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.

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- **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.

August 26, 2024

Maryland Prescription Affordability Board
16900 Science Drive
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Bowie, MD 20715

Submitted electronically: comments.pdab@maryland.gov

Re: Maryland Prescription Drug Affordability Review Board

Dear Members of the Maryland Prescription Affordability Board:

On behalf of the Association of Women in Rheumatology (AWIR), I am writing to offer our comments regarding the *Board's 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 you 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
Vice President
AWIR

Stephanie Ott, MD
Advocacy Co-Chair
AWIR

Biosimilars
FORUM

Maryland Prescription Drug Affordability Board
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August 26, 2024

RE: Draft Upper Payment Limit Action Plan

To Whom it May Concern,

The Biosimilars Forum appreciates the opportunity to submit testimony to the Prescription Drug Affordability Board (PDAB) in Maryland in response to proposed procedures for establishing Upper Payment Limits (UPL) for selected products. Our organization remains concerned with the ability of the PDAB to review and place artificial price controls on biosimilars. This decision will negatively impact patients that need access to lower-cost medicines. It is crucial for patients to have the ability to access FDA-approved, lower-cost biosimilars, and we urge you to revisit the decision to include biosimilars as potential products that may be subject to a UPL and focus, instead, on policies that support patients and access to biosimilars.

The Biosimilars Forum is a non-profit trade association representing the companies with the most significant U.S. biosimilars development portfolios, including Amneal Pharmaceuticals, Biocon Biologics, Coherus BioSciences, Meitheal Pharmaceuticals, Organon, Pfizer, Samsung Bioepis, Sandoz, and Teva Pharmaceuticals. Our comments today represent the views of our members, all of whom manufacture or market biosimilar products in the U.S. as well as other parts of the world.

First, it is important to revisit the benefits that biosimilars can deliver and the challenges they face uniquely in an already intensively competitive marketplace.

Biosimilars are FDA-approved, lower-cost, safe, and effective treatments that mirror reference biological medicines. Biosimilars treat chronic and debilitating conditions like cancer, arthritis, diabetes, psoriasis, Crohn's Disease, chronic skin and bowel diseases, kidney conditions, macular degeneration, some cancers, and more. These medicines effectively promote long-term cost savings by selling at lower prices than their reference biological products and by promoting competition which leads to the reference biological product being forced to lower its price to compete. In fact, biosimilars cost on average 30% less than reference biological products, which, despite being just 2% of U.S. prescriptions, account for 40% of all drug spending. Through promoting lower costs, biosimilars: (1) help expand access to safe and effective treatment options for clinicians and patients, and (2) reduce health equity burdens to families, caregivers, payers, and the entire health care system.

The lower prices obtained after biosimilars enter the market also make it easier for patients to afford and, therefore, remain on their medications, leading to better outcomes and lower overall costs to patients, payers, and healthcare systems. Biosimilars can save the U.S. healthcare system up to $133 billion if they are accessible, while cost savings from biosimilar medicines can be used to treat 1.2 million more patients.

The potential application of an upper payment limit to biosimilar medicines raises serious concerns about the ability of biosimilar medicines to continue to exert competitive pressures on prices of reference products and on other biosimilars and to maintain sustainable product supply and manufacturing operations. In turn, this has the potential to cause biosimilar manufacturers to reduce or eliminate important patient support programs, may contribute to creating or exacerbating shortages or make further participation in the Maryland market prohibitive. In effect, the intent and benefits of biosimilars

in the market will be frustrated rather than advanced by the imposition of an UPL on biosimilars, the risk of future shortages and supply chain interruption increased, and restrict the availability of support for patients.

Concern about the risk of shortages is a noteworthy element of Maryland's PDAB enabling legislation. In fact, the language of the statute prohibits the establishment of an UPL for products listed in shortage by the FDA and requires recission of a UPL when a product experiences a shortage. (MD Code, Health Gen Section21-2C-14(c) To the extent that a UPL for a biosimilar has the potential to create the unintended consequence of a shortage, the prudent course for Maryland is for the Board to exercise its permissible discretion to expressly forgo the establishment of a UPL for biosimilars given their demonstrated positive impact on health care savings, in spite of the many existing barriers to access in the US. Biosimilars provide lower cost options for patients and the application of a UPL could potentially create future shortages of biosimilars which is currently not a concern in the biosimilar market.

As a draft working document, the "Policy Review Process and Upper Payment Limit (UPL) Development" lacks details about criteria to be applied or the methodologies that will result in setting UPLs. Yet, these details will determine what payment limit will be set, and the implications of the UPL on patient access to medicines on which they rely, and the cascade of consequences, intended or not, on the market dynamics within Maryland and beyond. As such, the process of evaluating products and determining reimbursement limits must be completely transparent and subject to scrutiny and input from all affected parties. The complexity of the market, supply chain, benefit design and the implications of impacts in these areas on patients demand this.

There are several elements of the draft proposal where attention to this concern is most vital.

In Section 1, **Staff Recommends Methodologies and Factors to Establish a UPL**, (p.8). in addition to maintaining staff receptivity to input as it develops its recommendations to the Board, the process of adopting a methodology should require that Board provide its rationale for adopting its methodology, including why it was determined to be the most relevant or effective, and how it minimizes the risks of negative unintended consequences by comparison with other methodologies it chose not to employ. This will enable a process of continuous improvement.

In the **Cost Effectiveness Analysis** section (p.9), the Board should disclose its reliance on third-party cost effectiveness analysis and make that analysis, along with its own internal analysis, available for review and comment by affected parties before implementing the analysis in establishing the UPL.

In the **Therapeutic Class Reference Upper Payment Limit** section (p.9), because the route of administration, ease of use and other factors affecting patient adherence can frequently be overlooked in comparative effectiveness analyses, and since these product characteristics may be most important to more vulnerable patient populations, it should be mandatory that the Board consider differences within patient populations and disease in deciding whether to include or exclude a product from the reference basket. The addition of patient advisers to the process should be considered.

In the **Launch Price-Based Upper Payment Limit** section (p.9), biosimilars should be excluded from this consideration. Prices at market entry are developed a complex set of considerations that are designed to arrive at a price that will allow the biosimilar to compete effectively with its reference product, address the various PBM and other purchaser expectations that affect whether the biosimilar is made available on plan formularies, the patient out of pocket costs, utilization management parameters, patient support programs for complex health conditions, reliability of supply and manufacturer sustainability. Artificially setting a UPL that is divorced from these complex considerations will threaten the ability of new biosimilars to introduce price competition into the market and to achieve plan formulary access that makes products available to patients, issues already compounded by existing PBM practices.

In a larger sense, across all products, biosimilars, reference and innovative new products, making market entry price the reference price establishing a UPL ignores the complexities of the market and supply chain demands which may, over time, require price adjustments to meet competition. This can result in limitations on the availability to patients of important treatments and lower cost alternatives.

The Same **Molecule Reference** UPL section, (p10)

Therapeutic Class Reference UPL

While the Draft Working Document does not provide an explicit definition, it appears that drugs will be grouped together for a therapeutic class reference UPL if they share "similar chemical structures and act through similar pathways to treat the same conditions." It is not clear how "similar" drugs must be in terms of their structure and pathway to fall within a therapeutic class. For example, will the Board adopt a bright-line rule that certain structural changes will always categorically be considered similar or different or will it implement a case-by-case approach? The former may provide certainty, though at the cost of rigidity; while the latter allows flexibility, it risks inequitable application across different fact patterns. Regardless of the approach, these types of comparisons are scientifically complex to make, and it is not clear how the Board will ensure the relevant expertise informs these determinations.

The Board also retains discretion to exclude products from the therapeutic class, including based on "comparative effectiveness research," and may not consider information on products that are "provenly less effective." At the outset, there is no rationale for limiting this analysis to comparative efficacy and not also including comparative safety. Nevertheless, and regardless of the scope, these types of product comparisons are complicated, and it is not clear what scientific evidence would be utilized in making these determinations or how to demonstrate a drug is "provenly" less effective. For example, would the Board follow FDA's lead, in which the agency carefully weighs evidence of superiority claims, ensuring that any such claims are supported by substantial evidence (typically, an adequate and well-controlled clinical trial designed to establish superiority)?[1] If not, how does the Board intend to select, review, and weigh evidence?

Same Molecule Reference UPL

We recommend deleting the sentence "This approach can be used when there are other products with the same indications and little evidence of differences in clinical effectiveness." The standards for approving a generic and a biosimilar mean that there is no difference in the safety or effectiveness of these products. To the extent the objective is to preclude the use of the same molecule reference UPL when there are clinical differences with other originator products (*i.e.*, those approved in New Drug Applications ("NDAs")), then the text should be revised to make that explicit. As noted above, however, there are substantial challenges with such comparisons.

The text also suffers from numerous technical flaws. For example, an authorized generic is not another product; rather, it is the approved drug, just marketed under a different labeling, packaging product code,

labeler code, trade name, or trademark.[2] Second, drugs approved under the section 505(b)(2) pathway are approved in NDAs, rendering "brand name drugs under the 505(b)(2) pathway" redundant with "products approved under an original NDA." Third, notwithstanding the "same molecule" phrase, approval of a generic or biosimilar does not demand complete identity of the molecules.[3]

Accordingly, we recommend revising the text to read as follows:

"Same molecule" reference UPL refers to setting a UPL based on the prices of the following products: (1) generic drug products referencing the product under the review; (2) **authorized generics** of the product under review; (3) biosimilars referencing the product under review; and (4) approved New Drug Applications ("NDAs") that have the same active

[1] *See, e.g.*, FDA Guidance for Industry, *Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products — Content and Format* (2006).
[2] 21 U.S.C. § 355(t)(3).
[3] *See, e.g.*, FDA Draft Guidance for Industry, *Sameness Evaluations in an ANDA – Active Ingredients* (Nov. 2022); FDA Draft Guidance for Industry, *Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products, Questions and Answers* (Apr. 2024).

ingredient and are approved in the same indication as the product under review. Under such an approach, the Board may set the UPL to be the price of the lowest-priced product with the "same molecule."

Lastly, we note that the text only included biological products if they were biosimilar to the drug under review, and, therefore, would not include other biological products that were approved in Biologics License Applications ("BLAs") submitted under section 351(a) of the Public Health Service Act. It was unclear if this decision was intentional.

The two sections on **Domestic and International Reference UPLs** (p.10) suffer the same shortcomings as the Launch-Price UPL, with the additional concern that international reference prices have no connection with the unique characteristics of the US healthcare system and fail entirely to account for pricing considerations necessary to remain competitive and sustainable in the US healthcare system, or to assure that patients can maintain access to products they rely on.

While the Board continues its work in determining how, when or whether to impose use of the UPL, the Biosimilars Forum strongly encourages the Board to review the abusive practices of PBMs, which create excess expenses for patients across the state and block these patients from accessing the cost-effective medications they need.

Ultimately, biosimilars are a commonsense solution to one of the most important budgetary challenges in Maryland. But these promising, life-changing medicines face many hurdles threatening their ability to help patients. The Biosimilars Forum supports free market competition in the pharmaceutical industry. We stand ready to help prioritize patients and provide more choices for lower-cost drugs. Otherwise, the cost-savings promise of biosimilars could be lost forever.

We thank the Board for the opportunity to submit comments and appreciate the attention to the role biosimilars play in the healthcare system.

Respectfully Submitted,

Juliana M. Reed
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VIA Electronic Delivery August 26, 2024

Mr. Van Mitchell, Chair
Maryland Prescription Drug Affordability Board (PDAB)
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Maryland Prescription Drug Affordability Board Plan of Action for Implementing the Process for Setting Upper Payment Limits

Dear Chairman Mitchell:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Maryland Prescription Drug Affordability Board's (PDAB or Board)'s Draft Plan of Action for Implementing the Process for Setting Upper Payment Limits (Draft Plan).

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 believed 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, Maryland's Draft Plan of Action for Implementing the Process for Setting UPLs (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. While BIO strenuously disagrees with Maryland's approach to effectuating a UPL system, our comments are intended to ensure the PDAB provides the necessary transparency and accountability for stakeholders and that the PDAB does not act outside of its

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statutory limits. We are also disappointed that key aspects of Maryland's Draft Plan were proposed without any stakeholder input or any clear deadlines for public comment. The Board's stated goals of transparency and engagement require immediate reconsideration of the PDAB's approach.

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 has serious concerns regarding Maryland's inadequate efforts to solicit stakeholder input for the Draft Plan and other important documents set forth by the PDAB. Periods for public comment on drafts must allow for sufficient time for stakeholders to review and provide response, recognizing the limited resources for many groups. As it stands, a two-week comment period is insufficient for stakeholders to provide thoughtful and constructive feedback. Additionally, not all stakeholders are able to provide written feedback. Maryland should allow for multiple feedback channels (including written and verbal feedback), provide sufficient time for groups to offer meaningful responses, and ensure that timelines and process to incorporate feedback are clear and transparent.

BIO is also concerned that the Draft Plan does not adequately consider the policy's impact on patients. While the Draft Plan includes a few mentions of stakeholder input and opportunities for public comment, there are no mentions of specific patient input. While the PDAB states that it will conduct a cost review study to determine whether the drug has led to "affordability challenges for the State health care system **or** high out of pocket costs for patients," it is clear from this statement that patient impact is de-emphasized. The Draft Plan gives the PDAB carte blanche to move decisions forward without public comment. It is evident that the PDAB needs to properly consider patient impact 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.

The Draft Plan also does not provide a clear mechanism for stakeholders, including manufacturers, to offer detailed comments during the UPL setting process. The Draft Plan does not outline any process for collecting and incorporating public and stakeholder feedback going forward. An illustration or diagram would help stakeholders better understand the sequencing of the many steps outlined in the Plan. The Board should also set forth a reasonable time period, a 30- or 60-day timeframe, for stakeholders to comment and engage after each phase of the Draft Plan. A detailed process to collect feedback, especially from patients and manufacturers, is crucial as each drug has unique development costs, market conditions, and value propositions that need to be considered. Manufacturers, including but not limited to those who develop rare disease

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treatments, often have highly specialized knowledge about the conditions they treat, the relevant patient populations, and the broader impact of their therapies. In-depth discussions are needed so the PDAB can gain relevant insight into the unique aspect of certain treatments, including the challenges of small patient populations, complex manufacturing processes, and ongoing patient support programs that are often necessary for rare disease therapies.

BIO urges the Board to create a defined, sequential timeline for all stages of the Draft Plan with meaningful opportunities to provide response and clear deadlines for public comment. As currently outlined, the Draft Plan creates conflicting timelines that may result in premature and rushed policies without meaningful opportunity for stakeholders to participate constructively. BIO strongly urges the Board to develop a process and decision on whether a UPL is appropriate *before* the Board begins the process of setting a UPL. As drafted, it appears the information on potential upper payment limits could influence the decision on whether UPLs or another policy are appropriate to address affordability challenges. The decision on whether to establish a UPL should be evaluated separately and independently of the calculation of a proposed UPL and should be focused on whether it addresses the drivers of the affordability challenges and the impact on patient access and OOP costs. Further, the Draft Plan should be finalized *before* the RFI's are sent out to be completed by manufacturers.

Additionally, the Draft Plan allows the Board to adopt the final cost review report and the UPL at the same Board meeting. Instead, BIO recommends a phased approach in which the Board approves the final cost review report and the UPL at separate meetings, which would be preferable to provide a more meaningful opportunity for stakeholders to participate constructively.

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

[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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affordability. The Board 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 deeply concerned by the Draft Plan's lack of consistent and clear information on how affordability will be defined. In some sections, affordability is defined as "cost of administering the drug and delivering the drug to consumers as well as other relevant administrative costs" while other sections include mention of out-of-pocket costs. BIO urges the PDAB to clearly define affordability and spell out how the PDAB will determine whether a drug has led or will lead to affordability challenges. This clarity is critical to avoid an arbitrary process where assessments could change over time and not reflect patient values. Thus, BIO urges the PDAB to establish a clear and consistent definition of affordability within the Draft Plan and clarify the process that the PDAB will take to assess affordability. It is critical that the PDAB ensures 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 PDAB'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." Throughout the Draft Plan, the PDAB 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. While the Board states that it "may recommend other policy actions, which 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 does not mention how it will evaluate other policy solutions or what parameters will be used to determine the appropriate mechanism to address affordability challenges. It is also 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 PDAB to follow its stated commitment and not make baseless assumptions and recommendations without sufficient consideration for all policy tools. Policy tools, including those that require additional legislative authority, should be given equal consideration.

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

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and consistency could lead to different approaches used for each drug, which presents challenges in ensuring efficient stakeholder engagement, data collection and decision-making. BIO urges the PDAB to clearly specify the UPL development process, including the exact criteria that will be met or considered, how the criteria will be weighed or prioritized, how data from various sources will be validated and used in setting UPLs, and publish clear steps to be taken to ensure the process is transparent, repeatable and applied equitably. 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.

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 Maryland envisions it being implemented, the result could create product access barriers or could even increase costs for patients. For example, upper payment limits do not account for portfolio or bundled discounts. Overall plan net costs may be adversely impacted if a UPL drug is removed from a bundled discount, such that net cost savings for the UPL drug may be less than net cost savings of the bundled discount.

Further, it is unclear how the criteria listed on page 3 of the Draft Plan interact with the UPL factors and methodologies listed on pages 8-11. Both sections of the Draft Plan purport to guide the Board when setting an UPL. The Board should instead separate and clearly distinguish between the criteria that will be used when determining whether a UPL is an appropriate policy solution and to assess other policy solutions, and the methodologies/criteria to be used when selecting a UPL amount.

As the Board seeks to clarify and clearly define important aspects of the Draft Plan, we urge the Board to further clarify the following:

- The Draft Plan states that the Board "shall prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug" (p. 3). The Board should clarify that out-of-pocket costs should be determined based on the actual costs incurred by patients, taking into account all rebates, coupons, manufacturer-assistance programs, and government-assistance programs. Failing to do so could result in a cost calculation that is arbitrary and capricious.

- There are numerous mentions in the draft regarding quasi-legislative hearings. The Board should clarify its definition of "quasi-legislative" and provide additional information regarding expected rulemaking processes and timelines.

- The Board states that it will not set an upper payment limit if utilization of the product by Eligible Government Entities is "minimal." BIO urges the

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Board to clarify its definition of "minimal" and clearly identify the process that will be used by the state to assess "minimal" utilization.

- The Draft Plan states that "the criteria for setting a UPL shall include consideration of the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs." BIO urges the Board to clarify how and to whom administrative costs would be considered. For instance, retained rebates are a form of administrative costs. Further, administrative costs are beyond a manufacturer's control.

- The Draft Plan should clarify how the Board will assess combination products, drugs that treat multiple diseases, and/or products with multiple FDA-approved indications.

- The Draft Plan states that the Affordability Board may not set a UPL for generic prescription drug products that have nine or more marketed therapeutic equivalents. However, the Board does not provide any systematic explanation as to how it developed this arbitrary threshold.

- The statute provides that the "process for setting upper payment limits [submitted to the legislature] shall" require the Board to "[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.[3]" However, the Draft Plan does not discuss these requirements or otherwise provide any information about the Board's plan after a UPL may be set. It is evident that the Board should address these statutory requirements.

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

BIO strongly opposes the PDAB's proposed use of cost effectiveness analysis due to its widely inappropriate and discriminatory nature. 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

[3] Md. Code, Health-Gen. § 21-2C-13(c)(2).

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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.[4] BIO urges Maryland 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 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.

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

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Potential Disclosure of Confidential, Proprietary, and Sensitive Information

As BIO has stated in previous comments to the Board, 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.

BIO is especially concerned about the Board's ability to "request that manufacturers submit documents explaining the relationship between the price of a prescription drug product and the cost of development and therapeutic benefit; the total amount of price concessions, discounts, and rebates provided to different payor types in Maryland; and net manufacturer revenue for the prescription drug product." It would be deeply disruptive to commercial markets if such proprietary information were disclosed or used in violation of confidentiality requirements. The Board also states that it is considering how the UPL may impact Medicaid Best Price. Given the confidential nature of Best Price, BIO is extremely concerned that this determination could result in disclosure of confidential pricing information.

Inappropriate and Inconsistent Methodologies to Establish a UPL

As mentioned above, BIO is strongly concerned by the menu of UPL methodologies from which the Board can choose, which seems to authorize use of different methodologies for different drugs. Applying inconsistent criteria and considerations across the UPLs of different drugs is extremely problematic and increases the potential for bias and discrimination for some therapeutic areas over others. It is absolutely essential that the Board ensure that it applies its methodology or methodologies in a consistent, non-arbitrary manner across different drugs and therapeutic areas. BIO recommends that the Board weigh these methodologies and clarify how it will select from among these methodologies.

Further, the proposed methodologies for setting UPLs focus primarily on cost containment rather than value assessment. This approach fails to account for the full spectrum of benefits that innovative drugs can provide, including improved patient outcomes, reduced hospitalizations, increased productivity, and overall healthcare system savings. In the case of vaccines, it is also evident that widespread vaccine administration allows costs to be avoided or averted, including costs associated with prevented absences or decreased disease severity. Many modern drugs, offer significant value that may not be immediately apparent in simple cost comparisons. For rare disease treatments, this issue is even more pronounced. These drugs often address previously untreatable conditions,

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potentially offering life-changing or life-saving benefits. The Draft Plan's emphasis on cost rather than value does not capture the full impact of treating diseases, including reduced caregiver burden, improved quality of life, and the societal value of addressing unmet medical needs.

