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By Electronic Submission to HCA_WA_PDAB@hca.wa.gov

March 14, 2025

Washington Prescription Drug Affordability Board
Washington Health Care Authority
PO Box 42716
Olympia, Washington 98504-2716

Re: Washington Prescription Drug Affordability Board: Comments on Draft Submission Guidance for February 27, 2025 Meeting

Dear Members of the Washington Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the draft Manufacturer Data Submission Guide, Manufacturer Submission Form for Affordability Review, and 2025 Manufacturer Data Submission Sheet (collectively, the "Draft Submission Guidance") circulated by the Washington State Prescription Drug Affordability Board ("Board") ahead of its February 27, 2025 meeting. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat, and cure disease.

PhRMA has previously commented on various aspects related to the Washington Health Care Authority's ("HCA's") and the Board's implementation of SSSB 5532, 2022 Sess. Laws ch. 153 (the "PDAB Statute"), codified at Wash. Rev. Code §§ 70.405.010 *et seq*., and its implementing regulations codified at Wash. Admin. Code § 182-52-0005 *et seq*.[1] PhRMA is concerned that the Draft Submission Guidance contemplates a series of sweeping and vaguely worded requirements that mandate disclosure of significant amounts of confidential, proprietary, and trade secret information to the Board that, as discussed below, are not directly relevant to the PDAB's statutory mandate to conduct affordability reviews. Below, we highlight comments and concerns of particular importance regarding the Draft Submission Guidance..

I. Much of the Information Described in the Draft Submission Guidance Is of Unclear Relevance to the Board's Affordability Review Process and Falls Outside the Scope of the Board's Statutory Authority

[1] *See, e.g.*, Letter from PhRMA to Board Regarding Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials (Dec. 9, 2024); Letter from PhRMA to Board Regarding Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials (Oct. 15, 2024); Letter from PhRMA to Board Regarding the Draft Eligible Prescription Drugs Policy (July 12, 2024); Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials (June 18, 2024); Letter from PhRMA to Board Regarding Draft Methodology (Apr. 11, 2024); Letter from PhRMA to Board Regarding Draft Policies and Procedures (Mar. 1, 2024); Letter from PhRMA to Board Regarding Draft Policies and Procedures (Jan. 23, 2024); Letter from PhRMA to HCA Regarding HCA Proposed Regulations (WSR 23-21-082, filed October 16, 2023) (Nov. 20, 2023); Letter from PhRMA to HCA Regarding August 2023 Draft Regulations (Aug. 15, 2023); Letter from PhRMA to HCA Regarding HCA Advance Notice (Aug. 25, 2020). In filing this comment letter, PhRMA reserves all rights associated with its prior comment letters and, to the extent applicable, incorporates by reference all comments, concerns, and objections that it has raised in its previous comments. PhRMA also reserves all rights to legal arguments with respect to the constitutionality of the PDAB Statute and its regulations.

Much of the information requested in the Draft Submission Guidance exceeds the Board's authority under the PDAB Statute. Additionally, because the Board has not yet developed a plan for how it will perform affordability reviews, it is unclear how the data elements described in the Draft Submission Guidance will be operationalized and how they relate to the Board's statutory mandate to assess whether a drug has led or will lead to excess costs, which is defined as "costs of appropriate utilization of a prescription drug that exceed the therapeutic benefit relative to other alternative treatments" or that "are not sustainable to public and private health care systems over a 10-year time frame."[2] PhRMA understands and appreciates the Board's desire to better understand the value of drugs, but the Draft Submission Guidance contemplate disclosure of significant amounts of information that may not be relevant to the Board's affordability reviews and, as discussed below, are not within the Board's authority to require manufacturers to submit.

The Board should clarify the legal basis for requesting each data element and should clearly describe how such data will be used to determine "whether a drug has or will lead to excess costs to patients" in Washington.[3] The Board should then narrow its requests to only those data that will be used to perform the affordability review.

The following non-exhaustive list of examples illustrates some of the required reporting elements in the Draft Submission Guidance that are of unclear relevance to the Board's affordability review process:

A. International Pricing Information

The Draft Submission Guidance contemplates mandatory reporting of international pricing information. It is unclear how international pricing is relevant to the Board's statutory mandate to determine whether utilization of a prescription drug leads to excess costs in Washington, and unless the relevance of this information the affordability review process can be established, it falls outside the scope of authority conferred by the PDAB Statute.[4] The Board should explain how it intends to use information from dissimilar health care systems and unrepresentative, international patient populations to determine whether the use of a drug has led or will lead to excess costs for patients in Washington.

In addition to directly contravening the PDAB Statute, international pricing information is an inappropriate reference point for policy decisions in Washington for numerous reasons, including the following:

- Prices set by other countries are influenced by a variety of country-specific factors such as patient populations and demographics, needs and preferences, economic conditions, and cultural norms that may differ markedly from those in Washington, or even the U.S.

- International pricing data are generally collected at different levels of granularity in each country. For example, in some countries, data are collected at the hospital level. In other countries, data are collected only at a higher level, such as the wholesale level.

[2] Wash. Rev. Code §§ 70.405.040(2), 70.405.010(5); Wash. Admin. Code §§ 182-52-0010, 182-52-0040(2) ("For drugs chosen for the affordability review, the board must determine whether the drug has led or will lead to excess costs to patients.").
[3] Wash. Rev. Code § 70.405.040(2).
[4] *See* Wash. Rev. Code §§ 70.405 *et seq.*

- International pricing data aggregators often use proprietary methods to estimate whole-country sales volumes and prices. As a result, these data represent proprietary and non-transparent estimates of drug sales and volume and are not reflective of actual transaction or volume information. These proprietary estimates would be unreliable sources for affordability reviews.[5]

- Pharmaceutical products may also differ across countries, depending upon the authorizations required by regulators and other factors, and countries may have different patent protection schemes. These differences factor into international drug pricing and complicate direct comparison.

Fundamentally, comparing drug prices in the United States to prices in other countries is an apples-to-oranges comparison. Other countries have pricing and reimbursement regimes that are not market-based or governed by U.S. healthcare laws, and their healthcare systems and policies do not match those found in the U.S. or any individual state or territory. In many countries, for example, governments are the primary or only health care payer and in effect dictate drug prices as a condition of market access.[6] Some of these governments set prices directly—including drawing complicated distinctions about what types of fees, taxes, or other elements are included in (or excluded from) pricing. Such prices are not relevant considerations for pricing in the U.S., and using them to conduct an affordability review would raise constitutional concerns.

For all these reasons, PhRMA urges the Board to carefully consider the propriety and scope of its contemplated demands for international pricing information to manufacturers.

B. R&D Costs

It is unclear how a manufacturer's R&D costs are relevant to whether a prescription drug under review leads to excess costs. The Board's requests for R&D costs are imprecise and highly burdensome, and such costs may be difficult to accurately break down by drug product or indication, particularly where R&D was conducted over several years (if not decades) by multiple companies or affiliates. R&D efforts may span an entire portfolio and reflect broader analysis of new modalities of treatment. They may also relate to multiple commercially available drug products, in addition to failed antecedent drug candidates. Additionally, the Board's requests do not accurately reflect and account for the full scope of investment in the drug development process, which often builds on discovery and study of hundreds, if not thousands, of potential molecules. The costs of this iterative process, including failed antecedent drug candidates, are necessarily part of R&D spend and reflected in the prices of drugs that ultimately make it to market. All this makes it difficult for manufacturers to disaggregate their R&D costs and attribute them to a particular drug or drugs. Adding to this difficulty, manufacturers track R&D cost information in different ways, often

[5] IQVIA, Comment Letter on Interim Final Rule Implementing Most Favored Nation (MFN) Model (Jan. 26, 2021), https://www.regulations.gov/comment/CMS-2018-0132-3860 ("While the use of MIDAS data for analytic purposes is suitable for the study of international drug pricing, for the reasons stated below, the use of MIDAS data or any other locally sourced IQVIA national market research data ('IQVIA Market Research Data') is *not suitable for calculation of actual adjustments in pricing or reimbursement*.") (emphasis added).

