Genentech
A Member of the Roche Group

600 Massachusetts Ave. NW, Suite 300
Washington, DC 20001
Phone: (202) 296-7272
Fax: (202) 296-7290

February 14, 2025

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

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

Dear Members of the Oregon Prescription Drug Affordability Board:

Based on discussions during the Board's January 15, 2025 meeting, we continue to have concerns about the Board's approach to drug selection and strongly urge the Board to consider the following comments as you proceed with your deliberations. We are also resubmitting comments we shared ahead of the Board's November 2024 meeting which provide several recommendations to the Board to support a reliable, consistent, and data-driven approach to the Board's future decision making.

In January, we observed several elements which remain unchanged from the 2023-2024 drug selection and affordability review process which, if left unaddressed, will continue to create challenges for the Board and ultimately lead to arbitrary outcomes that will not help patients access the medicines they need. Below we offer additional comments and recommendations to address these observations.

1. **Data available to the Board lacks necessary context to guide the Board's drug selection process.**

As we have commented previously, it is essential to the Board's work that discussions and decisions are anchored to accurate and complete data. Further, all data reviewed by the Board must be contextualized to provide appropriate comparisons across eligible drugs for review. For example, during the January 2025 meeting, the Board asked staff to sort data for "per prescription cost." When reviewing data for "per prescription cost" it is imperative to understand the dosing schedule that provides the necessary context with which to evaluate the drug's cost at that unit. A drug which is taken or administered every month cannot be compared to a drug taken or administered only twice a year on the basis of "per prescription cost" without first calculating a cost per prescription that accounts for the drug's dosing regimen to ensure any comparison is both accurate and appropriate. Without this critical comparison, the Board risks undermining all of their work.

2. **Any drug the Board intends to select for an affordability review should be directly discussed by the Board in advance of selection to determine whether the drug is a suitable candidate for review.**

To avoid pitfalls encountered by the Board throughout your processes in 2023-2024, it is vital the Board discuss each drug on its subset list of drugs for which the Board is considering selection for an affordability review. By undertaking a discussion of each drug for possible selection, the Board can focus its attention on drugs which present the greatest suitability for an affordability review based on the Board's selection and affordability review criteria. A drug-specific conversation prior to any drug selection decision could result in identifying data and characteristics that do not support the Board moving forward in an affordability review. Ultimately, such actions will allow the Board to conduct its activities in the most efficient and effective manner.

3. **The Board's approach to drug selection and affordability reviews should be meaningfully different from its prior approach.**

During the Board's January 2025 meeting, several Board members and staff reflected on the data, process and approach used by the Board in prior years. Given the Board's decision to pause all reviews in June 2024 and commit to re-evaluating its processes and approach, the Board should implement a meaningfully different process and approach for future drug selection and affordability reviews that is consistent with the Board's statutory authority. Genentech's November 14, 2024 letter offers several recommendations for the Board that would support a meaningfully different approach in 2025. We urge the Board to discuss and deliberate the changes to be made to their processes and transparently share all findings relevant to the evaluation of prior processes.

4. **Initial carrier data has not been vetted to eliminate drugs that are not eligible for review under the statute.**

To comply with the Board's statute, the board cannot review drugs designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition. As discussed in January, the Board should remove any drugs meeting this criteria and otherwise ensure that it is applying its eligibility criteria appropriately.

If you have any questions or want to discuss our feedback, please contact Tim Layton, Director of State Government Affairs at layton.timothy@gene.com or (206) 403-8224.

Sincerely,

Mary Wachter, RN
Executive Director
State & Local Government Affairs

Encl. Genentech Comment Letter to Oregon PDAB, November 15, 2024

Genentech
A Member of the Roche Group
600 Massachusetts Ave. NW, Suite 300
Washington, DC 20001
Phone: (202) 296-7272
Fax: (202) 296-7290

November 15, 2024

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

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

Dear Members of the Oregon Prescription Drug Affordability Board:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

For example, stakeholder engagement tactics undertaken by Boards in other states have included focus groups, open public surveys, and direct stakeholder meetings. Boards are also

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

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

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

Sincerely,

Mary Wachter, RN
Executive Director
State & Local Government Affairs

February 14, 2025

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

TO: Members of Oregon Prescription Drug Affordability Board

I am writing to share my concerns regarding the Oregon Prescription Drug Affordability Board's process for selecting medications and conducting affordability reviews. As a physician, my primary focus is the well-being of my patients, and I am deeply troubled that the current approach to affordability reviews may jeopardize access to essential medications.

As a board-certified pediatrician and rheumatologist, I have spent my career caring for children and young people with chronic or disabling conditions. Many of my patients, including those with juvenile idiopathic arthritis and lupus, rely on specialized, innovative, yet often expensive therapies.

Unfortunately, the current process prioritizes payer and manufacturer data over patient needs, focusing on abstract cost analyses rather than real-world affordability challenges. Instead of ensuring that medications remain within financial reach for those who depend on them, the Board's approach risks restricting critical therapies without fully considering the consequences for patient care. A truly patient-centered approach would place affordability in the context of medical necessity and quality of life, rather than relying solely on opaque and inaccessible cost assessments.

For example, the data sets and OAR 925-200-0010 criteria used to select drugs for affordability reviews rely on aggregated insurer and manufacturer information that is not easily accessible or understandable to the public who depend on access to these therapies. Given the complexity and importance of these issues, more transparency on how the drugs are being selected for review and what factors are influencing affordability determinations should be made more apparent for all stakeholders involved before the Board votes.

As you have stated in previous meetings, the PDAB board values transparency in its decision-making process. Yet meeting agendas and relevant materials have not been made available well in advance to allow physicians, patients, and advocates to engage meaningfully. Improvements to this process should include accessible and timely updates so those most affected are not left in the dark about critical policy decisions that could impact their treatment options. Proactive communication—such as detailed summaries of discussions, proposed actions, and opportunities for public input—would ensure all stakeholders stay informed and involved. Transparency should not depend on one's ability to attend a meeting; the Board must make its work more accessible and understandable.

While I support efforts to address prescription drug costs, the current process—lacking sufficient pathways for patient and healthcare provider input—risks limiting access to essential medications. Physicians and patients are eager to collaborate with the Board to ensure affordability decisions reflect real-world patient needs, but this requires a more thoughtful, patient-centered approach. As it stands now, the Board's actions could inadvertently restrict access to medications for those who need them most in Oregon.

Thank you for your attention to this critical issue.

Sincerely,

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

PATIENT INCLUSION COUNCIL

February 14, 2025

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

RE: Public Comments on Drug Selection Criteria and Cost Reviews

Dear Members and Staff of the Oregon Prescription Drug Affordability Board:

We thank you for this opportunity for ***patients*** to provide comments on the Drug Selection Criteria and Cost Review process. Patient Inclusion Council (PIC) members are all patients and caregivers, some who have extensive professional experience as Patient Research Partners (PRPs). These members reviewed the patient-facing portion of the survey draft and have provided recommendations to enhance patient-facing data collection efforts.

