goes on list a number of methodologies and factors used in setting UPL's but contains little information on how the Board would select one over another and under what circumstances. We are concerned that the procedures for setting a UPL may be done administratively by PDAB staff rather than in another public plan that includes stakeholder review and comment. Adopting such procedures without public input would run counter to the Board's goal of transparency in its proceedings.

Thank you for the opportunity to comment and for your consideration of the issues raised herein.

Sincerely,

Kelly Schulz
CEO, Maryland Technology Council

October 18, 2024

Legislative Policy Committee
Department of Legislative Services
Annapolis, Maryland 21401
ryane.necessary@mlis.state.md.us
dana.tagalicod@mlis.state.md.us

Via Electronic Correspondence

RE: Prescription Drug Affordability Board's Upper Payment Limit Action Plan

Dear Members of the Legislative Policy Committee:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We are writing to provide written testimony on the Maryland Prescription Drug Affordability Board's Upper Payment Limit Action Plan.

As the Legislative Policy Committee reviews the Action Plan, Aimed Alliance urges the Committee to require the Board to revise its plan to:

(1) Incorporate patient perspectives;
(2) Mandate ongoing consumer engagement;
(3) Ensure that any savings are passed directly to consumers; and
(4) Prohibit the use of quality-adjusted life years (QALYs).

I. Prioritize Patients' Perspectives and Lived Experiences

Currently, the cost review study process established within the draft Action Plan would assess prescription drugs to determine if the drug "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients." Among the many factors that the Board would consider during the review, it would consider patient access, cost-sharing, and public input. Aimed Alliance appreciates these efforts to include the patient perspective and urges the Board to take additional steps to ensure the patient perspective and lived experience are appropriately weighted and considered during the review study process.

Research consistently demonstrates the benefits of involving patients in healthcare decisions. Studies show that patient inclusion leads to improved health outcomes, greater satisfaction with care, and reduced healthcare costs.[1] Including patients in health policy decisions also enhances the quality and accessibility of care.[2] Because patients are the primary beneficiaries of medications, their perspectives are necessary for accurately evaluating the value of these treatments. Engaging patients in decision-making provides valuable insights into disease

[1] Lisa Baumann, et al., *Public and patient involvement in health policy decision-making on the health system level – A scoping review*, 126 HEALTH POL. 1023-38 (Oct. 2022), https://www.sciencedirect.com/science/article/pii/S0168851022001919.
[2] *Id*.

management, access barriers, treatment preferences, and other important factors related to medication use.[3] Their firsthand experiences can help ensure that healthcare policies address the needs of those they aim to serve.[4] Including patient, provider and caregiver perspectives also enables the PDAB to access a wealth of firsthand knowledge that is essential for making well-informed and patient-centered decisions about prescription drug affordability and value.[5]

To ensure that the perspective of patients, caregivers, and providers are properly valued and included, Aimed Alliance urges the Committee to require the Board to explain in its report how consumer feedback was considered in rendering a decision on "affordability." Moreover, we urge the Board to work with advocacy and patient organizations to collect robust data on the impact of prescription drug costs on consumers. Importantly, the Board must make affirmative efforts to engage patients, providers, and caregivers, and cannot rely solely on advocacy organizations to bring these perspectives to the Board. Lastly, we urge the Board to exercise diligence when reviewing data from surveys and responses as many consumers may share information that is not applicable to the state's determination of affordability. For example, a Medicare beneficiary living in Maryland may comment on the affordability of a prescription drug despite their health insurance cost-sharing being established by the federal government. Ultimately, prioritizing the experiences of consumers with chronic conditions will help ensure the Board better address the needs of the populations these policies are meant to serve.[6]

II. Mandate a Continuous Consumer Engagement and Oversight Process

Aimed Alliance applauds the Committee for considering a variety of policy recommendations once a prescription drug has been deemed unaffordable. The drug pricing system in the United States is complex and UPLs may not directly impact the cost of prescription drugs for consumers. As such, diverse approaches are needed to ensure that consumers can afford and access their necessary medication.

While the proposal states the Board will consider public written comments throughout the UPL setting process, it does not address how the Board will monitor the impact of the UPL on access and affordability. Therefore, Aimed Alliances urges the Committee to ensure the Board's obligation to engage patients, providers, and caregivers extends beyond the UPL setting process to ensure UPLs do not impair or impede access to therapeutics with UPLs. Specifically, we urge the Committee to require the Board maintain an ongoing commitment to actively seek input from a diverse array of stakeholders, including patients, caregivers, providers and other community stakeholders.

As stated above, the obligation to continuously seek feedback on access and affordability for UPL selected prescription drug must include an affirmative obligation for the Board to engage these communities. Patients and caregivers often juggle work, family commitments, and treatment plans while also navigating complex healthcare systems to ensure optimal care for

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[3] Alex Krist, et al., *Engaging patients in decision-making and behavior change to promote prevention*, 240 STUDENT HEALTH TECHNOLOGY INFORMATION 284-302 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996004/.
[4] *Id.*
[5] *Id.*
[6] *Id.*

themselves or their loved ones. Therefore, the responsibility to be aware of and engage in the UPL-setting process should not fall solely on consumers; the Board should share the responsibility to engage these communities.

Ultimately, establishing clear channels for consumers to voice concerns regarding any access barriers from the implementation of UPLs is critical to ensuring equitable access to essential medications. By fostering a culture of transparency and responsiveness, the Board can effectively address emerging challenges that may arise following the implementation of UPLs.

