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

Dear Members of the Prescription Drug Affordability Board,

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

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

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

In Brief:

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

Key Concerns Regarding UPLs:

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

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

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

Recommendations:

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

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

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

November 26, 2024

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

Re: Oregon Prescription Drug Affordability Board: Comments On Draft Upper Payment Limit Study

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the revised draft of the Oregon Prescription Drug Affordability Board's (the "PDAB's" or "Board's") Senate Bill 192 Upper Payment Limit ("UPL") Study ("Draft UPL Study"), recently discussed at its November 20, 2024 meeting.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease.

PhRMA strongly disagrees with the Board's rushed decision on November 20 to vote to approve the draft UPL Study for transmittal to the Legislature.[2] As PhRMA has previously noted, UPLs are an unimplemented theory that could restrict patient access, result in fewer new treatments for patients, and ultimately do not carry any guarantee that savings will be passed on to patients.[3] These concerns are not addressed in the Draft UPL Study, nor were they given adequate time and discussion at the Board's November 20 meeting.[4] Rather, the Draft UPL Study continues to perpetuate inaccurate and overly simplistic views of how a UPL would work within the complex pharmaceutical supply chain and, ultimately, fails to fulfill the Legislature's mandate.[5]

Since the Board began operating in 2022, PhRMA has raised significant administrative and operational concerns about the process and work of the Board, including with respect to implementation of affordability reviews and the potential implementation of UPL-setting authority.[6] The Board itself has recognized that further issues need to be addressed with respect to its processes, as evident by its decision on June 26,

[1] *See* Meeting Materials (Nov. 20, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/20241120-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. *See, e.g.*, Letter from PhRMA to Board (Nov. 1, 2024); Letter from PhRMA to Board (Oct. 12, 2024); Letter from PhRMA to Board (Sept. 15, 2024); Letter from PhRMA to Board (June 28, 2024); Letter from PhRMA to Board (Apr. 13, 2024); Letter from PhRMA to Board (Mar. 15, 2024); Letter from PhRMA to Board (Feb. 17, 2024).

[2] *See* Board, Webinar recording of Nov. 20 meeting, *available at* https://www.youtube.com/watch?v=F6oxpkN9frA (For example, Board staff urging Board members to limit discussion prior to voting to adopt the report, at around 1:02:00, 1:17:00, and 2:08:00.)

[3] *See, e.g.*, Letter from PhRMA to Board 1 (June 28, 2024).

[4] As PhRMA has previously explained, we also have concerns that the limited timeframe the Board has afforded for review of and comment on materials in advance of meetings has not allowed full and adequate opportunity for meaningful participation by stakeholders on the important and complex issues before the Board, including the Draft UPL Study. *See, e.g.,* Letter from PhRMA to Board 1 (Nov. 1, 2024); Letter from PhRMA to Board 1-2 (Oct. 12, 2024); Letter from PhRMA to Board 2 (Sept. 15, 2024).

[5] *See* Or. Senate Bill 192, § 3(1) (see further discussion in Section I, below).

[6] PhRMA has filed 31 comment letters to date with the Oregon PDAB, detailing, among other things, our ongoing concerns with the Board's affordability review process and procedures and the Draft UPL Study. *See, e.g.*, Letter from PhRMA to Board (Sept. 15, 2024); Letter from PhRMA to Board (May 12, 2024); Letter from PhRMA to Board (Feb. 17, 2024); Letter from PhRMA to Board (Oct. 15, 2023).

2024, to postpone further affordability reviews until 2025 while it reviews and improves its affordability review criteria and methods. Despite these concerns, the Draft UPL Study provides an incomplete picture of potential UPL implementation in Oregon, and fails to substantially address each of the mandated elements set out for the study by the Oregon Legislature. Prior to submitting the Draft UPL Study to the Legislature, the Board should continue to revise the Draft UPL Study so that it provides additional, and far more detailed, policy proposals and analyses regarding the potential adoption of a UPL scheme.[7]

I. The Draft UPL Study Fails to Fulfill the Board's Statutory Mandate for a UPL Plan

The PDAB Statute requires that the Board's "plan for establishing [UPLs]" include both a methodology for establishing UPLs and a series of analyses of both the implementation and impact of UPL-setting.[8] Several of these elements are notably either absent from the Draft UPL Study, or addressed only in a cursory manner.[9] Specifically, the Draft UPL Study fails to provide a clear and concrete "methodology for establishing" UPLs or analyses of the "resources needed" for implementation, how UPLs "would be enforced," or how UPLs "would be implemented with respect to" specific payers.[10] And while the Study's Executive Summary acknowledges that "[t]he directive from SB 192 requires the Oregon PDAB to develop a plan for implementing UPLs that promotes affordability while ensuring patient access and financial sustainability within Oregon's healthcare system,"[11] the Draft UPL Study does not address how the Board intends to monitor and protect patient access, nor does it provide sufficient financial modeling to analyze the potential financial impact of UPLs.