Budget Impact-Based Upper Payment Limits

BIO is strongly concerned that the use of budget impact-based UPLs could unfairly penalize highly effective drugs that have high upfront costs but long-term positive patient outcomes. Budget impact analyses need to consider the long-term savings from treating previously unaddressed conditions, which may not be apparent in short-term budget calculations. The PDAB does not provide any information on how the Board will determine whether a product impacts the budget and how much a particular drug impacts the budget.

BIO strongly believes that it is inappropriate to establish a UPL based on non-health related external factors. There is no rational relationship between how the budget is allocated and how the Board intends to support patient access. Further, the methodology lack of any details on how the Board would determine the percentage of the budget that should not be exceeded. Such a decision would be extremely arbitrary and completely disregard the holistic value of the drug itself and the value of the drug to the overall healthcare system.

Therapeutic Class Reference Upper Payment Limit

The Draft Plan notes that a therapeutic reference class would be set for the lowest net price among the competitor products. However, the exact process for selecting therapeutic alternatives is not listed and the source and assumptions for the net price is also missing. This lack of critical detail is present for all of the proposed methodologies and factors presented in the document. BIO urges the Board to update the UPL plan to include detail on all methods and factors presented, including how the Board will determine whether a drug is "less effective," the planned sources for information, the exact definition of metrics (i.e., net price), the differences in safety and clinical profiles of the selected drugs and the therapeutical alternatives, and the documented process/best practices to be followed.

BIO also requests that the Board consider and evaluate the potential implications of using the lowest net price among all competitor products. The lowest net price is influenced by many factors and using it may actually result in Best Price implications for products under review if competitive net price is below the product under review.

International Reference UPL

As BIO has stated in other comments, we are strongly opposed to using methods that rely on international reference pricing, which divorces a product's

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reimbursement from the value it provides in favor of prices set by foreign governments based on factors that are not applicable to the U.S. market. International reference pricing does not account for possible variations in drug pricing due to differences in healthcare systems, market sizes and conditions, such as competition or negotiation practices, and pricing structures between countries. Additionally, international reference prices may not account for variations in purchasing power, healthcare expenditures, cost of living, or currency exchange rate fluctuations. International reference pricing threatens the development of new treatments, may impact global trade practices, and fails to account for the fact that patients in many other countries experience delays in accessing new medicines that are available in the U.S. International reference pricing is particularly problematic as many rare disease drugs may not be available or priced similarly in other countries due to even smaller patient populations Studies have shown that countries that use QALYs have severe restrictions on patient access to innovative medicines in other countries. For example, one study has shown that between 2002 and 2014, 40% of medicines that treat rare diseases were rejected for coverage in the United Kingdom.[5]

Further, most countries outside the United States use discriminatory measures of value, such as QALY analysis, to assist in price setting. This is prohibited at the federal level under the Inflation Reduction Act. It is essential that the PDAB recognize the discriminatory nature of QALYs and not utilize International Reference Pricing accordingly.

Finally, the Draft Plan's open-ended terminology creates the risk for potential bias and a subjective choice of countries that the Board may deem appropriate. It is evident that any comparison of international pricing requires a careful examination of local health outcomes and treatment effectiveness data to inform a rationale for selection.

Launch Price-Based UPL

BIO opposes the launch price-based methodology which penalizes manufacturers for market dynamics that are outside of their control. There are innumerable factors that impact a drug's pricing over time, whether it be new indications, new data such as Health Economics and Outcomes Research (HEOR)/Real World Evidence and new indication trial data, changes in production, or changes in the ecosystem. Accordingly, list price increases can reflect countless marketplace dynamics, including discounts to supply chain entities, new clinical data that increases the product's value, or increases in supply chain costs. Launch price-based UPLs ignore the clinical and economic value of drugs and their market factors and instead only address a partial context of price changes, which is significantly misleading and

[5] Mardiguian, S., Stefanidou, M., et al. "Trends and key decision drivers for rejecting an orphan drug submission across five different HTA agencies." Value in Health Journal. 2014. https://www.valueinhealthjournal.com/article/S1098-3015(14)03070-8/fulltext

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provides an inaccurate interpretation of pricing data.

Domestic Reference Upper Payment Limit

BIO is concerned about the Board's use of this methodology, which requires the use of confidential information. BIO opposes methodologies that sets the UPL for a particular company/product based on the price of a separate product manufactured by another company.

Same Molecule Reference Upper Payment Limit

BIO is concerned with the Board's use of this methodology and opposes its use to establish the UPL. As with the other methodologies, the UPL for a particular company/product should not be set based on the price of a separate product manufactured by another company. In addition, setting a UPL based off the prices of other products with the same active ingredients has significant and negative impacts on innovation. By comparing drugs by active ingredients, the Board leaves no incentive for therapeutic advancement and harms investments into new therapies, including for orphan and hard to treat diseases. This methodology would also significantly stifle generic/biosimilar competition at a time when product shortages are increasing.

Blend of Multiple Methodologies

The Board's proposal to blend multiple methodologies is problematic due to the arbitrary nature of methodology selection. The Board does not provide any consistent explanation on how they would analyze or weigh different methodologies, which if implemented, would lead to unpredictable and unreliable outcomes. An arbitrary blending of methodologies without a coherent strategy would compromise the validity and reliability of results, lead to outcomes that are not well-suited to addressing patient access considerations, and would lead to further confusion among stakeholders. Rather than blending methodologies, it is important that the Board focus on a well-defined and systematically applied methodology that is based on economically and scientifically sound principles that can be applied across products equally.

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. BIO remains particularly concerned around the Draft Plan's language that allows, in the setting of the UPL, any information that can be "derived from the manipulation, aggregation, calculation, and comparison of any available information." This broad language is extremely concerning as it appears to allow the Board to use any information in any

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way they chose to establish a UPL. 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.

Expert Testimony Hearings

The Draft Plan lacks detail regarding what expert testimony is needed and the sources for the expert testimony. It is important that the Board ensure that the testimony is directly relevant and helps inform patient access considerations that are crucial for informed decision-making.

Board Staff Research and Analysis

The Draft Plan indicates that staff may provide the Board with policy research and analyses related to "the drivers of potential affordability," suggesting that the research will be focused on general prescription drug affordability as opposed to specific research related to the drug under consideration. Meanwhile, there is no mention of how the information collected will be utilized or weighed; accordingly, the general research could carry as much weight as product-specific considerations and effects on specific patient populations.

Insufficient Detail Regarding Staff Calculations of Market Basket and Staff Proposed UPL Amount

The Draft Plan does not provide any definition of "market basket", or any details on what amounts will be included in the "market basket" of UPL amounts and how they will be determined. BIO urges the Board to include a description of the calculations and analysis used to develop the "market basket", and to outline how they will prioritize the values considered in the "market basket." It is critical that the Board set forth a clearly established process to determine the UPL values in a transparent and repeatable manner.

Potential Conflict with Federal Pricing and Reimbursement Mechanisms

The Draft Plan's criteria for setting an UPL go far beyond statute and conflict with federal pricing and reimbursement mechanisms. Even if the Affordability Board tries to avoid impacts to statutory or regulatory amounts, it's unknown how a UPL may affect these metrics. The interaction between state-level UPLs and federal pricing programs like Medicaid Best Price is complex. While the plan states that UPLs should not impact these programs, it's unclear how this will be practically implemented. There is a risk that UPLs could inadvertently trigger lower prices in federal programs, affecting nationwide pricing. Given the significant federal preemption concerns, the Board should clarify how it intends to ensure a UPL will

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not impact statutory or regulatory amounts like the Medicaid Best Price, either directly or indirectly. The Draft Plan should further specify which statutory and regulatory amounts it is referring to beyond Best Price.

While the Draft Plan states that "the Board shall not set an upper payment limit amount that impacts statutory or regulatory amounts, such as Medicaid Best Price," other statutory calculations could be impacted by transactions at a UPL. Sales and discounts to CCS (City, County, State) are not exempt from government pricing calculations. Establishing an UPL for CCS sales could result in sales transactions included in government pricing calculations impacting Average Manufacturer Price (AMP), Average Sales Price (ASP), and impacting 340B – even when the UPL is capped at best price. The Board must clarify how they will ensure that other statutory calculations will not be impacted, including how they will prevent 340B duplicate discounts.

Further, rare disease drugs often rely on complex pricing arrangements to balance access and sustainability given their small patient populations. These may include outcomes-based contracts, annuity payments, or other innovative pricing models. It's not clear how these would interact with the proposed UPL system, potentially creating conflicts with federal pricing requirements or disrupting carefully balanced access programs.

Lack of Mention of Important Recommendations from Previous PDAB Meetings

BIO would like to note several recommendations from previous PDAB meetings that have not been considered in this Draft Plan and warrant consideration. In the July PDAB meeting, staff recommended that UPLs initially apply only to select eligible government entities through a "pilot program." If the Board chooses to proceed with the UPL, it should be done through a pilot program with appropriate tracking and measurements to ensure that there are no negative consequences on patients.

BIO also notes in previous PDAB meetings held in late 2023, staff had offered multiple options for how a UPL, if established, may be executed. We encourage the Board to discuss these options further and allow for an opportunity for stakeholders to comment on these options.

Lack of Appeals Process and Other Safeguards

The Draft Plan does not address any safeguards to mitigate unintended impact to drug manufacturers such as duplicate discounting. This occurs when a manufacturer sells a drug at a statutory discount and the manufacturer subsequently pays a rebate on that drug to a health plan. Without sufficient safeguards, this could result in the drug being sold below cost.

BIO is also concerned that the Draft Plan does not contain any mention of an

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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 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.

***

BIO appreciates the opportunity to provide feedback to the Maryland PDAB through this Draft Plan. We look forward to continuing to work with the Board 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/

Jack Geisser
Senior Director,
Healthcare Policy,
Medicaid, and State Initiative

/s/

Melody Calkins
Senior Manager
Healthcare Policy and Reimbursement

CSRO
Coalition of State Rheumatology Organizations

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August 26, 2024

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

Re: Setting Upper Payment Limits

The Coalition of State Rheumatology Organizations (CSRO) is comprised of nearly every active state rheumatology society in the nation, representing over 40 states, with a mission of advocating for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

Rheumatologic disease is systemic and incurable, but innovations in medicine over the last several decades have enabled rheumatologists to better manage these conditions. With access to the right treatment early in the disease, patients can generally delay or even avoid damage to their bones and joints, as well as reduce reliance on pain medications and other ancillary services, thus improving their quality of life.

The Board is tasked with setting "an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences." It is with this in mind that we write to express concerns regarding unintended consequences of the Board's plan of action for implementing a process for setting upper payment limits. We fear this proposal may actually drive up the cost of physician administered medications instead of making them more affordable for patients, while simultaneously causing significant financial strain on physician practices throughout Maryland.

Physician Administered Medications

We appreciate that the Board has recognized the importance of considering "the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs (HG § 21-2C-13(b))" when establishing an upper payment limit (UPL). This is critically important to healthcare providers who directly administer medications to their patients, as the UPL places these providers at significant risk if they are not able to cover acquisition costs for these medications.

As currently drafted, the UPL caps provider reimbursement for a prescription drug consistent with the rate determined by the Board. It does not, however, require that providers acquire the medication at a rate sufficiently below the UPL to account for acquisition costs to the provider. This is highly problematic for healthcare providers who administer medications directly to patients in outpatient settings.

Healthcare practices that directly administer medications on an outpatient basis are typically engaged in a practice known as "buy and bill." These practices pre-purchase drugs and bill a payer for reimbursement once the medication is administered to a patient. Margins for practices engaged in buy and bill are thin. To maintain the viability of administering drugs in these setting – which are often more cost-effective settings

for the payer and safer for immunocompromised patients – reimbursement must account for acquisition costs, such as intake and storage, equipment and preparation, staff, facilities, and spoilage insurance.

Currently, most payers reimburse providers for the cost of the medication plus an add-on payment at a bundled rate to cover the acquisition costs and make provision of service economically viable. Reimbursement rates that do not sufficiently compensate for these costs put healthcare practices at risk. Unfortunately, the UPL outlined in the Board's proposal would prevent healthcare providers from collecting this add-on payment, making it untenable for healthcare providers in outpatient settings to administer medications that are subject to the UPL. If patients are unable to receive their medications in outpatient settings, they will be forced to receive provider administered care in hospital settings, which are more expensive to the payer.

Pharmacy Dispensed Medications

The Board has recognized that "a UPL may not be the preferred policy solution for every affordability challenge," and is therefore granted the authority to recommend other policy actions. While the Board has placed a strong emphasis on prices and costs associated with the initial steps in the pharmaceutical supply chain, it is important to note that many pharmacy benefit plans are utilizing a variety of programs that undermine the effectiveness of programs created to keep patient costs down, such as copay assistance programs. These plans, organized by pharmacy benefit managers (PBMs), are contributing significantly to patient out-of-pocket costs, driving unaffordability.

We encourage the Board to consider the role PBMs play in driving up the cost of prescription medications. If the Board pursues a UPL without any guardrails in place for the PBMs, it is likely that these middlemen will manipulate the formularies so that these newly priced drugs are put on a much higher tier, and therefore less accessible to patients. PBM business practices favor higher priced drugs because they have the potential to hear more off those medications. We strongly encourage the Board to consider mechanisms that will ensure that drug placement on the formulary remains consistent even after a UPL is implemented.

UPL Criteria

The Board has identified a robust set of methodologies and factors to establish the UPL. We respectfully have concerns with the use of several of the proposed.

Therapeutic Class. In setting the UPL to the lowest net price among all competitor products, the Board will significantly disrupt the market by arbitrarily cutting the most expensive product while still allowing products in the median to remain at market value. We fear this may cause manufacturers to limit the availability of the medications impacted by the UPL. This has ripple effects throughout the system, such as driving medication shortages. But it also hurts patients who may respond better to certain medications over others. Rheumatologic patients often require a highly personalized approach as we manage their chronic illnesses. All patients will not be able to manage their conditions optimally if forced to switch to an alternate medication with the therapeutic class.

Small Molecule Reference. In setting the UPL to the lowest priced product with the same molecule, the Board may unintentionally limit access to biologic and biosimilar products. These complex medications are often administered by healthcare providers to patients with chronic conditions. When biosimilars were brought to the market, we hoped they would offer a more cost-effective alternative to brand biologics. Unfortunately, pharmacy benefit managers (PBMs) have created perverse incentives around formulary placement that have caused manufactures to over rebate their drugs for preferred placement, which has in turn led to a precipitous drop in the average sales price and ultimately slashed reimbursement rates. Most rheumatology practices across the country are underwater due to insufficient biosimilar reimbursement, threatening patient access. In creating a UPL based on small molecule reference, the Board may unintentionally exacerbate this problem and limit patient access to these biologic and biosimilar medications.

Domestic Reference. In setting the UPL to the Medicare Maximum Fair Price (MFP), the Board risks patient access as MFP is likely to under reimbursed for physician administered medications. (It's important to note that the first set of MFP drugs was just selected, and implications of the program are yet realized.) Much like our comments above, we have serious concerns that MFP will not properly account for acquisition costs. If MFP based reimbursement drops below acquisition costs for selected drugs, medical practices will suffer financial instability and may stop offering the selected drugs until acquisition costs can meet reimbursement levels.

International Reference. In setting the UPL to the lowest price paid by the United Kingdom, Germany, France or Canada, the Board neglects to recognize that the pharmaceutical supply chain operates very differently in these countries than it does in the United States. The most notable difference is that PBM middlemen do not play a role in drug pricing in the included countries. Therefore, formulary construction is completely different. We believe it is ill advised to reference these international prices when the way in which those prices are set is so vastly different than the U.S. market.

Furthermore, we encourage the Board to adopt criteria that require any UPL to also account for healthcare provider acquisition costs – including, but not limited to, intake and storage, equipment and preparation, staff, facilities, and spoilage insurance – so that healthcare providers are not responsible for personally funding the difference in healthcare costs and expenditures.

Actual Out-of-Pocket Costs

CSRO believes it is important for the Board to consider typical out-of-pocket expenses for patients when considering whether the drug should be assigned a UPL. Copay assistance programs are designed to defray cost-sharing amounts charged to the patient by the plan for their prescription drug. These programs cover most or all of the patient's cost-sharing responsibility through a direct payment at the point of sale in order to enhance affordability for patients.

We recognize that high priced drugs that do not offer copay assistance are a real financial threat to patient access, which has become more prevalent among some generic medications. However, when copay assistance programs are offered, the patient will typically pay between $0 to $25 at the pharmacy counter for their medication. Copay assistance programs also help defray costs associated with administration for the provider administered formulation, making the copay assistance program particularly generous. While a drug's cost in a vacuum may induce sticker shock, these costs are almost never what a patient actually pays for a drug at the end of the day. We encourage the Board to consider actual patient out-of-pocket costs when reviewing medications.

We appreciate the Board's consideration and are happy to provide further insights to these comments as the Board considers its recommendations to the state legislature.

Respectfully,

Gary Feldman, MD, FACR
President
Board of Directors

Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs
Board of Directors

August 26, 2024

Mr. Andrew York
Executive Director
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Mr. York:

I am writing on behalf of the Color of Gastrointestinal Illness (COGI) to comment on the Board's ongoing cost review activities, particularly as it pertains to Skyrizi. COGI represents black, indigenous and other people of color (BIPOC) who are affected by inflammatory bowel disease (IBD), digestive disorders, gastrointestinal cancer and associated chronic illnesses.

Skyrizi is a highly effective and needed treatment for many in our community. One of COGI's key missions is breaking down the barriers preventing people of color from achieving optimal health outcomes. We have serious concerns that the work the PDAB is doing will have the unintended consequence of putting up more barriers for our patients to access Skyrizi and other needed treatments.

Due to the historic perception that people of color are not impacted by gastrointestinal diseases, it often takes far too long for patients in our community to get an accurate diagnosis. Given this delay, it is essential that once we are diagnosed, we are able to quickly and efficiently access the medications we need – additional delays only enhance the disparities in care that patients of color already face. For many patients, Skyrizi is needed to manage conditions like Crohn's disease and others may a different drug. It is imperative to protect patients from unintended consequences for accessing Skyrizi or for encouraging step therapy and prior authorization policies that create barriers to other drugs that treat Crohn's disease or ulcerative colitis.

Therefore, we have real concerns that the PDAB's actions related to Skyrizi may lead to the drug being unavailable to patients in Maryland and/or may lead to more aggressive utilization management being employed by insurers on competitor products that some of our patients also need. This outcome would be a significant step back in the push for health equity. We urge the PDAB to carefully consider this reality as it moves forward with cost reviews and proposed upper payment limits.

We support the intent to help patients access the care they need – which is only possible if the Board meaningfully engages and listen to patients. We have been consistently concerned that the Board's processes for cost reviews are not centered on the patients and people with disabilities impacted by its decisions. As a small patient advocacy organization, we do not know how our engagement makes a difference or how the information we provide to the Board may be used in its decisions. With a process that values our input, COGI stands ready to help the Board conduct its work in a patient-centered manner.

We are pleased to be working with the Ensuring Access through Collaborative Health (EACH) Coalition on a new survey for patients that elicits information about their challenges accessing affordable medications. When that survey becomes available, we look forward to sharing it with patients in an effort to get reliable information to the Board about the real-world experiences of patients.

Thank you for your consideration of our comments.

Sincerely,

Melodie C. Narain-Blackwell

Melodie C. Narain-Blackwell
President & CEO
Color of Gastrointestinal Illnesses (COGI)

COMMUNITY ACCESS NATIONAL NETWORK

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August 24, 2024

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

RE: Maryland Draft Upper Payment Limit Action Plan Approval

Dear Honorable Members of the Maryland Prescription Drug Affordability Board,

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 are writing with specified concerns and requests for clarification relative to the Draft Upper Payment Limit Action Plan.

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". The question is not so much a matter of agreeing on the definition of the word "affordability". It is more 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". 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, but to 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 that have 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. 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.

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.

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.

We thank you for the opportunity to provide feedback on the draft working document. We respectfully ask that you consider all the concerns raised and welcome dialogue concerning any questions you may have regarding our comments.

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

August 22, 2024

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

Dear Members of the Maryland Prescription Drug Affordability Board:

On behalf of the people living with cystic fibrosis (CF) in Maryland, the Cystic Fibrosis Foundation writes to provide comments on the *Maryland Prescription Drug Affordability Board Plan of Action for Implementing the Process for Setting Upper Payment Limits*. We appreciate the need to improve affordability of care for Marylanders and address rising costs to ensure sustainability of the state's health care system. However, the paramount goal must be preserving access to care and therapies for people living with a disease, and we are glad that the Maryland Prescription Drug Affordability Board (PDAB) recognizes that it may be working towards two separate aims that require separate consideration and policy solutions: reducing drug costs for the state of Maryland and reducing drug costs for consumers. Policies that cap reimbursement for drugs may not ultimately impact what Marylanders pay at the pharmacy counter and it is important that the PDAB recognize this distinction. The Maryland Prescription Drug Affordability Board must ensure that the needs of people living with a disease, including CF, at the center of the discussion when considering whether and how to set an upper payment limit (UPL).