III. Require Payors and PBMs to Pass UPL-derived Cost Savings to Patients

PDABs are intended to lower the cost for state payors and consumers. Currently, the proposed UPL process does not guarantee any savings for consumers. Because UPLs serve as a cap on what payors can reimburse for a drug, precise language is needed in the UPL Action Plan to ensure these savings are passed down to consumers. Under the currently proposed program, payors are likely to retain the benefits of these savings without alleviating the financial burden on patients. Therefore, the UPL-setting plan should incorporate statutory language requiring any cost savings resulting from UPLs to be passed on to consumers through reduced prescription drug costs or lowered cost sharing requirements.

IV. Prohibit the Use of QALYs in PDAB Assessments

Under the proposed Action Plan, the Board may use "cost-effectiveness analysis" when setting the UPL for a prescription drug. Typically, cost-effectiveness analysis requires assessors to determine how much improvement in health outcomes is gained per dollar spent on a prescription drug. These frameworks can limit patient access to care by assigning a fixed value to a medication, without considering individual needs or circumstances. For example, quality-adjusted life years (QALYs) are a measure used to quantify the health benefits of medical interventions or healthcare programs that are often used in decision-making to ration healthcare resources.[7]

Aimed Alliance reiterates its longstanding position against using QALYs to evaluate any treatment. The use of QALY measures raises significant ethical concerns, as these measures effectively place a monetary value of human life based solely on a diagnosis, suggesting that individuals with chronic, debilitating, and rare conditions are less valuable than those with common conditions. This approach treats individuals' lives and health as a commodity and ignores patients' and practitioners' individualized perception of the value of a specific treatment. Therefore, Aimed Alliance urges the Committee to mandate the Board to prohibit the use of QALYs throughout the UPL-setting process and in any cost effectiveness analysis.

V. Conclusion

In conclusion, we urge the Legislative Policy Committee to require the Board to revise its UPL Action Plan to prioritize patients by integrating patient perspectives, mandating continuous

[7] Gabriel Andrade, *Ethical Shortcomings of QALY: Discrimination Against Minorities in Public Health*, CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS, 1-8 (Jan. 15, 2024).

consumer engagement, requiring that any savings benefit consumers directly, and prohibiting the use of QALYs.

We appreciate the opportunity to provide written testimony. If you have any questions or would like to further discuss our concerns. Please contact us at policy@aimedalliance.org.

Sincerely,

Olivia Backhaus
Staff Attorney
Aimed Alliance

October 18, 2024

Legislative Policy Committee
Department of Legislative Services
Annapolis, Maryland 21401

Via email: ryane.necessary@mlis.state.md.us and dana.tagalicod@mlis.state.md.us

Dear Senate Chair Ferguson, House Chair Jones, and Members of the Committee:

I am writing to you today on behalf of the National Community Pharmacists Association (NCPA) to oppose the Maryland Prescription Drug Affordability Board's Upper Payment Limit Action Plan. Below we share our concerns, which mirror those expressed by other pharmacy stakeholders during the draft's comment period. We urge the Legislative Policy Committee to insist on appropriate protections for pharmacies that will ensure patient access.

NCPA represents the interest of America's community pharmacists, including the owners of more than 19,400 independent community pharmacies across the United States and approximately 328 in Maryland, which employ more than 3,900 residents and which filled more than 27.1 million prescriptions in 2022.

As crafted, the Upper Payment Limit would cap reimbursement for pharmacy claims at a reference rate without recognition of existing cost-based pharmacy reimbursement schemes. These cost-based reimbursement schemes are, in fact, aligned with the objective of reducing the cost of drugs. By not minding these reimbursement schemes, the reference rate will likely ensure below-cost pharmacy reimbursement and create unintended patient access challenges.

Since the Centers for Medicare and Medicaid Services' (CMS) Covered Outpatient Drugs rule was implemented in 2016, pharmacy reimbursement has been heading toward cost-based reimbursement. The Rule established a two-pronged cost-based requirement scheme in Medicaid programs with the creation of transparent benchmarks for both product reimbursement and a "professional dispensing fee." If such transparent reimbursement methodologies were adopted nationwide, federal Medicaid spending would drop by almost $1 billion over 10 years.[1]

[1] https://www.finance.senate.gov/imo/media/doc/2020-03-13%20PDPRA-SFC%20CBO%20Table.pdf

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The National Average Drug Acquisition Cost (NADAC) benchmark for drug product reimbursement is based on a national survey of pharmacies and updated monthly. NADAC does not ensure a pharmacy makes a profit and, in fact, some pharmacies lose money on NADAC. However, on average, the benchmark results in fair and adequate reimbursement, provided there is an appropriate professional dispensing fee. A professional dispensing fee is based on a state-level survey of pharmacies' cost to dispense. CMS must approve these professional dispensing fees and their survey methodology.

NCPA believes cost-based pharmacy reimbursement is in alignment with the aims of reducing drug spending, the intention of Prescription Drug Affordability Boards. However, as laid out in the Action Plan, there is no explicit protection of the cost-based reimbursement scheme. There is no mention of NADAC and no mention of a professional dispensing fee. It is not sufficient in the Action Plan criteria that "The Board shall consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs."[2]

Without reimbursement protections, pharmacies will be disincentivized from carrying drugs with Upper Payment Limits. This will likely create patient access issues for vulnerable patients.

We urge the Legislative Policy Committee to insist on appropriate protections for pharmacies that will ensure patient access. Thank you for receiving our perspective. Please do not hesitate to contact me any time at (703) 600-1186 or joel.kurzman@ncpa.org.