Where the Draft UPL Study does provide financial analysis, it is inaccurate and overly simplistic, as discussed further below.[12] Accordingly, the Draft UPL Study does not satisfy the required elements of SB 192, and the Board revisit its draft in light of the concerns raised in order to comply with the mandates of the statute.

II. The Draft UPL Study Relies on Flawed Assumptions and Oversimplifications of a UPL Scheme

[7] PhRMA reiterates its concern that if UPL authority is ultimately enacted by the Oregon Legislature, the Oregon Administrative Procedures Act ("APA") requires that a separate rulemaking be conducted to establish the specific definitions, standards, and processes that will govern any UPL processes. *See* Letter from PhRMA to Board 1, n.4 (Nov. 1, 2024). *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).

[8] Or. Senate Bill 192, § 3(1) (codified at ORS § 646A.685(1)) ("The plan shall include: (a) A methodology for establishing upper payment limits; (b) An analysis of the resources needed by the board to implement the plan; (c) An analysis of how upper payment limits would be enforced; and (d) An analysis of how upper payment limits could be implemented with respect to: [certain enumerated payers and plans in Oregon]").

[9] For example, in the section titled "Analysis of Resources Needed," the Draft UPL Study merely identifies broad categories of resources that "may" be needed without providing any concrete projection of the specific resources that may be required. *See, e.g.*, Draft UPL Study 26 (noting that the Board "could" engage with wholesalers "to supply UPL products ... and work with manufacturers to prevent diversion" without explanation of what implementation and anti-diversion efforts would consist of and without any cost projections for contracting with those entities); *id.* (stating broadly that "[r]esource requirements will be driven by the many options that are still under development"). Similarly, the Draft UPL Study describes the proposed UPL approaches in very general terms, identifying various considerations without any actual analysis. *See, e.g.*, *id.* at 22 (describing the "Budget Impact-Based" approach to "[e]stablish a UPL such that spending on the drug does not exceed a certain percentage of a given budget" but not explaining how the Board would determine the "given budget" or the percentage threshold); *id.* at 19 (explaining that the Board "considered a number of *high-level* approaches (*general* concepts) to setting a UPL" (emphasis added)); *see also* Letter from PhRMA to Board 2-3 (Nov. 1, 2024) (commenting that the draft UPL methodologies lack sufficient detail to meaningfully evaluate).

[10] Or. Senate Bill 192, § 3(1).

[11] Draft UPL Study 4.

[12] *See Ford v. Multnomah Cnty.*, 331 Or. App. 712 (2024) (agencies must explain their analyses and decisions in a "meaningful way"); *Feitelson v. City of Salem*, 46 Or. App. 815, 822 (1980) ("If there is to be any meaningful judicial review, an agency must demonstrate that it has considered the factors prescribed by statute and its own regulations and has not acted in an arbitrary manner or on an ad hoc basis"); *see also* Or. Rev. Stat. § 183.335(3)(a) (also requiring the agency to "fully" consider information in submissions).

PhRMA continues to have serious concerns that the Draft UPL Study fails to account for the significant complexities and challenges inherent in a UPL scheme.[13] Notably, establishing UPLs in the pharmaceutical supply chain would require navigating a highly regulated and interdependent system involving a number of stakeholders, and would present a wide range of legal, logistical, and market-based challenges. Instead of addressing these issues directly, the Draft UPL Study paints a highly simplistic picture of how a UPL scheme would work. In reality, UPL implementation would unavoidably involve challenges that are far more difficult to resolve. For example, the Draft UPL Study does not explain how a UPL would be effectuated in the supply chain; it does not address diversion concerns; it does not consider the role of manufacturer rebates and PBMs; it continues to focus on retaining flexibility at the expense of providing for consistent processes;[14] and it relies on a number of flawed, unfounded assumptions about supply chain behavior and about the availability and quality of data sources and other implementation resources.[15] Furthermore, the Draft UPL Study fails to demonstrate how a UPL will generate savings, nor how any potential savings would outweigh the significant risks associated with establishing and implementing a UPL in the state.[16] These concerns remain unaddressed in the revised Draft UPL Study.

