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April 16, 2023

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

Re: Oregon Prescription Drug Affordability Board Draft Outline: Affordability Reviews for Eligible Prescription Drugs

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to review and comment on the Draft Outline titled "Affordability Reviews for Eligible Prescription Drugs" ("Draft Outline") and published on April 12, 2023, by the Oregon Prescription Drug Affordability Board ("Board") for discussion at the Board's April 19, 2023, meeting.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

We provide below our comments, concerns, and recommendations with respect to the Draft Outline. PhRMA appreciates the Board's work to develop potential policies with respect to its responsibilities under Oregon Senate Bill 844 (2021) (the "PDAB Statute"). PhRMA has concerns, however, about the approach contemplated by the Draft Outline. Among other things, as detailed below, PhRMA has specific concerns about the proposed selection criteria for affordability reviews. PhRMA also has concerns about the Board's proposed amendments to the criteria used in conducting affordability reviews.

I. Affordability Review Selection Process

As PhRMA has explained in detail in its prior comments, an overarching concern with respect to the Draft Outline is that it lacks adequate detail about how the affordability review selection process will be operationalized.[2] Although the most recent Draft Outline incorporates several newly proposed selection criteria, it does not resolve PhRMA's core concern that the Board has not set forth a principled and specific methodology for the selection of eligible drugs. Rather, the Draft Outline continues largely to provide a laundry list of possible data that the Board may consider as part of selecting eligible drugs for affordability reviews without explaining how the Board specifically intends to obtain these various data or how information will be weighed, compared, and considered both independently and relative to other information and factors. ***PhRMA urges the Board to more clearly define a specific methodology to be used in this process.***

The Board's approach fails to give stakeholders needed transparency into whether, how, and under what circumstances the Board will use various categories of information. It is also inconsistent with the requirements

[1] PhRMA also continues to have concerns about the Board's Temporary Procedural Rule OAR 925-100-0003, as described in our letter to the Board, and about the constitutionality of the Oregon PDAB statute more generally. *See* Letter from Pharmaceutical Research and Manufacturers of America to Or. Prescription Drug Affordability Board (Oct. 19, 2022) [hereinafter, "Oct. 19, 2022 PhRMA Letter"]. In filing this comment letter requesting changes to the Draft Outline, PhRMA reserves all of its legal arguments.

[2] *See* Letter from Pharmaceutical Research and Manufacturers of America to Or. Prescription Drug Affordability Board (Feb. 11, 2023), pp. 1-3 [hereinafter, "Feb. 11, 2023 PhRMA Letter"].

of the Oregon Administrative Procedures Act ("APA"), which requires the Board to render decisions in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary."[3] Standardless, ad hoc evaluations and decisions are contrary to this basic requirement of administrative law and contravene the Board's obligation to ensure that it "make[s] policies for even application" across regulated entities and products.[4]

PhRMA specifically reiterates two issues previously expressed:[5]

- First, whenever the Board considers cost and price factors as part of its selection criteria, the Board's consideration should take into account the broader context of rebates, discounts, and other price concessions. ***The Board should adopt a methodology that clearly weighs true cost to payers and patients after discounts and price concessions.***

  Many available sources of price and cost data do not include data on the price concessions that are provided by manufacturers to health plans and pharmacy benefit managers ("PBMs"), and therefore significantly overestimate the amount that plans are spending on medicine. The impact of these price concessions on actual costs (compared to gross spending) should not be dismissed or minimized. In 2021, rebates, discounts, and other payments made by manufacturers to PBMs reached $236 billion.[6] Rebates lower the price that plans are actually paying for medication by an average of 49%.[7]

  Plans and PBMs too-often reap the benefit of these price concessions while refusing to pass price concession amounts on to patients at the pharmacy counter. Failing to consider price concessions not only distorts estimates of the prices paid and costs incurred by plans and PBMs, it also unfairly ignores the role that these carriers and PBMs play in contributing to the inability of Oregonians to afford their health care.

- Second, the Board should consider whether the data sources it draws upon for its selection criteria are complete, validated, and trustworthy. Certain sources of information may be unreliable or offer only a selective portion of the full picture relevant to the Board's assessment. Use of erroneous data would impact the reliability of the Board's assessments. The Board should adopt procedures for reviewing and evaluating the accuracy and completeness of the information it will consider, and for permitting manufacturers and other stakeholders to provide input where information may be inaccurate or incomplete.