About the Patient Inclusion Council (PIC). We aim to empower patients and caregivers to shape healthcare policy through peer-led education, perspective sharing, and activities to ensure patient-reported needs are incorporated into drug affordability solutions.
The PIC is the only patient and caregiver coalition created to advocate for drug affordability policies that benefit patients. All patients and caregivers are welcome to participate, and are invited to speak their truth related to drug affordability without involving personal opinions regarding PDABs, pharmaceutical companies, or insurers/payers.

In addition to utilizing creative and inclusive methods to capture all voices, members with experience as Patient Research Partners (PRPs) are also invited to participate in data collection question design, coding, and analysis related to PIC-created surveys and in regards to reviewing PDAB initiated surveys.

The PIC operates both independently and in collaboration with the Ensuring Access through Collaborative Health (EACH) side of this two-part coalition.

General Revision Suggestions
We appreciate the time and dedication spent by the OR PDAB to develop this initial draft of questions that aim to collect meaningful data from those who have experience taking the drugs under review. The following are patient-reported recommendations that address who should be completing the survey and language improvements.

- **Clarification regarding who should take this survey**. We are uncertain why "the general public" is included in a section intended for data regarding personal experience with prescription drug use: *"Questions for patients, caregivers, advocacy groups, and general public."* What value would the board gain from hearing experiences (or opinions) about prescription drug costs from anyone other than those who have utilized the drug? If the purpose is to also collect information from people who may have been prescribed

the drug but were unable to obtain access, then this should be stated in place of "and general public."

    - **Drug usage (timing).** Will your data collection be limited to patients currently on the drug or will it include patients who have been on the drug in the past? If the latter, what is the time restriction for gathering data from those no longer on the drug? Due to a variety of contextual influencers (such as inflation related to drug costs, benefit design, COVID era, and a time when access to medications was tied to pre-existing conditions), understanding when the patient used the drug, or if they are currently using the drug, would be beneficial for analysis.

- **Confidentiality clarification.** "Answers are not confidential and if received by this date, will be included in the board materials prepared for the affordability review and posted on the website."
    - **Suggestion**: Given providing personal information (i.e., name, contact information) is optional, clarify publicly available information does not include personal information and by providing personal information this is done only to reach out for clarification in answers.

- **Link/References to (OAR-925-200-0020 2.k.A.i.II).** We are assuming these links are added as a guide for reviewers to view the statute requirements and will only be included in the header/opening information of the survey once published. It is not needed, and is intimidating, to add it to every question.

Question Specific Revisions and Suggestions

We hope the following recommended changes will ensure robust patient-reported data is collected.

- **2. Dosage, *strength*, and frequency**. Provide definitions/examples, in particular for strength to avoid answers such as, "I take the strongest dose." Additionally, we are not certain the difference between dosage and strength.
    - **Suggestion**: Please provide more details, including Dosage (example: 150 mg), Frequency (example: once a day). Clarify what data intended to collect from "strength".

- **3. Medical condition or disease**. Our coalition launched a pilot survey in 2024, which is being relaunched in February 2025. Due to numerous responses that included a multitude of diagnoses for this question, we have updated our question and suggest this revision in your survey design as well.
    - ***Suggestion: ADDITIONAL Question - Co-existing conditions or multiple diagnoses.*** Given most people are diagnosed with more than one condition, and this often impacts which prescription drug they should or should not take, we suggest collecting this information, too.

- **4. What is the expected outcome of the treatment of the disease?** Our patient reviewers requested more guidance on how to answer this question. Patient outcomes and expectations are varied based on many factors, such as disease duration, disease

progression, existing damage, potential for remission or not, etc. As worded, we anticipate the board could capture answers such as, “To achieve remission.” We suggest clarifying endpoints (what the board hopes to gain from this question), then rewording it to do so. Once we are clear of the boards goals for this question, we are happy to provide more revisions.

- **5. Are there therapeutic alternatives* (for example, a *different therapeutic agent)* for this drug?** If the goal of this question is to understand if the patient has ever taken any other similar drug to treat this condition, or if there are other options, this should be worded to reflect this (do not use “therapeutic alternatives”, as most patients will tell you there is no therapeutic alternative to the drug that works for them and, in turn, you will not gather the data you hope to from this wording.) Also, using a “different therapeutic agent” is too high level and should be reworded altogether.

  This is the same issue in Q9 - What are the benefits of using this prescription drug compared **to therapeutic alternatives (for example, a different therapeutic agent)? and Q10 -** What are the disadvantages of using this prescription drug therapeutic alternatives (for example, a different) therapeutic agent)?

  Your definition of therapeutic alternative: *Therapeutic alternative means, a drug product that contains ***a different therapeutic agent*** than the drug in question, ***but is FDA-approved, recognized as off-label use for the same indication***, ***or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose.***

  This definition is exceptionally high level and would be very confusing for a patient. Rewording this at a 5th grade level is recommended.

- **6. What is the patient treatment preference?** We do not understand what the board is trying to obtain with this question. Is the board looking for the patient to say, “This is the drug I prefer?” or “I prefer to be on a different drug but I’m on this one, because” or is this about method of application (i.e., infusion versus injection versus pill)? It would be difficult to answer the follow up questions (7. Why is it the preferred treatment? 8. If the patient is not using the preferred treatment, why not?) until this is clarified.

- **11. How much did you pay out of pocket for this drug?** First, is the board asking for out of pocket costs *for the month*? For *the year*?

  Second, as worded, it would be difficult to capture **important contextual factors, such as any differences in out of pocket costs based on different times of the year and causes related to times of elevated costs** (i.e., insurance companies not applying copay assistance programs in a timely manner, switching jobs mid-year, etc.)

  Additionally, how long a person was taking this drug influenced the response to this question. For example, some people who have been taking the drug for 8 years have cycled through different types of insurance. Once on commercial insurance and

paying $10 out of pocket, are now on Medicare and have higher out of pocket costs. In the survey we have designed for patients, we had to go back and analyze all the open-ended responses to understand the complexity of this question and have incorporated these changes into our most recent survey. *Keep in mind, we also asked how long they have been taking the drug and if they stopped taking it, how long ago. This may be another consideration for addition to your data collection to ensure robust analysis.*

    - **Suggestion: (Based on our wording from our survey) -** Thinking of the impact of (drug name) what was the most recent monthly out of pocket cost that you paid for this drug? We also suggest considering adding clarity (month or year) and the addition of questions to determine if they are currently on the drug or when they stopped the drug.