PhRMA reiterates and expressly incorporates by reference all prior comments regarding the Board's development of its UPL study.[17] Additionally, we highlight the following non-exhaustive examples of added inaccuracies and oversimplifications in the revised Draft UPL Study.

- **Patient Access:** The revised Draft UPL Study includes some additional discussion of how UPL implementation could affect pharmacy stability and patient access.[18] PhRMA supports consideration of these important factors. However, the added discussion largely acknowledges these concerns without discussing how the Board would address them.

- **Lessons from Other States:** No state has implemented a UPL or put forward a framework for UPL effectuation, and yet the Draft UPL Report represents in several places that the Board has incorporated lessons learned from "other states."[19] In reality, and as acknowledged in the Draft UPL Report, the work of PDABs in other states does not at this point provide helpful experience for the Board to draw from, nor can it be used to understand the impact of any of the referenced methodologies or strategies.[20] Moreover, even if another state were in a position to serve as a model, the Board should not rely on the work of other states' PDABs without considering the different statutory processes, state-specific factors, and other contextual considerations which may render comparisons across states misleading.

[13] *See* Letter from PhRMA to Board 6-8 (Nov. 1, 2024).
[14] *See, e.g.*, Draft UPL Study 19 (indicating that the Board may use multiple different UPL approaches that could vary based on market conditions and other factors).
[15] *See, e.g.*, Draft UPL Study 29 (explaining that "[a] statewide UPL is generally intended to be self-enforcing" because supply chain entities "have no incentive to buy a UPL product at cost higher than the UPL …" without acknowledging the complexities of the various incentives facing such entities).
[16] For example, the Draft UPL Study acknowledges analyses suggesting that implementing a UPL could introduce costs or otherwise fail to generate savings but does not engage with these possibilities and largely ignores consideration of whether imposing UPLs would result in any patient benefits. *See, e.g.*, Draft UPL Study 32-33 (describing an analysis undertaken by the Oregon Health Authority that found UPLs could result in a cost *increase* without meaningfully analyzing these findings or other downstream consequences of UPLs).
[17] *See* Letter from PhRMA to Board (Nov. 1, 2024); Letter from PhRMA to Board (Oct. 12, 2024).
[18] Draft UPL Study 28-29.
[19] *See id.* at 4, 24 (discussing "[e]xperiences from other states").
[20] *Id.* at 39 ("Participants [in constituent group surveys] also struggled to assess the impact of a UPL, indicating a need to better understand how it would be developed and implemented, and reflecting a lack of experience to draw from in other states.")

- **Descriptions of Supply Chain Entities:** PhRMA acknowledges the Board's revisions to the descriptions of supply chain entities to include additional details, but we remain concerned that these descriptions remain misleading or inaccurate.[21] For example, the descriptions of wholesalers and group purchasing organizations do not mention that these entities often operate on a multi-state basis and may face significant administrative hurdles in operating under a UPL.[22] The Draft UPL Study also refers to the "significant influence" of some entities over drug pricing, but does not recognize or discuss the role that insurers and PBMs play in dictating the terms of coverage for medicines and the amount a patient ultimately pays.[23] Finally, it is inaccurate and misleading in its assertion that payers "offer or connect patients with patient assistance programs."[24] Payers do not offer patient assistance—manufacturers and state and federal programs do.

- **UPL Approaches:** While the revised Draft UPL Study includes some additional discussion of the various UPL approaches, PhRMA reiterates its concern that this discussion lacks sufficient detail for stakeholders to meaningfully comment.[25] The Draft UPL Study both fails to address crucial considerations for each potential UPL approach, including those previously raised by PhRMA,[26] but also correspondingly fails to provide a "methodology" for establishing UPLs as required by the PDAB Statute.[27] Although the Board chose to reframe the "Payer Return on Investment (ROI)" section as "Value," PhRMA remains concerned that this approach would still rely on pharmacoeconomic research and Cost Effectiveness Analyses which may use discriminatory metrics that should be avoided due to their potential to entrench health inequities.[28]

- **Data Limitations:** PhRMA recognizes the Board's additional consideration of concerns related to the quality and availability of data sources for the establishment and enforcement of UPLs, including the acknowledgement that Oregon's public meeting laws may prevent Board members from accessing net pricing on drugs.[29] However, PhRMA continues to stress that any UPL-setting process would likely raise substantial confidentiality concerns.[30]