[6] Government price-setting practices like these force artificially low prices, delay patient access to new medicines, and keep some innovative treatments off the market entirely. For example, 85 percent of all new medicines launched between 2012 and 2021 and reimbursed in the U.S. Medicare and Medicaid programs, only 61 percent of new medicines are reimbursed in Germany, 48 percent in the United Kingdom, 43 percent in France, and 21 percent in Canada. PhRMA, Global Access to New Medicines Report (Apr. 2023), https://phrma.org/resources/global-access-to-new-medicines-report.

at the corporate-enterprise level. Given these reporting limitations, it remains unclear how the Board would use collected data to inform its review of a particular drug or indication for use.

II. The Draft Submission Guidance Inappropriately and Unlawfully Relies on Flawed Comparative- and Cost-Effectiveness Analyses and Health Technology Assessment ("HTA"), Including from Outside the United States

PhRMA is concerned about the Board's proposed approach to use of HTA or cost-effectiveness analyses to gather data on price and availability of therapeutic alternatives.

A. Reliance on Assessments by ICER and Ex-US HTA Bodies is Problematic and Violates Washington Law

The Board's heavy reliance on assessments conducted by ICER and HTA bodies outside the U.S. raises concerns. First, the comparator selection and comparative effectiveness research conclusions are both highly variable in HTAs due to factors such as the time of the assessment, the available evidence base, differences in assumptions and evidence evaluation, and the health authorities' over-arching budget objectives, which can influence underlying cost effectiveness conclusions.[7]

In addition, these HTAs often are performed soon after a medicine's initial approval, meaning the choice of comparators and evidence base may be several years out of date. Because any prescription drug under review will have been on the market for at least seven years, there will be a substantial body of evidence to draw on. The Board should use the best available post-approval evidence, across the range of clinical and other benefits that matter to patients (such as productivity, caregiver burden, treatment burden and quality-of-life), to inform its affordability determinations.

Further, both ICER and several HTA organizations listed in the Draft Submission Guidance have been known to use analyses that rely on the flawed quality-adjusted life year ("QALY") or other similar metrics based on the QALY (including the equal value of life years gained ("evLYG")). While PhRMA appreciates the Board's acknowledgement that it "must not use quality-adjusted life years that take into account a patient's age or severity of illness or disability" pursuant to Washington law, we are concerned that the Board has not established adequate guardrails to prevent QALYs and other similar measures from being used within, or impacting, the affordability review process and, consequently, the upper payment limit ("UPL")-setting process.[8] The use of such measures would violate the PDAB Statute and perpetuate longstanding differences in health care and health outcomes among patient populations,[9] but the Draft Submission Guidance offers no explanation of how the Board would filter out all statutorily prohibited

[7] *See* Rick A. Vreman et al., *Differences in Health Technology Assessment Recommendations Among European Jurisdictions: The Role of Practice Variations*, 23 VALUE IN HEALTH 10 (2020), https://www.sciencedirect.com/science/article/pii/S1098301519323411.
[8] Draft Manufacturer Data Submission Form at 21 (citing Wash. Rev. Code § 70.405.050); *see* Wash. Rev. Code § 70.405.050 ("The [UPL-setting] methodology determined by the board must not use quality-adjusted life years 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 may not employ a measure or metric which assigns a reduced value to the life extension provided by a treatment based on a preexisting disability or chronic health condition of the individuals whom the treatment would benefit.").
[9] *See, e.g.*, Letter from PhRMA to Board Regarding Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials at 7–8 (Oct. 15, 2024); Letter from PhRMA to Board Regarding August 2023 Draft Regulations at 3–4 (Aug. 15, 2023).

information from consideration.[10] PhRMA urges the Board to adopt robust procedural safeguards to require that no information directly or indirectly based on QALYs or similar measures are considered in the course of the affordability review process.[11]

B. Coercing Drug Manufacturers to Use the ICER Analytics Modeler Is Inappropriate and Unconstitutional

PhRMA is concerned by the Board's requirement that manufacturers submit a cost-effectiveness model and, particularly, the Board's endorsement of the ICER Interactive Modeler.[12] PhRMA is concerned that, by endorsing this model, the Board may rely too heavily on a single organization (ICER) that is known to utilize traditional, flawed methods of CEA.[13]

The Draft Submission Guidance currently contains the following instructions: "Submission of a budget-impact analysis model is strongly recommended by using the ICER Analytics Interactive Modeler, if there is any relevant model published already ... Alternatively, a copy of the in-house model file for the budget impact analysis in an Excel format can be submitted. A detailed description or a manual explaining the model, the parameters, and assumptions are requested, so that Board staff can verify and make adjustments if needed for the Board's requests." These instructions raise several serious concerns.

i. Legal Concerns

The First Amendment bars the government from using "the threat of invoking legal sanctions" to compel favored speech and suppress disfavored speech.[14] Yet the Board's Draft Submission Guidance would compel drug manufacturers—under threat of civil fine—to adopt and speak through ICER's analytical framework, while at the same time discouraging the use of alternative models.

The instructions push pharmaceutical manufacturers to use the ICER model instead of an in-house or alternative third-party model. Despite statements made at the February 27, 2025 Affordability Review Process webinar, the Draft Submission Guidance instructions "strongly recommend[] ... using [the] ICER Analytics Interactive Model" when submitting the required cost-effectiveness analysis model, and they warn that the Board will closely scrutinize a manufacturer's use of any "alternative" model. That scrutiny comes with a serious risk: If the Board finds a manufacturer's submission wanting, it can impose a

[10] *See* Draft Manufacturer Data Submission Form at 18, 20–23, 31–32; Letter from PhRMA to Board Regarding Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials at 7 (Oct. 15, 2024); *see also, e.g.*, Alliance for Aging Research, *ICER and Drug Price Negotiation – What's at Stake?*, https://www.agingresearch.org/icer-facts/ (last visited Mar. 3, 2025). *See generally* 89 Fed. Reg. 37,522, 37,615 (May 6, 2024) ("The use of value assessment methods that result in discrimination on the basis of race, color, national origin, age, disability and sex are prohibited under [Patient Protection and Affordable Care Act] section 1557's general mandate of nondiscrimination").

[11] *See* Letter from PhRMA to Board Regarding August 2023 Draft Regulations at 3–4 (Aug. 15, 2023). Additionally, the requirements contemplated in the Draft Submission Guidance for modeling from HTA organizations would require a robust and resource-intensive process to ensure the protection of intellectual property, sufficient reporting of model specifications, and additional reporting to review and respond to HTA changes to the model. *See* further discussion

[12] Draft Manufacturer Data Submission Form at 22–23. We note that the Board does not appear to have formally discussed the ICER Interactive Modeler, including its assumptions and potential biases, at an open meeting. PhRMA has additional concerns regarding whether the development of the Draft Submission Guidance is consistent with the requirements of the Washington Administrative Procedure Act, *see* Section IV.B, *infra*.

