COMMUNITY ACCESS NATIONAL NETWORK

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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

HIV+HEP
POLICY INSTITUTE

October 11, 2024

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

Re: Public Comment for October 16, 2024 Board Meeting-Policy Recommendations for Oregon Legislature

Dear Members of the Oregon Prescription Drug Affordability Board:

The **HIV+Hepatitis Policy Institute** is a leading organization advocating for quality, affordable healthcare for individuals living with or at risk of HIV, hepatitis, and other serious or chronic health conditions. As the legislature considers modifications to SB 844, **we write to express our support for proposed legislative recommendations including enhancing transparency around the use of copay accumulators, copay maximizers, and alternative funding programs.**

In recent years, insurers and their PBMs have implemented harmful policies that shift financial responsibilities for prescription costs to patients by not applying copayment assistance from drug manufacturers and sometimes charitable organizations. Cost-shifting mechanisms, such as copay accumulators, copay maximizers, and alternative funding programs (AFPs), have become increasingly common in commercial insurance plans. By 2022, it was estimated that 39% of beneficiaries under commercial insurance were enrolled in plans with copay accumulators[i], 41% in those with copay maximizers[ii], and 12% in plans using AFPs.[iii] In Oregon, five out of six insurers on the marketplace are implementing these programs.[iv] These programs introduce additional cost barriers for patients and healthcare providers, complicating timely access to necessary medications.

People living with HIV, hepatitis, and other serious chronic conditions rely on medications for their health and survival. Individuals with HIV and hepatitis B must follow lifelong drug regimens, while those with hepatitis C can be cured within 8 to 12 weeks. However, despite having health insurance, access to these medications can be delayed or even denied due to these insurance practices.

Support for Reporting on Copay Accumulators and Maximizers

Requiring insurers to report on the use of copay accumulators and maximizers is crucial for transparency and accountability in healthcare cost-sharing. These programs shift costs onto patients by excluding manufacturer copay assistance from deductibles and out-of-pocket limits,

which often leads to higher expenses and reduced adherence to medication. Additionally, insurers and PBMs are collecting the copay assistance and keeping it for themselves. Since the copay assistance does not count towards the beneficiary's cost-sharing obligations, they then turn to the beneficiary to collect additional funding and therefore, are "double billing". By mandating detailed reporting, the Board can assess the impact of these programs on patient affordability and access to medications.

Add Reporting Requirements on Alternative Funding Programs

We also recommend the Board consider extending these reporting requirements to include Alternative Funding Programs (AFPs). AFPs are used by self-funded employer health plans to shift the cost of expensive specialty medications away from the insurance plan. These programs typically classify specialty medications as "non-essential," excluding them from regular insurance coverage. Patients needing these medications must navigate third-party assistance programs, which is meant for people without insurance coverage. This often involves complex and time-consuming processes to access medications, sometimes through manufacturer patient assistance programs or international pharmacies. AFPs selectively avoid covering individuals with higher health risks, such as those with pre-existing conditions, disproportionately impacting people with chronic or rare diseases who rely on specialty medications, raising serious concerns about health equity.

AFPs can lead to significant treatment delays, which can have serious consequences for patients with HIV and hepatitis and broader public health implications. Even a brief delay in treatment can trigger viral resistance, rendering that medication and the entire class of medications like it an ineffective option for that patient. Consistent use of these treatments helps suppress viral load counts and reduce the chances of spreading these infectious diseases.

Requiring insurers to disclose the extent and impact of AFPs would allow the Board to better understand how these programs affect patient affordability and access to these critical medications. This reporting would also highlight how many patients are denied timely access to medications and expose ethical concerns, such as the diversion of charitable resources intended for the uninsured or underinsured. Increased transparency would help ensure that AFPs do not compromise patient care under the guise of cost savings.

We also support the proposed change relative to the number of drugs to be reviewed per year and the consideration of patient assistance programs, which substantially contribute to patient affordability of medications.

These recommendations promote fairness, transparency, and accountability in the pharmaceutical and insurance sectors, prioritizing patient well-being. We urge you to support the adoption of these measures to improve access to affordable prescription medications for all Oregonians.

