January 15, 2025

Gail Mizer, MD and Prescription Drug Affordability Board

Division of Insurance

1560 Broadway, ste 850

Denver, CO 80202

Re: PDAB Violations of State and Federal Law

Dear Dr. Mizner:

Thank you for your service on the Board.

We, the undersigned, are all patient and disability advocacy groups for chronic and rare disease patients—all of whom rely upon pharmaceutical treatments for their health and well-being. We write to you because we are deeply disturbed by the discussion of the Colorado Prescription Drug Affordability Board ('the Board") and its vote to finalize its rule on its use of Quality Adjusted Life Years ("QALYs"). Though we respect you, your fellow board members, and the PDAB's staff and your and their service, we believe that the actions that were taken in the December 6, 2024 meeting are violative of the prohibition on QALYs under CRS Section 10-16-1407(3), failed to address patient input as required by CRS Section 10-16-1406(h), are arbitrary and capricious in violation of the Colorado Administrative Procedure Act, C.R.S. Section 24-4-101, *et seq*., and are discriminatory in violation of various federal and state laws.[1]

A. Our Prior Comments

Prior to the PDAB meeting, as you know, we and others expressed a series of concerns. Those included: 1) the Board has explicitly considered QALY information in affordability determinations, which necessarily will taint any subsequent UPL process; and (2) the consideration of QALY information, at any point in the Board's work, is an act of unlawful discrimination based on disability and health condition under federal law. We explained, at length, why QALYs are broadly discriminatory.

In offering those and other concerns, we noted that the statute, CRS Section 10-16-1406(h), explicitly states the Board must secure and consider "[i]nput from ... [p]atients and caregivers affected by the condition or disease treated by the prescription drug that is under review".

[1] We have previously described in our letter dated October 15, 2024 why we believe that numerous prior actions taken by the PDAB are unlawful and discriminatory under federal and state law. We reincorporate that earlier correspondence by reference here.

We also stressed that CRS Section 10-16-1407(3) also explicitly provides that, in determining a UPL, the Board both "must consider the impact to older adults and persons with disabilities" and, as a companion to that mandate, "shall not place a lower value on their lives". The Legislature then makes its point triply sure, by stating that the Board "[s]hall not consider research or methods that employ a dollars-per-quality adjusted life year, or similar measure, that discounts the value of a life because of an individual's disability or age".

B. Your Subsequent Action

At the December meeting, the PDAB met, discussed the proposed rule on the use of QALYs, and voted to adopt that proposed rule, without revision. That rule, PDAB Rule 3 CCR 702-9, states:

> The Board may identify if the literature uses a quality-adjusted life-year analysis or a similar measure that discounts the value of a life because of an individual's disability or age. The Board may use information that uses a quality-adjusted life year analysis to evaluate relative financial effects, but will not use quality adjusted life year analysis to determine an upper payment limit or other appropriate costs of a prescription drug. If quality-adjusted life year analysis is used during affordability review, the Board will acknowledge any health equity impacts to priority populations.

Several points are important to make about the rule, as adopted by the PDAB. As a threshold matter, the rule admits, unequivocally, that "a quality-adjusted life year", in fact, "discounts the value of a life because of an individual's disability or age". *Id.* That is a concession that QALYs are, in fact, discriminatory based on both "disability" and "age", clearly protected classifications under both federal and state law.

Further, this admittedly discriminatory measure, the Board states, can be used by it in its evaluations, though not to "determine an upper payment limit or other appropriate costs of a prescription drug". *Id.* Under the rule, information can be used in affordability decisions by Board members, though they are not supposed to, under any circumstances or to any extent, use that very same information during the related UPL process. The rule does not address any step that will permit Board members that have reviewed, studied, and acted on QALYs in one context to then negate it entirely in a subsequent, closely related context.

C. Public Comments Prior to the Vote

Without attempting to capture fully the public comments made prior to the Board's vote, several comments are worth noting, in particular. First, a public commenter expressed the concern that the use of QALYs, as proposed, was unlawful, pointing, for instance, to the Centers for Medicare and Medicaid Services ("CMS") Federal Register condemnation of discriminatory value assessments. CMS, Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522, 37615 (May 6, 2024).