  For example, the All-Payer All Claims (APAC) database that the Board has indicated it will rely on for information regarding cost-sharing does not include all payers and thus does not capture claims data for all insured individuals in Oregon. Rather, the APAC categorically excludes various groups—including certain smaller-sized commercial health plans, individuals insured through various federal programs (such as service members or veterans insured under TRICARE or the Veterans Health Administration), and other sub-populations.[8] There are also notable gaps in the APAC even in some categories of insured individuals not categorically excluded from the database. For example, for self-insured health plans, well over 60% of

[3] *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007).
[4] *Id.* at 72.
[5] Feb. 11, 2023 PhRMA Letter, pp. 2-4; *see also* Letter from Pharmaceutical Research and Manufacturers of America to Or. Prescription Drug Affordability Board (Mar. 12, 2023), p. 4 [hereinafter, "Mar. 12, 2023 PhRMA Letter"].
[6] Drug Channels Institute. The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. March 2022.
[7] IQVIA. Use of Medicines in the US.: Spending and Usage Trends and Outlook to 2026, April 2022.
[8] Oregon All Payer All Claims Database (APAC): An Overview 7 (2018), available at: https://www.oregon.gov/oha/hpa/analytics/apac%20page%20docs/apac-overview.pdf.

enrollees may not be represented in the dataset based on the state's own estimates.[9] ***We ask that the Board adopt mechanisms to verify APAC-based data points in light of the recognized limitations of all-payer claims databases***. ***PhRMA requests that stakeholders be given an opportunity to review and critique any APAC data that the Board intends to rely upon and provide additional or alternative data or context for the Board's consideration.***

PhRMA also highlights the following specific concerns related to the proposed selection criteria:

- **Prescription Drug Selection Criterion – Top 25 Lists**.[10] PhRMA is concerned that the proposed selection criterion related to "top 25 lists" gives undue weight to payer costs without giving adequate consideration to patient out-of-pocket costs.

  Under the Oregon Prescription Drug Transparency Act, payers report certain information about the top 25 drugs that are most frequently prescribed, most costly, and that cause the greatest increase in plan spending.[11] However, these top 25 lists focus on reported payer costs (and certain utilization and administration cost data). As such, the Board's proposal to rely on such lists fails to give due weight to patient out-of-pocket costs, as well the range of factors driving such out-of-pocket costs, including benefit design. For example, patient out-of-pocket cost are impacted by cost-sharing requirements such as coinsurance and deductibles; copay accumulator adjustment[12] and maximizer programs[13]; and fees, rebates, and other price concessions paid by drug manufacturers to PBMs and plans that are not shared directly with patients at the point of sale. These factors, which are determined by the PBMs and plans, are contributing to the inability of Oregonians to afford their health care needs and should be given due weight in the Board's selection process.

  The "25 most costly drugs" list does not take into account rebates, discounts, and other price concessions, which – as described above – materially decrease the actual cost of the drug for the plans.

  The Board should consider the information provided in the "Top 25" lists in context to avoid drawing incorrect conclusions. For example, the "2022 Top 25 Most Costly Prescription Drugs Reported by Oregon Carriers" lists spending on COVID-19 vaccines as the 5th highest for plans.[14] However, the cost of COVID-19 vaccines was covered by the federal government, while health plans were responsible for the cost of administration of a significant number of vaccines.[15] If the cost of administration for drugs is being reported as total drug spend, that should be reflected in the Board's consideration.

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[9] *See* Oregon Health Authority, All Payer All Claims Reporting Program, https://www.oregon.gov/oha/hpa/analytics/Pages/All-Payer-All-Claims.aspx (last visited Apr. 14, 2023).
[10] Draft Outline § 3(a)(A).
[11] *See* DFR, Prescription Drug Price Transparency, https://stage-dfr.oregon.gov/drugtransparency/Pages/insurers.aspx (last visited Apr. 13, 2023).
[12] Accumulator adjustment programs are insurance benefit designs that exclude the value of manufacturer-sponsored cost-sharing assistance from a patient's accrual of out-of-pocket expenses toward out-of-pocket limits through a plan benefit year.
[13] Copay maximizer programs are insurance benefit designs that generally restructure patients' cost sharing obligations for a particular drug to equal the full value of manufacturer cost sharing assistance available for that drug. Such programs skirt the protection of the Affordable Care Act's annual limit on cost sharing for some plans by designating medications as non-Essential Health Benefits.
[14] The March 15, 2023 Oregon PDAB meeting materials, on page 29, lists COVID-19 vaccines as the 5th costliest prescription drug with $20.6 million in total spending.
[15] California Department of Managed Health Care. "Prescription Drug Cost Transparency Report. Measurement Year 2021". https://www.dmhc.ca.gov/Portals/0/Docs/DO/SB172021Report.pdf.