Thank you for considering these important policy proposals. We look forward to your support in advancing these recommendations. If you have any questions or need any additional information, please do not hesitate to reach out via phone at (202) 462-3042 or email at cschmid@hivhep.org.

Sincerely,

Carl E. Schmid II
Executive Director

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[i] Fein AJ. Copay Accumulator and Maximizer Update: Adoption Plateaus as Insurers Battle Patients Over Copay Support. Drug Channels.

[ii] Pharmaceutical Strategies Group. 2023 Trends in Specialty Drug Benefits Report.

[iii] Fein AJ. Employers Expand Use of Alternative Funding Programs—But Sustainability in Doubt as Loopholes Close. Drug Channels.

[iv] The Aids Institute: Copay Assistance Diversion Programs in Oregon

Johnson & Johnson

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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).

PIPC Partnership to Improve Patient Care

October 13, 2024

Ms. Shelley Bailey, MBA
Chair, Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Mr. Ralph Magrish,
Executive Director, Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Dear Chair Bailey and Mr. Magrish:

I am writing to again share the comments submitted by the Partnership to Improve Patient Care (PIPC) on May, 14, 2024 urging the Prescription Drug Affordability Board (PDAB) to avoid policies that would potentially discriminate by relying on discriminatory metrics such as the Quality-Adjusted Life Year (QALY) that have detrimental implications for access to needed care and treatment, as well as encouraging the Board to include patients and people with disabilities throughout its decision-making process. Additionally, we wanted to share the following comments related to the discussion at the prior PDAB meeting on October 2, 2024.

OHSU presented to the PDAB options for consideration that demonstrate its lack of awareness of the existing law and policy that bars the use of QALYs and similar metrics. The presentation outlined potential approaches for setting upper payment limits that included reference pricing to existing benchmarks. Among those included reference to prices in other countries, Veterans Affairs, and Medicare. OHSU also proposed use of cost effectiveness analyses, which historically rely on QALYs and similar measures. Like the Program on Regulation, Therapeutics and Law (PORTAL), the Institute for Clinical and Economic Review (ICER) and the National Association of State Health Policy (NASHP), OHSU's presentation is aligned with their perspectives supporting the use of tactics that devalue people with disabilities and ignore the potential consequences for patient access to care. The PDAB has continuously heard from patients and people with disabilities about their concerns with the PDAB's reliance on entities that support or at a minimum are complicit in the use of QALYs and similar measures. In fact, I testified to the Oregon legislature before it passed a bill barring the use of a "quality of life in general measure" like the QALY or similar measures[1] and testified on multiple occasions to the Health Evidence Review Committee.[2] Yet, the PDAB continues to rely on advice from entities that historically support their use, thereby creating distrust from people with disabilities and serious chronic conditions.

In response to OHSU's suggested reference to foreign health systems, we would emphasize that referencing other countries is contrary to federal laws governing disability discrimination. PIPC

[1] http://www.pipcpatients.org/blog/pipc-chair-testifies-before-oregon-house-committee-on-sb-1508
[2] http://www.pipcpatients.org/blog/chairmans-corner-chairman-coelho-testifies-in-oregon-against-use-of-qalys

and others have commented on proposed federal policies that would reference prices in other countries, raising concerns that such a policy would import discriminatory standards from other countries, and lead directly to lack of access to needed treatments for many Americans.[3] We encourage the Board to review PIPC's paper on the German system in which we discussed its limited use of evidence, inappropriate comparators and endpoints, exclusion of health outcomes that are important to patients, and failure to capture heterogeneity of patient populations.[4] PIPC would encourage the PDAB to also reference the work of the National Council on Disability, an independent federal agency advising Congress and the administration on disability policy, which has consistently recommended against referencing foreign prices in comments related to a proposed international pricing index,[5] Most Favored Nation policy,[6] and federal legislation.[7] The NCD's recommendations against reliance on cost effectiveness are largely reflected in the new federal regulations discussed below, providing increased clarity on the prohibited use of discriminatory value assessments.

