NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

3307 Northland Dr, Ste 160 ▪ Austin, TX 78731
www.infusioncenter.org ▪ info@infusioncenter.org

January 23, 2024

Re: Impact of Upper Pricing Limits and Infusion Provider Reimbursement

Oregon Prescription Drug Affordability Board,

On behalf of the infusion providers we represent in your state, thank you for your service and commitment to the people of Oregon. As a nonprofit trade association that provides a national voice for non-hospital, community-based infusion providers; we ask you to please consider our concerns surrounding the establishment of upper payment limits on drugs sold in Oregon that are subject to affordability review by the OR Prescription Drug Affordability Board.

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of infused and injectable medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in high-quality, non-hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in quality of care and safety across care settings, and enable care delivery in the highest-quality, lowest-cost setting.

Our organization writes to express concerns with upper payment limits for drugs that the board has flagged as affordability challenges for Oregon patients and the healthcare system. We applaud Oregon lawmakers for attempting to address drug costs for patients. However, we believe that not only would an upper payment limit fail to achieve this goal, it would also harm the very vulnerable groups it intends to serve, unless certain measures are taken.

In practice, upper payment limits will hinder patient access to life-saving medications by disrupting the delicate economics of medical benefit drug delivery and putting smaller, community providers—that represent the lowest-cost care setting for these expensive medications—out of business. Infusion providers typically acquire, administer, and bill for drugs through a buy-and-bill model. Providers are reimbursed for the drug and provided a small payment for professional services that does not begin to cover the overhead of their business. To remain in business, infusion centers must rely on their drug payments to offset the incredible cost-reimbursement disparity on the professional services side. Drug payments are the

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economic lynchpin to offset practice expenses, including inventory management, staff salaries, and office space. Lower drug payments to infusion providers will force most of the state's community-based infusion centers to shutter their doors or discontinue administering certain drugs, forcing patients into more expensive hospital care settings or potentially ending their treatments.

Upper pricing limits put a ceiling on the reimbursement for certain drugs, but they do not guarantee that the drug will actually be cheaper for patients. An upper payment limit will only establish how much insurers in the state pay for a drug. It will not change the actual cost of drug acquisition and administration for providers, and it will not change what insurers require from patients through copays and coinsurance (most infusion patients use copay assistance to cover the cost of their medications, which insurers are trying to prevent through copay accumulator programs). Though well-intended, we fear that upper payment limits will harm infusion providers and their patients, leading to access issues across the state.

NICA suggests that the Oregon Drug Affordability Board takes some time to better understand the buy-and-bill model that most, if not all, infusion providers rely on. We hope that the board will be open to exploring other options, such as pushing for a legislative amendment that would exempt infusion providers from the impact of this bill - a provider carve-out. This would avoid disruptions to community-based care delivery and keep Oregon infusion centers and patients safe. Thank you for your consideration. If we can provide any additional information, please do not hesitate to reach out.

Sincerely,

National Infusion Center Association (NICA)

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

February 9, 2024

Ralph Magrish, Executive Director
Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter St. NE
Room 410
Salem, OR 97309

Submitted via pdab@dcbs.oregon.gov

Re: Vaccine Eligibility and Upper Payment Limit Actions

Dear Mr. Magrish,

On behalf of our members operating in Oregon, the National Association of Chain Drug Stores (NACDS) is writing to comment on the Prescription Drug Affordability Board's February 21st meeting to review the pre-selected list of prescription drugs deemed eligible for affordability review. We are concerned with the inclusion of vaccines in PDAB affordability reviews, and we fear that there may be significant impact on the availability and accessibility of certain prescription drugs at a patient's neighborhood pharmacy through the unintended consequences of inadequate and unfair pharmacy reimbursement by some payers resulting from the establishment of Upper Payment Limit (UPL) policies.

