National
Multiple Sclerosis
Society

November 1, 2024

Oregon Division of Financial Regulation
Oregon Prescription Drug Affordability Board
350 Winter St. SE
Salem, OR 97309

RE: National Multiple Sclerosis Society, policy comments

Dear Members of the Oregon Prescription Drug Affordability Board:

Thank you for your continued engagement with all stakeholders and for focusing on the patient's perspective. The National Multiple Sclerosis Society (Society) appreciates the Prescription Drug Affordability Board's (Board) leadership and investigation into the high cost of prescription medications. We encourage the Board to continue its review of all practices that limit access to needed life-changing therapies and increase the price that patients pay for those therapies.

Multiple sclerosis (MS) is an unpredictable, often disabling, disease of the central nervous system, which interrupts the flow of information within the brain and between the brain and the body. Symptoms range from numbness and tingling to blindness and paralysis. The progression, severity, and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are moving us closer to a world free of MS. The Society works to cure MS while empowering people affected by MS to live their best lives. To fulfill this mission, we fund cutting-edge research, drive change through advocacy, facilitate professional education, collaborate with MS organizations around the world, and provide services designed to help people affected by MS move their lives forward.

Costs of living with MS

People with MS have a variety of healthcare needs including, but not limited to, addressing neurological symptoms, emotional and psychological issues, rehabilitation therapies to improve and maintain function and independence, and long-term care. These needs vary dramatically from person to person and can change year-to-year as the disease progresses.

MS is a highly expensive disease, with the average total cost of living with MS calculated at $88,487 per year[1]. MS may impact one's ability to work and can generate steep out-of-pocket costs related to medical care, rehabilitation, home & auto modifications, and more. For individuals with MS, medical costs are an average of $65,612 more than for individuals who do not live with this disease. Disease-modifying treatments (DMTs) are the single largest component of these medical costs. As of February 2024, the median annual brand price of MS DMTs was more than $107,000. Five out of

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9109149/

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seven of the DMTs that have been on the market for at least 13 years are priced at over $100,000 annually and continue to see regular price increases.

Public input and meeting processes
The Society appreciates the efforts in public transparency and accountability that the Oregon Board has demonstrated since its establishment. The Board has made their meetings accessible to all Oregonians via online broadcasts and shared materials, as well as by providing multiple forms and points of outreach to interested and concerned stakeholders. These initial efforts should be recognized, applauded, and built upon for continued success. However, we strongly suggest the agenda packet and other materials be posted in a timelier manner, allowing for proper review by both the public and interested parties. Providing the full agenda packet at least two weeks in advance of all meetings would greatly benefit and increase stakeholder engagement and participation.

Stakeholder participation
Robust public participation from patients, patient groups, and other direct contact stakeholders is key to understanding the true impact of the high cost of prescription drugs. The Society appreciates the Board's continued outreach to patient groups and other stakeholders and highlights the recommendations from the October 16 meeting Agenda Packet regarding the "…desire to establish an advisory committee or council that includes representatives of the constituent community including patients, providers, caregivers, and others…" The Society supports outreach and inclusion of patients and others with direct, lived experience regarding the prescription drug under consideration. The Society recommends the Board enact a more formalized process to include the patient voice in all discussions and deliberations moving forward.

Upper payment limits
The Society maintains its support for policies related to upper payment limits (UPLs). The Society understands the complex nature of these policy discussions and therefore we appreciate the flexibility highlighted during the Board discussions.

The Society supports Upper Payment Limits and looks forward to the Boards robust discussions around any prescription drugs selected for study. The Society views UPLs as having the potential to lower out-of-pocket costs for patients by directly addressing the dollar cost of prescription medications. High out-of-pocket costs are typically due to co-insurance, which is when the patient must pay a percentage of the wholesale acquisition cost (WAC), or list price, as opposed to a flat copay amount. This is especially true for MS DMTs. A lower UPL would in turn create lower out-of-pocket costs for those who must pay co-insurance.

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UPL resources needed for implementation
Depending on what mode or modes of UPL methodologies the board considers, additional resources may be necessary to ensure continued access to up to date data to confront any challenges identified in the review processes as well as to maintain continued public and stakeholder group participation. As previously referenced in this letter, the Society encourages the establishment of a formalized patient advisory group or council to provide direct lived experience and expertise from patients and patient groups.

Again, *the Society fully supports the study and establishment of UPLs* and continues to view UPLs as having the potential to lower out-of-pocket costs for patients by directly addressing the dollar cost of prescription medications. Any realized savings should be used to improve healthcare outcomes in the state.

Board proposed policy recommendations SB 844 "clean-up"
The Society offers the following comments on selected passages from the proposed policy recommendations presented at the October 2 meeting.

Up to nine drugs per year
The Society appreciates the Boards focus on affordability balanced with capacity. The Society supports giving the board more flexibility by removing the statutorily mandated "nine drugs a year" to the proposed language of "up to nine drugs a year".

Enhanced PBM and insurer reporting, maximizers and accumulators
The proposal to implement reporting on copay maximizer and accumulator programs should provide more data on how these programs may alter access to, and costs of, medications for Oregon consumers. The Society supports full reporting on both copay maximizer and copay accumulator programs. Additionally, the Society suggests the board look at the data around alternative funding programs or AFPs, as these are the third type of insurance program that change a plan's prescription spending.

Enhanced Patient Assistance Program Reporting
Patient Assistance Programs (PAPs) are vital for people living with MS in affording their medications. People living with MS often face a high deductible and cost-sharing burdens and are responsible for thousands of dollars in out-of-pocket costs—even with health insurance. Because patients are responsible for all their health care costs until their annual deductible is met, prolonging the deductible period by not counting copay assistance funds can put other medical needs financially out of reach. The Society recommends that all forms of third-party financial assistance be applied to a person's annual deductible and out-of-pocket costs/copays.

The National Multiple Sclerosis Society knows that the price of the medication is but one aspect of what makes access to these high-cost prescriptions out of reach for many people with MS and

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other conditions. The Society will continue to look at the entire healthcare system and encourages legislatures and boards like this to continue their work in addressing all aspects of the prescription drug supply chain that get between patients and their medications.

Respectfully,

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Subject: Concerns Regarding the Implementation of Upper Payment Limits (UPLs) and Impacts on Oregonians to HIV Medication Access and Ecosystems

Dear Members of the Prescription Drug Affordability Board,

I am writing to express my concerns regarding the potential implementation of Upper Payment Limits (UPLs) for prescription drugs in Oregon and their potential impact on the HIV care ecosystem, including the Ryan White AIDS Drug Assistance Program (RWP ADAP), which operates through the Oregon Health Authority's CAREAssist program.

The testimony provided at your recent public hearing raises significant concerns about the readiness and efficacy of UPLs as a tool for cost containment. While affordability is a critical issue for many Oregonians, especially those living with chronic conditions like HIV, the risks associated with premature UPL implementation—*without sufficient data and stakeholder alignment*—could inadvertently harm patient care and access.

Our position on this issue has remained consistent over the course of your nearly two-year journey: any implementation of UPLs must be informed by comprehensive data, robust stakeholder engagement, and careful consideration of potential impacts on critical programs like CAREAssist and the broader HIV care ecosystem.

In Brief:

While the intent behind UPLs is estimable, the risks of implementation—particularly for prioritized populations reliant on programs like ADAP— far outweigh potential benefits at this time, given your data. I urge the Board to delay moving forward with UPLs and instead explore alternative strategies that genuinely enhance affordability while preserving access and equity in Oregon's healthcare system.

Key Concerns Regarding UPLs:

1. **Data Inadequacy:**
    a. Multiple speakers highlighted the incomplete and unreliable data on which UPL determinations would be based. This lack of clarity undermines the ability to accurately predict savings or assess the downstream impacts on patient access, especially for life-saving medications like antiretrovirals used in HIV treatment. Instituting a UPL without robust metrics and evaluation frameworks risks destabilizing essential care programs.
2. **Impact on the HIV Ecosystem and ADAP Programs:**
    a. HIV care in Oregon relies heavily on programs like CAREAssist, which leverage 340B pricing and other mechanisms to ensure medication access for low-income individuals. UPLs could disrupt these systems by altering the delicate balance of rebates, cost recovery, and drug availability.
    b. Testimony suggests UPLs might lead to cost-shifting—where savings for payers result in increased out-of-pocket expenses for patients, directly undermining the goals of affordability and equity central to the Ryan White Program. And dialogue over the course of your work also suggests that no public review of the HIV impact has been made available.

c. Additionally, restrictive UPLs may disincentivize pharmacies, clinics, and manufacturers from participating in ADAP-related programs, threatening the continuity of care for people living with HIV.

3. **Litigation Risks and Financial Implications:**
   a. The testimony pointed to ongoing litigation in other states implementing similar policies. Legal challenges not only consume valuable state resources but also create uncertainty for stakeholders, further jeopardizing the ability to sustain essential public health programs.
4. **Utilization Management Concerns:**
   a. UPLs could inadvertently empower Pharmacy Benefit Managers (PBMs) to apply restrictive utilization management practices, including prior authorizations or formulary exclusions, which disproportionately affect vulnerable populations relying on consistent medication access.
   b. Without clear mechanisms to ensure UPLs do not exacerbate these issues, patients may face additional hurdles to receiving timely care.

Recommendations:

1. **Require Publicly Reported Consultation with CAREAssist and OHA:**
   a. Prior to instituting any UPL on HIV medications, the Board should require a thorough consultation with the Oregon Health Authority *and* CAREAssist. This consultation must specifically analyze and publicly report the potential effects of UPLs on RWP ADAP—including implications for 340B savings, program sustainability, and patient access. Before moving forward, engage directly with organizations serving people with HIV, prioritizing CAREAssist; as well as those Federally Qualified Health Centers (FQHCs), 340B HRSA covered entity that are also community-based organizations and community health centers (like Cascade AIDS Project and PRISIM. This engagement should focus on understanding the potential repercussions of UPL implementation on access to medications, program sustainability, and the broader HIV care ecosystem. Consider how UPLs interact with federal programs, including the Ryan White Program and 340B drug pricing, to avoid unintended consequences such as reduced funding for essential HIV care services.
2. **Develop a Rigorous Data Framework:**
   a. Ensure that decisions on UPLs are supported by complete, accurate, and Oregon- specific data. This includes modeling potential impacts on patient costs, program sustainability, and access to medications for chronic conditions like HIV.
3. **Delay UPL Implementation Until Federal Guidance Stabilizes:**
   a. With ongoing federal reforms like the Inflation Reduction Act and state-level litigation on UPLs, Oregon should avoid premature adoption of policies that could destabilize its healthcare system. Instead, prioritize reforms with proven efficacy, such as enhanced PBM regulation and rebate transparency.

Thank you for your attention to this critical matter. I am happy to provide further information or participate in stakeholder discussions to support a more equitable approach to prescription drug affordability.

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November 1, 2024

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Re: Comments On Draft Upper Payment Limit Study

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's (the "Board's") Senate Bill 192 Upper Payment Limit ("UPL") Draft Study ("Draft UPL Study"), recently discussed at its October 16, 2024 meeting.[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. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease.

PhRMA continues to have concerns that any UPL scheme would set arbitrary limits on drug prices and ignore policy options that could lower the cost of medications for people in Oregon.[2] UPLs could restrict patient access to medicines, result in fewer new treatments for patients, and ultimately do not carry any guarantee that savings will be passed on to patients. These concerns are not addressed in the Draft UPL Study nor were they considered at the Board's recent October 16 meeting.[3] As discussed in greater detail below, PhRMA is particularly concerned that the Draft UPL Study oversimplifies the complexities and challenges of a UPL scheme, is based on a number of flawed and unsupported assumptions, and fails to demonstrate that the potential benefits of a UPL would outweigh the risks. PhRMA cautions the Board against moving forward with recommending the Draft UPL Study given the lack of meaningful consideration of these critical issues.[4]

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[1] *See* Draft UPL Study (October 16, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/UPL-draft-report-20241009.pdf.

[2] A proposed UPL scheme would raise concerns under the Supremacy Clause of the U.S. Constitution, among other constitutional concerns. *See, e.g.*, *BIO v. District of Columbia*, 496 F.3d 1362 (2007); *Amgen v. Colo. Prescription Drug Affordability Rev. Bd.*, No. 1:24-cv-00810 (D. Colo. filed Mar. 22, 2024). In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB Statute"). PhRMA also incorporates by reference all prior comment letters to the extent applicable.

[3] As PhRMA has previously explained, we also have concerns regarding the limited timeframe that the Board has afforded for review of and comment on materials in advance of past meetings did not allow a full and adequate opportunity for meaningful participation by stakeholders on the important and complex issues before the Board, including the Draft UPL Study. *See, e.g.,* Letter from PhRMA to Board (Sept. 15, 2024), 2. *See also* Letter from PhRMA to Board (Oct. 12, 2024).

[4] PhRMA also emphasizes that if UPL authority is ultimately enacted by the Oregon Legislature, the Oregon Administrative Procedures Act ("APA") requires that a separate rulemaking be conducted to establish the specific definitions, standards, and processes that will govern any UPL processes. As detailed below, the Draft UPL Study fails to provide adequate specificity that stakeholders would need to understand how a UPL would be operationalized and would not be sufficient to implement a future UPL process. Even if granted the statutory authority to impose a UPL, the Board could not implement a UPL consistent with the requirements of the Oregon APA unless the Board first adopts comprehensive regulations governing each procedural step, factor, and methodology described in the Draft UPL Study through notice-and-comment rulemaking. A UPL process implemented without notice-and-comment rules providing consistent and transparent guidelines to govern it would undermine the ability of the Board to conduct its work in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary," as required under the Oregon APA. *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007). *See also, e.g.*, Letter from PhRMA to Board (Feb. 11, 2023), 2 (providing a more detailed discussion of the Board's obligations under the APA).

I. The Draft UPL Study Oversimplifies the Complexities and Challenges of a UPL Scheme

PhRMA is very concerned that the Draft UPL Study fails to account for the significant complexities and challenges inherent in any UPL implementation process. Developing and implementing a process that would establish and monitor UPLs in the pharmaceutical supply chain in Oregon would require navigating a highly regulated and interdependent system involving a number of stakeholders and would present a wide range of legal, logistical, and market-based challenges. Instead of addressing these issues head-on, the Draft UPL Study provides an overly simplistic picture of how a UPL scheme might operate. In reality, UPL implementation would unavoidably involve challenges that are far more difficult to resolve. The Draft UPL Study drastically oversimplifies the complexity of the pharmaceutical payment and reimbursement system and the operational concerns posed by UPLs across a variety of supply chain entities, and we urge the Board to further revise its draft to directly address those issues.

Since the Board began its activities in 2022, PhRMA has raised significant administrative and operational concerns about the process and work of the Board, including with respect to implementation of UPLs.[5] The Board itself has recognized that these issues need additional time and consideration in order to be fully addressed, as evident by its decision on June 26, 2024 to postpone further affordability reviews until 2025 while it reviews and improves its affordability review criteria and methods.[6] The Board should, in the same manner, continue to work toward developing the Draft UPL Study in order to provide additional, and far more detailed, policy proposals regarding the adoption of a UPL plan before moving forward.

PhRMA highlights the following non-exhaustive examples regarding the Draft UPL Study's oversimplification of the complexities associated with developing and implementing a UPL scheme.

- **Draft UPL Methodologies Lack Sufficient Detail to Meaningfully Evaluate.** While the Draft UPL Study describes several potential methodologies to set a UPL, each presents its own set of challenges and concerns. Taken altogether, the discussion of potential approaches lacks key details on how each of these methods would be implemented and operationalized. The lack of specificity in the report inhibits the ability of stakeholders to meaningfully comment.[7] PhRMA reiterates previously shared concerns as to each specific method based on the limited information that the Board has provided:[8]

    - The "Net Cost" approach suggests setting UPLs based on the average net price after rebates and discounts, but it lacks clarity on which specific net price to reference, making it difficult to evaluate risks and implementation challenges.[9]
    - The "Reference Pricing to Existing Benchmarks" approach raises concerns about using benchmarks like the Maximum Fair Price under the Medicare Drug Price Negotiation Program, which is still in its early stages and won't take effect until 2026. It will take years to understand its effect on patient affordability and access. Additionally, using international drug prices as benchmarks is problematic due to the documented negative impact of government price setting

[5] PhRMA has filed 30 comment letters to date with the Oregon PDAB, detailing, among other things, our ongoing concerns with the Board's affordability review process and procedures and the Draft UPL Study. *See, e.g.*, Letter from PhRMA to Board (Sept. 15, 2024); Letter from PhRMA to Board (May 12, 2024); Letter from PhRMA to Board (Feb. 17, 2024); Letter from PhRMA to Board (Oct. 15, 2023).
[6] Board, June 26, 2024 meeting minutes, at 1, https://dfr.oregon.gov/pdab/Documents/20240626-PDAB-approved-minutes.pdf.
[7] *See* Letter from PhRMA to Board (Sept. 15, 2024), 2.
[8] PhRMA refers the Boards to its September 15 letter to the Board for additional information regarding its concerns with the UPL methods in the Draft UPL Study. *See* Letter from PhRMA to Board (Sept. 15, 2024), 3-6.
[9] Draft UPL Study, at 19.

on patient access in other countries.[10]

- The "Reference Pricing to Therapeutic Alternatives" approach could lead to inappropriate comparisons and pricing based on erroneous assumptions that might not account for patient needs or provider expertise.[11]
- The "Launch Price Indexing" approach lacks detail on how launch prices would be adjusted for inflation.[12]
- The "Percentage off of WAC" approach doesn't account for the rebates, discounts, and other price concessions already provided to the government, PBMs, and health insurers by drug manufacturers, potentially leading to arbitrarily set UPLs that could harm patient access.[13]
- The "Payer Return on Investment" approach is also concerning as it relies on pharmacoeconomic research and Cost Effectiveness Analyses which may use discriminatory metrics that should be avoided due to their potential to entrench health inequities.[14]
- The "Budget Impact-Based" approach is minimally detailed, making it hard to evaluate how the Board would determine the "given budget" that the UPL would be measured against, and how the Board would determine what percentage or threshold of the budget that the expenditure on a particular drug would be capped at.[15]

- **The Draft's Discussion Oversimplifies UPL Implementation and Operational Requirements.** The Draft UPL Study provides only a high level overview of potential approaches to implementing a UPL, which drastically oversimplifies the complexity and interconnected nature of the pharmaceutical supply chain.[16] For example, the Draft UPL Study notes that a UPL "will work best if the UPL applies statewide—to all purchases, payments, billings, and reimbursements of public and private purchasers, payers, and patients," but contradicts itself in the appendices to the Draft UPL Study by acknowledging that "[s]tates cannot require that Medicare B, nor C and D plans reimburse pharmacies and providers at the UPL" due to federal Medicare preemption.

  The process of establishing, implementing, and monitoring a UPL would carry significant administrative and operational burdens and concerns, which the Draft UPL Study fails to address. Results of the Board-directed stakeholder feedback report highlighted these concerns were present throughout the entire supply-chain. For instance, The August meeting materials highlight "A number of participants also expressed concerns regarding administrative burden, stating that adding a UPL to existing complex processes, in a highly regulated environment, would increase the level of effort required to serve patients, perform routine business operations, and manage contracts."[17] Additionally, those same meeting materials describe that "participants found it challenging to discuss UPL methodologies and frequently requested information regarding how a UPL would be developed and implemented."[18] The Board should not minimize the complexity of these issues and should recognize in the Draft UPL Study that they add significant complexity to UPL processes.

[10] *Id.*
[11] *Id.* at 20.
[12] *Id.*
[13] *Id.* at 20-21.
[14] *Id.* at 21.
[15] *Id.*
[16] *See, e.g.*, Draft UPL Study at 18, 55, 58.
[17] Board, August 21, 2024 meeting materials, at 27.
[18] *Id.*

The study similarly downplays the potential interplay between a UPL and the 340B program as well as broader market effects. The Oregon Primary Care Association testified in the Board's July meeting that a UPL would be "just not workable given the overlay of the federal [340B] program and how it works and was designed to work with federally qualified health centers and other covered entities."[19] The 340B program itself is already incredibly complex, and both the Government Accountability Office and the Health and Human Services Office of Inspector General have identified significant issues with diversion of 340B prescriptions to ineligible individuals and duplicate Medicaid and 340B discounts paid on the same unit of medicine despite statutory prohibitions.[20] Recent research as also found the 340B program increases costs for employer-sponsored health plans,[21] which can lower state income tax collections and increase costs for state and local government health plans.[22] It is crucial for the Board to be aware of these complexities and the potential for misdirection of 340B funds and further abuse.

- **The Board Cannot Reasonably Pursue Multiple Simultaneous UPL Approaches**. The Draft UPL Study contemplates that the Board "may want to specify several different approaches it would use as appropriate but maintain flexibility to use additional approaches when needed."[23] But the Draft UPL Study does not explain how could reasonably develop, implement, and select between multiple different approaches to UPL-setting, nor does that idea appear to be consistent with the complexity of developing and implementing even a single UPL-setting method. Although four states have enacted laws that would allow them to set a UPL for certain medicines, no state has implemented a UPL to date.[24]

  Further, the assumptions that the report makes about various methods of implementing UPL approaches underscore the lack of understanding of the complexity and interconnected nature of the pharmaceutical supply chain. For example, wholesalers and plans often have contracts that span entire regions, making restricting sales within a state operationally burdensome. In the pharmaceutical supply chain, retail drugs typically move from manufacturers to wholesalers (and to dispensers) throughout the United States based on WAC. Utilizing a different metric (for instance, a UPL) solely for Oregon would present significant complexities that the Board has not addressed. PhRMA encourages the board to seek more detailed input from supply chain stakeholders, including wholesalers, to better understand the complexity of the pharmaceutical supply chain and the potential impact of changes to business operations.[25]

- **Challenges Faced by Other States with UPL Authority.** While the Draft UPL Study references others states that have enacted laws that would allow for the setting of UPLs for certain medicines, it overlooks the challenges those states have faced in implementing their UPL regimes.[26] The policies for evaluating

[19] Board, July 24, 2024 meeting, testimony of Marty Carty, Oregon Primary Care Association, https://youtu.be/VntX-UHodJ0?si=0OkEM6_E3qQssuMg&t=7993.
[20] Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements. December 2020.; OIG. State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. June 2016; GAO. 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. January 2020.
[21] IQVIA. The Cost of the 340B Program Part 1: Self-insured Employers. 2024.
[22] North Carolina State Treasurer. Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program. May 2024.
[23] Board, August 21, 2024 meeting materials, at 39.
[24] *See* Letter from PhRMA to Board, June 28, 2024, at 2.
[25] In addition, PhRMA is concerned that attempting to implement multiple UPL-setting approaches would cause the Board to improperly apply different methodologies across different drugs, resulting in arbitrary and capricious decision-making by the Board. Courts have consistently held that agency actions are arbitrary and capricious where they treat similarly situated entities or products differently without providing a reasonable justification for such differential treatment, or where they exhibit unexplained inconsistencies with the agency's prior decisions. *See, e.g.*, *Melody Music, Inc. v. FCC*, 345 F.2d 730, 733 (D.C. Cir. 1965).
[26] Draft UPL Study at 11-14.

affordability and establishing UPLs in these states have consistently lacked clear, specific, and meaningful standards.[27] For example, the policies incorporate extensive lists and categories of information and data sources that they must (or may) consider as part of the multi-step affordability review and UPL-setting process, but have been devoid of specific rules that explain *how* the implementing agencies would utilize such information in a consistent and balanced way to make informed assessments about questions of affordability and the need for a UPL.

- **The Draft UPL Study Does Not Address Diversion Concerns.** The Draft UPL Study downplays the significant diversion risks that implementation of a UPL would pose. For example, there is no mechanism described in the Draft UPL Study to limit access to UPL-priced drugs to entities that are statutorily authorized recipients. The Draft UPL Study references the Drug Supply Chain Security Act ("DSCSA"), suggesting that the DSCSA could be used to avoid diversion under a UPL framework.[28] Despite passage in 2013, the DSCSA has not yet been fully implemented. Furthermore, this reliance on the DSCA is misplaced as it incorrectly presumes that pricing information is included in the data tracked for drugs under the DSCSA. While the DSCSA is designed to track the distribution of pharmaceuticals to help enhance drug distribution security, it does not require the tracking and reporting of pricing data that would be needed to monitor for diversion under a UPL framework.[29] Relying on the DSCSA as a safeguard against diversion is impractical. PhRMA stresses that the Board should not underestimate the challenges associated with monitoring and policing diversion.

- **The Board Has Not Considered the Role of Manufacturer Rebates and PBMs.** The Draft UPL Study emphasizes that, "[a]ny conversation about the drug supply chain must recognize the influence of manufacturer-paid rebates on the distribution of drugs."[30] This characterization ignores the fact that negotiation of rebates between manufacturers and payers and their PBMs is a two-way agreement subject to market-driven forces and the relative leverage between the negotiating parties.

  As discussed at length in previous letters, manufacturers provide significant discounts, rebates, and other price concessions to PBMs and health plans, but many patients do not benefit directly from these discounts due to the refusal by insurance companies and their PBMs to pass these savings through to patients at the pharmacy counter. Concern about the influence of PBMs on the supply chain have been raised by Oregon,[31] Congress, and the Federal Trade Commission.[32] In 2023, Oregon's Secretary of State performed an audit of PBM practices in the state, finding that "there is growing public interest in assessing the role, value of, and significant power and influence held by third-party organizations known as pharmacy benefit managers."[33] The failure of the Draft UPL Study to account for these factors in its discussion of the supply chain demonstrates the lack of complexity in its analysis of how a UPL may impact them.

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[27] *See, e.g.*, Letter from PhRMA to Board (June 23, 2023); Letter from PhRMA to Washington PDAB (Apr. 11, 2024); Letter from PhRMA to Maryland PDAB (June 30, 2023); Letters from PhRMA to Colorado PDAB (Nov. 14, 2022) (regarding draft affordability review and UPL regulations).

[28] Draft UPL Study at 22.

[29] *See* Food and Drug Administration, DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry, at 2 (September 2023), https://www.fda.gov/media/171796/download.

[30] Draft UPL Study at 8.

[31] Oregon Health Authority, *Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies* (Aug. 2023).

[32] Press Release, Federal Trade Commission, FTC Launches Inquiry into Prescription Drug Middlemen Industry (June 7, 2022); Press Release, Federal Trade Commission, FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023),

[33] Oregon Health Authority, *Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies* (Aug. 2023).

II. The Draft UPL Study Relies on Flawed Assumptions Instead of Facts

As described below, the Draft UPL Study relies on a number of flawed assumptions, drawing broad conclusions without providing sufficient facts to support them. Instead, the report incorporates, without qualification, a limited number of sources, many of which also fail to cite research or other information that supports their assertions. PhRMA highlights the following non-exhaustive examples regarding the Draft UPL Study's unsupported assumptions regarding implementation of a UPL scheme:

- **Unfounded Assumptions of Supply Chain Behavior:** the Draft UPL Study is predicated upon assumptions regarding the behavior of various entities in the supply chain, contributing to the oversimplified view that a UPL would work neatly under the existing system.[34] For example, the Draft UPL Study notes that health plans and PBMs may voluntarily change key aspects of their business model based on agreement with the Board.[35] As stated in one of the appendices "[a] board should have *the agreement* of as many commercial and employer health plans as possible to modify their formularies to reflect the lower product cost (the UPL) pharmacies and other providers will charge. Plans should be *asked to reconsider* utilization tools applied to the drug product if those policies address cost rather than clinical issues." However, none of these changes to business models are required or incentivized and in fact recent research suggests health plans would do the exact opposite of what the Draft UPL study suggests. According to a payer expert that was surveyed about the Colorado PDAB, "Payers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences," and in addition "utilization management will undoubtedly go up with UPLs [upper payment limits], whether for the drugs subjected to them or for competition."[36]

- **Assumptions Not Supported by Research:** in discussing the benefits of statewide UPLs, the report states that "UPLs should improve market function for prescription products that have a UPL."[37] But neither the appendix document nor the Draft UPL Study offers any additional background on the basis for this assumption, or for the other assumptions in the report regarding various aspects of the market, including patient access.[38] PhRMA notes that the report frequently relies on sources that are not peer-reviewed or validated. For example, much of the discussion of the draft UPL Approaches appears to reflect input from a single source that may provide a biased basis of information used to develop the UPL Study.

- **Insufficient Analysis of Available Data Sources:** The draft UPL Study notes in multiples places that granular, claims-level, or pharmacy-specific data may be required, but not readily available.[39] However, the study does not identify the specific sources from which the Board would acquire the data, whether they are available to the state, or what additional restrictions or limitations may apply to their use.[40] For example, the description of the "Reference Pricing to Therapeutic Alternatives" approach fails to specify

[34] *See, e.g.*, Draft UPL Study at 22 (explaining that "a statewide UPL is generally intended to be self-enforcing" because supply chain entities "have no incentive" not to enforce a UPL, without acknowledging the complexities of the various incentives facing such entities).
[35] *Id.* at 49.
[36] Partnership to Fight Chronic Disease, "Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies And Benefit Design But Won't Reduce Patient Costs," March 2024.
[37] *See, e.g.*, Draft UPL Study at 28; Horvath Health Policy, Upper Payment Limits at 57 (2024).
[38] *Id.* at 57 (discussing changes that could or 'should' happen in the market, without sources to support these claims.).
[39] *See, e.g.*, Draft UPL Study at 29, 30.
[40] *Id.* at 19-22 (discussing possible data sources to "[c]onsider" using, while also noting drawbacks to such data).

how the Board would ascertain the prices of drugs that it determines can be used in place of the selected drug, despite the Board's previous difficulties in assessing pricing of therapeutic alternatives.[41]

The Board should not move forward with its Draft UPL Study without first analyzing what specific data would be needed and whether it may be available to the Board. PhRMA previously expressed similar concerns regarding the lack of specificity in data sources that the Board intended to use for affordability reviews.[42] The Board did not address that issue, and instead conducted several affordability reviews without a significant portion of the data that it was required to review under its statute and regulations.[43] The lack of data was one of the reasons that Board members voted to suspend affordability reviews in June 2024.[44] PhRMA once again asks the Board to clarify the exact sources of information that would be used for each UPL approach, and how the Board would verify the accuracy of such data.[45]

- **Data Quality Concerns:** the Draft UPL Study also fails to provide adequate processes and safeguards to verify the reliability of data used to support a potential UPL. The UPL-setting process, similar to the Board's affordability reviews, would be dependent on the accuracy and completeness of the information being relied upon in the Board's decision-making. Information bearing on the criteria for evaluating affordability or setting a UPL is likely to be drawn from a variety of sources, including reports from insurers, manufacturer data, and various other third-party sources. Certain sources of information may be unreliable or offer only a selective portion of the full picture relevant to the Board's selection of drugs for affordability review.

- **Inadequate Consideration of Resources Required for Implementation:** the Draft UPL Study does not meaningfully address or analyze the resources required to implement a UPL. While the Draft UPL Study characterizes UPLs as "self-enforcing," it nonetheless contains a lengthy list of regulatory authorities and investments by the state that would be necessary.[46] And while it acknowledges the significant resources that would be needed, it is limited to general statements without cost projections; further,

[41] *See* Ozempic Affordability Review updated (May 15, 2024), 12, https://dfr.oregon.gov/pdab/Documents/20240515-PDAB-document-package.pdf#page=5 (explaining that estimated net price for therapeutic alternatives "is not included due to lack of information in discounts, rebates, and other price adjustments"). The Draft UPL Study also discusses the possibility of using "[c]ommercial products" to "assist with determining the estimated impact and availability of rebates in the non-Medicaid space" but provides no further information regarding such products or the data underlying these estimations. Draft UPL Study at 22.