Separately, ***PhRMA also requests further clarification as to how the Board intends to operationalize the proposed criterion***. Among other things, the Board should clarify how it will use and weigh these top 25 lists.

- **Prescription Drug Selection Criterion – Approval Pathway**.[16] As an initial matter, PhRMA notes that the Draft Outline mentions consideration of "orphan" as one type of expedited approval, but the PDAB Statute categorically excludes orphan drugs from selection for affordability review.[17] Also, orphan drug designation is not an expedited review program and does not hasten FDA review.[18]

  PhRMA requests clarification of the Board's intent regarding the proposal to consider whether a drug was approved through an "expedited pathway" as a selection criteria.[19] The Draft Outline does not explain how the Board intends to weigh this information in its decision-making, and we ask that the Board clarify how it plans to use the information. Prescription drugs approved through FDA's accelerated approval pathway are critical for the treatment of many diseases.[20] Drugs granted accelerated approval must adhere to the same statutory standards for safety and effectiveness as medicines receiving a traditional FDA approval, including substantial evidence of effectiveness based on adequate and well-controlled clinical investigations.[21]

  Moreover, the approval pathways cited by the Board in the Draft Outline provide earlier access to lifesaving medicines. The availability of FDA's accelerated approval pathway is important because the development of innovative medicines is a lengthy and complex process, taking an average of 10 to 15 years. The accelerated approval pathway has expedited the availability of drugs that offer substantial health gains, making therapies available to patients many years (a median of 3.2 years) earlier than under traditional pathways.[22] In fact, research has shown that drugs approved through the accelerated pathway "offered larger health gains, compared to drugs approved through conventional review processes."[23]

- **Insulin Drug Selection Criterion – Carrier Reported Data**.[24] As previously mentioned, PhRMA urges the Board to not give undue weight to payer costs in its drug selection criteria without giving appropriate consideration to patient out-of-pocket costs and the impact of rebates, discounts, and other price concessions.[25] Two of the three proposed metrics for selecting insulin products for affordability review focus solely on payer-related costs.[26] For insulin products in particular, the net cost of medicines is significantly lower on average than their gross cost. For instance, in 2021 the net price for the most

[16] Draft Outline § 3(a)(B).
[17] PDAB Statute § 646A.694(2) ("A drug that is 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 is not subject to review under subsection (1) of this section.").
[18] FDA Guidance for Industry – Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014), https://www.fda.gov/media/86377/download.
[19] We also note that § 3(a)(B) of the Draft Outline includes consideration of the drug's FDA approval date. The FDA approval date of a drug does not bear on its affordability, value, or effectiveness. The Board should clarify how it intends to use this information in its considerations.
[20] Nat'l Org. for Rare Diseases, FDA's Accelerated Approval Pathway: A Rare Disease Perspective (2021), available atNRD-2182-Policy-Report_Accelerated-Approval_FNL.pdf (rarediseases.org).
[21] FDA, Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014), available at https://www.fda.gov/media/86377/download.
[22] Beakes-Read, G., Neisser, M., Frey, P. et al. Analysis of FDA's Accelerated Approval Program Performance December 1992–December 2021, Ther Innov Regul Sci (2022), available athttps://doi.org/10.1007/s43441-022-00430-z.
[23] James D. Chambers et al., Drugs Cleared Through the FDA's Expedited Review Offer Greater Gains Than Drugs Approved by Conventional Process, 36 HEALTH AFFAIRS 1408, 1408 (2017).
[24] Draft Outline § 3(a)(C).
[25] See discussion in "Prescription Drug Selection Criterion – Top 25 Lists," *supra*.
[26] *Id.* ("Overall spend" and "Per-patient spend").

common insulins dropped 84% with rebates and discounts.[27] Additionally, while the Board is directed to consider patient out-of-pocket costs, it is not clear what data source the Board will use for this metric.[28]