Additionally, it is important to recognize that the Veterans Health Administration has a partnership with ICER, a relationship that we are unaware of having changed since the recent regulations that bar all recipients of federal financial assistance from using discriminatory value assessments. As background, on June 27, 2017, ICER announced an agreement to work with the Department of Veterans Affairs (VA) Pharmacy Benefits Management Services office (PBM) to support its use of ICER drug assessment reports. Under this agreement, ICER works with VA staff to integrate ICER's academic reports into the VA formulary management process of evaluating the comparative effectiveness and value of drugs. ICER relies on QALYs and the similar measure evLYG to assess the value of medications, measures barred by statute from use in Medicare due to its implications for discrimination. ICER's value determinations are based on population-level averages that do not reflect individual differences among veterans and the military.

On November 13, 2017, organizations representing veterans, military families, patients and people with disabilities expressed concern to the VA about their partnership with ICER, stating, "Prescription drug coverage determinations based on flawed analyses like those conducted by ICER are not the answer and can only serve to further limit access to care for veterans with disabilities and serious chronic conditions, thereby exacerbating the challenges that they and their caregivers often face."[8] Advocates expressed concern that ICER's assessments do not reflect the unique needs of veterans, thereby potentially exacerbating the existing access

[3] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_stakeholder_comment_on_importing_qalys.pdf
[4] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/germany_draft_2022_9-21_edited_clean.pdf
[5] https://www.ncd.gov/2020/08/05/ncd-statement-on-harm-of-using-international-pricing-index-for-u-s-prescription-drug-pricing/
[6] https://www.ncd.gov/letters/2021-01-15-ncd-letter-to-cms-on-most-favored-nation-rule/
[7] https://www.ncd.gov/letters/2021-04-29-ncd-letter-to-house-committees-with-concerns-regarding-h-r-3/
[8] See http://www.pipcpatients.org/uploads/1/2/9/0/12902828/va_letter_final.pdf

challenges that they and their caregivers often face. The VA formulary is already more limited than Medicare's formulary. The VA National Formulary frequently does not cover medications that ICER decides to be of low to intermediate value or imposes utilization management strategies recommended by ICER that create barriers to coverage through lengthy appeals or step therapy.

With regard to the Medicare Drug Price Negotiation Program, it has not yet provided clarification on its use of elements of studies that include QALYs or how it will use similar measures. Additionally, the agency has not provided patients and people with disabilities insight on how its decisions are being made, including how patient input is used or how cost effectiveness analyses are used. We cannot support reliance on Medicare's decisions related to the Medicare Drug Price Negotiation Program knowing that the implications for patient access to care are unknown, the agency lacks transparency as to the evidence base for its decisions, and its methods for patient engagement have not been rigorous or robust.[9]

Finally, it is important to note that cost effectiveness analyses always come with risky tradeoffs for patients and people with disabilities. It is now widely recognized that traditional methods and metrics of value assessment – even beyond the QALY – have significant shortcomings. Well-intentioned development of other measures and approaches that developers assert to be nondiscriminatory and more patient-centered come with tradeoffs, need for improvement, and inherent methodological flaws. We urge the PDAB to avoid the use of cost effectiveness analyses that violate federal nondiscrimination laws and regulations and/or force tradeoffs such as whether to value life extension or quality of life improvement. No patient is average, and no measure of value should assume so.[10]

We appreciate your consideration and urge the PDAB to also review our prior letter sharing details of the law and existing regulations governing its use of cost effectiveness analyses. We look forward to development of strategies for incorporating input from patients and people with disabilities in a meaningful way, including use of the new survey developed by the Patient Inclusion Council.[11]

Sincerely,

Tony Coelho

Tony Coelho
Chairman, Partnership to Improve Patient Care

[9] http://www.pipcpatients.org/resources/cms-publishes-final-guidance-for-2026-2027-implementation-of-negotiation-program
[10] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_value_critique_updated.pdf
[11] https://eachpic.org/pic-launches-patient-created-survey-on-drug-affordability-and-access/

PIPC Partnership to Improve Patient Care

May 14, 2024

Ms. Shelley Bailey, MBA
Chair
Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Mr. Ralph Magrish,
Executive Director
Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Dear Chair Bailey and Mr. Magrish:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) to comment on the Oregon Prescription Drug Affordability Board's ongoing affordability review activities. Our comments follow letters sent to the Board urging it to avoid policies that would potentially discriminate by relying on discriminatory metrics such as the Quality-Adjusted Life Year (QALY) that have detrimental implications for access to needed care and treatment, as well as encouraging the Board to include patients and people with disabilities throughout its decision-making process.[1] I am writing to update the Board on recent federal policy developments that increase clarity on the state's obligations and limitations related to its use of discriminatory value assessments and to request robust engagement of patients and people with disabilities.