About Cystic Fibrosis & the Cystic Fibrosis Foundation
Cystic fibrosis is a progressive, genetic disease that affects the lungs, pancreas, and other organs. There are close to 40,000 children and adults living with cystic fibrosis in the United States, including more than 570 people in Maryland, and CF can affect people of every racial and ethnic group. CF causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to lung damage, life-threatening infections, malnutrition, and other complications. Cystic fibrosis is both serious and progressive; lung damage caused by infection is often irreversible and can have a lasting impact on length and quality of life, resulting in extended hospitalizations, transplant, or premature death. As a complex, multi-system condition, CF requires targeted, specialized treatment and medications. There is no cure.

As the world's leader in the search for a cure for CF and an organization dedicated to ensuring access to high-quality, specialized CF care, the Cystic Fibrosis Foundation supports the development of CF clinical practice guidelines and accredits more than 130 care centers nationally—including two in Maryland.

Policy Review Process
While UPLs may address overall prescription drug spending for the state and help bring down premiums, it may not ultimately impact what Marylanders pay at the pharmacy counter. To this end, we support the robust policy review process in the UPL action plan that encourages the PDAB to consider policy solutions other than a UPL to address the drivers and market failures causing the affordability challenge. A UPL may not always be the best solution to lower costs for consumers, depending on specific drug and market considerations. The PDAB should have the freedom to consider all economic and political levers

to determine what would be most effective and appropriate to lower prices for consumers, and we appreciate that the UPL Action Plan provides this flexibility.

Due to the complexity of the U.S. health care system, there are many factors and entities involved in determining what patients pay for their drugs. For instance, while people with CF rely on expensive specialty drugs, their out-of-pocket costs for these medications are often more affordable because of manufacturer or non-profit copay assistance programs. Navigating intricacies of health plans and assistance programs can be burdensome and time consuming, but often means that people may be able to afford the cost-sharing for their most expensive therapies. Far too many people with CF still struggle to afford all of their care—which includes an extensive treatment and care regimen—but their affordability challenges are not always driven by the cost of one specialty drug. We recognize that copay assistance programs can mask bigger cost and affordability issues; however, we share this information to highlight that affordability challenges for the system do not always align with affordability challenges for consumers.

As the PDAB considers a range of policy remedies to address drug affordability, the Foundation recommends consideration of measures related to accumulator programs and PBM reform. We supported legislation during Maryland's 2024 legislative session that would ban accumulator programs by requiring insurers to apply patient assistance to their health plan cost-sharing requirements. Patients with chronic diseases like CF often struggle to afford their care and rely on copay assistance to access vital medications. We recognize that copay assistance is problematic—allowing pharmaceutical companies to charge payers high prices, while shielding many individual patients from the costs—but banning copay accumulator programs helps ensure patients' health and financial wellbeing are not sacrificed in the ongoing debate between payers and pharmaceutical companies about prescription drug prices.[1] Additionally, many states are pursuing reforms of pharmacy benefit managers (PBMs) to address drug affordability, including establishing fiduciary requirements, prohibiting spread pricing, increasing transparency, and pharmacy network reforms. We are encouraged to see that the Maryland legislature has considered legislation that would implement some of these provisions.[2] These measures will create more pressure on plans and PBMs to put the interests of the patient first and will have a direct impact on consumer costs.[3]

Stakeholder Engagement and Transparency

We are glad to see that the UPL Action Plan includes stakeholder processes through which people living with a disease and their caregivers can provide input on the PDAB's consideration of policy solutions to address drug unaffordability, including setting UPLs. We recommend that the PDAB to provide diverse opportunities for stakeholder involvement to address time and technology limitations at all stakeholder engagement points, including when a preliminary determination is made, during the policy review process, and when considering a UPL. For example, we encourage the Board to provide multiple hearings at a variety of times to accommodate adults living with a disease and adult caregivers that are working and unable to join a meeting during business hours. Other avenues for public engagement can include online surveys and focus groups. It is also crucial that people living with a disease and caregivers be involved in the development of survey and focus group questions. All of these processes should be

[1] Cystic Fibrosis Foundation letter supporting SB 595 that would require insurers to apply patient assistance to their health plan cost-sharing requirements. February 27, 2024. Available at: https://www.cff.org/statements/2024-02/maryland-ban-co-pay-accumulators-alternative-funding-plans

[2] SB 896. Available at: https://mgaleg.maryland.gov/2023RS/bills/sb/sb0896F.pdf

[3] U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulations of Pharmacy Benefit Managers*, March 18, 2024. Available at: https://www.gao.gov/products/gao-24-106898

conducted if the PDAB begins any development of policy recommendations or determinations of upper payment limits.

We also appreciate that the UPL Action Plan requires the PDAB to be transparent about their processes and methodologies for determining whether a drug has led to or will lead to an affordability challenge, whether to set a UPL or pursue other policy actions, and what amount the UPL should be. We emphasize the importance of explaining the process in a lay friendly manner to ensure the public can understand the process and authentically engage with the PDAB throughout the proposed policy review process and any UPL determinations. The UPL Action Plan should also require the PDAB to educate people living with a disease, providers, and other members of the public about its process and timeline for setting a UPL, how the UPL will be calculated, and any potential outcomes. The PDAB should be transparent to the public about how data and information collected, especially from people living with a disease, will be used in the decision-making process and with whom it will be shared as well.

Consideration Criteria

While we appreciate the inclusion of the proposed criteria, we request that the UPL Action Plan include additional criteria when deciding whether to set a UPL.

Availability of therapeutic alternatives

We urge you to include the availability of therapeutic alternatives as a criterion the PDAB must consider when determining whether to set an upper payment limit, as this is a critical factor in understanding the market for a particular therapy and deciding whether to establish a UPL. In CF care, treatments are finite and therapeutic alternatives are often not available. For example, a class of drugs called CFTR modulators only works for individuals with certain genetic profiles; they are not interchangeable and there are currently no generics or therapeutic alternatives. When evaluating the market for a particular drug and whether to establish a UPL, The PDAB must consider the availability of therapeutic alternatives as there are unique access concerns for drugs without alternatives.

Moreover, given that the PDAB only has authority over state and local government spending, the board has limited leverage for drugs without therapeutic alternatives. In contrast to Medicare price negotiation—where manufacturers would be hard pressed to walk away from all Medicare beneficiaries—the PDAB is dealing with a relatively small market and a single source manufacturer may be willing to give up the state market rather than accept a UPL. UPLs may hold more promise for drugs with therapeutic equivalents. It is feasible that a state could achieve savings in this scenario while preserving access for patients.

Orphan drug status

The CF Foundation urges the PDAB to include orphan drug status as a criterion when the PDAB determines whether to set an upper payment limit. The small number of people in rare disease populations can create unique challenges for drug development and present different market considerations compared to other therapies. This limited market size for these kinds of drugs is a factor in determining the price of these therapies, and it is important to preserve financial incentives to bring more drug developers into this space as there are many rare diseases without any approved treatment. For instance, some CF treatments are indicated based on specific genetic variants and therefore even for a disease like CF with many approved treatments, there must still be incentives to continue investing in this space. The PDAB should consider orphan drug status alongside other existing factors already outlined in the UPL Action Plan to ensure a more comprehensive view of the treatment and access landscape for people living with a rare disease.

Length of time on market
The UPL Action Plan should establish a minimum period of time that drugs must be on the market before they are eligible for a UPL. While data from clinical trials is important for establishing safety and efficacy, it can take years to fully understand the benefits of a given drug. For instance, collection of real-world evidence is vital to understand how a drug impacts people living with a disease in a real-life setting. Such data also allows researchers to capture information on additional outcomes beyond those evaluated in a clinical trial, such as patient-reported outcomes related to quality of life, productivity, and well-being. For diseases with complex care regimens such as cystic fibrosis, it is also important to also give adequate time to study the impact of a new therapy on other aspects of care. These studies require ample time to assess changing existing care in response to new treatments. Collection of real-world evidence takes time as well and may not be available until a drug has been on the market for a number of years.

Moreover, in cystic fibrosis, the Food and Drug Administration initially approved CFTR modulators for people with certain genotypes ages 12 and up. As sponsors collect additional data, the labels have been expanded to include additional genotypes and younger age groups. As a progressive disease, understanding the impacts of CFTR modulators on younger populations is essential for a comprehensive affordability review as these treatments may delay or halt disease progression, thus impacting healthcare utilization, productivity, and the overall trajectory of cystic fibrosis. As such, the UPL Action Plan should establish a minimum time that drugs must be on the market before they are eligible for a UPL.

Lived experiences of people living with a disease
Cost-effectiveness methodologies cannot accurately measure value if they do not include data on the experiences, preferences, and outcomes reported by people living with a disease. To that end, the UPL Action Plan should require that the PDAB seek out patient-reported data for UPL determinations, including patient surveys, focus groups, presentations from patient-focused drug development meetings, and registry data. This is essential to complement data from clinical trials, claims data, and other sources and give a full picture of how a therapy works for people living with a disease.

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Thank you for the opportunity to comment on the *Maryland Prescription Drug Affordability Board Plan of Action for Implementing the Process for Setting Upper Payment Limits*. The Cystic Fibrosis Foundation stands ready to serve as a resource as the Maryland PDAB explores solutions to improve access to and affordability of care for Marylanders. Please contact Amanda Attiya, State Policy Specialist, at aattiya@cff.org or (240) 482-2879 with any questions about this issue.

Sincerely,

Mary B. Dwight
Chief Policy & Advocacy Officer
Senior Vice President, Policy & Advocacy
Cystic Fibrosis Foundation

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

August 26, 2024

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

RE: Public Comments on Draft Upper Payment Limit Action Plan

Dear Members and Staff of the Oregon Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) Coalition is a network of national and state patient organizations and allied groups that advocate for treatment affordability policies that consider patient needs first.

We appreciate the opportunity to provide comments to the board on the draft Upper Payment Limit Action Plan to ensure that the process ultimately protects and improves health care for patients. We respectfully urge the board to consider the concerns of patient organizations outlined in this letter. We offer our organization as a resource to board members seeking to connect with patient organizations and patients.

Implement Rigorous Standards and Proceed with Appropriate Due Diligence

We applaud the board's dedication to improving healthcare in the state and each board member's willingness to commit time and energy to a noble endeavor. The board has been tasked with addressing high drug costs for patients, a mission we share. However, we also urge the board to conduct proceedings with care and caution.

The authorizing statute in Maryland allows for interventions in cases where a drug's cost "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients." Without the implementation of rigorous standards for analysis and careful decision making, such a broad mandate could allow for unnecessary and overly broad interventions into the healthcare marketplace.

We urge the Maryland board and staff to take the utmost care at the beginning of the cost review process to carefully outline standards, metrics, and processes that will guide the board's decisions and help prevent overreaching conclusions or interventions, now and in the future.

Seek the Best Policy Solution to Address the Patient Problems

We are encouraged that the board acknowledges in their draft plan that "a UPL may not be the preferred policy solution to every affordability challenge". While well intentioned, we are concerned that cost reviews and upper payment limits (UPLs) can have unintended consequences for patients and result in worse outcomes for those who rely on the drugs under review.

Because the board has expressed a willingness to explore alternative policy solutions, we encourage them to do so prior to conducting their initial round of cost reviews. Proceeding without doing so increases the likelihood that the board will resort to implementing UPLs simply because other policy solutions have not been explored and are therefore not available to implement.

Therefore, we urge the board to suspend its planned cost reviews and dedicate board meetings for the remainder of the year to exploring other potential policy options. According to the old adage, when you only have a hammer, everything looks like a nail. Currently, the board simply does not have enough tools to address patient needs and lower drug costs.

Ensure a Methodical Review and Process

The board outlines in its draft plan that the preliminary determination that a drug poses affordability challenges will allow the board to start its policy review process. While we understand the board's need to function with efficiency, we are concerned that finalizing the cost review process while also beginning consideration of a UPL will rush a critical decision-making process.

We urge the board to conduct and finalize its cost reviews as an independent process. This will allow both the board and stakeholders appropriate time to thoroughly review and consider the data presented. Stakeholders, including patients and their advocates, will have the opportunity to provide input, questions, and share their personal experiences with board members before any final cost review decisions are made.

Once concluded, the board should then proceed with reviewing all policy reviews to address any affordability challenges identified. This will also allow for a more comprehensive review of any and all policy solutions, rather than deferring only to UPLs as the next course of action.

Focus on Patient Experiences and Perspectives

Finally, we urge the board to ensure that patient experiences are a critical focus of the process to identify the appropriate policy remedy. Rather than immediately proceeding to a UPL, the board should instead take the opportunity to seek broad patient input to better understand the source and reasons for affordability challenges.

We urge that the board utilize the policy review process to gather more in-depth input from patients in the form of roundtables or focus groups. We urge the board to utilize this organization and its members as a direct conduit to understanding and incorporating patient and caregiver perspectives, as well as those of patient organizations who have an understanding of the life cycle of disease from the lens of prevention, diagnosis, and disease management.

While our health system and the policies that impact it are complicated, one principle is simple: every change that we make and policy we implement should ultimately benefit patients. We urge the board to keep this principle as a singular focus of the policy review process.

We appreciate your laudable efforts to improve our health system and your steadfast commitment to protecting patients. We look forward to working together to achieve these goals.

Sincerely,

Tiffany Westrich-Robertson

Tiffany Westrich-Robertson
Ensuring Access through Collaborative Health (EACH) Coalition

August 23, 2024

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

Honorable Members of the Maryland Prescription Drug Affordability Board,

The Alliance for Health Innovation (Alliance) is a group of cross-sector stakeholders representing patients, providers, caregivers, academia, biopharmaceutical innovators, and business communities.

Led by the Global Coalition on Aging (GCOA), the Alliance is committed to establishing the importance of innovation in achieving healthy aging. We advocate for state policy solutions that support a thriving innovation sector, enabling Maryland residents and other communities to live longer and healthier lives.

We thank the Board for the opportunity to comment on the working draft of the "Maryland Prescription Drug Affordability Board Plan of Action for Implementing the Process for Setting Upper Payment Limits" (UPL Plan).

Today, we write with significant concern about several aspects of the draft UPL Plan, including the overall lack of specific details about the metrics and measures that will be used to determine drug affordability and UPLs. These aspects can harm patient access and innovation to life-saving therapeutics.

In June 2024, the Alliance convened an expert roundtable of patients and patient advocates, policy experts, caregivers, academia, biopharmaceutical innovators, and business communities to discuss PDABs and UPLs, the risks they pose to patients, and the innovation needed to safeguard healthy aging and improve health equity. The themes and concerns shared during this roundtable have informed much of our commentary on the draft UPL Plan.

1. **Lacking Definition of Affordability: What is it & to Whom?**

In the draft UPL Plan, there is no clear definition of affordability and its meaning to specific groups or individuals. The only criterion included in the document is under the "Cost Review" section, stating that it "has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients."

The lack of a definitive "affordability challenge" raises many questions. Will the threshold of affordability change based on the product being considered? Will it be different for different entities – the health system versus out-of-pocket patient costs? Further, under "Criteria for Setting an Upper Payment Limit" states, "The Board shall not set an upper payment limit for the prescription drug product if the utilization of the product by Eligible Government Entities is minimal." While this bodes well for patients with rare conditions requiring low-volume therapeutics, this further indicates inconsistent affordability metrics.

Moreover, the UPL Plan lacks meaningful opportunities for engagement from patients, caregivers, and other impacted stakeholders regarding the implementation of UPLs on the treatments they may rely on to stay healthy.

In June 2024, the Oregon PDAB opted to halt all drug affordability reviews for the remainder of the year and regroup in 2025, so that, among other things, the Board could determine what affordability means. Before this, the Board was undertaking drug reviews without a clear definition of the very variable they were seeking to assess.[1] The Maryland PDAB should consider a similar action: clearly define affordability before deciding whether a product poses an "affordability challenge."

2. Impact on Patient Care, Access & Health Equity

UPLs can inadvertently restrict patient access to essential medications and treatments. When reimbursement caps are imposed, there is a risk that the availability of necessary medications may become limited. In particular, this impacts individuals with chronic or complex conditions who rely on specific treatments to manage their health effectively. Such restrictions can lead to delayed access to treatments or the necessity to resort to less effective or alternative therapies, ultimately compromising short- and long-term patient health outcomes.

Further, we have significant concerns regarding the introduction or exacerbation of health equity issues rooted in access to care. In addition to Maryland governmental employees covered by their employer health care plan, UPLs will affect "prescription drug products that are "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: State or county correctional facilities; State hospitals; and health clinics at State institutions of higher education.""

[1] Aimed Alliance (2024, July 1). Oregon PDAB Postpones Drug Reviews Until 2025. Aimed Alliance. https://aimedalliance.org/oregon-pdab-postpones-drug-reviews-until-2025/

This will disproportionately affect underserved populations in Maryland, as they have higher enrollment in the programs subject to UPLs. For example, UPLs will affect prescription drug products purchased by State correctional facilities. In Maryland, Black people are incarcerated at a rate of 4.5 times higher than white people, and an estimated 90% of Maryland prisoners qualify for Medicaid upon release.[2,3] Further, the population of Black people in Maryland is 31% of the state's residents, but 52% of people in jail and 69% of people in prison.[4]

Medicaid beneficiaries are more likely to have a chronic disease compared to patients not enrolled in Medicaid.[5] Further, three-quarters of non-elderly residents enrolled in state Medicaid are people of color.[6] Should the Maryland PDAB consider and select drugs for affordability reviews based on the conditions faced most frequently by this patient population, they threaten to stunt innovation and the discovery of future treatments for conditions that disproportionately affect Maryland's Medicaid beneficiaries, such as heart disease, cancer, and HIV.

Third, PDABs have the potential to reduce access to critical medications, with strong negative impacts on healthy aging. According to the 2020 Census, the U.S. population aged 65 and over grew nearly five times faster than the total population over the 100 years from 1920 to 2020. Our country's rapidly growing aging population signals a need for solutions that promote innovation that can keep individuals working and contributing for longer, rather than policies that threaten patient outcomes and increase the burden on our healthcare system.

2. Threats to Medical Innovation & Unintended Consequences

The healthcare sector thrives on innovation, driven by the need to develop new treatments and technologies that improve patient care. Financial constraints imposed by UPLs deter pharmaceutical companies and researchers from investing in research and development efforts to discover and bring to market groundbreaking therapies. The prospect of lower returns on investment may lead to decreased funding for these critical R&D efforts, stifling the progress that is necessary to address unmet medical needs and advance healthcare solutions.

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[2] Vera Institute of Justice. (2019). Incarceration Trends in Maryland. https://www.vera.org/downloads/pdfdownloads/state-incarceration-trends-maryland.pdf

[3] Li-Rodenborn, E. R., Navarro-Serer, B., Pitts, S., Kavya Anchuri, K. (2020, October). Policy Memo: Improving Healthcare Access Among the Newly Decarcerated. *Journal of Science Policy & Governance*. https://doi.org/10.38126/JSPG170209

[4] Ibid.

[5] Joszt, L. (2017, November 28). Identifying the Most Prevalent and Costly Chronic Conditions in Medicaid. *AJMC*. https://www.ajmc.com/view/identifying-the-most-prevalent-and-costly-chronic-conditions-in-medicaid

[6] KFF. (2024, August). Medicaid in Maryland. https://files.kff.org/attachment/fact-sheet-medicaid-state-MD

UPLs can also impact pharmaceutical companies' willingness to bring new drugs to market. When the return on investment is not there, companies may be less inclined to undertake the substantial risks of developing new and potentially life-saving medications. This disincentive can result in fewer new treatments being introduced, limiting the options available to patients and slowing the pace of medical progress.

Further, UPLs are unlikely to reduce patients' out-of-pocket costs. Research from the Partnership to Fight Chronic Disease (PFCD) explored payer perspectives on UPLs, which revealed the potential impacts of PDABs' use of these tools to set price limits on prescription medicines.[7]

- *Most surveyed payers (five of six) did not anticipate that UPL-related savings would be passed on to patients through lower premiums, deductibles, or cost sharing.*
- *Payers expressed that UPLs may place unintended financial pressures on provider-administered UPL drugs.*

All payers interviewed noted that drugs subject to a UPL and competitors in the therapeutic class are likely to see increased utilization management should the UPL restructure new benefit designs.

While controlling healthcare costs is a critical objective, UPLs can have far-reaching adverse effects on patient access to medicine, healthy aging, the pace of medical innovation, and the overall efficacy of the healthcare system. We urge the Maryland PDAB to consider these potential consequences and explore alternative approaches that balance cost control with the need to ensure patient access to essential treatments and foster ongoing medical advancements. The Maryland PDAB must consider these consequences in the context of the current draft UPL Plan.

Thank you for allowing us to share our concerns and for your commitment to finding solutions to the affordability challenges that Maryland patients face. We would be happy to discuss these concerns further or answer any questions you might have.