- **12. If you used a patient assistance program, how much did it cover?** The wording on this question suggests the board is asking the patient to come up with a percentage ("It covered 100%" or "It covered about 80%").

- **14. Is the drug covered by your insurance?** A patient may not actually know how to answer this question, as many scenarios are possible.
    - One example: "My doctor prescribed it and the insurance company said they won't cover it," when they likely mean that the insurance company applied step therapy and maybe they could gain access (and afford it), but at this time the insurance company technically does not cover the drug.
    - Another example: "My insurance covers this drug, but I can't afford it because I just can't keep up with my deductible and pay $500 a month for it, no one could!" What they could be trying to explain is that their insurance company covers the drug but they have an accumulator program, so the patient cannot meet their deductible and so their insurance to cover the drug does not kick in. After 6 months, the copay assistance runs out and they are left with the full bill.
        - **Suggestion:** Be prepared for a lot of qualitative analysis for this one! And enlist the help of PRPs from the PIC to assist to ensure responses include intended context. The board may also utilize our services to facilitate continued conversations with respondents (peer-to-peer) to gain clarity for the board.

Demographics

Please **circle** which applies to you:
Private health insurance_____
Medicare
Medicaid

- Is the board asking for patients to print out the survey, circle the type of insurance, and mail it back in?
- Patients will need a definition of what is meant by private insurance. As worded, many will likely respond with the insurer's name (i.e., Cigna)

PATIENT INCLUSION COUNCIL

- *We strongly encourage the board to clarify when collecting Medicare information that the PDAB cannot address Medicare*. While it is good practice to identify affordability issues for all Oregoneans, it is ethically responsible to educate patients who are responding - and who think the PDAB may help them - that Medicare is out of their jurisdiction and information collected will be forwarded to CMS.

Thank you again for the opportunity for patients to weigh in on survey questions that will be used to ensure robust data is collected from those utilizing the prescription drugs under review. We respectfully urge the board to consider the suggestions provided by patients, as outlined in this letter. We offer the PIC as a resource to board members seeking to connect more with patients, not only during recruitment for data collection, but also as advisors for question design and analysis.

Sincerely,

Tiffany Westrich-Robertson
Person living with Axial Spondyloarthritis
Patient Inclusion Council (PIC)

EACH PIC COALITION

EACH PIC COALITION

February 14, 2025

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

RE: Public Comments on Drug Selection Criteria and Cost Reviews

Dear Members and Staff of the Oregon Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

We appreciate the decision of the board to pause affordability reviews last year due to the complex nature of the task. We applaud the board for acknowledging the significance of the work, responding to stakeholder feedback, and committing to improve the review process.

To date, we are unclear about what concrete improvements to the cost review process have been made to prevent the same obstacles that the board faced in 2024 from recurring in 2025. Before the board proceeds with drug selection and cost reviews, we urge board members to clearly present to the public what changes have been implemented and allow additional stakeholder feedback before finalizing the new process and proceeding with reviews. Furthermore, we urge the board to clearly outline metrics and define affordability to ensure that reviews are performed with consistency and a clear focus on patient benefit.

We look forward to engaging with the board to improve the cost-review process and ensure it ultimately benefits the patients who rely on the drugs under review. We respectfully urge the board to consider the suggestions of patient organizations outlined in this letter. We offer our coalition as a resource to board members seeking to connect with patient organizations and patients.

Integrate Patients and Patient Organizations into Cost Review Process

We urge the board to put significant emphasis on gathering input from patients throughout the cost review process. This will ensure that the board is appropriately identifying and addressing real patient problems and that patients' lived experiences are addressed by board proposed policy solutions.

We feel the board should be required to hold meetings, focus groups, or other scheduled events at varied times and locations to get input on the drugs under review. This will ensure members of the public are given adequate opportunity to attend and provide patients with the opportunity to share their experiences on each drug directly with board members and staff. Also, focus groups and surveys should have basic parameters for both structure and participant numbers to be considered representative of the viewpoints of the public.

We appreciate the board publishing the proposed request for information forms; however, we are concerned that the current draft of the patient form is not very friendly to a layperson/patient audience and therefore will not achieve the desired result from patient input. For an in depth, patient-led review of the questions, which includes detailed recommendations for improvements, please refer to the letter submitted by the Patient Inclusion Council (PIC).

Additionally, we recommend a separate form for patients to avoid overwhelm and any potential confusion regarding what is expected from their participation. We also think the board should establish a minimum threshold for patient information submissions on each drug to ensure that they are receiving adequate input from patients.

Because of the complex nature of this process and the information being sought, we appreciate the inclusion of patient organizations as a stakeholder group representing patient voices. There are many proven methods patient organizations have used to collect meaningful, unaltered data from patients (including discussion sessions, surveys, etc.) that we could facilitate, acting as a bridge to enable more voices to be heard. We could combine these efforts with those conducted by the board, in a transparent way that ensures the raw patient data is untouched, thus increasing real-world evidence without any perceived bias of data submission.

Focus Policies on Patient Burdens and Affordability

Ultimately, we know that defining affordability is a key aspect of the drug review process that the Oregon board is seeking to improve. We urge the board to prioritize patient costs as a key aspect and focus of any affordability measurement, specifically out-of-pocket costs. To the extent that is possible within statute, we implore the board to focus on defining affordability based on patient-reported costs and concerns.

Furthermore, we urge the board to focus on patient-reported obstacles to care and address the underlying factors that contribute to patient hardship in affording and accessing their needed medications. Failing to resolve the underlying factors that lead to higher costs for patients can result in short-term relief and uneven benefits – aiding some but potentially leaving others with higher costs and drug accessibility challenges.

Patient Access Cannot Be Compromised

We urge the board to implement a methodical and thoughtful approach to reviewing and implementing the drug selection criteria that will be used for cost review. Due to statutes set for drug selection criteria, many of the medications subject to review are biologics or specialty drugs.

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

For these patients, therapeutic alternatives may not be alternatives at all. Very often drug interactions or other health conditions would prevent individual patients from being able to switch to an alternative medication that, on paper, seems like it would be an appropriate

treatment. Further, patients with chronic conditions can build up a tolerance to medications over time, so they must retain access to all treatments in a class of drugs to prolong their treatment.

Cost Reviews Could Compromise Patient Access to Medications

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

We are concerned that interventions on individual drugs will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies. We don't know yet how either insurers or manufacturers will react to state-by-state interventions and encourage the board to utilize its mandate to interview industry stakeholders to determine how cost reviews will impact patient access before proceeding with reviews.

Sound Health Policy is Founded on Patient Perspectives

Finally, we urge this board to keep as a primary focus the needs of patients and work diligently to ensure that access to all treatments is protected. We strongly urge the board and staff to utilize the authority of the board to fully explore with all healthcare stakeholders how cost reviews will be implemented and identify in advance any adverse impact to patients.