The State of Oregon has a long history related to the use of QALYs in developing its prioritized list of services under Medicaid. Over the last few years, PIPC was engaged in advocacy with the Health Evidence Review Commission (HERC) to shift away from the use of quality-adjusted life years (QALYs) and similar measures that discriminate. Recently, the legislature passed Senate Bill 1508 barring the use of generalized quality of life measures by statute.[2] We have been very concerned that the legislative provisions governing the use of QALYs and similar measures in legislation creating the Prescription Drug Affordability Board may be interpreted narrowly. Entities supporting the use of QALYs as the gold standard for value assessment, such as the Program on Regulation, Therapeutics and Law (PORTAL) and the Institute for Clinical and Economic Review (ICER), may be playing a role in the Board's decisions.

On May 9, 2024, the final new regulations governing Section 504 of the Rehabilitation Act were published, protecting the rights of people with disabilities in programs and activities receiving

[1] https://caringambassadors.org/pnw-advocates-confab/
[2] https://www.droregon.org/releases/landmark-legislative-healthcare-wins-for-people-with-disabilities

federal financial assistance.[3] In response to the proposed rule last year, PIPC joined 100 organizations and individuals on a letter supporting agency rulemaking to bar the use of quality-adjusted life years and similar measures in decisions impacting access to care.[4]

The U.S. Department of Health and Human Services' rule represents a critical step forward to protecting patients and people with disabilities and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards historically used by payers. As described in the final rule, the new regulations would bar health care decisions made using measures that discount gains in life expectancy, which would include measures such as the quality-adjusted life year (QALYs) and the combined use of QALYs and equal value of life years gained (evLYG). The agency broadly interpreted what constitutes the discriminatory use of value assessment in its description of the rule, stating, "The Department interprets recipient obligations under the current language of § 84.57 to be broader than section 1182 of the Affordable Care Act, because it prohibits practices prohibited by section 1182 (where they are used to deny or afford an unequal opportunity to qualified individuals with disabilities with respect to the eligibility or referral for, or provision or withdrawal of an aid, benefit, or service) and prohibits other instances of discriminatory value assessment." As you may be aware, section 1182 of the ACA bars Medicare's use of QALYs and similar measures that that discount the value of a life because of an individual's disability. PIPC was pleased the final rules governing Section 504 would be interpreted as broader than section 1182.

The agency referenced both § 84.56 and § 84.57 as relevant to entities receiving federal financial assistance, which includes state Medicaid programs. For example, the agency stated, "Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as § 84.56's prohibition of discrimination based on biases or stereotypes about a patient's disability, among others." Therefore, it will be critical for compliance with these rules that the Board understand the methods for generating the utility weights in any clinical and cost effectiveness studies that it may be using to make decisions to ensure they do not devalue people with disabilities. As PIPC and others noted in its comments to HHS, studies have confirmed inherent bias against people with disabilities in the general public, finding much of the public perceives that people with disabilities have a low quality of life.[5] Therefore, the potential for discrimination is significant when value assessments rely on public surveys, for example.

[3] https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov
[4] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf
[5] Ne'eman Et. Al, "Identifying and Exploring Bias in Public Opinion on Scarce Resource Allocation During the COVID-19 Pandemic," October 2022, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00504.

In summary, the new rules clarify that recipients of federal financial assistance, including Medicaid programs, may not rely on measures like QALYs.