Sincerely,

Michiel Peters

Michiel Peters

Head of Advocacy Initiatives, Global Coalition on Aging

[7] PFCD. (2024, April 2). New Insurer Perspectives Highlight Considerable Patient Challenges Anticipated from Prescription Drug Affordability Boards. *PFCD*. https://www.fightchronicdisease.org/latest-news/new-insurer-perspectives-highlight-considerable-patient-challenges-anticipated

August 26, 2024

VIA ELECTRONIC FILING

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

Dear Members of the Maryland Prescription Drug Affordability Board:

GSK appreciates the opportunity to submit written comments in response to the Board's Plan of Action (Plan) for Implementing the Process for Setting Upper Payment Limits (UPLs). 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 proposed Plan and recommends alternative strategies to ensure patient access to life-saving medications.

UPL Effectuation
While the Plan considers methodologies for establishing an UPL, the Plan does not discuss, explain, or consider 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 is not clear on whether UPLs will be implemented 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. This could result in the drug being sold below cost. Additionally, UPLs may adversely impact provider and health plan net costs if medications subject to an UPL no longer qualify for multi-product discounts, leading to instances where the savings from an UPL are less than the previous savings with muti-product or bundled discounts. Furthermore, the Plan does not address how an 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 an UPL.

If an 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 purchases from an UPL

required business and a non-UPL business will be indicated to manufacturers. For discount transactions, manufacturers can generally offer upfront discounts or provide the discount subsequent to the sale in the form of a rebate. In both cases, manufacturers require certain data to verify UPL transactions were appropriate.

UPL Criteria Considerations

The language explaining how an UPL will be determined and evaluated is vague and missing key details. The criteria set out for assessing affordability and potentially recommending and setting an UPL contain significant gaps. Without pharmacy benefit manager (PBM)/plan transparency concerning rebates and fees, neither manufacturers nor the state have 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 an 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 an 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 an 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 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 an essential oversight in what the Board must evaluate in an UPL process.

Finally, the criteria listed for consideration when setting an UPL are not clear. The Plan says, "the Board shall not set an 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 an 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.

UPL Methodology and Data Considerations

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, 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.

Furthermore, the listed methodologies 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. For example, the Plan does not include formulary placement (including tiering, cost-sharing, and utilization management) in the information to be collected from eligible government entities. Without this information, it is not possible to understand either the true affordability concern for patients or what may be driving it, such as benefit design. The Plan does not mention how proprietary information would be handled, which is of great concern for stakeholders who may wish to provide supplemental information during the review process. The Plan also 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.

International Reference Pricing (IRP)

While GSK disagrees with many of the 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 an 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 is prohibited for certain government programs in the United States under 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, use of IRP as described above would involve the use of CEA. The countries mentioned 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 Maryland Prescription Drug Affordability Board's Plan of Action for Implementing the Process for Setting UPLs 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 an 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 an 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 the review of formulary placement, including tiering, cost-sharing, and utilization management, as well as 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 an 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.
6. **Ensure Confidentiality:** The Plan must include a procedure for the handling of proprietary information submitted by stakeholders.
7. **Establish a Clear Timeline:** The Plan should specify how long it is expected to take and include clear deadlines for public comment that are enshrined in regulations to allow for effective engagement.
8. **Remove IRP:** An UPL set through IRP overlooks key differences between the United States and the international market, and would import the use of potentially discriminatory QALY-

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

based methodologies. It fails to account for different pricing mechanisms and legal structures that will not translate to an American market.

9. **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 an 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.
10. **Consider Alternative Policy Solutions:** The Board should consider other policy solutions as alternatives to the establishment of an UPL, including requiring PBMs to pass 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.

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

Sincerely,

Chris Bryce
Director, State Government Affairs
GSK

HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

August 26th, 2024

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

Healthcare Distribution Alliance Comments
Re: Draft Upper Payment Limit Action Plan

On behalf of our member companies, the Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide comments on the Maryland Prescription Drug Affordability Board's Plan of Action for Implementing the Process for Setting Upper Payment Limits. We believe our comments are critical for ensuring a resilient supply chain in Maryland.

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.

Distributors do not set list prices or determine the amount patients pay for medicines, but rather are the logistical experts in the supply chain. As communicated by HDA in previous comment letters, most recently regarding the RFI cost review process wherein HDA shared that much of the data requested by the wholesaler RFI is best collected directly from manufacturers, 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 such, HDA would like to share some potential impacts of the proposed draft actions on the physical supply chain:

Domestic or International Reference Upper Payment Limits Would Have Adverse Outcomes and Unintended Consequences. HDA appreciates the language 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. We respectfully request that the Board

keep in mind 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 could 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 independent pharmacies are already struggling to maintain their businesses, reducing their ability to maintain overhead when dealing with specific medications would undoubtedly lead to further consolidation in the pharmacy and provider community.

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. 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 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.

Upper Payment Limits 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 Board consider applying 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.

In summary, HDA is concerned with the overall disruption that establishing a UPL 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 producing 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."

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. As our membership continues to assess the developing draft policies from the Board, HDA may have additional comments to share, and we hope to continue to engage in an ongoing conversation with Board staff.

Sincerely,

Kelly Memphis
Director, State Government Affairs
Healthcare Distribution Alliance

HealthHIV

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August 26th, 2024,

HealthHIV remains committed to advocating for the health and well-being of People with HIV (PWH) and recognizes the Maryland Prescription Drug Affordability Board's (PDAB) efforts to address prescription drug affordability. However, we have significant concerns about the potential impact of Upper Payment Limits (UPLs) on the HIV care continuum, particularly within AIDS Drug Assistance Programs (ADAPs) and across FQHC 340B Ryan White HIV/AIDS Programs and Community-Based 340B HIV service providers. Accordingly, we look forward to revisions to the UPL plan that prioritize access to care for PWH and align with federal non-discrimination laws

Impact on ADAPs and 340B HIV Providers

ADAPs and 340B HIV Ryan White providers are essential to ensuring that PWH—especially those who are low-income, uninsured, or underinsured—have access to life-saving medications. The financial sustainability of these programs depends heavily on the rebates and discounts obtained through the 340B program, which are reinvested into expanding services and enhancing care rather than being returned to consumers. These funds cover the costs of HIV medications and support a comprehensive care model that addresses the diverse needs of PWH.

Implementing Upper Payment Limits (UPLs) without fully considering the intricate rebate and discount structures within the 340B program—across all provider types, including FQHCs and Ryan White Clinics—could severely limit the resources available for patient care. During Dr. Rome's June 2023 PORTAL presentation, there was a notable absence of discussion on how 340B programs balance the crucial factors of comparative effectiveness, cost-effectiveness, and budget impact. This omission underscores the importance of thoroughly understanding these programs before moving forward with UPLs. It is essential to assess how much additional benefit a drug provides to patients compared to therapeutic alternatives, ensuring that UPLs do not inadvertently prioritize cost over patient outcomes. Additionally, evaluating the costs associated with these benefits is critical, as UPLs could restrict access to medications that offer significant health improvements but come at a higher price.

Finally, the impact of purchasing a drug on payer budgets must be carefully considered–especially within the 340B framework–where savings are reinvested into patient care, particularly for organizations serving highly SDOH-impacted communities.

Minimizing Unintended Consequences

Missteps in the PDAB's approach to affordability—which may not fully reflect real-world costs, particularly for PWH eligible for public programs—could lead to unintended consequences, such as reduced access to critical treatments, ultimately compromising patient care. If Upper Payment Limits (UPLs) are enacted, patients may be required to switch medications, placing additional demands on medical case management services. These services are essential for ensuring that patients adhere to

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new treatment plans and for managing any side effects or efficacy issues that may arise from medication changes. To effectively support patients during these transitions, increased investment in medical case management agencies is crucial.

Without adequate support and resources, the process of switching medications could result in reduced access to critical treatments, leading to compromised patient care. This is particularly concerning for PWH, who require consistent and effective treatment to maintain viral suppression, prevent disease progression, and reduce the risk of communicable transmission.

Transition Management

When transitioning from one HIV medication to another—especially in the context of Upper Payment Limits (UPLs)—several practical and logistical challenges must be addressed to ensure continuity of care and maintain patient health outcomes. Capping payments on HIV antiretrovirals (ARVs) could significantly strain the resources of medical case management contractors, who are vital in helping people with HIV, particularly those enrolled in programs like Ryan White and Title XIX Targeted Case Management, achieve and maintain viral suppression.

High-acuity patients, who often require additional support, may face greater risks during such transitions, as these changes could necessitate more intensive engagement from medical case managers. This added burden could increase healthcare costs beyond the typical scope of services, as additional resources would be needed to ensure continued adherence and manage potential treatment disruptions.

Logistically, the timing of medication switches is crucial to avoid gaps in treatment or unnecessary waste. Ensuring the availability of new medications at local pharmacies, managing potential changes in medication pick-up logistics, and addressing insurance or reimbursement challenges are essential factors that could impact patient adherence and overall system efficiency.

Moreover, any disruptions in access to necessary medications due to UPLs could lead to an increase in HIV infections and overall healthcare costs. *Preventing a single case of HIV is estimated to save the health system approximately $379,668 over the course of an individual's lifetime (per the CDC, in 2010 dollars!)*. These significant savings arise from reduced healthcare costs–including fewer high-acuity medical needs associated with managing HIV–which will significantly raise those incurred expenses.

However, the public has yet to be informed of any plans by the PDAB or PDSAC to mitigate these potential impacts on Maryland Department of Health (MDH) HIV contractors.

HIV antiretroviral (ARV) medications are not entirely interchangeable. Effective management of ARV substitutions, switches, or transitions requires comprehensive planning and coordination among healthcare providers, pharmacies, and insurers. This coordination is essential to minimize the risk of

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adverse health outcomes and to ensure that the healthcare system can accommodate these changes without compromising patient care**.**

Historical Context of HIV Medication Rebates

The inception of rebate programs for HIV medications can be tied to broader healthcare policies aimed at expanding access to life-saving treatments amidst the AIDS crisis. Rebates in the context of HIV treatments were not initially conceived purely for market share manipulation but as a part of negotiated agreements to make these medications accessible to more patients through programs like Medicaid and ADAPs. This occurred when the government first refused to step in or provide appropriate resources to support the effective uptake of these—***again, life-saving***—treatments.

Why Rebates for HIV Medications Are Important to Consider Today

1. **Access and Affordability Concerns**: Access and Affordability Concerns: Rebates have played a crucial role in making HIV treatments affordable to state-run programs like ADAP, which rely on federal and state funding to provide treatment for underinsured and uninsured individuals. These rebates enable programs to maximize their budgets and expand access to more patients. While the importance of rebates is generally recognized, there may be a lack of awareness about the critical risk of losing access to essential treatments for communicable diseases—especially those with legal statutes against exposure—if rebates are reduced.

2. **Negotiation Power**: Programs such as ADAP use their purchasing power to negotiate better pricing through rebates directly with manufacturers. This negotiation helps to lower the overall out-of-pocket costs for HIV care for eligible PWH, ensuring that public health programs can continue to provide necessary and life-saving treatments despite budgetary constraints.

3. **Health Equity Considerations**: Rebates are a critical tool in addressing long-standing health disparities—particularly in HIV care, where they help ensure that marginalized and economically disadvantaged communities receive necessary treatments. Without rebates, the price of HIV medications would likely be prohibitive for many, only widening the health equity gap.

4. **Changing Treatment Landscape**: The landscape of HIV treatment has evolved with advancements in medical science leading to more effective and less toxic treatments. Rebates have supported this evolution by making it financially feasible for programs to update their formularies with newer medications that offer better health outcomes and fewer side effects– improving both the medication adherence and long-term health outcomes of PWH.

5. **Innovation Funding**: While it's true that pharmaceutical companies use a portion of their revenue (including that generated through rebates) to fund ongoing research and development, this also means that rebates indirectly support the innovation of new and more effective HIV treatments.

Concerns About Access and Affordability

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We understand that UPLs aim to address the affordability of prescription drugs; however, the unique needs of the HIV community must be carefully considered. With only 61% of People living with *diagnosed* HIV in Maryland achieving viral suppression (AHEAD HIV Dashboard), any disruption in access to necessary medications could severely impact public health outcomes and undermine efforts to improve this rate. The (federal HRSA-administered) Ryan White Program and ADAPs have been instrumental in achieving near-universal viral suppression among those in care—a public health success that must not be compromised by policies that unintentionally restrict access to essential medications.

We strongly urge the Board to prioritize the perspectives of people whose care may be impacted by its decisions as it finalizes the Plan of Action for Implementing UPLs. If you do choose to enact UPLs, there are numerous considerations that must be carefully addressed to mitigate potential negative impacts on patient care and the healthcare system.

UPL Implementation Considerations

We are prepared to assist in outlining these considerations, which include, but are not limited to:

1. **Impact on Medication Access**: Ensuring that patients continue to have uninterrupted access to essential HIV medications is paramount, with the potential imposition of UPLs. This includes addressing potential shortages, delays, or changes in medication availability at local pharmacies.

2. **Transition Management**: Coordinating the transition process for patients who may need to switch medications due to UPLs, ensuring there are no gaps in treatment and that patients receive adequate support during the transition.

3. **Support for High-Acuity Patients**: High-acuity patients may require additional resources and support during transitions (as outlined above), including intensified case management to maintain adherence and prevent adverse health outcomes.

4. **Financial Implications for Providers**: Assessing the financial impact on 340B providers, including those that are community-based, not just FQHCs or Ryan White clinics. This includes evaluating how UPLs might affect their ability to continue providing comprehensive services to patients, and what steps can be taken to mitigate this.

5. **Broader Public Health Impacts**: Considering the broader implications of UPLs on the public health ecosystem and community, particularly in *maintaining* (and improving) Maryland's viral suppression rates and *preventing* a syndemic resurgence of HIV transmission.

As the PDAB implements its plans, it is essential to recognize that the imposition of UPLs—while understandably intended to improve affordability—must not overlook the unique and complex needs of the HIV community. The absence of a detailed, publicly communicated, strategy for managing potential transitions across various antiretroviral therapy combinations raises significant concerns

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about access and continuity of care. *This absence could potentially jeopardize the substantial progress made in achieving both viral suppression and advancing positive public health outcomes.*

UPL Determination Process Considerations

That said, we encourage the Board to specifically consider:

1. **Developing a Concrete Plan to Monitor Utilization Management**: The Board should ensure that the implementation of UPLs does not lead to increased use of restrictive utilization management strategies or adverse formulary placements that could hinder access to HIV medications. The Board must also monitor the availability of drugs subject to UPLs to prevent shortages and consider suspending UPLs if access to these medications becomes compromised.

2. **Improving Patient Engagement Practices—and the Data Used to Support UPL Assumptions:** While UPLs are often justified by the assumption that they will reduce expenses and improve affordability, this approach may not hold true for HIV care. The Board should enhance its patient engagement efforts by incorporating Maryland Department of Health (MDH) HIV community service data, Ryan White Service (RSR) data, and real-world qualitative and quantitative survey data. These insights from diverse communities, especially PWH, are crucial to ensuring that all affected populations are adequately represented in decision-making processes. Transparent communication about how patient input is incorporated is essential for building trust and ensuring that policies genuinely reflect the needs of the community.

While All-Payer Claims Data (APCD) can provide valuable insights, it does not offer a complete picture of the patient experience or the actual costs to the healthcare system. APCD data primarily reflects what payers present as justification for charges to patients and often fails to capture instances of coverage denials, the complexities of rebate data, or the nuances of manufacturer patient assistance programs. Even when rebate information is provided by manufacturers, it remains unclear how much of these rebates directly benefit patients or employers, how much is absorbed as profit by PBMs, or how these rebates influence formulary positioning and cost-sharing.

Moreover, APCD data does not account for how costs are mitigated by manufacturers, government programs, or private charitable organizations that work to reduce the financial burden on patients. Without extensive outreach to patients, the cost review process risks missing critical aspects of the patient experience—an issue that has been observed in other states, such as Colorado.

3. **Avoiding Discriminatory Value Assessments:** The Board should avoid using cost-effectiveness analyses, such as quality-adjusted life years (QALYs) or similar methods, that could result in discriminatory practices against people with disabilities or chronic conditions like HIV. Such practices are prohibited under federal regulations, specifically Section 504 of the Rehabilitation Act of 1973, which mandates non-discrimination on the basis of disability in programs receiving federal financial assistance. The Board must ensure that its policies align with these legal requirements to avoid perpetuating discrimination and to uphold equitable healthcare practices.

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4. **Avoiding Reference to Drug Prices in Other Countries**: The Board should refrain from using international drug prices as a reference for setting UPLs, as this could import discriminatory standards that do not account for the unique needs of PWH in the U.S..

Overall Board Recommendations

Given these concerns, we recommend that the Board:

1. **Exempt HIV Medications from UPLs**: Given the pivotal role that HIV medications play in public health—especially the options of one pill, once daily, and now, with injectable treatments—it is crucial to consider exempting these medications from Upper Payment Limits (UPLs). Such an exemption would help safeguard the financial stability of AIDS Drug Assistance Programs (ADAPs) and all 340B HIV providers, ensuring uninterrupted access to essential treatments. Unlike viral Hepatitis (specifically HCV), HIV is a communicable and incurable disease, recognized under COMAR 18.601.1, which underscores its significant public health importance. Disruptions to care, particularly for prioritized populations, could exacerbate health disparities and increase transmission risks, undermining the progress made in HIV prevention and treatment over the years. Since the Board has not, as of yet, adequately engaged with these latter complications, we recommend the implementation of this exemption on a statutory and regulatory basis to safeguard the progress that has been made regarding HIV in Maryland.
2. **Engage with HIV Service Providers**: Actively engage with ADAPs, 340B clinics, and community-based HIV service providers to fully understand the implications of UPLs on HIV care. By consulting with those on the front lines, the Board can develop policies that do not inadvertently harm vulnerable populations who rely on these services for their survival, and that actively work toward health equity and holistic wellness.
3. **Consider the Long-Term Impact**: Evaluate the long-term public health implications of UPLs on HIV care, including the potential for increased HIV infections and higher healthcare costs due to reduced access to medications. The success of Maryland's public health efforts in achieving viral suppression and managing HIV relies on *sustained, uninterrupted access* to effective treatment options.

We look forward to revisions to the UPL plan that prioritize access to care for PWH and align with relevant and legally-binding federal non-discrimination laws. HealthHIV stands ready to collaborate with the Board to ensure that any policies implemented affirmatively protect the interests of PWH and maintain the full integrity of the HIV care continuum.

Thank you for your ongoing attention to this important–and precedent-setting–issue, and <u>specifically</u> for People with HIV.

Respectfully submitted,

Scott D Bertani, MNM, PgMP

Director Advocacy

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James H. Gutman

Columbia, MD

August 23, 2024

RE: Proposed Upper Payment Limit Action Plan

TO: comments,pdab@maryland.gov

Dear Fellow Members of the PDAB Stakeholder Council:

Please note that I am sending these comments as an individual member of the Stakeholder Council representing the public and not as a representative of any organization I am associated with.

I first want to applaud this PDAB document as thoughtful and comprehensive. In particular, the proposed processes allow for various kinds of Upper Payment Limits (UPLs). The document also proposes an efficient use of time to bring these necessarily complex and mandated processes to a conclusion as soon as feasible.

The proposal rightly states that if the PDAB makes a preliminary determination that use of a given drug has led or will lead to affordability problems, the board's policy-review process (including procedures for setting a UPL) would "run parallel" to the process for making a final determination and the cost-review study report. It also is good that key actions leading up to setting a UPL "shall be performed sequentially," although it would be helpful to have more details on how this would be done. And it is commendable that the proposed process allows for various kinds of UPLs.

The proposed criteria for setting a UPL, however, don't appear to enable the PDAB to take into account the value of any government-funded research used in developing the drug in question. Since the cost of such research is, in effect, borne by U.S. taxpayers,

there should be a mechanism for using that as a factor in determining an appropriate UPL for a drug found to present an affordability challenge.

There also is a question of whether some criteria in the document are broader than they need to be. In particular, the proposed provision that "the Board shall not set an upper payment limit amount that impacts statutory or regulatory amounts, such as Medicaid Best Price," might limit the board unnecessarily. Even if it is desirable to exempt Medicaid, which has specific issues that lend itself to needing separate provisions, this does not mean the UPL criteria document needs to rule out UPLs that impact government-involved markets in other situations.

I hope that these comments are useful to the Stakeholder Council and to the PDAB as a whole, and I look forward to the UPL process moving forward in ways that will benefit Maryland residents for many years to come.

Sincerely,

James H. Gutman

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August 26, 2024

By Electronic Submission

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Re: Draft Outline Upper Payment Limit Action Plan

Dear Members of the Maryland Prescription Drug Affordability Board ("Board" or "PDAB"):

Eli Lilly and Company ("Lilly") appreciates the opportunity to offer comments on the Board's Draft Outline Upper Payment Limit ("UPL") Action Plan (the "Plan").[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

Lilly offers the following comments notwithstanding its grave concerns about the constitutionality of the State of Maryland's attempt to authorize the PDAB to impose UPLs, including the application of UPLs to patented drug products. The Supreme Court has long explained that patents confer a statutory period of market exclusivity on patent holders, during which manufacturers are permitted to charge market prices for their drugs.[2] State price control laws like UPLs fundamentally disrupt the intent of the federal patent laws and federal drug exclusivity periods, and thus are preempted under the Supremacy Clause of the United States Constitution.[3] Lilly also believes that any application of a UPL to the Maryland Medicaid Program is precluded by the Social Security Act. Lilly expressly reserves all available arguments regarding the legality of the

[1] *See* Draft Plan, available here.
[2] *See Sears, Roebuck & Co. v. Stiffel Co*., 376 U.S. 225, 229 (1964).
[3] *See Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1363, 1373 (Fed. Cir. 2003).