Vaccine Eligibility for PDAB Review

Community pharmacies provide many vital preventive services, including administering vaccines. To date, over 307 million COVID-19 vaccinations alone have been provided by pharmacies.[1] NACDS strongly believes that vaccines should not be subject to affordability review. Vaccines currently undergo a cost effectiveness and economic value assessment process through the CDC's Advisory Committee on Immunization Practices (ACIP) after FDA approval. They are reviewed and recommended by the ACIP before they can be accessed by the public or covered by public and private insurance. Both the Affordable Care Act and the Inflation Reduction Act mandate that all CDC-recommended vaccines are covered without cost-sharing for all publicly and privately insured individuals. For patients, this means that out-of-pocket costs are largely nonexistent. Additionally, federal safety net programs provide access to vaccines without cost-sharing for uninsured and underinsured individuals. Finally, high utilization of vaccines and preventing associated medical costs is the goal of the Oregon Immunization Program and helps address healthcare inequities. Vaccines should not be subject to an affordability review based on high or increasing utilization, as this conflicts with public health goals to increase immunization rates as an important prevention tool.

Reimbursement Concerns

Without necessary guardrails, any proposals for the creation of a UPL on selected prescription drugs could inadvertently result in inadequate reimbursements to pharmacy providers and pharmacies by failing to make up the difference between the UPL and the pharmacy's cost to acquire and dispense the prescribed drug. This outcome could force pharmacies to either operate at loss, make tough decisions regarding certain medications to stay afloat, or even potentially close their doors permanently or completely—ultimately worsening patient access and outcomes and reducing medication adherence. Careful consideration of the impact on pharmacies is important to help avoid

[1] https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html#closing-out

preventable adverse downstream consequences on patient access to vital medications and overall health outcomes under these actions.

Consequently, the PDAB must ensure that any established UPL, at a minimum, covers the cost for the pharmacy to acquire/purchase the prescription drug. This means that a prescription drug product purchaser or third-party payer should not reimburse a pharmacy licensed by the state for a prescription drug product in an amount less than a UPL for the prescription drug product. Second, the UPL must include a requirement for payers to provide a professional dispensing fee or administration fee aligned with Oregon Medicaid's professional dispensing fee rates on any prescription claim subject to a UPL.

NACDS appreciates the board's endeavors to reduce prescription drug costs and enhance affordability for Oregonians. We strongly encourage removing vaccines as eligible for review by the board, and the incorporation of adequate reimbursement safeguards in any plans to establish UPLs for selected drugs. This will help ensure that the PDAB protects all community pharmacies while continuing its vital work to minimize patient costs. For questions or further discussion, please get in touch with Sandra Guckian, Vice President of State Pharmacy and Advocacy, at SGuckian@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

cc: Oregon Prescription Drug Affordability Board Members

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

SAFE
COMMUNITIES
COALITION

February 16th, 2024

Dear Members of the Oregon Prescription Drug Affordability Board:

We write today on behalf of SAFE Communities Coalition & Action Fund, a non-profit organization whose purpose is to support pro-vaccine policies and legislation. We appreciate your consideration of our comments for your upcoming meeting on February 21st, 2024. We believe that vaccines are a critical component of public health infrastructure and ask that the board not consider any vaccine as part of their review process.

We ask that vaccines not be subject to an affordability review based on high utilization, as this conflicts with the goal of decreasing overall healthcare costs through immunization. The high utilization of immunizations is, by design, a goal and necessary outcome of a successful inoculation program. High utilization of immunizations has been proven to reduce healthcare costs in the long term. Additionally, the prevention of infectious disease through immunization will have a direct impact, in line with the stated goal of the OR PDAB, of the use (and costs) of prescription drugs to treat diseases that could have been prevented.

The process of reviewing and recommending vaccines for the American public, including cost-effectiveness, has already been given great consideration at the federal level by the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC). ACIP's Evidence to Recommendation Framework, used when vaccines are reviewed for recommendation, already considers many of the economic factors that may be considered by OR PDAB.