[42] Letter from PhRMA to Board (Oct. 15, 2023), 1-3.

[43] *See, e.g.*, Humulin R U-500 KwikPen Affordability Review - version 2, at 9-10 (Jan. 26, 2024), https://dfr.oregon.gov/pdab/Documents/Affordability-Review-Humulin-R-U-500-v2.pdf (acknowledging drawbacks of using package wholesale acquisition cost (WAC) as an indication of historic price trends for the drug and noting that "[n]o additional data or information was found or provided to reflect the relative financial effects of the prescription drug on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment" and "[n]o additional data or information was found or provided to quantify the total cost of the disease and the drug price offset"); Ozempic Affordability Review updated, at 12 (May 15, 2024), https://dfr.oregon.gov/pdab/Documents/20240515-PDAB-document-package.pdf#page=5 (explaining that estimated net price for therapeutic alternatives "is not included due to lack of information in discounts, rebates, and other price adjustments"); Trulicity Affordability Review updated, at 9 (May 15, 2024), https://dfr.oregon.gov/pdab/Documents/20240515-PDAB-document-package.pdf#page=42 (same). *See also* ORS § 646A.694(1)(f), (1)(g), (1)(j); OAR 925-200-0020(1)(j), (2)(i)(A), (2)(i)(B).

[44] Board member Robert Judge stating at the June 26th meeting "There are huge gaps … in the data that we have to make an informed decision on an affordability review that's consistent, and has consistent criteria for making a determination." *See* https://youtu.be/9z2VkDiR_XA?si=_W7reQ5nXVkmYc_P&t=926.

[45] PhRMA has consistently stressed in our comments that, under the Board's existing authority, it has not adequately addressed how it will maintain confidentiality of the materials it receives as part of its affordability reviews. Letter from PhRMA to Board (May 14, 2023), 5; Letter from PhRMA to Board (Apr. 16, 2023), 8; Letter from PhRMA to Board (June 20, 2022), 3-4. These concerns would be heightened if the Board were also given authority to establish UPLs, particularly if, as part of the UPL process, the Board sought to obtain sensitive financial or commercial information from additional stakeholders.

[46] Draft UPL Study at 22-23

the Draft UPL Study states that it would be premature to complete an analysis of the costs to implement a UPL.[47] As the Board is aware, it is required by SB 192 to provide the Oregon Legislature with an analysis of "the resources needed by the board to implement the plan."[48] The limited discussion of the resources needed to implement a UPL in Oregon is inconsistent with the Board's statutory direction. PhRMA asks the Board to revise its Draft UPL Study to provide a substantive analysis of the resources that would be needed to support UPL-setting activities.

III. The Draft UPL Study Fails to Demonstrate that Potential Savings from a UPL Outweigh the Substantial Risks

The Draft UPL Study fails to demonstrate how a UPL will generate savings, nor does it show that any savings would outweigh the potential risks associated with establishing and implementing a UPL in the state. This failure is the result of the many process concerns discussed above and underscores the lack of consideration given to numerous aspects of adopting a UPL. PhRMA urges the Board to revisit its draft analysis in order to objectively evaluate both the potential risks and benefits associated with UPL-setting.

PhRMA highlights the following non-exhaustive examples regarding the Draft UPL Study's failure to address the various considerations required to objectively and accurately assess the value of a UPL scheme.

- **Lack of Cost Savings for Patients:** PhRMA is concerned that the Draft UPL Study fails to demonstrate how a UPL would result in cost savings or otherwise benefit patients in Oregon. The UPL process described in the Draft UPL Study would focus on capping the prices set by the biopharmaceutical manufacturers and ignore the function of other stakeholders in determining what patients ultimately pay for medicines, including insurers, PBMs, wholesalers, and the government. The important role that these entities play in determining drug coverage and patient out-of-pocket costs seems to be overlooked by the Draft UPL Study. There is also no mechanism described in the Draft UPL Study to require that savings generated by the various UPL approaches that the Draft UPL Study would ultimately flow to Oregon patients. For example, the report acknowledges analyses suggesting that implementing a UPL could introduce costs or otherwise fail to generate savings,[49] but does not engage with these possibilities and largely ignores consideration of whether imposing UPLs would result in any patient benefits.[50] The fiscal modeling submitted by the Oregon Health Authority (OHA) in September's meeting materials projected that 90% of state employees would see no change in their prescription cost sharing with a UPL.[51] Furthermore, for the state Medicaid program, OHA's fiscal modeling found that there

[47] Draft UPL Study at 28.
[48] ORS 646A.685(1)(b).
[49] Draft UPL Study at 26-27 (discussing PEBB/OEBB analysis and modeling exercise undertaken by the Oregon Health Authority ["OHA"]) ("Potential savings and costs are indeterminate at this time … the most likely outcomes range from a cost savings of $18.7 million (price reduction exceeds existing rebates) to a combined increase of $12.1 million in plan spend (where the modest price reduction is less than existing rebates).")
[50] *See* Myers & Stauffer, Constituent Group Engagement Report Draft (Aug. 14, 2024), https://dfr.oregon.gov/pdab/Documents/OR-PDAB-UPL-Report-Draft-20240821.pdf.
[51] Board, "PDAB Upper Payment Limit (UPL) Analysis: Oregon Educators Benefit Board (OEBB) and the Public Employees' Benefit Board (PEBB) / Medicaid FFS and CCO," included in the Meeting Materials for the PDAB's Oct. 2, 2024 meeting, at 35-36. PhRMA analysis based on the model's statements that: "enrollment is based on average 2024 enrollment of 141,065 and 136,536 members for PEBB and OEBB respectively"; and that "For PEBB, future member cost share is set equal to current member cost share per unit … because all plans have a copay structure for prescription drug claims." OHA modeled 80% of OEBB member cost share would not change and "roughly 20 percent of OEBB members have a prescription drug plan based around coinsurance rather than copay. For those members, their cost will decrease with the cost of the drug." Taken together, the modeling assumes that 90% of state employees will not see changes to their member cost sharing.

would most likely be no reduction in costs to the state.[52]

- **Minimization of Stakeholder Concerns:** the Draft UPL Study consistently minimizes the areas of concern raised by stakeholders in the supply chain. While those concerns and limitations are acknowledged in the report,[53] the report does not discuss or respond to the concerns raised in the constituent listening sessions, and it underplays the risk of unintended consequences to the healthcare system.[54] For example, the report notes patient impact concerns centering on potential manufacturer responses as well as responses by PBMs or payers that would shift utilization to non-UPL drugs through formulary and benefit design, but the report never meaningfully addresses these concerns. Any cogent analysis of establishing a UPL scheme must confront such concerns and how they would have to be addressed.

  Additionally, the Draft UPL Study fails to address the impact that a UPL would have on pharmaceutical innovation. Implementing price controls would diminish the incentives for biopharmaceutical manufacturers to invest in and introduce new medicines and could limit the prescription drug options available to Oregon residents. There are a range of policy alternatives to UPLs that more directly and effectively address issues of affordability and access, while also better preserving incentives for innovation and investment in research and development of new and potentially transformative medicines.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the Draft UPL Study, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy
Sacramento, CA

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[52] *Id.* at 34 ("For both Fee for Service (FFS) and Coordinated Care Organizations (CCO), the modeling assumed no changes to existing rebates. Both assumptions mean that actually attainable savings will be lower. Additionally, due to state and federal budget mechanics, OHA advised that reductions in cost from implementing a UPL would more likely be reinvested in other OHP services rather than directly reducing state costs.").
[53] Draft UPL Study at 16.
[54] Myers & Stauffer, Constituent Group Engagement Report Draft (Aug. 14, 2024).

Johnson & Johnson

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Via Electronic Submission

November 12, 2024

Shelley Bailey
Board Chair
Oregon Prescription Drug Affordability Board
pdab@dcbs.oregon.gov

Dear Board Chair Bailey:

Johnson & Johnson writes to express concerns regarding the Report on Pharmacy Benefit Manager (PBM) Drug Price Transparency as presented to the Oregon Prescription Drug Affordability Board (the Board or OR PDAB) during the October 16, 2024 Board meeting. J&J respectfully submits a copy of the "2023 Johnson & Johnson Innovative Medicine U.S. Pricing Transparency Report" (the J&J Transparency Report). We urge the Board to **1) recommend policy solutions that would further increase transparency around practices of PBMs and their affiliated entities that increase costs and limit access for patients; and 2) recommend patient-centered solutions, such as requiring that PBM rebates and discounts be directly shared with patients at the pharmacy counter as an alternative to upper payment limits (UPLs).**[1]

During the October 16, 2024 meeting, OR PDAB staff presented information from the Drug Price Transparency Program (DPT) Report on data collected from PBMs. The DPT Report noted that 18 of 59 PBMs received over $287M in rebates and payments from manufacturers[2], of which they passed approximately $283 million to insurers and only $2.2 million (1 percent) to plan enrollees. The remaining 41 PBMs claimed they were exempt from reporting.

As reflected in the J&J Transparency Report, rebates, discounts, and fees have been increasing, net prices have been decreasing, and yet, patient out-of-pocket costs have continued to rise. This begs the question, where is this money going? We would like to highlight the following points in advance of the November 20th Board meeting:

- **Johnson & Johnson's rebates, discounts, and fees have risen significantly from 2016-2023, particularly for private insurers and PBMs, and our net prices have declined.** Between 2016 and 2023, rebates, discounts and fees to commercial insurers have grown eight times from $1.7B (2016) to $13.4B (2023). Nearly one-third of our discounts, rebates, and fees go to health insurers and PBMs. [3]

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[1] Johnson & Johnson, *2023 Johnson & Johnson Innovative Medicine U.S. Pricing Transparency Report*, https://transparencyreport.janssen.com/transparency-report-2023. Last visited October 30, 2024 [J&J 2023 Transparency Report].
[2] Oregon Prescription Drug Affordability Board, Agenda (Oct. 16, 2024), https://dfr.oregon.gov/pdab/Documents/20241016-PDAB-document-package.pdf.
[3] J&J 2023 Transparency Report, *supra* note 1.

- **Patients are not directly benefitting from lower net prices.** J&J's net prices have declined by nearly 20% over the past seven years, and yet, patients still face multiple access challenges based on their plans' benefit design.[4]

J&J urges the Board to take action that would further increase transparency around the practices of PBMs and their affiliated entities that increase costs and limit access for patients. For example, the DPT Report does not capture any vertical integration between the 18 PBMs and the insurers that received approximately $283 million in rebates. As the Federal Trade Commission noted in its recent Interim Staff Report, "[v]ertically integrated PBMs may have the ability and incentive to prefer their own affiliated businesses, which in turn can disadvantage unaffiliated pharmacies and increase prescription drug costs."[5] The DPT Report also does not appear to capture the administrative fees that PBMs retain. Yet, a recent Nephron Research report showed that PBMs are moving toward a model of collecting opaque fees from manufacturers, pharmacies, health insurers, and employers to avoid policymakers' efforts to enhance transparency.[6] Likewise, the OR PDAB Report does not reflect profits that PBMs capture through spread pricing, in which PBMs overcharge payers, underpay pharmacies, and retain the difference—a practice that PBMs will be required to report on in Oregon beginning in April 2025.[7]

Finally, while the DPT Report shows that PBMs pass 1 percent of their rebates on to patients, it does not capture how much PBMs are collecting from patients in turn. Research has shown that, on average, patients enrolled in plans with three or more tiers pay between 25 percent and 38 percent out of pocket for their prescription drugs.[8] Additionally, when in the plan's deductible phase, a patient pays 100 percent of prescription drug costs until the deductible is met. Conversely, during that time, PBMs pay zero percent of the prescription drug cost but still collect rebates, and in some cases, copay assistance, from manufacturers.

Although J&J acknowledges these challenges, we are steadfast in our commitment to supporting affordable access to our innovative therapies and lowering patient costs. We support patient-centered reforms that would:[9]

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[4] J&J 2023 Transparency Report, *supra* note 1.

[5] Federal Trade Commission, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, Interim Staff Report (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[6] Stephen J. Ubl, "New Analysis Shows PBMs Use Fees as a Profit Center," PhRMA (Sept. 18. 2023), https://phrma.org/Blog/New-analysis-shows-PBMs-use-fees-as-a-profit-center.

[7] OR HB 4149 (2024).

[8] KFF, *2023 Employer Health Benefit Survey* (Oct. 18, 2023), https://www.kff.org/report-section/ehbs-2023-section-9-prescription-drug-benefits/#:~:text=%5BFigure%209.6%5D.-,Among%20covered%20workers%20in%20plans%20with%20three%20or%20more%20tiers,tier%20drugs%20%5BFigure%209.6%5D.

[9] Janssen, The 2021 Janssen U.S. Pricing Transparency Report, https://transparencyreport.janssen.com/_document/the-2021-janssen-u-s-transparency-report?id=00000186-0e8d-da28-a1fe-9edd83aa0001 (last visited Nov. 7, 2024).

- **Require that PBM rebates and discounts be directly shared with patients at the pharmacy counter.**

- **Examine the use of utilization management tools (e.g., formulary exclusion lists, prior authorization, step therapy, and nonmedical switching) and evaluate how best to regulate them in the interest of patient access and reducing out-of-pocket costs.**

- **Prohibit diversion of patient cost-sharing assistance (i.e., copay accumulator programs and maximizer programs) to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.**

J&J asks the Board to take these points into consideration as you move forward with your recommendations on PBM transparency. To that end, we thank Chair Bailey for her recommendation to consider passthrough rebates as an alternative to UPLs. Requiring that PBM rebates and discounts be directly shared with patients at the pharmacy counter is a more patient-centered option.

As one of the nation's leading healthcare companies, J&J has a responsibility to engage with stakeholders in constructive dialogue to address these gaps in affordability, access and health equity as well as protect our nation's leading role in the global innovation ecosystem.

We know that patients are counting on us to develop and bring accessible medicines to market. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives.

Sincerely,

Blasine Penkowski
Chief Strategic Customer Officer
Johnson & Johnson Health Care Systems Inc.

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VIA Electronic Delivery

November 17, 2024

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Re: Prescription Drug Affordability Board Upper Payment Limit Board Draft Report-DRAFT

Dear Oregon Prescription Drug Affordability Board (PDAB)

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Oregon Prescription Drug Affordability Board's (PDAB or Board)'s Draft Prescription Drug Affordability Board Upper Payment Limit Report (Draft Report).

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.

General Comments

BIO and our members have long argued that the underlying structure and utilization of an upper payment limit (UPL) is flawed and should not be enacted. UPLs will harm patient access to lifesaving medication while failing to protect patients from harmful plan designs, and other restrictive coverage strategies and barriers imposed by plans and PBMs. It is evident that setting UPLs without consideration for the drug coverage ecosystem and supply chain could have profound negative repercussions for patient access. BIO urges the Board to fully consider the impact of UPLs on patient access and to carefully examine additional feasibility concerns before the Board proceeds with any additional exploration of the use of an UPL in Oregon (OR). It is important that the Draft Report underscores the need to better understand the drivers of affordability challenges before being fixated on the single proposed solution of an UPL. We continue to encourage the Board to consider other affordability solutions, such as accumulator adjustment program bans and rebate models to ensure that rebates are passed through to patients, as alternatives to an UPL.

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

Executive Summary (p.4)

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BIO appreciates that the Draft Report highlights various stakeholders' concerns with UPL implementation and acknowledges that the majority of respondents voiced that it is unlikely that a UPL would result in cost-savings. The Draft Report notably also acknowledged the administrative and operational hurdles with developing a UPL. Despite this, the Draft Report notes that the Board still plans to continue with a "structured, phased approach" to develop OR's UPL framework. BIO urges the Board to not move forward with recommending UPL authority in light of the significant concerns raised by stakeholders.

BIO is also concerned that the Draft Report provides a biased account of how other states have navigated challenges related to UPL methodologies, which is informed by the same consultants that support the work of the PDABs in other states. This account does not adequately represent the fact that states are not far enough along in the UPL development process to fully understand the impact of any of the methodologies or strategies referenced in the Draft Report. It is critical that the Draft Report avoids making premature assumptions about UPLs when in fact the broader and longer-term impacts have yet to be realized.

Finally, it is problematic that the Draft Report fails to include a conflict-of-interest disclosure, particularly given that major sections of the Draft Report were not written by the Board itself. It is critical that the Board is informed by impartial and evidence-based analysis, and at a minimum, all parties that informed the Draft Report should submit a conflict-of-interest disclosure to ensure a fair, transparent, and accountable policy process.

Transaction Relationships in the Supply Chain (p.13)

The Draft Report makes biased and inaccurate claims that drug manufacturers "wield significant influence over drug costs and affordability, as they are responsible for setting the initial list price." This claim significantly oversimplifies market and supply chain dynamics and misattributes blame to manufacturers, leading to a biased narrative that blatantly ignores the multifaceted drug ecosystem. This misattributed blame fails to consider that manufacturers do not have control over net cost, patient OOP cost, and utilization, and the ability for a manufacturer to validate this information is very limited. Instead, the true drivers that impact patient OOP cost are determined by the patient's health plan design. Pharmaceutical benefit managers (PBMs) and plan sponsors have continued to shift more cost-sharing responsibility to patients, causing patients to struggle to afford and adhere to their medications. Instead of recognizing the drivers of patient OOP costs, the Draft Report claims that "payers play a crucial role in controlling affordability and ensuring access to medications by actively managing drug coverage." It is deeply troubling that this language is clearly skewed in favor of certain parties within the supply chain over others. It is even more concerning that the Draft Report ignores the reality of patients who face barriers to access and are charged significant OOP costs from their health plans. BIO urges the drafters to strike the language "wield significant influence over drug costs and affordability" and instead consider a holistic and balanced account of factors such as plan benefit design, copay structures, and other factors that impact patient OOP spending.

The Draft Report also claims that "more than 98% of rebates are passed through to payers." This figure is significantly misleading and fails to consider that the savings often do not get passed down to patients. Further reforms into PBM transparency are needed to fully

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understand PBM practices, including price-shifting tactics that negatively impact patient access and affordability. BIO urges the drafters to remove this figure from the Draft Report.

Plan for Establishing an Oregon-Specific UPL (p.18)

While the Draft Report states that "the board has engaged in an extensive and intensive process… to assess the feasibility of establishing a UPL in Oregon," the Draft Report fails to mention any research that was specifically conducted to address concerns raised by the many stakeholders regarding patient access and other considerations. The Draft Report itself admits that it has not been able to access data to properly analyze the impact of a UPL, stating that "legislative and regulatory support will be required to appropriately gain access to the data needed to fully evaluate the impact on supply chain" (p. 31). Accordingly, the Board should fully consider stakeholder concerns before any additional examination of the use of an UPL in Oregon.

UPL Potential Methodologies (p.19 & Throughout Horvath UPL Report)

BIO is concerned that the proposed models prematurely suggest that they will support the PDAB's missions of "improving affordability." As stated above, the Board does not have sufficient information to thoroughly understand the implications of the UPL, including the impacts on stakeholders in the supply chain and the effects on patient access. It is extremely misleading for the Draft Report to provide support for these methodologies without fully vetting the impact of the models and assessing the impact on patient access, provider reimbursement, and other impacts on the supply chain. Given these significant unknowns, BIO urges the drafters to remove all language in the UPL Approach chart that suggests that the method supports PDAB's mission to improve affordability.

It is also critical that the drafters remove any assertion that any potential UPL methodology will reduce costs for payers, reduce OOP costs for patients, or improve access for consumers. These claims are baseless and unsupported; there is no assurance that any potential savings will be passed on to lower OOP for patients. Instead, it is evident that any potential UPL methodology could disrupt patient access, as revealed by the numerous concerns expressed in the PDAB's own stakeholder interviews and focus groups.

BIO has concerns with each of the potential methodologies suggested throughout the Draft Report, outlined below.

> *Net Cost*: It is deeply problematic that the Draft Report is considering using information about a manufacturer's estimated or actual net price, which is highly confidential and/or trade secret information. As the Draft Report states, the methodology would "increase transparency by revealing the true cost of drugs after rebates." It is important that the Draft Report clearly specifies that it will not disclose any confidential, proprietary, and trade secret information. Further, the assertion that "leveraging publicly available ASP data..(can) ensure that patient OOP costs are based on reimbursement rates that reflect net price" is a vast oversimplification and not indicative of the current reality of many patients, where OOP costs do not reflect the rebates/discounts that health plans or PBMs receive. Finally, the methodology does not reference how it will impact Medicaid Best Price or other statutory amounts,

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which is critical if the Draft Report intends to recommend that the UPL be set below the current average net price.

Reference Pricing to Existing Benchmarks: The Draft Report's language in this section attempts to oversimplify a myriad of existing benchmarks into a single specific category, which requires significant nuance. Each benchmark that is referenced must be independently examined, as they each have very distinct specific circumstances and requirements. For instance, an attempt to use international reference pricing as a benchmark divorces a product's 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. Further, most countries outside the United States use discriminatory measures of value, such as QALY analysis, to assist in price setting. 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.[1] It is evident that the language in this section ignores and oversimplifies all of these considerations.

Reference Pricing to Therapeutic Alternatives: BIO opposes the use of this methodology, which demonstrates a lack of perceived value between therapeutic options, a lack of consideration for the complexity of dosing, and a lack of understanding for pricing complexities in the attempt of making prices equal across competitor sets. The lowest net price is influenced by many factors and using this methodology may actually result in Best Price implications for products under review if competitive net price is below the product under review. Given these complications, it is unlikely that states will be able to effectively operationalize this methodology.

Launch Price Indexing: BIO opposes the launch price-based methodology, which 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 provides an inaccurate interpretation of pricing data. 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. It is notable that this methodology could also have implications on Medicaid Best Price when utilized in the commercial

[1] 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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market.

Value: While BIO appreciates the switch from "payer return on investment" to "value," given that payers do not pass down savings to patients, it is concerning that the Draft Report chooses to reference quality-adjusted life years (QALYs) as a potential tool for deriving a value-based UPL. QALYs inherently devalue how some individuals rate quality of life utility measures, and consequently are discriminatory. Equal Value of Life Years Gained (evLYG) are similarly problematic as they do not fully capture quality of life improvements. Instead, value should be considered for distinct patient populations and differential disease states, informed by the patient experience, and metrics should be viewed holistically and prioritize patient-centered endpoints. BIO encourages the Board to further examine additional strategies that are aligned with a drug's value.

Budget Impact-Based: BIO opposes the use of budget impact-based UPLs, which 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. In addition, the Draft Report does not provide any information on how the threshold will be determined or set to ensure that patients' needs are met. It is problematic that the methodology could be determined by arbitrary cut points and potentially lead to the rationing of drug utilization.

Path to Net Pricing for Informed Decision Making (p.27)

In its attempt to estimate net pricing, the Draft Report ignores the significant complexity of the pharmaceutical supply chain and the sheer impossibility of collecting all the price concessions given to all entities that purchase or cover a given drug across the supply chain. Attempting to gather data on net pricing 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). While the vendors listed may be able to collect upfront insights, there would still be significant data gaps that could not be resolved.

Analysis of How UPL Would Be Enforced (p.29)

In its explanation of UPL enforcement, the Draft Report oversimplifies supply chain dynamics and makes premature assumptions regarding the impact of a UPL on stakeholders in the supply chain. As stated above, there has not been any concrete data or outcomes demonstrating the impacts of a UPL on the market, given that no state has implemented one yet. In addition, the Draft Report prematurely de-emphasizes the risk of diversion, citing the Drug Supply Chain Security Act (DSCSA) as an effective deterrent. This is another premature assumption as there has not been any concrete data or outcomes to suggest this, given that DSCSA has not yet been fully implemented.

Analysis of how UPLs Could be Implemented (p.30)

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It is problematic that the Draft Report does not provide any discussion on the impact of patients, and instead focus on an abstract mention of "the state's health care system." It is critical that the Board focus its affordability review solely on those patients who have direct experience using and paying for the particular drug under review and who are the ones directly impacted by such Board decisions and their consequences. Further, it is important that the section address the underlying issue for the state: maintaining two different systems- a system for drugs that have a UPL and a system for those that do not have a UPL.

Current Analysis of Potential Costs and Savings (p.31)

In the assessment of potential cost savings, it is important that the Draft Report give due attention to the potential impact of an UPL on rebates. The report briefly admits that "in general, if implementation of a UPL results in all rebates being removed, only the more aggressive UPL scenarios result in plan savings." It is critical that the Draft Report critically assess what a UPL's impact on rebates could do the affordability, accessibility, and sustainability within the healthcare system, and most importantly assess potential adverse outcomes for patients.

Medicare Maximum Fair Price Analysis (p.34)

The Draft Report suggests that using MFP across the eleven modeled drugs would yield $37 million in savings, which is a clear overestimation given that these drugs are already heavily rebated. Even compared with the other cost savings scenarios listed, such as the supposed $18.7 million in savings in PEBB/OEBB, it is evident that $37 million is overstated. The analysis does not even consider other measures passed in the IRA such as the inflation penalty, indicating a clear exaggeration of savings.

Amid IRA MFP effectuation, it is important that policymakers work together to ensure better data and linkages to validate claims and to eliminate duplicate discounts. Despite efforts to build compliance with MFP effectuation, it is evident that there are still significant operational issues that require the sharing of claims-level data.

Future Analysis of Potential Costs and Savings (p.34)

Rather than framing this section as an analysis of costs, this section should more accurately be depicted as the process needed in order to estimate costs and savings. The Draft Report must acknowledge that the potential impact on cost and savings will be informed by market response that have not yet been accounted for.

UPL Report by Horvath Health Policy

The UPL Report by Horvath Health Policy (UPL Report) provides a theoretical overview of how UPLs could function, and it is important that the Board regard this UPL Report as merely a single consultant's opinion on the potential impact of UPLs. The UPL Report cannot and should not be viewed as a comprehensive assessment, as it fails to understand impacts on the supply chain and most importantly impacts on patient access and OOP costs for patients. The UPL Report consistently lacks background or information to support its

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assumptions regarding market impact and continuously fails to consider that patients remain particularly vulnerable to the downstream effects of UPLs due to the significant unknowns related to implementation. As voiced by many stakeholders, patients may face increased utilization management for UPL drugs and competitors in a therapeutic class, including step therapy and prior authorization, and increased barriers within formulary designs. It is also deeply concerning that the UPL Report seems to target manufacturer patient assistance programs in reference to the UPL, meanwhile failing to mention how PBMs and health plans consistently refuse to pass down manufacturer-provided discounts, rebates, and price concessions to patients at the pharmacy counter.

Finally, the UPL Report does not adequately account for the significant manufacturing complexity needed to develop valuable innovative therapies. Many innovative therapies require sophisticated, costly, and often specialized manufacturing processes. For instance, 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. A rigid UPL process would not be able to appropriately assess and price these innovative therapies, potentially discouraging their development or limiting patient access.

***

BIO appreciates the opportunity to provide feedback to the Oregon PDAB through this Draft Report. We look forward to continuing to work with the Board to ensure Oregonians can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

/s/

Melody Calkins
Director
Health Policy and Reimbursement

Oregon Coalition for Affordable Prescriptions (OCAP)
Fighting to lower prescription drug prices

Members of the Prescription Drug Affordability Board,

My name is John Mullin, and I am here today representing the Oregon Coalition for Affordable Prescriptions (OCAP), a non-profit organization dedicated to advocating for meaningful transparency on the causes of high prescription drug prices and the reduction of prescription drug costs for Oregonians. On behalf of OCAP, I want to begin by expressing our gratitude to the Prescription Drug Affordability Board (PDAB or "Board") for your tireless commitment to carefully examine the impact of high drug prices on residents of Oregon, state and local governments, employers, commercial health plans, health care providers, and pharmacies, including your recent efforts to prepare a report on upper payment limits (UPL). Your work reflects a deep dedication to addressing the financial burden that prescription drugs place on Oregonians, and we commend your thorough research and stakeholder engagement.

Your ongoing work and the release of the report is a milestone in the Board fulfilling the reporting requirements outlined in SB 192. While we recognize that the pharmaceutical market is complex and decisions about UPL implementation are difficult, we encourage the board to move forward with its work. In learning from the experiences of other states like Maryland and Colorado, we know legal and political challenges are likely and anticipate the road to implementation will be long. However, the time to act is now, and we encourage the PDAB to continue moving forward with confidence.

The OCAP and PDAB have a shared mission of working to make prescription drugs more affordable for Oregonians and ensuring Oregonians have access to critical and life-saving medications. We look forward to collaborating with you as this work moves forward and exploring all the policy levers that can help address the root causes of high prescription drug prices.

Thank you for your hard work and thoughtful deliberation and consideration as we continue to make progress toward a healthier, more equitable future for all Oregonians.

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

November 17, 2024

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

RE: Public Comments on the UPL Report

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.

While we applaud the board's commitment to supporting patients and lowering the costs of prescription medications, we are concerned that upper payment limits (UPLs) can further complicate an already complex healthcare marketplace and result in worse outcomes 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.

UPLs Could Compromise Patient Access to Medications

While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies.

Payers in our health marketplace do not necessarily derive the most value from the lowest-cost drugs. According to reporting on PBMs by the New York Times, "Even when an inexpensive generic version of a drug is available, PBMs sometimes have a financial reason to push patients to take a brand-name product that will cost them much more."

Ultimately, this could mean that insurers and PBMs will place drugs subject to UPLs on higher formulary tiers or implement other utilization management tactics to steer patients away from these drugs. This could lead to higher out-of-pocket costs for patients who could face higher copay or coinsurance rates to retain access to that drug or alternatively be forced to switch to a more expensive drug that results in higher profits for their PBM.

These plan-prompted changes are collectively known as non-medical switching. Non-medical switches in medication can also cause unnecessary complications for patients. At a minimum, a switch in medication will require more doctor visits to monitor the efficacy of a new medication. Further, if the switch results in side effects or worsened outcomes, patients could face medical interventions or hospitalization and the additional costs borne out by both.

This eventuality was outlined by the Centers for Medicare and Medicaid Services in their May 3, 2024 Guidance on Medicare Drug Price Negotiation, "CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing

selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs."

Upper Payment Limits Don't Necessarily Translate to Patient Savings

The board's draft report states, "The UPL amount will be widely known in the State, and consumers will be aware of what they should be charged when paying for a drug." However, this grossly ignores the reality of the American health system.

Patients are rarely provided with a projected cost of their healthcare or medications, nor are they allowed to choose their treatments based on costs. Instead, patients and doctors choose medications that work best for their individual needs and are beholden to the rates set by insurers and PBMs to access that treatment. It is also these stakeholders that determine if cost-savings realized by the payer are subsequently shared with patients. Unfortunately, in most cases, they are not.

Minimize Uncertainty and Protect Patients

We applaud the board's efforts to seek ample input from market stakeholders and patient organizations on the UPL process. The board held multiple listening sessions, and town halls, conducted stakeholder outreach through questionnaires, and provided opportunities for written and verbal comments.

The results of these sessions are outlined in the report and demonstrate that there are significant concerns from the majority of stakeholders regarding UPLs and broadly, a lack of understanding both of the process and how healthcare in Oregon will be impacted by UPL implementation.

Despite these findings, the board has so far not responded to any of the concerns raised by stakeholders during these sessions. Further, the draft report does not appear to address any of the issues raised by stakeholders by altering course or making alternative policy recommendations.

Therefore, we strongly urge the board and staff to utilize the authority of the board to fully explore with all healthcare stakeholders how UPLs will be implemented and identify in advance any adverse impact on patients. We also urge the board to work with the state legislature to put in place safeguards for patients before moving forward with UPL policies. This will protect patients from increased utilization management, compromised access to drugs under review, and other unintended consequences of the board's actions.

In continuation of that point, 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 as it evaluates the impact of its cost reviews and UPLs.

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.