Additionally, we invite the board to utilize this organization and its members as a direct conduit to understanding and incorporating patient and caregiver perspectives, as well as those of patient organizations who have an understanding of the life cycle of disease from the lens of prevention, diagnosis, and disease management.

We appreciate your laudable efforts to improve our health system and your steadfast commitment to protecting patients. We look forward to working together to achieve these goals.

Sincerely,

Tiffany Westrich-Robertson
Ensuring Access through Collaborative Health (EACH) Coalition

HealthHIV

1630 Connecticut Avenue, NW, Suite 500
Washington, DC 20009

202.232.6749 | healthhiv.org

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

February 17, 2025

Dear Members of the Oregon Prescription Drug Affordability Board,

On behalf of HealthHIV, we appreciate the opportunity to provide ongoing feedback on the Board's affordability review process and its potential impacts on the communities we serve, including Oregon's HIV service ecosystems—Ryan White clinics, FQHCs, HRSA 340B-covered entities, and Oregon's ADAP, administered through the Oregon Health Authority's CAREAssist program.
As noted in previous discussions, public comments, and testimony, we remain engaged in the process to ensure that the Board's selection criteria and review processes do not undermine HIV treatment access, particularly within the Ryan White Program, 340B-covered entities, and safety-net providers that rely on drug pricing mechanisms to sustain critical services.

Clarifying Drug Selection and Stakeholder Input Prior to Affordability Review

The Board's framework should be grounded in clear, data-driven processes with direct engagement from stakeholders, including state agencies, contractors, and affected communities. A structured feedback loop before selection decisions are finalized is critical to preventing inconsistent methodologies that could lead to arbitrary outcomes or administrative inefficiencies.

To strengthen this approach, the Board should:

- Define explicit criteria for prioritizing affordability reviews based on patient needs and systemic cost impact.
- Engage directly with affected communities, including Ryan White clinics, HRSA 340B-covered entities, aligned CBOs, and FQHCs, as well as managed care organizations under Medicaid, to assess how drug selection decisions may impact the broader HIV ecosystem, program sustainability, and patient access.
- Incorporate methodologies that reflect real-world treatment access, including utilization management barriers such as prior authorizations and restrictive formularies.

Upholding Statutory Protections for Orphan Drugs and Safety-Net Considerations

Given the statutory exemption for orphan drugs, the Board should explicitly exclude HIV medications with orphan designation for pediatric use from affordability reviews. To ensure clarity and prevent unintended consequences, the Board should:

- Maintain a publicly available list of orphan-designated medications (HIV or otherwise) that are excluded from affordability reviews.
- Ensure that HIV medications granted orphan status for pediatric populations (e.g., Biktarvy, Triumeq, Atripla, Symfi Lo) remain exempt without ambiguity, avoiding disruptions to pediatric HIV treatment access.
- Assess the potential impact of affordability review decisions on 340B-covered entities and ADAPs to safeguard funding streams that support essential HIV services.

Ensuring Compliance with Section 504 and Implications for HIV Treatment Access

QALYs, which have been widely criticized for devaluing treatments for people with chronic conditions and disabilities, are restricted under Section 504 of the Rehabilitation Act and prohibited under Section 1182 of the Patient Protection & Affordable Care Act for use in federal healthcare programs. Oregon state law further bars the use of "Quality of Life in general" measures in cost-effectiveness assessments—protections advanced by *Disability Rights Oregon* to prevent affordability reviews from disproportionately impacting populations that rely on lifelong, condition-specific treatments, including People with HIV.

The Oregon PDAB has indicated that it may reference Institute for Clinical and Economic Review (ICER) studies and measures like Equal Value of Life Years Gained (evLYG) as part of its affordability review process.

Given existing legal protections, affordability reviews should not incorporate evLYG-based frameworks in a way that disadvantages safety-net providers or creates access barriers for:

- **Ryan White clinics, FQHCs, and HRSA 340B-covered entities** that reinvest drug pricing savings into patient services, including wraparound care and prevention initiatives.
- **ADAPs and Medicaid programs** that leverage manufacturer rebates to extend medication access for uninsured and underinsured individuals.
- **Community-based organizations (CBOs) and other 340B-covered entities** that depend on stable drug pricing structures to maintain care coordination and treatment adherence efforts.
- **Long-acting HIV therapies**, which may be misclassified as "higher-cost" under affordability reviews despite their benefits for adherence, reduced transmission rates, and long-term public health impact.

Developing a Rigorous Data Framework to Support Affordability Reviews

Ensuring that affordability review determinations are rooted in complete, accurate, and Oregon-specific data is critical to making informed decisions. To strengthen this process, the Board should:

- Consult with CAREAssist and the Oregon Health Authority before finalizing any Upper Payment Limit (UPL) determinations for HIV medications, ensuring a structured process to assess and publicly report potential impacts on ADAPs, HIV medical case management (MCM) contractors (including HRSA Ryan White and Medicaid Targeted Case Management programs), and both short-term and long-term sustainability of the 340B program.
- Model how UPLs and affordability reviews could affect access to essential HIV medications—incorporating existing real-world provider data, HRSA Ryan White Program Medical Case Management (MCM) data, and insights from aligned non-MCM supportive service providers, along with patient-centered cost assessments—to determine both downstream and upstream effects on patients if changes occur, as a result of UPL implementation.
- Require a more transparent and systematic approach to analyzing how affordability review decisions could affect broader healthcare ecosystems, including FQHCs and community-based HIV service providers.

We appreciate the Board's commitment to affordability and equitable healthcare access. And, we look forward to continued dialogue to ensure that affordability policies *strengthen* access.

Thank You all for your attention, once again.

Scott D Bertani, MNM, PgMP

Director of Advocacy for HealthHIV

Global Healthy Living Foundation
515 North Midland Avenue
Upper Nyack, New York 10960 USA
+1 845 348 0400
+1 845 340 0210 fax
www.ghlf.org

February 17, 2025

Oregon Prescription Drug Affordability Board
Submitted Online at: https://dfr.oregon.gov/pdab/Pages/public-comment.aspx

RE: Comment in advance of February 19, 2025 Meeting

Dear Board,

Our organization, the Global Healthy Living Foundation (GHLF), represents chronically ill patients across the country. These patients rely on various therapies – including medications under consideration by this body – to live the most fulfilling lives they can. As such, our organization has taken a keen interest in the work of Prescription Drug Affordability Boards (PDABs or Boards) in various states and the potential impact to our patients' accessibility to necessary drugs.

When considering costs related to drug usage, we implore you to listen to the concerns of patients. The treatment of chronically ill patients – who rely regularly on medications to live – should be of paramount importance.