Sincerely,

Joel Kurzman
Director, State Government Affairs

[2] https://pdab.maryland.gov/Documents/reports/Health%20General%20Article%20§%2021-2C-13%28d%29-%20Prescription%20Drug%20Affordability%20Board-%20Upper%20Payment%20Limit%20Action%20Plan.pdf

Testimony submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA")
on the Maryland Prescription Drug Affordability Board Upper Payment Limit Action Plan
before the Legislative Policy Committee
October 18, 2024

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates this opportunity to share our concerns with the Upper Payment Limit Action Plan ("UPL Action Plan") submitted to the Legislative Policy Committee ("Committee") by the Prescription Drug Affordability Board ("Board"). PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world.

The bulk of our testimony will focus on our significant concerns with the current UPL Action Plan. We reiterate our opposition to government price setting, including upper payment limits, and efforts to extend price setting to the commercial market.

UPLs can limit access to needed medicines, fail to address drivers of access and affordability challenges, and discourage crucial innovation

The primary concern surrounding UPLs is the impact on access to needed medicines. A UPL caps payment and/or reimbursement rates. Arbitrarily capping prices or profits within the drug supply chain could restrict patients' access to medicines and result in fewer new treatments for patients. For example, if a payor cannot obtain a therapy from a wholesaler at the state-prescribed price, and/or if a pharmacy or dispensing provider cannot stock the drug because it too cannot meet the state-prescribed price, then the medicine may not be available to patients. Additionally, providers could be left with substantial costs if they acquired the drug before the price control is in place yet could not bill for reimbursement that covers their acquisition costs.

In addition, rather than taking a holistic look at the health care system, UPLs fail to address the root causes of patient access and affordability challenges — abusive pharmacy benefit manager ("PBM") and health insurance practices leading to higher patient costs. Too often:

- Middlemen in the healthcare system pocket tens of billions in rebates, discounts, and other price concessions they receive on medicines instead of sharing the savings directly with patients.
- The link between medicine list prices, rebates, and compensation can create misaligned incentives that can pad PBMs' bottom lines at the expense of employers and patients.
- Patients are denied the full benefits of cost-sharing assistance due to harmful tactics employed by health insurers and PBMs, such as accumulator adjustment[1] and co-pay maximizer programs.[2] These tactics not only affect patients' health if treatment is impacted, but also their financial well-being.
- Systemic barriers to care prevent patients from accessing the medicines their doctors prescribe. Utilization management tools that PBMs decide to impose, such as requiring prior authorization or failing first on other therapies, can create significant obstacles to treatments.

1 Accumulator adjustment programs are insurance benefit designs that exclude the value of manufacturer-sponsored cost-sharing assistance from a patient's accrual of out-of-pocket expenses toward out-of-pocket limits through a plan benefit year.

2 Copay maximizer programs are insurance benefit designs that generally restructure patients' cost-sharing obligations for a particular drug to equal the full value of manufacturer cost-sharing assistance available for that drug. Such programs skirt the protection of the Affordable Care Act's annual limit on cost-sharing for some plans by designating medications as non-Essential Health Benefits.

There are many policy alternatives that can be implemented immediately by the legislature to help patients access and pay less for their medicines. Examples already enacted and implemented in other states include: (1) establishing a prohibition on health insurance companies blocking cost-sharing assistance manufacturers provide to patients from counting toward patients' deductibles and other cost-sharing requirements; and (2) requiring that the significant discounts manufacturers pay insurers and PBMs be shared with patients at the pharmacy counter.

Expansion of the PDAB authority to the commercial market is premature and untested, likely resulting in large-scale supply chain and patient access disruption

Despite years of administrative process and considerable public and private stakeholder input and expense, no state has implemented a UPL to date. Major questions remain as to how a UPL could ever operate in the complex pharmaceutical supply chain without resulting in systemic upheaval and material impact on patient access. UPLs and other arbitrary price setting efforts risk impacts on the supply chain that could put patients in a position to lose access to their current treatments or experience interruptions in care. In addition, UPLs could threaten the competitive market underlying rebate negotiations and have the potential to result in greater costs to the state, the federal government, and consumers. Maryland legislators should thus refrain from expanding the PDAB's authority to the commercial market without evaluation of any negative impact to access and affordability.

Concerns with the UPL Action Plan

Below is a summary of the concerns we previously shared with the Board regarding the UPL Action Plan. More detail is available in PhRMA's *Letter to the Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits-Draft Working Document* (August 26, 2024).

1. The policy review process gives overly broad discretion to Board staff, lacks transparency, and provides insufficient requirements for consideration of other policy recommendations.

PhRMA is concerned that the policy review process, described in the UPL Action plan, gives overly broad discretion to Board staff, including with respect to the categories of information gathered, the processes employed in gathering information, and the sources considered. Such broad discretion would likely result in inconsistent application of the process for evaluating different drugs.

In addition, the UPL Action Plan does not contain sufficient requirements for the Board to provide transparency to manufacturers and other stakeholders in how it conducts its policy reviews. Rather, the UPL Action Plan only states that the Board "may" convene informational hearings, "may" make public specific questions or topics in advance, and "may" provide the Board with summaries of the testimony and staff recommendations. Transparency and opportunities for stakeholder input are integral to safeguarding the accuracy and integrity of the process.