III. The Draft UPL Study Does Not Adequately Consider Alternative Policy Options to UPLs

PhRMA appreciates the Board's additional discussion of non-UPL policy options,[31] but we are concerned that this discussion does not provide clear standards for how such non-UPL policy options may be considered as part of a potential UPL-setting process. As detailed below, and in light of the lengthy Board deliberation on this topic at the November 20 meeting,[32] PhRMA encourages the Board to continue examining other cost-saving measures as an alternative to UPL-setting. PhRMA also urges the Board not to

[21] *Id.* at 13-16.
[22] *See id.* at 14-15.
[23] For further discussion, *see* Letter from PhRMA to Board 5 (Nov. 1, 2024); Letter from PhRMA to Board 4-5 (Sept. 15, 2024); Letter from PhRMA to Board 1-2 (June 28, 2024); Letter from PhRMA to Board 1-2 (Nov. 13, 2022).
[24] Draft UPL Study 15.
[25] *Id.* at 19-23.
[26] *See* Letter from PhRMA to Board 2-3 (Nov. 1, 2024); Letter from PhRMA to Board 2-7 (Sept. 15, 2024).
[27] *See* Or. Senate Bill 192, § 3(1).
[28] See discussion of this issue at length in our Letter from PhRMA to Board 5-6 (Sept. 15, 2024).
[29] *See* Draft UPL Study 27 ("Since Oregon public meeting laws currently don't allow for media to be absent from executive session, board members cannot access net pricing on drugs."). *But see* Letter from PhRMA to Board 3 (Sept. 16, 2023).
[30] *See, e.g.*, Letter from PhRMA to Board 4 (June 28, 2024). *See* Or. Senate Bill 192, § 3(1)(d); *see also id.* §§ 2(4), 8(7) (requiring preservation of confidentiality of information submitted to the Board and used in its reviews).
[31] Draft UPL Study 23-26.
[32] *See* Board, Webinar recording of Nov. 20 meeting, *available at* https://www.youtube.com/watch?v=F6oxpkN9frA (discussion from approximately 00:31:00 to 01:57:00).

consider such policy options as "complementary" approaches that could work "in tandem" with UPLs.[33] That description presupposes that a UPL is the appropriate policy solution, and is inconsistent with the Draft UPL Study's own acknowledgement that such approaches "can serve as either stand-alone solutions or complementary measures."[34] In order to facilitate consistent and transparent consideration of these policy options, we ask that the Board provide clear standards for evaluating UPL and non-UPL policy options and determining the optimal solution for addressing each specific affordability challenge that it identifies.[35]

PhRMA additionally highlights the following non-exhaustive examples of areas where the proposed policy alternatives require additional consideration:

- **Rebate Passthrough:** The revised Draft UPL Study includes discussion of a possible "Pass Through Pricing" model for prescription drugs.[36] However, it is unclear from the limited description of this model whether it refers to required pharmacy reimbursement levels or to required passthrough of rebates to the patient to lower their out-of-pocket costs.[37] PBMs and insurers get billions in rebates and discounts on medicines, yet they often refuse to pass these savings on to patients.[38] Passing state legislation requiring insurers and PBMs to share negotiated discounts and rebates at the pharmacy counter could save some patients nearly $1,000 each year.[39] Additionally "hidden fees and markups"[40] are worthy of additional consideration by the board; fees account for the fastest growing share of PBM profitability. The share of PBM profits from fees, including fees charged by PBM Group Purchasing Organizations ("GPOs"), has grown by more than 300% over the past decade.[41] Growth of administrative service fees is consistent with research showing that PBMs are increasingly shifting away from a compensation model based on retained commercial rebates – perhaps in response to increased public and employer scrutiny – in favor of revenues collected from spread pricing and administrative service fees assessed on manufacturers, payers, and pharmacies.[42] PhRMA encourages the Board to expand discussion of this concept for more clarity and detail on the benefits or risks of such a proposal.