Second, another commenter stated the concern that the Board had displayed a pattern of failing to consider, discuss, and respond to public concerns, which is required under CRS Section 10-16-1406(h).

Third, the same commenter urged the Board not to follow that pattern in this meeting and to meaningfully consider and respond to the public as part of its deliberative process, as required by state law.

D. Your Discussions Prior to the Vote

Prior to the vote, the Board conducted a short, superficial discussion of a small subset of the issues raised.

A board member acknowledged that the Board's use of QALYs and the proposal to confirm the use of that measure in the rule were the "big elephant in the room". He proposed that, in light of the fact that QALYs are "very controversial in nature for obvious reasons", that the Board could decide to use "much less controversial" value assessment measures.

Without considering those other measures (indeed, without even identifying them), Board members declined to investigate that option, declaring, for instance, that they would "hate to eliminate important information" and that- "the more information we have in front of us the better decision we are going to make". Similarly, board members stated that QALYs were "very valuable", in part because they supposedly were necessary to permit review of evidence from "other countries".

One board member proposed that, where "only a portion" of studies used QALYs, the Board could disregard that portion and review the rest, but this was policy option was not considered further, with the Chair reiterating that the proposal called for the use of QALYs in affordability determinations that does not "limit" the Board in any manner.

Despite the "fear of disability" bias and "discrimination", a board member declared that he was "comfortable" using QALY studies as a legal matter and "not concerned about violating a law". There was, however, no discussion as to why this was purportedly the case, no consideration of what the federal government has said about the discriminatory nature of various value assessments, or about the public concern that considering QALYs at the affordability stage would necessarily infect subsequent Board UPL determinations.

The discussion indicated that it would be an entirely sufficient safeguard, in any and all circumstances, for the Board to simply be made "aware" that a study that it considered used QALYs, which, as the Board concedes, explicitly discount the value of lives of the disabled and the aged.

At no time was there any discussion of the extensive literature critiquing the discriminatory nature of QALYs or alternatives to their use—none.

E. Federal Law

Federal law is clear that the ”use of value assessment methods that result in discrimination on the basis” of any protected basis, including “age [or] disability”, “are prohibited under section 1557's general mandate of nondiscrimination which applies to programs receiving federal financial assistance including state programs. Centers for Medicare and Medicaid Services, Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522, 37615 (May 6, 2024), citing Affordable Care Act Section 1557. That same requirement is a part of multiple other federal and state laws.

In that Federal Register discussion, CMS stated that “value assessment tools cannot be used to deny or afford an unequal opportunity to qualified individuals with disabilities or on the basis of age”. *Id.* “[M]ethods of value assessment are permissible”, CMS cautioned, only so long as they do “not discriminate in discounting the per-year value of life extension on the basis of age or disability”. *Id.* Again, multiple other federal and state laws compel the same result.

Additionally, federal rules against disability discrimination under Section 504 of the Rehabilitation Act address value assessment methods used to calculate QALYs and similar measures stating, “Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as § 84.56’s prohibition of discrimination based on biases or stereotypes about a patient’s disability, among others.” The agency clearly stated these rules – which also govern state programs receiving federal financial assistance – were broader than Section 1182 of the Affordable Care Act which explicitly bars Medicare from using QALYs and similar measures.

F. The Board’s Violations of Law

Your vote and your rule are unlawful, as noted above, for multiple reasons.

First, your vote and your rule were contrary to the PDAB law’s mandate that the Board must consider “[i]nput from ... [p]atients and caregivers affected by the condition or disease treated by the prescription drug that is under review”. CRS Section 10-16-1406(h). The Board failed to consider patient input regarding:

- the literature critical of QALYs;
- alternatives to the use of QALYs or alternatives in the manner of use of QALYs;
- the public concern that the use of QALYs at the affordability stage would taint UPL determinations, where the Board acknowledges that they are prohibited; and

- relevant federal and state anti-discrimination laws, regulations, and guidance including the Federal Register statement to which a commenter directed the Board regarding how value assessments.[2]

Second, each of the failures identified in the preceding paragraph rendered the Board's vote and rule arbitrary and capricious and in violation of the State Administrative Procedure Act, C.R.S. Section 24-4-101, *et seq*., as the Board failed to consider multiple, material aspects of the problem before it.