PDAB statute and its implementation, and we urge the Board to revise the Plan consistent with our comments below.

The Board Must Complete Cost Reviews, Policy Reviews to Consider Potential UPL and Non-UPL Options, and Calculations of UPLs at Separate Meetings with Sufficient Time at Each Step for Meaningful Stakeholder Input and Board Responses to Such Input

Lilly is concerned that the Board proposes to adopt a process that enables it to finalize its determination that an affordability challenge exists, determine that the adoption of a UPL is an appropriate policy solution, and adopt a UPL amount *all in the same Board meeting*. This means that the Board would be calculating UPL amounts *before* reaching a final decision on whether a drug actually presents an affordability challenge and *before* the Board determines that a UPL is an appropriate policy solution. Such an approach is neither consistent with the requirements of the PDAB statute, nor logically coherent.

First, the proposed consolidated timeline and process in the Plan violates the PDAB statute. Under Section 21-2C-09, if the Board decides to engage in a cost review for a prescription drug, it must determine "whether use of the prescription drug product . . . has led or will lead to affordability challenges for the State health care system or [whether] high out–of–pocket costs for patients are associated with affordability challenges."[4] Only after the Board has completed this step may the Board set UPLs "for prescription drug products *that have led or will lead to an affordability challenge.*" This statutory language necessarily requires a final determination of an affordability challenge, through the cost review process, *before* the Board evaluates possible policy solutions, including the potential imposition of a UPL.[5] In fact, under Section 21-2C-13, the Board must consider certain statutory factors when creating a UPL, including some of the very same cost data the Board must evaluate in making the final determination of whether an affordability challenge exists. The Plan fails to comply with these statutory requirements and deprives stakeholders—including patients and manufacturers—of the procedural safeguards imposed by the legislature.

Second, the Board's decisions at each stage of the statutory process should be rendered in *separate* meetings with a *separate* opportunity for public comment to ensure there are adequate opportunities for stakeholder input. As noted, the Plan contemplates that the final cost review report, policy recommendations, and proposed UPL amounts could be adopted sequentially, in a nod to the statutory requirements, but nevertheless at the same Board meeting.[6] Stakeholders should have the opportunity to comment on and engage in each of these processes separately, and the Board must meaningfully respond to those comments before proceeding onto the next step. Combining these steps would impair the integrity of the Board's decision-making, encouraging rushed conclusions that do not fully account for the full range of stakeholder feedback and perspectives relevant to each distinct decision. Abbreviating and consolidating the different steps

[4] Md. Code Ann., Health-Gen. § 21-2C-09.
[5] *Id.* § 21–2C–14.
[6] Draft Plan at 5.

of the Board's decision-making into a single meeting subverts these objectives and undermines the purpose of the comment periods and public hearings that precede the Board's key UPL-related decisions.

Third, the Plan does not require disclosure of the reasoning that led to the Board's preliminary affordability determinations, and merely says that the Board's *staff* "may" include such information to inform the Board's thinking. Given the absence of any clear requirement for the Board to memorialize its reasoning, disclose its reasoning to stakeholders at each step of the process, and engage substantively with comments, the Board's proposal to allow one-stop decision-making risks ignoring potential qualitative and quantitative changes that may occur as the affordability review moves from the preliminary to the final determination.

The totality of these procedural and substantive concerns create serious questions about arbitrary and capricious agency action, as the Plan suggests that the Board will pre-judge the outcome of its reviews through the development of UPLs before it is finally determined that a UPL is appropriate in the first instance, and before consideration of all the information and public comments provided during the review process.[7] Ultimately, this creates undue risk that the Board would impose a UPL without fully evaluating the appropriateness of such a price control, which risks dire consequences for patients by incentivizing rushed judgments that may fail to fully consider the potential negative repercussions of a UPL on patient access across the state. For all these reasons, the Board should not—*and lawfully cannot*—prematurely commit to a UPL before completing the cost review, and the Board must ensure adequate time for stakeholder review and input, and thoughtfully respond to such input.

The Board Must Comply with the Procedural Requirements of the Maryland Administrative Procedure Act ("APA")

[7] *Id.* at 6 ("The ***preliminary determination*** that the drug has led or will lead to affordability challenges is a predicate for the Board to start the policy review process to study and assess what, if any, policy tools are ***best suited to redress the identified affordability challenges, including whether a UPL is an appropriate policy solution***.") (emphasis added).

The Plan acknowledges that "setting a UPL is a quasi-legislative action"[8] and states that "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."[9] While Lilly agrees that the setting of any UPL must be adopted through rulemaking, Lilly believes that the Board must also clarify that the policies of general application summarized in the Plan itself must also undergo a rulemaking meeting the requirements of the Maryland APA *before* the Plan is finalized and sent to the Legislative Policy Committee for approval.[10]

The Plan is unclear as to what the Board intends to promulgate through future rulemaking. The Board cannot simply adopt the UPL amount in a subsequent regulation via rulemaking without subjecting the processes that lead to the setting of that UPL amount (i.e., the Plan) to the rulemaking process as well. Under Maryland law, all agency policies "of general application" must be established through rulemaking.[11] This requirement applies not only to legislative rules that establish substantive standards and requirements but also to "organizational rules, procedural rules, interpretive rules and statements of policy."[12] As Maryland courts have long explained, "where an agency statement of general applicability implements, interprets or prescribes law or policy, it is a rule which *must* comply with the APA."[13]

Simply put, the Board cannot use the Plan as a mechanism to evade the requirements of the APA.[14] The Plan represents a policy of general applicability because it describes the approach the Board will apply going forward in reviewing drugs for purposes of deciding whether to impose UPLs and set UPL amounts. As with any other statement that "implements, interprets, or prescribes law or policy" and will be applied to future proceedings, the Board *must* undertake a notice-and-comment rulemaking with respect to the Plan itself and *must* ensure that such rulemaking complies with the APA.[15]

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[8] Lilly also requests that the Board clarify how it is defining what constitutes a quasi-legislative action. Maryland courts often refer to "quasi-legislative" action to refer to any agency action that involves creating or changing a rule of "general application," which prescribes a new plan or policy rather than merely facilitating the administration of an existing law. *Kor-Ko Ltd v. Md. Dep't of the Env't*, 451 Md. 401, 409 (2017). It is unclear to Lilly if the Board is using the term "quasi-legislative" action in this sense, or if the Board has adopted some alternative understanding of the term.

[9] Draft Plan at 2. The Board also suggests that certain activities like Expert Testimony Hearings are "quasi-legislative *hearings*" for which the Board must adopt subsequent regulations. *See, e.g.*, *id.* at 7 (emphasis added).

[10] Md. Code, Health-Gen. § 21-2C-13.

[11] *Venter v. Bd. of Educ.*, 185 Md. App. 648, 678 (2009); *see also* Md. Code Ann., State Gov't, tit. 10, subtit. 1, pt. III.

[12] *Eng'g Mgmt. Servs., Inc. v. Md. State Highway Admin.*, 375 Md. 211, 232–33 (2003) ("Under the Maryland APA, an agency's organizational rules, procedural rules, interpretive rules and statements of policy all must go through the same procedures as required for legislative rules").

[13] *Perini Servs., Inc. v. Md. Health Res. Plan. Comm'n*, 67 Md. App. 189, 212 (1986) (emphasis added).

[14] *See* Md. Code, Health-Gen. § 21-2C-13 (no exemption from APA requirements in provision authorizing the Board to submit its plan of action).

[15] *Perini Servs., Inc. v. Md. Health Res. Plan. Comm'n*, 67 Md. App. 189, 212 (1986).

Lilly is deeply concerned that, to date, the Board's processes have failed to abide by the APA's requirements. The APA requires that rules of general applicability (like the Plan) be proposed and published in the Maryland Register,[16] as well as the Board's website,[17] with "at least 30 days" opportunity for public comment, and cannot be finalized until "at least 45 days after [] first publication in the Register."[18] Notably, the Board released the Plan after the close of business on Friday, August 9th, never published it in the Maryland Register, and requires comments be submitted just two weeks later. Fourteen days is less than ***half*** the time required under the APA, and not nearly enough time for stakeholders to meaningfully review and comment on the Board's plan to operationalize key aspects of the PDAB statute, including the Board's blueprint for setting a UPL. Manufacturers and other members of the public are entitled to the full protection of the APA's requirements, including a full opportunity to comment.[19]

Lilly also emphasizes that the Plan fails to address critical details about the substance of the Board's newly proposed processes, which as noted above, also must be implemented through notice-and-comment rulemaking. As explained in more detail below, critical definitions, standards, and procedures are either left undefined or only addressed at a summary level without providing key details about how they will be operationalized in practice.

Definitions

Lilly is concerned that the Board has not provided clear and practical definitions for a number of key terms in the Plan. The lack of transparency in how these terms will be interpreted and applied hinders stakeholders' ability to effectively engage with the Board. Further, the absence of clear definitions may lead to arbitrary and inconsistent application in the UPL setting process and other unintended consequences. Lilly urges the Board to adopt the following recommendations with respect to certain key terms and their definitions:

- Affordability challenge: The Board should define the term "affordability challenge" to be limited to "state health care system entities"[20] and their patients. In particular, affordability should be analyzed with reference to the specific governmental entities that can be subject to UPLs as enumerated in the PDAB statute and their patients—meaning state or county correctional facilities and their patients; state hospitals and their patients; health clinics at state institutions of higher education and their patients; health benefit plans making

[16] Md. Code Ann., State Gov't § 10-112.
[17] *Id.* § 10-112.1.
[18] *Id.* § 10-111.
[19] Lilly is similarly concerned that the Board's acceleration of the date on which it plans to approve the Plan—from September 23 to September 10—further limiting the time allowed for stakeholders and the Board to consider the implications of the Plan. The irregular nature of these proceedings raises serious questions about whether stakeholder comments will be seriously considered by the Board.
[20] Md. Code Ann., Health-Gen. § 21-2C-09(b)(1).

payments on behalf of a unit of state or local government and enrollees thereof, and (to the extent legally permissible) the Maryland State Medical Assistance Program and Medicaid enrollees.[21] Because the PDAB statute makes clear that these are the only entities that could be subject to a UPL established by the Board, it would not be logical or consistent with the statute to evaluate affordability from the perspective of other entities, such as private health plans or other private purchasers for which a UPL would have no bearing.[22] Rather, the statute dictates that affordability be analyzed from the perspective of these entities and their patients. Lilly also recommends that the Board define "affordability challenge" in a manner that requires consideration of both the net price at which state health care system entities currently access the drug and the level of purchases and utilization by those entities.[23]

- High out-of-pocket costs: The Board should similarly ensure that "high out-of-pocket costs" is defined and that such definition is specific to patients of the state health care system entities that could be subject to a UPL. Just as the PDAB statute contemplates that "affordability challenges" be defined by reference to state health care system entities, so too does the statute contemplate "high out-of-pocket costs" be analyzed from the perspective of the patients of those state health care systems. Otherwise, the Board's UPL analysis would be of patient populations that have no bearing to the scope of the UPL as defined under the statute. Further, a more expansive definition could risk incorporating factors that are not directly relevant to the patients that would benefit from the UPL, potentially leading to unintended consequences in setting the UPL. As discussed in more detail below, all consideration of out-of-pocket costs should also take account of the fact that out-of-pocket costs are the byproduct of benefit design choices made by independent health plans and pharmacy benefit managers (PBMs), which are outside of the control of manufacturers and others in the pharmaceutical supply chain.[24]

- Therapeutic class: Lilly recognizes that the Board has defined the term "therapeutic class" in regulation to mean, "a group of drugs containing active moieties that share scientifically documented properties and are defined on the basis of any combination of three attributes: mechanism of action, physiologic effect, and chemical structure."[25] Lilly is concerned that use of this unduly broad definition, especially in the UPL setting process, would result in prices being set based on invalid comparisons between materially distinct products.[26] We urge the Board to adopt a different definition of therapeutic class that focuses instead on

[21] *Id.* § 21-2C-14(a). As noted above, Lilly reserves its argument that UPLs cannot be imposed with respect to the Maryland State Medical Assistance Program. However, we refer to the state Medicaid program and its enrollees in the above list to maintain consistency with the language in the PDAB statute.
[22] *See id.* § 21-2C-14(a)(1)–(3) (limiting UPLs to transactions involving certain state or local government entities).
[23] *See* Board, Draft Supply Chain Report at 21–23, (Dec. 12, 2023), available here.
[24] *Id.* at 39–41, 96–97.
[25] COMAR 14.01.01.01(62).
[26] Lilly also has concerns about this existing definition in the context of cost reviews, but focuses its comments on the UPL setting process because it is the focus of the Draft Plan.

therapeutic alternatives, and specifically therapeutic alternatives available to state health care system entities consistent with the statutory scope of UPLs under the PDAB statute.

While Lilly believes a focus on therapeutic alternatives is far more appropriate for all of the above reasons, to the extent the Board continues to adopt a broader approach, the Board should at least establish a definition of therapeutic class that avoids arbitrary comparisons between dissimilarly situated products and accounts for clinical and practical distinctions between disparate products.[27] Different products that are sometimes colloquially described as belonging to the same class can still have material distinctions including chemical formula, mechanism of action, mode of administration, and safety and effectiveness. These differences can translate into significant differences in whether they are an appropriate choice for a given patient, given their individualized circumstances and needs.

Preliminary Recommendation Process

The Board appears to have established different standards for the Preliminary Recommendation based on whether a UPL is the proposed solution. For example, the Board only proposes to require evaluation of the strengths and weaknesses of non-UPL solutions without establishing a corresponding requirement when evaluating the appropriateness of a UPL.[28]

This raises concerns under the Maryland APA, which requires similarly situated circumstances to be treated in a similar fashion absent some reasoned basis for differentiation.[29] It also raises overarching concerns about whether the review of potential policy solutions will be biased in favor of UPL-based options.

Criteria and Requirements Related to Setting a Upper Payment Limit

Lilly recommends refinements to the criteria that the Board intends to apply when determining whether a UPL is appropriate and when setting a UPL amount.[30] In principle, Lilly agrees that specific criteria should be adopted to guide the Board's discretion in determining whether to impose a UPL (as well as the amount of any such UPL). Lilly is concerned, however, that the criteria in the Plan disregard important details that bear on how they would be implemented, and that the Plan also fails to mandate consideration of other important factors that should be included as mandatory criteria.

First, Lilly urges the Board to add an additional criterion that prevents the Board from establishing a UPL (or setting a particular UPL amount) unless there is an evidence-based determination by the Board that the UPL (or UPL amount) will not negatively affect patient access in the state.

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[27] Lilly further addresses its concerns with the Therapeutic Class UPL methodology below.
[28] *Id.* at 7–8.
[29] *Md. State Bd. of Soc. Work Examiners v. Chertkov*, 121 Md. App. 574, 588 (1998).
[30] *See* Draft Plan at 3.

As the Board itself has acknowledged, the decision to impose a UPL requires the balancing of "many competing interests."[31] While the Board asserts that if a UPL could simulate a "perfectively competitive [market] equilibrium," it could "in theory" address potential market failures, it has also acknowledged that "the pharmaceutical supply chain is complex and imperfect competition exists at multiple levels."[32] As a consequence, there is a serious risk that a UPL could have meaningful unintended negative consequences, including significantly impairing patient access. The Board should be attentive to this risk and thoroughly analyze the threat to patient access posed by a given UPL to ensure that UPLs are only imposed where they do not risk impairing patient access.[33]

An evidence-based criterion focused on patient access also would help safeguard against arbitrary decision-making, as it would work to ensure that the Board lays out both its reasoning and the factual basis in support of that reasoning should it determine to impose a UPL or any specific UPL amount. Reliance on such an evidence-based criterion would also be consistent with the intent of the legislature, which was to target use of UPLs only where most appropriate.[34] As the Board itself has stated, "there is no single approach that will address" all problems of affordability, and the Board should limit its use of UPLs to situations where it can confirm that these price controls will not have negative repercussions for patient access.[35] The Board should also commit to disclosing such a determination to the public and providing a meaningful opportunity for comment.

Second, Lilly provides the following additional comments on the current criteria set forth in the Plan:

- Costs to be considered in setting a UPL. The PDAB statute does not limit the cost categories the Board may consider in setting a UPL, and therefore the Board should not limit itself to consideration of only those three categories of costs identified in statute: the cost of administering the drug, the cost of delivering the drug to consumers, and other relevant administrative costs related to the drug.[36] As part of the cost review process, the Board may obtain a range of different information related to whether a drug may create affordability challenges (e.g., patient out-of-pocket cost data, expenditures by the statutorily-specified state purchasers and payers subject to any UPL) from public sources and other stakeholders, and the Board should thoughtfully consider the reliable and relevant information used in the cost review process in deciding whether to impose a UPL and the most appropriate UPL amount.

[31] Board, Draft Supply Chain Report at 65.
[32] *Id.* at 52.
[33] Such analysis would necessarily need to account for the unique patient population characteristics and supply chain issues relevant to the specific drug at issue.
[34] Md. Code Ann., Health-Gen. § 21-2C-07(1)(ii) (implicitly acknowledging that UPLs are not the right solution for *every* affordability challenge by requiring study of other policy options).
[35] Board, Draft Supply Chain Report at 49.
[36] Md. Code Ann., Health-Gen. § 21-2C-13(b).

- UPLs shall not impact statutory or regulatory amounts, such as Medicaid Best Price. Lilly agrees that UPLs should not impact statutory or regulatory amounts like Medicaid Best Price. A UPL that alters Best Price would be preempted by the Medicaid Drug Rebate Program ("MDRP") statute, as it would fundamentally disrupt the MDRP's complex and interlocking scheme of federal coverage and pricing for the Medicaid program. Specifically, under the MDRP, Congress intended to strike a "grand bargain" under which manufacturers must agree to provide rebates to states in exchange for coverage and payment of their products under Medicaid and Medicare Part B. A UPL that alters Best Price would fundamentally disrupt this carefully negotiated regulatory scheme, and stand as an obstacle to the "accomplishment and execution of the full purposes and objectives of Congress," which would render it preempted under the Supremacy Clause of the United States Constitution.[37] The same arguments apply to other federal price points, such as the Part B Average Sales Price (ASP) and the federal 340B ceiling price, both of which are also set with reference to transactions considered in the Medicaid Best Price calculation.

- A UPL shall not be set lower than the Medicare Maximum Fair Price ("MFP"). Lilly agrees that a UPL should not be set below the MFP, but also stresses that a UPL should not be set at the MFP itself. When Congress enacted the Inflation Reduction Act ("IRA"), it expressly chose to limit the scope of the MFP to the Medicare population, which differs significantly in demographics, age, and diversity from the Maryland patients that would be affected by a UPL. Expansion of the MFP by states to non-Medicare populations would fundamentally disrupt the careful balance that Congress struck in enacting the IRA, jeopardizing patient access to and hindering innovation of new and potentially life-saving medicines. In addition to being unsound public policy, use of the MFP would raise serious preemption concerns by expanding the reach of the MFP beyond what Congress ever intended, thereby fundamentally disrupting the structure of the federal scheme and creating increasing disincentives to participation in the Medicare program.

- Prioritization of drugs with high proportion of out-of-pocket costs as compared to net cost. Lilly requests that the Board clarify how this criterion will be implemented and applied. Among other things, it is not clear "when" this criterion will be applied by the Board, much less "how" it will be operationalized. Specific details are needed for stakeholders to meaningfully comment on whether the Board's proposal is a reasonable one or if the criterion should be eliminated. For example, the Board's proposal raises a number of operational questions, as it is not clear how the Board would define "net cost," verify the data relied upon in calculating the ratio of net cost to out-of-pocket cost, or determine what constitutes an unacceptably "high" proportional difference. Stakeholders therefore need more specific information and a new opportunity to comment to be able to meaningfully address this proposal.

[37] *Crosby v.* NFTC, 530 U.S. 363, 372–73 (2000); *see also Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Methodologies and Factors to Establish UPLs

Lilly has a number of questions and concerns about the different proposed methodologies laid out for calculating UPL amounts. In general, Lilly is concerned that the methodologies lack sufficient detail for stakeholders to fully understand and comment on them.