Vaccines are one of the most important pillars of public health in Oregon and across the nation. We must ensure, as has already been done by ACIP, that vaccines remain affordable, accessible, and widely utilized. Anything less undermines the public's health

and puts our communities, schools, and those most susceptible to vaccine-preventable diseases at risk.

Finally, subjecting any vaccine to affordability measures beyond what has already been established by ACIP could have a chilling effect on the entire vaccine development process, slowing and possibly limiting the future development of lifesaving vaccines. The impact of a decision of the OR PDAB to add any vaccine, which is a unique and critical classification of products, to the list of reviewed prescription drugs, could have a knock-on effect, threatening vaccine access across the nation.

We ask that the board not consider any vaccine as part of their review process.

Thank you for your consideration and the work that you do to make sure that all Oregonians have access to affordable healthcare.

Northe Saunders
Executive Director
SAFE Communities Coalition & Action Fund
info@safecommunitiescoalition.org

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February 17, 2024

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

Re: Oregon Prescription Drug Affordability Board: Agenda and Meeting Materials Related Affordability Reviews

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing to express its concerns regarding the Board's ongoing affordability review process, as demonstrated in the Board's agenda and discussion materials for the Oregon Prescription Drug Affordability Board's ("Board's") February 21, 2024 meetings (collectively, the "Meeting Materials").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

As described below, PhRMA is concerned that the Board's affordability reviews to date have been conducted in a manner that is inconsistent the requirements of the Board's authorizing statute as well its own regulations.[2] PhRMA respectfully requests that further action on the Board's affordability reviews be suspended until the Board implements an affordability review process that appropriately considers all required statutorily and regulatorily enumerated criteria and is consistent with its obligations under the Oregon Administrative Procedures Act ("APA").

I. Affordability Reviews Do Not Consistently Consider Mandatory Criteria

The PDAB Statute and the Board's regulations provide an enumerated set of criteria that must be considered as part of each affordability review. As detailed in PhRMA's prior letters, the Board has a clear obligation under the APA to act in a principled and fair manner that is consistent with the statute and its regulations.[3] Even where an agency has discretion in considering certain statutory or regulatory factors,

[1] *See* February Meeting Materials, *available at* https://dfr.oregon.gov/pdab/Documents/20240221-PDAB-document-package.pdf. We note that certain issues described in this letter may also apply to the affordability reviews conducted by the Board during its January 26, 2024 meeting. *See* January Meeting Materials, *available at* https://dfr.oregon.gov/pdab/Documents/20240126-PDAB-document-package.pdf.

[2] Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB Statute"). In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to the Oregon PDAB statute. PhRMA also incorporates by reference all prior comment letters to the extent applicable.

[3] *See, e.g.*, Letter from PhRMA to Board (Apr. 16, 2023), at 1-2; Letter from PhRMA to Board (Feb. 11, 2023), at 1-2. *See also, e.g.*, *Lane Cnty. v. Land Conservation & Dev. Comm'n*, 138 Or. App. 635, 641 (1996) (It is a "fundamental" principle of administrative law that agencies may not act in a manner contrary to their statutory authority); *See Realty Grp., Inc. v. Dep't of Revenue*, 299 Or. 377, 383 n.3 (1985) ("The agency is bound to follow . . . [a] rule until it replaces the rule, [and] the validity of a rule can always be challenged by one in a procedural posture to do so."). Agency actions cannot be upheld where they are

the agency "must explain to the public why they have executed the law in the manner selected" and why the agency's actions are "not *ad hoc* and arbitrary."[4]

PhRMA is concerned that the Board's affordability reviews to date have failed to consistently consider statutorily or regulatorily enumerated criteria, without providing an explanation as to why and without considering how the lack of these criteria may impact its affordability review process. PhRMA specifically highlights below examples of how the Board has failed to consider the following criteria, all of which are enumerated under the PDAB Statute or the Board's regulations:

- **Health Equity**. The PDAB Statute requires the Board to evaluate as part of its affordability reviews "whether the prescription drug has led to health inequities in communities of color."[5] The Board has promulgated regulations further stating that, to the extent practicable, the Board must consider "[w]hether the pricing of the prescription drug results in or has contributed to health inequities in: (A) under-resourced communities; or (B) regions with limited pharmacy access."[6]

  Despite these mandates, the three affordability reviews described in the February Meeting Materials contain no information regarding health equity.[7] Nor has the Board provided explanation for why such statutorily required information has not been included for its consideration.