- **General Selection Criterion – Therapeutic Alternatives**.[29] PhRMA strongly recommends the Board use caution when considering information regarding "therapeutic alternatives" to particular medications. Drugs within a particular therapeutic class will often have significant differences, including in their chemical formulas, mechanism of action, and safety and effectiveness profiles, even though the drugs treat a similar clinical indication. A patient who can safely and effectively use one drug in a therapeutic class may experience increased risk of negative outcomes (e.g., drug interactions, side effects, treatment failures) with another drug in the class. Patients respond differently to treatment because of a number of factors, such as genetics, age, sex, socioeconomic status, drug-drug interactions, diet, environment, and co-morbidities. This means that treatments that are the best option for some individuals are not as effective for others.[30]

  The Board should carefully consider when and under what circumstances it will consider information regarding therapeutic alternatives, especially those that are not therapeutically equivalent. Accordingly, the Board should establish a definition of "therapeutic alternative" that requires a drug to have been shown through peer-reviewed clinical studies to have similar therapeutic effect, a similar safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose in order to be considered a therapeutic alternative. Additionally, in any situation where the Board considers therapeutic alternatives, patients with unique requirements, such as immunocompromised patients, pediatric patients, women (particularly those who are pregnant) and the elderly, who require multiple medications for acute and chronic illnesses, should be given special consideration.

  The Board should clarify how it will compare information regarding therapeutic alternatives to the reference product. PhRMA cautions against the use of estimated net sales or net cost information to form comparisons for drugs the Board considers to be therapeutic alternatives. While the statute contemplates consideration of information regarding both the comparator drug and therapeutic alternatives, the Board should carefully avoid making "apples to oranges" comparisons based solely on sales or cost data.

- **General Selection Criterion – Medicare Negotiation List**.[31] PhRMA is concerned that it is premature for the Board to incorporate elements of the federal Inflation Reduction Act ("IRA") Medicare price setting process into its affordability review selection process before the federal process is fully implemented and its impact on patients' drug access is well understood. The Medicare drug price setting process, enacted in August 2022 as part of the federal IRA, is not yet fully implemented and its price setting will not take effect for several additional years. Incorporating elements of the IRA into Oregon's affordability review process will create additional complexity and uncertainty given the many operational and legal issues of both processes that remain to be sorted out. The federal methodology is also designed to target drugs commonly used in an older and/or more disabled Medicare population, not the broader, younger, and more diverse population of Oregonian patients. Until the federal methodology has been implemented and taken effect, the Board will be unable to determine the impact that IRA will have on a drug's

[27] Partnership to Fight Chronic Disease, *Sharing Rebates on Diabetes Medicines Could Save Patients $3.7 Billion a Year* 1, *available at* https://www.fightchronicdisease.org/sites/default/files/PFCD-Diabetes%20Rebates-USA-Final%20%281%29.pdf.
[28] *See id.* (noting that the criterion is based on "carrier reported" cost information).
[29] Draft Outline § 3(a)(E).
[30] McRae, J., Onukwugha, E. Why the Gap in Evaluating the Social Constructs and the Value of Medicines?. PharmacoEconomics (2021), available at https://doi.org/10.1007/s40273-021-01075-w.
[31] Draft Outline § 3(a)(F).

accessibility and patient affordability. ***We therefore urge the Board to refrain from adding any reference to the Medicare process into these rules until that process is fully implemented and its impact on patients is understood.***

II. Conducting an Affordability Review

PhRMA reiterates the concerns raised in prior comments pertaining to the Board's proposals for conducting affordability reviews.[32] PhRMA continues to have serious concerns about the Board's proposed process. Because the Board proposes only one substantive change to the policies related to conducting affordability reviews, PhRMA specifically refers the Board back to PhRMA's February 12, 2023 comment letter for a detailed description of these concerns.[33]

With respect to the new proposal contained in the April Draft Outline relating to conducting affordability reviews, PhRMA notes the following:

- **Affordability Review – Potential Market and Budgetary Impact for Payers**.[34] PhRMA is concerned about the Board's proposal to consider the "potential market" of a prescription drug (as determined based on labeled indication), as well as the budget impact on various payers in the state.[35] Estimating market potential based only on population data could lead to inflated and misleading estimates. The real-world market size of a given prescription drug is limited by numerous factors, including clinical considerations, existing competitor products, and health plan-imposed utilization management and coverage limitations.