[13] *See, e.g.*, Draft Manufacturer Data Submission Form at 31 ("Submission of a budget-impact analysis model is strongly recommended by using the ICER Analytics Interactive Modeler[.]").

[14] *Nat'l Rifle Ass'n of Am. v. Vullo*, 602 U.S. 175, 189 (2024) (cleaned up).

$100,000 fine.[15] The instructions thus strong-arm pharmaceutical manufacturers into using the ICER model, instead of an in-house or alternative third-party model, for disclosing its budget-impact analysis.

That regulatory choice has content-based implications because the ICER model is not neutral: As part of a conscious effort to bring down drug prices through negotiation, it consistently undervalues drugs compared to "alternative" models.[16] Nor is ICER Analytics free; its users must pay for the privilege. By inducing manufacturers to use ICER in order to avoid additional scrutiny (and the accompanying threat of serious penalties), the Board is favoring a particular view on manufacturer pricing—and forcing manufacturers to fund it—at the expense of other viewpoints expressed by other models. The First Amendment does not allow the government to pressure private parties to speak in such a content-based manner.[17]

The instructions in the Draft Submission Guidance also amplify the confidentiality concerns that plague other parts of the guidance, as discussed below.[18] To make the ICER model work, drug manufacturers would have to hand over significant amounts of confidential information to ICER. But ICER is a third party, and drug manufacturers lack control over how it handles its data. The Board cannot force manufacturers to trust this self-interested private party with their most sensitive data, much of which is protected under federal and state law.

ii. Other Concerns

As an initial matter, ICER often utilizes CEA studies that rely on QALYs or similar QALY-based metrics, as discussed above.[19] In addition, access to the ICER Interactive Modeler requires licensing fees that impose an additional burden on manufacturers. Moreover, while some inputs in the ICER Interactive Modeler can be adjusted, many key elements, including underlying methodological assumptions and the incorporation of societal costs, cannot be modified. This rigid structure means manufacturers may be forced to submit data through a framework that does not accurately reflect the full value of their products to patients.

The Board has attempted to provide an alternative to the ICER Interactive Modeler by allowing manufacturers to submit a modifiable version of an Excel-based cost-effectiveness model.[20] However, this approach also presents significant challenges and does not address issues with how CEA methodologies fail to account for the unique needs of specific patient populations.[21] Constructing any sort of value assessment model that meaningfully accounts for patient differences and disease-relevant outcomes is a highly technical and resource-intensive process that manufacturers cannot reasonably be expected to complete within the 30-day response window. Further, the Board has not provided any clarity on how it intends to evaluate or modify submitted models.

Reliance on any one model, especially ones with significant flaws that rely on assumptions and biases not vetted by the Board, could hurt or delay patient access to lifesaving treatments. As such, PhRMA urges the Board to explicitly permit reliance on multiple CEA models and address specific flaws with traditional

[15] Wash. Rev. Code § 70.405.040.
[16] https://www.nopatientleftbehind.org/press-releases-1/nplb-statement-on-icers-flawed-value-assessment-framework
[17] Wash. Rev. Code § 70.405.040.
[18] *See* Section V, *infra*.
[19] *See* further discussion in Section II.A, *supra*.
[20] Draft Manufacturer Data Submission Form 23.
[21] https://www.ncd.gov/assets/uploads/reports/2022/ncd_alternatives_to_the_qaly_508.pdf.

models such as those often relied on by ICER, and provide manufacturers the option of providing CEA information based on multiple models. These could include, for example, alternatives such as Multi-criteria Decision Analysis ("MCDA"), which can do a better job showing variability in value when compared to traditional CEA methodologies; Generalized Cost Effectiveness Analysis ("GCEA"), which captures elements of value like productivity, caregiver burden and genericization that often are ignored in traditional CEA; and the Generalized Risk-adjusted Cost-Effectiveness Analysis ("GRACE") model, which adjusts for disease severity in ways that traditional CEA does not, helping it better reflect value for the perspective of the patient and caregiver. No one CEA model is adequate to establish a simple "rule" for policy decision-making and, when considered, a CEA should represent a tool to inform decisions. By endorsing a specific model, the Board risks over-relying on a single, flawed method as the basis for its decisions.

In light of these concerns, the Board should reconsider its reliance on ICER's Interactive Modeler and remove any reference to ICER from its guidance, as well as any sanction or barrier to manufacturers relying on alternative modelers.

III. The Draft Submission Guidance Imposes an Unreasonable and Unnecessary Administrative Burden on Manufacturers

The reporting requirements contemplated in the Draft Submission Guidance would impose an unreasonable administrative burden on manufacturers in terms of volume, scope, level of detail, and response time. The PDAB Statute requires manufacturers to submit all requested information to the Board within 30 days.[22] However, the significant volume and scope of information contemplated in the Draft Submission Guidance would render compliance with the 30-day reporting requirement exceedingly difficult. This is especially concerning given that manufacturers may be subject to fines between $25,000 and $100,000 "for each failure" to comply with a request for information.[23]

The Board's statutory mandate is to determine whether a product selected for affordability review has led or will lead to excess costs to patients in Washington State.[24] However, the sheer magnitude of information the Board's Draft Submission Guidance would require far exceeds that which is feasible to report, relevant to the Board's affordability review process and statutory authority, and can legally be disclosed. For numerous data categories, the Board proposes to collect both current and historical data, as well as future data projections. This exacerbates the unreasonable burden on manufacturers and calls into question whether the Board could—or has sufficient available resources to—meaningfully consider all of this information in the course of its affordability review. And, because manufacturers only have 30 days to respond to the Board's requests—or risk steep civil penalties—these compelled (and overreaching) disclosures compound PhRMA's pre-existing concerns about the Board's methodologies and processes.[25]

The Board should revise its Draft Submission Guidance to narrow the scope of its information requests and make it more feasible for manufacturers to respond within the reporting deadline, which should be extended significantly to provide manufacturers sufficient time to prepare meaningful responses to the Board's inquiries.

[22] Wash. Rev. Code § 70.405.040(3).
[23] Wash. Rev. Code § 70.405.040(3)-(4).
[24] Wash. Rev. Code § 70.405.040(2).
[25] See, e.g., Letter from PhRMA to HCA Regarding HCA Proposed Regulations (WSR 23-21-082, filed October 16, 2023).

Below, PhRMA provides a non-exhaustive list of areas where the Draft Submission Guidance would impose an unreasonable and unnecessary burden on manufacturers:

A. Data Available from Other Sources

Some of the information sought by the Board is not typically maintained by, or even accessible to, pharmaceutical manufacturers. In conducting affordability reviews, the Board has the authority to collect information from drug manufacturers, publicly available information, "and other relevant sources."[26] The Board should first leverage data sources and information already accessible by or available to it, including, but not limited to, the following:[27]

- Information on drug labeling, prescribing details, safety and efficacy, orphan drug status, and drug shortage status is publicly available through peer-reviewed or government-managed data, such as Food and Drug Administration ("FDA") databases. FDA's Orange Book and Purple Book, which are publicly available, contain information on generic equivalents and biosimilars.

- Prevalence and incidence data can be gathered from public peer-reviewed journal articles, federal public health data, or existing data from the Washington State Department of Public Health or other public health authorities.