ENSURING ACCESS THROUGH
COLLABORATIVE HEALTH

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
Ensuring Access through Collaborative Health (EACH) Coalition

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November 15, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon Prescription Drug Affordability Board Drug Selection & Affordability Reviews

Dear Members of the Oregon Prescription Drug Affordability Board:

Throughout the last year, Genentech has monitored and engaged in the Board's activities with interest and has submitted prior written comments addressing the Board's processes, and has participated in two manufacturer stakeholder meetings. Most recently, the Board's discussions have focused on SB 192 legislative requirements that the Board develop a plan for future legislative consideration around the implementation of an upper payment limit. As we shared in the two manufacturer stakeholder discussions, we have similar concerns about the complexities and challenges that have been identified with an upper payment limit as a tool for addressing drug affordability. Earlier this year, we were encouraged by the Board's decision in June to pause all prescription drug affordability reviews in 2024 and revisit your processes and data sources before beginning a new drug selection and review process in 2025. As we believe we have all experienced, this process alone is challenging enough, and we strongly recommend that the Board focus on this work before requesting new authorities from the legislature.

With that in mind, as the Board prepares to resume discussions on drug selection and affordability, we urge the board to adopt the following recommendations to ensure future processes yield a reliable, consistent, and data-driven result. We offer three key areas for the Board's consideration:

1. The Board must clearly establish its affordability goals and reevaluate its prioritization of affordability review criteria before embarking on a new drug selection and affordability review process.
2. The Board must address data limitations by broadening its data sources and contextualizing these data as part of the drug selection process.
3. The Board must implement enhanced methods of both soliciting and incorporating stakeholder feedback into its drug selection and affordability review processes.

The Board must clearly establish its affordability goals and reevaluate its prioritization of affordability review criteria before embarking on a new drug selection and affordability review process.

As the Board returns to a discussion on drug selection and conducting affordability reviews, the Board must first discuss and prioritize its affordability goals, including a defined framework of what affordability is, for whom it applies, and its views on how best to understand affordability through varying criteria and corresponding data. Focusing first on a robust discussion of the Board's affordability goals can create clarity for all stakeholders in the Board's focus and intentions while also establishing alignment for the following steps in the Board's drug selection and review processes. For example, if the Board's affordability goals are driven by an assessment of drug affordability for Oregonians, it may require solicitation and deeper analysis of certain national and Oregon-specific data, such as plan benefit designs, to fully understand patient out-of-pocket spending. Insights from Oregon-specific data (such as the all payer claims database) should be interpreted alongside consideration of the limitations of the data in capturing factors that impact patient spend, including but not limited to indirect and indirect costs of their disease that may be impacted by treatment (e.g., changes in total cost of medical care over time, negative health outcomes avoided, travel costs impacted by dosing frequency, use of rescue medications, use of copay assistance). These factors should then be clearly identified as part of the criteria for drug selection.

If the Board's affordability goals include an assessment of affordability for health systems and payers, the Board must ensure it assesses appropriate data on cost offsets delivered by the medicine under potential review. Genentech believes it is imperative for the Board to consider the many factors aside from a drug's price that shape affordability and the value of a medicine, including but not limited to the role of benefit design, the supply chain, and drug delivery method in a patient's out-of-pocket costs as well as how a drug contributes to cost offsets in other care.

To aid in defining the Board's affordability goals, Genentech urges the Board to consider implementing the following recommendations:

- The Board should revisit its drug affordability review criteria and seek input from third-party stakeholders on prioritized criteria;
- Following public discussion of these review criteria and incorporation of stakeholder feedback, the Board should conduct a new survey of Board members to establish a new calculated average rank to be applied in any future drug selection weighting exercises; and,
- The Board should, with appropriate notice and opportunity for public comment, update its drug affordability rules to align with its identified affordability goals and ensure such rules appropriately align with the Board's statutory authority; we recommend the Board begin this work by revisiting its proposed rule language presented and discussed on March 15, 2023, which included a more robust section (3) on "Selecting Drugs for Affordability Review" than what was adopted in the final rule, published as OAR 925-200-0010. In particular, the earlier draft specifically highlighted important data elements that should be included and discussed in the drug selection process, such as health equity and patient out-of-pocket costs.

Implementing these recommendations will support a more thorough, well-defined and transparent approach to both the drug selection and affordability review processes.

The Board must address data limitations by broadening its data sources and contextualizing these data as part of the drug selection process.

The Board's statute directs the Department to provide the Board with data, as reported under ORS 646A.689 (2) and (6) and ORS 743.025, to initiate its drug selection and drug affordability review processes. In its 2023 drug selection process, the Board focused heavily on limited cost data on a narrow subset list of drugs prioritized based on the state's Drug Price Transparency programs. However, the 2023 process, as we have commented previously, was conducted without regard for the necessary context associated with specific data. In 2025, it is essential the Board incorporate broader sources of data with which to contextualize aggregated data.

Specifically, following decisions regarding the Board's affordability goals, the Board should revisit its data call solicitation and accelerate this solicitation to allow for consideration of additional data and context during the Board's drug selection deliberations. The Board should be transparent about the methods that will be used to narrow initial lists of drugs eligible for an affordability review, and these deliberations should be conducted in public meetings of the Board and be open for input from interested stakeholders, including manufacturers. Transparency regarding data sources, methods used to create any necessary calculations, and a broader set of data will enhance the Board's deliberations while also providing necessary clarity to third-party stakeholders. In addition, such transparency will support the ability of third parties to validate the data used to inform the Board's decision-making.

When conducting the drug selection process, we urge the Board to individually discuss each of the drugs on any subset list and provide a robust rationale for their possible selection for an affordability review, including reference to the data sources and methods used to identify the drug for possible selection. In undertaking an approach to discuss each drug appearing on any subset list of drugs for selection, the Board can avoid many of the challenges encountered in 2023 and ensure the drugs it ultimately selects for an affordability review have been thoroughly evaluated and are appropriate to undergo a drug affordability review. We urge the Board to refine these processes and ensure all steps in the drug selection process are transparent, well-defined, and well-understood by the Board's stakeholders.

The Board must implement enhanced methods of both soliciting and incorporating stakeholder feedback into its drug selection and affordability review processes.

The statute requires that "[t]he board shall accept testimony from patients and caregivers affected by a condition or disease that is treated by a prescription drug under review by the board and from individuals with scientific or medical training with respect to the disease or condition." While acceptance of testimony is required by statute, it should not be the only method by which the Board engages with third-party stakeholders. We strongly urge the Board to develop additional tactics to seek input from stakeholders and specify how their input will be considered and incorporated into each part of the Board's drug selection and affordability review process. These actions should be identified and discussed publicly prior to proceeding with any drug affordability reviews.

For example, stakeholder engagement tactics undertaken by Boards in other states have included focus groups, open public surveys, and direct stakeholder meetings. Boards are also partnering with patient organizations that represent the impacted community to engage those with lived experience and solicit their input. Further, some boards are currently considering means by which to host expert testimony or other informational hearings, which would afford the Board and stakeholders more opportunity for public dialogue and interaction in contrast to a simple open comment period with no opportunity for direct engagement with Board members. It will be essential to identify several tactics to incorporate in a revised approach to drug selection and affordability reviews.

We strongly encourage the Board to meet directly with interested third-party stakeholders, including patients, caregivers, and providers and the advocacy organizations representing them to design a myriad of meaningful and appropriate engagement strategies and tactics.

Thank you for your consideration of our feedback in your ongoing deliberations. We believe it is essential for the Board to thoroughly revisit the drug selection and drug affordability processes before conducting affordability reviews in 2025 or advancing any other actions of the Board. If you have any questions or want to discuss our feedback, please contact Tim Layton, Director of State Government Affairs at layton.timothy@gene.com or (206) 403-8224.

Sincerely,

Mary Wachter
Executive Director
State & Local Government Affairs

COMMUNITY ACCESS NATIONAL NETWORK

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November 15, 2024

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

RE: Comment on Proposed UPL Legislative Report Draft

Honorable Members of the Oregon 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 write with exceptional concerns and suggestions regarding the proposed draft of the UPL Legislative Report.

Cost/Necessary Additional Appropriations Due to UPL Impacts Requires Consideration of UPL as a Failed Approach

Data weakness should not be diminished or washed over (page 32)

In the *Current Analysis of Potential Costs and Savings* section the Board lists a range of potential Upper Payment Limit (UPL) scenarios. It was acknowledged that the interpretations were largely theoretical due to the variations in quality and completeness of data. Additionally, the potential "savings" are described as being nearly equal to potential "costs". Insisting on additional UPL action without greater clarity diminishes the potential magnitude of the negative implications of a UPL. It is important to remember that CMS projected any 'savings' would likely be due to cost-shifting -- any governmental savings, no matter how minimal, would result in increased out-of-pocket costs for patients. The Centers for Medicare and Medicaid Services' National Health Expenditure Projections (2023-2032) also explains how the Inflation Reduction Act is expected to result in increases in Medicare spending due to institution of drug price negotiations,

otherwise referred to as the "Maximum Fair Price" (MFP). National Health Expenditure growth is expected to outpace average GDP growth largely due to hospital and provider payments and Medicaid enrollment is expected to decline. These are all health expenditure issues, directly affecting patients financially in which a UPL does not address. Similarly, imposition of the MFP is not necessarily expected to cause overall "savings", rather cost shift, as discussed further below.

Clarification Needed to Effectively Describe WAC Manipulation by PBMs
Transaction Relationships in the Supply Chain: Manufacturers (page 13)

This section asserts that drug manufacturers are solely responsible for, control, and set the Wholesale Acquisition Cost (WAC). There is nuance in that this is not unequivocally true. The recent complaint filed by the Federal Trade Commission against Pharmacy Benefit Managers (PBMs) explains that while manufacturers offer multiple WACs per medication, PBMs often select higher WAC medications since that allows PBMs to obtain a larger rebate retention which increases the overall WAC. The following citations from the FTC complaint illustrate this:

139. Rather than cutting list prices on their existing insulin products and risking losing formulary access, Lilly, Novo, and Sanofi each launched new, unbranded low WAC products. These low WAC insulin versions were identical to the high WAC versions in all clinical respects. The only differences were that they did not include branding and were significantly lower list price.

143. The insulin manufacturers continued to offer the high WAC, highly rebated versions while pricing their low WAC insulin at roughly "net price parity" with the branded versions. Essentially, although the low WAC version had a different list price, the smaller rebate it offered resulted in a net price roughly equivalent to that of its high WAC counterpart. Manufacturers adopted this pricing strategy "so that the payer would be neutral" or "indifferent" between the two versions.

144. The PBM Respondents, however, were not indifferent between the high WAC and low WAC insulin versions. Instead, they methodically disfavored the low WAC insulin products on their flagship commercial formularies, preferring only the high WAC versions, with high rebates and fees.

PBMs Gatekeep Formularies and Plan Design, Patient Experiences in "Affordability" and Access
Transaction Relationships in the Supply Chain: Pharmacy Benefit Managers (PBMs) (page 14)

In this section, it is important to emphasize PBM gatekeep formularies. According to the FTC, the three largest pharmacies administer approximately 80% of all prescriptions in the United States. Additionally, they base the coverage, tier, prior authorization and other formulary decision metrics on what is profitable to PBMs, not what is 'affordable' for patients or government payers.

Roles Should be Better Defined
Transaction Relationships in the Supply Chain: Pharmacy Benefit Managers (Payers) (page 14)

The report conflates the roles of "payers," PBMs, and Managed Care Organizations (MCOs) in the case of Medicaid. These roles should not be commingled. Employers and governmental bodies should be ascribed the role of payer separate from PBMs. Much of what is currently attributed to payers is managed by PBMs and MCOs.

Plight of Independent Pharmacies Needs Greater Emphasis as Access and System Sustainability Issue
Transaction Relationships in the Supply Chain: Pharmacies (page 15)

This section does not explicitly address concerns raised by non-chain, independent pharmacies. A UPL's impact must be explicitly described within this particular context of the ecosystem. These independent pharmacies are faltering because of PBM under-reimbursement. According to the National Community Pharmacists Association, 32% of independent pharmacies are exploring closing in 2024.

Perverse Incentives Drive PBM Practices
Perverse incentives caused by PBM practices (page 16)

The report effectively notes how PBMs may use rebates to identify preferred formulary placement. However, the report doesn't mention the perverse incentives this causes. The FTC complaint explains that PBM profitability is the product of a focus on rebate chasing as a priority. This results in selecting higher WAC because higher list price = better formulary placement. This adversely affects affordability for patients and the system because the better formulary placement is not based on clinical benefit or medical necessity for patients. The board would be served well to encourage investigations similarly situated to those of OH (Attorney General Dave Yost) and Indiana's overspending to the tune of $1B because of PBM greed. Investigating these situations as they do or do not apply to Oregon would have a more direct benefit to both the state and patients in Oregon, without the risks a UPL poses on access.

CMS Data Needs to be Included
UPL Potential Methodologies (page 19)

This discussion Fails to mention CMS' National Health Expenditure Projections (2023-2032) analysis conclusions. CMS expects both patient and system costs to rise most significantly related to hospital care and physician and clinical services, whereas CMS projects prescription drug spending to slow. It is important to note CMS *also* projects that implementation of the MFP will largely cost shift rather than "save", reducing government spending while increasing patient out-of-pocket costs. A UPL, either as established by MFP or independently, similarly risks such a shift, further reducing patient "affordability" and access.

Reference Pricing is Problematic, Disregards Statutory Prohibition on use of QALYs, and Runs Counter to Federal Non-Discrimination Rules
Other countries' prices should not be used as references (page 20)

The "Reference Pricing to Existing Benchmarks" section includes referencing pricing to other countries. Other countries use discriminatory quality metrics, such as Quality Adjusted Life Years (QALYs), which are prohibited by Oregon's convening statute and by federal non-discrimination rules, *inviting unnecessary litigation*. Referencing other countries' pricing considerations directly undermines statutory requirements. The board considering international reference of any kind should be prohibited as it is a "back door" vehicle of QALY use.

The U.S. Department of Health and Human Services and Centers for Medicare and Medicaid Services finalized federal rules recognizing "quality adjusted life years" and similarly situated metrics as necessarily discriminatory toward persons with chronic health conditions and older patients. Those same rules, integrating protections under the Americans with Disability Act and Section 504 are directly addressed in terms of "cost containment" efforts as detailed below from 89 FR 4006, Nondiscrimination on the Basis of Disability In Programs or Activities Receiving Federal Assistance (Section: Value Assessments [84.57]);

Comment:
The Department requested comment on how value assessment tools and methods may provide unequal opportunities to individuals with disabilities. Numerous commenters indicated that value assessment methods could limit people with disabilities' access to health care goods and services, including pharmaceutical interventions, and expressed concern that the use of the QALY unfairly limited access to emerging pharmaceutical interventions that could extend the lives of people with disabilities.

Response:
While the nondiscriminatory use of value assessment is an important tool for health care cost containment, the Department agrees that discriminatory usages of value assessment harm people with disabilities and provide unequal opportunities.

Comment:
One commenter argued that the use of the QALYs and other methods of value assessment that frequently entail discounting the value of life extension on the basis of disability are not discriminatory because they are "only one step" in a process of decision-making, noting that policymakers also take into account other factors in their ultimate decision-making.

Response:
Although recipients may make use of multiple factors to influence their decision-making, the use of a measure of value that assigns lower value to extending the lives of people with disabilities to determine eligibility, referral, or provision or withdrawal of an aid, benefit, or service can be nonetheless discriminatory.

Additional Data Limitations
There are additional limitations of the Oregon APAC data (page 27)

APAC data does not capture denials or other actions by payers which may negatively impact patient experience and affordability. Furthermore, APAC data is not often audited for actuarial assessment. Any use of APAC data must recognize the limitations and that all data points provided are done solely through the lens of PBM stakeholders.

We Applaud the 340B Impact Analysis
We applaud the 340B revenue impact analysis (page 28)

We thank you for your discussion of the UPL's possible impacts on 340B providers and pharmacists. Additionally, we'd like to add that you must also include potential for funding allocation to Medicaid and other state payers, like the State AIDS Drug Assistance Programs (ADAP), which might face similar concerns.

Request for Additional Authority is Inappropriate, given Report Content
All told, the Board's Own Report Evidences No Need for Additional Authority (page 30)

The board has self-identified the condition of not presently having sufficient data or a developed, amplified, "fleshed-out" plan. As such it would appear presently inappropriate to seek additional statutory authorities when they may not fit within the plans that the board finally develops. Additionally, ineffectively requesting the additional authorities now could adversely affect the granting of requests for additional powers that result after more deliberation and information gathering.

Clarification of Factors Driving Patient Costs
Correction needed under "Current Analysis of Potential Costs and Savings" (page 32)

Patient copayments and other aspects of plan design are NOT based on the total cost of a medication but based on profitability to the PBM (see FTC complaint). The Board's conclusions in this respect are troubling considering these facts and further support this not being the appropriate juncture at which to seek additional authority.

Pertinent Data cannot be Omitted
Senate Bill 192 requires a thorough analysis of the costs of implementing a plan: Future Analysis of Potential Costs and Savings (page 34)

This section states that a detailed analysis is premature currently. The Board does not have the option to disregard the cost of implementation from various stakeholders in the supply chain. Disregarding the requisite analysis also necessarily means the Board has not considered all costs associated with implementing a UPL - further undermining the likelihood of any "savings" and only increasing the potential costs as unpleasant surprises for the legislature to grapple with later down the line.

340B Risks are Facts not Merely Personal Interpretation
340B effects are not just survey perspectives but actual fact (page 39)

The observation section on page 39 catalogs the adverse effects of a UPL on 340B covered entities, especially FQHCs, as concerns listed by survey respondents. This information should be listed as factual assessment and not just community interpretation. The 340B risks to the health equity efforts of covered entities, such as FQHCs, should be listed as facts under the **340B Covered Entities** segment of the *Future Analysis of Potential Costs and Savings* section of the report beginning at the end of page 36 going into page 37. Categorizing these effects under community survey response diminishes the issue as 'subjective opinion' or 'emotional response' instead of data-driven fact.

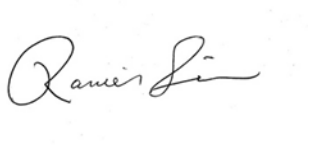
Recommendations Continue to Fail to Establish Monitoring Metrics

One of the most significant failures of this report is the lack of monitoring metrics designed to evaluate continued patient access to lifesaving and life-sustaining medications. Similarly, the lack of the metrics also fails to continue assessments of patient "affordability" because of either legislative or Board actions.

In totality, the Board's effort regarding this report is extensive and should be applauded. However, by and large the conclusions of the report can be summarized as "we don't know, things could be bad but let us find out anyways". This approach recklessly disregards not only patient access to care, but the legislature's fiduciary duty to taxpayers, and significantly consequential impacts on providers and the state's public health programs.

We encourage you to consider our commentary in the development of the legislative draft letter. We also appreciate all your continued mindful efforts in effectively deliberating what is best for Oregon patients as well the healthcare system.

Respectfully submitted,



Ranier Simons
Director of State Policy
Community Access National Network

On behalf of

Jen Laws
President & CEO
Community Access National Network

November 14, 2024

Oregon Prescription Drug Affordability Board
c/o Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

TO: Members of Oregon Prescription Drug Affordability Board

As a physician who has spent decades caring for patients whose families struggled to access and afford their needed medicines, I urge you to reconsider approving the Senate File 192 Upper Payment Limit draft report and seek additional and more diverse stakeholder input. I am deeply concerned that the proposed implementation of UPLs could inadvertently restrict access to necessary medications for patients, especially those with rare or complex conditions.

As a board-certified pediatrician and rheumatologist, I have dedicated my career to serving children and youth with chronic or disabling conditions. Many of my young patients, including those with juvenile idiopathic arthritis or lupus, depend on specialized, innovative and, unfortunately, expensive therapies. At your October 16th meeting, board members acknowledged the lack of physician input in developing this report; remedying this deficit prior to filing your final report would be valuable. While I fully support the creation of a constituent advisory board, this should not be substituted for robust public input opportunities.

Currently, the public has limited ability to engage—just one minute of stakeholder comments for every nine minutes of Board discussion is scheduled at your November 20th meeting. Oregonians and Oregon lawmakers deserve recommendations informed by comprehensive and extensive stakeholder feedback. Physicians and patients are concerned that the current approach risks overlooking individual patient needs and could disadvantage certain populations.

I understand and support the urgency of addressing prescription drug costs, but the proposed UPL implementation has the potential to actually decrease access to critical medications for those who need them most. The draft's suggested options lack sufficient safeguards to ensure that affordability measures do not undermine the availability of essential treatments.

Focusing solely on UPLs to address treatment costs is akin to pulling on a single thread in a large quilt. By targeting one price in a multi-faceted drug pricing ecosystem, I believe this approach is too narrow to address the root causes of high out-of-pocket costs. As raised during the Board's recent discussions, this strategy risks falling short of its mandate to improve affordability for patients since it does not directly address the patients' payments.

Among the many complexities not yet considered in creating a UPL is the role of national and out-of-state group purchasing organizations and the unique cost structures for infusible or other administered medicines. Medications can only remain accessible if providers can afford to purchase and administer them; restrictive UPL policies may jeopardize these critical care sites, resulting in decreased access to care. The Coalition of State Rheumatology Organizations, National Infusion Center Association and others have highlighted these challenges, underscoring the fact that these are not isolated state-level concerns. Ensuring that medications remain locally available and affordable is critical to prevent patient care disruptions and unintended outcomes.

I urge the Board to seek authority to review and provide recommendations that include the roles of **all** players in the system, since payors and pharmacy benefit managers (PBMs and others are involved in setting both the list prices and patient costs. Without examining the entire drug supply and distribution chain, we cannot achieve the goal of improving access to affordable, life-saving drugs. Effective solutions must focus on what patients actually pay, not inflated list prices.

I commend your discussion around providing policy recommendations for Senate Bill 844 and your recognition of the need for more data and broader stakeholder input. While this may extend the timeline, it will ultimately better serve Oregonians.

In conclusion, I am concerned that the Board's current focus seems overly fixated on meeting arbitrary legislative deadlines rather than prioritizing the lives and well-being of the patients directly impacted by the Board's decisions. Physicians and patients remain committed to working with you to ensure affordable medications for all Oregonians, but to accomplish this goal will require a more thorough, comprehensive, and extensive consideration.

Thank you for your attention to this critical issue.

Sincerely,

Harry L. Gewanter, MD, FAAP, MACR
President, Virginia Society of Rheumatology
Board Member, Let My Doctors Decide Action Network

COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

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PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

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Email: jen@tiicann.org

October 11, 2024

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

RE: Oregon Prescription Drug Affordability Board Guidelines

Dear Honorable Members of the Oregon 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 write with commentary regarding your ongoing thorough efforts to set up the Prescription Drug Affordability Board (PDAB) for success.

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

In expressing our support for certain recommendations from the PDAB, we also wish to highlight concerning findings from the PDAB's own contracted consultants reviewing the cost-benefit of imposing an "Upper Payment Limit" (UPL). In the Stauffer-Meyers UPL Draft Report, authors noted a few concerns which are particularly important to under-served and marginalized communities highly impacted by health disparities. The most noted being that imposition of a UPL on a best-case basis may produce less than half a million dollars in "savings" to Oregon's Medicaid program due to reductions in rebate values applied to the program (pg. 27). This does not consider the negative fiscal impact of potentially reducing federal matching dollars (FMAP) in assisting the state of Oregon in meeting its Medicaid population's needs.

Furthermore, as the report notes, an analysis could not be made regarding any impact on 340B covered entities, however, given the estimation relative to Medicaid rebate reductions, a similar reduction in 340B discount values should be expected. For 340B covered entities serving marginalized populations and otherwise operating as safety net entities, such a reduction would likely prove damaging to patient affordability and access and harmful to the financial sustainability of these entities, particularly federally qualified health centers.

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

2024 Proposed Policy Recommendations

We applaud the three items you refer to in your policy analysis as "Potential Senate Bill clean-up." Changing the language from locking in a mandatory set number of drugs for review empowers the Board to focus on medicines that effectively meet the future affordability challenge criteria the Board sets instead of forcing designations of drugs merely out of statute, potentially unnecessarily causing access issues for patients.

We also thank you for considering the reporting changes regarding removing the requirement of the generic drug report and the quarterly DCBS prescription drug list requirement. Accurate and relevant data is required to serve your citizens and your health system beneficially. This is important to ensure your KPIs or metrics truthfully address your concerns.

Additional Recommendations

Your recommendations, which you labeled 'additional recommendations', are also practical.

We support your recommendations for enhanced reporting regarding copay accumulators and maximizers and other benefit design issues. Requiring PBMs to assume the burden of responsibility for reporting will improve transparency, strengthen the quality of the collected data, and remove the onus of data collection from the Board.

We support the recommendation of a statewide preferred drug list for all classes of prescription drugs for OHP FFS. This not only reduces the administrative burden for providers but improves patient access. Ensuring all patients have the same access to all approved drugs agnostic of the FFS plan results in all patients benefiting from the well-researched drug list and helps them maintain consistency as their circumstances change, which could result in plan migration over time.

We support the recommendation of the OHP, FFS, and CCOs purchasing through a statewide purchasing group. In addition to cost savings and logistical efficiency, the purchasing group could provide funding. Administrative fees charged to the participating vendors could be used to support programs and other needs of the various members, resulting in reduced system expenditures and, ultimately, cost savings being passed on to patients.

We support the suggestion of minimum dispensing fees across all payers and the prohibition of below-cost pharmacy reimbursement. This will shield the financial stability of pharmacies from being adversely affected by any market response to future drug affordability policy actions.

We support the uniform reimbursement rate recommendation for CAPs and the PBMs that contract with them. CAPs service underserved areas and do not benefit from high-volume purchasing. This recommendation would protect the stability of operation. Protecting them from actions, such as PBMs restricting reimbursement or forcing mail-order utilization, which could potentially prevent pharmacy closures that would create pharmacy deserts and harm patient access.

Additional Potential Considerations

We would also like to propose potential considerations to be added as policy recommendations as reflected by the recent Federal Trade Commission (FTC) complaint against three specific PBMs:

- Prohibit PBMs from designing benefit plans that base patients' cost-sharing (i.e., deductibles or coinsurance) on list price rather than the net costs after rebates.
- Prohibit contracting resulting in PBM compensation being tied to a drug's list price or related metric or "de-linking" rebate structures from PBM profitability.
- Prohibit PBMs from discouraging the use of or excluding low WAC versions of drugs made by the same manufacturers opting to favor the high WAC drug on formularies.
- Imposing a critical eye at price reporting data such as WAC and AMP. The FTC report referenced herein details how PBMs manipulate both ecosystem and state-specific data by prioritizing high WAC medications over low WAC medications, even when manufactured by the same company. Thus, the price metrics considered by the PDAB are "contaminated" and the PDAB's conclusions will similarly be tainted by this data flaw.

CANN remains steadfast in urging PBM reform and enforcement of same as the most direct means to aiding patients and Oregon's health system. The unfortunate reality is the state's PDAB is not currently empowered to address these issues. We look forward to continuing to work with the Board, sharing our experiences from other states regarding PDABs, and ensuring that the best outcomes for patients remain a priority.

Respectfully submitted,

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

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

Johnson & Johnson

Johnson & Johnson Health Care Systems, Inc.
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Via Electronic Submission

October 11, 2024

Shelley Bailey
Board Chair
Oregon Prescription Drug Affordability Board
pdab@dcbs.oregon.gov

Dear Board Chair Bailey:

Johnson & Johnson (J&J) is offering comments on materials presented to the Oregon Prescription Drug Affordability Board (the "Board") during the October 2, 2024 meeting. During that meeting, staff presented a report created by Myers and Stauffer titled "PDAB Upper Payment Limit (UPL) Analysis: Oregon Educators Benefit Board (OEBB) and the Public Employees' Benefit Board (PEBB), Medicaid FFS and CCO" ("M&S Report").[1] This taxpayer-funded analysis was created at the direction of the Board, but did not receive adequate discussion. In this comment, J&J would like to call attention to key finds in the M&S Report, which reinforce the findings of J&J's report "Influence of Prescription Drug Affordability Boards and Upper Payment Limits on the State Drug Pricing Ecosystem," previously submitted to the Board.[2] Importantly, the M&S Report finds that a UPL is an untested methodology that is unlikely to achieve its goal of cost savings. It also determines that a UPL could have negative impacts on parties throughout the supply chain. J&J recognizes that SB 192 requires the OR PDAB to submit a plan for establishing UPLs and their potential cost-savings to the Legislature. ***Therefore, pursuant to the mission of the Board and in light of the M&S Report findings, J&J requests that the Board recommend 1) that a UPL is unlikely to result in cost-savings; and (2) against establishing UPL authority.***

The Board was established to purportedly lower costs for "residents of Oregon, state and local governments, commercial health plans, health providers, pharmacies licensed in Oregon, and others within the health care system in this state."[3] Yet, according to the following findings of the M&S Report, a UPL would not achieve that goal for any of those parties:

- **The UPL may not only fail to lower patients' out-of-pocket (OOP) costs, but potentially *increase* costs for patients.** The M&S Report notably fails to say that patients' OOP costs will be lowered, despite the stated goal of the PDAB. To the contrary, the M&S Report states that if a manufacturer does not sell at the UPL price, then the reimbursement rate may be too low for pharmacies and hospitals. In actuality, given the complexities and interconnected nature of the supply chain, there could be a range of factors and

[1] https://dfr.oregon.gov/pdab/Documents/20241002-PDAB-document-package.pdf
[2] https://transparencyreport.janssen.com/influence-of-prescription-drug-affordability-boards-and-upper-payment-limits-on-the-state-drug-pricing-ecosystem
[3] https://dfr.oregon.gov/pdab/pages/index.aspx

entities contributing to pharmacy and hospital under-reimbursement.[4] Rather than risk taking losses, pharmacies and hospitals may choose to shift some costs to patients. In other words, the M&S Report notes that patients could pay more for drugs subject to a UPL than they pay without a UPL. ***Therefore, a UPL is unlikely to benefit Oregonian patients/residents.***

- **A UPL may negatively impact patient access, creating potential disparities for Oregonians.** There are many parallels in findings between the J&J and M&S Reports, including the potential for a UPL to create access issues for patients. The M&S Report notes that pharmacies and wholesalers may be unwilling to stock products subject to a UPL because they may have to buy or sell those products at a loss. As noted in the J&J Report, patients may face access issues due to challenges with effectuating a UPL among various entities in the supply chain. The M&S Report also said that a UPL could create disparities in drug coverage for Oregonians versus other states, and it is unclear how a UPL could impact health equity. ***Again, a UPL is unlikely to benefit Oregonian patients/residents.***

- **A UPL may not provide cost savings to the health care system.** The M&S Report found that a UPL could cost programs like PEBB and OEBB upwards of $8.9 million and $3.1 million respectively due to lost rebates. The M&S Report also found that a UPL would not provide any savings to Oregon Health Plan (OHP) FFS and CCOs. Instead, any savings would "be reinvested into other OHP services rather than directly reducing state costs."[1] Even then, the M&S Report notes that due to timing and data constraints, they were unable to model any rebate impact and that "offsetting for rebates forgone would reduce that potential savings/reinvestment."[1] Essentially, the more the UPL reduces rebates for the state, the less likely it is for PEBB, OEBB, OHP, FFS, and CCOs to achieve cost savings. ***Therefore, a UPL is unlikely to benefit state and local governments.***

- **A UPL is likely to have unintended consequences for other entities in the supply chain.** The M&S Report states that a UPL could result in pharmacists operating at a loss, which could result in more pharmacy closures. Likewise, the J&J Report points out that a UPL would place downward pressure on reimbursement rates in programs such as Medicare Part B, potentially resulting in under-payment for providers who administer drugs. The M&S Report hints at this potential harm by stating that it is "unclear how an UPL will affect other benefit plan coverage (Third Party Liability or Medicare for Part B drugs)" and that "OHA would need to revise reimbursement methodology to ensure outpatient hospital [settings] are paid at least their acquisition cost."[1] ***Therefore, a UPL is unlikely to benefit pharmacists, health care providers, and others in the health care system.***

All of these findings follow M&S's last report requested by the Board in which M&S summarized

[4] There are a number of factors that could contribute to under-reimbursement. For example, a pharmacist or hospital may only be able to purchase certain specialty drugs from distributors outside of Oregon. However, those distributors may not be required to comply with the UPL, resulting in a loss for pharmacists or hospitals.

input from seven constituent groups—340B covered entities, carriers, hospitals, patient advocacy groups, pharmaceutical manufacturers, pharmacy benefit managers, and retail pharmacies.[5] All seven constituent groups provided consistent feedback that a UPL would result in losses across the supply chain with no corresponding benefit to anyone.[7]

Given the findings of the M&S report and the consistent feedback from stakeholders, we strongly urge the Board not to seek UPL authority. Instead, J&J recommends that the Board continue to explore policy solutions that would help patients gain more affordable access to their medicines. For example, the following solutions could reduce Oregonian patients' out-of-pocket costs without negatively impacting their access to the most appropriate, effective treatment options and sites of care:

- **Require that PBM rebates and discounts be directly shared with patients at the pharmacy counter.[6]**

- **Examine the use of utilization management tools (e.g., formulary exclusion lists, prior authorization, step therapy, and nonmedical switching) and evaluate how best to regulate them in the interest of patient access and out-of-pocket costs.[4]**

- **Prohibit diversion of cost-sharing assistance (i.e., copay accumulator programs, maximizer programs, and alternative funding programs) to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.[7]**

As one of the nation's leading healthcare companies, J&J has a responsibility to engage with stakeholders in constructive dialogue to address gaps in affordability, access and health equity as well as protect our nation's leading role in the global innovation ecosystem. Our mission is clear: we are focused on developing innovative medicines to help patients fight their diseases. We live this mission every day and are humbled by the patients who trust us to help them live healthier lives.