Third, your vote and your rule were also arbitrary and capricious under state law because they were based on unsupported and illogical propositions, including the positions that:

- all information should be considered, no matter how flawed or discriminatory it might be, because the receipt and consideration of "any" information creates a "better" result;[3]
- QALYs are "very important" and "valuable", a conclusion made on a categorical basis, without citing any support or having considered any alternatives;
- the Board can, as a practical matter, "consider" QALYs in one context and then completely exclude what it has already considered in another, related context;
- the false premise that non-US evidence would be broadly or entirely excluded if QALYs are not permitted;[4] and

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[2] A single board member stated that he was "comfortable", but that conclusory statement of a single board member that failed to mention, let alone discuss, the substantive concerns arising under multiple laws does not constitute any meaningful consideration of a significant aspect of the problem presented.

[3] The absurdity of this position is manifest. Your rational would permit, for instance, the use of studies that are discriminatory based on sex, race, or national origin. Under your absurdist rational, any information, no matter how discriminatory or vile, should be considered because it will supposedly "improve" the resulting decision.

[4] It is factually incorrect to suggest that QALYs must be considered to consider non-US evidence. Many non-US studies do not use QALYs.

Attachment A
CF United is led by Coloradans with cystic fibrosis to ensure continued, affordable access to cystic fibrosis medications.
Advocates for Compassionate Therapy Now works with medically complex families in Colorado to increase access to all therapies, natural and pharmaceutical. https://advocatesforcompassionatetherapy.com/480-2/
Global Coalition on Aging Alliance for Health Innovation is the leading voice on age-related policy and strategy. https://globalcoalitiononaging.com/about/
The ARC - Pikes Peak Region promotes and protects the human rights of people with intellectual and developmental disabilities and actively support their full inclusion and participation in the communities of the Pikes Peak Region throughout their lifetimes.
Infusion Access Foundation works everyday to make sure people can get treatment when they need it, so they don't get sicker, and above all, so they can continue living their best lives. https://www.infusionaccessfoundation.org/about
The Bonnell Foundation - Living with Cystic Fibrosis gives emotional and/or financial support to parents who have a loved one with cystic fibrosis.

- concluding that the rule was not discriminatory without offering any rational in support of that conclusion or assessing the impact of QALYs.

Fourth, the rule violates federal and state anti-discrimination laws. Your rule speaks for itself. Where federal law is clear that the ”use of value assessment methods” cannot discriminate on the basis” of “age [or] disability”, as they “are prohibited under section 1557” and other laws, your rule concedes, on its face, that QALYs “discount[] the value of a life because of an individual's disability or age”. *Id.*

We ask that you take steps immediately to rectify these violations of law. If you do not so, you will be creating a serious risk of legal action that will undermine the Board’s work.

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Thank you for your attention to our serious concerns.

Respectfully Submitted,

Cystic Fibrosis United
Amanda Boone

Born a Hero
Carolina Sommer

Advocates for Compassionate Therapy Now
Bridget Dandaraw-Seritt

Partnership to Improve Patient Care
Sara Traigle van Geertruyden

Caring Ambassadors
Loren Sandt

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https://thebonnellfoundation.org/about/
Colorado Springs and Southern Colorado Area Special Needs Families provide support for special needs families in Southern Colorado.
Partnership to Improve Patient Care has been at the forefront of applying principles of patient-centeredness to the nation’s healthcare systems from the generation of comparative clinical effectiveness research at the Patient-Centered Outcomes Research Institute (PCORI), to the translation of evidence into patient care in a manner that archives value to the patient. https://www.pipcpatients.org/mission-and-priorities.html
International Cancer Advocacy Network assists and empowers late stage patients worldwide with cutting edge information regarding anticancer drugs in clinical trials as well as physician referrals at the patient’s request based on the patient’s reported medical situation. https://askican.org/about.html
Chronic Care Policy Alliance is a network of state and re