- The National Average Drug Acquisition Cost ("NADAC") is calculated based on surveys of data voluntarily submitted by pharmacies on how much pharmacies pay for prescription drugs.[28] It is maintained and updated weekly by the Centers for Medicare and Medicaid Services ("CMS"). It is not a metric calculated or maintained by manufacturers.

- Information related to the cost of drug delivery, including clinical costs and equipment to administer the drug, would be better sourced from the providers and payers who determine what services and equipment will be needed and the cost for patients.

- In determining the treatment pathway for a drug, the Board should rely on clinical practice guidelines published by relevant professional medical societies and organizations, which evaluate the best available evidence to make recommendations informing the appropriate course of treatment. These guidelines can provide the most relevant information regarding the population eligible for treatment with the reviewed drug, the context of the approved use of the drug within the treatment pathway, and other issues related to comparator technologies or current clinical practices. The Board should also independently obtain information from the reviewed drug's FDA label to determine factors such as its approved line of treatment, as this information is publicly available and does not need to be submitted by manufacturers.

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[26] Wash. Rev. Code § 70.405.040(2). Note also that the purpose of an affordability review is to determine if the Board will impose an upper payment limit on payer reimbursement. Wash. Rev. Code § 40.405.040.

[27] As PhRMA has previously commented, the Board should also provide manufacturers an opportunity to review and comment on all data that the Board intends to rely upon as part of its affordability review process and provide additional data or context for the Board's consideration. *See* Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials at 4 (June 18, 2024).

[28] *See* CMS, NADAC, https://www.medicaid.gov/medicaid/nadac (last visited Mar. 3, 2025). If the Board proceeds with its requirement to report NADAC, it should revise the Draft Submission Guidance to recognize that not all drugs have a NADAC.

The Board should revise the Draft Submission Guidance to eliminate requirements that manufacturers report data more appropriately sourced from other stakeholders.

B. Reporting Related to Therapeutic Alternatives

In the Draft Submission Guidance, the Board would require by indication information relating to the efficacy, safety, and cost of therapeutic alternatives.[29] Manufacturers should not be required to provide information regarding other manufacturers' products that the Board may consider to be therapeutic alternatives. For example, it is unreasonable to expect manufacturers to provide revenue or market share information or projections for other manufacturers' products, especially when these data are not publicly available. Moreover, manufacturers should not be expected to provide comparative safety and efficacy information for other manufacturers' products. These reporting requirements are especially troubling given the excessively broad scope of products deemed "therapeutic alternatives" by the Board.[30]

Third-party compendia that report list prices of drugs are a possible resource for pricing information for other manufacturers' drugs. PhRMA respectfully encourages the Board to utilize these third-party resources for any such information utilized in connection with an affordability review.

C. Manufacturer Responsibility for Third-Party Information

The Board requests information regarding third parties, including cost-effectiveness and budget impact analyses. To the extent the Board wishes to review such information, it would be more appropriately collected from third parties that may undertake these studies.[31] More fundamentally, the Board should clarify that manufacturers are not responsible for the accuracy of information they are required to provide that is not in their control, such as third-party information.

D. Estimated or Speculative Responses Where Information May Be Unavailable

Materials posted by the Board further suggest that even where information is unavailable, manufacturers will be required to provide estimated or speculative responses to satisfy the Board's requests.

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[29] In addition, the Board proposes an exceptionally complex approach to providing comparative cost and efficacy information for therapeutic alternatives. This would require submission of a significant volume of data across a wide range of indications and multiple potential comparators. However, the Board does not explain how data across these indications will be considered in its decision-making. PhRMA urges the Board to describe how this evidence will be factored into its decisions, and review whether the basis for reporting such information can be simplified.

[30] *See* Draft Manufacturer Data Submission Form 17 ("All drugs within the same therapeutic class, as well as drugs from different therapeutic classes evaluated within guidelines for treating the same disease and the same severity, should be evaluated under [the therapeutic alternatives] section."). As PhRMA has noted in prior comments, therapeutic classes are broad and cut across distinct therapies used for a wide range of indications. *See* Letter from PhRMA to Board Regarding Health Care Authority Proposed Regulations (WSR 23-21-082, filed October 16, 2023) at 4–5 (Nov. 20, 2023); Letter from PhRMA to Board Regarding August 2023 Draft Regulations at 5, 7–8 (Aug. 15, 2023). Drugs within a particular therapeutic class will often have significant differences, including in their chemical formulas, mechanisms of action, and safety and effectiveness profiles, even though the drugs treat similar clinical indications. Treatments that are the best option for some individuals may not be for others. PhRMA continues to advocate for the Board to adopt a narrower, more selective definition of "therapeutic alternative" to help limit the Board's considerations to therapeutic alternatives based on demonstrated clinical evidence and input and to help avoid inappropriate drug comparisons.

[31] PhRMA discusses additional concerns related to CEA studies in Section II.B, *supra*.

Manufacturers should not be required in those circumstances to provide such information or subject to civil penalties for not responding.

E. Drug Efficacy and Safety

In the Draft Submission Guidance, the Board would require information pertaining to the efficacy and safety of drugs, including outcome measures and descriptions of data from clinical trials. Rather than requesting efficacy and safety information from manufacturers, PhRMA respectfully directs the Board to FDA approvals of the pertinent drug products and FDA's own determinations on these areas.

F. Off-Label Usage

The Board would also require that manufacturers provide a list of every off-label indication for a reported drug, including narrative descriptions of safety and efficacy information, the estimated number of Washingtonians using the drug for the off-label indication, and the relative frequency of use for the off-label indication versus for the labeled indication.[32] It is unclear whether manufacturers would have information on "every" off-label indication for the drug. It is also not clear how the Board intends to use this information and how it is relevant to the Board's statutory mandate.

G. International Pricing Data

It may be exceptionally difficult, if not impossible, for a manufacturer to compile international pricing data required by the Board. Some drugs sold in other countries may be licensed to a foreign entity, such that the U.S. manufacturer may not have influence over foreign pricing decisions or access to pricing data.[33] Additionally, international pricing information is often subject to significant confidentiality requirements, and some data may be confidential by law. Where available, many sources of international pricing data are licensed on a confidential basis to subscribers for their internal use only.

IV. The Draft Submission Guidance Lacks Necessary Clarity, Violates Washington's Administrative Procedure Act, and Undermines Due Process

A. Insufficient Clarity Regarding Reporting Obligations

The Draft Submission Guidance fails to provide sufficient clarity for manufacturers to ascertain what information they must report to satisfy some data requests. The following non-exhaustive list of examples illustrates some of the definitional shortfalls requiring further clarification:

- ***Level of Information Not Specified.*** Throughout the Draft Submission Guidance, the Board does not always explicitly indicate whether it is seeking company-level or drug-level information. Likewise, the Draft Submission Guidance often does not specify whether data elements are to be

[32] Washington State Health Care Authority, *Manufacturer Information Submission Form for Affordability Review* at 33, https://www.hca.wa.gov/assets/program/pdab-manufacturer-form.pdf.