Also, the UPL Action Plan permits the Board to make other policy recommendations in lieu of or in addition to implementing a UPL but does not *require* the Board to consider or review non-UPL policy recommendations. There are many alternative policies available to state legislatures to address patient access to medicines and affordability that are proven and available to implement immediately. It should be required that the Board consider all policies available. In addition, the Board should be required to provide a written, public explanation as to which alternative policies were considered and why the decision was made to recommend or not recommend them.

2. Lack of detail in the UPL Action plan

The current UPL Action Plan provides insufficient detail as to how the Board intends to operationalize many aspects of the plan. The lack of specifics, especially with regard to how the Board will solicit and review stakeholder input, may lead to inconsistent recommendations and should be remedied prior to approval of the plan. Specifically, the plan should not be approved until it provides greater details on:

- how the Board will ensure uninterrupted and undiminished patient access to critical medicines under a UPL;
- how to limit the impact of a UPL on other regulatory drug pricing programs;
- how to consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs;
- the specific regulatory criteria that the Board will assess or utilize, with a requirement that the Board provide stakeholders an opportunity to comment on these criteria; and
- the specific methodologies and factors that will be considered when establishing a UPL and explanation of what a blend of methodologies means.

In addition, the UPL Action Plan should:

- require the Board to hold a hearing to receive technical input and testimony as part of the process of establishing a UPL amount. UPL-setting analyses and calculations are complex. It would be inappropriate for the Board to set a UPL without first holding a technical hearing to consider stakeholder testimony on the proposed UPL amount and other UPL considerations, including how a proposed UPL will affect Maryland patients' access to drugs;
- address *all* the statutory requirements for setting UPLs, including the Board's plan for monitoring a UPL after it is set;
- create guardrails around the information that can be considered to establish a UPL to help ensure decision-making is grounded in statutorily relevant criteria and considerations; and
- make publicly available the calculations or other data operations used in its processes to allow stakeholders to understand the basis of the Board's determinations and provide feedback, except where protected against disclosure due to confidential or proprietary information.

3. Need for increased detail on factors that determine out-of-pocket costs

The UPL Action Plan's criteria for setting UPLs requires the Board to prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug. The current plan should clarify that any contemplation of high out-of-pocket costs must take into consideration the full range of factors driving such costs including:

- benefit design choices (e.g., cost-sharing requirements such as coinsurance and deductibles, and accumulator adjustment and copay maximizer programs);
- fees, rebates, and other price concessions paid by drug manufacturers to PBMs and health insurers that are not shared directly with patients; and
- formulary and benefit design that is applicable to the specific prescription drug product (e.g., complex tiering mechanisms and utilization management applicable to the drug).

In addition, the UPL Action Plan should provide clarification on how the Board will determine that the information it receives provides adequate detail about these factors. Failing to do so could result in misleading cost calculations that are not reflective of the actual costs to Maryland patients.

4. Use of Cost Effectiveness Analysis ("CEA")

The UPL Action Plan is unclear as to what CEAs the Board will use in its decision-making. Policies, including UPLs, that are based on cost-effectiveness determinations can prevent patients from accessing the treatments that best meet their

personal needs and preferences and override physician judgment in making individualized treatment decisions. By combining average study results into a single numeric judgment of value, CEAs overlook the significant differences in the needs of individual patients, many of whom do not fit the average. It has also been widely noted by stakeholders that CEA discriminates against individuals with disabilities and chronic illnesses by undervaluing their lives. For example, use of Quality Adjusted Life Years ("QALYs") or other metrics like "equal value of life year gained" ("evLYG") raise especially significant equity concerns, as these metrics have been shown to discriminate against people with disabilities, the elderly, and communities of color by placing lower value on their lives and the preservation of life. PhRMA believes that the Board should refrain from utilizing CEA.

5. Upper Payment Limit Calculation Options

Below is a summary of PhRMA's concerns with the UPL calculation options as described in the UPL Action Plan.

- **Therapeutic Class Reference UPL:** The UPL Action plan does not fully explain how it will identify whether drugs fall into the same "therapeutic class." As described in the plan, the current approach could lead to certain therapies being identified as within the same therapeutic class that are not appropriate for all patients using the therapies and should not be compared for the purposes of determining a UPL.

- **Launch Price-Based UPL:** This methodology contains insufficient detail as to how the Board intends to adjust launch prices for inflation and specifically, which inflation measures it intends to use for this purpose. Inflation measures are not necessarily aligned with what is happening in health care, as medical inflation may be higher than general inflation. Rather than setting UPLs based on pricing decisions made years ago, the Board should focus on patient-centric drug pricing reforms that lower patient out-of-pocket costs for medicines today.

- **Same Molecule Reference UPL:** PhRMA is concerned that reliance on the same active ingredient to identify drugs subject to the same UPL is likely to result in broad and misleading comparisons that could result in products being improperly grouped together.

- **Domestic Reference UPL:** In setting the domestic reference UPL, the UPL Action Plan allows the Board to consider the Medicare Maximum Fair Price. The Maximum Fair Prices recently released by the Centers for Medicare and Medicare Services do not go into effect until 2026. Consideration of any part of the program is thus premature. The Program is in its infancy, and it will take years to understand its effect on patient affordability and access. Additionally, the federal program considers prices for the Medicare population, which is different in key respects (including demographics, age, and diversity) from the Maryland patient population that may be considered for UPLs. The UPL Action Plan's focus should be limited to data relevant to the patient populations targeted under the PDAB Statute for UPLs, as well as to approaches that have been proven to not restrict patient access to drugs and for which there is a demonstrated understanding of impact on patient affordability.