- **Value Based Pricing:** Broadly speaking, voluntary innovative contracts are a viable option for potentially reducing costs, and PhRMA supports the Board in considering strategies that align the price or price concession of a product directly to the outcomes or value the medicine brings to

[33] *Id.* at 5, 23.
[34] *Id.* at 23.
[35] Other PDABs have acknowledged that UPLs are not always the right solution. *See* Md. PDAB UPL Action Plan 7 (Sept. 10, 2024), *available at* https://pdab.maryland.gov/Pages/reports.aspx (directing the PDAB to consider "*if* a UPL is an appropriate policy option" (emphasis added)); *see also id.* at 4–5 (acknowledging that "a UPL *may not be the preferred policy solution* for every affordability challenge") (emphasis added).
[36] Draft UPL Study 23-24.
[37] *See also* PhRMA, *State Policies Could Save Patients Nearly $1,000 Annually on Their Medicines* (2022), *available at* https://phrma.org/en/resource-center/Topics/Cost-and-Value/Share-the-Savings-States; PhRMA, *Pass-Through Rebates Do Not Violate Non-Interference Clause But They Do Increase Savings for Seniors* (July 2, 2018), *available at* https://phrma.org/en/Blog/pass-through-rebates-do-not-violate-non-interference-clause-but-they-do-increase-savings-for-seniors.
[38] PhRMA, *State Policies Could Save Patients Nearly $1,000 Annually on Their Medicines* (2022), *available at* https://phrma.org/en/resource-center/Topics/Cost-and-Value/Share-the-Savings-States.
[39] *Id.*
[40] Draft UPL Study, 23
[41] Percher E. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. Nephron Research. September 2023. https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/
[42] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021.

patients or the market as predetermined by the contracting entities. However, the Draft UPL Study's description of value-based arrangements does not clarify what role the Board may play in this approach. PhRMA asks the Board to provide more information on the policy options it may consider in this area.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments regarding the Draft UPL Study approved at the November 20 meeting of the Board. 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

PacificSource
HEALTH PLANS

December 13, 2024

Oregon Prescription Drug Affordability Board
c/o Ralph Magrish, Executive Director
Department of Consumer and Business Services
350 Winter St NE
Salem, OR 97309-0405

Delivered via email: pdab@dcbs.oregon.gov

Re: Policy Recommendations to Legislative Assembly

Chair Bailey, Vice-Chair Burns and Members of the Board:

The PacificSource companies are independent, not-for-profit health insurance providers based in Oregon. We serve over 600,000 commercial, Medicaid, and Medicare Advantage members in four states. PacificSource Community Solutions is the contracted coordinated care organization (CCO) in Central Oregon, the Columbia River Gorge, Marion & Polk Counties, and Lane County. Our mission is to provide better health, better care, and better value to the people and communities we serve.

Thank you for the opportunity to provide brief written comment on the potential policy recommendations the Board is considering transmitting to the Legislative Assembly. In 2021, PacificSource supported the creation of the Prescription Drug Affordability Board through the passage of SB 844 (2021) (Act). At the time the Assembly was deliberating on the Act, we wrote that building from drug transparency, "more work needs to be done to bring about accountability and help control the cost of prescription drugs."

Section 5 of the Act that passed largely mirrored a provision in the Drug Price Transparency Act, HB 4005 (2018). This section directs the Board to make "recommendations, if any, for legislative changes necessary to make prescription drug products more affordable in this state."[1] Clearly, the Board is not required to make recommendations. But if it does, those recommendations need to be related to making drugs more affordable. Reading the legislation in context, we believe that affordability recommendations should work to lower the cost of prescription drugs at their source. After all, the Board was formed for the stated purpose of protecting consumers and health benefit plans from the high cost of prescription drugs. Recommendations that simply mask or redirect the price of prescription drugs from consumers, however well-intentioned, do not fit within this legislative charge.

In perusing the report for which the Board plans to vote next week, the additional policy recommendations for the Board to consider do not work to make drugs more affordable at their

source. For example, optional recommendations to set minimum reimbursement rates and dispensing fees for pharmacists will not ultimately reduce the cost of prescription drugs for consumers. A legislative workgroup convened over the summer to study this very issue, and in no conversation did it become clear that consumers would experience savings in drug costs due to changes in reimbursement. Likewise, the optional recommendation that the state require its managed Medicaid entities to utilize a statewide preferred drug list does not consider the interactions with the Medicaid best price rules and the unpredictable nature of rebates states may negotiate in addition to CMS rate negotiations. In either case, assertions that these proposals will protect consumers and health plans by lowering drugs at their source are not supported by any data or evidence in the report and exceed the Board's statutory mandate.

Our perspective is that the Board should not recommend these optional items to the Assembly, and instead focus its efforts and energy on policy recommendations that would lower the price of prescription drugs.