  PhRMA is especially concerned because the Draft Outline indicates that a drug's potential market size will be used to estimate its budgetary impact on various payers in the state. ***It is critical that the Board develop a clear methodology that provides more accurate estimates of the true potential market size for a given prescription drug.***

- **Affordability Review – References to "Price Concession, Discount, or Rebate."** In order to facilitate clear and consistent consideration of these criteria, ***PhRMA recommends the Board adopt the following definition of "rebate" to capture the full range of price concessions***:

  > "Rebate" means: (i) Negotiated price concessions including but not limited to base price concessions (whether described as a "rebate" or otherwise) and reasonable estimates of any price protection rebates and performance-based price concessions that may accrue directly or indirectly to the insurer during the coverage year from a manufacturer, dispensing pharmacy, or other party in connection with the dispensing or administration of a prescription drug, and (ii) Reasonable estimates of any negotiated price concessions, fees and other administrative costs that are passed through, or are reasonably anticipated to be passed through, to the insurer and serve to reduce the insurer's liabilities for a prescription drug.

[32] *See* Draft Outline § 4.
[33] Feb. 11, 2023 PhRMA Letter, pp. 2-4
[34] Draft Outline § 4(E).
[35] *Id.*

PhRMA further urges the Board to clarify that assistance that manufacturers provide to patients (e.g., coupons), which helps patients access and afford their medicine, is **not** a price concession, discount, or rebate "provide[d] to health insurance plans."[36]

- **Affordability Review – Impact on Safety Net Providers.** In the Draft Outline, the Board proposes to consider if a drug is available through the 340B Program. ***The Board should provide clarity on how the data collected from safety net providers participating in the federal 340B program will be used in conducting an affordability review, if the Board will consider if these discounts lead to direct patient savings, and how this information will be considered in determining a drug's affordability for payers and patients.*** To the extent that this proposal could result in access to and consideration of sensitive information related to the 340B Program that is protected from disclosure under federal law, PhRMA requests that the Board ensure appropriate safeguards regarding that information consistent with federal law, including safeguards that protect against indirect disclosures.[37]

III. Protections Against use of Quality-Adjusted Life Years (QALYs)

PhRMA recognizes that the Board is restricted by the PDAB statute from using QALYs or similar information to evaluate a drug's cost-effectiveness. This statutory prohibition reflects the legislature's recognition that, consistent with the views of experts, QALYs discriminate against older adults, chronically ill individuals, many communities of color, and people with disabilities by placing a lower value on their lives. Measurements accounting for "clinical efficacy" often obscure the distinct needs of disadvantaged populations, including communities of color, by rendering judgments about value based on "average" study results, which often reflect primarily white populations and ignore diversity in preferences and other factors that impact health, such access to care, education, and literacy.[38] For example, the value of a lifesaving treatment for Black patients can be automatically valued up to 10% less than for white patients due to biased value metrics such as QALY.[39]

Suggestions that other metrics similar to QALYs, such as the "equal value life year gained" (evLYG) metric, could be used by the Board should be carefully considered. As discussed below, the flaws in the evLYG metric are such that its use is nonetheless prohibited by the PDAB Statute's bar on use of QALYs "or a similar formula that takes into account a patient's age or severity of illness or disability."[40]

The evLYG metric was developed in response to stakeholder feedback on the QALY, but the metric introduces new problems, including documented equity and technical issues as well as inaccurate and incomplete capture of the full impact of treatments on patients.[41] For example, the evLYG devalues drugs for conditions that do not extend life expectancy, like eczema or blindness, so therapies for these conditions would be seen as having no value.[42] The evLYG would also value two drugs, one that reduces side effects and one that does not, as of equal value, even though side effects have a significant impact to patients.

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[36] We note that this distinction is included in section 4(b)(K)(i)-(ii) of the Draft Outline and reflected in some of the Board member comments included in the Draft Outline.

[37] *See, e.g.*, 42 U.S.C. § 1396r-8(b)(3)(D); HHS, PPA § V.

[38] *See, e.g.*, National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability. (Nov. 2019), *available at* https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.

[39] Broder, M, Ortendahl, J. Is Cost-Effectiveness Analysis Racist? Partnership for Health Analytic Research. 2021. Available at: https://blogsite.healtheconomics.com/2021/08/is-cost-effectiveness-analysis-racist/.

[40] Or. Rev. Stat. § 646A.697(4)(a) (enacted as § 2(4)(a) of the PDAB Statute).