[33] In addition, this data may be maintained in different formats, thereby complicating efforts to compare such data. *See, e.g.*, Nat'l Pharmaceutical Council, *U.S. vs. EU: Not a Direct Comparison When it Comes to Drug Pricing* (Jan. 29, 2021), https://www.npcnow.org/resources/us-vs-eu-not-direct-comparison-when-it-comes-drug-pricing; Andrew W. Mulcahy, Daniel Schwam & Susan L. Lovejoy, RAND, *International Prescription Drug Price Comparisons* at 28-29 (Feb. 1, 2024), https://www.rand.org/pubs/research_reports/RRA788-3.html.

reported for the State of Washington or the entire nation.[34] Without greater specificity, the Board may receive inconsistent information that cannot be meaningfully compared.[35]

- ***Vague or Absent Definitions.*** The Draft Submission Guidance leaves several key terms undefined or defined only in vague terms that do not permit manufacturers to understand their reporting obligations. For example, the Board has not defined the "Cost of Delivering the Drug to Patients" or "Cost of Administering the Drug to Patients." In some instances, the Draft Submission Guidance only cites examples of the types of data requested, rather than providing more concrete definitions to guide manufacturers' responses. In many cases, in lieu of setting forth clear methodologies, the Board simply asks the manufacturer to explain its methods for arriving at the reported information. This raises serious concerns about the comparability of the information collected across the different drugs under review.

V. ***Data Time Periods.*** The Draft Submission Guidance lacks consistency in the age of data being considered and compared. For example, the section on drug price information would require data on the "most current WAC" for a year of treatment,[36] but should instead require the WAC for the year of the APCD claims data that the Board has reviewed (in this case, 2022); otherwise, manufacturers may submit pricing data for 2025 or another time period, creating a mismatch with other data considered by the Board.

VI. ***Lobbying Expenditures.*** PhRMA is concerned that the Board seems to be conflating lobbying with marketing and advertising. Unlike marketing and advertising, which is regulated by the FDA, lobbying generally is not directed toward promoting a brand or selling a particular drug product; rather, it typically relates to public policy and legislation.[37] The Board should explain how and what lobbying expenditures relate to the affordability review process and how the Board intends to use such expenditures to assess the affordability of a particular drug. If the Board decides to proceed with collecting this information, the Board should explain why the information is relevant to its statutory mandate and should clarify that these expenditures are distinct from marketing and advertising.

- ***Word Limits.*** The 1,000-word (or in some cases, 500-word) limits contemplated by the Draft Submission Guidance does not provide sufficient opportunity for manufacturers to provide the Board with a complete picture of the requested information.

- ***Supplemental Information.*** PhRMA asks the Board to confirm that all supplemental information that is submitted will be considered by the Board and given equal weight to information submitted as part of the primary entry.

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[34] *See, e.g.*, Draft Manufacturer Data Submission Guide at 24 (PAP eligibility template); Draft Manufacturer Data Submission Form at 15 (Manufacturer Patient Assistance Program and Coupons).

[35] PhRMA also asks that the Board revise the Draft Submission Guidance to clarify that any required information may be reported in an aggregated form. *See* Section V.A, *infra*.

[36] *See* Draft Manufacturer Data Submission Form at 9.

[37] *See* 2 U.S.C. § 1602 (defining "lobbying contact" to include communications to covered officials with regard to "formulation, modification, or adoption" of legislation and policies, "nomination or confirmation of a person for a position subject to confirmation by the Senate," and other matters not clearly attributable to a specific drug product); Instructions for IRS Form 990 (defining "lobbying activities" for purposes of tax liability as "all activities intended to influence foreign, national, state, or local legislation").

A. Violation of State Administrative Procedure Act Requirements ("APA")

Washington's Administrative Procedure Act broadly defines a "rule" as any "agency order, directive, or regulation of general applicability" that "establishes, alters, or revokes any mandatory standards for any product or material which must be met before distribution or sale."[38] That descriptions fits the Draft Submission Guidance: when finalized, the Draft Submission Guidance will generally apply to all drug manufacturers and will establish the mandatory standards for any affordability review submissions.

As a state agency, the Board cannot lawfully adopt these rules without complying with the rulemaking requirements of the APA.[39] "Those procedures include providing the public with notice of the proposed rule and an opportunity to comment on the proposed rule."[40] The Board has so far failed to satisfy that requirement.[41] Among other things, the Board has not filed a notice of proposed rulemaking in the Washington State Register. Nor has it held subsequent public hearings at which interested parties can comment orally and in writing on that notice.[42] In ignoring these (and other) procedural requirements, the Board denies "members of the public" the opportunity to "participate meaningfully in the development" of its policies, and all resulting rules will be invalid.[43]

The Board must develop its Draft Submission Guidance and any other rules to implement the PDAB Statute through notice-and-comment rulemaking—providing adequate time for stakeholders to review draft materials and submit feedback—in order to develop an affordability review process that clearly establishes how and what factors will be considered in affordability determinations.[44]

B. Due Process Concerns

Multiple aspects of the Draft Submission Guidance raise serious due process concerns. First, the vagueness of many of the information requests, as well as the potential arbitrariness of the enforcement mechanisms, fail to provide constitutionally adequate guidance about what is required of regulated parties. "A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required."[45] "This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause," and it "requires the invalidation of laws that are impermissibly vague."[46]

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[38] Wash. Rev. Code § 34.05.010(16).
[39] *City of Tacoma v. Dep't of Ecology*, 555 P.3d 390, 395 (Wash. 2024) (en banc).
[40] *Id.* (citing Wash. Rev. Code § 34.05.320, .325).
[41] *See* Wash. Rev. Code § 34.05.320.
[42] *See* Wash. Rev. Code § 34.05.325.
[43] *Hillis v. State, Dep't of Ecology*, 131 Wash. 2d 373, 399 (1997); *accord City of Tacoma*, 55 P.3d at 395.
[44] Notice and comment is an "essential" procedural safeguard under the APA and is "both a statutory and constitutional imperative" even for interpretive rules. *Mahoney v. Shinpoch*, 732 P.2d 510, 516 (Wash. 1987) (explaining the scope of the notice-and-comment requirement under the Washington APA); *see also* Letter from PhRMA to Board Regarding Advisory Group Proposal and Draft Methodology for Identifying Drugs for Affordability Review at 2 (Mar. 1, 2024). The PDAB Statute does permit the Board to identify "[a]ny additional factors" for consideration during an affordability review, but, as PhRMA has previously noted, any such factors must first be identified through rulemaking before they can be incorporated into the affordability review process. Wash. Rev. Code § 70.405.040(6)(f); *see* Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials at 3 (June 18, 2024).
[45] *FCC v. Fox Television Stations, Inc.*, 567 US. 239, 253 (2012).
[46] *Id.*

Simply put, "regulated parties should know what is required of them so they may act accordingly," and "precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way."[47] "The terms of a law cannot require wholly subjective judgments without statutory definitions, narrowing context, or settled legal meanings."[48] Thus, "[a] law is unconstitutionally vague if it does not give a person of ordinary intelligence fair notice of what is prohibited or if it is so standardless that it authorizes or encourages seriously discriminatory enforcement."[49]

As explained above, the Draft Submission Guidance is replete with vague requirements. For example, it calls for the submission of broad categories of information that are difficult to interpret with reasonable specificity. This lack of specificity in terms of the information required is all the more problematic when combined with the potential for arbitrary enforcement. The statute provides that "each failure to comply with an information request from the board" is subject to a fine "of up to $100,000."[50] It is unclear what constitutes a "failure to comply with an information request from the board"—whether that means a failure so submit a form at all, a failure to answer part of the form, an allegedly incomplete answer, or something else entirely. It also is equally unclear whether "each failure to comply with an information request from the board" refers to the form as a whole, or instead to each separate request for information contained within the form. And indeed, the statute leaves the enforcement mechanism unstated, allowing the Board to create it: "The process for the assessment of a fine under this subsection shall be established by the authority in rule ..."[51]