International Cancer Advocacy Network
Steve Horn

TIDE Advocacy & Inclusive Sports
Heather Kluck

Biomarker Collaborative
Steve Horn

Exon 20 Group
Steve Horn

MET Crusaders
Steve Horn

PD-L1 Amplifieds
Steve Horn

Colorado Springs and Southern Colorado Area Special Needs Families
Lauren Schoepp

The Bonnell Foundation
Laura Bonnell

PlusInc.
Brandon Macsata

Global Coalition on Aging
Michiel Peters

cc: William Sarraille

Hi Lila and team,

CANN has schedule conflicts that may or may not interfere with our ability to provide veral comments during public comment at tomorrow's meeting.

We are kindly asking the following materials be submitted to Board members for review as educational materials from the Federal Trade Commission and the New York Times.

FTC 2nd PBM Report: https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf

The FTC's 1st PBM report outlined how PBMs drive up list prices of medications, often with consequential benefit design concerns, should manufacturers reject forced increases in list prices. This is, directly, profiteering and poisons the well of information and metrics the Board considers in "affordability reviews".

The FTC's second PBM report outlines how PBMs similarly profiteer off of generic medications, or, as far as the PDAB should be concerned, "therapeutic alternatives". More pointedly, PBMs manipulate yet another weighted consideration of the Board. Yet neither of these issues or how they might interact with a UPL have been directly addressed by the Board as it pushes ever forward.

Lastly, and most importantly as far as CANN is concerned, today, the New York Times has covered the destabilizing impact of the IRA's insulin cap among FQHCs and raised out-of-pocket costs for patients. A UPL would similarly do so for selected medications, which was outlined in the OR PDAB's Stauffer-Meyer report.

The NYT article can be found here: https://www.nytimes.com/2025/01/16/health/insulin-prices-federal-clinics-340b.html

We would like to point out that this very issue was raised in CANN's first public comment letter to the Board, just under two years ago but has remained unaddressed.

Again, we are kindly requesting the entirety of this email be sent to Board members for appropriate consideration along with other public comments related to tomorrow's meeting. If we are able, we will keep verbal comments short and sweet, referencing these issues.

Thank you kindly,

Jen Laws

He/Him
President & CEO
Community Access National Network
tiicann.org

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December 4, 2024

Colorado Prescription Drug Affordability Board
1560 Broadway, Suite 850
Denver, CO 80202

Submitted via electronic mail: dora_insurance@state.co.us

Re: Colorado Prescription Drug Affordability Board: Draft Memo

Dear Members of the Colorado Prescription Drug Affordability Board ("Board"):

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the Board staff's draft memorandum titled, "Upper Payment Limit Benchmarks - Cost & Price Metrics and Data Details" (the "Draft Memo"), which was published by the Board on November 22, 2024.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are 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 recognizes the Board's ongoing work to carry out its responsibilities under Part 14 of Article 16 of Title 10 of the Colorado Revised Statutes, as recently amended by HB 23-1225 and SB 24-203 (the "PDAB Statute"). However, PhRMA continues to have concerns that any upper payment limit ("UPL") scheme would set arbitrary limits on drug prices and could restrict patient access to medicines, result in fewer new treatments, and ultimately would not carry any guarantee that savings will be passed on to patients. PhRMA is also concerned that the Board's focus on UPLs ignores policy options that could more meaningfully lower the cost of medications for people in Colorado, while encouraging appropriate access to potentially life-saving treatments.[2]

In addition, PhRMA continues to have significant concerns about the Board's implementation of the PDAB Statute. As detailed below, PhRMA is concerned that the Draft Memo lacks clear and meaningful standards with respect to how the process for setting UPLs will be implemented, including with respect to how the Board will evaluate the data and pricing benchmarks that it will utilize as part of establishing UPLs. A UPL-setting process that lacks clear and meaningful standards will not provide safeguards against arbitrary and inconsistent decision-making by the Board in violation of the requirements of the Colorado Administrative Procedure Act ("APA").[3] PhRMA is also concerned that the lack of detail in the Draft Memo does not provide a full and meaningful opportunity for stakeholder comment, as it is difficult to fully evaluate and provide feedback on the Board's UPL-setting process given that many important details are not addressed in the Draft Memo.