Sincerely,

Blasine Penkowski
Chief Strategic Customer Officer
Johnson & Johnson Health Care Systems Inc.

[5] https://dfr.oregon.gov/pdab/Documents/20240821-PDAB-document-package.pdf
[6] Janssen. "The 2021 Janssen U.S. Pricing Transparency Brief." Accessed May 6, 2024.
[7] Janssen. "The 2022 Janssen U.S. Pricing Transparency Brief." Accessed May 6, 2024.

724 Columbia St. NW, Ste. 310 • Olympia, WA 98501 • PHRMA.ORG

October 12, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon Prescription Drug Affordability Board: Meeting Materials for October 16, 2024 Meeting

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's ("Board's") agenda packet for its October 16, 2024 meeting, including the Board's draft discussion of the Senate Bill 192 Upper Payment Limit ("UPL") Draft Report ("Draft UPL Report"), and other materials that the Board intends to discuss at its meeting (collectively, the "Meeting Materials").[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. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease.

I. Lack of Opportunity for Meaningful Comment

PhRMA strongly objects to the Board's process for soliciting comment on materials in connection with its upcoming meeting to be held on October 16. As PhRMA has previously explained, the limited timeframe that the Board has afforded for review of and comment on materials in advance of past meetings did not allow a full and adequate opportunity for meaningful participation by stakeholders on the important and complex issues before the Board.[2] Those concerns are substantially exacerbated by the comment schedule imposed by the Board for its October 16 meeting, which violates constitutional and statutory requirements.

The PDAB Statute requires the Board to "[p]rovide the public with opportunity to submit written comments on any pending decision of the board."[3] It is a bedrock principle of due process, both under the federal and Oregon Constitutions, that an "opportunity" for input into governmental decision-making must come "at a meaningful time and in a meaningful manner."[4] This principle is also reflected in the State's Administrative Procedures Act (APA),[5] which imposes numerous mandatory notice periods for decisions involving public comment, which are designed to "give interested persons reasonable opportunity to submit data or views."[6]

The notice provided by the Board in advance of its October 16 meeting falls far short of these requirements. On October 9, the Board circulated materials for its upcoming meeting, which consisted of 95 pages that included:

[1] *See* Meeting Materials (October 16, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/20241016-PDAB-document-package.pdf. In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB Statute"). PhRMA also incorporates by reference all prior comment letters to the extent applicable.
[2] *See* Letter from PhRMA to Board (July 31, 2022), 2-3.
[3] ORS § 646A.693(13)(b).
[4] *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965); *accord Portland Gen. Elec. Co. v. Ebasco Servs., Inc.*, 353 Or. 849, 860 (2013).
[5] ORS Ch. 183.
[6] ORS § 183.335(3)(a).

a draft version of the report that the Board will present to the Oregon legislature detailing the Board's plan for establishing Upper Payment Limits (UPL Report); and a white paper from Horvath Health Policy that addresses, in part, the dormant Commerce Clause arguments in the Colorado *Amgen* case.[7] Under the Board's standard practice, the deadline for submitting written comments regarding these materials is 72 hours ahead of the scheduled meeting. As a result, PhRMA—and any other affected stakeholder—has approximately two business days, and four calendar days overall, to review these materials and respond substantively for the Board's consideration. Exacerbating matters in this instance, one of the two business days includes the start of a Jewish High Holiday (which continues through the next day), and Oregon's comment period does not provide additional time for holiday observances.

This sharply truncated timeframe does not comply with legal requirements. First, as PhRMA has previously noted in its prior comments, many of the decisions adopted by the Board through informal policy guidance constitute rules that must be adopted through a formal rulemaking process under the APA.[8] That is certainly true of the UPL Report, which satisfies the APA definition of a "rule."[9] The Board's failure to follow the procedures specified in that statute for rulemaking, including the required notice-and-comment period, is accordingly unlawful.

Second, the "exceedingly short duration of the comment period" offered in advance of the October 16 meeting "d[oes] not provide a meaningful opportunity for comment."[10] As courts have recognized, a 10-day comment period is generally not "adequate,"[11] and even a comment period of "thirty days for a rule of [significant] magnitude" is remarkably "short."[12] Here, the Board afforded commenters a timeline that results in "shorten[ing] the period further still and undercut[ting] the purpose of the notice process."[13]

II. Medicare Maximum Fair Price (MFP) Modeling Presentation, October 2, 2024

PhRMA is concerned that the Board discussed the "Medicare MFP Modeling Presentation" at its October 2, 2024 meeting without first releasing the materials to the public and giving stakeholders the opportunity to review and comment. As above, stakeholders must have an opportunity to comment on this type of modeling and analysis to ensure that the materials the Board relies on in its decision are as accurate and complete as practicable to avoid erroneous or incomplete information that could inappropriately influence the Board's decision making.

PhRMA has significant concerns that the Board has not described the methodology used on the MFP modeling. Without explaining the underlying calculations, the modeling potentially vastly overstates savings or may use erroneous calculations. The analysis does not provide details on what inputs were used to calculate savings based on the MFP for a 30-day supply. If estimated savings is calculated based on WAC, that would dramatically overstate potential savings as many drugs selected for MFP are in highly rebated classes. If, on the other hand,

[7] *See Amgen, Inc. v. Colorado Prescription Drug Affordability Rev. Bd.*, No. 24-cv-810 (D. Colo.).
[8] *See* Letter from PhRMA to Board (July 31, 2022), at 1-2.
[9] ORS § 183.310(9).
[10] *N.C. Growers' Ass'n v. UFW*, 702 F.3d 755, 770 (4th Cir. 2012).
[11] *N.C. Growers' Ass'n*, 702 F.3d at 770.
[12] *Pangea Legal Servs. v. U.S. Dep't of Homeland Sec'y*, 501 F. Supp. 3d 792 (N.D. Cal. 2020); *see, e.g.*, *N.C. Growers' Ass'n*, 702 F.3d at 770; *California v. U.S. Dep't of Interior*, 381 F. Supp. 1153, 1176-77 (N.D. Cal. 2019).
[13] *Pangea Legal Servs.*, 501 F. Supp. 3d at 819. While "the presence of exigent circumstances in which agency action [i]s required in a mere matter of days" can sometimes justify shortening the comment period, the Board has identified no such exigent circumstances that would justify the foreshortened comment period at issue here. N.*C. Growers' Ass'n*, 702 F.3d at 770; *see Omnipoint Corp. v. FCC*, 78 F.3d 620, 629-30 (D.C.Cir.1996) (upholding 15-day comment period given the "urgent necessity for rapid administrative action," as evidenced by "congressional mandate [to act] without administrative or judicial delays") (citation omitted).

estimated savings is calculated based on "average price per prescription" there is no indication this was calculated to be equivalent to a 30-day supply, indicating serious methodological issues. PhRMA requests that the Board publish the methodology used for this modeling for stakeholder review. In addition, as PhRMA has repeatedly addressed, we remain concerned that the Draft UPL Report does not include any mechanism to ensure that savings accrued by health plans will ultimately flow to Oregon patients.[14]

III. Draft Upper Payment Limit Study

PhRMA continues to have concerns that any UPL scheme would arbitrarily cap pharmaceutical prices, fail to recognize the complexity of the pharmaceutical supply chain, and overlook meaningful policy alternatives that would substantially reduce the cost of medicines for Oregonians. In light of the abbreviated comment period, PhRMA intends to provide a more comprehensive response to the Draft UPL Report at a subsequent date, and we reserve the right to do so with respect to other matters before the Board in the future. PhRMA will provide additional comments that address, but are not limited to, the following concerns regarding the Draft UPL Study:

- Broad assumptions in the Draft UPL Report about implementation of a UPL in Oregon, the technical capabilities of the supply chain, and other areas.
- A lack of consideration of the complex interconnected responses to a UPL by supply chain entities.[15]
- An oversimplified account of the administrative and operational challenges associated with implementing a UPL, including a lack of clear and specific description of what data sources would be used or the mechanisms that would be needed for confidential and proprietary data from across the supply chain to be housed, verified, and protected from unlawful disclosure.

PhRMA cautions the Board against moving forward with any UPL plan given the risks and unanswered questions associated. UPLs could restrict patient access to medicines, result in fewer new treatments for patients, and ultimately do not carry any guarantee of savings being passed on to patients. Finally, PhRMA does not herein address arguments raised in the ongoing *Amgen* litigation. PhRMA reserves its right to address those issues at an appropriate time, and must be provided an adequate opportunity to do so before the Board takes any action based on them.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the information provided in the Meeting Materials, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy
Sacramento, CA

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[14] *See* Letter from PhRMA to Board (September 15, 2024), at 2; Letter from PhRMA to Board (June 28, 2024), at 1.
[15] *See, e.g.*, Letter from PhRMA to Board (September 15, 2024).

National
Multiple Sclerosis
Society

September 10, 2024

Oregon Division of Financial Regulation
Oregon Prescription Drug Affordability Board
350 Winter St. SE
Salem, OR 97309

RE: National Multiple Sclerosis Society Policy Recommendations, Upper Payment Limits

Dear Members of the Oregon Prescription Drug Affordability Board:

Thank you for your continued engagement with all stakeholders and for focusing on the patient perspective. We appreciate the Prescription Drug Affordability Board's (Board) leadership and investigation into the high cost of prescription medications. We encourage the Board to continue its investigation into all practices that limit access to needed life-changing therapies and increase the price that patients pay for those therapies.

Multiple sclerosis (MS) is an unpredictable, often disabling, disease of the central nervous system, which interrupts the flow of information within the brain and between the brain and the body. Symptoms range from numbness and tingling to blindness and paralysis. The progression, severity, and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are moving us closer to a world free of MS. The Society works to cure MS while empowering people affected by MS to live their best lives. To fulfill this mission, we fund cutting-edge research, drive change through advocacy, facilitate professional education, collaborate with MS organizations around the world, and provide services designed to help people affected by MS move their lives forward.

The Society fully supports the establishment of Upper Payment Limits. We look forward to commenting on the Board recommendations for any MS-related medications identified as cost burdensome. We applaud the multiprong approach in identifying these medications by referencing data as well as continuing to engage with stakeholders who are impacted by these costs

The National Multiple Sclerosis Society knows that the price of the medication is but one aspect of what makes access to these high-cost prescriptions out of reach for many people with MS and other conditions. The Society will continue to look at the entire healthcare system and encourages legislatures and boards like this to continue their work in addressing all aspects of the prescription drug supply chain that get between patients and their medications.

Respectfully,

Seth M. Greiner
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September 15, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
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Re: Oregon Prescription Drug Affordability Board: Draft UPL Approaches and Proposed Policy Recommendations

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's ("Board's") agenda packet for its September 18, 2024 meeting, including the Board's draft discussion of potential approaches to UPL-setting ("UPL Approaches (General Concepts)") and Proposed Policy Recommendations ("Proposed Policy Recommendations") documents (collectively, the "Meeting Materials").[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. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease.

PhRMA continues to have concerns that any Upper Payment Limit ("UPL") scheme would arbitrarily cap pharmaceutical prices, fail to recognize the complexity of the pharmaceutical supply chain, and overlook meaningful policy alternatives that would substantially reduce the cost of medicines for Oregonians.[2] UPLs could restrict patient access to medicines, result in fewer new treatments for patients, and ultimately do not carry any guarantee of savings being passed on to patients. These concerns are not addressed in the draft UPL Approaches document. PhRMA cautions the Board against moving forward with recommending any UPL plan given the risks and questions associated with such price controls. Below, PhRMA provides more details about its concerns regarding the potential approaches to UPL setting and implementation described in the Meeting Materials.

I. Lack of Opportunity for Meaningful Comment

PhRMA reiterates its concerns that stakeholders are not being provided adequate time to meaningfully comment on the Board's meeting materials.[3] Consistent with its general practice, the Board has only provided two business days to analyze and comment on the concepts described in the Meeting Materials.

[1] Referred to herein, respectively, as the "draft UPL Approaches" and "Proposed Policy Recommendations" documents. *See* Meeting Materials (September 18, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/20240918-PDAB-document-package.pdf. PhRMA is not commenting on the "Presentation by OHSU Center for Evidence-Based Policy". Similarly, the "Medicare MFP modeling presentation & Senate Bill 192 upper payment limit discussion" material was not included in the September meeting materials and PhRMA reserves its comments on those materials until a later date.

[2] A proposed UPL scheme would raise concerns under the Supremacy Clause of the U.S. Constitution, among other constitutional concerns. *See, e.g.*, *BIO v. District of Columbia*, 496 F.3d 1362 (2007); *Amgen v. Colo. Prescr. Drug Affordability Rev. Bd.*, No. 1:24-cv-00810 (D. Colo. filed Mar. 22, 2024). In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB Statute"). PhRMA also incorporates by reference all prior comment letters to the extent applicable.

[3] *See* Letter from PhRMA to Board (July 31, 2022), 2-3.

In order to get meaningful feedback from a broad range of stakeholders, the Board should provide more than half a week to analyze and draft comments on these materials, especially given the complexity of analyzing different UPL alternatives and the significant ramifications of any Board recommendations to the Legislature. Key stakeholders may not be able to provide full written feedback given the Board's artificially short timeline. The Board should allow for a more reasonable time period to analyze and comment on its policy deliberations as well as clear timelines and processes for the Board to address stakeholder feedback in a manner that is clear and transparent.[4]

II. Draft UPL Approaches

The draft UPL Approaches document lists several potential methods to calculate UPLs, but lacks key details on how these methods would be implemented and operationalized. PhRMA reiterates that the lack of specificity in the document inhibits our ability to meaningfully comment on these materials. In addition, although the Board indicates that four states have enacted laws with authority to set a UPL for certain medicines, no state has implemented a UPL to date.[5] Similar to the policies contemplated in those other states, the Board's draft UPL Approaches document drastically oversimplifies the complexity of the pharmaceutical payment and reimbursement system and the operational concerns posed by UPLs across a variety of supply chain entities.[6]

PhRMA notes that much of the discussion in the draft UPL Approaches document appears to reflect input from a single source and does not incorporate the feedback that constituent stakeholders have provided to the Board over the past few months via the constituent surveys, focus groups, and panel discussion. The Board should consider whether the apparent lack of consideration of information from other stakeholders may have biased the draft UPL Approaches document, and in particular, whether it may have not considered the potential downsides of each approach or consideration of issues that could affect implementation in Oregon. Finally, there is no mechanism to ensure that any savings generated by the various UPL approaches would ultimately flow to Oregon patients. PhRMA reiterates that the Board should provide additional, and far more detailed, policy proposals regarding UPL calculation methods.

These approaches lack sufficient detail to provide a meaningful evaluation of the impacts or challenges of any approach. Notwithstanding its concerns, PhRMA addresses each potential UPL approach described in the draft UPL Approaches document below and seeks to offer its feedback and concerns regarding the potential options based on the limited information that the Board has provided:

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[4] PhRMA also emphasizes that if UPL authority is ultimately enacted by the Oregon Legislature, the Oregon APA requires that a separate rulemaking be conducted to establish the specific definitions, standards, and processes that will govern any UPL processes. As detailed below, the draft UPL Approaches and other Meeting Materials fail to provide adequate specificity that stakeholders would need to understand how a UPL would be operationalized and would not be sufficient to implement a future UPL process. Even if granted the statutory authority to impose a UPL, the Board could not implement a UPL consistent with the requirements of the Oregon APA unless the Board first adopts comprehensive regulations governing each procedural step, factor, and methodology described in the draft UPL Approaches document through notice-and-comment rulemaking. A UPL process implemented without notice-and-comment rules providing consistent and transparent guidelines to govern it would undermine the ability of the Board to conduct its work in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary," as required under the Oregon Administrative Procedures Act ("APA"). *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007). *See also, e.g.*, Letter from PhRMA to Board 2 (Feb. 11, 2023) (providing a more detailed discussion of the Board's obligations under the APA).

[5] Meeting Materials at 21-23.

[6] *See, e.g.*, Letter from PhRMA to the Maryland Prescription Drug Affordability Board (Aug. 26, 2024).

- **"Net Cost":**[7] The Board's "Net Cost" approach describes setting a UPL "at or near the existing average net price of the drug after any rebates or discounts negotiated between the drug manufacturer and the PBM."[8] However, it is unclear which "average existing net price" the UPL would reference, since the net price of a drug is unique to a specific payor, market, and group of patients. This approach lacks sufficient detail for a meaningful evaluation of risks or implementation challenges. Additional details are needed to provide more specific comments on the approach, as the Board has offered only a vague description of how it would identify the average net price of a particular drug.

- **"Reference Pricing to Existing Benchmarks":**[9] PhRMA has serious concerns about the use of reference prices under this approach, as well as the specific reference benchmarks under the Board's consideration. For example, one possible reference point included in the approach is the Maximum Fair Price under the Medicare Drug Price Negotiation Program.[10] Consideration of the Maximum Fair Price is premature. The Centers for Medicare & Medicaid Services only recently released the Maximum Fair Prices for the first set of qualifying drugs, and they do not go into effect until 2026. Further, the federal program has only just gotten off the ground and, as such, it will take years to understand its effect on patient affordability and access. Additionally, the federal program considers prices for the Medicare population, which is drastically different in key respects (e.g., demographics, age, and diversity) from the Oregon patient population for which the Board may eventually consider setting a UPL. PhRMA encourages the Board to focus on data and benchmarks that are relevant to the Oregon patient population, which is the focus of the PDAB statute.[11]

  The document also includes "the price of drugs negotiated by other countries" as another potential reference price benchmark.[12] This approach lacks specificity, but the use of international pricing data to determine UPLs is concerning. The Board's approach does not acknowledge the demonstrated negative effect of international prices on patient access. The prices in many non-U.S. countries are the result of government price setting that have significantly limited patient access to new drugs. For instance, 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.[13]

  Additionally, the international reference pricing approach does not include any discussion of the data that the Board will use to determine international reference prices. If 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

[7] Draft UPL Approaches at 4.
[8] *Id.*
[9] Draft UPL Approaches at 4-5.
[10] Draft UPL Approaches at 4.
[11] ORS § 646A.693(1).
[12] Draft UPL Approaches at 4.
[13] *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).

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 aggregators 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 a UPL. Further, 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 approach would plan to use the data to establish a UPL, given such restrictions on use.

- **"Reference Pricing to Therapeutic Alternatives":**[14] Consistent with PhRMA's previous comments on the Board's definition of therapeutic alternatives, PhRMA is concerned that this approach would lead to invalid comparisons being used for purposes of determining UPL amounts, as well as products being erroneously designated as therapeutic alternatives, even where such products are not appropriate options for all patients.[15] PhRMA urges the Board to consider how it would define therapeutic alternatives to avoid misleading comparisons between distinct products and setting prices based on those flawed comparisons.[16] Additional details are needed to provide more specific comments on the approach, as the Board has offered only a vague description of how it would identify a UPL based on whether other drugs are identified as "therapeutic alternatives."[17]

- **"Launch Price Indexing":**[18] With only minimal detail, the Board describes a "launch price indexing" UPL as one potential approach.[19] PhRMA requests the Board provide additional clarification regarding this approach, 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.

- **"Percentage off of WAC":**[20] The document's "percentage off of WAC" approach describes establishing "a UPL that is a fixed percentage off of" a drug's Wholesale Acquisition Cost ("WAC").[21] However, WAC is an inappropriate metric by which to set a UPL for a drug, as it does not account for the rebates, discounts, and other price concessions provided to the government, pharmacy benefit managers, and health insurers by drug manufacturers. Policymakers should be cautious about proposals that attempt to set prices for drugs based only on list, or WAC, price without taking into consideration what patients are likely to actually pay for their medications. Policies like

[14] Draft UPL Approaches at 5-6.
[15] *See* Letter from PhRMA to Board regarding Oregon Prescription Drug Affordability Review: Meeting Materials Related to Affordability Review Rule 925-200-0010 at 2 (Oct. 15, 2023).
[16] Specifically, PhRMA asks that the Board establish a process through regulation for each drug to determine whether it can be appropriately considered to be a "therapeutic alternative." The process should include meaningful engagement with the manufacturer and local medical professionals on potential therapeutic alternatives; 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 alternatives.
[17] Draft UPL Approaches at 5–6.
[18] Draft UPL Approaches at 6.
[19] *Id.*
[20] *Id.*
[21] *Id.*

this ignore the role played by health insurers and PBMs, which dictate the terms of coverage for medicines and the amount a patient ultimately pays. Because WAC does not account for these factors, PhRMA is concerned that this approach would lead to UPLs that are arbitrarily established and could result in serious repercussions for patient access.

- **"Payer Return on Investment (ROI)":**[22] PhRMA is concerned that the Payer Return on Investment (ROI) approach described by the Board would rely on "pharmacoeconomic research on value/cost savings" for determining a UPL, which would incorporate Cost Effectiveness Analyses ("CEA") into the process of establishing a UPL.[23] While this approach does not specify the types of CEAs that the Board would rely on, PhRMA emphasizes that the PDAB Statute prohibits using certain types of CEA, including CEAs that use Quality Adjusted Life Years ("QALYs") "or similar formulas that take into account a patient's age or severity of illness or disability" as part of its affordability reviews.[24] QALYs and other metrics like "equal value of life year gained" ("evLYG") raise 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.[25] For this reason, PhRMA believes that the use of QALYs is inappropriate in setting a potential UPL.

  More broadly, policies 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, "[i]t 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."[26] It has also been widely noted by stakeholders that CEAs discriminate against individuals with disabilities and chronic illnesses by undervaluing their lives.[27] 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."[28]

  Cost-effectiveness analysis can also contribute to perpetuating longstanding inequities in health care and health outcomes. The assumptions used in CEAs disadvantage marginalized populations through use of QALYs, health care costs, as well as assumptions around lost productivity.[29] 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

[22] *Id.*
[23] *Id.*
[24] ORS § 646A.694(4)(a).
[25] 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/.
[26] 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.
[27] *Id.*
[28] P. Neumann, G. Sanders, et al. *Cost Effectiveness in Health and Medicine* (2d. ed., 2017).
[29] Sanjay Basu, Atheendar S. Venkataramani, & Dean Schillinger, *The Risk Of Perpetuating Health Disparities Through Cost-Effectiveness Analyses*, 43 Health Affairs 1165–72 (2024).

Board to reconsider its potential use of CEAs, as these methods result in "systematic underestimation of cost-effectiveness for marginalized populations [and] can contribute to further entrenchment of health inequities."[30]

- **"Budget Impact-Based":**[31] The Board has only offered minimal detail on how this approach would be implemented, so it is difficult to provide meaningful comment on or evaluate the approach.[32] Among other things, PhRMA requests that the Board offer additional information on how the Board will determine the "given budget" that the UPL would be measured against, and how the Board would determine what percentage or threshold of the budget that the expenditure on a particular drug would be capped at. PhRMA notes that payers and other analysts have historically overestimated the potential costs of providing access to new medicines, and the speculative nature of such projections makes them inappropriate to use for UPL-setting.[33]

- **"340B Program-Specific":**[34] The Board is required by SB 192 to provide the Oregon Legislature with an analysis of the "potential savings from or costs of implementing the [UPL] plan with respect to: The state; Insurers, Hospitals, Pharmacies, and Consumers."[35] As the PDAB examines the impact of UPLs on 340B entity reimbursement as part of this analysis, PhRMA asks the Board to consider the breadth of research on the 340B program's impact on state spending, consumer and employer costs, and overall costs to the health care system. Studies have found that the federal 340B program can increase costs to patients, insurers, states, and employers.[36] PhRMA asks that the Board account for the dynamics highlighted in these studies if the Board considers 340B program-specific elements as part of the UPL implementation approach in its SB 192-required savings analysis.

The draft UPL Approaches document also includes high-level bullets describing potential approaches to implementing a UPL in the pharmaceutical supply chain. The assumptions that the Board appears to make about various methods of implementing a UPL demonstrate a lack of understanding of the complexity and interconnected nature of the pharmaceutical supply chain. PhRMA encourages the board to seek input from other supply chain stakeholders, including wholesalers, to better understand the complexity of the pharmaceutical supply chain and the potential impact of any changes to business operations.

While the details provided are minimal, PhRMA provides feedback on what the Board has provided, as follows:

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[30] *Id.*
[31] Draft UPL Approaches at 7.
[32] *Id.*
[33] See, for example, ICER, "ICER Releases Final Report on Use of PCSK9 Inhibitors for Treatment of High Cholesterol," Nov. 24, 2015, *available at*: https://icer.org/news-insights/press-releases/icer-releases-final-report-on-use-of-pcsk9-inhibitors-for-treatment-of-high-cholesterol-2/; Drug Discovery & Development, "Analysis Finds Actual Cost of New Drugs Is Far Less than Predicted," Apr. 25, 2017, *available at*: https://www.drugdiscoverytrends.com/analysis-finds-actual-cost-of-new-drugs-is-far-less-than-predicted
[34] *Id.*
[35] 2023 Or. Laws ch. 466 (Senate Bill 192), sec. 3(2)(b) (codified at ORS § 646A.685) (cleaned up).
[36] *See* Martin R, Illich K. IQVIA, https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf; Liu ITT, Wang J, Sarpatwari A, Kesselheim A, Feldman WB. Commercial markups on pediatric oncology drugs at 340B pediatric hospitals. Pediatr Blood Cancer. 2024; 71:e31158. https://doi.org/10.1002/pbc.31158; N.C. State Health Plan for Teachers and State Employees, "State Treasurer Folwell Finds North Carolina 340B Hospitals Overcharged State Employees for Cancer Drugs, Reaped Thousands of Dollars in Profits Per Claim," https://www.shpnc.org/what-the-health/north-carolina-340b-hospitals-overcharged-state-employees-cancer-drugs

- **"Supply Chain UPL":**[37] The Board's discussion of this effectuation approach seems to imply that a "supply chain UPL" would be simpler to implement than other alternatives.[38] It is unclear what the basis of such an assumption is, as a supply chain UPL could raise operational complexities, and the Board's description of this option fails to address complex methodological issues that this method would inevitably create. For example, in the pharmaceutical supply chain, retail drugs typically move from manufacturers to wholesalers (and to dispensers) throughout the United States based on WAC. Utilizing a different metric (for instance, a UPL) solely for Oregon would present significant complexities that the Board has failed to address.[39] The Board should not underweight the complexity of this approach and how it may not align with how the pharmaceutical supply chain functions.

- **"Rebate UPL":**[40] The discussion of this option notes that "[r]ebate UPLs may be more resource intensive than supply chain UPL for manufacturers and providers or health plans depending on how they are structured."[41] It is unclear how the Board came to this conclusion. PhRMA requests additional information on how the Board would effectuate a UPL using post-sale (retrospective) rebates, including how the Board would ensure that only UPL-eligible patients receive the UPL price. As the Board continues to consider options for implementing the UPL, we strongly encourage the Board to continue to seek robust feedback from supply chain stakeholders, including those with first-hand experience with post-sale price adjustments, about the feasibility of various UPL implementation options.

- **Best Price Impact:** The Board states, as part of its discussion of potential UPL approaches, that "[u]nder current law, a Board should avoid creating a UPL that creates a new Best Price, as it would likely automatically be extended to every state Medicaid Program."[42] PhRMA requests that the Board provide greater detail as to how the Board envisions establishing and implementing various UPLs in a manner that prevents impacting Best Price. As the Board is aware, a UPL might not impact Best Price at the time the UPL is put in place, but that may change, as a drug's Best Price can fluctuate over time as it is reported on a quarterly basis. We encourage the Board to further detail how it intends to avoid setting a new lower Best Price, which as the Board acknowledges, could have nationwide effect. The Board should also allow for further stakeholder comment on this topic.

III. Proposed Policy Recommendations

The Meeting Materials include a series of Proposed Policy Recommendations. Without specific legislative language to reply to, PhRMA offers high-level comments on several of the proposed policy recommendations outlined in the Board's Meeting Materials, as follows:

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[37] Draft UPL Approaches at 8-9.

[38] *Id.* (characterizing the "Supply Chain UPL" approach as "the process used today for most drugs using WAC pricing," while stating that the "Rebate UPL" "may be more resource intensive" for stakeholders).

[39] PhRMA highlights that, for both the Supply Chain and Rebate UPL approaches, the UPL Approach document has provided no details on how it would limit the UPL to its intended scope. There is no mechanism described in the document to ensure that UPL prices are limited to those that are statutorily authorized to be the recipients of that price. As the document notes that "[p]reventing/monitoring for diversion may be easier using rebate UPL" than for the Supply Chain UPL approach, this concern is particularly acute with respect to the Supply Chain UPL approach.

[40] *Id.*

[41] *Id.*

[42] Draft UPL Approaches at 7.

- **"Nine Drugs Per Year" Requirement:** The Board proposes to recommend that the legislature "revis[e] language in SB 844 to remove [the] requirement to review nine drugs and change the language to 'review up to nine prescription drugs.'"[43] The Board indicates the reason for this recommendation is to "ensure that the board focuses on reviewing drugs that are known to cause affordability challenges, based solely on cost or criteria, rather than trying to identify drugs that may or may not cause challenges to the health system or out-of-pocket costs to meet legislative thresholds."[44] The PDAB Statute currently requires that the Board "identify nine drugs … that [it] determines may create affordability challenges … *based on*" its review of the criteria for those drugs.[45] In other words, the Board is tasked with conducting a review of those criteria, and compiling its list of drugs that may create affordability challenges only *after* it has conducted this review pursuant to its statutory and regulatory processes. PhRMA is concerned that the Board's proposal refers to focusing its review on drugs "known to cause affordability challenges" before its review has even been conducted. We request that the Board revise its proposal to avoid presupposing or biasing the outcome of its affordability review process before the review has been conducted.