These procedural deficiencies are further exacerbated by the limited time afforded to manufacturers to respond. The statute imposes a 30-day deadline for "submit[ting] all requested information to the board."[52] As noted above, each failure to respond is subject to a fine of up to $100,000.[53] The Draft Submission Guidance would require substantial amounts of information, much of which is outside of the scope of the Board's authority, not clearly relevant to Board's affordability review process, unreasonable or unnecessary to require of manufacturers, or is insufficiently clear, among other issues. When combined with the potential imposition of substantial monetary penalties for noncompliance, the 30-day requirement to gather, synthesize, and submit all of the required information in the format demanded—which may or may not match the format in which a manufacturer keeps any of the requested information internally, even assuming the manufacturer has the information—likely violates due process.[54]

VII. The Information Described in the Draft Submission Guidance Raises Significant Concerns Regarding the Treatment of Confidential, Proprietary, and Trade Secret Information

A. The Board Has Not Implemented Sufficient Protections for Manufacturers' Confidential, Proprietary, and Trade Secret Information

PhRMA has serious concerns that the Board has not yet developed sufficient protocols and procedures for the protection of confidential, proprietary, and trade secret information. Given the significant volume of

[47] *Id.*
[48] *Tucson v. City of Seattle*, 91 F.4th 1318, 1329 (9th Cir. 2024) (cleaned up).
[49] *Id.*
[50] Wash. Rev. Code § 70.405.040(4).
[51] *Id.*
[52] Wash. Rev. Code § 70.405.040(3).
[53] Wash. Rev. Code § 70.405.040(4).
[54] *See Miller v. French*, 530 U.S. 327, 350 (2000) ("[W]hether the time is so short that it deprives litigants of a meaningful opportunity to be heard is a due process question.").

sensitive information included in the Board's contemplated requirements, the Board should not proceed with finalizing the Draft Submission Guidance until it has implemented adequate safeguards for manufacturers' confidential, proprietary, and trade secret information, as required by state law.[55]

The Board should provide clear guidance on how this information will be maintained, stored, and used to prevent unauthorized disclosures, whether intentional or inadvertent. Specifically, the Board should ensure that all confidential, proprietary, and trade secret information is stored in a secure location, accessible only to individuals whose work assignments require access, and used solely for purposes directly related to the Board's statutory obligations. The Board should also ensure that adequate protections extend to all third-party contractors and subcontractors and other entities with whom confidential information may be shared. Moreover, PhRMA requests a mechanism for advance review of any determination by the Board that information is subject to public release, as well as an appeal mechanism for the Board's determinations with respect to confidential, proprietary, and trade secret information.

PhRMA also notes that that the Draft Submission Guidance does not outline how manufacturers should identify information as confidential in their data submissions. Without a well-defined confidentiality designation process, manufacturers face uncertainty regarding how their most sensitive business information will be handled, further heightening concerns about potential unauthorized disclosures.

Beyond the lack of clear confidentiality protections, the scope of the Board's data requests is excessively broad, encompassing information far beyond what is necessary to fulfill the Board's statutory mandate. The Board should identify the minimum amount of confidential and/or proprietary information that is necessary to inform its review, rather than imposing unnecessarily burdensome disclosure requirements that expose highly sensitive business data. For example, one particularly concerning request is the Board's requirement that manufacturers submit "existing information produced for and reviewed by your organization's senior leadership ... sufficient to describe the pricing strategy for the drug, such as memos, PowerPoint presentations, or other communication."[56] This type of internal documentation is among the most sensitive trade secret information a manufacturer possesses. Requiring disclosure of such materials could undermine competitive forces in the marketplace and directly impact pricing negotiations. Moreover, it is unclear what would be considered "sufficient." The Board should remove this language and instead focus on requesting only the specific data points necessary to conduct its review.[57]

Without stronger confidentiality protections and a more narrowly tailored data request process, the Draft Submission Guidance risks exposing highly sensitive business information in a manner that could have significant competitive and legal consequences. PhRMA urges the Board to revise its approach to ensure that manufacturers' confidential information is adequately safeguarded and that data requests are limited to only what is strictly necessary for the Board's review. Among such safeguards, we ask that the Draft Submission Guidance be revised to clarify that any required information may be reported in an aggregated form.

B. The Draft Submission Guidance Would Compel Manufacturer Submission of Information Protected from Disclosure Under Federal and State Law

[55] Wash. Rev. Code § 70.405.040(7).
[56] Draft Manufacturer Data Submission Form at 32.
[57] Draft Manufacturer Data Submission Form at 7, 17.

i. Federal Healthcare Program Drug Pricing Data Is Confidential Under Federal Law

The Draft Submission Guidance would require manufacturer disclosure of various types of highly confidential federal healthcare program drug pricing information, which is protected from public disclosure under federal law. As a general matter, federal health care program-specific authorities broadly restrict access to and sharing of such information even by the government agencies that receive it. The attempt to collect such information undermines Congress's clear intent to safeguard it against disclosure, in effect attempting to authorize a state to do what the federal government itself is disallowed from doing. The penalties that would apply to manufacturers for failure to respond to a request from the Board for information effectively compels manufacturers to disclose the following information expressly protected as confidential under federal law, raising serious preemption concerns:

- **Medicaid Drug Rebate Program Average Manufacturer Price ("AMP") and 340B Ceiling Price Information**

AMP is a pricing metric that manufacturers participating in the Medicaid Drug Rebate Program ("MDRP") report to CMS on a regular basis pursuant to the federal Medicaid statute and its implementing regulations. CMS uses this data to calculate the MDRP unit rebate amount ("URA"). States then use the URA to invoice manufacturers for Medicaid rebates.

The Medicaid statute requires manufacturer reporting of AMP but categorically protects AMP as "confidential."[58] The Medicaid statute generally restricts disclosure even by state Medicaid agencies, except for disclosures in service of discrete purposes in furtherance of the Medicaid statute or related to program integrity.[59] Congress thereby made clear that even those agencies authorized to receive AMP information under federal law can use the pricing data only for extremely limited purposes connected to the administration of the Medicaid program. For a state to be able to require AMP reporting and use it for other purposes—particularly in connection with a PDAB statute that has broad-based applicability, including application to non-Medicaid payers—would contravene clear statutory safeguards and would potentially jeopardize the confidentiality of the information.

Relatedly, federal law also protects as confidential 340B ceiling prices, which are considered confidential due to the proprietary nature of the underlying data.[60] The Health Resources and Services Administration ("HRSA"), which administers the 340B Drug Pricing Program, calculates 340B ceiling prices using a

[58] 42 U.S.C. § 1396r-8(b)(3)(D).