- **International Reference UPL:** Setting a UPL at the lowest price among a sub-set of countries risks relying on this data without proper context. Among other considerations, the prices in these countries are the result of government price setting that has been shown to significantly limit patient access to new drugs. While 85 percent of all new medicines launched between 2012 and 2021 are reimbursed in the Medicare and Medicaid programs, only 61 percent of new medicines are reimbursed in Germany, 48 percent in the United Kingdom, 43 percent in France, and 21 percent in Canada. In addition, several of the countries that Maryland proposes to reference rely on rigid CEA standards to determine coverage and payment, resulting in patients in those countries who have diseases such as cancer or diabetes facing significant restrictions on access to treatments.

  Further, there are numerous issues with the data itself, including that international pricing data is generally collected at different levels in each country such as hospital level or wholesale level, and international pricing data

aggregators often use proprietary methods to estimate whole-country sales volumes and prices that are not reflective of actual transaction or volume information.

- **Budget Impact-Based UPL:** The UPL Action Plan should provide greater detail on how a budget impact-based UPL would operate, including how the Board will determine whether a product impacts the budget; what constitutes a "disproportionate" impact on the budget; and how the Board will determine what percentage or threshold of the budget that a particular drug cannot exceed.

6. Need for Confidentiality

The Draft UPL Action Plan does not address the protections that will be afforded for confidential, trade secret, and proprietary information that stakeholders may be asked to provide as part of the new processes outlined in the plan. PhRMA is particularly concerned because the Board's current regulations governing confidentiality elide many critical details, and it is not clear that they will adequately protect the sensitive information provided as part of the new processes outlined in the UPL Action Plan.

Thank you for your consideration of our concerns. If there are any questions or interest in additional information, please contact Kristin Parde at Kparde@phrma.org.

PIPC Partnership to Improve Patient Care

October 15, 2024

Senator Bill Ferguson
Department of Legislative Services
Annapolis, Maryland 21401

Delegate Adrienne A. Jones
Department of Legislative Services
Annapolis, Maryland 21401

Dear Senator Ferguson and Delegate Jones:

Since its founding, the Partnership to Improve Patient Care (PIPC) has been at the forefront of applying principles of patient-centeredness to the nation's health care system – from the generation of comparative clinical effectiveness research at the Patient-Centered Outcomes Research Institute (PCORI), to the translation of evidence into patient care in a manner that achieves value to the patient. Having driven the concepts of patient-centeredness and patient engagement in the conduct of research, PIPC looks forward to bringing the voices of patients and people with disabilities to the discussion of how to advance patient-centered principles throughout an evolving health care system.

I am writing to share PIPC's serious concerns about the Upper Payment Limit Plan submitted to Maryland's General Assembly Legislative Policy Committee by the Prescription Drug Affordability Board (PDAB) for its review and approval. We share the goals of health care affordability and want to be engaged partners with you in addressing the challenges facing patients. For too long, patients and people with disabilities have been subjected to adverse utilization management strategies that force use of a treatment that fails patients before gaining access to a treatment that works – or outright coverage denials of prescribed treatments. Their real-world experiences are critical to allow policymakers to understand what is driving affordability challenges and develop policy solutions addressing their economic burdens.[1]

Unfortunately, the Maryland PDAB process was less focused on the perspectives of patients and people with disabilities and more focused on payer perspectives. For example, recent written comments on the draft UPL Plan were ignored by the Board. 38 organizations sent a letter to the Maryland PDAB suggesting changes to its draft UPL Plan.[2] That letter was not immediately posted to the PDAB website, it was not listed among letters considered by the Board, and it was not discussed at the PDAB meeting during which the revised UPL Plan was

[1] PCORI advanced a patient-engaged process to determine economic burdens. See https://www.pcori.org/sites/default/files/PCORI-Patient-Centered-Economic-Outcomes-Landscape-090524.pdf
[2] See http://www.pipcpatients.org/uploads/1/2/9/0/12902828/maryland_pdab_comments_final.pdf

approved to be sent to the Legislative Policy Committee.[3] Unsurprisingly, the revised UPL Plan did not address any of the concerns expressed in that letter.

Moreover, regulations were finalized in May, 2024 under Section 504 of the Rehabilitation Act barring disability discrimination that included provisions barring the use of discriminatory value assessments in decisions impacting access to care, including reimbursement and coverage.[4] PIPC and its partners have reiterated to the Maryland PDAB several times that federal law bars the use of cost effectiveness measures such as quality-adjusted life years (QALYs) and similar measures that devalue disabled lives.[5,6,7] That includes reference to international prices in countries that use such measures and do not prioritize care for people with disabilities and serious chronic conditions. Yet, the Maryland PDAB is relying on entities such as the Program on Regulation, Therapeutics and Law (PORTAL) and the Institute for Clinical and Economic Review (ICER) that favor use of discriminatory value assessments to inform its work.[8,9] Their advice is not centered on achieving access to affordable care for patients and people with disabilities yet seems to be taken most seriously. We are concerned about Board members' ties to entities that view the QALY and similar measures as the gold standard for assessing value in healthcare.[10] Those concerns were amplified by the PDAB's failure to provide answers to credible questions from the disability community as to how UPLs may impact the use of payer tools to restrict formularies and increase out-of-pocket costs for patients, whether for the drug under review or other drugs in its class.