Sincerely,

/s

Richard Blackwell
Director, Oregon Government Relations

HIV+HEP
POLICY INSTITUTE

December 13, 2024

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

Re: Public Comment for December 18, 2024 Board Meeting

Dear Members of the Oregon Prescription Drug Affordability Board:

The **HIV+Hepatitis Policy Institute** is a leading advocate for equitable and affordable healthcare for individuals living with or at risk of HIV, hepatitis, and other serious or chronic health conditions. As the Board begins reviewing its initial list of prescription drugs, we believe that affordability reviews of HIV medications fail to fully account for the intricacies of the existing HIV safety net, which makes lifesaving HIV treatments affordable for most people. We also want to raise numerous factors in the global HIV drug ecosystem that would be difficult for a state to consider. Finally, we reiterate our support for the proposed legislative policy recommendations that enhance transparency around insurers' use of copay accumulators, maximizers, and the need to consider alternative funding programs.

Affordability Reviews of HIV Medications

Since the onset of the AIDS crisis in the 1980s, our community has tirelessly fought for access to effective treatments, leading to the establishment of vital safety net programs that ensure HIV care and medications remain affordable. Programs such as the Ryan White HIV/AIDS Program provide $2.5 billion annually to ensure HIV treatments and care to low-income people living with HIV[i]. The Ryan White Programs generates $2.8 billion in drug purchases through the 340B program[ii] enabling crucial wraparound services and provide care and treatment to those who cannot afford it. Additionally, drug manufacturers contribute over $1 billion in rebates directly to state AIDS Drug Assistance Programs-all to help with affordability of HIV drugs.[iii]

For example, Oregon's ADAP, known as CAREAssist, operates with a diverse funding stream totaling approximately $50 million, sourced from Part B funding, rebates, and program income. This funding covers essential medications and services for people living with HIV[iv]. Further affordability is achieved through additional rebate programs, such as Medicaid drug rebates, which help reduce the financial burden on public programs.

Pharmaceutical manufacturers also play a key role, contributing billions through copay assistance, free medication programs, and global initiatives like PEPFAR, which expand access to

affordable HIV treatments worldwide. While gaps in coverage remain, this robust safety net has been instrumental in ensuring people living with HIV receive the care and medications they need at an affordable rate.

Federal policies have further reinforced this safety net, helping to expand access to preventive care. For instance, the Affordable Care Act (ACA) and recommendations from the U.S. Preventive Services Task Force (USPSTF) have eliminated financial barriers by mandating that PrEP (pre-exposure prophylaxis) be available at no cost to most insured individuals. This policy ensures that those vulnerable to HIV can access lifesaving preventive treatments, complementing safety net programs and helping to reduce the spread of the virus-for free.

Affordability reviews of HIV medications may fail to fully capture the complexity and interdependence of safety net programs, which not only ensure affordability for patients but also sustain the broader HIV care infrastructure. Pricing interventions, such as the imposition of upper payment limits (UPLs), could destabilize this ecosystem, jeopardizing access to care and disincentivizing pharmaceutical manufacturers from continuing the research and development that has driven remarkable progress. The transformative innovations enabled by this investment—including longer-acting treatments, preventive therapies, vaccines, and the hope of an eventual cure—could be at risk if the delicate balance of these systems is disrupted.

The impact of these advancements cannot be overstated. Antiretroviral therapy (ART) has drastically changed the prognosis and quality of life for people living with HIV. When the first highly effective ART became available in 1996, a 20-year-old newly diagnosed with HIV had a life expectancy of just 10 years. Today, thanks to modern therapies, individuals with HIV enjoy lifespans comparable to the general population, with improved tolerability and far fewer side effects. These innovations have transformed HIV from a terminal illness into a manageable chronic condition for millions.

Importantly, high out-of-pocket costs for patients often stem from systemic issues unrelated to drug pricing, such as insurer practices and pharmacy benefit manager (PBM) strategies. Policymakers should focus on addressing these barriers through targeted reforms, such as regulating PBMs, capping out-of-pocket expenses, and ensuring that copay assistance counts toward deductibles. These solutions can improve affordability for patients without undermining the infrastructure and progress that have revolutionized HIV care.

We strongly believe that affordability reviews of HIV medications are unnecessary, given the comprehensive safety net programs that effectively ensure access to lifesaving treatments. Any future pricing interventions, such as the imposition of UPLs, could destabilize this well-established network, threatening access to care for people living with HIV. Programs like the Ryan White HIV/AIDS Program, the 340B program, and manufacturer copay assistance are critical to sustaining the progress and innovation that have transformed HIV treatment.