[59] *Id.* Specifically, federal law only permits HHS or state Medicaid agency disclosure of AMP information for the following narrow and exhaustive set of purposes: "(i) as the Secretary determines to be necessary to carry out this section, to carry out [discrete rebate-related provisions of the Medicaid statute]…; (ii) to permit the Comptroller General to review the information provided; (iii) to permit the Director of the Congressional Budget Office to review the information provided; (iv) to States to carry out this subchapter; (v) to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly [AMP and average retail pricing as specifically authorized under the Medicaid statute]; (vi) in the case of categories of drug products or classification information that were not considered confidential by the Secretary on the day before April 18, 2019; and (vii) to permit the Executive Director of the Medicare Payment Advisory Commission and the Executive Director of the Medicaid and CHIP Payment and Access Commission to review the information provided." *Id.*

[60] *See* Health Resources and Services Administration, Office of Pharmacy Affairs, 340B OPAIS, at https://340bpricingsubmissions.hrsa.gov/Help/Manufacturer/IntroTopics/GettingStarted.htm.

statutory formula that is based on the formula used to calculate Medicaid drug rebates.[61] Per federal law, HRSA is allowed to disclose ceiling prices to 340B covered entities (with access restricted to designated representatives of eligible 340B covered entities with authenticated 340B Office of Pharmacy Affairs Information System accounts),[62] but not to state Medicaid programs, to any other government agency, or to the general public. Disclosure of such information to the Board would undermine Congress's intent to keep this information confidential except for the limited and narrow federally defined purposes.

- **Federal Supply Schedule ("FSS"), Department of Veterans Affairs ("VA"), Department of Defense ("DoD"), Coast Guard, and Public Health Service ("PHS") Prices and Related Discounts**[63]

Both statutory and contractual confidentiality protections apply to these categories of information. Under the Veterans Health Care Act, the prices reported to the Secretary must be kept confidential "except as the Secretary determines necessary to carry out this section and to permit the Comptroller General and the Director of the Congressional Budget Office to review the information provided."[64] The Medicaid statute reinforces the restrictions on VA pricing disclosures in connection with these programs.[65] As in the case of Medicaid and 340B pricing information, Congress made clear its intent that such federal agency pricing information remain confidential and protected from disclosure. Indeed, Congress tied the hands of the federal agencies that are authorized to receive this information, precluding further dissemination of the information. PhRMA accordingly has serious concerns about the Board's attempt to use federally reported pricing information in a manner that Congress disallows even for those federal agencies that collect the information. Additionally, there are drug prices and discounts extended to these federal agencies pursuant to federal procurement contracts, which contain confidentiality provisions that prevent disclosure of pricing and other terms under such arrangements.

The Board's attempt to collect such information therefore raises preemption concerns.[66] Congress clearly intended for state agencies to maintain the confidentiality of such information and to use it, if at all, only for limited and identified purposes. Those purposes do not include the PDAB's statutory mandate. But even if the Board could claim authority under state law to collect this information, which it cannot, federal law does not allow a state agency to use this federally protected information for non-enumerated purposes, such as affordability reviews. Accordingly, any state law or rule that would require disclosure of information subject to federal protections, or that would enable an agency to use the information for non-enumerated purposes, would be preempted under the Supremacy Clause and subject to challenge under the Washington's Administrative Procedure Act.[67]

ii. Other Requested Information Is Protected as Confidential, Proprietary, and Trade Secret Information under Federal and State Law

[61] 42 C.F.R. § 10.10.
[62] Public Health Service Act § 340B(D)(1)(b)(iii). *See* 340B Pharmaceutical Pricing Agreement § V(a). Section 340B(a)(4) of the Public Health Service Act specifies which covered entities are eligible to participate in the 340B Program.
[63] 38 U.S.C. §§ 8126(e)(2) and (4).
[64] 38 U.S.C. §§ 8126(e)(2) and (4). *See* U.S. Department of Veterans Affairs, Master Agreement.
[65] 42 U.S.C. § 1396r-8(b)(3)(D) ("Information disclosed by manufacturers under this paragraph or under an agreement with the Secretary of Veterans Affairs [in compliance with 38 U.S.C. § 8126] … is confidential and shall not be disclosed by the Secretary of Veterans Affairs or a State agency" except for the reasons listed in Footnote 1).
[66] *See Valle del Sol, Inc. v. Whiting*, 732 F.3d 1006, 1022-23 (9th Cir. 2013).
[67] Wash. Rev. Code § 34.05.510, *et seq*.

Much of the information sought by the Board is protected from disclosure under federal and state statutes protecting trade secrets, as well as other laws that safeguard confidential and proprietary information.[68] PhRMA is concerned that the Board's request for such information undermines these protections and amplifies the risk of unlawful further (public or non-public) disclosure of such information, in violation of manufacturers' legal rights. Accordingly, PhRMA strongly urges the Board to limit the collection of confidential, proprietary, and/or trade secret information to the bare minimum required under the PDAB Statute and ensure robust protections for any such disclosed information.

1. State and Federal Law Protects Confidential, Proprietary and Trade Secret Information

While the Washington Public Records Act requires agencies to make various public records available for public inspection, the Act enumerates several important exemptions.[69] Among other things, the Act protects records that are prohibited from disclosure under another statute (the so-called "other statute" exemption).[70] In addition, the Act exempts from disclosure various financial, commercial, and proprietary information, including trade secret information.[71] Public records that meet one of these exemptions must be protected from disclosure if: (1) disclosure would clearly not be in the public interest, and (2) disclosure would substantially and irreparably damage a person.[72] As described below, in various instances, Board-requested information would cause substantial and irreparable damage to a manufacturer if it were to be disclosed; and, even insofar as there is public interest in disclosure, it is unlikely that such public interest outweighs these significant manufacturer harms.

Washington has also adopted the Uniform Trade Secrets Act, protecting from disclosure and misappropriation information that: (1) derives independent economic value from not being generally known to, and not readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (2) is the subject of reasonable efforts to maintain its secrecy.[73] Washington courts have interpreted disclosure of trade secrets through public records as an improper means of acquiring knowledge of a trade secret.[74] In addition to Washington's legal protection of various information that the Board requests, federal law protects trade secret information under the Defend Trade Secrets Act.[75]

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[68] Wash. Rev. Code § 19.108.010 *et seq*; Wash. Rev. Code § 70.405.040(7) ("All information collected by the board pursuant to this section is confidential and not subject to disclosure under chapter 42.56 R.C.W.").

[69] Wash. Rev. Code § 42.56.001 *et seq*.

[70] Wash. Rev. Code § 42.56.070(1).

[71] Wash. Rev. Code § 42.56.270(11) ("Proprietary data, trade secrets, or other information that relates to: (a) A vendor's unique methods of conducting business; (b) data unique to the product or services of the vendor; or (c) determining prices or rates to be charged for services, submitted by any vendor to the department of social and health services or the health care authority for purposes of the development, acquisition, or implementation of state purchased health care as defined in R.C.W. 41.05.011").

[72] Wash. Rev. Code § 42.56.540. *See Robbins, Geller, Rudman & Dowd, LLP v. Washington*, 179 Wash.App. 711 (2014).

[73] Wash. Rev. Code § 19.108.010 *et seq*.

[74] *See, e.g.*, *Progressive Animal Welfare Soc. v. Univ. of Washington*, 125 Wash. 2d 243, 262–63 (1994).

[75] 18 U.S.C. §§ 1836-39 *et seq*. "The relevant portions of the [federal Defend Trade Secrets Act] and [the Uniform Trade Secrets Act] are almost identical,' and thus they can be analyzed together." *Replenium Inc., v. Albertsons Companies, Inc.*, 2025 WL 460057 at 8 (W.D. Wash. 2025) (*quoting Bombardier, Inc. v. Mitsubishi Aircraft Corp.*, 383 F. Supp. 3d 1169, 1178 (W.D. Wash. 2019); *see Walbridge Aldinger LLC v. Vanfossen*, 2020 WL 12846593 at 4 (E.D. Wash. 2020) ("The relevant portions of the DTSA are almost identical to those in Washington's UTSA…The same evidence used to establish liability under Washington's UTSA will also establish liability under the DTSA").