Alternatively, PIPC recommends:

- The Board should engage directly with patients and people with disabilities to learn about their real-world experiences, consistent with recommendations from experts in the patient and disability communities.[6,7,8,9]
- The Board should collaborate directly with the patient and disability communities to solicit information. To date, we have seen very little participation from patients in the Board's meetings and listening sessions. We are also concerned that the Board did not develop its survey for patients in collaboration with patients. We have learned from other states how survey data may be misleading or fail to solicit the kind of information that is most useful to Board decisions.[10,11]
- The Board should respond to new federal regulations by making its process and decisions transparent related to its use of value assessments. We hope that the evidentiary basis for its decisions will be made public in a manner that is accessible and clear.

Thank you for your consideration of our comments.

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

[6] https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf
[7] https://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/programs/PATIENTS/pdf/Patient-driven-recommendations-for-the-Medicare-Drug-Price-Negotiation-Program.pdf
[8] https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf
[9] https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/
[10] https://drive.google.com/file/d/1oYGIPVVLrXL7ZXeu-eZ2vLZEunPhzN3u/view
[11] https://drive.google.com/file/d/1hF5-4Lxf5IHNNHMunRVm-fBaDt6QF-M3/view

October 16, 2024

Dear Members of the Oregon Prescription Drug Affordability Board,

On behalf of Regence BlueCross BlueShield of Oregon and our members, we thank the Prescription Drug Affordability Board and Staff for the opportunity to comment the Board's proposed policy recommendations to the legislature.

As one of the state's largest health insurers, Regence is committed to addressing persistent and emerging health needs for the nearly 1 million Oregonians we serve. In keeping with our values as a tax-paying nonprofit, 85% of every premium dollar goes to pay our members' medical claims and expenses. We are driven to ensure that our members receive the right care, at the right time, in the right place, and at the right cost.

We appreciate the Board's dedication to addressing affordability and access to prescription drugs for Oregonians, particularly focusing on high-cost drugs. While many of the proposed policy recommendations align with the Board's mission, we have concerns about proposals to mandate reimbursement rates and minimum dispensing fees across all payors. We believe that recommending specific payment thresholds and parameters for minimum payment is too complex for adoption without further study. Their inclusion is likely to undermine the Board's core mission to make drugs more affordable for Oregonians by potentially increasing consumer prices at the pharmacy counter and health insurance premiums.

As other board members mentioned during the Oct. 2nd meeting, we would encourage the Board to consider the Pharmacy Benefit Manager Workgroup led by Rep. Rob Nosse during the 2024 interim. This stakeholder forum exhaustively discussed the complexities of applying payment mandates across all payer types and the potential consumer impacts of tying dispensing fees to Medicaid FFS rates. Our data, as well as that of other carriers, shows that any increase in dispensing fees will be felt immediately by patients at the pharmacy counter.

For example, 60% of Regence members are currently paying their medication cost (or the "usual and customary rate") because it is lower than their copay amount. If the Medicaid FFS dispensing fee system were mandated, this would instantly increase the amount members are paying. To illustrate this, consider a fictional member who has three monthly generic prescriptions for which they pay $5 per month at the usual and customary rate (for a total of $15 per month for all prescriptions). If a mandated dispensing fee at the Medicaid FFS rate was implemented and the usual and customary rate was no longer less than their copay, they may instead be paying double the amount ($10/retail

prescription, $30 total) per month for the same medication, assuming their retail copay amount is $10 and they have not yet hit their deductible for the year. This scenario would vary depending on the member's pharmacy benefit plan design, but it illustrates what patients will experience if the Board's proposal were implemented.

At any rate, further study is needed on this issue to better understand the affordability implications of increasing prices at the pharmacy counter, and how it will affect consumers at the pharmacy counter and in their premiums. This is particularly true given that 61% of Oregonian adults have already expressed challenges affording medical care; the board should be extremely cautious in supporting policies that can increase consumer costs and that would undermine their goal of making health care more affordable for Oregonians.

Once again, we appreciate the opportunity to offer comment on the Board's proposed policy recommendations to the legislature. Regence shares the Board's concerns about affordable access to prescription drugs, as well as the goal of supporting our pharmacy partners. We hope the Board will consider our comments and remove specific recommendations for payment amounts and dispensing fees. We encourage Board members to explore existing avenues through which this work is already occurring and are happy to discuss any additional follow-up items.

Sincerely,

Mary Anne Cooper
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