First, certain of the proposed methodologies raise significant concerns even based on the high-level summaries provided in the Plan. Lilly highlights the following specific concerns about the methodologies described in the Draft Plan:

- Cost effectiveness analysis. Lilly believes that any cost effectiveness analysis used in determining a UPL must account for net price available to State health care system entities and patients, not the list price. Lilly is also concerned that the description of this methodology in the Plan suffers from an overriding lack of clarity and specificity. Among other things, the Board has not described the type of cost effectiveness analyses it intends to use. This raises serious concerns because there are a wide range of different types of cost effectiveness analyses, all of which have differing levels of reliability, validity, and robustness. For example, some types of cost effectiveness analyses raise serious concerns, such as Quality-Adjusted Life Year ("QALY") analyses, which have been shown to discriminate against the sick, elderly, and historically under-represented minority populations.[38] Further, it is not clear whether the Board intends to conduct its own independent cost effectiveness analyses or rely on third party analyses. It is also unclear what controls the Board will put into place to prevent cherry-picking of data (e.g., if the Board is relying on third party analyses, it is not clear how the Board will choose among cost effectiveness analyses performed by different third party institutions).

- Therapeutic class reference UPL. Consistent with our comments above regarding the definition of "therapeutic class," the Board should ensure that, any therapeutic class UPL setting process should focus on products that are therapeutic alternatives to the product at issue. The therapeutic alternatives must also be available to state health care system entities and their patients (e.g., they must be products currently commercially available for purchase by the state health care system entities subject to UPLs for use with the entities' patients)—because the statutory focus of any UPL established by the Board should be the patients of certain state health care system entities.[39] Consideration should also be given to meaningful distinctions between different products, even if they are considered to share the same therapeutic class or be a therapeutic alternative. The Board should not rely on an unduly expansive understanding of therapeutic class to establish a reference UPL that ultimately results in prices being set based on arbitrary comparisons between materially,

[38] *See, e.g.*, P. Schneider, The QALY is ableist: on the unethical implications of health states worse than dead, 31 Qual. Life Res. 1545 (2021).
[39] *See* Md. Code Ann., Health-Gen. § 21-2C-14(a)(1)–(3).

clinically, or practically distinct products, as this could harm patients by distorting market incentives in a manner that discourages access to a more clinically appropriate therapy.

- Domestic reference UPL. Any domestic reference UPL should account for any performance requirements that are a condition of that domestic reference UPL being made available to other US-based entities. Otherwise, using such a reference UPL could result in apples-to-oranges comparisons that fail to consider the context in which the reference price is being provided. In other words, a non-arbitrary domestic UPL reference price should focus on similarly situated entities to those state and local government entities that will be the target of UPLs under the PDAB statute. Accordingly, domestic reference UPLs should focus on the net price paid by other governmental purchasers and payers—not commercial or non-governmental payers that are materially different situated than the types of entities that will be subject to the Maryland UPL. Moreover, when referring to the net price paid, the Board should also consider the underlying factors that contributed to that price, such as a drug's placement on a preferred formulary tier or minimal utilization requirements that facilitated its availability.

- International reference UPL. Lilly recommends that this reference price methodology be eliminated. UPLs based on international reference are inappropriate. There are fundamental differences in the United States marketplace versus the market landscape in ex-U.S. countries, including with respect to market sizes and conditions, national income, regulatory structure, supply chain distribution structure, and a host of other factors. This prevents non-arbitrary comparisons of pricing levels between different countries, as it is virtually impossible to control for these diverse variables. International reference pricing also does not account for the fact that patients in other countries often face delays in accessing new medications compared to patients in the U.S., making comparisons to these prices misleading and potentially harmful.[40] Therefore, Lilly urges the Board to remove any consideration of international pricing in the UPL setting process.

Second, Lilly also has comments about several other aspects of the Board's proposed UPL process, including as follows:

- Calculation of "market basket" of UPLs. Lilly requests clarification on how the Board intends to calculate and use the proposed "market basket" of UPL values. The Plan indicates that Board staff would develop a "'market basket' of UPL amounts consistent with certain regulatory criteria," and that the Board would consider the "market basket" in selecting a proposed UPL amount.[41] Lilly believes more detail is needed to understand

[40] *See, e.g.*, PhRMA, New Analysis Shows that More Medicines Worldwide Are Available to U.S. Patients (June 5, 2018), available here (finding that from 2012-2017, "90 percent of [220] newly launched medicines were available in the United States, compared to just two-thirds in the United Kingdom, half in Canada and France, and one-third in Australia.").
[41] Draft Plan at 3; *see also id.* at 11–12.

what the Board means. Additional clarity is also needed as to how the Board will use the market basket and the overarching purpose of the market basket. Absent such clarifications (with an opportunity for subsequent comment), Lilly does not believe it is possible to meaningfully comment on the proposal, and such proposal should be removed.

- State expenditure data. Lilly agrees that use of state expenditure data is an important starting point in considering the appropriateness of a UPL or UPL amount. Such data are important in determining whether an affordability challenge has or will exist because the PDAB statute contemplates that reviews of affordability must focus on costs for specifically referenced entities to the State health care system.[42] Accordingly, Lilly emphasizes that the state expenditure data that the Board relies upon must be appropriately tailored to the statutory objectives of the PDAB statute. This means that the only state expenditure data relevant to the Board's consideration is the expenditure data of the *specific* state and local government entities that are the subject of UPLs under the Maryland PDAB statute.[43] Also, given the attenuated distribution, payment, and reimbursement relationships in the prescription drug market, it is essential that "expenditures" be defined as "net expenditures," not "gross expenditures" and the state should expressly commit to this principle. As the Board itself has acknowledged, "it is important to differentiate between the payments and flow of money on the product side[,] . . . which results in the gross spend on the drug, and on the payment side (PBM payment to the pharmacy, manufacturer rebates to PBM), which results in the net cost of the drug *to the health system and patient*."[44]

- Application of different methodologies to different drugs. The Plan states that the Board "may select or prioritize one or more of the methodologies and factors, and direct staff to use those methodologies and any other methodology identified by the Board, to conduct analyses and calculations to obtain upper payment limit amounts."[45] Lilly is concerned that this proposal would allow for the improper, arbitrary, and unexplained application of different methodologies to different drugs, leading to inconsistencies in how these products are evaluated. As noted above, Maryland courts have consistently held that agency actions are arbitrary and capricious where they treat similarly situated entities or products differently without a reasonable justification for such differential treatment, or where there are unexplained inconsistencies with prior agency decisions.[46] To avoid setting UPLs in an arbitrary and capricious manner, the Board should revise the Plan to ensure that it applies its methodologies consistently across similarly situated products and provides a clear rationale for the methodologies used for each specific case.

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[42] *See* Md. Code Ann., Health-Gen. § 21-2C-09(b)(1).
[43] *See id.* § 21-2C-14(a)(1)–(3) (enumerating the entities subject to UPLs).
[44] Board, Draft Supply Chain Report at 21 (emphasis added).
[45] Draft Plan at 8.
[46] *See, e.g.*, *Christopher v. Montgomery County Dep't of Health & Human Servs.*, 381 Md. 188, 215 (2004); *Md. State Bd. of Soc. Work Examiners v. Chertkov*, 121 Md. App. 574, 588 (1998).

* * *

Lilly appreciates the opportunity to comment on the Board's Plan and looks forward to continued engagement with the Board on these topics. Please do not hesitate to reach out if you have any questions or clarifications.

Sincerely,

Cynthia Ransom
Sr. Director, Government Strategy

MARYLAND ASSOCIATION
OF CHAIN DRUG STORES

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

August 26, 2024

Chair Van T. Mitchell
Maryland Prescription Drug Affordability Board 16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Draft Upper Payment Limit Action Plan

Dear Chair Mitchell,

On behalf of the Maryland chain pharmacy industry, the Maryland Association of Chain Drug Stores (MACDS) is writing to submit comments on the Maryland Prescription Drug Affordability Board's Plan of Action for Implementing the Process for setting Upper Payment Limits (UPLs). 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 UPL 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

[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

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 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 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 urge Maryland lawmakers and the Maryland PDAB to ensure increased patient access and fair and adequate reimbursement for pharmacists, pharmacies of all sizes, and the Marylanders they serve.

Sincerely,

Cailey Locklair
President, Maryland Retailers Alliance

Maryland
Hospital Association

August 26, 2024

Van T. Mitchell
Chair
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Draft Upper Payment Limit Action Plan

Dear Chair Mitchell:

On behalf of the Maryland Hospital Association's (MHA) member hospitals and health systems, we appreciate the opportunity to provide comments on the draft Upper Payment Limit Action Plan (draft action plan).

Maryland hospitals support the Prescription Drug Affordability Board's (PDAB) efforts to combat high drug prices. The high price of prescription drugs creates financial challenges, and patients who can't afford their medications may delay, ration, or even forego their prescriptions, which can harm their health outcomes. The federal government recently started to implement the Inflation Reduction Act's provisions to curb high drug prices for Medicare, and we encourage PDAB to develop an action plan that works synergistically with the federal government's policies.[1]

While hospitals support PDAB's work to rein in high drug prices, we have concerns about the lack of details in two areas in the draft action plan.

Draft action plan needs to provide more details in the event of a drug shortage

As the draft action plan acknowledges, an upper payment limit (UPL) cannot be applied to a drug that is on the federal Food and Drug Administration's (FDA) prescription drug shortage list. PDAB, according to the draft action plan, will also reconsider or suspend an UPL if PDAB becomes aware of a drug shortage.

The draft action plan, however, does not explain how PDAB intends to monitor the availability of drug products in the state. Sole reliance on the FDA's shortage list may be problematic as

[1] 1. "Fact Sheet: Biden-Harris Administration Announces New, Lower Prices for First Ten Drugs Selected for Medicare Price Negotiation to Lower Costs for Millions of Americans," The White House, Aug. 15, 2024, https://www.whitehouse.gov/briefing-room/statements-releases/2024/08/15/fact-sheet-biden-harris-administration-announces-new-lower-prices-for-first-ten-drugs-selected-for-medicare-price-negotiation-to-lower-costs-for-millions-of-americans/.

there is often a delay between when a drug shortage occurs and when the shortage is recognized on the FDA list. We urge PDAB to identify additional benchmarks or indicators to ensure that it has real-time awareness of drug availability.

Furthermore, the draft action plan does not explain how PDAB intends to reconsider or suspend an UPL if a drug shortage occurs. We encourage PDAB to develop and publish a transparent review process to address potential drug shortages. The process should include details such as the frequency of the reviews, the standards PDAB will use to determine reconsideration or suspension of UPL, and the extent of public participation. An open process will better help patients and providers navigate the challenges during a drug shortage.

Draft action plan should develop contingencies for when manufacturers won't accept UPL

A frequent concern of the UPL policy is that manufacturers may not accept the payment limit as sufficient reimbursement for their products. If a manufacturer does not accept the UPL as payment in full, patients—and potentially providers—will be forced to pay the difference between the UPL and the manufacturer's demand. This can create additional affordability challenges and impede access to medication.

We encourage PDAB to consider instituting a surveillance mechanism in the draft action plan to monitor manufacturer behavior. PDAB should also develop response options if the establishment of the UPL does not improve affordability, or worse, leads to *increased* out-of-pocket costs for patients. PDAB should have response options that mitigate the burden on patients and providers should manufacturers refuse to honor the UPL.

Thank you for the opportunity to comment. We look forward to working with PDAB to ensure vital prescription medications are affordable and accessible for all Marylanders. Please do not hesitate to contact me, or Steven Chen, MHA director of policy, if we can be of assistance.

Sincerely,

Andrew R. Nicklas. Esq.
Senior Vice President, Government Affairs & Policy

MARYLAND TECH COUNCIL

August 26, 2024

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

Re: Written comment PBAB Draft Plan of Action for Implementing the Process for Setting Upper Payment Limits ("UPL")

Dear Members of the Prescription Drug Affordability Boad,

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") Stakeholder Council to comment on the draft Plan of Action for Implementing the Process for Setting Upper Payment Limits (the "Draft 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 Draft Plan and how it impacts the life sciences community.

1. *We encourage patient out-of-pocket costs to be a major consideration in the "Cost Review Study Process".*

The Draft 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 Draft Plan does not specifically call out patient out-of-pocket costs as part of this analysis. It is possible that out-of-pocket costs will be considered as a component of the factors listed, however, we are concerned that it is not specifically mentioned. 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 Draft 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 Draft 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 Draft 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 Draft 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 Draft 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 Draft 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 Draft 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.

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

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

The Draft 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 Draft 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 Draft 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 the Board's goal of transparency in its proceedings.

As a final comment, I urge the Board to take all stakeholder comments received seriously and to specifically respond to them as a component of the Board's deliberations. The MTC, MTC member companies, and all stakeholders have submitted comments to the Board throughout the Board's proceedings. The Board rarely addresses these comments in its public meetings. Therefore, it is difficult for the public to know whether feedback and recommendations contained within the comments were seriously considered by the Board. I recommend the Board develop a process to more thoroughly address, in a public forum, comments that are submitted to the Board. Thank you for the opportunity to comment and for your consideration of the issues raised herein.

Sincerely,

Kelly M Schulz

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August 26, 2024

Mr. Van T. Mitchell
Chair
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Chair Mitchel and Board members:

As organizations representing patients and people with disabilities, we strongly urge the Maryland Prescription Drug Affordability Board (PDAB) to prioritize the perspectives of people whose care may be impacted by your decisions as it works to finalize a Plan of Action for Implementing the Process for Setting Upper Payment Limits. Therefore, we would like to provide the following recommendations:

- 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.
- Improve the Board's patient engagement practices and use of survey data.
- Avoid the use of discriminatory value assessments.
- Avoid reference to drug prices in other countries.

We are deeply concerned with recommendations from academia to states implementing PDABs that are not centered on helping patients gain affordable access to the drugs that patients and doctors determine to be the most effective treatment.[1,2] Patients and people with disabilities have consistently expressed opposition to policies advancing use of discriminatory value assessments, closed formularies, utilization management strategies in which a drug must fail before patients can access a drug that works, non-medical switching to "therapeutic alternatives" as determined by a payer based on cost considerations, and formulary exclusions. Ultimately, we urge the Board to advance policies that support high-quality shared decision-making between patients and providers, ensuring patients can access the care that will have the most optimal impact on their quality of life and health outcomes. Adopting the recommendations below will be a strong start to protecting people with disabilities and serious chronic conditions in Maryland.

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.

[1] NASHP Toolkit to PDABs https://nashp.org/prescription-drug-affordability-board-toolkit/
[2] https://pdab.maryland.gov/documents/stakeholders/2023/havard_med_brigm_prst.pdf

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

patients and people with disabilities and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards historically used by payers. As described in the final rule, the new regulations would bar health care decisions made using measures that discount gains in life expectancy, which would include measures such as the quality-adjusted life year (QALYs) and the combined use of QALYs and equal value of life years gained (evLYG) that are most common methodologies for calculating cost effectiveness. The agency broadly interpreted what constitutes the discriminatory use of value assessment in its description of the rule, stating recipient obligations under the rule are broader than section 1182 of the Affordable Care Act. Section 1182 of the ACA bars Medicare's use of QALYs and similar measures that that discount the value of a life because of an individual's disability. Therefore, it is important for the Board to avoid the use of cost effectiveness analyses to make decisions that affect reimbursement and coverage of prescription drugs to remain aligned with federal law and regulations barring discrimination.

It is now widely recognized that traditional methods and metrics of value assessment – even beyond the QALY – have significant shortcomings. Well-intentioned development of other measures and approaches that developers assert to be nondiscriminatory and more patient-centered come with tradeoffs, need for improvement, and inherent methodological flaws. We urge the Board to avoid the use of cost effectiveness analyses that at worst violate federal nondiscrimination laws and regulations and at best force tradeoffs such as whether to value life extension or quality of life improvement. No patient is average, and no measure of value should assume so.[8]

Avoid reference to drug prices in other countries.

The Board's draft plan also proposes use of an international reference upper payment limit using drug prices in other countries. Referencing other countries is similarly contrary to federal laws governing disability discrimination due to their reliance on discriminatory value assessments, including QALYs. The Board's proposed policy would import those discriminatory standards from other countries and lead directly to lack of access to needed treatments for many Americans.[9] While Germany is often raised, we encourage the Board to review the German system, including its limited use of evidence, inappropriate comparators and endpoints, exclusion of health outcomes that are important to patients, and failure to capture heterogeneity of patient populations.[10] In Canada, the current coverage and reimbursement process for new drugs impedes access to care due to its reliance on QALY-based assessments conducted by the Canadian Agency for Drugs and Technologies in Health (CADTH).[11] In the United Kingdom, medicines exceeding the National Institute for Health and Care Excellence (NICE) cost-per-QALY threshold are not deemed cost effective, leading to a high rate of

[8] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_value_critique_updated.pdf
[9] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_stakeholder_comment_on_importing_qalys.pdf
[10] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/germany_draft_2022_9-21_edited_clean.pdf
[11] Guidelines for the Economic Evaluation of Health Technologies: Canada. July 2017

rejections denying patients access to new medicines.[12] Ireland similarly denies patients care based on QALY thresholds.[13]

We encourage the Board to reference the work of the National Council on Disability, an independent federal agency advising Congress and the administration on disability policy, which has consistently recommended against referencing foreign prices in comments related to a proposed international pricing index,[14] Most Favored Nation policy,[15] and federal legislation.[16] The NCD's recommendations against reliance on cost effectiveness are largely reflected in the new federal Section 504 regulations, providing increased clarity on the prohibited use of discriminatory value assessments.

Thank you for the opportunity to comment on the draft UPL plan. We look forward to revisions that prioritize policies centered on access to care for patients and people with disabilities. Please reach out to sara@pipcpatients.org with any questions.

Sincerely,

Alliance for Aging Research
Alliance for Patient Access
ALS Association
American Association of Kidney Patients (AAKP)
Asthma and Allergy Foundation of America
Biomarker Collaborative
Cancer*Care*
Caring Ambassadors Program
Coalition of State Rheumatology Organizations (CSRO)
Color of Gastrointestinal lllnesses
Cystic Fibrosis Research Institute
Derma Care Access Network
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Disability Equity Collaborative
Epilepsy Foundation
Exon 20 Group
Familia Unida Living with MS
GO2 for Lung Cancer

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[12] Drummond, M. and Sorenson, C. Nasty or Nice? A Perspective on the Use of Health Technology Assessment in the United Kingdom. Value in
Health 2009; 12(S2).
[13] National Centre for Pharmacoenomics (NCPE). http://www.ncpe.ie/about/
[14] https://www.ncd.gov/2020/08/05/ncd-statement-on-harm-of-using-international-pricing-index-for-u-s-prescription-drug-pricing/
[15] https://www.ncd.gov/letters/2021-01-15-ncd-letter-to-cms-on-most-favored-nation-rule/
[16] https://www.ncd.gov/letters/2021-04-29-ncd-letter-to-house-committees-with-concerns-regarding-h-r-3/

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

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By Electronic Submission

August 26, 2024
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

RE: Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document

Dear Members of the Maryland Prescription Drug Affordability Board ("Board" or "PDAB"):

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document ("Draft Action Plan") drafted by the Board as part of implementing its upper payment limit ("UPL") setting process.[1] 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.

PhRMA recognizes the Board's ongoing work to implement and carry out its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] PhRMA continues to have concerns, however, about the Board's implementation of the PDAB Statute, including through the processes outlined under the Draft Action Plan.[3] PhRMA addresses its specific questions and concerns regarding the Draft Action Plan below.

I. Lack of Clear and Meaningful Standards

PhRMA is concerned that the Draft Action Plan lacks sufficiently clear and meaningful definitions, standards, and processes. As detailed below, if the Draft Action Plan is finalized and approved, the Board

[1] *See* Draft Action Plan, *available at* https://pdab.maryland.gov/Documents/comments/Draft%20Outline%20UPL%20Action%20Plan.2024.08.09.1700.pdf.
[2] *See* Md. Code Ann., Health-Gen. §§ 21-2C-01 to -16.
[3] In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to the constitutionality of the Maryland PDAB statute. PhRMA also incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Board's implementation of the PDAB Statute. *See* Letter from PhRMA to Board Regarding Selected Drug List (July 16, 2024); Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); Letter from PhRMA to Board Regarding List of Proposed Therapeutic Alternatives and Sample Dashboard (May 10, 2024); Letter from PhRMA to Board Regarding Cost Review Study Process (Apr. 24, 2024); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule; Confidential, Trade-Secret, and Proprietary Information; Public Comment Procedures; and Cost Study Review Process (Oct. 23, 2023); Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade- Secret, and Proprietary Information; and Cost Review Study Process (June 30, 2023); Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Draft Regulations on Public Information Act (May 4, 2023); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023); Letter from PhRMA to Board Regarding Cost Review: Additional Metrics for Identifying Potential Drugs Presentation (Sept. 2022).

must establish clear and specific rules governing the new processes outlined in the draft plan prior to beginning its UPL-setting processes. Not only does the Maryland Administrative Procedure Act ("APA") require such standards be established through separate rulemaking, but such clear and specific standards are a necessary safeguard against arbitrary and inconsistent agency decision-making.[4]

The lack of clear and specific standards in the Draft Action Plan also impacts the ability of stakeholders to fully and meaningfully comment on the plan. This issue is further compounded by the limited time window provided for comment, as the two-week comment period provided for the Draft Action Plan does not allow for full or meaningful stakeholder participation. Key stakeholders in the UPL process may not be able to provide written feedback given the short timeline. Going forward, we request that the Board provide multiple opportunities for stakeholder feedback (written or verbal), sufficient time for public comment (at least 60 days), as well as timelines and steps for the Board to incorporate and address feedback are clear and transparent.