People in the United States pay more for medicine than people living in many other parts of the world simply because our system allows for secret negotiations between drug manufacturers, pharmacy benefit managers, and health insurers that artificially inflate drug prices through complex contracts that include rebates and discounts. Yet, these savings never trickle down to patients. When assessing drug costs the Board should review extensively the role of pharmacy benefit managers (PBMs) in rising patient costs.

Patients often spend years trying different medications before they can find one that leads to stabilization of their condition. Disruptions in the marketplace could have devastating consequences for these patients. Just in terms of costs: the cost to an individual who ceases to be stable could include lost income, increased childcare costs associated with the inability to rear their children, and medical expenses not covered by existing plans. Beyond the fiscal costs are the human ones: to through chaos into the system can destabilize chronically ill patients leading to mental health ailments that can take years to remedy.

Our organization would rather see drug pricing discussions focused on rebates and how they can lower patient costs rather than forcing drug manufacturers to comply with a price limit that, without greater transparency, seems arbitrary. We hope to see further discussions on this topic continue to involve patients and caregivers to ensure that they are not left behind in the name of

lower price tags.

We thank you for your time, and again, hope that you will consider the patient voices as you deliberate on the costs of drugs.

Sincerely,

Steven Newmark
Chief Policy Officer
Global Healthy Living Foundation

CSRO
Coalition of State Rheumatology Organizations

BOARD OF DIRECTORS

Aaron Broadwell, MD
President

Gary Feldman, MD
Immediate Past President

Madelaine Feldman, MD
VP, Advocacy & Government Affairs

Michael Saitta, MD, MBA
Treasurer

Firas Kassab, MD
Secretary

Erin Arnold, MD
Director

Leyka Barbosa, MD
Director

Kostas Botsoglou, MD
Director

Mark Box, MD
Director

Michael Brooks, MD
Director

Amish Dave, MD, MPH
Director

Harry Gewanter, MD, MACR
Director

Adrienne Hollander, MD
Director

Robert Levin, MD
Director

Amar Majjhoo, MD
Director

Gregory Niemer, MD
Director

Joshua Stolow, MD
Director

EXECUTIVE OFFICE

Leslie Del Ponte
Executive Director

555 E. Wells Street, Suite 1100
Milwaukee, WI 53202-3823
Phone: 414.918.9825
Email: info@csro.info
Website: www.csro.info

February 17, 2025

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

Request for Information: Individuals with scientific or medical training per OAR-925-200-0020

Members of the Oregon Prescription Drug Affordability Board:

The Coalition of State Rheumatology Organizations (CSRO) appreciates the opportunity to provide feedback on the Request for Information (RFI) that will be used for future drugs selected by the PDAB for affordability reviews. CSRO serves the practicing rheumatologist and is comprised of over 40 state rheumatology societies nationwide with a mission of advocating for excellence in the field of rheumatology and ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease.

Rheumatologic diseases, such as rheumatoid arthritis, psoriatic arthritis and lupus, are systemic and incurable, but innovations in medicine over the last several decades have enabled rheumatologists to better manage these conditions. With access to the right treatment early in the disease, patients can generally delay or even avoid damage to their bones and joints, as well as reduce reliance on pain medications and other ancillary services, thus improving their quality of life.

CSRO has been an active participant in the PDAB's public hearings and comment periods, offering feedback on the impact of the PDAB's policies on patient access and provider reimbursement. We recommend the following improvements to the RFI so that the information offered to the Board offers helpful insights as decisions impacting patient access to medications are made.

Q5. What is the administrative burden of the drug (prior authorization, step therapy, for example)?

We appreciate the Board's attention to the prevalence of utilization management protocols that often delay or prevent patient access to essential medications. As we know, patients will be unable to afford most medications without health insurance coverage. Thus, medication coverage and inclusion on the plan's prescription drug formulary is the essential first step in ensuring patient affordability.

However, this question fails to recognize that the utilization management protocols, including prior authorization and step therapy, will be different for every health plan and is completely dependent on the individual health plan's prescription drug formulary. Even within a single plan, patients who are prescribed the same medication for different conditions will experience different protocol under the same health plan. Instead, to recognize the prevalence of utilization management across all health plans, we recommend the RFI ask:

In the past year, has this drug been subject to utilization management protocols by private health insurance, group health insurance, Medicaid, CHIP or the Marketplace/Exchange health plan?

We believe the responses will be illuminating for both the PDAB and other state bodies.

Q6. Are there therapeutic alternatives for this drug? (OAR-925-200-0020 2.k.B.ii)

Q7. Benefits of the prescription drug compared to therapeutic alternatives.

While we recognize that the statute incorporates "therapeutic alternatives" as criteria for drug affordability reviews, we would be remise if we did not continue to highlight that not all therapeutic alternatives are therapeutically equivalent, having drastically different clinical outcomes for patients. When healthcare providers evaluate medication substitutions, they typically consider therapeutic equivalents – not alternatives.

Deeming medications "therapeutic alternatives" is a one-size fits all approach that disrupts the physician's ability to exercise their medical expertise in concert with their patient. Patients that suffer from complex chronic conditions, such as rheumatoid arthritis and other rheumatologic diseases, require continuity of care to successfully manage their condition. Patients may spend months or years of trial and error, working with their physician to find a treatment regimen that properly manages their condition. The resulting course of treatment must carefully balance each patient's unique medical history and co-morbidities, as well as balance the side-effects of other drug interactions.

Slight deviations in treatment and variations between drugs, even those in the same therapeutic class, can cause serious adverse events. Aside from the needless suffering endured by the patient as they work with their physician to find the right course of treatment, any disease progression caused by a delay in appropriate treatment can be irreversible, life threatening, and cause the patient's original treatment to lose effectiveness. Therefore, we strongly recommend that the Board recognize these clinical practice standards and update the question within the RFI to ask:

> *Are there therapeutic equivalents, as recognized by the U.S. Food & Drug Administration, for this drug?*
>
> *Benefits of the prescription drug compared to therapeutic equivalents.*

Furthermore, we encourage the Board to adopt **additional questions** on the RFI to highlight the expertise of scientific or medically trained individuals, such as:

- *If the patient was prescribed an alternate drug in this class, how could that impact the patient's condition?*
- *How could delayed access to this medication impact the patient's condition?*
- *Do your patients typically utilize patient assistance programs or other medication assistance to access this drug?*
    - *If covered under insurance, have patients typically experienced difficulty affording this medication after the use of patient assistance programs or other medication assistance programs?*
- *For provider administered medications,*
    - *Do you currently source this product from a national distributor or out of state?*
    - *Do you currently bill an add-on payment to cover acquisition costs on top of the drug list price?*
    - *Would you be able to continue administering this medication without an add-on payment?*

We believe these additional questions will provide helpful insights that are critical for the Board's understanding within the affordability review process, as well as the true impact of implementing future upper payment limits on these medications. We encourage the Board to allow responses to the RFI to be accepted beyond the small space allotted on this form so that the PDAB can gain a full understanding of the questions at hand.