As we look to the future, it is essential to protect and strengthen these systems that have saved and transformed countless lives. Policymakers must prioritize targeted solutions that enhance

affordability without compromising the stability of the infrastructure that has been pivotal in the fight against HIV. By preserving this delicate balance, we can continue to provide hope and care for millions living with HIV while advancing toward the ultimate goal of ending the epidemic.

Proposed Legislative Recommendations

We support the following legislative recommendations, which focus on increasing transparency, protecting equitable access to medications, and improving affordability through enhanced accountability and patient-centered policies.

Enhance Reporting on Copay Accumulators and Maximizers: Requiring insurers to report on the use of copay accumulators and maximizers is vital for ensuring transparency and accountability in healthcare cost-sharing. These programs are increasingly prevalent, it was estimated that 39% of beneficiaries under commercial insurance were enrolled in plans with copay accumulators[v] and 41% in those with copay maximizers.[vi] In Oregon, five out of six insurers on the marketplace are implementing these programs.[vii] with 39% of commercially insured patients enrolled in plans with copay accumulators and 41% in plans with copay maximizers as of 2022. In Oregon, five out of six marketplace insurers have adopted these practices. By excluding manufacturer copay assistance from deductibles and out-of-pocket limits, these programs shift significant costs onto patients, often resulting in higher expenses and reduced adherence to essential medications. Moreover, insurers and pharmacy benefit managers (PBMs) frequently collect the copay assistance for themselves while excluding it from patients' cost-sharing calculations, then charge patients additional amounts—a practice commonly referred to as "double dipping." Mandating detailed reporting would enable the Board to assess these programs' financial and access-related impacts, ensuring patients are not unfairly burdened when relying on financial assistance.

Expand Transparency Requirements to Alternative Funding Programs (AFPs): We recommend the Board extend reporting requirements to include AFPs, which self-funded employer health plans use to shift the cost of expensive specialty medications outside traditional insurance coverage. These programs often classify specialty medications as "non-essential," forcing patients to navigate third-party assistance programs designed for the uninsured. This process can be complex, time-consuming, and reliant on resources such as manufacturer assistance programs or international pharmacies. AFPs disproportionately impact individuals with chronic or rare diseases by selectively excluding those with higher health risks, raising significant concerns about health equity and access to care.

Although AFPs aim to reduce employer costs, they often lead to significant treatment delays, with severe consequences for patients managing conditions like HIV or hepatitis. Even brief interruptions in treatment can result in viral resistance, rendering medications ineffective and posing broader public health risks. Requiring insurers to disclose the scope and impact of AFPs would provide critical insight into these programs' effects on patient access, treatment delays, and the diversion of charitable resources intended for the uninsured. Increased transparency would ensure these programs do not compromise patient care under the guise of cost savings.

Support Adjustments to Drug Reviews and Patient Assistance Consideration: We also support the proposed adjustments to the number of drugs reviewed annually and the inclusion of patient assistance programs in these reviews. Patient assistance programs play a crucial role in improving medication affordability and ensuring timely access to treatments for those in need.

Thank you for considering these important policy proposals. We look forward to your support in advancing these recommendations to ensure that all Oregonians have access to affordable, effective, and equitable healthcare. 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] Ryan White HIV/AIDS Program Funding: FY 2015–FY 2024 appropriations by program
[ii] 2023 340B Covered Entity Purchases
[iii] 2024 National RWHA Part B ADAP Monitoring Project Annual Report
[iv] KFF: Distribution of ADAP Budget by Source
[v] Fein AJ. Copay Accumulator and Maximizer Update: Adoption Plateaus as Insurers Battle Patients Over Copay Support. Drug Channels.
[vi] Pharmaceutical Strategies Group. 2023 Trends in Specialty Drug Benefits Report.
[vii] The Aids Institute: Copay Assistance Diversion Programs in Oregon

Regence | 200 SW Market St.
Portland, OR 97201

December 11, 2024

Regence offers the following comments to the Oregon Prescription Drug Affordability Board:

We thank the Prescription Drug Affordability Board and Staff for the opportunity to comment on 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. Consistent with our values as a tax-paying nonprofit, 88% of every premium dollar pays for our members' medical claims and expenses.

We appreciate the Board's commitment to protecting Oregon's residents, health plans, providers, and pharmacies from the high costs of prescription drugs. While we acknowledge that some of the proposed policy recommendations do align with the PDAB's mission, we are concerned about the impacts the proposals for dispensing fees across all payers and mandating reimbursement rates would have on consumers.