As described below, the Draft Submission Guidance would require the submission of various trade secret-protected information, disclosure of which would cause significant injury to a manufacturer. We therefore strongly urge the Board to narrow its collection of trade secret or other protected information.

2. Board-Requested Information Is Subject to Federal and State Protections

Much of the information that would be required under the Draft Submission Guidance is confidential, proprietary, and/or trade secret information that is subject to robust protection under federal and state trade secrets laws and Washington's public records statute. While PhRMA recognizes that PDAB Statute expressly exempts such information from public disclosure under the Public Records Act and mandates its confidentiality,[76] PhRMA is concerned that the scope of the data being requested far exceeds what is necessary for the PDAB to fulfill its statutory mandate. As above, PhRMA urges the Board to collect the bare minimum of such information.[77]

Information that is requested by the Board, but that is otherwise protected from disclosure as confidential, proprietary, and/or trade secret information, includes (but is not limited to) the following:

- ***R&D Costs.*** The Board is requesting granular-level information of manufacturer R&D costs. Disclosing such detailed R&D information could reveal a manufacturer's innovative strategies, potential future products, and overall competitive strategy, enabling competitors and others to discern (or even replicate) the disclosing manufacturer's business plans. Manufacturers go to great lengths to maintain the secrecy of their R&D information, for instance by requiring employees to execute non-disclosure agreements, enforcing intellectual property protections, and limiting access to a need-to-know basis. Manufacturers could face potentially significant losses in profitability and market share if disaggregated, individualized data about their R&D expenditures for particular drugs were to be shared.[78] There is little conceivable public benefit that would arise from such disclosures—certainly none that would override the serious harm to manufacturers from disclosure.[79]

- ***Drug Acquisition Costs.*** The Draft Submission Guidance also contemplates requiring the disclosure of the funding sources and acquisition costs for acquired drugs. [80] This information, too, is often closely held by manufacturers and protected from public disclosure. In many instances, manufacturers are prohibited from disclosing this information under the terms of the pertinent purchase agreement.

- ***Net Pricing Data (AMP, Discounts, Rebates, Other Price Concessions, and U.S. and Foreign Net Pricing Information).*** The Draft Submission Guidance includes various categories of pricing information that are highly confidential, proprietary, and trade secret-protected. Notably, the underlying statute only generally authorizes the collection of "relevant factors contributing to the

[76] Wash. Rev. Code § 70.405.040(7).
[77] Wash. Rev. Code §§ 70.405.040(5) and (6).
[78] Wash. Rev. Code §§ 70.405.040(5) and (6).
[79] These concerns are amplified for information related to future commercial plans or developments, such as on clinical trials for potential future indications or future profits and revenue, the disclosure of which could have implications under federal and state securities law.
[80] Wash. Rev. Code §§ 70.405.040(5) and (6).

price paid for the prescription drug, including … discounts, rebates, or other price concessions,"[81] without requiring unit-based pricing information or particular pricing metrics that are safeguarded under other laws. As stated above, AMP and 340B ceiling prices are specifically protected from disclosure by federal law.[82] Similarly, pricing information for the FSS, VA, DoD, Coast Guard, and PHS are expressly protected under federal law.[83]

Various other discount, rebate, price concession, and net pricing information is confidential and proprietary, and often constitutes trade secrets. Manufacturers negotiate drug prices, rebates, discounts, and other price concessions with various stakeholders (*e.g.*, pharmacy benefit managers and payers), and their ability do so effectively would be seriously undermined—and their overall competitive strategy compromised—if these negotiated amounts were required to be disclosed, particularly at the granular drug-unit level. This is exactly the type of sensitive information protected by the Uniform Trade Secrets Act and Defend Trade Secrets Act. Here, too, manufacturers risk substantial, irreparable harm from any disclosure of the information, and there is unlikely to be a public benefit from disclosure that would outweigh these harms.

In the case of drug prices in other developed countries, moreover, such information is subject to these same legal protections and, in certain instances, could be subject to additional protections in the affected foreign jurisdictions.[84] It seems doubtful that the Board has the legal authority to override another sovereign's laws safeguarding confidential information and, indeed, doing so could raise serious constitutional concerns under the Foreign Commerce Clause, among other concerns.

- ***Life-Cycle Management Information*.** The Board also requests information regarding manufacturers' life cycle strategies, including contemplated reformulation of a drug, clinical studies for potential new indications, and patent protection strategy across formulations, among other types of information.[85] This type of detailed information regarding manufacturers' prospective regulatory, clinical trial, and/or patent strategy is fundamental to a company's competitive or market strategies and therefore quintessentially confidential and trade secret information.[86] Given the high stakes and serious risk of irreparable harm to manufacturers from any disclosures of such information, the Board should limit any such requests and should examine "life-cycle management" based on publicly available information alone.

[81] Wash. Rev. Code §§ 70.405.040(5).
[82] As a result, the AMP is automatically entitled to protection from disclosure under the "other statute" exemption of the Washington Public Records Act. Wash. Rev. Code § 42.56.070(1).
[83] 42 U.S.C. § 1396r-8(b)(3)(D). This information is likewise entitled to protection from disclosure under the "other statute" exemption of the Public Records Act.
[84] Pierluigi Russo, Angelica Carletto, Gergely Nemeth & Claudia Habl, *Medicine price transparency and confidential managed-entry agreements in Europe: findings from the EURIPID survey*, 125 Health Policy 1140, 1142 (2021), available at https://www.sciencedirect.com/science/article/pii/S0168851021001652#:~:text=In%2068%25%20of%20surveyed%20countries,pharmaceutical%20companies%20and%20public%20payers ("In 68% of surveyed countries, the confidentiality of [managed-entry agreements] information is required by non-disclosure clauses in the agreements between pharmaceutical companies and public payers").
[85] Wash. Rev. Code § 70.405.040(6)(a).
[86] *Ed Nowogroski Ins., Inc. v. Rucker*, 137 Wash.2d 427, 437-39 (1999) (finding misappropriation of trade secrets where a former employee solicited employer's clients using confidential information); *Replenium, Inc. v. Albertsons Companies, Inc.*, 2025 WL 460057 (W.D. Wash. 2025) (finding misappropriation of trade secrets where a former client of a software-as-a-service ("SaaS") company developed its own platform for auto-replenishment services at grocery stores based on information from the software it licensed from the company).

- ***Manufacturer Patient Financial Assistance Programs.*** In the Draft Submission Guidance, the Board requests detailed information regarding manufacturers' patient assistance programs and copayment/coupon support to patients. This information, too, is confidential, proprietary, and trade secret-protected.

- ***Marketing, Advertising, and Other Expenditures.*** In the Draft Submission Guidance, the Board requests narratives and data on marketing, advertising and other expenditures. This information is crucial to manufacturers' competitive strategy and is, therefore, closely held as confidential and subject to trade secret protection.

* * *

PhRMA thanks the PDAB for this opportunity to provide comments and feedback on these Draft Submission Guidance and for your consideration of our concerns and requests for revisions. Although PhRMA continues to have concerns, we stand ready to be a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide, please contact dmcgrew@phrma.org.

Sincerely,

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