HealthHIV

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August 20, 2024

We would like to first commend the Board for its inclusion—*and the effective synthesis*—of the concerns from constituent groups in its recent report. As the Board continues its efforts to evaluate the cost of prescription drugs in the State of Oregon, ongoing stakeholder engagement remains incredibly important.

However, we are concerned that during the Board's paused considerations of HIV antiretroviral (ART) drug affordability reviews, some of Oregon's largest community-based HIV service organizations, as well as the state's AIDS Drug Assistance Program (ADAP), were not publicly included in these initial PDAB stakeholder engagement opportunities. While we recognize that certain 340B entities were involved, we believe that the absence of these critical HIV-focused advocacy groups and ADAP limits the representativeness and inclusivity of the discussions, particularly concerning person-first HIV care continuum considerations.

Additionally, it was mentioned during previous meetings that the Oregon Health Authority (OHA), which oversees CAREAssist, has been in conversations with the Board and CAREAssist's service contractors, including 340B covered entities, regarding the potential effects of any resulting PDAB work products (such as UPL effects on ecosystems).

As you are aware, CAREAssist is vital in helping low-income Oregonians living with HIV access and afford necessary medications, medical care, and other outpatient support services. We would also welcome any additional feedback from those discussions, or from others involving additional payors, such as OHA's HIV Care and Treatment Program, which plays a crucial role in coordinating services for people living with HIV, including those on Medicaid. This program ensures that HIV providers have the necessary support and resources to deliver care to low-income individuals living with HIV who are enrolled in Oregon Medicaid.

We look forward to continued engagement in the Board's ongoing work.

Respectfully stated,
Scott D. Bertani
Director of Advocacy, **HealthHIV**

Consumer Cost Factors in Capping Drug Prices

My name is Mark Sturbois and this will be the 3rd time I have testified to this committee. I have pretty much the same message. I won't belabor the research and development which is my only avenue to cure my untreatable terminal cancer. I will focus on outside factors that are part of the equation .

I would like to incorporate some of the testimony from the last meeting in my remarks. First we need to reform the independent board that decides reimbursement for Medicare and Medicaid. This year they imposed a 3.4 to 3.6 increase when the Models forecast 4 to 4.1%.

This causes many rural providers to stop accepting Medicare patients because they start off losing money. This causes patients to have to drive to other areas just to see a doctor.

This board needs to at least come to a break even point.

Second let’s stop allowing carriers to form a dummy non transparent company and buy out rural and in store clinics and folding them into their networks. State leader Ben Bowman has been a champion on this matter.

Third I learned from the last meeting that when the cost of insulin was capped some manufacturers stopped making it because it ate into their profit margin creating shortages in some cases.

Fourth many prescription benefit managers can change the preferred drug of choice for certain conditions and offer incentives to prescribe. What this can do is take a drug someone has been taking long term and move it from the let’s say $8 price range to perhaps 30 or 40.

This plays havoc with small pharmacies like the Brooklyn Pharmacy in Portland who testified at the last meeting that the flux is making it hard for him to stay in business.

Thank You for your time

Oregon Prescription Drug Affordability Board and Drug Price Transparency Program
350 Winter Street NE
Salem, OR 97309-0405

Dear Members of the Oregon Prescription Drug Affordability Board and Drug Price Transparency Program**:**

Thank you for the opportunity to comment on efforts led by the American Diabetes Association (ADA) that would improve access to continuous glucose monitors (CGMs) for Medicaid beneficiaries diagnosed with diabetes who use insulin or have a history of problematic hypoglycemia.

Continuous glucose monitors help people with diabetes to manage their blood glucose levels to avoid or delay serious short-term or long-term complications, hospitalizations, and even death.

To ensure appropriate access to CGMs, ADA advocates for expanded coverage and elimination of overly restrictive barriers. Through this work, ADA is partnering with people with diabetes, health care professionals, advocacy groups, and policy makers to address disparities with CGM access in Medicaid programs. Together, we are working for health equity through improved access and positive health care outcomes for people with diabetes.

In addition to providing glucose information directly to the person with diabetes, these devices also support medication administration in the following ways:

- CGMs can connect with insulin pumps to automatically adjust insulin delivery.
- Data from using CGMs can help providers adjust medications to prevent adverse diabetes events.

New data featured at the American Diabetes Association's June 2024 Scientific Sessions highlighted the benefits of continuous glucose monitoring (CGM) in improving glycemic control and overall diabetes management. [1]

Some key findings include:

- CGM use in type 2 diabetes results in more than a 50% reduction in all-cause hospitalizations and acute diabetes-related hospitalizations. [1]
- The use of CGM substantially improves glucose control in type 2 diabetes patients across *all therapeutic treatments*. [1]

Utilization controls and restrictive coverage policies sometimes prevent these devices from being accessible to individuals who would benefit from them. A recent study conducted by the American Diabetes Association (ADA) found that poorer, older, black and brown Americans are less likely to get CGMs. [2] According to the study, Medicaid beneficiaries who take insulin were two to five times less likely to use a CGM than those with commercial health insurance coverage. [2]

Examples of current burdensome criteria for Medicaid beneficiaries in Oregon are the requirement that a beneficiary has a baseline A1C of 8% and that they are on short-or intermediate-acting insulin.

The ADA is advocating that the Oregon Health Plan provide coverage for continuous glucose monitors and related supplies for the treatment of a Medicaid recipient if:

- The recipient has been diagnosed by his or her primary care physician, or another licensed health care practitioner authorized to make such a diagnosis, with type 1 diabetes, type 2 diabetes, gestational diabetes, or any other type of diabetes; and
- Is treated with insulin; or
- The recipient has a history of problematic hypoglycemia

These changes would align with recent changes made by CMS with respect to Medicare.

To qualify for continued coverage, we recommend that the Medicaid recipient be required to participate in follow-up care with his or her treating health care practitioner, in-person or through telehealth, at least once every 6 months during the first 18 months after the first prescription of the continuous glucose monitor has been issued to assess the efficacy of using the monitor for treatment of his or her diabetes. After the first 18 months, we recommend that follow-up care must occur at least once every 12 months.

We thank you for your consideration and encourage the Oregon Prescription Drug Affordability Board & Drug Price Transparency Program to support efforts to improve access to CGMs to improve health outcomes and address health disparities for Oregonians living with diabetes.

Should you have any questions regarding these comments please contact me at mprokop@diabetes.org

Sincerely,

Matt Prokop
Director, State Government Affairs

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[1] American Diabetes Association 2024 Scientific Sessions: https://diabetes.org/newsroom/press-releases/breakthrough-studies-automated-insulin-delivery-and-cgm-type-2-diabetes#:~:text=Using%20the%20same%20database%2C%20findings,2%20Diabetes%20Not%20Using%20Insulin

[2] American Diabetes Association: https://diabetes.org/sites/default/files/2023-09/ADA-CGM-Utilization-White-Paper-Oct-2022.pdf

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
Senior Manager, Advocacy
Seth.Greiner@NMSS.org

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

September 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: 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,

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[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.