Also, the Maryland PDAB process has not prioritized accessibility. Comment deadlines and meeting dates and times often change, leaving patients and people with disabilities unable to participate. Comments submitted by the public are difficult to find on the website and are not posted in a timely manner. Accessing the recorded PDAB meetings for older meetings is challenging and are difficult to navigate on the Maryland PDAB website. Public participation has clearly not been a priority for the PDAB, much less participation from the disability community or patients personally affected by decisions related to drugs under review. Recent federal regulations issued by the U.S. Department of Justice covering Title II of the ADA require the accessibility of web content and mobile applications (apps) for people with disabilities. To be compliant, state and local governments must make their websites and mobile applications

[3] See https://pdab.maryland.gov/Pages/2024-Board-Meeting.aspx
[4] 45 CFR § 84.56 and § 84.57
[5] See http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_maryland_pdab_2024.pdf
[6] See https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_maryland_pdab_050223.pdf
[7] See https://valueourhealth.org/wp-content/uploads/2021/08/MD-Letter-Final.pdf
[8] PORTAL Presentation to PDAB, https://pdab.maryland.gov/documents/meetings/2023/havard_med_sch_prst.pdf
[9] ICER Presentation to PDAB, https://pdab.maryland.gov/documents/presentations/Leveraging_ICER_Rpt_for_Prescription_Drug_Affordability.pdf
[10] Dr. Gerard Anderson has reported grants from Arnold Ventures, which is a primary funder of the Institute for Clinical and Economic Review and supporter of their QALY-based methodology, as well as funder of PORTAL Research and NASHP.

accessible. Beyond what is legally required, we had hoped that the PDAB would proactively want to make the process accessible for patients and people with disabilities and prioritize responding to their concerns and incorporating their input.

As the original author and sponsor of the Americans with Disabilities Act and a person with epilepsy, I have spent my adult life fighting for disability rights and against these types of policies that devalue us. I have had personal experience with non-medical switching imposed by my insurer, with adverse outcomes that were entirely unavoidable. As an older adult now, I am do not subscribe to the idea that my life is worth less, as most measures of cost effectiveness would have you believe. With recent federal regulations to more clearly guide us, the disability community is now fighting for enforcement of U.S. laws that protect patients and people with disabilities.

The Legislative Policy Committee should not approve a UPL Plan that does not protect against disability discrimination and adverse utilization management strategies by payers. The goal of the PDAB should be to improve patient access to the care they and their doctors determine to be most effective. By pausing this process, the Legislative Policy Committee could take the time to understand the implications of the PDAB's UPL Plan and engage with patients and people with disabilities on solutions that are meaningful for advancing affordable access to care and in compliance with disability rights laws.

Thank you for your consideration.

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

We appreciate that the statute governing the Board's activities calls for cost reviews that determine whether a treatment "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients." It is our hope that the Board is first and foremost seeking to protect patients and people with disabilities seeking to access the treatment that is recommended by their providers and most effective for the patient. By now, the Board is aware that affordability challenges are often associated with placement on formularies, utilization management strategies imposed by payers to restrict access to certain drugs, and outright denials that force patients to pay out-of-pocket for access to the drug on which they are most stable. It does patients and people with disabilities little good to lower the price of a drug if the outcome is to make it harder to access that drug or an alternative drug that may be more effective for the patient but is no longer on a preferred tier or is subject to a fail first policy.

The Board has significant latitude to determine whether an Upper Payment Limit (UPL) is the policy solution for an affordability challenge. What many patients know to be true is getting the drug they need is often difficult and burdensome. Meaningful policies to genuinely help patients address their out-of-pocket costs must mitigate the use of discriminatory value assessments by payers to justify restricting access to care for people with disabilities and serious chronic conditions, as well as older adults. Addressing affordability starts with policies that support shared decision-making between patients and providers and ensure affordable coverage of the treatment plan that patients and providers determine to be most effective.

Therefore, we urge the Board to develop a concrete plan to monitor and respond to potential increased use of utilization management strategies and adverse formulary placements for both selected drugs *and* their alternative treatments, which could increase patient costs and impede physicians' judgment about the best care for individual patients. The draft plan states the Board will set UPLs in a way to minimize adverse outcomes and minimize the risk of unintended consequences, as well as monitor availability of prescription drugs subject to a UPL to protect against shortages. We hope the Board will go further to ensure patients and people with disabilities are not losing access due to coverage denials, step therapy, prior authorization, etc. We appreciate that the Board proposes to reconsider or suspend UPL's where they find selected drugs to be unavailable and propose the Board adopt the same policy to respond to payers that restrict access to selected drugs or other alternatives.

Improve the Board's patient engagement practices and use of survey data.

The Board states in its draft UPL plan that its process is transparent and offers multiple opportunities for public engagement and input. Yet, it is not clear to stakeholders how information submitted by patients is used by the Board to make decisions. We would urge the Board to review the work of experts in patient engagement such as the patient-Centered Outcomes Research Institute (PCORI), National Health Council, the University of Maryland, AcademyHealth and the Innovation and Value Initiative on how to best engage the patient community in its work. For meaningful engagement on the factors listed for consideration by

the Board – including therapeutic alternatives, patient access, comparative clinical effectiveness research, cost sharing, clinical information and disease burden – we recommend the Board:

- Develop a formalized process to ensure continuous, robust engagement of patients and people with disabilities at multiple levels.
- Use patient insights to clearly communicate how it intends to use the input it receives, and how that input is reflected in the final negotiated prices.
- Solicit input from diverse communities to ensure representation of the diversity of the patients and communities affected by the topic.
- Ensure that opportunities for patient engagement are accessible.
- To gauge both successes and challenges, establish a structured process for continuous review and assessment of its engagement strategy.
- Avoid one-size fits all value metrics.[3]