- **PBM and Insurer Reporting on Accumulators and Maximizers:** The Board proposes to "[i]mplement mandatory reporting on copay accumulator and maximizers programs to ensure equitable access to essential medications and prioritize transparency."[46] As PhRMA has stated in prior comment letters, accumulator and maximizer programs, which are determined by plans and PBMs, contribute to the inability of people in Oregon to afford their health care and medications.[47] Accumulator adjustment programs ("AAPs") block manufacturer cost-sharing assistance from counting towards cost-sharing requirements, including deductibles and maximum out-of-pocket limits. This means patients could be paying more at the pharmacy than they should be. Maximizers involve inflating patients' cost-sharing to fully deplete available cost-sharing assistance before insurance coverage kicks in. PhRMA recommends that the Board also consider expanding this requirement to include Alternative Funding Programs ("AFPs"). AFPs utilize third-party vendors, sometimes in partnership with smaller PBMs, to convince employers to drop coverage of some or all specialty medicines, and assist patients in getting access to those medicines through patient assistance programs intended for uninsured or underinsured patients instead. AFPs are a type of cherry-picking strategy to avoid individuals with higher health risks, such as individuals with pre-existing conditions. These programs disproportionately affect individuals living with chronic and rare conditions who need life-saving specialty medications, which raises health equity concerns.[48]

- **Patient Assistance Program Reporting Expansion:** The Board proposes expansions to patient assistance program ("PAP") requirements by "includ[ing] manufacturer coupons and any other payment that reduces a patient's out-of-pocket cost to fill a prescription" and by requiring reporting

[43] Proposed Policy Recommendations at 1.
[44] *Id.*
[45] ORS § 646A.694(1).
[46] Proposed Policy Recommendations at 2.
[47] *See* Letter from PhRMA to Board regarding Oregon Prescription Drug Affordability Board: April 17, 2024 Agenda and Meeting Materials Related to Affordability Reviews (Apr. 13, 2024); Letter from PhRMA to Board regarding Oregon Prescription Drug Price Affordability Review Regulations: Selecting Prescription Drugs for Affordability Reviews (925-200-0010) and Conducting an Affordability Review (925-200-0020) (May 14, 2023).
[48] *See* National Black Caucus of State Legislators, Resolution HHS-24-37, *available at*: https://nbcsl.org/wp-content/uploads/2023/12/Resolution-HHS-24-37.pdf.

on all patient assistance programs that manufacturers maintain or fund.[49] Requiring manufacturers to submit additional confidential and proprietary information, such as data on all patient assistance programs that a manufacturer has offered or funded for any drug, exacerbates existing legal concerns with the Oregon transparency law.[50]

While the Board included in its 2022 policy recommendations the argument commonly made by insurance carriers with respect to patient assistance programs, such arguments do not withstand scrutiny. Insurers have propagated the idea that manufacturer coupons (also referred to as "cost-sharing assistance") pushes patients to brand medicines when generic medicines are available. But the data show that less than 1% of coupons are used on products for which a generic is available.[51] For this small percentage of the market, a patient may use cost-sharing assistance for brand medicines rather than the generic version because their doctor prescribed that brand medicine based on their specific needs. It is not clear how this additional reporting requirement, which will a create significant administrative burden for the state, would provide useable information to the Board.[52]

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On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the information provided in the Meeting Materials, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.
Sincerely,

Dharia McGrew, PhD
Director, State Policy
Sacramento, CA

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[49] Proposed Policy Recommendations at 2.
[50] *See* PhRMA v. Stolfi, --- F. Supp. 3d ----, 2024 WL 1177999 (D. Ore. Mar. 19, 2024), appeal pending, No. 24-1570 (9th Cir. filed Mar. 15, 2024).
[51] IQVIA. "Evaluation of Co-Pay Card Utilization. Patient savings programs, in particular co-pay card programs, continue to bear scrutiny across the industry." https://www.iqvia.com/locations/united-states/library/fact-sheets/evaluation-of-co-pay-card-utilization.
[52] PhRMA also notes that manufacturer support for charitable foundations typically is not directed to supporting a specific drug, given that federal guidance from the U.S. Department of Health and Human Services Office of Inspector General limits such direct support. Rather, donations are made by a manufacturer to a charitable foundation, and the foundation retains the authority and discretion to apply such support as they see fit (which may include providing cost-sharing assistance for multiple drugs from different manufacturers or providing financial support to patients for other, non-pharmaceutical products or services). Manufacturers retain no influence or control over how the charity administers its assistance program.

Global Coalition on Aging

Policy Brief: The Risks of Prescription Drug Affordability Boards and the Importance of Innovation for Healthy Aging and Health Equity

September 2024

Preface

Roundtable Overview

On June 6, 2024, **The Global Coalition on Aging** (GCOA)[1] hosted an expert roundtable discussion entitled "The Risks of PDABs and Importance of Innovation for Healthy Aging and Health Equity." The roundtable brought together cross-sectoral experts who represent patients, caregivers, academia, biopharmaceutical innovators, and business communities to discuss PDABs, UPLs, and the risk they pose to the innovation that is needed to safeguard healthy aging and improve health equity.

This brief builds on two previous GCOA Alliance for Health Innovation policy briefs—the first from June 2023 on healthy aging and innovation and the second from September 2023 on the intersection of healthy aging, innovation, and oncology.

This policy brief was generated by the Global Coalition on Aging and highlights participant insights from the roundtable discussion. The brief is intended to raise awareness of the unintended consequences of PDABs and provide policy recommendations to ensure healthy aging for all. The comments and quotes made by participants contained throughout this brief may not represent the views of the entire group.

Roundtable Participants

Tiffany Westrich-Robertson

Chief Executive Officer & Co-Founder, International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)

Brian DuVal

Patient Advocacy Manager, AiArthritis

Adina Lasser

Public Policy Manager, Alliance for Aging Research

Laura Bonnell

President, The Bonnell Foundation

Meredith Marden

Analyst, Community Health Programs and Public Policy, The Boomer Esiason Foundation (BEF)

Maxine Miller

Coordinator of Policy & Advocacy, Cancer Support Community (CSC)

Amy Goodman

Vice President and Counsel for Policy + Advocacy, Colorado BioScience Association

Carl Schmid

Executive Director, HIV+Hepatitis Policy Institute

India Peterson Valentine

Vice President of State Government Affairs, Gilead Sciences

Melissa Mitchell

Executive Director, Global Coalition on Aging (GCOA)

Scott Bertani

Director of Public Policy, HealthHIV

Desmond Banks

Policy Director, National Black Caucus of State Legislators (NBCSL)

Gretchen C. Wartman

Vice President for Policy and Program, National Minority Quality Forum (NMQF)

Candace DeMatteis

Policy Director, Partnership to Fight Chronic Disease (PFCD)

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Introduction

Across the United States, many patients and policymakers are increasingly concerned about rising healthcare costs. While much of the focus has centered recently around price-setting provisions in the Inflation Reduction Act (IRA), a growing number of states have advanced or proposed policies to review the cost of prescription medicines within their state lines. Many of these policies have taken the form of Prescription Drug Affordability Boards, commonly known as PDABs.

Key Terms[2]

Prescription Drug Affordability Board (PDAB): A state government-appointed board that has the authority to review prescription drug costs and determine if they present an affordability challenge for patients.

Upper Payment Limit (UPL): A ceiling amount that a healthcare payer (e.g., Medicaid, commercial insurer) can reimburse for the purchase of a medication that a PDAB deems to be unaffordable.

PDABs are often described to legislators and constituents as a way to lower costs for patients in their state, often taking the shape of a third-party board of appointed members who periodically assess the "affordability" of specific drugs.[3] While PDABs are often positioned as a solution to lower costs for patients, in practice there are significant flaws in the current approach. It's critical that boards focus on methods to directly reduce out-of-pocket costs for patients, informed by meaningful engagement from impacted communities throughout the affordability review and decision-making processes. In doing so, boards must ensure they safeguard patient access to medicines and do not threaten to institute barriers to care that could ultimately lead to higher patient costs. Despite patients voicing concerns around potential consequences of PDAB efforts, the implementation and review processes to advance these boards in the first few states to do so have failed to address these critical considerations.

Four Critical Patient Concerns With PDABs

This brief will highlight key concerns raised by patients surrounding PDABs and their ability to set prices for prescription medicines, and explore perspectives, findings, and resources that highlight their impact on access, equity, and healthy aging.

1 **First, PDABs have been provided with a singular tool to set prices for drugs they deem unaffordable: an upper payment limit (UPL).** A UPL is a ceiling amount that a healthcare payer, such as Medicaid or a commercial insurer, can reimburse a provider or clinic for the purchase of a medication that a PDAB deems to be unaffordable. UPLs are more aligned with cost containment strategies for states rather than lowering patient costs at the pharmacy counter. Five years after the establishment of the first PDAB, patients are still waiting for the board to deliver on their promise to lower patient out-of-pocket costs for prescription drugs. This is also the case in other states that have established a PDAB since then.

2 **Second, PDABs' review processes can harm the patients who need access to drugs and therapeutics the most, introducing significant health equity concerns.** States such as Colorado and Maryland have selected drugs to undergo "affordability reviews," which disproportionately impact patients who are managing hard-to-treat conditions and aging populations. As a result of PDAB efforts in these states, the very medications developed and brought to market, which are currently demonstrating efficacy to enable us to lead healthy and productive lives, are subject to arbitrary cost review processes with unproven benefits to patients.

Across states with prescription drug affordability review initiatives such as PDABs, those patients enrolled in public plans – Medicaid populations in particular – will be disproportionately impacted, which threatens to further widen health disparities within the US population.[4]

- **Relative to White children and adults, Medicaid covers a higher share of Black, Hispanic, and American Indian and Alaska Native (AIAN) children and adults.**[5]
- **Medicaid covers 40% of non-elderly adults with HIV in the U.S.**[6]
- **In 2021, Medicaid covered four in ten children, eight in ten children in poverty, one in six adults, and almost half of adults in poverty.**[7,8,9,10]

Medicaid beneficiaries are more likely to have a chronic disease compared to patients not enrolled in Medicaid.[11] Should PDABs 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 such as heart disease, cancer, and HIV.

3 **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.

4 **Fourth, PDABs are established to improve affordability for patients. However, in practice, UPLs are not a proven tool to reduce patient out-of-pocket costs. The debate within PDABs centers around improving affordability for patients but boards must mitigate the potential for patient risk and harm to health outcomes in the name of cost containment for states.** For patients, affordability differs depending on an individual's health status and numerous other factors in their lives. Despite access to life-saving and life-extending medications hinging upon PDABs' definition of affordability under the current model, boards have largely been unable to strictly define this criteria. 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. Prior to this, the Board was undertaking drug reviews without a clear definition of the very variable they were seeking to assess.

PDABs are a short-sighted, often politically-driven, policy primarily focused on cost containment for the state rather than meaningful benefits for patient communities. All too often, PDABs are implemented in a way that ignores the long-term implications of drug price setting, such as through the use of a UPL, in favor of more immediate savings in a state's budget.

Good health policy must result in improved health outcomes for underserved and vulnerable populations, and to date PDABs have not met that objective. The current landscape, including input from patients, providers, and other impacted stakeholders, makes clear that these boards must do more to engage trusted partners and impacted populations to ensure patients benefit.

> The mission of NMQF is to reduce patient risk by assuring optimal care for all. NMQF's vision is an American health services research, delivery, and financing system whose operating principle is to reduce patient risk for amenable morbidity and mortality while improving quality of life. PDABs with UPL authority risk assigning a higher valence to the costs of prescription drugs rather than the assurance of best possible outcomes for all patient cohorts."

Gretchen C. Wartman

Vice President for Policy and Program, National Minority Quality Forum (NMQF)

Table 1: PDABs across the United States*

8	Eight states have enacted PDAB legislation.[1] • Four states (CO, MD, MN, WA) have PDABs that have or have the power to request authority to set a UPL.[12] • Four states (ME, NH, NJ, OR) have PDABs that review the affordability of prescription drugs but do not have the authority to set a UPL.[13] Oregon's legislature is set to vote on this issue in 2025.[14]
17+	During the 2024 state legislative sessions, at least seventeen states were considering PDAB legislation.[15]
$700,000	Colorado and Maryland, the two states furthest along in PDAB implementation, had start-up costs over $700,000.[16,17]
3	Just three drugs have been deemed "unaffordable" following a PDAB review.
0	To date, there have been zero dollars worth of patient savings as a result of PDABs.

**As of September 2024*

[1] For this metric, states with "enacted PDAB legislation" includes only those states with PDABs or councils currently in place which review drugs purchased by both public and private insurers. This excludes New York and Massachussetts, both of which are engaged in affordability review initiatives focusing solely on drugs purchased by their corresponding Medicaid Agencies, and Vermont, which currently has a Board that is directed to study existing PDABs and develop a similar initiative in the state.

Analysis & Impact of UPLs

The only tool many established PDABs have to lower the costs of medications is a UPL, which may harm the very patients PDABs were created to protect.

When used by PDABs, **UPLs set a maximum amount that a payer can reimburse** providers for a drug they purchase.

→

UPLs lead to lower reimbursement rates after the provider has already purchased and dispensed the medication.

→

Providers may be forced to not purchase the drug for financial reasons, leaving patients without access to critical medications.

→

Patients may be forced to switch to a **less effective treatment plan or even abandon a provider-recommended treatment plan.**

> **"UPLs do not ultimately impact the bottom line at the pharmacy for patients."**
>
> Desmond Banks, Policy Director, National Black Caucus of State Legislators (NBCSL)

UPLs do not impact the purchase price of a medicine; instead, they set a limit on the amount that a provider responsible for stocking, storing, and administering the medicine can reimburse for that treatment.[18] When providers, such as pharmacists, are faced with these lower reimbursement rates, they are forced to make difficult decisions – either prescribe a treatment that may not be their first-line recommendation for a patient to ensure reimbursement at the adequate rate or take a financial loss on a treatment that they know is preferred for their patient.[19]

The National Alliance of State Pharmacy Associations (NASPA) identified five key risks incurred through the establishment of PDABs and UPLs in states, particularly as they relate to pharmacy reimbursement.[20] NASPA concerns include:

- Reduced reimbursement rates
- Impacts on pharmacy cash flow
- Increased administrative burden
- Impacts on patient care
- Incentives for generic substitutions

With local and independent pharmacies serving as essential community hubs for healthcare resources and information, and frequently operating with thin profit margins, negative consequences as a result of UPLs threaten these institutions' continued ability to keep their doors open and provide care to the patients they serve.

These impacts extend to independent providers, such as clinical oncologists, dermatologists, and rheumatologists, who have expressed concerns about the potential consequences of UPLs. Such consequences, including lower reimbursement rates, stand to negatively impact providers' ability to pay staff, stock and administer critical treatments, and keep their doors open to provide care to their patients.[21]

A draft resolution introduced by the Association for Clinical Oncology, American Academy of Dermatology Association, American College of Mohs Surgery, American Contact Dermatitis Society, and the American College of Rheumatology in April 2024 calls for the American Medical Association (AMA) to conduct a study to determine how PDAB-enacted UPLs impact reimbursement for physician-administered drugs and patient access.

> "...state PDAB legislation that includes UPL authority often lacks language that would allow physcians to seek reimbursement for storage and handling of a physician-administered drug subject to a UPL." [22]
>
> American Medical Association House of Delegates

> "It is not the role of the government, let alone a state government, to get involved in the list price of the drug. It's just too complicated for a state to know everything about the ecosystem for a drug price."
>
> Carl Schmid
>
> Executive Director, HIV+Hepatitis Policy Institute

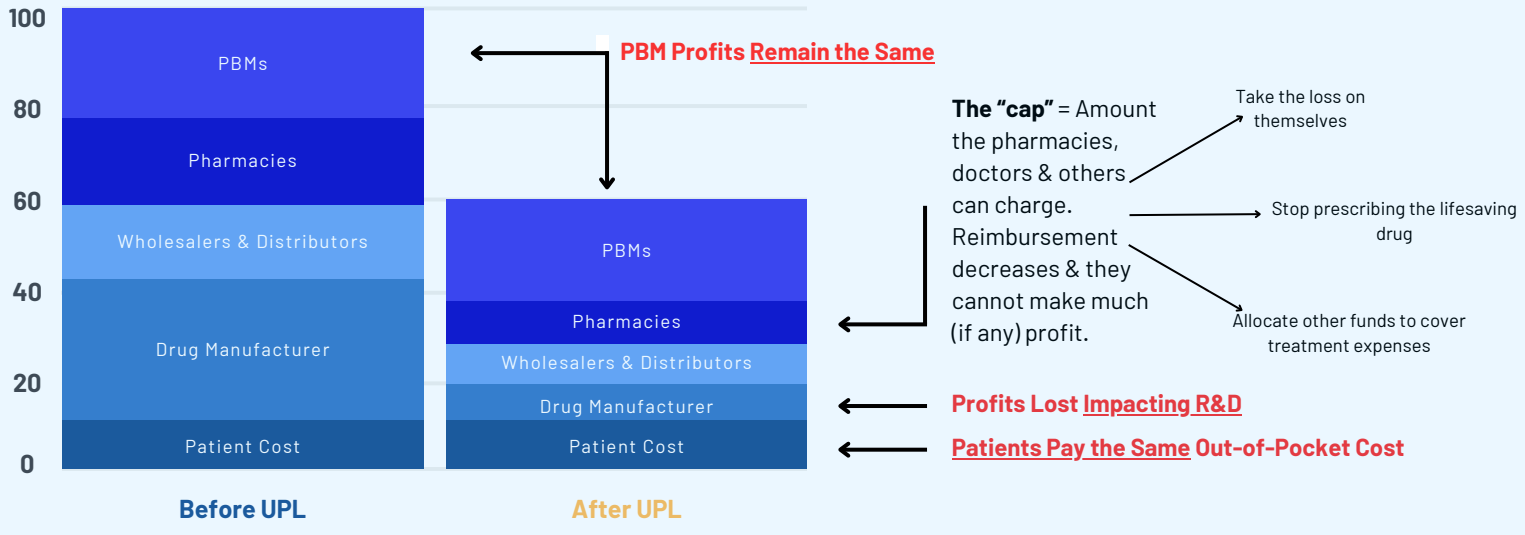
UPLs also fail to address one of the significant drivers of healthcare costs – pharmacy benefit manager (PBM) practices. PBM profits are unaffected by UPLs. By placing caps on medication reimbursement rates, not only are patients not saving money at the pharmacy counter, but providers are forced to stop prescribing recommended treatments, and research and development efforts are negatively impacted.

What is a Pharmacy Benefit Manager (PBM)?[23]

PBMs are third-party, for-profit entities that act as middlemen between pharmaceutical companies, payers (both public and private), and pharmacies. They have a direct impact on both drug prices and patient access because they both create and update formularies of preferred drugs, and negotiate the prices, rebates, and discounts from manufacturers while also determining the prices that insurers pay and reimbursement rates for pharmacies.

PBMs generate profit in three primary ways: through administrative fees paid by insurers for their services, by capturing some of the savings from the rebates they negotiate from drug manufacturers, and through spread pricing, where PBMs charge a higher payment from insurers for a drug than PBMs pay to pharmacies for the same drug. In the latter two cases, PBMs keep these differences as profit, driving up prices for patients at the pharmacy counter.

Figure 1: PBM Mechanisms[24]



Source: The National Black Caucus of State Legislators

Impacts Across the Healthcare Ecosystem

The pharmaceutical supply chain—responsible for bringing treatments from the lab to patients—is a complex ecosystem that relies on alignment and cooperation between all players within it. If just one link in the healthcare supply chain is impacted, patients will bear the brunt of those changes as the end users.

Both the model legislation that many states have enacted and new PDAB legislation under consideration empower the governor-appointed board members with the ultimate authority to determine access to treatments that patients rely on to stay healthy and alive. In several cases, patient advocates have voiced concerns about a lack of knowledge from boards about a specific treatment or therapeutic area. As these state boards make decisions that significantly impact patient lives and health outcomes, board members must be equipped with tools and knowledge informed by stakeholders across the supply chain to mitigate broader, system-wide impacts.

With zero evidence to suggest that implementing a UPL through a PDAB can lead to meaningful cost savings for patients—and research pointing to the contrary—states must consider additional methods to meaningfully lower patient costs.

> “Upper payment limits will never help the patient. The cost will only help the insurance companies. Savings are never going to reach the patient and it will impact future research and development.”
>
> Laura Bonnell
> President, The Bonnell Foundation

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.[25]

- *Most surveyed payers (five of six) did not anticipate that UPL-related savings would be passed on to patients in the form of 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 UPL drugs and competitors in the therapeutic class are likely to see increased utilization management should the UPL restructure new benefit designs.

> **"In response to patients expressing concern that board decisions may impact our access to treatments, some of the PDABs expressed that this whole exercise is about affordability, not about patient access to treatments."**
>
> Tiffany Westrich-Robertson, Chief Executive Officer & Co-Founder, International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)

The Case Against PDABs & UPLs

Patient Access Implications

Patients, advocates, providers, industry members, and other stakeholders have come forward to share their perspectives and voice their concerns about the impact PDABs and UPLs could have on patients' ability to access and afford prescription medications. While on the surface PDABs may sound promising for patients, they are often implemented in the name of politics under the guise of patient access.

> **"PDABs raise several alarm bells when it comes to access. They're focused on one thing which is cost and often at the expense of access and innovation for patients."**
>
> Derek Flowers
> Executive Director, Value of Care Coalition

There is an inequitable approach to addressing cost, given that affordability parameters vary by patient, region, disease state, and circumstance. Many PDABs do not define affordability or make clear the criteria they will use to determine whether or not a drug is affordable. This lack of clarity introduces significant risks to health equity, furthering the risk that where someone lives will determine their health status and access to medicines by creating greater variance state by state.[26]

> Colorado has a really small cystic fibrosis (CF) community, but it is very vocal. There wasn't anyone on the Colorado PDAB who knew more than the CF community. However, that advocacy was challenging because not everyone on the Board was receptive. They didn't even speak to their rare disease advisory council until one of us suggested it."

Laura Bonnell,
President, The Bonnell Foundation

> Through the Colorado PDAB process, we saw the power and the importance of patient advocacy. The CF community really galvanized and spoke up for themselves."

Meredith Marden,
Analyst, Community Health Programs and Public Policy, The Boomer Esiason Foundation

Many patients have felt excluded by the PDAB process. PDABs largely lack patient representation and tend to be monolithic in other ways.[27] Further, opportunities for patient input are few and far between and are often communicated at the last minute – in some cases, only a few hours before a meeting. For many, participation is not feasible on such short notice, especially when the time allotted to a speaker can be as little as a couple of minutes.

> **"PDABs are a buzzword solution that sounds like it will make prescription drugs less expensive. But really, we know when you pull up the hood and look at all the moving parts, they really threaten patient access near term, and innovation long term."**

Candace DeMatteis, Policy Director, Partnership to Fight Chronic Disease (PFCD)

1 in 3

One in three cancer patients and caregivers reported experiencing treatment delays due to a provider being forced to wait for approval from an insurer for a medication or test as a result of a utilization management tactic known as prior authorization.[28]

PDABs further threaten patient access through the threat of increased utilization management protocols and other practices implemented by PBMs and insurers. With these practices, like step therapy, a patient's provider-recommended course of treatment can be delayed. In contrast, the patient must first attempt cheaper therapies that must fail before a new regimen can be tried. Further, many metrics utilized in these practices and PDAB guidelines are discriminatory or misleading by design – such as value assement frameworks (e.g., quality-adjusted life years (QALYs)) and international reference pricing.

Innovation Implications

> **"Controlling healthcare costs is undeniably important...but fostering an environment that encourages the development of new treatments is equally vital."**

Scott Bertani
Director of Public Policy, HealthHIV

12+ years

The timeline to bring a drug from a test tube to the market can take 12 years and often much longer.[29]

Beyond the more immediate impacts on patients, PDABs and UPLs threaten to create negative consequences for medical innovation, which will have a downstream negative impact on patients looking to manage symptoms and live longer and healthier lives.

If pharmaceutical companies cannot recoup the cost of their research and development, economics dictates that they will not be able to continue producing that drug and others. A successful drug that comes to market for a company does not only provide for the investment in its own development—it also provides for the many drugs that never make it to market and in which billions have been invested. This externality is not considered in most measures of a drug's profitability, and if it were included, this metric would likely lower substantially.

> I want people to have access to low-cost drugs, but if it impacts R&D, then you will have collateral damage, which equals loss of life. How do we get a solution where we both win – for the patient?"

Maimah Karmo,
Chief Executive Officer & Survivor, Tigerlily Foundation

> It is so important for pharma companies to invest in rare diseases, and they're not going to if they can't make money. It is a business, making money isn't a bad thing. We can't hate pharma. We can't hate the insurance companies. We all have to work together."

Laura Bonnell
President, The Bonnell Foundation

Recently, the CEOs of three large pharmaceutical companies testified in front of the United States Congress regarding drug pricing, where they spoke to the enormous costs of bringing a drug to market, the average being more than $2 billion.[30] Additionally, while Americans may face higher drug prices than those in other countries, they enjoy faster and greater access to life-saving therapies.

> **Health innovation requires significant capital and a stable, predictable regulatory environment to bring patients new medicines. Investors want to do everything they can to avoid risk. The threat of UPLs creates substantial uncertainties and challenges, making it harder for companies to raise capital to conduct research and development for new medicines. Setting UPLs could have serious unintended consequences not only on patients' access to life-saving and life-changing medicines, but also on the feasibility of bringing new, innovative therapies to patients with unmet medical needs."**

Amy Goodman
Vice President and Counsel for Policy + Advocacy, Colorado Bioscience Association

The positive contributions that biotech and pharmaceutical companies have on local, state, and national economies is also often overlooked. Smaller biotechnology companies do a significant amount of drug development for rare diseases, facing high start-up costs that must be financed privately, such as by venture capital.[31] It is only after a drug delivers promising results that a small company can attract more stable financing, meaning that this critical research area is highly risky for potential investors. This has a huge impact on smaller communities that are often buoyed by biotech start-ups – which bring jobs and positive economic contributions. If these companies cannot operate due to a risky financial environment, there will also be a disproportionate negative impact on rare disease research.

Healthy Aging Implications

The impacts of PDABs and UPLs on access and incremental innovation threaten to directly impact patients' ability to age healthily and live longer lives.

The longevity we enjoy today is due in no small part to access to innovative treatments. Reduced access threatens healthy aging. By 2054, 84 million adults ages 65 and older will make up an estimated 23% of the U.S. population, many of whom will be living with at least one medical condition requiring intervention.[32]

> “Advances in HIV medication have historically transformed the prognosis and quality of life for individuals living with HIV, and it turned a once fatal disease into a manageable condition with access. Continued progress in the field: It is essential for addressing emerging challenges. That is about drug resistance, coinfections, and the need for more accessible treatment. As we talk about upper payment limits, they significantly slow the pace of innovation, coming from a field that lies on continual advancements – I am a glowing example of that, living with HIV for 30 years. Without the treatments, I, too, would not be here.”

Scott Bertani
Director of Public Policy, HealthHIV

Case Study: Implications of PDABs on Treatments for HIV & Unique Patient Population Needs

To avoid instituting additional barriers to treatment and care, individual patient and caregiver experiences must be taken into account through meaningful engagement tailored to specific populations. The Colorado PDAB found that a reviewed treatment for HIV is not unaffordable, in part due to the state, federal, and manufacturer-provided programs that make such treatments accessible and affordable to those who need them.

A white paper from HealthHIV highlights the need for PDABs to meaningfully consider the unique needs of specific patient populations while examining the role of patient assistance programs, such as the 340B Drug Pricing Program, in linking patients with care – particularly as it relates to HIV.[33]

> *"PDABs are meant to make prescription drugs cheaper, but their actual impact on what people pay in the real world can vary. This highlights the need to balance cost-cutting carefully, keeping healthcare choices open while supporting critical programs like 340B."*

Community Access National Network (CANN) developed a resource to highlight the specific impacts of PDABs and UPLs on efforts to end the HIV epidemic in the United States.[34]

The 340B program was established by Congress in 1992 with the intention of enabling hospitals and clinics to provide care to low-income and uninsured patients.

CANN shed light on the impact of UPLs on providers and patients as it relates to 340B:

- *340B's value is found in the "spread" between the reimbursement rates and a reduced acquisition cost by way of drug manufacturer 340B rebates*
- *Reducing reimbursement rates by way of an "upper payment limit" will reduce the value realized by 340B rebates*
- *Providers end up with less money, which means they can afford to fund less services*

If PDABs and UPLs lead to lower reimbursement rates for clinics that provide lower-cost care, they threaten access to critical HIV treatments for patients and the ability of these providers to keep their doors open. PDABs must ensure that their efforts do not negatively impact ongoing policies and programs that are making treatments, such as those for HIV, more accessible to those who rely on them to stay healthy and live longer.

A Framework for Patient, Caregiver & Provider Engagement

In the states furthest along in implementing their PDAB—Colorado and Maryland—advocates and stakeholders have voiced concerns about a lack of transparency within the PDAB process and a lack of engagement from those who stand to be most impacted by such policies and decisions.

> **State PDABs and the implementation of UPLs do not account for the complexities of the intricate healthcare ecosystem that facilitates treatments from manufacturers to patients. One single state doesn't have the ability or insight beyond their own borders to bring together the data and input required to mitigate system-wide ripple effects that ultimately stand to negatively impact patients."**
>
> India Peterson Valentine, Vice President of State Government Affairs, Gilead Sciences

A Case Study in Drug Selection

Consider the process in Maryland. In February 2024, the Maryland PDAB received an initial list of over 2,000 prescription drugs eligible for a cost review based on the Board's rules and regulations. In March 2024, the Board selected eight drugs for a cost review. However, unlike in other states, this process was not transparent, with the list of eligible drugs only being shared with Maryland Board members.[35] This left patients wondering whether a treatment they rely on to manage their health might be put out of reach.

The healthcare supply chain is incredibly complex and spans far beyond just one state's borders. In many cases, states lack the knowledge and ability to control for impacts throughout the supply chain, and the visibility to consider all relevant data regarding a specific treatment, given the various factors that impact this delicate process outside of one state. In an effort to better understand what affordability truly means, members of the Oregon PDAB unanimously voted during a June 2024 meeting to "pause" their work of selecting drugs for affordability reviews until 2025. The pause is intended to facilitate alignment around terms and processes central to their efforts, including data collection around the net prices of treatments and a definition of affordability.[36]

> We need to keep working to establish a framework of patient engagement throughout the entire implementation and policy-making process."

Maxine Miller,
Coordinator of Policy & Advocacy,
Cancer Support Community (CSC)

How do we ensure patients are at the table? Even as I'm working on the PDAB issue, I am often the only patient in the room, and the only Black patient in the room. So it is my job to bring this work to people who are on the ground, who are like me.

Maimah Karmo,
Chief Executive Officer & Survivor,
Tigerlily Foundation

Barriers to Participation

Across states, patients and other concerned stakeholders have demonstrated that the onus is put on them to engage with the PDAB, with boards failing to recognize the time, administrative, and financial barriers that may hinder patients' ability to attend a meeting or develop remarks to submit to the board. PDABs and staff must empower patients and caregivers to bring forward their stories and voice any concerns or questions while also proactively and meaningfully engaging key stakeholder communities throughout each stage of the process to mitigate unintended consequences on treatment access.

Accessible Engagement

> We have to understand how we prioritize within communities, within academia, and within research what their priorities and needs are. We are a very trusted voice in our community, and we are the voice of members of our community. We've established a number of community advisory boards and a community task force that go out and talk about what we need to inform people of, and various topics, that we make sure to connect to the existing healthcare system. Aligning ourselves with existing partnerships and existing organizations are very key strategies. It is imperative to sustain our efforts in those community settings and other academic institutions as well."
>
> Maisha Standifer, Director, Population Health, Satcher Health Leadership Institute, Morehouse School of Medicine

> The only real way to make a difference is to build in and require engagement.
>
> Sara Traigle van Geertruyden, Executive Director, Partnership to Improve Patient Care (PIPC)

Meaningful patient engagement with policies that impact their health outcomes and treatment access cannot be limited to a 90-second public comment period from a limited and homogenous group of patients. PDABs must ensure broader and more accessible engagement with the patient communities their policies and price limits stand to impact most to mitigate severe consequences on efforts to advance health equity and healthy aging.