A. Need for Subsequent Rulemaking

PhRMA emphasizes that, if the Draft Action Plan is finalized and approved by the Legislative Policy Committee of the General Assembly (or the Governor and Attorney General),[5] the Maryland APA nonetheless requires that separate rulemaking be conducted to establish the specific definitions, standards, and processes that will govern the UPL processes outlined in the Draft Action Plan.[6] Specifically, under the Maryland APA, all policies "of general application ... must be accomplished by rulemaking."[7] This includes both legislative rules that establish substantive standards and requirements, as well as "organizational rules, procedural rules, interpretive rules and statements of policy."[8] Further, the Maryland APA establishes clear processes and timelines that govern the proposal and finalization of new rules.[9] The Board must, consistent with these requirements, adopt comprehensive regulations governing each procedural step, factor, and methodology described in the Draft Action Plan through notice and comment rulemaking.

Further, to be consistent with due process requirements, regulations implementing the UPL Action Plan must do more than repeat the broad descriptions in the Draft Action Plan or the PDAB Statute. Rather, the Board's rules must set forth the *specific definitions, processes, guidelines, and standards* that the Board proposes to apply to the UPL process. As courts have explained, agencies must establish clear and specific processes that give certainty "in advance to persons dealing with the agency" as to the rules of the road

[4] *See Harvey v. Marshall*, 389 Md. 243, 302 (2005) ("[A]n agency action nonetheless may be 'arbitrary or capricious' if it is irrationally inconsistent with previous agency decisions.").
[5] Md. Code Ann., Health-Gen. § 21-2C-13(d).
[6] *See* Md. Code Ann., State Gov't, tit. 10, substit. 1, pt. III. As the Board notes, formally setting UPLs also requires the adoption of "a regulation through notice and comment rulemaking." Draft Action Plan 2. PhRMA understands the Draft Action Plan to be acknowledging that the Board will undertake a separate rulemaking for setting UPLs, with a distinct notice and comment period that complies with the requirements of the Maryland APA. PhRMA urges the Board to set forth clear timelines for such subsequent rulemaking to help ensure the adequacy of the notice and comment process associated with it.
[7] *Venter v. Bd. of Educ.*, 185 Md. App. 648, 678 (2009).
[8] *Eng'g Mgmt. Servs., Inc. v. Md. State Highway Admin.*, 375 Md. 211, 232–33 (2003) ("Under the Maryland APA, an agency's organizational rules, procedural rules, interpretive rules and statements of policy all must go through the same procedures as required for legislative rules").
[9] *See* Md. Code Ann., State Gov't, tit. 10, subtit. 1, pt. III. *See also Kor-Ko Ltd v. Md. Dep't of Env't*, 451 Md. 401, 409 (2017) (rules "of general application prescribing a new plan or policy [as opposed to] one which merely looks to or facilitates the administration, execution, or implementation of a law already in force and effect," require adoption through notice and comment rulemaking.)

that will be applied.[10] "Only then can there be some assurance against arbitrary and capricious conduct on the part of the agency."[11] Likewise, the agency's substantive rules should not merely reproduce statutory language.[12] Just as agencies cannot "simply [] parrot general statutory requirements or rest on broad conclusory statements" when rendering findings, the agency's substantive rules cannot either and should establish sufficiently clear and specific standards to guide the agency's discretion and limit arbitrary and inconsistent, ad hoc determinations.[13] PhRMA therefore urges the Board to establish clear and specific definitions, processes, and standards in its regulations governing the UPL-setting process that allow for consistent decision-making across the various areas identified in the Draft Action Plan. The Board should also clarify how it intends to specifically define and weigh the various criteria and factors it describes in the Draft Action Plan.

B. Examples of Lack of Clear Standards

PhRMA provides below a non-exhaustive list of examples of areas where greater clarity and specificity should be provided in the Board's plan and subsequent regulations:

- **Policy Review**. The Draft Action Plan outlines the Board's contemplated policy review process, but does not provide clear standards and processes for how it will be implemented in a manner that provides clear and consistent decision making. PhRMA is concerned that the Policy Review process would give unduly 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 and ad hoc application of the process for evaluating different drugs, which could result in such reviews being conducted in a manner that is arbitrary and capricious.[14] Maryland courts have long held that agency action can be found to be arbitrary and capricious if similarly situated entities or products are treated differently without a rational basis for such differential treatment,[15] and have likewise struck down decisions that have unexplained inconsistencies with prior agency decisions.[16]

  PhRMA is also concerned that the Draft Action Plan does not require the Board to provide transparency to manufacturers or other stakeholders in how it conducts its policy reviews. Rather, the Draft 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.[17]

[10] *Calvert Cnty. Plan. Comm'n v. Howlin Realty Mgmt., Inc.*, 364 Md. 301, 322 (2001).
[11] *Id.*
[12] *See, e.g.*, Hanah Metchis Volokh, *The Anti-Parroting Canon*, 6 NYU J.L. & Liberty 290, 293 (2011).
[13] *Rodriguez v. Prince George's Cnty.*, 79 Md. App. 537, 550, 558 A.2d 742, 748 (1989); *see also Myers v. State*, 248 Md. App. 422, 437 (2020) (due process prevents even legislatures, much less agencies, from establishing rules "so standardless that it invites arbitrary enforcement").
[14] *Harvey*, 389 Md. at 302.
[15] *Maryland State Bd. of Soc. Work Examiners v. Chertkov*, 121 Md. App. 574, 588 (1998). As further discussed below, while the Draft Action Plan refers to certain elements of the UPL-setting process as "quasi-legislative" in nature, these processes should also incorporate procedural protections consistent with the requirements for contested cases under the Maryland APA. *See* below, pp. 8-9.
[16] *See, e.g.*, *Christopher v. Montgomery Cnty. Dep't of Health & Human Servs.*, 381 Md. 188, 215 (2004).
[17] Draft Action Plan at 6-7.

In addition, the Board's Draft Action Plan permits the Board to make "other (non-UPL) policy recommendations" in lieu of or in addition to implementing a UPL.[18] The Draft Action Plan, however, does not *require* the Board to consider or review non-UPL policy recommendations. PhRMA recommends that the Board establish regulations governing consideration of UPL alternatives that include a requirement the Board provide a written, public explanation as to which alternative policies were considered and why the Board does or does not adopt alternative policy recommendations provided by the Board or the Board's staff.

- **Regulatory Price Impact**: PhRMA acknowledges the Board's efforts to limit the impact of UPLs on other regulatory drug pricing programs, but is concerned about the lack of detail as to how the Board intends to operationalize the prohibition on setting a UPL amount that "impacts statutory or regulatory amounts, such as Medicaid Best Price."[19] PhRMA requests that the Board provide greater detail as to how the Board envisions this limitation being implemented as well as the scope of regulatory prices that the Board considers impacted by this approach. As the Board knows, statutory and regulatory amounts are not static, may not be publicly available, and can be impacted by criteria established under other laws. For example, Medicaid Best Price is calculated quarterly.[20] Thus, while a particular UPL may not impact Best Price at the time it is put in place, that may change as Best Price fluctuates over time. We encourage the Board to further detail this requirement and allow for stakeholder comment on this concept.

- **Statutory Requirements for Establishing UPL**: The Draft Action Plan is silent on several statutory requirements for setting UPLs and monitoring UPLs that are put into place.[21] The Board should ensure it addresses *all* statutory requirements for setting UPLs, including the Board's plan for monitoring a UPL after it is set.[22]

- **Out-of-Pocket Costs**: The Draft Action Plan's criteria for setting UPLs contemplates that the Board "shall prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug."[23] As PhRMA has emphasized in prior comments, any consideration of high out-of-pocket costs should account for the full range of factors driving such costs.[24] This includes benefit design choices and fees, rebates, and other price concessions paid by drug manufacturers to pharmacy benefit managers ("PBMs") and plans that are not shared directly with patients.[25] These factors are outside of the control of manufacturers and can be significant contributors to patients' out-of-pocket costs, and should be given appropriate consideration, as they directly bear on issues of patient affordability, but are the result of the decisions of independent third parties, namely health insurance carriers and PBMs

[18] *Id.* at 12.
[19] *See id.* at 3.
[20] *See generally* 42 C.F.R. § 447.505.
[21] As an example, the Draft Action Plan does not address that "[the] process for setting upper payment limits [submitted to the legislature] shall" require the Board to "[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." Md. Code Ann., Health-Gen. § 21-2C-13(c)(2). The PDAB Statute specifically requires the Board to provide a "plan of action for implementing" the UPL-setting process to which the monitoring requirement would apply. *See id.* 21-2C-13(a).
[22] *See id.* 21-2C-13(c).
[23] Draft Action Plan at 3.
[24] *See* Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process 3-4 (May 1, 2023).
[25] *See id.*

PhRMA is especially concerned that simply comparing net cost and out-of-pocket costs for particular drugs would be misleading. It would not account for the relationship between patient out-of-pocket expenses and the benefit design choices and fee and rebate practices of health plans and PBMs. Consistent with our prior comments, PhRMA also reiterates its request that the Board clarify how it will determine that the information it receives provides adequate detail about the 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).[26] The Board should also clarify that out-of-pocket costs will appropriately account for the full range of factors driving such out-of-pocket costs, including benefit design (e.g., cost-sharing requirements such as coinsurance and deductibles, and accumulator adjustment[27] and copay maximizer programs[28]) and fees, rebates, and other price concessions paid by drug manufacturers to PBMs and health insurance carriers that are not shared directly with patients at the point of sale. Failing to do so could result in misleading cost calculations that are arbitrary and capricious, and not reflective of the actual costs to Maryland patients. For additional context, the Board should also consider the impact of PBMs requiring the use of PBM-owned specialty pharmacies and retail pharmacies has on patient out-of-pocket costs.

- **Board Technical Hearing**: The Draft Action Plan states that the Board "may" convene a hearing to receive technical input and testimony as part of the process of establishing a UPL amount, and states that the Board will adopt regulations governing these quasi-legislative hearings.[29] Given the complexity of UPL-setting analyses and calculations, 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. In order to provide for sufficient stakeholder input as well as transparency into its UPL processes, the Board should adopt provisions in its Draft Action Plan and subsequent implementing regulations that make these technical hearings mandatory. Requiring a technical hearing will also give stakeholders an opportunity to provide the Board with additional information and technical feedback on how a proposed UPL will affect Maryland patients' access to drugs before a UPL is put in place.

- **Cost of Drug Administration**: The Draft Action Plan states that "[t]he criteria for setting a UPL shall include consideration of the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs."[30] PhRMA seeks clarification on how the Board intends to implement this criterion, specifically on how this factor would be considered in setting any UPL amounts, as these costs reflect the charging practices of independent third parties in the pharmaceutical supply chain. As noted in our prior comment letters, health insurance carriers and PBMs determine the out-of-pocket costs for patients, so considering their impact on the cost of administration of the drug is imperative.[31]

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[26] *See* Letter from PhRMA to Board Regarding Request For Information Draft Forms 3-4 (July 12, 2024).

[27] 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.

[28] 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.

[29] Draft Action Plan at 12. *See* further discussion of the UPL-setting process as a quasi-legislative process below, pp. 8-9.

[30] *Id.* at 2.

[31] *See* Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process 3-4 (May 1, 2023).

- **Regulatory Criteria for Determining the Appropriateness of a UPL**: The Draft Action Plan refers to "certain regulatory criteria" that will be considered to determine if the UPL is an appropriate policy to address an affordability challenge.[32] However, the Draft Action Plan does not include the specific regulatory criteria that the Board will assess or utilize. PhRMA recommends that the Board clarify the specific criteria that will be assessed and utilized to determine if the UPL is the appropriate solution, and solicit comment on these proposed criteria consistent with the requirements of the Maryland APA.

- **Blend of Multiple Methodologies**: The Board's plan suggests that "Board staff may provide recommendations on the potential values for the UPL" under a "[b]lend of [m]ultiple [m]ethodologies."[33] PhRMA requests that the Board clarify its intent for how and when its staff may blend multiple methodologies, as this may lead to inconsistent recommendations.

- **Factors for Additional Context for Setting a UPL**: The Draft Action Plan would allow Board staff to recommend methodologies and factors to establish a UPL to the Board.[34] PhRMA asks that the Board revise the Draft Action Plan to provide specific factors that will be considered when establishing a UPL instead of authorizing subsequent staff recommendations. The Board should subsequently propose regulations specifying how these additional factors will be considered and weighed. Considering the importance of the information included as additional factors in the Draft Action Plan, it is critical that the Board have clear criteria and guidelines for the operationalization, use, and weighting of these factors.

- **UPL Calculation Data**: The Draft Action Plan permits the Board staff to use "[a]ny information that can be derived from the manipulation, aggregation, calculation, and comparison of any available information" as a factor for providing "additional context for setting a UPL."[35] PhRMA is concerned that this additional factor is unduly broad and vague. We reiterate that the Board's UPL decision-making must be based on "factors which [the legislature] ... intended it to consider," and grounded in statutorily relevant criteria and considerations.[36] It would therefore be inappropriate for the Board to operate in a manner that permits it to adopt additional extra-statutory considerations, or modify the ways it uses and considers data, on an ad hoc, case-by-case basis. PhRMA recommends the Board create guardrails around the information that can be considered and utilized to establish a UPL. Additionally, PhRMA recommends that the Board make publicly available the calculations or other data operations used in its processes. Except where protected against disclosure due to confidential or proprietary information, such data should be available to the public to allow stakeholders to understand the basis of the Board's determinations and provide feedback where the Board's data operations appear inappropriate or based on erroneous data assumptions.

- **Market Basket**. The Board's Draft Action Plan refers to staff calculation of a "market basket of UPL values."[37] However, the Draft Action Plan does not include a clear definition of "market basket,"

[32] *Id.* at 3.
[33] Draft Action Plan at 10.
[34] *Id.* at 8.
[35] *Id.* at 11.
[36] *Maryland Dep't of Env't v. Anacostia Riverkeeper*, 447 Md. 88, 121 (2016) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).
[37] Draft Action Plan at 11.

or meaningful details on what will be included in a "market basket." PhRMA recommends that the Board clarify the definition of "market basket" and how it will inform the determination of UPL amounts. Absent more clarity on how the Board defines and intends to use the "market basket," stakeholders cannot meaningfully comment on the Board's proposal.

- **Quasi-Legislative Hearings:** The Draft Action Plan includes three references to "quasi-legislative hearings" related to expert testimony, informational, and Board technical hearings.[38] As the Board itself appears to acknowledge,[39] it must establish through regulations detailed processes governing all such quasi-legislative hearings.

  Further, under the Maryland APA, agency hearings implicating a statutory (or constitutional) right, duty, entitlement, or privilege are considered contested cases[40] and are subject to various procedural requirements, including rights to a hearing conducted by an agency head or Administrative Law Judge;[41] reasonable notice of the agency's action and the hearing;[42] trial-like protections for the hearing process;[43] and judicial review.[44] PhRMA urges the Board to adopt procedural protections for stakeholders impacted by a UPL-setting process that are consistent with the requirements of the Maryland APA.

  The Draft Action Plan and subsequent regulations should also provide additional details as to how these hearings will be operationalized. For example, provisions governing the Board's use of expert testimony should include details as to how decisions are made on whether expert testimony is needed and how individuals are chosen to deliver such testimony. The Draft Action Plan and subsequent regulations should also address how conflict of interest disclosure and recusal procedures will be implemented to require that any testimony given as part of these hearings is unbiased. The definition of conflict of interest that the Board adopts should be consistent with the statutory definition of conflict of interest for members of the Board.[45] The conflict of interest procedures should also cover relationships with all entities in the prescription drug supply chain (e.g., payers, distributors, PBMs, and associated trade associations).

II. Sequence of Cost Reviews, Policy Reviews, and UPL Calculation

PhRMA is concerned that the Draft Action Plan proposes to begin addressing affordability challenges and calculating UPL amounts *before* a final decision is made that the drug at issue has or will lead to affordability challenges. Such sequencing is not consistent with the process described in the PDAB Statute.

The PDAB Statute contemplates the cost review and UPL determinations be separate and distinct processes conducted in sequence. First, Section 21-2C-09 of the PDAB Statute says that a cost review must

[38] Draft Action Plan at 7, 12.
[39] For example, the Draft Action Plan says that the information gathering process described in the Draft Action Plan includes the potential convening of "expert testimony hearings," and states that the Board will adopt regulations to govern these hearings.
[40] Md. Code Ann., State Gov't, tit. 10, subtit. 2, pt. II.
[41] *Id.* at pt. V.
[42] *Id.* at pt. VII-VIII.
[43] *Id.* at pt. XIII.
[44] *Id.* at pt. XXII. We note that the PDAB Statute at § 21-2C-15 also explicitly provides for appeal rights, including judicial review, for any "person aggrieved by an upper payment limit set by the Board."
[45] "Any conflict of interest, including whether the individual has an association, including a financial or personal association, that has the potential to bias or has the appearance of biasing an individual's decision." Md. Code Ann., Health-Gen. § 21-2C-03(a)(5).

be conducted to determine if certain products are associated with affordability challenges.[46] Then, in Section 21-2C-14 of the PDAB Statute, the legislature states that UPLs may only be set "for prescription drug products that have led or will lead to an affordability challenge,"[47] as determined through cost reviews. By codifying cost reviews and UPL-setting as separate and distinct procedural steps under separate sections of the law, the legislature demonstrated its intent that only drugs for which a cost review process has been completed, and which have been determined to be associated with affordability challenges, may be eligible for a UPL.[48] In other words, the law intends for the two processes to be distinct and sequential, not parallel and combined, as the Draft Action Plan contemplates.

Further, PhRMA is concerned that the Board's combined sequencing may bias the Board's final decision as to affordability in a manner that would be arbitrary and capricious. Until the cost review is finalized, the Board has not made a determination that a drug raises affordability challenges, much less determined that UPLs are the appropriate recourse. Prematurely beginning the UPL determination process risks prejudicing the outcome of the cost review process. It also signals that the Board may presume that a UPL is the only appropriate solution if an affordability challenge is identified, and limits the opportunities for stakeholders to provide information for the Board's consideration. The legislature specifically recognized that UPLs are not the only policy option that can be appropriate to address affordability challenges,[49] and the Board should not appear to prejudge the appropriateness of a UPL before making a final determination that affordability challenges exist with respect to a given drug.

PhRMA is especially concerned about this risk because the wording of the Draft Action Plan appears to presume that the Board will ultimately decide a given drug is unaffordable and that a UPL should be implemented.[50] While the Draft Action Plan states that there will be a public comment period after the preliminary affordability determination is made, and that the preliminary affordability decision is "non-final and subject to revision and modification," the sequencing of processes contemplated under the Draft Action Plan creates the appearance of bias or (at worst) even suggests that the final affordability determination would be *a fait accompli*.[51]

For these reasons, PhRMA asks that the Board revise its Draft Action Plan to make clear that the cost review will be finalized *before* the Board initiates its policy review, which could lead to the initiation of the UPL-setting process. Additionally, PhRMA requests that the Board clarify that it will separately consider other policy options before determining whether to set a UPL. As the Draft Action Plan itself correctly acknowledges, a UPL may not be the appropriate policy solution for every affordability challenge.[52] As such, it is unclear why the Board would devote resources to the technical development of a potential UPL before the Board has even determined whether a UPL is the proper tool to address affordability concerns.

In addition, PhRMA is concerned about the language in the Draft Action Plan that would allow the adoption of the final cost review report, policy recommendations, and proposed UPL amounts at the same Board meeting. Stakeholders should have the opportunity to separately comment on and participate in each of

[46] *Id.* § 21-2C-09.
[47] *Id.* § 21-2C-14.
[48] *Compare id.* § 21-2C-09 *with* § 21-2C-14.
[49] *See id.* § 21-2C-07(2).
[50] "The *preliminary determination* that the drug has led or will lead to affordability challenges is a predicate for the Board to start the policy review process to study and assess what, if any, policy tools are *best suited to redress the identified affordability challenges, including whether a UPL is an appropriate policy solution*." Draft Action Plan at 6 (emphasis added).
[51] *Id.* at 4.
[52] *See, e.g.*, Draft Action Plan 3, 6.

these processes independent of one another. Joining these processes together would not allow for meaningful stakeholder participation, and would undermine the fidelity of the Board's processes by encouraging rushed decision-making that does not incorporate the full range of stakeholder feedback, information, and perspectives that bear on each of these distinct decision points.