The Board has received substantial comments about the factors that drive affordability challenges for patients and people with disabilities, yet the Board continues to focus its work on establishing UPLs without addressing the economic burdens that patients too often face, whether it be transportation, caregiving, utilization management strategies blocking coverage of prescribed care, etc. Entities such as the Patient-Centered Outcomes Research Institute (PCORI) have invested significant resources in engaging patients to identify the full range of clinical and patient-centered outcomes, including the potential burdens and economic impacts of health care services[4,5]. Additionally, a patient-developed survey is now available to help the Board determine the many factors that can lead to affordability and access challenges for patients, led by the Patient Inclusion Council, also known as the PIC.[6] We urge the Board to use these resources to better understand the burdens facing patients and to develop patient-centered strategies for improving access to care.

Avoid the use of discriminatory value assessments.

The Board highlights in the draft that it may consider many different factors part of a cost review, including cost effectiveness analyses. Yet, on May 9, 2024, the final new regulations governing Section 504 of the Rehabilitation Act were published, protecting the rights of people with disabilities in programs and activities receiving federal financial assistance against the use of discriminatory value assessments also known as cost effectiveness analyses.[7] The U.S. Department of Health and Human Services' rule represents a critical step forward to protecting

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[3] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_recommendations_for_patient_engagement_final.pdf

[4] https://www.pcori.org/sites/default/files/PCORI-Out-of-Pocket-Cost-Taxonomy-Scoping-Review-Sept-2023.pdf

[5] https://www.pcori.org/sites/default/files/PCORI-Assigning-Costs-to-Healthcare-Utilization-Report-March-2023.pdf

[6] https://www.surveymonkey.com/r/PatientDrugAffordability

[7] https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov

Headache and Migraine Policy Forum
Health Hats
HealthHIV
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
Lupus and Allied Diseases Association, Inc.
MET Crusaders
MLD Foundation
Monica Weldon Consulting, LLC
National Infusion Center Association (NICA)
National Infusion Center Association (NICA)
Partnership to Fight Chronic Disease (PFCD)
Partnership to Improve Patient Care
Patients for Patient Safety - US
PD-L1 Amplifieds
The Bonnell Foundation: Living with cystic fibrosis
The Coelho Center for Disability Law, Policy and Innovation
The IMAGE Center for People with Disabilities

cc: Stakeholder Council

Testimony in Support of the Prescription Drug Affordability Board's Upper Payment Limit Action Plan

Submitted by Progressive Maryland

October 22, 2024

Dear Speaker Jones, President Ferguson, and Members of the Legislative Policy Committee,

Thank you for the opportunity to express our strong support for the Upper Payment Limit Action Plan being considered for approval today. Our affiliates, our grassroots members, and all the Marylanders struggling to afford their medicines have been waiting for action to rein in drug company profiteering and this is plan is the right course of action. We hope you will advance the action plan today.

The plan presented before you will give us the opportunity to take the game changing step in making prescription drugs more affordable for our state and local government entities. We'll all benefit from lifting the burden on tight government budgets, and freeing resources to go to fund important public services.

Please support this measure.

The creation of the Prescription Drug Affordability Board is something we should all be proud of. Both its staff and the five appointed Members have worked diligently to understand the complexities of the issue, including the entire supply chain, and to design a clear and comprehensive approach to prescription drug affordability.

To make matters even better, two of the prescription drug products with a newly determined Medicare Maximum Fair Price are also being considered by our Prescription Drug Affordability Board. Should the Upper Payment Limit Action Plan be approved, the Board could implement these federal rates as a state upper payment limit in time to impact upcoming prescription drug plan negotiations for state and local governments.

Thank you for the work that you have done as the legislative leaders of the Maryland General Assembly to make our state a leader in addressing the crisis of skyrocketing prescription drug costs.

With your swift approval of the Upper Payment Limit Action Plan, the Prescription Drug Affordability Board can move forward with its groundbreaking work.

Value of Care Coalition

October 18, 2024

Legislative Policy Committee
Department of Legislative Services
Annapolis, Maryland 21401

RE: Prescription Drug Affordability Board / Upper Payment Limit Action Plan

Dear Members of the Legislative Policy Committee:

As a broad coalition of advocacy organizations including patients, caregivers and health care providers, we write on behalf of the undersigned groups to share our concern with the Upper Payment Limit Action Plan as approved by the Prescription Drug Affordability Board in September, due to be considered by the Legislative Policy Committee (LPC).

We would respectfully request your consideration of our concerns that fall into three categories:

1) Process and procedure for setting the upper payment limit (UPL)
2) Risks to patient health due to diminished access to treatment resulting from the UPL
3) Lack of patient savings resulting from the UPL

We recognize the importance of lowering health care costs and do appreciate some aspects of the plan. However, we hope the Legislative Policy Committee will consider these concerns as it debates approval of the plan.

Concerns About Process and Procedure

The plan states that "The Board shall set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences." However, it does not identify what adverse outcomes or unintended consequences that are of concern and that should be minimized. Nor does the plan define the threshold for tolerance of these outcomes and consequences to be determined minimal. During its September meeting, one Board member suggested this vague language is necessary due to the uniqueness of each drug. However, the primary adverse outcome that concerns patients, providers and caregivers is a reduction of access to the drugs subject to the UPL or their competitor drugs for the same condition. When Marylanders' health is at stake, this concern should be addressed with greater specificity.