- **Burden of Disease**. The PDAB Statute also requires the Board to evaluate "[t]he relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives."[8] Additionally, the Board has promulgated regulations stating that, to the extent practicable and where quantifiable, the Board must also consider "the relative financial effects of the prescription drug on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment" and "the total cost of the disease and the drug price offset."[9] The affordability reviews to date contain no information regarding the financial effects of the relevant prescription drugs on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment, or the total cost of the relevant disease and the drug price offset.

  In the Meeting Materials to date, the Board has provided no explanation for why such information was not included or considered. The Board's regulations *require* the Board to consider this

"inconsistent with agency practice, or violate a statute or constitutional provision." *Johnson v. Dep't of Pub. Safety Standards & Training*, 253 Or. App. 307, 317 (2012).

[4] *Sachdev v. Oregon Med. Bd.*, 312 Or. App. 392, 405 (2021).

[5] PDAB Statute § 646A.694(1)(a).

[6] Or. Admin. R. 925-200-0020(2)(a).

[7] We also note that none of the affordability reviews to date has specifically evaluated "whether the prescription drug being reviewed has led to health inequities in communities of color," or whether pricing of the prescription drug contributed to health inequities in under-resourced communities or regions with limited pharmacy access.

[8] PDAB Statute § 646A.694(1)(j).

[9] Or. Admin. R. 925-200-0020(2)(i).

information to the extent it is available and quantifiable, and the Board has not provided any specific rationale as to why such information could not be obtained or quantified.

- **Input from Patients and Caregivers**. The PDAB Statute also requires the Board to accept testimony from patients and caregivers affected by a condition or disease treated by a prescription drug subject to affordability review.[10] The Board's regulations further require the Board to "*seek input from* patients and caregivers affected by a condition or disease that is treated by the prescription drug" subject to affordability review.[11] Specifically, pursuant to its own regulations, the Board must gather information from patients and caregivers on the impact of the disease, treatment preferences, the benefits and disadvantages of using the prescription drug, and available patient assistance in purchasing the prescription drug, and the Board must attempt to gather "a diversity of experience" among patients from different socioeconomic backgrounds.[12]

  Despite the statutory and regulatory requirements, the Board has not identified any process for soliciting patient and caregiver input, and has not considered such input in its affordability reviews. There is no reference to patient or caregiver feedback in the Meeting Materials to date.[13] Nor is there any explanation for why the Board has not specifically sought out this information, as required under the PDAB Statute and the Board's own regulations.

- **Net Pricing**. The regulations require the Board to consider, to the extent practicable, the "estimated net price" of the prescription drug under review.[14] This can be estimated by taking into account discounts, rebates, and price concessions provided for the drug under review, which data the Board is also required to compile and consider.[15] Despite this, the Board has not included this information in a majority of the written materials for its affordability reviews to date, and has not provided a rationale for its failure to consider these factors.[16]

The failure by the Board to consistently consider statutorily and regulatorily required criteria across its affordability reviews to date, and the Board's failure evaluate the data available to it in a manner consistent with applicable statutory and regulatory considerations raise serious questions about the validity of the Board's affordability review process. "Agencies are creatures of statute" and their actions "may also be circumscribed the agency's own regulations."[17] The Board cannot fail to consistently consider statutorily required factors or ignore its own regulatory requirements without a valid explanation for why