[1] Draft Memo (Nov. 22, 2024), *available at* https://drive.google.com/drive/folders/1fy-esESbU4_ep8y8alR5f6VunaSIqz2r.
[2] PhRMA also continues to have concerns about the constitutionality of the Colorado PDAB Statute more generally. In filing this comment letter, PhRMA reserves all legal arguments, including with regard to the constitutionality of the PDAB Statute. PhRMA also incorporates by reference all prior comment letters to the extent applicable. *See, e.g.*, Letter from PhRMA to Board (Oct. 16, 2024); Letter from PhRMA to Board (Nov. 14, 2022); Letter from PhRMA to Board (Aug. 17, 2022).
[3] Colo. Rev. Stat. § 24-4-106(7)(b)(I).

I. Lack of Clear and Meaningful Standards Regarding UPL Benchmark Data

The Draft Memo outlines a list of data points that the Board intends to calculate as UPL Benchmarks for each drug under review and each identified therapeutic alternative but does not provide sufficient methodological detail to understand how these data points will be analyzed, weighed, and applied to specific UPL calculations. Because of this lack of detail, the Draft Memo does not provide a consistent and predictable basis for how the Board will analyze the information it collects and make determinations in accordance with the PDAB Statute. The Draft Memo also fails to account for the distinct challenges associated with each contemplated benchmark. Consistent with our prior comments regarding the Board's implementation of the PDAB statute, PhRMA encourages the Board to revise its Draft Memo to establish clearer standards to guide consistency in the use of benchmark data and other information relied upon in establishing UPLs.[4] Below, PhRMA provides a non-exhaustive list of issues demonstrating the need for greater clarity in the Draft Memo.

- **Methodology for Assessing and Weighing Benchmarks.** The absence of a clear methodology for assessing and weighing data undermines the reliability of the UPL-setting process. While the Draft Memo identifies several benchmarks, such as Average Sales Price ("ASP"), net price, and Maximum Fair Price ("MFP"), it provides no guidance on how these benchmarks will be compared, prioritized, or applied in calculating UPLs.[5] PhRMA is concerned the Board has not established a structured methodology with clear criteria for how it intends to evaluate, weigh, and utilize applicable benchmarks to ultimately determine a UPL. In addition, PhRMA requests the Board consider the broader implications that a particular UPL would have on patient access, therapeutic alternatives, and supply chain stability.

  Greater transparency is also needed to provide manufacturers and other stakeholders with a clear understanding of the Board's methodology for establishing UPLs. This, in turn, will facilitate more informed notice of the Board's decision-making and allow stakeholders to assist the Board in identifying any errors or oversights as the Board operationalizes an inherently complex and multi-faceted process.[6]

- **Data Ranges and Timeframes.** For many of the benchmarks, the Draft Memo fails to specify the date ranges for data that will be used by the Board.[7] Historical data may not accurately reflect current market conditions, and using data from different time periods and different units may lead to inconsistent and inaccurate comparisons. The Board should provide clear details on the dates associated with each of the benchmarks being utilized, especially where the Board intends

[4] *See, e.g.*, Letter from PhRMA to Board (Oct. 16, 2024); Letter from PhRMA to Board 1-3 (Nov. 14, 2022); Letter from PhRMA to Board 1-3 (Sept. 29, 2022). We also ask that stakeholders be given an opportunity to review and provide input on further revisions to the Draft Memo and related materials prior to their adoption by the Board.

[5] Below, PhRMA also addresses specific concerns about the contemplated use of an MFP-based benchmark.