We thank you for your consideration and are happy to further detail our comments to the Board upon request.

Respectfully,

Aaron Broadwell, MD, FACR
President
Board of Directors

Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs
Board of Directors

COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

Jen Laws
Phone: (313) 333-8534
Fax: (646) 786-3825
Email: jen@tiicann.org

February 17, 2025

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

RE: February 19, 2025 Meeting Public Comment

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.

Today, we write with comments and concerns regarding current Board considerations.

Conflict of Interest Policy is Appropriate

We applaud the Board's consideration and the gravity of the discussion surrounding conflict of interest (COI) concerns. However, clarification of the verbiage is needed. Are Board members required to disclose at every instance a COI occurs? If so, when will the public be made aware of these disclosures and any deliberative process regarding them? The policy states Board members will review the draft agenda prior to each meeting and identify any potential conflicts of interest, recuse themselves, and submit the conflict of interest form.

Additionally, it states Board staff will be notified as well to ensure the member does not have access to information related to the topic requiring recusal. However, the policy also states conflict of interest can be disclosed within five days after a conflict is identified. Is this instruction related to COI that occurs during the discussion of an unexpected topic? How will that be handled in retrospect to decisions already made if a member fails to disclose or forgets to remind members?

Data sets for consideration contain multiple HIV antiretrovirals.

Three of the five data Excel sheets contain multiple HIV antiretrovirals. We want to reiterate previous commentary that Oregon should not submit any HIV antiretrovirals for affordability review and subsequently endanger access to the medications. **No actions should be taken that could potentially disrupt necessary personalized care.** HIV regimens are complex, and many factors, including contraindications and side effects, go into prescribing optimal regimens based on the individual. HIV antiretroviral prescriptions are very individualized and patients' needs change. Failure to ensure personalized care can and does result in adverse health outcomes for patients, up to and including drug class resistance or virologic failure, increasing health risks for both that particular patient and increasing overall transmission risks - objectively working against Oregon's own public health interests and goals. Thus, access to the full gamut of the most effective doctor-recommended antiretrovirals must remain robust.

Additionally, generics of any HIV medications are not alternatives because the most effective regimens are single-pill regimens that contain multiple drugs. Any generic substances would require a patient to be on a multi-pill regimen, which data shows results in lower adherence rates and is not treatment-appropriate for many. The carrier preliminary aggregated information list indicates that the HIV antiretrovirals on the list have multiple therapeutic alternatives. That is simply not how HIV therapies work - failure of the Board to recognize the lack of sufficient, specified medical knowledge *and* healthcare system knowledge is a Red Flag the Board and staff should be startled by. As people living with HIV, we certainly are.

We would also like to refer the Board to our December 13, 2024, submitted letter explaining the harms a UPL on antiretrovirals would inflict on the Ryan White HIV/AIDS Program, its providers, and the federally funded, state-administered AIDS Drug Assistance Program (ADAP), known in Oregon as CAREAssist due to the potential to reduce 340B revenues. The Ryan White Program provides desperately needed services for vulnerable populations, and the ADAP program exists to ensure patients have low to no-cost access to the lifesaving medications on your lists.

HIV is one of Medicare's Six Protected classes. As such, the policy means that people living with HIV are to have access to "all or substantially all" of the drugs available for their care. Notably, Colorado and Maryland have concluded that HIV antiretrovirals should not be considered for affordability review. Patients using HIV antiretrovirals typically have very low copayments and benefit from easily accessible manufacturer-patient assistance programs.

An important note is the appearance of Sunlenca on the new specialty list. Sunlenca is a long-acting injectable HIV medication that is the only FDA-approved twice-yearly treatment for people with multi-drug-resistant HIV. It is used in combination with other HIV medications and is the only way that treatment-resistant patients are achieving viral suppression. Long-acting injectables already have low uptake due to multiple access issues. It should not be considered for any affordability review that would exacerbate the problem. Long-acting injectables need pathways to broader access, not barriers.

We implore the Board to not consider any HIV antiretrovirals for cost-containment measures. We also urge the Board not to make any decisions that inadvertently harm the health and well-being of Oregonians as well as the fiscal stability of the state.

Respectfully submitted,

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

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

VIA Electronic Delivery February 19, 2025

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

Re: OR PDAB Policy and Procedures, Affordability Review RFI, and Criteria to Select Subset of Drugs for Affordability Reviews

Dear Oregon Prescription Drug Affordability Board (PDAB)

The Biotechnology Innovation Organization (BIO) and Oregon Bioscience Association (Oregon Bio) appreciate the opportunity to comment on the Oregon Prescription Drug Affordability Board's (PDAB or Board)'s Policy and Procedures, Affordability Review Request for Information, and Criteria to Select Subset of Drugs for Affordability Reviews ahead of its February 2025 meeting.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

The Oregon Bioscience Association (Oregon Bio) represents the state's robust bioscience ecosystem, including nearly 2,000 private bioscience firms that, together with life science research activities, employ over 28,000 Oregonians. Oregon Bio's members include biotechnology companies, research institutions, and other stakeholders driving innovation in medicine, healthcare, and life sciences. Through collaboration with industry leaders, academia, and policymakers, Oregon Bio works to advance medical breakthroughs, improve patient outcomes, and strengthen the state's economy. The association advocates for policies that support innovation, accessibility, and sustainability to ensure Oregonians benefit from cutting-edge medical advancements.

Lack of Clear Standards on Affordability Definition

BIO and Oregon Bio have long argued that the Board's premise behind establishing an affordability review process is flawed. An overt focus on cost savings for the state rather than patient value will harm patient access to lifesaving medication while failing to protect patients from harmful coverage restrictions imposed by plans and PBMs. Given these high stakes for patients, it is essential that the Board carefully consider the downstream impacts

of its affordability review process. BIO and Oregon Bio were pleased by the Board's decision last year to pause its affordability reviews while committing to a robust discussion of what it means for a drug to be deemed "affordable." However, this year, the Board has seemingly forsaken its commitment to establish a thorough definition of affordability and has not posed any meaningful changes to its affordability review process. In the January meeting materials, several documents outlined potential metrics determining whether an Rx could create an affordability challenge, including "average patient copayment or other cost-sharing" "insurance coverage" and "market competition." However, these materials were never discussed in the January meeting nor were they included on the agenda as an item of discussion for the February meeting. We strongly urge the Board to clarify how it will use these previous materials to clearly define "affordability," and what metrics will be used to make this calculation of "affordability." It is critical that the Board set forth specific and clear affordability goals, criteria, and parameters for affordability as the Board works with stakeholders to fully assess the impact of its policies.