[41] ICER. (2018). "The QALY: Rewarding the Care that Most Improves Patients' Lives. Available at: https://icer.org/wp-content/uploads/2020/12/QALY_evLYG_FINAL.pdf.

[42] Cohen JT, Ollendorf, DA, Neumann PJ. (2018). "Will ICER's Response to Attacks on the QALY Quiet the Critics?" Tufts Center for the Evaluation of Value and Risk in Health. Available at: https://cevr.tuftsmedicalcenter.org/news/2018/will-icers-response-to-attacks-on-the-qaly-quiet-the-critics.

While the evLYG may not value certain individuals' lives as worth less than others' lives, the evLYG still fails to capture the full benefits, both direct and indirect, that treatments may have on improving a patient's quality of life. These issues have been pointed out by both patients and academics. For example, researchers at Tufts University noted the shortcomings associated with the evLYG metric can harm patients if used to inform coverage and reimbursement decisions and that any use of the evLYG should be limited to sensitivity analyses.[43] The National Council on Disability (NCD), an independent agency responsible for advising Congress, echoed these concerns in a 2022 whitepaper.[44] In that report, NCD argued the evLYG is not a suitable alternative to QALYs as it falls short in fully addressing the discriminatory aspects of QALYs and that the metric still undervalues health interventions in patients with disabilities, chronic conditions, and the elderly.[45]

Research has consistently reinforced that the evLYG metric produces results that are largely similar to that of the QALY. One study found that in most cases, results differed only modestly, and differences in ratios between cost-per-QALY and cost-per-evLYG were too small to adequately provide end-users of the reports with actionable intelligence.[46] The PDAB Statute restricts the Board from utilizing metrics that fail to "weigh the value of the quality of life equally for all patients," and as a result, use of the evLYG is prohibited by the PDAB Statute as well.[47]

IV. **CONFIDENTIALITY**

The Draft Outline does not address how the Board will ensure the confidentiality of the materials it reviews in accordance with PDAB Statute.[48] State and federal law protect manufacturers' confidential, trade secret, and proprietary information from disclosure; such information cannot be publicly disclosed without violating state and federal prohibitions against the misappropriation of trade secrets. In addition, the Fifth Amendment's prohibition against taking private property without just compensation similarly prohibits the uncompensated disclosure of trade secrets. Courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality ... can amount to an unconstitutional 'taking' of property." Consistent with these state and federal requirements, the Legislature incorporated into the PDAB Statute an independent obligation on the PDAB to "keep strictly confidential any information" that is "[c]onfidential, proprietary or a trade secret," including "[i]nformation submitted to the department by a manufacturer under ORS 646A.689." ***PhRMA encourages the Board to incorporate clear standards in the Draft Outline regarding how it will maintain the confidentiality of relevant information consistent with state and federal law.***

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[43] Center for the Evaluation of Value and Risk in Health. Tufts Medical Center. "Will ICER's Response to Attacks on the QALY Quiet the Critics?" 2018, available at https://cevr.tuftsmedicalcenter.org/news/2018/will-icers-response-to-attacks-on-the-qaly-quiet-the-critics.
[44] National Council on Disability. Policy Brief: Alternatives to QALY-Based Cost-Effectiveness Analysis for Determining the Value of Prescription Drugs and Other Health Interventions. 2022.
[45] *Id.*
[46] Chapman RH, Berger M, Weinstein MC, Weeks JC, Goldie S, Neumann PJ. When does quality-adjusting life-years matter in cost-effectiveness analysis? Health Econ. 2004 May;13(5):429-36. doi: 10.1002/hec.853. PMID: 15127423.
[47] Or. Rev. Stat. § 646A.697(4)(a) ("If the board considers the cost-effectiveness of a prescription drug in criteria adopted by the board ... the board may not use quality-adjusted life-years, or similar formulas that take into account a patient's age or severity of illness or disability, to identify subpopulations for which a prescription drug would be less cost-effective. For any prescription drug that extends life, the board's analysis of cost-effectiveness must weigh the value of the quality of life equally for all patients, regardless of the patients' age or severity of illness or disability.")
[48] Or. Rev. Stat. § 646A.694(7) (enacted as § 2(7) of the PDAB Statute).

We thank you again for this opportunity to provide comments and feedback on the Draft Outline and for your consideration of our concerns and requests for revisions. Although PhRMA has concerns with the Draft Outline, we stand ready to be a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide as these regulations are further developed, please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law