[6] Clear and transparent standards will also help safeguard against arbitrary decision-making by the Board that would violate the requirements of the APA. Colo. Rev. Stat. § 24-4-106(7)(b)(I); *see also Bracco Diagnostics v. Shalala*, 963 F. Supp. 20, 27-28 (D.D.C. 1997) (agencies act arbitrarily if they treat similar situations inconsistently, unless there is a statutorily relevant point of distinction that rationalizes differential treatment); *see also Regular Route Common Carrier's Conference v. Pub. Utils. Comm'n*, 761 P.2d 737, 748 (Colo.1988) (where a state APA provision parallels the federal APA, it is appropriate to consider federal precedent).

[7] Draft Memo 3-6. Compare, for example, the dates of available data for "Carrier Paid Amounts" ("data from January 2019 through December 2023, with incomplete claims through July 2024") against other benchmarks. *Id.*

to rely on historical data. PhRMA also asks that the Board clarify how it will base its benchmarks on consistent and contemporaneous data.

- **Data Quality Concerns**. The Draft Memo also fails to provide adequate processes and safeguards to verify the reliability of data used to support a potential UPL. Like the Board's affordability reviews, the UPL-setting process is dependent on the accuracy and completeness of the information being relied upon in the Board's decision-making. Certain sources of information may be unreliable or offer only a select or biased view of affordability.

  For example, the Board intends to rely on the All Payer Claims Database ("APCD") for calculating several benchmarks, but the Draft Memo fails to account for the significant limitations associated with this data source.[8] As the Board acknowledges, pharmacy claims within the APCD do not include diagnosis codes,[9] making it challenging to accurately assess therapeutic alternatives or the utilization of specific drugs within certain patient populations. In addition, the lack of Medicare Fee-for-Service ("FFS") data in the affordability reports presents a substantial gap in understanding the impact of UPLs on older adults and individuals with disabilities.[10] We ask the Board to revise the Draft Memo to address how the Board will account for situations where diagnosis codes or routes of administration may not be available within the APCD data, or where other limitations may affect the Board's ability to use its data sources as it intends. Failure to account for these limitations in the data risks underestimating utilization metrics and could increase the risk of access being negatively impacted for Colorado patients.

- **Maximum Fair Price ("MFP") Benchmark.** PhRMA continues to have serious concerns with the inclusion of the MFP as a benchmark in the Draft Memo.[11] While the Centers for Medicare & Medicaid Services ("CMS") recently released the MFPs for the first set of qualifying drugs, they do not go into effect until 2026 and there is a lack of real-world data necessary to evaluate their impact.

  This impact will likely be significant; the Inflation Reduction Act ("IRA's") price setting provisions are beginning to disrupt and reduce Medicare Part D beneficiaries' access to medicines, as Part D plans narrow formularies and many independent pharmacies indicate they may not stock medicines subject to price controls. A recent survey found that 78% of Part D plans said they expect to decrease the number of products on formulary for classes containing one or more IRA-selected drugs due to heavier preference for lower net price-products.[12] In addition, the National Community Pharmacists Association ("NCPA") also warned in a recent press release: "An informal NCPA poll of community/LTC pharmacy owners and managers in October 2024 finds that 92 percent of them are considering not stocking [MFP] drugs as a result" of the imposition of the

[8] *See id.* at 4, 6; *see also, e.g.*, Letter from PhRMA to Board 1-2 (May 26, 2023) (providing more discussion about the shortcomings of the APCD).
[9] Draft Memo at 7.
[10] Colorado Prescription Drug Affordability Board, Prescription Drug Affordability Review Reports *available at* https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board.
[11] *Id.* at 5. *See* Letter from PhRMA to Board 4 (Nov. 14, 2022)
[12] Magnolia Market Access, Inflation Reduction Act Payer Insights Report, Chartbook: Summary of Key Findings at 5 (2024), *available at* https://www.magnoliamarketaccess.com/wp-content/uploads/MMA_IRA-Payer-Insights-Survey-4.0_Chartbook_2024.07.31.pdf.