We believe that recommending specific payment thresholds and parameters for a minimum payment is too complex and can unintentionally burden consumers and plans with the added weight of extra costs. Both proposals carry the consequences of increased costs for plans and members, which ultimately undermines the Board's mission to make drugs more affordable for Oregonians.

Furthermore, we have concerns about the Board also including the proposal requiring reimbursement rates and dispensing fees in the complementary approaches to the upper payment limit concepts in the Board's Upper Payment Limit Report. The Pharmacy Benefit Manager Workgroup led by Rep. Rob Nosse during the 2024 interim extensively discussed the complexities of applying payment mandates across all payers and the potential impacts to consumers of tying dispensing fees to Medicaid FFS or other independently determined rates. Regence data, along with other carriers, demonstrates that increasing dispensing fees will immediately be felt by patients at the pharmacy counter, and will contradict the state's affordability goals. While we agree that pharmacies need to be reimbursed appropriately for their services, balancing

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pharmacist reimbursement is delicate and is an issue that the Board has not invested sufficient time in studying and understanding.

We are concerned that the potential risk to the well-being of consumers is not fully considered with these proposals and further study is needed on this issue to better understand the affordability implications of increasing costs at the pharmacy counter. As of 2021, 77% of Oregonian adults were worried about affording their health care. We hope the Board exercises caution in supporting policies that automatically increase costs for consumers at the pharmacy counter.

We appreciate the opportunity to comment on the Board's policy recommendations to the legislature. Regence shares concerns over affordable access to prescription drugs and supporting our pharmacy partners. We hope the Board will consider our comments and not pass recommendations for payment amounts and dispensing fees. We encourage the Board members to explore existing avenues through which this work is already occurring and engage with that work rather than make recommendations on a topic that has not been fully vetted by the Board.

We are happy to discuss any follow-on considerations.

December 13, 2024

VIA ELECTRONIC SUBMISSION TO pdab@dcbs.oregon.gov

Oregon Prescription Drug Advisory Board
c/o Ralph Magrish, Executive Director
350 Winter Street NE
Salem, OR 97309-0405

Re: Upper Payment Report to Legislative Assembly

Chair Bailey and Members of the PDAB Board:

Cigna Healthcare and Evernorth Health Services are major providers of medical pharmacy, dental and related products and services. In Oregon, Cigna provides medical coverage to approximately 305,000 members and processes over three million prescriptions statewide annually. At Cigna, we believe a system where all Americans have access to high-quality, accessible, and affordable health care is possible. We continue to focus on delivering care that is affordable, predictable, and simple, so our Oregon members can live healthier, more vibrant lives.

On behalf of our Cigna members and employer groups, we would like to provide comment on the recently discussed legislative policy recommendations by the Oregon Prescription Drug Advisory Board. Our comments below are specifically directed at potential policy recommendations regarding pharmacy reimbursement rates and dispensing fees the Board may send to the 2025 Oregon Legislative Assembly.

The Board's discussion and potential policy recommendation to increase both pharmacy reimbursement for prescription drugs and dispensing fees will directly conflict with the Boards' stated goal of making prescriptions more affordable for Oregon health care consumers. Reimbursement rates, including dispensing fees, are negotiated at arms' length between two sophisticated parties based on current market factors and pricing. The Board's endorsement of mandatory reimbursement floors and dramatic increases in dispensing fees only works to create guaranteed profitability for pharmacies and removes any incentive for all pharmacies to purchase drugs at the lowest price available, thus keeping down the cost for the very consumers they serve.

PDAB's policy recommendation to increase reimbursement and dispensing fee amount not only contradicts your own stated goal of reducing prescription drug costs, but it also disregards the comprehensive discussion with legislators, pharmacists, insurers, and advocates on prospective legislation regulating pharmacy benefits. Cigna was an active participant in Rep. Rob Nosse's Pharmacy Benefit Manager Workgroup in 2024 discussing all possible legislative proposals from pharmacy activists. We detailed the very likely dramatic increase in out-of-pocket costs to Oregon consumers should the legislature move forward with increased reimbursement regulations and mandatory dispensing fees. We strongly urge the Board to narrow their policy recommendations to issues that will lower costs for consumers, not raise them.

We would welcome the opportunity to discuss these issues with you in more detail.

Respectfully,

Jennifer Baker
State Government Affairs Director