Importance of Stakeholder Engagement

BIO and Oregon Bioremain deeply concerned by the lack of sufficient stakeholder engagement throughout the affordability review process. For instance, for this February meeting, the Board has given stakeholders a mere three business days to review the posted materials before the meeting, which is insufficient time to provide meaningful and robust feedback. Further, it is not apparent how the Board has considered or included stakeholder feedback throughout the decision-making process. It is evident that the Board must revise its process to allow for robust stakeholder engagement and a clear consideration of feedback in decision-making. We cannot overemphasize the importance of engaging consistently with the patient community and relevant stakeholders, particularly to gain relevant and impactful insight into the unique challenges of different patient groups.

Concern for Data Inaccuracies

BIO and Oregon Bio are strongly concerned with inaccuracies in the 2025 Affordability Review Data and dashboard, including incorrect WAC average calculations and incorrect designations for orphan designations and biosimilar/generic competition. In the January meeting, the Vice Chair raised some concerns about some of these errors, yet they remain uncorrected. For instance, erroneous assumptions exist on improper WAC averages in the "Carrier 2023 Preliminary Aggregated Information" spreadsheet. For some of the drugs, the "total annual net rebate spend per enrollee" appears to be inaccurate based on the number of enrollees. While BIO and Oregon Bio do not agree with the principle that WAC is an appropriate measurement of a drug's affordability, to the extent that the Board does use WAC, the calculations should be weighted to the dosing regimens of the product, among other areas. In addition to these incorrect calculations, there have also been a number of drugs on the dashboard for which orphan designation status has been incorrectly recorded. It is essential that the Board not only quickly correct these faulty assumptions and incorrect designations but also work to avoid future errors by carefully vetting data and improving the data collection process to ensure accuracy.

Need for Confidentiality within RFI Submission

BIO and Oregon Bio find it deeply problematic that the Request for Information From Manufacturers states that "Answers are not confidential and if received by this date, will be included in the board materials prepared for the affordability review and posted on the website." Within the RFI the Board is clearly requesting commercially sensitive data, including data related to net pricing, rebates, and discounts from manufacturers, all of which is highly confidential and/or trade secret information. It is evident that the RFI must provide a way for manufacturers to submit information confidentially and clearly outline a process for keeping this sensitive and protected information confidential.

RFI Form Overly Burdensome

It is highly burdensome for manufacturers to provide or estimate the information requested in the RFI. For instance, "the list of drugs that will be part of the affordability review process outlined in ORS 646A.694" appears to be referring to the carriers' list of drugs, which includes over 150 drugs. Much of the requested information is not what would be used in the ordinary course of business, let alone be available for the significant number of drugs on the list. It is also infeasible for manufacturers to report on information regarding net sales, price concession, discount, or rebate data of therapeutic alternatives, as therapeutic alternatives are usually separate products manufactured by another company or even competitor products. Manufacturers do not have insight into, nor should be required to report on, information on another manufacturer. In addition, the Board should clarify its language throughout the RFI to ensure that all points are well-defined, including the definition of "financial assistance," as the Board requests information on "financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities." As it stands, the scope of "financial assistance" remains unclear.

Declaration of Abstention Should be Required

Under Policies and Procedures (1) "Quorum, Decisions, and Voting" the proposed language suggests that Board members provide an explanation of why they are abstaining from a vote to avoid conflicts of interest. BIO and OR BIO supports this language with amendment; the language should be amended to "*shall* include a brief explanation such as a potential conflict of interest or other relevant reason." In the past, Board members have made statements that have mischaracterized key subjects without disclosing conflict of interest. It is critical that the Declaration of Abstention should be made into a requirement to improve transparency and avoid future mischaracterization.

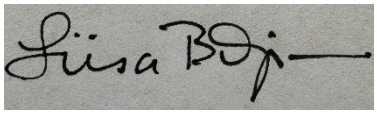
Implications of Transparency Proposed Rule

Oregon state's current proposed rule amending transparency requirements, while not a part of this specific rulemaking, has implications toward the PDAB's drug pricing discussions and therefore warrant consideration by the Board. BIO and Oregon Bio are concerned by the new proposed change to the definition of "new prescription drug," which considers "each product with a unique national drug code" as a new prescription drug and excludes any "product that is only for use under an emergency use authorization (EUA). Given the broad

reaching implications of this new change, we request that the Board carefully consider and address this new proposal before the state seeks to finalize this language.

***

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



/s/

Melody Calkins
Director
Health Policy and Reimbursement

Liisa Bozinovic
Executive Director

National
Multiple Sclerosis
Society

February 19, 2025

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

RE: National Multiple Sclerosis Society Comments Affordability Review Criteria and Review RFI

Dear Members of the Oregon Prescription Drug Affordability Board:

Thank you for the opportunity to submit comments on the Oregon Prescription Drug Affordability Board. The National Multiple Sclerosis Society (Society) is pleased that the State of Oregon and the Prescription Drug Affordability Board (Board) are seeking public comments and input throughout each step in this process. The Society has been actively involved in the creation and implementation of Prescription Drug Affordability Boards nationwide, as we believe they provide important information regarding the high cost of prescription medications. The Board and the Society share a common goal in ensuring affordable access to medications for all Oregon residents.

Background

Multiple sclerosis (MS) is an unpredictable disease of the central nervous system. Currently there is no cure. Symptoms vary from person to person and may include disabling fatigue, mobility challenges, cognitive changes, and vision issues. An estimated 1 million people live with MS in the United States. While there is not yet a cure, we do know that early diagnosis and treatment are critical to minimizing disability. Significant progress is being made to achieve a world free of MS.

The Society, founded in 1946, is the global leader of a growing movement dedicated to creating a world free of MS. Oregon has a higher prevalence of MS than many states across the country, with a direct adjusted MS prevalence of 292 to 332 per 100,000 individuals[1]. There is a strong association between latitude and prevalence, with higher prevalence estimates in northern latitudes

Costs of Living with MS

People with MS have a variety of healthcare needs including but not limited to addressing neurological symptoms, emotional and psychological issues, rehabilitation therapies to improve and maintain function and independence, and long-term care. These needs vary dramatically from person to person and can change year on year as the disease progresses. Prescription medications, known as disease-modifying therapies (DMTs), are central to most treatment regimes.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10186207/figure/noi230024f3/ (attn. figure 3)

National Multiple Sclerosis Society

MS is a highly expensive disease, with the average total cost of living with MS calculated at $88,487 per year[2]. MS may impact one's ability to work and can generate steep out-of-pocket costs related to medical care, rehabilitation, home & auto modifications, and more. For individuals with MS, medical costs are an average of $65,612 more than for individuals who do not live with this disease. Disease-modifying treatments are the single largest component of these medical costs. As of July 2024, the median annual brand price of MS DMTs is more than $107,000. Five out of seven of the DMTs that have been on the market for at least 13 years are priced over $100,000 annually and continue to see regular price increases.