MFP.[13] As the IRA causes plans and pharmacies to limit patient access to drugs, this will shift incentives for research and development away from many diseases and illnesses, including those that disproportionately affect underserved communities such as diabetes, heart disease, and certain cancers.[14] In light of these concerns, PhRMA recommends that the Board refrain from using MFP as a benchmark for setting UPLs.

- **Public Health Care Program Fee Schedules Benchmark.** PhRMA is also concerned with the lack of clarity regarding which state or federal fee schedules may be used as part of the "Public Health Care Program Fee Schedules" benchmark.[15] For example, it is unclear whether the Board intends to rely solely on Medicaid fee schedules or include fee schedules from other programs. PhRMA requests that the Board clarify the specific fee schedules it intends to utilize and develop a consistent approach for analyzing fee schedules across drugs as part of conducting UPL determinations.

- **Intra-Product Differences Impacting Pricing and Access.** The Draft Memo also does not account for unique characteristics of selected drugs in its benchmarks, including different indications or routes of administration of a product that may be associated with distinct reimbursement methodologies and supply chain considerations (e.g., for physician administered versus retailed-based versions of a product). PhRMA is concerned that commingling data for such a product without recognizing these distinctions could lead to flawed UPL determinations. PhRMA requests that the Board provide clarification regarding how its UPL methodology will consider different routes of administration, different patient populations, and other significant differences.

- **Therapeutic Alternatives.** The Draft Memo also lacks clear standards for identifying and assessing therapeutic alternatives.[16] Consistent with our prior comments, PhRMA reiterates its concern that the Board's approach to therapeutic alternatives risks inappropriate comparisons that could lead to inaccurate UPLs.[17] PhRMA urges the Board to develop a clear framework for identifying therapeutic alternatives that incorporates opportunity for input from medical practitioners, manufacturers, and other experts. The Board should also establish standards for determining therapeutic alternatives that are clinically comparable and supported by evidence-based research and guidelines.

  When determining the therapeutic alternative for a drug, PhRMA recommends that the Board use "clinical appropriateness" as the standard for decision-making and exclude cost from consideration. It is important that experts, including manufacturers and clinicians, be the primary resources for determining therapeutic alternative(s) and associated data for a particular drug. In order to determine the clinical appropriateness of a therapeutic alternative, the Board should do the following:

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[13] Press Release, Nat'l Cmty. Pharmacists Ass'n, NCPA: Biden's Drug Program Will Fail if Pharmacies Are Paid Too Little and Too Late (Oct. 3, 2024), *available at* https://ncpa.org/newsroom/news-releases/2024/10/03/ncpa-bidens-drug-program-will-fail-if-pharmacies-are-paid-too.

[14] Kenneth E. Thorpe, *Penny Wise and Pound Foolish: IRA Impact on Chronic Disease Costs in Medicare*, Health Affairs (June 27, 2024), *available at* https://www.healthaffairs.org/content/forefront/penny-wise-and-pound-foolish-ira-impact-chronic-disease-costs-medicare ("[C]hronic disease ... is the largest driver of health care costs and a significant source of disparate health outcomes in underserved and marginalized communities[.]").

[15] *See* Draft Memo 4.

[16] *See id.* at 3-5.

[17] *See, e.g.*, Letter from PhRMA to Board 2-3 (Nov. 14, 2022); Letter from PhRMA to Board 5-6 (Aug. 17, 2022).

- Engage meaningfully with the manufacturer on potential therapeutic alternative(s) and comparator(s). Manufacturers are in a strong and unique position to inform the determination of appropriate therapeutic alternative(s), based on their extensive expertise and research on the benefits and impacts of their medicines throughout the product lifecycle.
- Look to clinician guidance, including physician-driven evidence-based clinical guidelines, as a resource.
- Reference other widely recognized, scientifically rigorous, evidence-driven resources to identify therapeutic alternative(s).