In some cases, PDABs consult with an advisory council made up of representatives from various stakeholder communities, sometimes including patients. However, these councils have little to no authority over the PDAB and in many cases, their recommendations to the board have been disregarded and rejected. There is missed opportunity to provide a more meaningful consultation to all stakeholders, including patients, families, and caregivers.

Best Practices for Meaningful PDAB Engagement

Patients must be considered the experts on the treatments being considered and reviewed by PDABs to address affordability challenges while avoiding negative impacts on access. Patients can serve a critical role in educating PDABs and advisory boards once meaningfully engaged and recognized throughout the process.

PDABs must carefully consider the short- and long-term impacts of setting price limits on medicines to mitigate unintended consequences on patient health outcomes, healthy aging, and health equity.

The impact on treatments for rare diseases must be taken into account by PDABs during affordability reviews, given the small size of the patient population that treatments for rare or orphan conditions serve and the unique structure of patient assistance programs for those medicines.

PDABs cannot treat engagement surrounding each drug considered or selected for affordability review as a one-size-fits-all process. For certain conditions, such as HIV, there continue to be intersectional impacts and stigma surrounding a diagnosis or treatment, which may create further barriers to engagement with the PDAB process.

Every patient and caregiver has a unique perception of the value of any given treatment. Considering what patients value in relation to their prescription medicine will be critical as PDABs conduct affordability reviews and determine whether treatments are ultimately unaffordable.

- *Examples of factors that influence this include the cost of treatment compared to the financial, administrative, and time burden of increased hospital visits, decreased ability to work, etc., due to a lack of access to treatment.*

Data collected and considered as part of any affordability review must be comprehensive and relevant to the population impacted by any potential price-setting policy. PDABs can engage patients in the data collection by developing surveys to accurately and effectively capture patient perspectives and input and proactively empower patients to participate in the survey.

Patients are willing to engage with PDABs and work with boards throughout the implementation process. By engaging patients in meaningful and ongoing ways, PDABs can work to reduce the risk of adverse consequences on access in the long term.

KEY TAKEAWAY:

Policymakers interested in reducing out of pocket costs for patients must consider the negative impacts in policy decision making. Furthermore, incorporating diverse patient voices and perspectives into the PDAB engagement process and ongoing feedback loop surrounding the affordability review of any specific prescription medication is essential to mitigate unintended impacts on patients and other disruptions to the complex pharmaceutical supply chain.

Conclusion

Existing PDABs and states across the country that are considering the establishment of such boards must consider the broader consequences of implementing UPLs on patient access, innovation, and healthy aging before advancing any such efforts. Further, existing PDABs must provide transparency into the affordability review process, methodologies used, and any implementation of UPLs to ensure patient and other stakeholder concerns about access and innovation are carefully considered and addressed.

By meaningfully engaging patients and other impacted stakeholders – and heeding their concerns – around board decision-making processes and the use of UPLs, PDABs can mitigate widespread short- and long-term negative consequences on access and affordability in their state and beyond for prescription drugs that are proven to support the health and well-being of vulnerable communities and healthy aging.

The growing body of evidence on PDABs, alarms from diverse patient communities, and processes that have played out in states with such boards demonstrates the significant risk that PDABs pose and why the patient voice must always be front and center in decisions that impact treatment access and health equity.

Key Resources

HealthHIV: Prescription Drug Affordability Boards (PDABs) and Upper Payment Limits (UPLs) Impact on Patients, Drug Pricing, and Innovation

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Community Access National Network (CANN): PDABs Action Center, PDABS: A Threat to Ending the HIV Epidemic?

AiArthritis: Ensuring Access through Collaborative Health (EACH) & the Patient Inclusion Council (PIC)

NBCSL: NBCSL Region X Meeting PDABs Panel Presentation

Endnotes

1. The Global Coalition on Aging (GCOA) Alliance for Health Innovation aims to establish awareness of the importance of innovation in achieving healthy aging through investments, policy reforms, and strategic partnerships – both for the value to patients and for health system sustainability. GCOA's Alliance for Health Innovation is made possible through support from Gilead Sciences.

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National
Multiple Sclerosis
Society

August 14, 2024

Oregon Division of Financial Regulation
Oregon Prescription Drug Affordability Board
350 Winter St. SE
Salem, OR 97309

RE: National Multiple Sclerosis Society, Upper Payment Limits & Affordability Review Process comments

Dear Members of the Oregon Prescription Drug Affordability Board:

Thank you for taking the time to consult all stakeholders and for the opportunity to provide direct comments regarding upper payment limits. This letter is to provide clarity to the National Multiple Sclerosis Society (the Society) position related to upper payment limits and the affordability review process.

UPLs related to copays and MS infusible products
The Society views the establishment of upper payment limits (UPL) as creating the potential to lower out of pocket costs for patients. High out of pocket costs are typically due to co-insurance, which is when the patient must pay a percentage of the wholesale acquisition cost (WAC), or list price, as opposed to a flat copay amount. This is especially true for MS disease-modifying therapies (DMTs). A lower UPL would in turn create lower out-of-pocket costs for those who must pay co-insurance.

One important caveat to this is that for infused medications, which include several of the most prescribed MS DMTs, patients face significant additional costs from the administration of, and additional services attached to, an infused product. These additional costs can include infusion center fees, hospital or provider facility fees, additional provider and specialist fees, and ancillary medication charges for side effects or infusion management. A UPL would not affect this additional expense and, as a result, might not substantially lower patient out-of-pocket costs for the overall infused medication services.

Affordability review process
The Society sees affordability reviews as key to partially understanding prescription drug pricing within the broader healthcare system. We recommend any affordability review process include all available sources of data so long as the scientific methodology is sound, and the sources are considered both reputable and knowledgeable. These sources may include but not be limited to; all-payer databases, state-produced reports, and data and reports from other state reviews. Additionally, the long-term costs associated with MS DMTs vs. the shorter-term costs of other medications should be considered when discussing affordability.

National
Multiple Sclerosis
Society

When undertaking the review, the Society recommends considering additional factors which could influence affordability including:

- Average monetary price concessions, discounts, or rebates the manufacturers provide to health plans and PBMs (expressed as a percentage of WAC),
- Price of therapeutic alternatives sold in the Washington State,
- Average cost to state health plans based on typical patient access to a drug,
- Impacts on patient access resulting from cost of the drug and insurance benefit design,
- Current or expected dollar value of the drug-specific patient access programs supported by the manufacturer,
- Average patient's copay or any other cost-sharing amount, and
- Any other information the manufacturer would like to provide or other factors the board determines it may need.

The Society knows that the price of the medication is but one aspect of what makes access to these high-cost prescriptions out of reach for many people with MS and other conditions. The Society will continue to look at the entire healthcare system and encourages legislatures and entities like the Oregon Prescription Drug Affordability Board to do likewise.

Respectfully,

Seth M. Greiner
Senior Manager, Advocacy
Seth.Greiner@NMSS.org

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

August 16, 2024

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Public Comments on Cost Reviews and Upper Payment Limits

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 applaud the board's recent decision to pause affordability reviews and work on improving the affordability review process for the remainder of 2024. We appreciate the board's willingness to acknowledge the complex nature of cost-reviews, the significant undertaking with which the board has been tasked, and the stakeholder feedback outlining concerns with the process.

We look forward to continued engagement with the board to improve the cost-review process to ensure it ultimately benefits the patients who rely on the drugs under review. 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.

Cost Reviews and UPLs Could Compromise Patient Access to Medications

While we applaud the board's commitment to supporting patients and lowering the costs of prescription medications, we are concerned that cost reviews and upper payment limits (UPLs) can further complicate an already complex healthcare marketplace and result in worse outcomes for patients.

At their core, cost reviews necessitate selecting individual drugs for review and implementing market interventions for the selected drugs. This alone puts PDABs in a position of picking winners and losers between drugs and within the broader population of Oregon patients. Individual drug reviews unnecessarily create inequities between patient populations.

While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies. This eventuality was outlined by the Centers for Medicare and Medicaid Services in their May 3, 2024 Guidance on Medicare Drug Price Negotiation, "CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs."

Additionally, many of the drugs under cost review are administered directly by physicians under a "buy and bill" model. Physician reimbursement rates are already being squeezed, and UPLs

could additionally lower opportunities for treatment costs to be recouped. As a result, it is likely that physicians would adjust treatment recommendations to avoid facing financial deficits, leaving patients with fewer treatment options.

Finally, creating a unique pricing structure in Oregon will create state-specific conditions for coverage. We don't know yet how either insurers or manufacturers will react to state-by-state exceptions, but this has potential to cause either of these stakeholders to limit availability in the state and could cause confusion for patients and providers in the state.

Upper Payment Limits Don't Necessarily Translate to Patient Savings

Assuming that UPLs directly translate to lowered costs for patients ignores the complicated nature of our healthcare system. In our system, patients are not responsible for paying the full cost of their prescription medications nor are they allowed to freely select from the full range of treatments medically approved for their condition. Instead, these decisions are determined by their insurance company and pharmacy benefit manager (PBM). It is also these stakeholders that determine if cost-savings realized by the payer are subsequently shared with patients. Unfortunately, in most cases, they are not.

Payers in our health marketplace do not necessarily derive the most value from the lowest cost drugs. According to reporting on PBMs by the New York Times, "Even when an inexpensive generic version of a drug is available, PBMs sometimes have a financial reason to push patients to take a brand-name product that will cost them much more. For example, Express Scripts typically urges employers to cover brand-name versions of several hepatitis C drugs and not the cheaper generic versions. The higher the original sticker price, the larger the discounts the PBMs can finagle, the fatter their profits — even if the ultimate discounted price of the brand-name drug remains higher than the cost of the generic."

Ultimately, this could mean insurers and PBMs place drugs subject to UPLs on higher tiers of the formulary. This could lead to higher out-of-pocket costs for patients who could face higher copay or coinsurance rates to retain access to that drug or alternatively be forced to switch to a more expensive drug that results in higher profits to their PBM.

These plan-prompted changes are collectively known as non-medical switching and were also noted in the excerpt from CMS above. Non-medical switches in medication can also cause unnecessary complications for patients. At a minimum, a switch in medication will require more doctor visits to monitor the efficacy of a new medication. Further, if the switch results in side effects or worsened outcomes, patients could face medical interventions or hospitalization and the additional costs borne out by both.

Patient Access Cannot Be Compromised

Chronic conditions are incredibly complex to treat. Each patient faces a unique experience and should be able to work with their doctor to identify the treatment that works best for them. Substituting or requiring patients to change drugs based on cost considerations instead of medical needs can disrupt continuity of care and result in complications and higher overall medical costs.

We urge this board to seriously consider the unique circumstances faced by these patients and work diligently to ensure that access to all treatments is protected. We strongly urge the board

and staff to utilize the authority of the board to fully explore with all healthcare stakeholders how UPLs will be implemented and identify in advance any adverse impact to patients.

Identify and Resolve Patient-Reported Obstacles to Care

As we have outlined, while well-intentioned, UPLs fail to address many of the underlying causes and complicated factors that result in higher prescription drug costs for patients. Therefore, we urge the board to focus its time on identifying and addressing patient-reported obstacles to drug affordability.

Failing to resolve the underlying factors that lead to higher costs for patients can result in short-term relief and uneven benefits – aiding some but potentially leaving others with higher costs and drug accessibility challenges. Additionally, regulators should clearly define cost-saving targets, including what percentage will be patients and what will be the state or the broader healthcare system.

Ultimately, we know that defining affordability is a key aspect of the drug review process that the Oregon board is seeking to improve. We implore the board, to the extent that it is able to within statute, focus on defining affordability based on patient reported costs and concerns.

Sound Health Policy is Founded on Patient Perspectives

In continuation of that point, 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 as it evaluates the impact of its cost reviews and UPLs.

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.

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,

Ensuring Access through Collaborative Health (EACH) Coalition

Boehringer Ingelheim

Mr. Jean-Michel Boers
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900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368

Oregon Prescription Drug Affordability Board
Sent Via Email: PDAB@DCBS.Oregon.gov

Re: Oregon Prescription Drug Affordability Board's Constituent Focus Groups Surveys: Pharmaceutical Manufacturer Survey on the Use of Upper Payment Limits (UPLs)

Dear Members of the Oregon Prescription Drug Affordability Board:

On behalf of Boehringer Ingelheim Pharmaceuticals, Inc., we would like to provide feedback to the "Pharmaceutical Manufacturer Survey" issued by the Oregon Prescription Drug Affordability Board ("Board") regarding the use of upper payment limits.

Founded in 1885 and independently owned since, Boehringer Ingelheim is a research driven company with 53,000 employees around the world dedicated to the discovery and development of breakthrough therapies that transform lives, today and for generations to come. As a leading research-driven biopharmaceutical company, we create value through innovation in areas of high unmet medical need focused on breakthrough therapies and first-in-class innovations.

Boehringer understands the scrutiny over prescription drug prices. The U.S. healthcare system is complex and often does not work for patients, especially the most vulnerable. In some instances, patients face prices at the pharmacy counter that are out of reach. While we understand that there is a need to find ways to concurrently reduce state budget expenditures and reduce patient out of pocket costs, we note some important considerations with respect to the use of an upper payment limit ("UPL") and offer solutions that may address the root of the problem.

An Upper Payment Limit is Unlikely to Reduce Cost for Patients:

Applying an upper payment limit to a prescription drug for the insurer or pharmacy benefit manager ("PBM") will not directly help people at the pharmacy counter. Pharmacy counter prices are controlled by the patient's insurance plan in the form of copay or co-insurance.

Generally, pharmaceutical manufacturers provide significant discounts and rebates off the list price of their medicines to insurers, PBMs and other parties. Unfortunately, these discounts are commonly withheld from patients by these other entities. As insurers and PBMs increasingly shift the cost of care to patients, patients are faced with high out-of-pocket costs at the pharmacy counter. To help alleviate the burden of these tactics', Boehringer offers additional financial support for patients designed to support and assist patients who are unable to afford their medication because they are either uninsured or are exposed to high out-of-pocket costs due to their health plan design, i.e. the underinsured. Commercial health plans and PBMs have progressively developed various tactics — including copay

accumulators, copay maximizers, and alternative funding—that siphon patient assistance and we urge the Board to consider their direct harm to patients.

Furthermore, because of the PBM system, prescription drugs subject to an UPL will result in less favorable price concessions to PBMs which will result in PBMs shifting utilization to more expensive drugs with more favorable rebate terms to the PBM. PBMs and other middlemen seek greater rebates from manufacturers that rarely reach patients while claiming they are providing cost savings to their customers. Their goal is not to ensure the best patient outcome but to continue to extract rebates for formulary access.

An Upper Payment Limit Would Likely Hurt Patient Access and Undermine Medical Decision-Making:

Boehringer shares the Board's goal of ensuring patients have access to medicines and life-saving treatments; however, implementing an UPL may further restrict access for some patients.

Given the interconnected nature of the pharmaceutical supply chain, we are increasingly concerned that the substantial rebates and discounts provided by pharmaceutical manufacturers do not directly benefit the patient nor offset their costs at the pharmacy counter. We are concerned that the application of an UPL could exacerbate access barriers for patients – partly due to the perverse financial incentives PBMs and insurers reap – and additionally undermine the patient and physician medical decision-making process. At the sole discretion of PBMs and insurers, if they are not satisfied with rebate negotiations, they may identify another prescription drug as "preferred" and place the low-rebate (UPL-applied) drug on a less preferred tier, increasing the patient out-of-pocket costs. Additionally, the PBM and health plan may choose to remove the treatment from their formulary altogether, which could impose on the medical decisions made between physicians and their patients. A patient might be forced to forego the treatment selected by their physician, for a product deemed as "preferred" by their health plan solely due to financial incentives.

Conclusion

Boehringer recognizes the prescription drug access and cost challenges patients are burdened with, and we are committed to promoting policies that protect patients in Oregon. We encourage meaningful reforms that will help lower the price patients pay for medicines at the pharmacy, such as making monthly costs more predictable, preventing deceptive alternate funding programs (AFPs), and sharing negotiated savings on medicines with patients.

We thank you for considering feedback on the use of UPLs and consideration of our concerns. Steadfast in our commitment to our patients and access to life-saving treatments, we stand ready to be a constructive partner in this initiative.

Regards,

Bridget Walsh
VP, Government Affairs and Public Policy
Boehringer Ingelheim Pharmaceuticals, Inc.

Pharmaceutical Manufacturers

*Name of person completing survey: ***Blasine Penkowski, Chief Strategic Customer Officer***

*Name of facility/entity: Johnson & Johnson Health Care Systems Inc.

*Email: ***bpenkows@ITS.JNJ.com***

*Organization Type (Carrier, Hospital or Health System, 340B Covered Entity, Pharmacy, Pharmaceutical Manufacturer, Pharmacy Benefit Manager, Advocacy Group, Wholesaler/Distributor, Group Purchasing Organization (GPO), Pharmacy Services Administrative Organization (PSAO))

Pharmaceutical Manufacturer

When thinking about drug affordability, how much concern do you have about the impact of the cost of drugs on patients?

- Very concerned
- Somewhat concerned
- Not concerned
- Not applicable
- ***Other – J&J is concerned about both patient access to and affordability of innovative medications due to high out-of-pocket costs and burdensome benefit utilization management. However, an upper payment limit (UPL) is not the solution. J&J urges the Oregon Prescription Drug Affordability Board (the Board) to make the following policy recommendations to the Oregon Legislature:***
    1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
    2. ***Examine the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing out-of-pocket (OOP) costs; and***
    3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

How do you anticipate that an upper payment limit would impact your organization's revenue and budgetary considerations?

- Positive impact
- Neutral impact
- Negative impact
- Not applicable
- ***Other – A UPL is an untested, unprecedented method, the impact on revenue or budget is unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.***

How do you perceive the potential effects of an upper payment limit on patient *access* to necessary medications?

[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." Accessed June 27, 2024.

• Create opportunities for a positive impact on patient access
• Neutral impact on patient access
• ***Create challenges to patient access***

What kind of impact do you think an upper payment limit would have on a patient's *ability* to afford their medications?
• Positive impact
• Neutral impact
• ***Negative impact***

What challenges might your organization face in adjusting to the constraints imposed by an upper payment limit (select all that apply)?
• Increased administrative burden
• Supply chain disruptions due to shortages or inability to sell into a market
• ***Compliance with regulatory requirements***
• ***Other (please specify) – A UPL is an untested, unprecedented method, with no existing system for implementation. In addition, UPLs will be in conflict with existing contracts across the entire supply chain. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences, including administrative burden, for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.***

What challenges do you foresee for your company if an upper payment limit is implemented? (Select all that apply)
• Reduced revenue
• Limited R&D funding
• ***Compliance concerns***
• Competitive disadvantages
• ***Other (please specify) – A UPL is an untested, unprecedented method, and the impact on revenue or budget is unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.***

The Oregon PDAB Is also interested in hearing about alternative policy approaches and recommendations that you may have. The following questions will provide you with an opportunity to provide more detailed information on approaches, recommendations, or concerns.

How could upper payment limits create meaningful cost savings for all consumers and purchasers?

• ***UPLs are unlikely to create any cost savings for consumers or purchasers. Patient OOP cost is set by health plans as a part of insurance benefit design, and health plans often base patients' coinsurance on the list***

price of a drug rather than the discounted net price plans receive.[2] A recent Avalere survey commissioned by the Partnership to Fight Chronic Disease further supports this assertion. In the survey, health plans stated "Payers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences."[1] Interviewed plans also stated that they were unlikely to lower plan deductibles or maximum out-of-pocket limits as a result of a UPL.[1]

How would your organization utilize savings resulting from an upper payment limit (if applicable)?
• ***Not applicable.***

What could be potential administrative burdens or operational challenges associated with implementing an upper payment limit?
• ***There is no current system for operationalizing UPLs. We have concerns about potential legal issues surrounding UPL operationalization. Moreover, as UPLs ignore the interconnected market realities of the drug pricing ecosystem and supply chain, these price-setting thresholds may have unintended consequences across payer and PBM formularies, price-reporting metrics, provider reimbursement and patient plan and benefit options.[3]***

Moreover, UPLs are unlikely to create any cost savings for consumers or purchasers. Patient OOP cost is set by health plans as a part of insurance benefit design, and health plans often base patients' coinsurance on the list price of a drug rather than the discounted net price they receive.[2] A recent Avalere survey commissioned by the Partnership to Fight Chronic Disease further supports this assertion. In the survey, health plans stated "Payers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences."[1] Interviewed plans also stated that they were unlikely to lower plan deductibles or maximum out-of-pocket limits as a result of a UPL.[1]

What recommendations, if any, do you have regarding the potential administrative burdens or operational challenges associated with implementing an upper payment limit?
• ***We recommend not implementing a UPL, and instead, we urge the Board to make the following policy recommendations to the Oregon Legislature:***

1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
2. ***Examine the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing OOP costs; and***
3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

Are there alternative policy approaches that you believe would be more effective in addressing drug affordability while preserving innovation and investment in research and development?
• ***Yes, we urge the Board to make the following policy recommendations to the Oregon Legislature:***

1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
2. ***Examine the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing OOP costs; and***
3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

How can policymakers ensure that an upper payment limit policy is implemented in a manner that promotes transparency, fairness, and affordability for both payers and patients?

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[2] PhRMA. "Commercially-Insured Patients Pay Undiscounted List Prices for One in Five Brand Prescriptions, Accounting for Half of Out-of-Pocket Spending on Brand Medicines." Accessed June 27, 2024.
[3] Janssen. "Influence of Prescription Drug Affordability Board and Upper Payment Limits on the State Drug Pricing Ecosystem." Accessed June 27, 2024.

• Given the complexity of the healthcare ecosystem, a UPL cannot be implemented in a manner that promotes transparency, fairness, or affordability for payers and patients. A UPL is an untested, unprecedented method, and the impacts on revenue or budget are unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.

What specific factors or considerations should policymakers take into account when setting an upper payment limit for prescription drugs?

• A UPL is an untested, unprecedented method, and the impact on revenue or budget is unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.

To avoid unnecessary spending of taxpayers' dollars, we urge the Board to make the following policy recommendations to the Oregon Legislature:

1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
2. ***Exam the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing OOP costs; and***
3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

June 28, 2024

VIA ELECTRONIC FILING

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, Oregon 97309-0405
pdab@dcbs.oregon.gov

Dear Members of the Oregon Prescription Drug Affordability Board:

GSK and ViiV Healthcare (ViiV) appreciate the opportunity to jointly submit a comprehensive response to the Oregon Prescription Drug Affordability Board's (Board) survey, as part of the development of a plan to establish upper payment limits (UPLs) required by Senate Bill 192.

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.

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV and those vulnerable to HIV. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care.

We reviewed the survey questions that were sent out to manufacturers and appreciated the interest in hearing stakeholder perspective on this important issue. However, we felt that many of questions did not leave room to expand on the nuances of UPL proposals. Therefore, we have elected to jointly submit this letter that explains the impact that UPLs will have on patients and access to medications.

Patient accessibility to medication has always been, and remains, a top priority for both GSK and ViiV. While there are many solutions that could have a positive impact on patient affordability and accessibility, establishing UPLs is not one of them.

GSK and ViiV are concerned that added complexity and lack of transparency on UPLs could drive supply chain costs higher over time and exacerbate patient access concerns. Numerous operational challenges associated with implementing UPLs exist, which are likely to create financial and logistical burdens for all stakeholders involved in the drug supply chain, including pharmacies, wholesalers, providers, payers, and patients.

For example, effectuating a UPL price through the supply chain could necessitate new pharmacy and wholesaler acquisition/tracking systems and the introduction of payment streams that do not exist today. Further, any challenges in pharmacy and wholesaler supply operations can directly lead to gaps in patient access, particularly if a patient's local pharmacy is unable to operationalize and comply with the UPL-driven requirements.

Also critical for patients, payers have indicated that drugs subject to UPLs or other drugs in their therapeutic class could have more utilization management (e.g., prior authorization) once a UPL is implemented, as well as cause changes in formulary tiering, which could increase patients' out of pocket costs.[1] UPLs are also likely to have long-term effects on the prescription drug ecosystem, including provider access, copay assistance needs, and manufacturer research and development (R&D).

Equally concerning, affordability reviews that inform upper limit decisions target the most innovative medicines, disproportionately impacting patients with diseases where there is high unmet need and where low-cost treatment options are often not available.

GSK and ViiV support policy solutions that transform our healthcare system into one that improves patient outcomes, achieves higher value care and rewards innovation. Policies that can positively impact patients include:

- Requiring pharmacy benefit managers (PBMs) to pass manufacturer rebates to patients at the pharmacy counter;
- Requiring PBMs to be paid a flat fee based on the value of the services they provide, rather than a percentage of a drug's list price; 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.

In summary, medications prescribed should be based on the best clinical outcomes as decided by providers and patients and not strictly by cost considerations. Imposing arbitrary UPLs guided by misinformed affordability reviews may limit access to life-saving medicines and vaccines and indirectly harm patients' health. GSK and ViiV urge the Board to consider these unintended consequences as it seeks to implement Senate Bill 192 and how its plan to establish an UPL may impact access to vital medications and vaccines for Oregonians.

Thank you again for the opportunity to engage with the Board and your survey efforts. We welcome a continued dialogue on this issue and look forward to future engagement with you on solutions that maintain and increase access to vital medications in Oregon. Please feel free to contact Christian Omar Cruz at Christian.O.Cruz@gsk.com with any questions.

Sincerely,

Harmeet Dhillon
Head, Public Policy
GSK

Carie Harter
Senior Director, Government Relations
ViiV Healthcare

[1] Avalere. April 2024. "Research Explores Health Plan Perceptions of PDABs and UPLs." Accessed at https://avalere.com/insights/research-explores-health-plan-perceptions-of-pdabs-and-upls.

PhRMA
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June 28, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon Prescription Drug Affordability Board: Pharmaceutical Manufacturer Survey Dated June 14, 2024

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's (the "PDAB" or "Board") Pharmaceutical Manufacturer Survey distributed June 14, 2024 ("Manufacturer Survey").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA is concerned that any proposed Upper Payment Limit ("UPL") scheme would arbitrarily cap pharmaceutical prices, fail to recognize the complexity of the pharmaceutical supply chain, and would overlook meaningful policy alternatives that would substantially reduce the cost of medicines for Oregonians. A proposed UPL scheme would also raise concerns under the Supremacy Clause of the U.S. Constitution, among other constitutional concerns.[2]

PhRMA continues to have significant concerns about the impact that UPLs would have on Oregonians. UPLs could restrict patient access to medicines and result in fewer new treatments for patients, and ultimately do not carry any guarantee of savings being passed on to patients. Further, the UPL process raises fundamental administrative and operational questions and concerns and creates risks of arbitrary decision-making by the Board. PhRMA cautions the state against considering moving forward with any UPL plan given the risks and legal questions associated with such price controls. Below, PhRMA provides more details about its concerns in its responses to the questions posed in the Board's Manufacturer Survey.[3]

I. How could upper payment limits create meaningful cost savings for all consumers and purchasers?

PhRMA is concerned that UPLs would not translate into meaningful cost savings for patients. UPLs focus on limiting the prices set by the biopharmaceutical industry and ignore the function of other stakeholders in determining what patients ultimately pay for medicines, including insurers, pharmacy benefit managers ("PBMs"), wholesalers, and the government. The important role that these entities play in determining drug coverage and patient out-of-pocket costs seems to be overlooked by the proposed UPL scheme. For example, PBMs and payers – which dictate the terms of coverage for medicines and the amount a patient ultimately pays – negotiate substantial rebates and discounts from manufacturers. If payers, PBMs, distributors, and other direct purchasers are not required to pass UPL-related discounts onto patients, it would ignore the role that these entities play in issues of consumer (i.e., patient) affordability.

[1] Manufacturer Survey (June 4, 2024), *available at* https://mslc.qualtrics.com/jfe/form/SV_39ijG1FM8LzFDMy.
[2] *See, e.g.*, *BIO v. District of Columbia*, 496 F.3d 1362 (2007); Amgen v. Colo. Prescr. Drug Affordability Rev. Bd., No. 1:24-cv-00810 (D. Colo. filed Mar. 22, 2024).
[3] In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB Statute").

Pharmaceutical manufacturers pay substantial rebates and discounts – approximately $267 billion in 2023 alone.[4] By focusing exclusively on the amounts paid by the direct purchaser (e.g., often the PBM or payer), UPL price controls do not ensure that existing rebates and discounts make their way to offsetting patient costs at the pharmacy counter.[5] This has real consequences for patients. According to research from the Berkeley Research Group ("BRG"), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year, while the share received by manufacturers has decreased over time. In 2021, net prices for brand medicines were, on average, 53% lower than the list prices due to significant rebates, discounts, and other payments from manufacturers.[6] Simultaneously, the growth rate of prescription drug costs has slowed in recent years, with average net prices for brand medicines grew by 3.0% in 2023, below the rate of inflation for the fifth year in a row. Looking ahead, average net price growth is projected to be -1 to -4% per year through 2028.[7] Increased rebates and discounts have largely offset these modest increases in list prices and reflect the competitive market for brand medicines, yet UPLs would not require that these existing rebates and discounts are actually carried forward by plans and PBMs to patients to make their medicines more affordable.

II. What could be potential administrative burdens or operational challenges associated with implementing an upper payment limit?

Establishing UPLs would carry significant administrative and operational burdens and concerns. UPLs restrict patients' access to medicines and result in fewer new treatments. In a recent study of health plan payers interviewed by Avalere about the impacts of a potential UPL, most payer interviewees indicated that "if a drug were to become subject to a UPL, then providers may experience challenges acquiring the product. Interviewees elaborated that provider reimbursement based on a selected drug's UPL may not be adequate relative to their acquisition costs."[8] The same study found that payers did not expect UPLs to lower patient out-of-pocket costs: "Most payers (five of six) did not anticipate that UPL-related savings would be passed on to patients in the form of lower premiums, deductibles, or cost sharing." This study highlights some the supply chain concerns and the potential impacts of UPLs on patients access to prescription drugs.

This concern is further demonstrated by the experience of states that have enacted UPL authority; four states have enacted laws that would allow them to set a UPL for certain medicines, but no state has implemented a UPL to date. Existing state UPL proposals drastically over simiplify the complexity of the pharmaceutical payment and reimbursement system and have created operational concerns across a variety of supply chain entities. For example, the Maryland Department of Public Health expressed concerns to the state legislature that a UPL could put federal matching dollars at risk for the state's Medicaid program and inadvertently cost the state more money than it might save.[9] Maryland's board has been meeting regularly since 2020, but has just begun the process of affordability reviews.[10] In November 2022, adoption of Colorado's rulemaking on the UPL was delayed to address concerns raised by stakeholders and give the board more time to work on the rule; the Colorado Hospital Association had notably raised concerns about the unintended consequences the

[4] IQVIA. "Use of Medicines in the U.S. 2024: Spending and Usage Trends and Outlook to 2028." April 2024.
[5] *See* A. Fein, *The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute (Mar. 2020).
[6] IQVIA. "Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028." Published April 2024.
[7] *Id.*
[8] Research Explores Health Plan Perceptions of PDABs and UPLs. April 2, 2024. Accessed at https://avalere.com/insights/research-explores-health-plan-perceptions-of-pdabs-and-upls.
[9] Letter to House Health and Government Operations Committee from Maryland Department of Health re: HB 279, February 2, 2023. https://mgaleg.maryland.gov/cmte_testimony/2023/hgo/1OoeMJLHVifacq1rfNcQYND5k-v0L8ThH.pdf.
[10] *See* Maryland PDAB, "Board Selected Drugs and any applicable information," https://pdab.maryland.gov/Pages/board-selected-da-info.aspx (subsection of page on "Timeline Information for Cost Review").