Affordability Review Criteria

In addition to the requirements detailed in Oregon Administrative Code § 925-200-0010, when undertaking the review, the Society recommends considering additional factors which could influence affordability including:

- Average monetary price concessions, discounts, or rebates the manufacturers provide to health plans and PBMs (expressed as a percentage of WAC),
- Price of therapeutic alternatives sold in Oregon,
- Average cost to state health plans based on typical patient access to a drug,
- Impacts on patient access resulting from the cost of the drug and insurance benefit design,
- Average patient out-of-pocket costs, copays, or any other cost-sharing amount.

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

Affordability Review RFI forms: Patients, Caregivers, Advocacy Groups, and General Public

The Society recognizes and appreciates the board's continued solicitation of expertise, experience, and input from affected stakeholders. To make the RFI process data more impactful the Society offers the following suggestions to the FRI form:

- Questions 5-10 seem to be more directed at providers and medical professionals familiar with specific terminology, treatment processes, and medical outcomes rather than patient centered information, knowledge, or experience. Offering separate, more targeted forms for patients and caregivers would likely provide better insight and stronger data.
- Income demographic questions may dissuade participants from utilizing the form. Additionally, patients at all income levels should have access to affordable medications. Either reframing or removing this question may lead to increased participation.
- For patients, ensure that the language used is accessible to the widest audience and that it is clear, concise, and uses consistent terminology.

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

National
Multiple Sclerosis
Society

Board Accessibility and Public Comment

The Society appreciates the efforts in public transparency and accountability that the Oregon Board has demonstrated since its establishment. The Board has made their meetings accessible to all Oregonians via online broadcasts and shared materials, as well as by providing multiple forms and points of outreach to interested and concerned stakeholders.

We continue to ask for the agenda packet and other materials to be posted in a timelier manner, allowing for proper review by both the public and interested parties. Providing a full agenda material packet at least two weeks (preferably more) in advance of all meetings would greatly benefit and increase stakeholder engagement and participation. Additionally, more specificity in what questions and information the board is seeking from the patient and stakeholder community may yield more actionable responses.

The National Multiple Sclerosis Society thanks you again for the opportunity to provide comments on the drug selection review criteria and draft stakeholder review RFI for the Oregon Prescription Drug Affordability Board. The Society welcomes the opportunity to work with the Board on the implementation of their legislative charge to improve affordability and access to prescription medications for all Oregonians. Should you have any questions, please contact Seth Greiner, Senior Manager of Advocacy, at seth.greiner@nmss.org.

Sincerely,

Seth Greiner
Senior Manager, Advocacy

OPCA
Oregon Primary Care Association

MEMORANDUM

To: Prescription Drug Affordability Board

From: Marty Carty, Governmental Affairs Director, Oregon Primary Care Association

Date: February 19, 2025

Re: Affordability RFI

On behalf of Oregon's 34 Federally Qualified Health Centers (FQHCs) we appreciate the opportunity to provide feedback on the Board's affordability review process. We applaud the Board's efforts to better understand how FQHCs made prescription drugs affordable for 470,000 Oregonians in 2023. We also appreciate the Board's interest in understanding the potential impacts of upper payment limits and other affordability policy levers on FQHCs and their patients who rely on them for far more than affordable prescription drugs.

Through previous public comments, participation in listening sessions, and engagement with Board staff we have remained engaged in the process to ensure that the Board's selection criteria, review processes, and policy recommendations do not undermine access to health care for patients or subvert the mechanisms by which Congress intended to stretch scarce federal resources to fund safety net providers like FQHCs.

We write today in response to the Board's draft Request for Information (RFI) that will be used for future drugs selected by the PDAB for affordability reviews. FQHCs are committed to transparently carrying out their mission as established by Congress to serve everyone regardless of their ability to pay or where they were born. One critical component of fulfilling that charge is the 340B Drug Pricing Program (340B). We have at previous Board meetings and listening sessions provided details on how FQHCs use 340B as Congress intended to stretch scarce federal resources. Furthermore, FQHCs are required by both federal law and HRSA regulation to reinvest all 340B savings directly into services and programs that expand access to health care and benefit their patient population.

The Draft RFI is a good starting point for the Board to better understand how FQHCs utilize 340B to make prescription drugs affordable for Oregonians. We believe the Board should consider the following:

1. It is unclear which 340B Covered Entities (CEs) are considered "safety net providers" for the purposes of the survey. We believe all CEs in this state should be subject to the RFI
2. Ensure that affordability review determinations are rooted in complete, accurate, and Oregon-specific data. To strengthen this process, the Board should:
    a. focus on greater 340B transparency for all CEs prior to making any affordability or policy

recommendations.

i. Any 340B transparency survey should include four important pillars
    1. Total amount paid for drugs under 340B
    2. Total reimbursement for drugs dispensed under 340B
    3. Total operating costs attributable to 340B drugs
    4. How the CE uses the savings, including the amount used to offset discounts (below the 340B + PDF price) on pharmaceuticals, and for other services / supplies

b. not base affordability determinations on a narrow subset of 340B prescriptions. Doing so will only provide a pinhole view of how the 340B program makes drugs affordable across entire formularies. This snapshot will result in skewed data and policy choices that could harm Oregonians

3. Question 3 should ask only for volume of non-Medicaid 340B eligible prescriptions. Medicaid members are not subject to any out-of-pocket costs for prescription drugs. Therefore, including Medicaid prescriptions skews the data and "affordability" picture
4. Questions 6 and 11 request sensitive information that if reported will lead to discriminatory reimbursement practices for CEs. We believe question 7 sufficiently achieves the necessary information
5. Questions 10 and 12 pose a significant administrative burden on CEs to answer. Each drug can have multiple strengths and formulations which makes answering this even for a fraction of dispensed drugs time consuming and for smaller CEs employing a single pharmacist it will disrupt patient access. Furthermore, this data point will not yield the information necessary for the Board to understand the total impact of the 340B program on affordability

We are grateful for the Board's commitment to improving drug affordability and health equity for Oregonians. We look forward to continued engagement with the Board to ensure that affordability policy recommendations increase access to prescription drugs and health care.

Sincerely,

Marty Carty
Governmental Affairs Director

The Oregon Primary Care Association (OPCA) is the nonprofit membership organization for the state's 34 federally qualified health centers (FQHCs). OPCA member clinics deliver comprehensive, culturally responsive integrated medical, dental, and behavioral health services for traditionally underserved communities. As a unifying voice of Oregon's FQHCs, OPCA drives transformative policy development to advance health equity across the state and beyond.

www.orpca.org