[10] PDAB Statute § 646A.694(3).
[11] Or. Admin. R. 925-200-0020(2)(k)(A), emphasis added.
[12] *Id*.
[13] Under "Patient feedback and additional stakeholder feedback" the February Meeting Materials reference only feedback from an insurer, with no mention of patients or caregivers. February Meeting Materials at 21.
[14] Or. Admin. R. 925-200-0020(2)(c).
[15] Or. Admin. R. 925-200-0020(2)(l).
[16] February Meeting Materials at 13-14, 38-39 (the only two affordability reviews to take into account price concessions).
[17] *City of Klamath Falls v. Env't Quality Comm'n*, 318 Or. 532, 545 (1994).

doing so is permissible under applicable laws and regulations.[18] Likewise, the Board cannot simply recite facts and information without "fully explain[ing] why those facts lead it to the decision it makes."[19]

* * *

For the above reasons, PhRMA believes that the Board's affordability reviews are inconsistent with the PDAB Statute, the Board's regulations, and the APA. We respectfully request that the Board pause further actions on affordability reviews until it has implemented an affordability review process that is consistent with its obligations under the PDAB Statute, its regulations, and the APA.

We thank you again for this opportunity to provide comments and feedback, and for your consideration of our concerns. Although PhRMA has serious concerns with the Board's initial implementation of its affordability reviews, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[18] *See id.*

[19] *Home Plate, Inc. Virginia Wheel v. Oregon Liquor Control Comm'n*, 20 Or. App. 188, 190 (1975). *See also United Acads. of Oregon State Univ. v. Oregon State Univ.*, 315 Or. App. 348, 356 (2021) (agencies must supply a 'rational connection between the facts and the legal conclusions it draws from them'") (internal citations omitted).

OREGON STATE PHARMACY ASSOCIATION
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February 18, 2024

Oregon Prescription Drug Affordability Board (PDAB)
Department of Consumer and Business Services
Salem, OR

Dear members of the board:

Oregon had 36 pharmacies close in 2023. Two more closed last month.

Following the release of the Oregon Secretary of State's audit on PBMs in August, the Oregon Health Authority recommended that the state "should enact legislation that focuses on patient and pharmacy protections and increasing transparency in the prescription drug supply chain."

The Oregon State Pharmacy Association (OSPA) has tried to pass comprehensive PBM reform bills through the legislature the past two years. Unfortunately, we have not been able to get across the finish line. Last year, it was due to the 6-week walkout by Senate Republicans. This year, we have seen HB 4149 stripped of protections for our patients and pharmacies.

We need your help to help improve patient access! We need the PDAB to take bold action because the legislative process is not working. At this point, **every pharmacy in Oregon should be considered a Critical Access Pharmacy.** Oregon has 4.2 million people and only 499 (2022) pharmacies.

According to the Health Policy Institute (2021), 66% of the U.S. population takes prescription medication. That's approximately 2.77 million Oregonians, which equates to over 5,500 patients per pharmacy. In 2019, the number of prescriptions dispensed was around 4.22 billion, for an average of nearly 13 prescriptions per person. That's approximately 71,500 prescriptions per pharmacy in Oregon. That **equates to 195 prescriptions that need to be dispensed from every Oregon pharmacy, every day!**

Mail order prescriptions only account for about 10%, so that reduces the number of prescriptions each day to an average of 175. However, there are problems with the mail order process such as delays in shipping, temperature storage concerns, inadequate telephone counseling with a pharmacist, auto renewal without confirmation, and extra waste.

Oregon has always been at the forefront of change to improve our state**. I am urging you to investigate the possibility of going to a single PBM.** There are models from Ohio and Kentucky that we can research, which has proven to be beneficial for those states. Moving to a single PBM for Oregon will help with patient access to medications, keep pharmacies in business, and save millions of dollars for the state of Oregon.

Thank you for your work to help all Oregonians!

Sincerely,
Brian Mayo
Executive Director

Leading Pharmacy, Advancing Healthcare