- **Confidentiality.** Consistent with our prior comment letters, PhRMA emphasizes the importance of maintaining safeguards against the disclosure of confidential information.[18] While the UPL-process is generally intended to be a transparent one, the legislature also recognized the need for robust protections of confidential information. In addition to the requirements of confidentiality imposed by federal law,[19] the PDAB Statute itself imposes stringent confidentiality requirements including a legal obligation on the Board to protect trade secret, confidential, and proprietary information from unlawful disclosure.[20]

  PhRMA urges the Board to revise its Draft Memo to provide the specific processes the Board intends to rely upon to balance the public's interest in a transparent UPL process with the need to safeguard statutorily protected confidential information. For example, while the Draft Memo acknowledges that several of the benchmarks may involve confidential information, it does not address how the Board intends to handle such information, or how it plans to communicate its processes and disclosure decisions in a manner that creates transparency without risking improper disclosure of confidential, proprietary, or trade secret information.[21]

II. Lack of Adequate Stakeholder Input and Process Safeguards

PhRMA is concerned that the Board has not provided sufficient opportunity for stakeholders to meaningfully engage on the establishment of UPLs for the first drugs subject to review. As explained in prior comments, and as noted above, both the PDAB Statute and the Colorado Open Meetings Law include specific requirements for the Board's processes to be transparent and collaborative.[22] These requirements are particularly critical in the context of establishing UPLs, as the UPL-setting process involves complex evaluations and comparisons, based on a broad range of highly diverse data sources. Stakeholder input should play a critical role in every part of the PDAB's processes. Prior to moving forward with the review of benchmark data, we urge the Board to solicit additional feedback—including by conducting a stakeholder survey to engage with entities in the supply chain, patients, caregivers, and other stakeholders about their concerns regarding the impact of a UPL.

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[18] *See, e.g.*, Letter from PhRMA to Board 6-7 (Nov. 14, 2022); Letter from PhRMA to Board 13 (Aug. 17, 2022).

[19] As PhRMA has explained in more detail in its prior comments to the Board, federal law incorporates numerous protects of manufacturers' confidential, proprietary, and trade secret information. Further, the Fifth Amendment's prohibition against taking private property without just compensation similarly prohibits the uncompensated disclosure of trade secrets. *See, e.g., Ruckelshaus v. Monsanto Co.,* 467 U.S. 986, 1002–04 (1984).

[20] Colo. Rev. Stat. § 10-16-1406(5) ("trade secret, confidential, or proprietary information obtained by the board may be accessed only by board members and staff [and qualified third parties]" and "[a]ny person with access to such information shall protect the information from direct or indirect publication or release to any person").

[21] *See, e.g.*, Draft Memo 4, 6.

[22] *See, e.g.*, Letter from PhRMA to Board 3 (Nov. 22, 2023).

PhRMA also reiterates that the Board should provide manufacturers an opportunity to review and provide feedback on the underlying data (e.g., WAC and net price estimations) that the Board intends to rely upon for each specific drug before the Board moves forward with its UPL process.[23] Among other things, we are concerned that the Draft Memo does not provide sufficient details about the amount of time stakeholders, including manufacturers, will be given to review and comment on the data discussed in the three rulemaking hearings described in the memo.[24] The Board should adopt procedures that require it to provide the data it intends to rely upon in its UPL process to the applicable manufacturers well in advance of each rulemaking hearing so that stakeholders have sufficient time to review and analyze such information and provide meaningful feedback on the Board's proposals.

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On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns with the Draft Memo, we stand ready to be a constructive partner in this dialogue. Please contact Katelin Lucariello at klucariello@phrma.org with any questions.

Sincerely,

_____/s/_____
Katelin Lucariello
Deputy Vice President, State Policy

_____/s/_____
Merlin Brittenham
Assistant General Counsel

[23] *See, e.g.*, Letter from PhRMA to Board 5 (Sept. 29. 2022).
[24] *See* Draft Memo 2. *See also Conn. Light & Power Co. v. NRC*, 673 F.2d 525, 530–31 (D.C. Cir. 1982); *see also Col. Mining Ass'n v. Urbina*, 318 P.3d 562 (Co. Ct. App. 2013) ("An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.").