UPL would have on hospital revenue and on their ability to bulk purchase drugs which further highlights concerns throughout the supply chain on the adoption of a UPL.[11]

Since Oregon's Prescription Drug Affordability Board began operation in 2022, PhRMA has raised signification administrative and operational concerns about the process and work of the Board.[12] The Board itself recognizes that there are issues that need to be addressed, as shown by its decision to on June 26, 2024 to postpone further affordability reviews until 2025 while it reviews and improves its affordability review criteria and methods. These issues and concerns would be exacerbated by the addition of a UPL scheme, which would significantly expand the potential consequences of the Board's work. We reiterate the following non-exhaustive list of challenges and concerns that we have previously raised with the Oregon PDAB and similar Boards in other states:

- **Lack of Clear, Specific, and Meaningful Standards**. Across states that have implemented affordability review or UPL regulations to date, the rules for evaluating affordability and establishing UPLs have consistently suffered from an overriding lack of clear, specific, and meaningful standards.[13] These rules incorporate extensive lists and categories of information and data sources that must (or may) consider as part of the multi-step affordability review and UPL-setting process, but have been devoid of specific rules that explain *how* the implementing agencies would utilize such information in a consistent and balanced way to make informed assessments about questions of affordability and the need for a UPL. PhRMA is concerned that any UPL-setting process in Oregon would similarly lack clear and concrete standards to guide the Board's discretion in establishing a UPL.

  Further, the vagueness of the standards adopted to date raises concerns regarding whether it would be lawful to impose UPLs based on such standardless evaluations. Notably, under the Oregon Administrative Procedures Act ("APA"), agencies are required to render decisions in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary."[14] As such, courts have long held that agencies like the Board must "make policies for even application" across regulated entities and products," which is directly contrary to affordability review and UPL rules that authorize evaluations based on undefined and unascertainable standards.[15]

- **Data Quality Concerns**. PhRMA also questions whether the Board would provide adequate processes and safeguards to verify the reliability of data used to support a potential UPL. The UPL-setting process, similar to the Board's affordability reviews, would be dependent on the fidelity of the information being relied upon in the Board's decision-making. Information bearing on the criteria for evaluating affordability or setting a UPL is likely to be drawn from a variety of sources, including reports from insurers, manufacturer data, and various other third-party sources. Certain sources of information may be unreliable or offer only a selective portion of the full picture relevant to the Board's selection of drugs for affordability review. Oregon's affordability review process to date has been rife with persistent errors, causing the board to

[11] Colorado PDAB, Draft Meeting Minutes, Friday November 18, 2022, https://drive.google.com/file/d/1qHM7PkGBGlXzVmq_T-kkQU85EEWUdt8f/view; Colorado Hospital Association, letter to CO PDAB, October 6, 2022, "Re: CHA Comments on Oct. 7 rulemaking hearing regarding the Proposed Draft Rule Part 4 – Upper Payment Limit Methodology."

[12] PhRMA has filed 27 comment letters to date with the Oregon PDAB, detailing, among other things, our ongoing concerns with the Board's affordability review process and procedures. *See, e.g.*, Letter from PhRMA to Board (May 12, 2024); Letter from PhRMA to Board (Feb. 17, 2024); Letter from PhRMA to Board (Oct. 15, 2023).

[13] *See, e.g.,* Letter from PhRMA to Board (June 23, 2023); Letter from PhRMA to Washington PDAB (Apr. 11, 2024); Letter from PhRMA to Maryland PDAB (June 30, 2023); Letters from PhRMA to Colorado PDAB (Nov. 14, 2022) (regarding draft affordability review and UPL regulations).

[14] *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007).

[15] *Sun Ray Drive-In Dairy, Inc. v. Oregon Liquor Control Comm'n*, 16 Or. App. 63, 72 (1973).

alter the number of drugs eligible for affordability review on multiple occasions, even after the list was finalized and the work of reviewing drugs had begun.[16]

- **Confidentiality Concerns**. UPL-setting is also likely raise substantial confidentiality concerns. PhRMA has consistently stressed in our comments that, under the Board's existing authority, it has not adequately addressed how it will maintain confidentiality of the materials it receives as part of its affordability reviews.[17] State and federal law protect manufacturers' confidential, trade secret, and proprietary information from disclosure; such information cannot be publicly disclosed without violating state and federal prohibitions against the misappropriation of trade secrets. Further, the Fifth Amendment's prohibition against taking private property without just compensation prohibits the uncompensated disclosure of trade secrets, and courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality ... can amount to an unconstitutional 'taking' of property."[18] The U.S. District Court for the District of Oregon recently ruled that the "public disclosure" of manufacturers' trade secrets violates the Fifth Amendment "[u]nless just compensation is provided" at the time of disclosure.[19] These concerns would be heightened if the Board were also given authority to establish UPLs, particularly if as part of the UPL process, the Board sought to obtain sensitive financial or commercial information from stakeholders.

III. Are there alternative policy approaches that you believe would be more effective in addressing drug affordability while preserving innovation and investment in research and development?

Implementing price controls diminishes the incentives for biopharmaceutical manufacturers to invest in and introduce new medicines and could limit the prescription drug options available to Oregon residents. Research shows that "[i]t is simply not true that government can impose significant price controls without damaging the chances for future cures."[20] Experts estimate a 50% decrease in the price of medicines would result in a 25% to 60% decrease in the number of new drugs in the pipeline.[21] U.S. patients enjoy earlier and less restrictive access to new therapies,[22] a finding that is reinforced by HHS's own analysis of Medicare Part B drugs which showed that only 11 of the 27 drugs examined (41%) were available in all 16 comparator countries, nearly all of which have single-payer healthcare systems.[23] In countries where governments set medicine prices, patients have access to fewer treatment options. For example, the U.S. has access to nearly 85% of all medicines launched between 2012 and 2021, while just 61% are available in Germany, 59% in the

[16] See, for example, the issues highlighted in PhRMA's comments regarding the Board's May 2024 and November 2023 meetings and meeting materials. Letter from PhRMA to Board (May 12, 2024); Letter from PhRMA to Board (Nov. 11, 2023).
[17] Letter from PhRMA to Board (May 14, 2023), 5; Letter from PhRMA to Board (Apr. 16, 2023), 8; Letter from PhRMA to Board (June 20, 2022), 3-4.
[18] *St. Michael's Convalescent Hosp. v. State of Cal.*, 643 F.2d 1369, 1374 (9th Cir. 1981).
[19] *PhRMA v. Stolfi*, --- F. Supp. 3d ----, 2024 WL 1177999 (D. Ore. Mar. 19, 2024), *appeal pending*, No. 24-1570 (9th Cir. filed Mar. 15, 2024).
[20] Kennedy, J. The Link Between Drug Prices and Research on the Next Generation of Cures. Information Technology & Innovation Foundation. Sept. 9, 2019. Available at https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures.
[21] Abbot, T. and Vernon, J. The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions. National Bureau of Economic Research. Available at https://www.nber.org/papers/w11114; Civan, A. & Maloney, M. (2009). The Effect of Price on Pharmaceutical R&D. The B.E. Journal of Economic Analysis & Policy, 9(1).
[22] IQVIA Institute, Global Oncology Trends 2017, Advances, Complexity and Cost. May 2017.
[23] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018.

U.K., 51% in Japan, 52% in France, 45% in Canada, and 34% in Australia.[24]

There are a range of policy alternatives to UPLs that more directly and effectively address issues of affordability and access, while also better preserving incentives for innovation and investment in research and development of new and potentially transformative medicines. PhRMA would like to highlight some proposed policies that we believe can help patients better afford their medications, without putting access to care at risk.

Biopharmaceutical manufacturers provide significant discounts, rebates, and other price concessions to PBMs and health carriers, but many patients don't benefit directly from these discounts. On average, pharmaceutical companies rebate approximately 53% of a medicine's list price back to insurance companies and middlemen like PBMs.[25] While health insurers claim that at least a portion of these discounts are used to reduce premiums, research shows that sharing these rebates and discounts directly with patients at the pharmacy counter would have little impact on premiums and significantly benefit consumers.[26] Studies predict that requiring health insurers and PBMs to share negotiated discounts and rebates at the pharmacy counter could save some patients $900 annually in out-of-pocket expenses without significantly increasing their premiums.[27] A study of recently enacted legislation in Arkansas requiring health insurance companies and PBMs to share rebates with patients found no evidence that the policy has caused premium increases.[28] Patients should benefit directly from negotiated rebates and discounts, and health insurers and PBMs should no longer be able to retain those price concessions.

In addition to rebates, PBMs have recently been increasingly profiting off fees and other compensation that are tied to the list price of a medicine, which has created perverse incentives in the marketplace. The largest PBMs wield significant sway over the marketplace, both by virtue of their market share and their relationships with other market participants including health plans, pharmacies, and other providers.[29] The combined market share of the three largest PBMs has grown significantly, from 48% in 2010 to 80% in 2021,[30] and just six companies control 96% of the PBM market.[31] Concern about the influence of PBMs on the supply chain have been raised by Oregon,[32] Congress, and the Federal Trade Commission.[33] When investigating PBMs, the U.S. Senate Finance Committee concluded that, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price – and PBMs may retain at least a portion of what they negotiate."[34] Oregon's Secretary of State performed an

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[24] PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration, European Medicines Agency, Japan Pharmaceuticals and Medical Devices Administration, Health Canada and Australia Therapeutic Goods Administration data. Note: Sample includes new active substances launched globally from January 1, 2012 to December 31, 2021. Updated June 2022.
[25] IQVIA. "Use of Medicines in the U.S. 2024: Spending and Usage Trends and Outlook to 2028." April 2024.
[26] PCMA, https://www.pcmanet.org/rx-research-corner/the-path-of-a-rebate-from-drug-companies-through-pharmacy-benefit-companies-to-the-employer-and-all-the-way-to-patients/12/04/2023/. Dec 4, 2023
[27] Milliman. "Measuring the Impact of Point of Sale Rebates on the Commercial Health Insurance Market." July 2021. https://www.milliman.com/-/media/milliman/pdfs/2021-articles/7-6-21-measuring-the-impact-of-point-of-sale-rebates.ashx.
[28] Milliman. "Premium Impacts of POS Rebate Implementation in the ACA Market in the State of Arkansas" January 2024.
[29] https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html.
[30] Fein AJ. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022.
31 Sweeney E. "Lawmakers ask FTC for retrospective review of PBM mergers," Fierce Healthcare. July 2018.
[32] Oregon Health Authority, "Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies," August 2023.. The Oregon Legislature has considered dozens of bills in the past few years to regulate and rein in the abusive practices of the PBMs. *See* "Drug supply companies squeezing pharmacies out of existence, Oregon lawmakers warn." January 26, 2023.; "Oregon set to tighten rules for pharmacy benefit managers. Here's what they do." March 10, 2024.
[33] Federal Trade Commission. "FTC Launches Inquiry into Prescription Drug Middlemen Industry." Press Release, June 7, 2022; Federal Trade Commission. "FTC Deepens Inquiry into Prescription Drug Middlemen." Press Release, May 17, 2023.
[34] Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," 2021.

audit of PBM practices in the state, finding that "there is growing public interest in assessing the role, value of, and significant power and influence held by third-party organizations known as pharmacy benefit managers."[35]

These abusive practices of PBMs not only raise pharmacy costs for patients, but they also contribute to higher overall costs in the health care system. A study by the Washington State Pharmacy Association and 3-Axis Advisors analyzed millions of pharmacy claims and found that PBMs are driving up costs by charging employers more than necessary to participate in plans, retaining increasingly more than pharmacies are reimbursed (a practice known as "spread pricing"), and steering plans and patients to their affiliated mail-order pharmacies, allowing them to retain more profit from each transaction.[36] A study of Oregon pharmacy claims found in one example, PBMs were marking up a generic drug by as much as 800%, and profiting approximately $1.9 million on the spread pricing of just one drug.[37]

Instead of untested proposals, patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy. PhRMA urges the Board to consider common-sense policies to address the lack of oversight of out-of-pocket pharmacy costs set by health insurers and middlemen. State policymakers can:

- Require middlemen to share the savings – rebates, discounts, and other price concessions they receive from manufacturers – directly with patients at the pharmacy counter;
- Make manufacturer coupons count toward deductibles and other out-of-pocket requirements so that patients get the full benefit of programs meant to help them access their medicines;
- Help patients from day one by requiring all plans to cover certain medications used to treat chronic conditions with no deductible; and
- Tying the fees pharmaceutical supply chain middlemen charge to the services they provide, not the list price of a medicine.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the potential addition of UPL authority in Oregon, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[35] Oregon Health Authority, "Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies," August 2023..
[36] Three Axis Advisors, "Understanding Drug Pricing from Divergent Perspectives State of Washington Prescription Drug Pricing Analysis", June 2024. https://cdn.ymaws.com/www.wsparx.org/resource/resmgr/pbm/3aa_washington_report_202406.pdf
[37] Three Axis Advisors, "Understanding Pharmacy Reimbursement Trends in Oregon: The High Costs of Low Prices", October 2022. https://oregonpharmacy.org/wp-content/uploads/2022/10/Oregon_Report_20221027-FINAL.pdf

House Committee on Education and The Workforce
"Competition and Transparency: The Pathway Forward For A Stronger Health Care Market"
June 21, 2023

Written Testimony of Greg Baker, BS Pharm
CEO of AffirmedRx

Chairman Good, Ranking Member DeSaulnier, and distinguished members of the House Subcommittee, I would like to thank you for the invitation to speak with you on the necessity of increasing competition and transparency in health care.

My name is Greg Baker. I, first and foremost, am a pharmacist. I am also the CEO of AffirmedRx which is a transparent PBM I founded, headquartered in Louisville, KY. I have spent the past 30 years working in different areas of pharmacy with the past 11 years dedicated to collaborating directly with jumbo self-funded employers to help define and develop their pharmacy programs. Our goal at AffirmedRx is to partner with employers to deliver patient-centric pharmacy benefits with a mission to improve health care outcomes by bringing clarity, integrity and trust to pharmacy benefit management.

With my expertise in pharmacy benefits, I will focus my comments on competition and transparency within this industry. While there are around 70 PBMs currently doing business in the United States, only three large PBMs control up to 80% of the market in the USA. These PBMs are not constrained by any obligation to be transparent on their pricing and what they pay their own pharmacy versus what they pay other community pharmacies. They are not transparent in what their corporately owned and newly conceived group purchasing organizations (GPOs) receive in total manufacturer revenue versus what they pay back out to employers to help drive down the total cost of care.

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They do not share global claims data or per claim level rebate amounts. They are not transparent on why they prefer branded medications over lower-cost generic medications which, for the 55% of self-funded patients with high deductible or co-insurance plans, increases their out-of-pocket costs at the pharmacy counter.

Additionally, over the past 5 years, through mergers and acquisitions, these PBMs have become part of large, vertically integrated systems. We have been told for years how this vertical integration will improve outcomes and lower the cost of health care. It is our view that instead of helping they have used their significant market position and profit-focused business practices to secure outsized margins for the services they provide. This has led to higher costs, lower medication adherence, lower condition control and has increased morbidity and mortality of U.S. citizens.

Let us consider these facts on the state of the pharmaceutical industry today:

- Medications can be a key component to reduce health risk, control chronic disease and treat illnesses. In the U.S., illness and death from non-optimized medication therapy cost $528.4 billion annually – equivalent to 16% of total U.S. healthcare expenditures.
- Patients starting new prescriptions as prescribed by their physicians abandoned 94 million prescriptions at pharmacies in 2022 with increasing frequency as costs rise.
- A JAMA article published in June 2021 suggest that while drug manufacturers may increase list prices in order to offer larger rebates to insurers, such increases were associated with increased out-of-pocket costs to patients:
    - This study found that between 2014-2018 list prices from manufacturers grew 13.3% while rebates paid to PBMs increased 24.4%.
    - With the manufacturers raising list prices they also found that every $1 increase in list price equated to an increase of $2.09 in patient out-of-pocket costs. While we have had much debate over the list

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price increases by pharmaceutical manufacturers, these numbers clearly show how PBMs are retaining the most value and the American public continues to suffer greater drug affordability issues.
- Finally, the report sadly pointed out that every $10 increase in patient out-of-pocket costs led to lower adherence rates. This is particularly concerning amongst individuals with lower incomes and older adults as increasing prescription cost sharing can be associated with increased emergency department use, more frequent hospitalizations and other poor health outcomes.

These numbers illustrate at a high level how current market behaviors are having negative impacts on the system. PBMs operate in the middle of the entire distribution chain for prescription drugs and control all the rules. For example, they decide what pharmacies are allowed to fill medications for their members. Many times, for specialty and chronic medications, PBMs are mandating prescriptions be filled by pharmacies they own. In these situations, they get to decide what they pay themselves and, as we pointed out in our House Oversight and Accountability written testimony from May 23, 2023, that number can drive significant corporate profits while increasing costs for plan sponsors and their members.

Beyond this, they decide what medication a physician can and cannot prescribe and are increasingly excluding more and more medications from their formularies as called out by a January 10, 2023 article in Drug Channels. This article appropriately calls out the fact these exclusionary formularies are used "as a powerful tool for PBMs to gain additional negotiating leverage against manufacturers."

Additionally, there has been discussion about rebates and the relationship between the pharmaceutical manufacturers and PBMs. I am not here to defend or hold manufacturers harmless when we are talking about why we have a drug affordability issue in our country. They are by no means innocent, but the PBMs

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bear a significantly larger responsibility for the problem than they do. There are hundreds of brand manufacturers and only three main rebate aggregators. These three aggregators are each owned by one of the "big three" PBMs. They not only negotiate rebates for those traditional PBMs, but they now provide these rebate services to almost every other PBM in the industry. These aggregators are Ascent - created in Switzerland by Express Scripts in 2019 and now owned by Cigna, Zinc - created by CVS in 2020 and Emisar - started in Ireland in 2022 and owned by United Health Care. Ascent and Zinc each contract for over one hundred (100) million American lives and Emisar contracts for sixty five (65) million. They use their scale to create competition between manufacturers.

If a manufacturer does not negotiate a high enough rebate and ends up on the ever-expanding list of medications found on the exclusionary drug list, they will lose access to be able to sell their medications to tens of millions of lives. For this reason, they are forced to pay higher and higher amounts in total revenue to these GPOs in order to maintain their formulary placement. The difference between list price increases as defined by manufacturers and the manufacturers' net revenues after paying all rebates and discounts has been coined the gross-to-net bubble by Drug Channels. In their April 4, 2023 article, they point out this difference has grown from $167 billion in 2016 to $223 billion in 2022. While I do agree that manufacturers are increasing their prices, this is only half of the story. We can publicly see list price increases from the manufacturer. It is time for PBMs and their GPOs to list how much total revenue they obtain from pharma to show what the total net prices should be to plan sponsors and patients, but the PBMs continue to fight against this level of transparency.

Two specific examples point to how PBMs influence manufacturer pricing decisions. These examples also show how the upcoming flood of new biosimilars may not have a significant impact in reducing pharmacy costs as plan sponsors have been hoping for. Semglee is the biosimilar to the blockbuster diabetes medication Lantus. When the FDA originally approved Semglee in July 2021, the manufacturer Viatris indicated it would price a vial at about $98 – much below

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the price of $285 a vial for Lantus at the time. By November 2021, Viatris changed their strategy by offering two versions - a branded version of Semglee priced at $270 per vial (with a rebate) and an unbranded version at $98 with no rebate. Amgen watched this play out and when they became the first biosimilar to hit the market for Humira earlier this year they followed the same pricing strategy to have one with a 5% discount to Humira with a higher rebate and another version at a 55% discount with a much lower rebate. If you look at most PBM formularies, they have picked up the higher priced, higher rebate version on their formulary. This negatively impacts plan sponsors – who are not getting claim-level data to ensure they are getting the lowest cost option – and patients who are having to pay a higher amount for a more costly medication.

Finally, it will be important in future policy to call out how the term "rebate" is defined. The industry has pushed this concept of passing through 100% of their rebate dollars over the past few years. While a portion of the funds they get from manufacturers is contractually called a "rebate," the GPOs are adding an ever-expanding list of fees which PBMs keep as profit. See the example below for a list of those fees and whether they are included or excluded in the monies shared with plan sponsors. This list is an example of 3 unnamed industry PBMs. All sources listed should be considered rebate revenue, yet many PBMs exclude them in the monies shared with plan sponsors.

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Pharma Revenue Streams Included in Rebate Offer			
Source	PBM #1	PBM #2	PBM #3
Administrative Fees	Excluded	Excluded	Excluded
Clinical Program Fees	Excluded	N/A	Excluded
Consulting Fees	Excluded	N/A	Excluded
Credits	Excluded	Included	Excluded
Discounts	Excluded	Excluded	Excluded
Education Program Fees	Excluded	N/A	Excluded
Financial Incentives	Excluded	N/A	Excluded
Formulary Placement or Access Fees	Excluded	Included	Excluded
Implementation Fees	Excluded	N/A	Excluded
Market Share Based Payments	Excluded	Included	Excluded
Price Concessions	Excluded	N/A	Excluded
Promotional Allowances	Excluded	N/A	Excluded
Pull Through Program Fees	Excluded	Included	Excluded
Rebates	Included	Included	Included
Rebate Submission Fees	Excluded	N/A	Excluded
Software Licensing Fees	Excluded	N/A	Excluded
AWP Inflation Coverage	Excluded	Excluded	Excluded
All Other Payments From Pharma	Excluded	Excluded	Excluded

In closing, I would like to point to the *Consolidated Appropriations Act, 2021* (CAA). As pointed out in a article from Pharmaceutical Commerce in May 2023, the CAA has been designed to level the playing field between PBMs and plan sponsors. It will ensure that as a fiduciary to the plan all PBM revenue is disclosed, all data for that plan is shared with the plan sponsors, all compensation – both direct and indirect – brokers receive is fully disclosed and we will have a health care system that is more transparent and allows for more competition to drive down costs while improving quality and the lives of all Americans.

Thank you, members of the committee, for the opportunity to speak today and I look forward to your questions.

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https://affirmedrx.com/what-is-a-pbm/

https://affirmedrx.com/8-things-every-employer-should-know-about-their-pharmacy-benefit-manager/

https://affirmedrx.com/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-1/

https://affirmedrx.com/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-2/

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House Committee on Oversight and Accountability
Role That Pharmacy Benefit Managers (PBMs) Play in the Pharmaceutical Market
May 23, 2023

Written Testimony of Greg Baker, BS Pharm
CEO of AffirmedRx

Chairman Comer, Ranking Member Raskin, and distinguished members of the House Committee, I would like to thank you for the invitation to speak to your committee on the necessity of PBM (Pharmacy Benefit Managers) reform in the United States.

My name is Greg Baker. I first and foremost am a pharmacist. I am also the CEO of AffirmedRx which is a transparent PBM I founded and is headquartered in Louisville, KY. I began my pharmacy career 30 years ago as a pharmacy technician for an independent pharmacy in Fort Wayne, IN that not surprisingly is no longer in business – for many reasons we will touch on today. Beyond that I have 11 years experience working directly with jumbo self-funded employers to help define and develop their pharmacy programs. Our goal at AffirmedRx is to partner with self-funded employers to deliver patient-centric pharmacy benefits with a mission to improve health care outcomes by bringing clarity, integrity and trust to pharmacy benefit management.

Currently, a handful of large PBMs control up to 80% of the market in the USA. This is problematic for every employer in the country. These PBMs are not constrained by any obligation to be transparent on their pricing or methodology and this has caused an extreme escalation of cost to all employers using a traditional PBM. This problem is also costing taxpayers significantly since some of the biggest health plans in the country are run by local, state and federal government entities. Medicare and Medicaid programs throughout the country are also deeply affected by the practices of traditional PBMs. And perhaps most importantly, it is also incredibly frustrating for practicing pharmacists who have a

professional duty and deep personal obligation to their patients to provide the best care possible and for the patients themselves who can no longer afford their medication which they need in order to live productive lives.

In August 2022 the American Bar Association published an article explaining trends and developments in price gouging at the state attorney general level. They define price gouging as the practice of raising prices of essential goods, services, or commodities to an unreasonable, unfair, or excessive level typically during a declared state of emergency. While only 37 states have price gouging laws other states can still bring about lawsuits as a violation of state consumer protection or similar laws. Most of these laws are only triggered by a declared state of emergency, the occurrence of a natural disaster, or an "abnormal market or economic disruption". I contend, based on current PBM practices and the state of the pharmacy industry in America, every attorney general should be actively pursuing pricing gouging lawsuits.

Let's consider some facts that make me believe we are in a state of emergency and at a minimum are dealing with "abnormal market or economic disruption".

- Medications can be a key component to reduce health risk, control chronic disease and treat illnesses. In the U.S., illness and death from non-optimized medication therapy cost $528.4 billion annually – equivalent to 16% of total U.S. healthcare expenditures
- Patients starting new prescriptions as prescribed by their physicians abandoned 94 million prescriptions at pharmacies in 2022 with increasing frequency as costs rise
- A JAMA article published in June 2021 suggest that while drug manufacturers may increase list prices in order to offer larger rebates to insurers, such increases were associated with increased out-of-pocket costs to patients

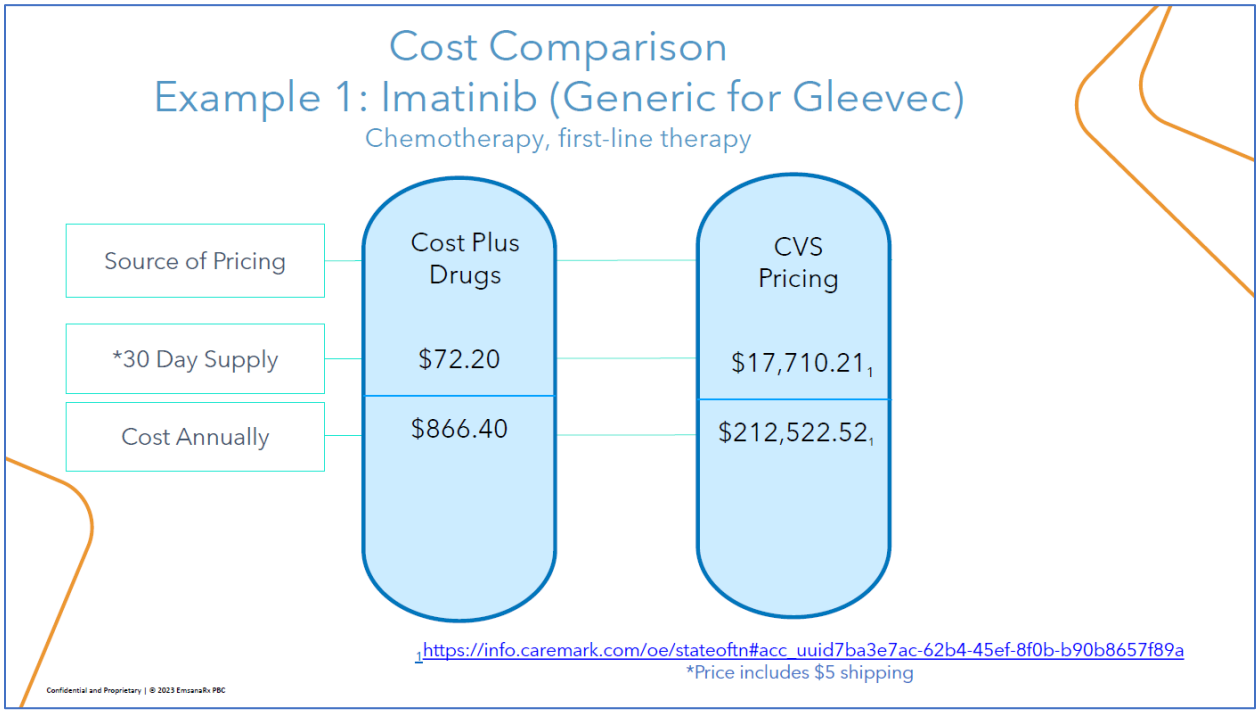
    - It found that between 2014-2018 list prices from manufacturers grew 13.3% while rebates paid to PBM's increased 24.4%.

- With the manufacturers raising list prices they also found that for every $1 increase in list price equated to an increase of $2.09 in patient out of pocket costs. While we have had much debate over the list price increases by pharmaceutical manufactures, these numbers clearly show how PBM's are retaining the most value and the American public continues to suffer greater drug affordability issues
- Finally, the report sadly pointed out that every $10 increase in patient out of pocket costs led to lower adherence rates. This is particularly concerning amongst individuals with lower incomes and among older adults as increasing prescription cost sharing can be associated with increased emergency department use, more frequent hospitalizations, and other poor health outcomes

While these numbers illustrate at a high-level overview how current market behaviors can have negative impacts on the entire system I have a specific example I would like to share with the committee. This points to the problem, but please understand this is just one out of the thousands of ways PBM's create profit for themselves at the detriment of our American society.

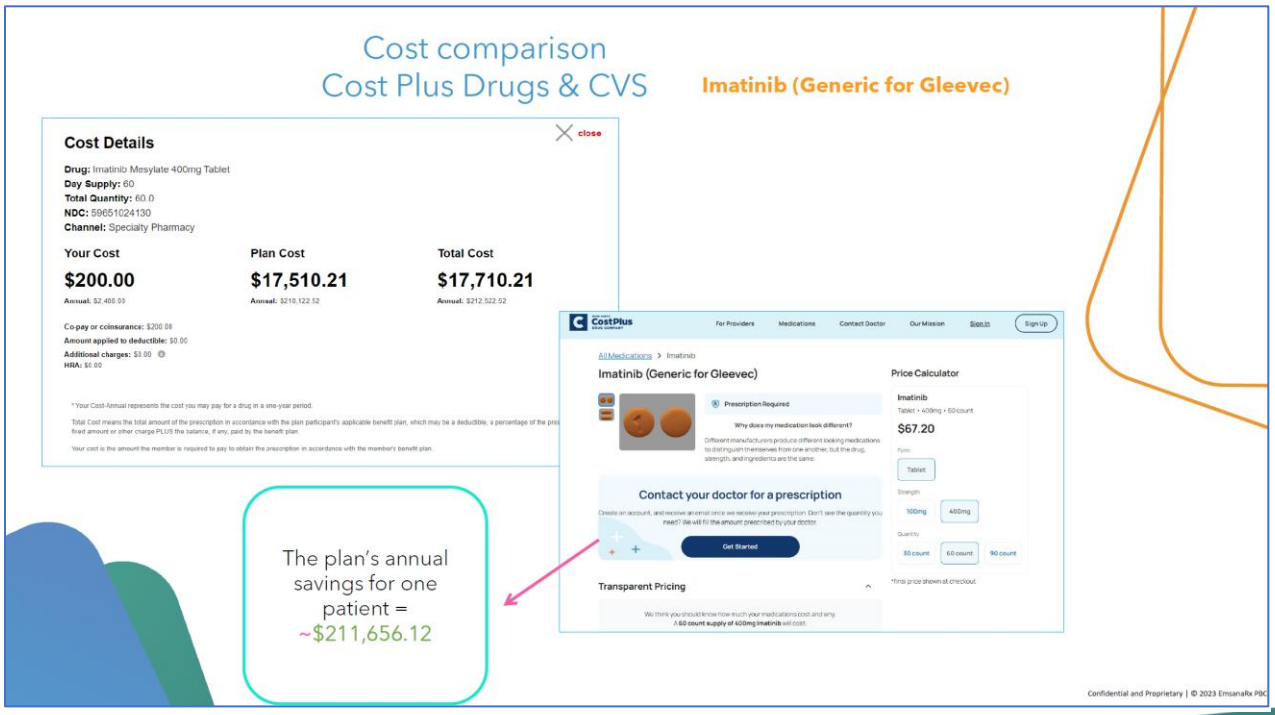
This example compares the cost of a medication provided transparently from Mark Cuban and his Cost Plus Drug Company. Mark posts all his invoices online so everyone can see what he is paying for the medications he sells. Traditional PBM's tell their clients they use their size and scale to get a better deal that smaller companies cannot compete with. We do know these large PBM's buy thousands of times more drugs than Mark Cuban and they very likely get a better acquisition cost, but they do not always use that purchasing power to help their clients. Below is one example which illustrates that the largest PBM's are likely making decisions in the best interest of their shareholder and not in the best interest of the patient. This is inexcusable at best in my opinion.