Several options for arriving at a UPL price are suggested in the draft plan. Many options raise concerns, such as utilizing metrics used by health economists, including QALY-like metrics, that

are widely viewed as biased against certain patient populations, referring to pricing in countries with healthcare systems unlike ours, and referring to federal pricing with a still-unknown impact on access. As concerning, none of the options outlined allow for consideration of individual patient needs.

The plan references opportunities for stakeholders to provide input throughout the process but does not formalize that process. Previous input opportunities have proven inadequate, including 90-second time limits for oral comment, and prevent meaningful input. Additionally, at its meeting in September, one Board member stated they see "diminishing returns" on public comments, validating stakeholder worries that comments are not being sufficiently considered by the Board as it makes its decisions.

The plan includes concurrent timeframes for cost review report approval and UPL-setting to occur without specifying that length of time. Given previous concerns expressed by the Board about staff bandwidth, the "parallel" processes detailed in the draft plan may not allow for the very specific evaluations that must be undertaken. This in turn could be met by a lack of confidence among impacted stakeholders that recommendations are thorough and thoughtful.

Additionally, the lack of specific timeframes between preliminary determination and final determination/UPL-setting undercuts the idea that adequate time will be available for stakeholder input to be sought, received and considered. This is underscored by the fact that a UPL may be set at the same meeting as final adoption of the affordability review.

Concerns regarding a rushed process have been confirmed by recent actions. The Board moved up the date of its meeting in September to speed the process and noted that its October meeting date may be moved up if the LPC approves the plan quickly.

Risks to Patient Access Left Unaddressed

We appreciate the Board has accepted public comment throughout this process. Through public comment, the Board has been made aware of risks to access posed by the setting of an upper payment limit.

A recent survey of payers, whose formularies determine patient access and cost, validated stakeholder concerns as they noted that UPLs will result in increased utilization management (typically arising in the form of delays or denials for treatment) as well as changes to copay or coinsurance amounts (potentially increasing costs for patients).[1]

[1] Partnership to Fight Chronic Disease. *Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies And Benefit Design But Won't Reduce Patient Costs*. 2024 March. https://www.fightchronicdisease.org/sites/default/files/FINAL%20PFCD%20Avalere%20PDAB%20Insurer%20Research.pdf

Despite this information being provided, at a subsequent meeting, one Board member wondered aloud, as quoted by State of Reform, "I don't understand how a lower price—I mean, as somebody trained in economics, if the price goes down, affordability and access goes up—[would do that] so people who make an argument that it's going to affect access and affordability … I really need to understand why you think a lower price would do that."

Board members consistently make statements indicating it is not their intention to reduce access or claim that their actions will not result in reduced access. However, the Board has not detailed *how* it will ensure continued access despite the statements from payers noted above.

When a person with a complex medical condition – much like those treated by the drugs under review by the Board – face a forced switch to a different medication, negative health outcomes can occur. This type of switch can lead to new side effects, symptom re-emergence, disease progression, more frequent visits to the doctor's office and hospitalization, resulting in additional medical costs and burdens on both patients and providers – all to treat a condition that was previously under control.

We encourage the LPC to require the UPL Action Plan explicitly include mechanisms to ensure patients have continued access to the treatments their doctors prescribe.

Lack of Patient Savings

Despite the risks to Marylanders' health outlined above, the UPL Action Plan does not provide for any savings by the people whose drugs are deemed to cause affordability challenges.

While the plan states, "The Board shall prioritize drugs that have a high proportion of out-of pocket costs compared to the net cost of the drug," no mechanism is included to ensure any savings achieved via the upper payment limit results in lower out-of-pocket costs for patients.

Patient cost is typically determined by premiums, deductibles, co-pays and co-insurances. Patients pay the amount their health plans dictate. For policy to be effective at minimizing patient costs, it must focus on benefit design and out-of-pocket expenses rather than a reimbursement limit.

The LPC should require the UPL Action Plan to address the potential patients face for increased cost sharing and ensure that patients participate in any cost savings.

Summary

In its current form, the UPL Action Plan offers great risk and little reward for people with complex medical conditions in Maryland. Given the gravity of the decisions being made by the Board and the direct impact these decisions have on Marylanders' health, we urge the Legislative Policy Committee to ask the Board for a more detailed, comprehensive plan – one that details how their policies will ensure continued access to doctor-prescribed treatments and details how out-of-pocket costs are lowered for patients.

On behalf of the undersigned organizations, thank you for your consideration.

AfPA Alliance for Patient Access

AiARTHRITIS International Foundation for Autoimmune & Autoinflammatory Arthritis

AIMED Alliance

American College of Allergy, Asthma & Immunology Advocacy Council

AWIR Association of Women in Rheumatology

The Bonnell Foundation: Living with Cystic Fibrosis. Live • Breathe • Inspire. Roadmap to CF™ | thebonnellfoundation.org

CSRO Coalition of State Rheumatology Organizations

Diabetes Leadership Council

Diabetes Patient Advocacy Coalition

DCAN Derma Care Access Network

Epilepsy Foundation

Epilepsy Foundation Maryland

Global Healthy Living Foundation

The Headache & Migraine Policy Forum

HIV+HEP Policy Institute

LGS Foundation Lennox-Gastaut Syndrome

Lupus and Allied Diseases Association, Inc.

Miles for Migraine

National Headache Foundation

NICA National Infusion Center Association

PIPC Partnership to Improve Patient Care

Patients Rising