In sum, the Board should revise the Draft Action Plan to require that the Board, in sequence: finalize the cost review; then (if a drug is determined to raise affordability challenges) consider multiple policy options before determining whether a setting a UPL is appropriate; and only then (if the Board decides to institute a UPL and provides justification of why another solution was not appropriate) conduct its methodology to determine the UPL amount. These decisions should be made in separate meetings, with separate opportunities for comment on each distinct procedural step.[53]

III. Cost Effectiveness Analysis

PhRMA remains concerned with the proposed consideration of cost effectiveness analyses ("CEA") as part of the factors used in determining UPL amounts. While the Draft Action Plan does not specify the types of CEA the Board contemplates relying on, PhRMA reiterates its prior concerns about the use of certain types of cost effectiveness analyses.[54] As explained in more detail in our prior comments, use of Quality Adjusted Life Years ("QALYs") or other metrics like "equal value of life year gained" ("evLYG") would 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.[55]

More broadly, 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. As one patient group has noted, "It is widely acknowledged that a summary measure such as [those used in CEAs] will never be able to adequately capture the vast differences in individual preferences and values."[56] It has also been widely noted by stakeholders that CEA discriminates against individuals with disabilities and chronic illnesses by undervaluing their lives.[57] Experts in the field of CEA recently acknowledged that "the problem of whether CEA unjustly discriminates against the disabled remains a deep and unresolved difficulty for the use of CEA."[58]

Cost-effectiveness analysis may also contribute to perpetuating longstanding inequities in health care and health outcomes. The assumptions used in CEA disadvantage marginalized populations through use of

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[53] As above, PhRMA also urges the Board to establish regulations specifically defining the processes that will govern each of these decisions.

[54] *See* Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process 12–13 (May 1, 2023).

[55] National Council on Disability, Quality-Adjusted Life Years and the Devaluation of Life with Disability 3 (Nov. 2019), *available at* https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf; Broder, M., Ortendahl, J., *Is Cost-Effectiveness Analysis Racist? Partnership for Health Analytic Research* (2021), *available at* https://blogsite.healtheconomics.com/2021/08/is-cost-effectiveness-analysis-racist/.

[56] Partnership to Improve Patient Care. "Measuring Value in Medicine: Uses and Misuses of QALYs." 2017. Available at: http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_white_paper_-_measuring_value_in_medicine_-_uses_and_misuses_of_the_qaly.pdf.

[57] *Id.*

[58] P Neumann, G Sanders, et al. Cost Effectiveness in Health and Medicine, Second Edition. 2017.

QALYs, health care costs, as well as assumptions around lost productivity. [59] These assumptions undermine health interventions that may improve health for marginalized populations and favor interventions that will further the status quo of inequity. PhRMA urges the PDAB to reconsider its use of CEA as "systematic underestimation of cost-effectiveness for marginalized populations can contribute to further entrenchment of health inequities."

IV. Upper Payment Limit Calculation Options

The Draft Action Plan lists several potential methods to calculate UPLs. PhRMA addresses its feedback and concern for these potential options below based on the descriptions contained in the Draft Action Plan.[60]

Therapeutic Class Reference UPL: PhRMA is concerned that the Board has not fully explained how it will identify whether drugs fall into the same "therapeutic class." As drafted, the contemplated "Therapeutic Class Reference" UPL method appears to define a therapeutic class by reference to "competitor products that have similar chemical structures and act through similar pathways to treat the same conditions."[61] Similar to concerns raised by PhRMA about the Board's unduly broad definition of therapeutic alternative, this 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.[62] PhRMA urges the Board to refine this calculation method to establish a more specific and nuanced definition of therapeutic class that avoids misleading comparisons between meaningfully distinct products. Specifically, the Board should establish through regulation a consistent process that each drug must be evaluated under for purposes of this UPL pathway to determine whether it can be appropriately considered to be in the same "therapeutic class." The process should include:

- Meaningful engagement with the manufacturer and local medical professionals on potential therapeutic class members;
- Review of clinician guidance, including physician-driven evidence-based clinical guidelines, as a resource; and
- Review of other widely recognized, scientifically rigorous, evidence-driven resources to identify therapeutic class members.

- **Launch Price-Based UPL:** The Draft Action Plan contemplates setting a UPL tied to "launch price adjusted for inflation."[63] PhRMA asks the Board to provide additional details regarding this methodology, including how it 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 typically is 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.

[59] The Risk Of Perpetuating Health Disparities Through Cost-Effectiveness Analyses, Sanjay Basu, Atheendar S. Venkataramani, and Dean Schillinger, Health Affairs 2024 43:8, 1165-1171.

[60] The Board has not provided detailed information about the different UPL options or provided specific definitions, standards, or processes that will govern the calculation of UPLs under each option. As explained in more detail above, if the Draft Action Plan is finalized and approved, more specific processes and standards must be outlined through a separate rulemaking consistent with the requirements of the Maryland APA.

[61] Board, Draft Action Plan at 9.

[62] *See* Md. Code Regs. 14.01.01.01(B)(61) (defining "[t]herapeutic alternative" as "a drug product that has the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug").

[63] Draft Action Plan at 9-10.

- **Same Molecule Reference:** The Draft Action Plan contemplates that the Board may set "a UPL based on the prices of other products with the same active ingredients with the same indications for use."[64] The products considered under this methodology range from generics, biosimilars, brand name drugs approved under 505(b)(2), products approved under an original New Drug Application ("NDA"), or authorized generics.[65] 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. Such improper groupings could lead to UPLs being proposed or established in an arbitrary and capricious manner and stifle innovation. Post-approval research and development often leads to new drugs and biological products with the same active ingredient providing meaningful treatment advances for patients.[66] For example, long-acting injectable formulations of antipsychotics have significantly improved patient adherence and treatment outcomes.[67]

- **Domestic Reference UPL:** In setting the domestic reference UPL, the Draft Action Plan would allow the Board to consider the Medicare Maximum Fair Price.[68] The Maximum Fair Prices recently released by the Centers for Medicare and Medicare Services do not go into effect until 2026, and as such, PhRMA reiterates that consideration of any part of the Medicare Drug Price Negotiation Program is premature.[69] The Program is in its infancy, and it will take years to understand its effect on patient affordability and access. Additionally, the Negotiation Program considers prices for the Medicare population, which is completely different in key respects (including demographics, age, and diversity) from the Maryland patient population that may be considered for UPLs.[70] PhRMA encourages the Board to limit its focus 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:** PhRMA continues to be concerned with the Board's contemplated use of international pricing data.[71] The Draft Action Plan states that the Board may set a UPL at

[64] Draft Action Plan at 10.
[65] *Id.*
[66] *See Anacostia Riverkeeper*, 447 Md. at 121 (agency decisions cannot be based on consideration of impermissible factors, run counter to the evidence before the agency, fail to consider important aspects of the issue being addressed, or be based on an implausible view of the evidence).
[67] Long-acting injectable (LAI) anti-psychotics improved medication adherence and patient outcomes leading to lower odds of hospitalization and fewer emergency room visits. Among Medicaid beneficiaries with schizophrenia, improved adherence due to LAI antipsychotics generated annual net savings of up to $3.3 billion, or $1,580 per patient per year, driven by lower hospitalizations, outpatient care, and criminal justice system involvement. Predmore Z.S., Mattke S., Horvitz-Lennon M. (April 1, 2015). Improving Antipsychotic Adherence Among Patients With Schizophrenia: Savings for States. Psychiatric Services. Available at: https://pubmed.ncbi.nlm.nih.gov/25555222/; Bera R., Offord S., Zubek D., et al. (February 2014). Hospitalization Resource Utilization and Costs Among Medicaid Insured Patients With Schizophrenia With Different Treatment Durations of Long-Acting Injectable Antipsychotic Therapy. Journal of Clinical Psychopharmacology. Available at: https://pubmed.ncbi.nlm.nih.gov/24135840/.
[68] Draft Action Plan at 10.
[69] Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process 5-6 (Apr. 24, 2024).
[70] *See* Md. Code Ann., Health-Gen. § 21-2C-14(a).
[71] Draft Action Plan at 10. PhRMA has provided detailed discussion of its concerns regarding international pricing information in its prior comments to the Board. *See, e.g.*, Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade-Secret, and Proprietary Information; and Cost Review Study Process (June 30, 2023).

the lowest price among a sub-set of countries. This risks relying on this data without proper context. Among other things, 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.[72]

Further, the Draft Action Plan lacks significant details on the source of the international pricing data. To the extent the Board intends to rely on public or proprietary sources for such data, it should be aware that there are numerous issues with international pricing data, including that international pricing data is generally collected at different levels in each country. For example, in some countries data is collected at the hospital level, while in other countries it is collected only at a higher level such as the wholesale level. International pricing data aggregator(s) often then use proprietary methods to estimate whole-country sales volumes and prices. As such, the data represents proprietary and non-transparent ***estimates*** of drug sales and volume and is not reflective of actual transaction or volume information. These proprietary estimates would not be appropriate to use as a method to establish an upper payment limit. Secondly, many sources of international pricing data are licensed on a confidential basis to subscribers for their internal use, and it is unclear how the Board's proposal would plan to use the data to establish an upper payment limit with such restrictions.

Finally, international reference pricing raises the same issues with cost-effectiveness analysis discussed above. 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 facing significant restrictions on access to treatments. Patients who have diseases such as cancer, diabetes and rare diseases, have faced access restrictions based on cost-effectiveness determinations. Recent analysis noted that these types of CEAs and recommendations, based on population-averages, fail to properly adjust to the demands of an evolving health care system and do not reflect the rapid pace of the science, or the needs and preferences of patients.[73]

- **Budget Impact-Based UPL:** The Draft Action Plan gives minimal detail or guidance on how a budget impact-based UPL would operate, so it is difficult to provide meaningful comment on this option. PhRMA requests that the Board more fully develop this option prior to finalizing the Draft Action Plan and address, among other things, 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. The Draft Action Plan's brief description of this option also raises a host of other significant questions (e.g., who determines the threshold or percentage of the budget a drug cannot exceed; whether the threshold will vary by drug category or therapeutic area), but lacks sufficient detail to fully explain how the Board intends to implement this option, which inhibits the ability of PhRMA to provide more detailed comments.

[72] *See* PhRMA analysis of IQVIA MIDAS and country regulatory data, October 2022 (Note: New active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021). A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where the medicine is reimbursed by the public plan. A medicine is considered publicly reimbursed in the United Kingdom if the medicine is recommended by England's National Institute for Health and Care Excellence (NICE) for funding by England's National Health Services (NHS).

[73] Context Matters. NICE Limits Reimbursement for Oncology Products beyond EMA Product Labeling. May 2014.

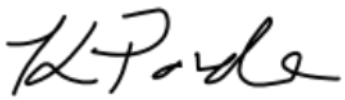
V. Confidentiality

The Draft 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. Consistent with our prior comment letters, PhRMA emphasizes the importance of the Board safeguarding this information from unlawful disclosure as part of its processes, as described and required by the PDAB statute and regulations consistent with state and federal law.[74] PhRMA requests that the Board provide greater detail as to how the Board and its staff members will identify and protect manufacturers' confidential, trade secret, and proprietary information. 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 Draft Action Plan.[75]

* * *

We thank you again for this opportunity to provide comments and feedback on the Board's Draft Action Plan and for your consideration of our questions, concerns, and requests for clarifications. Although PhRMA has concerns with the Draft Action Plan, we are ready to be a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide as the plan is further developed, please contact Kristin Parde at Kparde@phrma.org.

Sincerely,



Kristin Parde
Deputy Vice President, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[74] *See* Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process 2 (May 1, 2023).
[75] *See* Md. Code Regs. 14.01.01.04.

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August 26, 2024

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

RE: Board Selected Drugs (Skyrizi)

Dear Maryland Prescription Drug Affordability Members and Staff,

As a board-certified dermatologist practicing in the Washington, DC area for over 15 years, I have had the privilege of managing patients with psoriasis and psoriatic arthritis and have personally witnessed the remarkable advancements in therapeutic options available to manage the more than 8 million individuals living with psoriatic disease. I appreciate the opportunity to provide input on the Cost Review and would like to express my concerns regarding the inclusion of Skyrizi (risankizumab) on the referred list.

Psoriasis is an immune-mediated disease that causes inflammation throughout the body. Visible signs of inflammation, such as raised plaques and scales on the skin, may appear differently depending on skin type. The symptoms of psoriasis—including itch, pain, and flaking skin—can severely impact a patient's well-being, disrupt sleep, and hinder their ability to perform daily activities. Psoriasis is also associated with systemic conditions, including metabolic syndrome, cardiovascular disease, mental health disorders like depression and anxiety, and psoriatic arthritis (PsA), a potentially debilitating form of inflammatory arthritis. It is estimated that one in three people with psoriasis may develop PsA, with symptoms including swelling, stiffness, and pain in and around the joints. Research on PsA progression has shown that early treatment following the onset of symptoms is crucial in preventing, or at least minimizing, permanent joint damage.

Given the systemic nature of psoriasis and its profound impact on overall health and quality of life, access to highly effective and safe treatment options like Skyrizi is vital. Restricting access to such therapies would severely compromise my ability to provide optimal care for my patients. I urge you to take this into consideration when making your recommendations.

Sincerely,

Ben Lockshin, MD, FAAD

Value of Care Coalition

August 26, 2024

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

RE: DRAFT UPL ACTION PLAN

Dear Members of the Prescription Drug Affordability Board,

As a broad coalition of advocacy organizations representing patients, caregivers and health care providers, we write to share comments regarding the draft UPL Action Plan under consideration by the Prescription Drug Affordability Board (PDAB).

We recognize the importance of lowering health care costs and appreciate some aspects of the draft plan. However, several aspects of the draft action plan reinforce concerns that we and other stakeholders have expressed in comments previously submitted to the Board.

NARROW VIEW OF HEALTH CARE COSTS

Understanding that this is a plan focused on setting upper payment limits, it is appreciated that multiple times throughout the draft plan, the PDAB acknowledges that a UPL may not be the appropriate tool for affordability challenges and states that the Board may recommend additional policy actions.

However, no other policy options are outlined, no draft action plan for other policy options exists and at previous meetings the Board has expressed a disinterest in exploring other policy options this year. There is little evidence the Board is equipped with additional policy options and that those options are under active consideration. This validates concerns that the Board is taking too narrow a view regarding the drivers of cost in the health care system and ignores the complexity of the prescription drug supply chain, the way formularies are constructed, how patients access their medications and what determines out-of-pocket costs.

If the Board acknowledges that upper payment limits may not be an appropriate policy option to solve affordability challenges, the Board should let stakeholders know what other policies the Board is seeking authorization to enact, what the process is to enact those policies and how it would determine which policy option is best suited for certain situations. Without such forethought and disclosure, the acknowledgement of UPL shortcomings in the draft plan seems nothing more than an attempt to placate concerned advocates. This is especially urgent given

the timeline for ongoing affordability reviews and desire for swift action displayed at previous Board meetings.

LACK OF SUFFICIENT DETAIL

When planning a process that has potential to impact the way doctors practice medicine, pharmacists dispense medicine and patients access medicine, great care should be taken to provide details and assurances in order to avoid negative impacts and build confidence in the thoroughness of the plan. In this regard, the draft UPL Action Plan falls short.

For example, one criterion for setting an upper payment limit states "The Board shall consider the cost of administering the drug and delivering the cost to consumers, as well as other relevant administrative costs." While those who administer and deliver the drug may appreciate the consideration, the plan does nothing to explain how those considerations will be applied in a way that ensures providers and pharmacies continue to be able to administer or deliver the drug to patients. Without these details, concerns remain about the potential impact to access.

Another criterion states that "The Board shall determine that an upper payment limit is an appropriate tool to address the driver(s) of the affordability challenges identified for the prescription drug product." As mentioned above, the plan does not provide metrics or detail how this determination shall be made or provide for alternatives. As noted in previous comments to the Board, stakeholders have great concern that, in a complex health care system, the narrow view of health care cost taken by the implementation of a UPL could lead to a negative impact on access for patients.

The draft plan also 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 specify outcomes or consequences that are of concern and that should be minimized. Nor does the plan define the threshold for tolerance of adverse outcomes and unintended consequences that will be determined minimal. Vague guidance is inadequate when adverse outcomes and unintended consequences relate to Marylanders' health and livelihood.

CONCERNS ABOUT HASTE

In the section titled Cost Review Study Process, the steps outlined indicate great urgency for the Board but do not offer concrete timelines for each step. Given previous concerns expressed by the Board about staff bandwidth, the "parallel" processes detailed in the draft plan may 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, yet no time is specified for public input on a proposed UPL amount prior to its adoption. As the Board has moved up the date of its meeting in September to speed the process (per discussion during the August meeting), concerns about haste appear valid.

LACK OF PROCESS FOR STAKEHOLDER INPUT

In addition to concerns about the timeline and opportunities for public comment mentioned above, The Information Gathering section of the draft plan indicates the Board and staff *may* take several actions and consult several sources for input but does not require them to do so and does not lay out a timeline or process for those actions. The draft plan also does not specifically list patients, health care providers or caregivers as stakeholders under consideration for input. This is concerning, given that these stakeholders are those most directly impacted by the setting of an upper payment limit and have the best understanding of the value their treatments provide. It also reiterates concerns about adequate opportunity for stakeholder comment during this phase.

LACK OF PATIENT SAVINGS, LIKELY REDUCTION OF PATIENT ACCESS

The introduction of the draft plan states the "Board conducts a cost review study of a prescription drug product to determine whether use of the drug has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients."

The draft plan later states "The Board shall prioritize drugs that have a high proportion of out-of-pocket costs compared to the net cost of the drug."

While these statements make it seem as though a focus of the Board and the implementation of an upper payment limit is saving Marylanders' money at the pharmacy counter, the draft plan is silent on how any potential savings might be realized by patients whose out-of-pocket costs are determined to be the most burdensome.

It also fails to account for the fact that most out-of-pocket costs are set by health plans. As detailed in previous comments to the Board, health plans have stated that any savings achieved will likely not be passed down to patients and that utilization management – typically in the form of restrictions or delays on access – is likely to increase for drugs with a UPL or their

competitors.[1] Just as the plan lacks detail on patient savings, the plan also lacks detail on ensuring access.

CONCERNS RELATED TO METHODOLOGIES AND FACTORS FOR SETTING UPPER PAYMENT LIMITS

The draft plan lays out a list of methodologies for use to set the upper payment limit amount. Several of these options raise concern.

The QALY, or Quality Adjusted Life Year, and other QALY-like metrics are common forms of cost effectiveness analysis. Unfortunately, they're also widely viewed as discriminatory. In fact, they've been banned for use by some federal programs. These metrics should not be used by any state in determining the value of a treatment.

As described, the therapeutic class reference upper payment limit and same molecule reference upper payment limits may not consider the unique value each treatment provides to patients and health care providers. Comments submitted by the Value of Care Coalition regarding the six drugs chosen for cost review highlight the value of treatment choice to patients, allowing clinicians the ability to tailor treatment regimens to the needs of specific patients considering their comorbidities, tolerance for side effects and other factors. By discounting this value and setting the limit at the lowest net price among competitors or among drugs that are not deemed interchangeable, the Board may cause increased utilization management within the class which ultimately leads to less choice and more delayed or denied treatments.

For example, non-medical switching – a switch forced by a payer upon a patient for no medical reason – is a common tactic already used by health plans. Several states have taken steps to limit this practice, as studies have shown that, as symptoms re-emerge, diseases progress, different side effects leave their impacts, increased visits to doctors and hospitals mean non-medical switching does not necessarily lead to lower health care costs. Instead, Maryland should consider strategies that promote patient stability and improved health outcomes.

Reliance on the proposed domestic reference upper payment limit would mean that Maryland's prices would be set by some other jurisdiction even though the population and the needs of Maryland patients may not match those of another state or Medicare beneficiaries, for example. Maryland patients deserve local consideration.

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[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

The international reference upper payment limit seeks to tie prices in Maryland to those in countries with health care systems far different from our own, typically with much more limited access to a range of medicines. In addition to the systematic differences of those countries, those prices may also be reflective of the use of discriminatory value assessments as described above.

The budget impact-based upper payment limit seeks to put a cap on overall spending for a drug. For drugs that are widely utilized, this could cause an effective drug that is meeting an obvious health need for Maryland's population to become less widely available. For drugs treating rare diseases, this could effectively limit the number of patients able to acquire treatment.

SUMMARY

The Value of Care Coalition appreciates the work put into the draft plan as well as the ultimate goal – reducing the cost of health care. We also appreciate the acknowledgement that an upper payment limit may not be an appropriate solution and that other policy options should be available.

However, neither the draft plan nor recent discussion by the Board indicate that any other options are available and of interest to the Board. This highlights the narrow view of the drivers of health care costs being taken by the Board despite the complexity of the health care system.

The potential opportunities for public input are also appreciated, but the amount of discretion given to the Board on the input they seek, coupled with the lack of guidance on the timelines for input and what's done with the input, are concerning.

The draft plan specifies possible methodologies for determining a UPL that are inadequate at best, harmful and discriminatory at worst, and don't allow for consideration of individual patient needs in Maryland.

The haste expressed recently by the Board is of great concern. As other states' PDABs have acknowledged their own methodological shortcomings – some going so far as to pause their work as they reevaluate their definitions and processes – the Maryland Prescription Drug Affordability Board should act with prudence and caution, seeking to be as thorough and thoughtful as possible, given that their decisions impact Maryland patients' health and livelihood. While the Board is singularly focused on cost, it must be sure to take into account patient outcomes.

Finally, relating to patient outcomes, the plan does nothing to address the two most pressing concerns about the PDAB's work and the setting of an upper payment limit – how the upper payment limit reduces out-of-pocket costs for patients taking drugs deemed to cause

affordability challenges and how to ensure that access isn't threatened because of the upper payment limit.

As you consider the draft plan, we hope you'll also consider these concerns.

Sincerely,

Derek Flowers
Executive Director
Value of Care Coalition