Figure 1



And the screenshots directly from each website…

Figure 2



These practices provide massive payouts to the traditional PBM while disadvantaging the employers and taxpayers utilizing their services. The worst part is the fact that this example exists because PBMs define where medications can and cannot get filled. In this situation they tell the market that because this is an oncology product it needs to be filled only at their own specialty pharmacy. Because the PBM – as a for-profit company – gets to decide what it pays itself bad things happen.

Additionally, there has been much discussion about rebates and the relationship between the pharmaceutical manufacturers and PBMs. I am not here to defend or hold manufacturers harmless when we are talking about why we have a drug affordability issue in our country. They are by no means innocent, but the PBMs bear a significantly larger responsibility to the problem. There are hundreds of brand manufacturers and only three main rebate aggregators. These three aggregators are each owned by one of the big three PBM's. They not only negotiate rebates for those traditional PBMs, but they now provide these rebates services to almost every other PBM in the industry. These aggregators are Ascent which was created in Switzerland by Express Scripts in 2019 and now owned by Cigna, Zinc which was created by CVS in 2020, and Emisar which was started in Ireland in 2022 and is owned by United Health Care. Ascent and Zinc each contract for over 100 million American lives and Emisar contracts for 65 million. They use their scale to create competition between manufacturers.

Let's look at insulin as there has been much talk about insulin pricing. Using Novo Nordisk as the example – they know if they lose access to the formulary controlled by one of these PBM's their medications will no longer be available to tens of millions of lives. So, the PBM's use this to their advantage and continue to extract more and more rebates because if Novo does not want to pay the higher rebate amounts the GPO will find one of the other manufacturers willing to do so. The massive market consolidation is why – as I previous mentioned – rebates are going up faster than list prices.

There are numerous reasons why costs go up, but the PBMs are at the heart of many of them. They are creating "abnormal market and economic disruption" at a time of national crisis when people can no longer afford their medications. When patients are not adherent to their medication overall health care costs increase significantly. If every American could afford their medication and had convenient access to a community pharmacy I believe we could remove hundreds of billions of waste for what we have today in a $1.4 trillion health care system. This price gouging and other negative practices need to be exposed and halted.

The practices being engaged in by these PBMs are inherently harmful to pharmacies throughout the country, especially independent pharmacies for several reasons. The first example of this is steering patients away from their local pharmacies to large mail-order organizations owned by these traditional PBMs themselves. Another example is these large PBMs also have the ability to make anything a "specialty drug" and not allow local pharmacies to dispense the drug regardless of what is best practice as shown in the Figure 2. Finally, even when these independent pharmacies are included in PBM networks, often the reimbursement of drugs to the pharmacy is less than their acquisition cost. In the end, this harms patients and their care. It is possible to operate a PBM, restrain costs for the employer and taxpayers while still providing the best pharmacy care available. But changes must be made to require greater transparency and allow for greater competition for this to happen.

While this testimony has illustrated numerous ways PBMs hurt American society there are unfortunately still many more. These include:

- Formularies are built preferring high-cost drugs over generics or drugs with lower cost
    - This results in high costs for members at the pharmacy counter when they are on high deductible or coinsurance plan
    - This increases PBM's profits via retention of manufacturer fees
- Narrow/Preferred networks are used to drive patients to more profitable pharmacy locations for the PBM while also limiting patient access which can be particularly harmful in lower income areas

- Self-funded employers are not allowed access to their pharmacy data which limits their ability to understand costs or make better decisions on behalf of their plan participants that could lower premiums and out of pocket costs
- Most self-funded employers use consultants they believe to be unbiased. These consultants may be compensated by the PBM with monies that are never disclosed to their clients – creating a conflict of interest and inhibiting competition. This concept is expressly called out in several SEC filings as illustrated on pages 22-23 of the 10-K filed by Willis Towers Watson calling out "market derived income"

In closing, I would like to point to William Deming who is acknowledged to be the foremost thought leader in total quality management. He has two disparate quotes I would like to leave the committee with. His first quote states "Every system is perfectly designed to get the results it gets". I know there has been much discussion that the PBM system is broken. My contention is that the industry has created a system to enrich corporate executives and create the opportunity to buy back hundreds of billions worth of corporate stock. This in turn massively increases shareholder value at the expense of the American corporation and taxpayer. The system isn't broken – it is working perfectly. The problem is we have the wrong system.

With that said I point to my second Deming quote. While we consider a better system through our conversation today Deming also said that systems need to be "a network of interdependent components that work together to try to accomplish the aim of the system. The aim for any system should be that everybody gains, not one part of the system at the expense of any other".
I commit to you that AffirmedRx will continue to work with employers, state and federal health plans and pharmacies throughout the country to find solutions to the challenges faced by those employers trying to just make sure their employees have access to the drugs they need while keeping down unnecessary costs.

Thank you, members of the committee, for the opportunity to speak today and I look forward to your questions.

For more information here are links to articles aimed at educating purchasers about the PBM industry:

https://affirmedrx.com/how-gpos-work/

https://affirmedrx.com/how-pbms-make-money/

https://affirmedrx.com/what-is-a-pbm/

https://affirmedrx.com/8-things-every-employer-should-know-about-their-pharmacy-benefit-manager/

https://affirmedrx.com/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-1/

https://affirmedrx.com/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-2/

COMMUNITY ACCESS NATIONAL NETWORK

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July 17th, 2024
Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Dear Madam Chair and Honorable Members of the Oregon Prescription Drug Affordability Board,

About CANN: 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 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 each and every one of those health conditions.

Firstly, we thank you for the work you have done thus far and applaud your recent decision to pause affordability reviews and not pursue a work product for 2024. It shows your commitment to facilitating the best outcomes for all stakeholders, especially patients and consumers. In the June 2024 meeting, you engaged in a transparent and inclusive discourse regarding multiple concerns about the development of your 'reset'. We are writing today to contribute perspective for you to consider in your ongoing deliberations of rethinking your approach.

One of your most pertinent foundational expressed concerns is defining **affordability**. Being tasked with defining affordability for Oregonians, it is essential to note that affordability is a complex issue that encompasses so much more than the list price of a drug. Out-of-pocket costs for patients, pricing for PBMs, costs for payors, and entities vary significantly due to the complicated nature of discounts, rebates, and more. However, regarding patients and consumers, affordability is more encompassing than just price.

Affordability also entails access concerns. Consider a hypothetical example drug that costs five dollars for a prescription (assuming five dollars is not cost-prohibitive for a particular consumer). That drug costs more than five dollars if a patient's insurance requires that specific drug to be prescribed only by a specialist. The patient now has to wait for an appointment and pay for a visit to a specialist. If no geographically convenient specialist is available, the additional expense of travel and time is required to see the specialist. Conversely, consider the very real scenario of a drug prescription that does not result in profitability for the PBM associated with a patient's insurance. As such, that PBM places that particular drug on a higher formulary tier resulting in higher cost-sharing for the patient in addition to making it only available via specialty pharmacy. A patient may not have any specialty pharmacies that are easily accessible to them and/or may be forced to use the PBM's mail-order pharmacy, which comes with many challenges, including

continuity of care and lack of consistent patient-pharmacist communication. In the same vein, consider a drug where a UPL was set that was lower than the acquisition cost for a pharmacy. Pharmacies cannot afford to operate at a loss. Thus, in a particular geographic region, that drug would only be available at one or two pharmacies; therefore, patients would have to travel far to get to a pharmacy that carried what they needed. The aforementioned scenarios are just a few of the many lenses through which to view 'affordability.'

UPPER PAYMENT LIMITS (UPLs)

Drug affordability boards heavily focus on utilizing UPLs by statute and in practice. Two important foundational facts are that UPLs **do not** impact what manufacturers charge, **no**r do they change the acquisition costs that pharmacies have to pay to carry medication. Additionally, a recent study conducted by Avalere Health, a healthcare business consulting firm, involving feedback from executives from six different healthcare plans covering almost seven million people, showed that even insurers report UPLs will not reduce patient costs and will result in unintended negative consequences. A UPL only sets the maximum that insurance plans will reimburse for drugs. That is not a direct benefit to consumers because there is no mandate for plans to pass any realized savings on to patients, to retain medications with lower reimbursements, or for patients to be given lower cost-sharing requirements related to the medications. PBMs, not drug manufacturers, control and influence the costs and formulary construction, which directly affect the prescription financial burden of patients. The Federal Trade Commission released a report on July 9th detailing how PBMs inflate drug costs to boost their profits, to the detriment of patients and the overall healthcare system.

ATTACHMENT: Attached, you will find an "infographic" designed by CANN evaluating the potential impact of an "upper payment limit" on the state's AIDS Drug Assistance Program (ADAP – In Oregon, CAREAssist), particularly as it relates to the value of 340B rebates and their re-investment in "stretching scarce federal resources". While some commenters have previously dismissed the potential 340B impact by pointing to reduced acquisition costs under 340B, the value of 340B is found in the spread between reimbursement and a rebated acquisition cost. Reducing the reimbursement rate of **any** medication in which a 340B rebate is sought would necessarily reduce the value of the rebate – meaning safety net providers, not just the CAREAssist program, would be negatively impacted by the imposition of an upper payment limit (UPL). CAREAssist merely provides a "neat" and simplified example of a program which might be negatively impacted by a UPL.

We should note: Oregon does NOT contribute state dollars to CAREAssist. The program is exclusively funded by federal grant dollars for this purpose and further supported by 340B rebate revenues. Any imposition of a UPL would require the state of Oregon to either appropriate state dollars to the program *or* reduce services or persons served by the program due to decreased program revenue.

This example is not limited to CAREAssist. The impact would also be felt by federally qualified health centers and hospital systems in the state of Oregon. Similar to CAREAssist, the imposition of a UPL would require the state would to either appropriate dollars to fill the "gap" *or* readily tell residents that fewer medical services or locations might be the reality they face in the near future.

Furthermore, federal medical assistance percentages (FMAP) of matching federal dollars to state expenditures in Medicaid programs would similar be impacted by any imposition of a UPL. Oregon's FY2025 FMAP is 59% and federal multiplier is 1.44, meaning the state of Oregon pays less than half of the state's Medicaid budget, leveraging federal matching dollars to extend the program. This is particularly noteworthy because Oregon has taken advantage of matching federal dollars to benefit of patients and innovative programs. However, if a UPL is imposed, the state will be spending fewer dollars reimbursing medications and thus reducing state expenditure. For every one dollar "saved" for pharmacy benefit managers or managed care organizations administering Oregon's Medicaid program under the imposition of a UPL, at least two dollars will be lost to the Medicaid program's budget.

We understand these are not the intended consequences the Board or even Legislators might have considered when approaching "affordability" legislation, but they are the issues the Board must face and weigh. How "affordable" is it for patients or the state to divest from the laudable goals of these public programs and safety net provider entities?

ENGAGEMENT

CANN also applauds the board's desire to investigate and find robust ways to engage with patients, consumers, first-line medical professionals, community organizations, and more to gain first-hand perspectives of concerns around prescription affordability concerns. They appear to understand that claims data does not provide a thorough analysis of the patient experience nor the costs to systems. Claims data also does not capture information showing how much manufacturer rebates are passed on to patients or how much charitable private organizations and patient assistance programs help reduce patients' financial burden.

LEGISLATIVE REPORT

We understand that the actions of the board are significantly influenced by legislative statute. As you move forward, we encourage you to continue working with legislators to expand and modify the parameters in which the Board can utilize methodologies and desired information gathering to achieve its goals. Moreover, we encourage you to investigate other means of attaining the affordability goals you formulate, without the negative, unintended consequences UPLs pose. The state of Colorado's PDAB, in its legislative report, did heed advice offered from CANN and other patient advocates in elevating concerns related to plan design, patient protections regarding utilization management, and requested the legislature work to understand how rebate values are not sufficiently passed along to patients. We similarly encourage Oregon's PDAB to offer these meaningful and tangible potentials to the legislature.

CANN looks forward to working the board, sharing our experiences from other states regarding PDABs, and ensuring the best outcomes for patients remains a priority.

Respectfully submitted,

Ranier Simons
Director of State Policy

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

COMMUNITY ACCESS NATIONAL NETWORK

Prescription Drug Advisory Boards (PDABs)

Response Project for People Living with HIV

Prescription Drug Affordability Boards: A Threat to Ending the HIV Epidemic?

State AIDS Drug A33i3tance Program3, or ADAP3, are largely dependent on 3aving3 and revenue3 1rom the 34OB Drug Pricing Program to *"stretch scarce Federal resources as tar as possible reaching more eligible patients and providing more comprehensive services."*

Prescription Drug AVordability Boards, or PDABs, are considering "price control3" to set the cost of prescription drugs by setting an "upper payment limit" (UPL).

But here are some facts on why UPL price controls are bad for providers...and patients:

- 340B's value is found in the "spread" between the reimbursement rates and a reduced acquisition cost by way of drug manufacturer 340B rebates
- Reducing reimbursement rates by way of an "upper payment limit" will reduce the value realized by 340B rebates
- Providers end up with less money, which means they can afford to fund less services
- That's only *IF* a pharmacy can still afford to fill the medication
- Will your copay change" NO

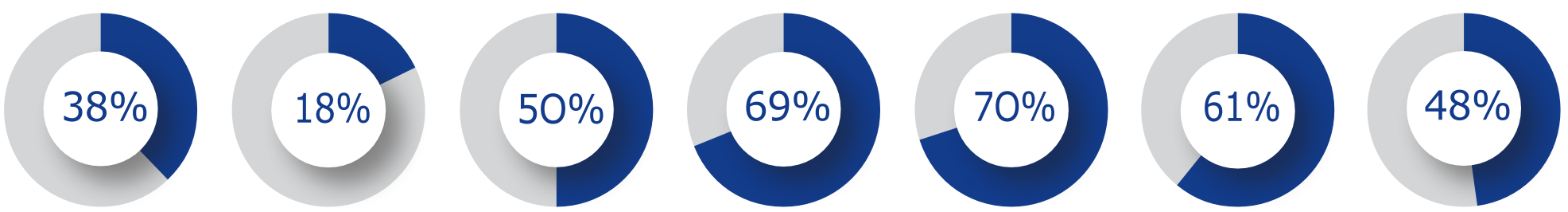
Ex.
Antiviral B Hypo:
- Normal reimbursement: $550
- 340B Price: $50
- Value of rebate: $500 - to be reinvested in HIV programming/providing medications

Under a UPL:
- UPL reimbursement: $350
- 340B Price: $50
- Value of rebate: $300 - to be reinvested in HIV programming/providing medications

What happens if the UPL is set below the cost of the medication?

Will your pharmacy be able to 1ill it?

This is particularly striking when we think about State ADAP Budgets, and NASTAD's 2023 RWHAP Part B ADAP Monitoring Report provide3 in3ight3. Take a look:



Mational Total	Colorado	Connecticut	Michigan	Mew Jersey	Oregon	Washington State
ADAP Funding (or about $802.66M)	SDAP (or about $3.9M)	(or about $16M)*	(or about $29M)*	(or about $66.1M)*	(or about $5.8M)*	(or about $11.7M)*

* ADAP State Contribution = $0

● = % of budget that is rebate

According to NASTAD, for most states, a majority of ADAP clients live at or below 300% of the Federal Poverty Level, meaning even when they're Medicaid Qualified, they still need help. Taking dollars out of ADAP by reducing the value of the rebates is a DISINVESTMENT 1rom HIV-related 1unding.

For more information, visit our website at www.tiicann.org/pdab-project.html

On behalf of HealthHIV, we genuinely appreciate the opportunity to provide comments on the Board's input on cost considerations—which includes the meaning of affordability, utilizing continuous quality and program evaluation metrics, and potential changes in access.

For background, HealthHIV is a national non-profit organization that works with healthcare organizations, communities, and providers to advance effective HIV, HCV, STI, and LGBTQI+ healthcare, harm reduction, and health equity through education and training, technical assistance and capacity building, advocacy, communications, and health services research and evaluation.

Implications of Upper Payment Limits Setting UPLs may seem like a straightforward solution to controlling drug costs, but it can lead to significant challenges in patient care. For instance, imposing a ceiling on reimbursement rates can discourage pharmacies and clinicians from offering certain medications if they are not adequately compensated. This can limit patient access to essential treatments and force individuals to seek care elsewhere, disrupting continuity and potentially leading to worse health outcomes and ultimately more cost to the system, including those the Oregon PDAB aims to improve. This is particularly concerning in the context of pharmacy deserts, where the closure of pharmacies can severely limit access to medications for underserved communities.

Operational Challenges and Financial Burdens Implementing UPLs could introduce numerous operational challenges and financial burdens across the drug supply chain, including for pharmacies, wholesalers, providers, payers, and patients. For example, effectuating a UPL price through the supply chain may require new pharmacy and wholesaler acquisition/tracking systems and introduce payment streams that do not exist today. Any challenges in pharmacy and wholesaler supply operations can directly lead to gaps in patient access, particularly if a patient's local pharmacy is unable to operationalize and comply with UPL-driven requirements.

Payers have indicated that drugs subject to UPLs, or other drugs in their therapeutic class, could face more utilization management (e.g., prior authorization) once a UPL is implemented, as well as changes in formulary tiering, which could increase patients' out-of-pocket costs. UPLs are also likely to have long-term effects on the prescription drug ecosystem, including provider access, copay assistance needs, and manufacturer research and development (R&D).

Issues with Step Therapy The use of step therapy protocols, where patients must try alternative medications before accessing their prescribed treatment, poses serious risks. These protocols often do not account for individual medical histories and can delay access to the most effective treatments. For patients with chronic conditions, such delays can result in deteriorating health and increased overall healthcare costs. While step therapy aims to control costs, it can ultimately create more downstream expenses due to complications arising from ineffective initial treatments.

Impact of Pharmacy Deserts on Patients and Links to Affordability One important consideration in establishing UPLs is the trend of pharmacy closures that disproportionately affect rural and underserved urban areas, creating pharmacy deserts. These closures are often exacerbated by pharmacy benefit managers (PBMs) routing patients to their preferred or contractual pharmacies. This can significantly stymie and create more inequitable access to medications, especially for those who rely on local, long-standing community pharmacies for their prescriptions and their localized approach to care and prevention. Without nearby preferred or trusted patient pharmacies, residents may face longer commutes, reduced access to medications, and increased time or out-of-pocket costs.

Additionally, patients might be routed to their plan's preferred pharmacy, which may stop carrying medications subject to UPLs, or they may have a harder time obtaining adjusted medications that replace those under UPL considerations—medications that have also been subject to UPL scrutiny across other states' PDABs. Addressing this issue requires innovative solutions, such as enhancing Medicaid reimbursements for low-volume pharmacies, incentivizing pharmacies to operate in underserved areas, and improving transparency around PBMs to ensure fair pricing and support for independent pharmacies. UPLs without these considerations can jeopardize the good work you've all already done.

Recommendations To ensure that the Board's efforts effectively balance cost control with patient care, we recommend the following:

1. **Review and Refine Methodologies:** More thoroughly review and refine the methodologies and CQI data (including real-world data) used in affordability evaluations to ensure decisions are based on more accurate and comprehensive information.

2. **Involve Stakeholders:** Engage a broader range of stakeholders—including patient advocacy groups, healthcare providers, and pharmacists, to gather diverse perspectives and address potential gaps in the current evaluation process. The efforts to date have yielded good success, and that should be carried forward.

3. **Ensure Patient Access:** Develop clear and robust exception processes within utilization management (specifically fail-first and step therapy protocols) as related to UPLs in efforts to more solidly protect patient access to essential health treatments and prevent adverse outcomes, like gaps in treatment.

4. **Enhance Data Transparency:** Improve the transparency of data analysis and the incorporation of patient input to ensure decisions reflect real-world patient experiences and costs.

5. **Address Pharmacy Deserts:** Implement policies to prevent pharmacy disruptions and deserts in underserved areas, such as enhanced Medicaid reimbursements for low-volume pharmacies, incentives for pharmacies in rural and urban underserved areas, and transparency in PBM practices to ensure fair pricing and support for independent pharmacies. Do this in concert with your current work.

By adopting these recommendations during the Board's "pause" it can better navigate the complexities of drug pricing and access, ensuring that cost control measures do not inadvertently harm our healthcare system.

Thank you for considering our input.

Thoughtfully—*and respectfully*—submitted for your consideration,

Scott D. Bertani

Director of Advocacy, HealthHIV

July 25, 2024

OR Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Room 410
Salem, OR 97309

Dear Members of the OR Prescription Drug Affordability Board:

On behalf of the Arthritis Foundation, representing the nearly 60 million Americans and over 833,000 Oregon residents living with doctor-diagnosed arthritis, we would like to submit comments following the Prescription Drug Affordability Board (PDAB) meeting July 24, 2024.

Many important questions and themes were discussed during the July 24 meeting, including the impact of both state and federal health system policies on patient affordability. A good example would be the recent passage of HB 4113 that ensures copay assistance counts towards a patient's out of pocket costs. When implemented, this protection will greatly impact affordability for many patients. We believe it is important for the PDAB to consider this law in relationship to the other criteria it is considering for determining affordability, in addition to the overall question of affordability to the patient.

We also want to raise some questions about the design and establishment of an Upper Payment Limit (UPL), which could have wide-ranging implications. While the Arthritis Foundation does not take a formal position on UPLs, we do have a number of questions about how a UPL would be designed and operationalized, including:

1. What methodologies would the PDAB consider in determining a UPL?
2. How would the PDAB ensure any methodology is patient-centered and accurately incorporates patient experiences and preferences?
3. How would the PDAB engage with the patient community in the design of the UPL?
4. Once implemented, how would the UPL affect other drugs in the class and the designation of preferred and non-preferred drugs?
5. How can the PDAB ensure that a UPL does not negatively impact access to Enbrel and the ability of Enbrel to remain on formularies?
6. Has the PDAB considered unintended consequences such as increased utilization management and the potential for patients to be inappropriately switched to a less effective drug?
7. What is the potential impact on other pricing structures, including Medicaid Best Price and 340B calculations?

8. What is the potential impact to providers and pharmacists in terms of reimbursement for stocking and/or administering the drug?

We would also caution that establishing a UPL will not necessarily make a drug more affordable for a patient. Insurance design and employer benefit packages are such that many patients are on high deductible health plans (often with no other option) and specialty drugs like Cosentyx are often placed on specialty tiers with co-insurance. For Exchange plans, it is not uncommon for co-insurance to reach 40-50%. Even if you set an UPL that is half the current list price, a 40% co-insurance will still make that drug unaffordable to most patients without some form of cost-sharing assistance.

With regard to methodology, we have developed several sets of principles and best practices regarding patient-centered value assessment methodologies and would highlight in particular a project in which we collaborated with the Innovation and Value Initiative (IVI) to better incorporate patient experience data into their modeling. We coordinated a focus group that yielded invaluable insights and as a result we co-authored a white paper highlighting the key themes and best practices for this patient-centered approach. While we have included this in previous comments to the OR PDAB, we are reiterating some of the key highlights here, as we believe these conclusions are critically important to take into consideration.

- Traditional clinical trials and research do not always capture the full complexity of living with RA, including comorbid conditions, fatigue, mental health, and the impact of hormonal changes.
- Access to effective treatment may be driven by insurance coverage or haphazard testing of treatments rather than by clinical guidelines.
- Costs related to RA include far more than direct medication costs and need to be captured.
- While RA is a progressive disease, people living with it are seeking independence and normalcy versus just symptom management.

The focus groups revealed a diverse range of experiences. From the paper:

- While severity of RA and response to treatment vary among individuals, commonly experienced symptoms include significant joint pain and weakness, stiffness, and fatigue.
- Most participants described fatigue as an unaddressed impact of RA, and a factor further exacerbated by many of the RA treatments as a side effect.
- Multiple individuals pointed to hormonal changes (puberty, pregnancy, menopause, etc.) as “triggers” to the onset of symptoms or treatment failures.

- Nearly every participant described significant psychological impacts of the disease, including depression, anxiety, and social isolation.
- Co-occurring conditions are common, and when present, complicate outcomes. Multiple participants reported co-occurring health conditions, including type 1 diabetes, fibromyalgia, spondyloarthropathy, lupus, anxiety, and depression.

The paper noted that even with only 14 participants, there was wide diversity in time to diagnosis (between 6 months and 5 years) and time to finding an effective treatment (between 1 year and never); treatment experiences from the paper:

- Participants reported that treatment choices appeared to be based on trial and error or insurance coverage, rather than clinical guidelines or assessment by their clinician.
- Many had difficulty finding effective treatment over time. Most were concerned about the durability of treatment and the lack of clarity about what might trigger sudden change or failure of a treatment. Several reported never finding a fully effective treatment option despite extensive regimen testing.
- Multiple individuals were concerned about running out of treatment options; there was a sense that each treatment had a “shelf life” or limited time horizon.
- Participants reflected a common experience or understanding that insurance coverage, socioeconomic status, and race impact the quality of and access to treatment.
- Participants described the impact of treatment on choices to have children, how having children impacts treatment options, and the ability to have children.

Also from the paper:
Other areas of less frequently measured costs that have high impact on patients’ experiences and outcomes include:

- Time spent in seeking, receiving, and recovering from treatment, with some calculating this cost to be upwards of a month a year.
- Diminished ability to work and lost wages due to early retirement or career impact, including choosing lower paying jobs to ensure health insurance access.
- Heavy burden of RA on caregivers (spouses, parents, and siblings), such as anxiety, missed work time, childcare, and job choice based on health insurance.
- Ancillary costs of seeking and receiving treatment, including transportation costs, non-medical supportive expenses (e.g., assistive devices), and non-covered benefits.

As you continue your work, we urge you to meet directly with patients to gain a more comprehensive understanding of the factors that contribute to their ability to access and afford their medications, and to work directly with patient groups like ours to design an appropriate, patient-centered methodology. Thank you for your consideration, and we look forward to engaging with you in the future.

Sincerely,

Melissa Horn
Director of State Legislative Affairs
Arthritis Foundation
MHorn@arthritis.org

National
Multiple Sclerosis
Society

July 26, 2024

Oregon Division of Financial Regulation
Oregon Prescription Drug Affordability Board
350 Winter St. SE
Salem, OR 97309

RE: National Multiple Sclerosis Society follow up Upper Payment Limits, Constituent Panels discussion

Dear Members of the Oregon Prescription Drug Affordability Board:

Thank you for taking the time to gather all stakeholders for the constituent panels discussion meeting regarding upper payment limits on July 24. The opportunity to provide direct feedback to the board from the patient perspective is much appreciated. This letter is to provide additional context and clarity to the National Multiple Sclerosis Society (the Society) comments related to upper payment limits.

UPLs related to copays and MS infusible products
The Society views the establishment of upper payment limits (UPL) as creating the potential to lower out of pocket costs for patients. High out of pocket costs are typically due to co-insurance, which is when the patient must pay a percentage of the wholesale acquisition cost (WAC) or list price as opposed to a flat copay amount. This is especially true for MS disease-modifying therapies (DMTs). A lower UPL would in turn create lower out-of-pocket costs for those who must pay co-insurance. Very important to note is that for infused medications, which include several of the most prescribed MS DMTs, patients face significant additional costs from the administration of, and additional services attached to, an infused product. A UPL would not affect this additional expense and, as a result, might not substantially lower patient out-of-pocket costs brought on by the overall infused medication services.

Costs of MS DMTs
When we discuss the cost of MS DMTs, we are not just talking about products new to the market. There are now over 20 DMTs on the market to treat relapsing-remitting courses of MS. 12 have been on the market for at least a decade, some of those have been on for even longer. The first DMT came onto the market in 1993 and was priced at approximately $11,000 annually. That same drug today has a WAC of over $126,000. It has not had any major formulaic changes. When researching the high cost of medications and the opportunity for review, we should keep in mind products such as these that are seeing continuous price increases year over year well above the rate of inflation with no true explanation.

The MS Society knows that price of the medication is but one aspect of what makes access to these high-cost prescriptions out of reach for many people with MS and other conditions. The Society will

National
Multiple Sclerosis
Society

continue to look at the entire healthcare system and encourages legislatures and boards, like the Oregon PDAB, to continue to work to address other aspects of the prescription drug supply chain that get in the way for patients, like continued attention to, and reform of, pharmacy benefit managers (PBMs) and utilization management protocols.

Respectfully,

Seth M. Greiner
Senior Manager, Advocacy
Seth.Greiner@NMSS.org

July 29, 2024

To whom it may concern:

I am a 3rd generation pharmacist/pharmacy owner and have practiced retail pharmacy for nearly 30 years. I welcome the opportunity to participate in this discussion regarding prescription drug affordability here in Oregon. I echo some of the comments that were made during the July 24, 2024 board meeting by other panelists. I feel that it would be helpful at similar panelist meetings in the future to have the intended questions shared with the panelists prior to the meeting so that we may be better prepared to answer them more accurately and it may make the flow of the meeting more efficient. I would also like to say that there seemed to be very little time for all of the panelists to comment if they had wanted to do so. I understand that with so many panelists invited to this meeting, it may be unrealistic to host a meeting for the length of time necessary to achieve this. I do applaud the PDAB for inviting so many stakeholders to this meeting.

I am concerned that any Upper Payment Limit (UPL) implemented may not make much of an impact with the current payment/reimbursement model. I am aware that rebates and other fees are involved with the Pharmacy Benefit Managers (PBMs) negotiation structure for placing medications (especially brand medications) on their formularies. PBMs' negotiating places higher cost drugs in a preferred status on many plans. Brett Michelin of Accessible Medicines identified that higher cost drugs are being purchased when less costly products are available on the market.

The patient and the public at large are shielded from the actual cost of medicine. As Brian Warren from Biotechnology Innovation Organization stated, what a patient pays at the pharmacy would define affordability for the general public. If prescription medications are not affordable to the pharmacy purchasing and dispensing them or if the pharmacy is not reimbursed at rates that would cover the overhead involved in filling them, then affordability of the medications for the patient are less of an issue than accessibility of the medications.

If pharmacies would be paid appropriately, as described above, and spread pricing (e.g., the pharmacy is paid $20 for a Rx and the PBM customer, such as the government or employer, is charged $80 for the same Rx) is removed from the current payment structure, then the bottle neck or path of greater resistance would not be at the pharmacy level. I feel that if accessibility if not an issue, then UPLs would be easier to implement.

One of the board members voiced that it seemed that some of the panelists were more concerned about protecting themselves than addressing the issue of medication affordability. It is almost too complex and interconnected to separate these out for some of us panelists.

During the meeting, I was very interested in hearing that 11 other states had implemented the type of policies that Oregon's PDAB is exploring. I would think it would be of great benefit to find out what these other states have implemented and what the results of those implementations have been (the good, the bad, and the unexpected).

Thank you for your attention and willingness to listen. I hope that it has been of some help.

Thomas Wade Irby, RPh
Irby Pharmacy