ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

May 21, 2025

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

RE: Public Comments on the Upper Payment Limit Rulemaking Process

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

The Ensuring Access through Collaborative Health (EACH) Coalition is a network of national and state patient organizations and allied groups that advocate for treatment affordability policies that consider patient needs first. We appreciate the opportunity to provide comments on the Upper Payment Limit (UPL) rulemaking process in Colorado.

We applaud the board for its transparency in disclosing that incorrect data was used during the cost review process. Acknowledging this issue is an important demonstration of integrity and a commitment to accountability. We also appreciate the Board agreeing with our request to stratify the data, separating Medicare information from the report. We would also like to remind the Board that in the Enbrel review, the drug was deemed unaffordable largely by reviewing an analysis report that included 50% of Medicare respondents and which citied 4 of 9 commercially insured respondents reporting they were in medical debt because of Enbrel; yet upon further inspection by the Patient Inclusion Council (PIC) patient research partners, it was realized all 4 of those respondents paid $0-$50 out of pocket a month. We encourage the Board to clean the data from the Enbrel patient-facing data report to reflect the realities of the information collected and, if possible, reach out to the respondents for clarity regarding why they responded in this way.[1][2]

Proceeding with UPL hearings based on determinations made using inaccurate or incomplete data would be premature and potentially harmful. We urge the board to take the time necessary to re-evaluate the affordability reviews for Enbrel, Stelara, and Cosentyx to ensure that decisions are informed by accurate evidence and reflect the true experiences and needs of patients.

We remain skeptical that the implementation of UPLs will actually lower costs for patients. A UPL is a ceiling on what insurers or the state may pay for a medication, not a cap on the amount a patient must pay at the pharmacy counter. The board does not have the authority to set limits on patient out-of-pocket costs, nor can it require insurers to adjust cost-sharing arrangements in line with a UPL. Without a mechanism to ensure that savings are passed along to patients, UPLs may offer little to no benefit to those who rely on the medications under review.

Moreover, we are concerned that UPLs could further complicate the already fragmented drug coverage landscape. Setting a UPL on a specific medication could trigger changes by insurers—such as reshuffling preferred drug lists, instituting new prior authorization requirements, or requiring patients to try other drugs first—all of which may delay or restrict

[1] PIC Comments, Enbrel 2024
[2] AiArthritis Comments, February 2024

access to the treatments patients need. Providers may also be impacted, as lower reimbursement rates could limit their ability to purchase, administer, or dispense certain medications. These disruptions can lead to care delays, increased administrative burdens, and diminished health outcomes.

Importantly, we do not yet know how insurers, manufacturers, or pharmacies will respond to a state-specific pricing model. Limiting reimbursement for certain products could result in reduced availability in states where UPLs are implemented, further limiting access and choice for patients.

As the board continues its work, we strongly urge you to ensure that patients and patient organizations have a meaningful and ongoing role in shaping the UPL process. Incorporating direct patient engagement and patients' lieve experience into the UPL rulemakings will provide essential insight into how affordability decisions affect real people—insight that cannot be captured through financial modeling alone.

Patient organizations are well-positioned to help gather input from diverse communities and can serve as trusted intermediaries to amplify the voices of those directly impacted by these policies. Listening sessions, patient surveys, and community forums—especially when co-designed with patient groups—can provide authentic, real-world data that is representative and useful for policy development. Furthermore the PIC side of our coalition includes patient research partner leaders, some with professional research backgrounds, who could assist the Board in creating and analyzing patient-facing data - including hosting follow up conversations with peers to better understand context.

We thank you for your efforts to improve the affordability of prescription drugs in Colorado and for your attention to the concerns outlined above. We remain committed to working alongside the board to ensure that the cost review and UPL processes promote affordability without compromising access or health outcomes for patients.

Sincerely,

Tiffany Westrich-Robertson
Ensuring Access through Collaborative Health (EACH) Coalition and Patient Inclusion Council (PIC)

COMMUNITY ACCESS NATIONAL NETWORK

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May 18, 2025

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

RE: Ongoing Rulemaking and UPL Development

Dear Honorable Members of the Colorado Prescription Drug Affordability Board,

Today, we write with concerns regarding ongoing rulemaking and UPL development.

The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions. State Prescription Drug Affordability Boards are of profound importance to our community.

Empty CBA Leaves Goals of Ongoing Developments Unclear

The cost-benefit analysis (CBA) posted in April left many vital questions unanswered. The overall theme of the report was that a UPL had not yet been set. Thus, potential impacts, expenditures, and other important considerations and assessments could not be made. In light of this, rulemaking developments are rolling forward. It seems they are moving forward with no clear goal given that the CBA does not indicate an understanding or consideration of benefits or harms.

While the All Payers Claim Database (APCD) data does have limitations such as only considering a subsection of the Colorado population and recent errors in the data highlighted in the April 11, 2025 meeting; examination of the existing data can be used to partially explain the status quo, specific desired

changes/percentages of change the Board would deem as successful outcomes of a UPL, and much more.

The 2013-2022 CO APCD Data provided on the Community Dashboard from the Center for Improving Value in Health Care contains data that staff could have utilized to present more informed parts of the CBA. For example, the data indicates the Risk Adjusted Medicaid Pharmacy Cost of Care increased from approximately $782.56 per person per year (PPPY) to $1372.73 PPPY from 2013 to 2022. The data also indicates that total Medicaid spending increased from roughly $2,588,197,590 in 2013 to $7,337,670,650 in 2022. These are just two of many data discussions that can be pulled from the existing data. A CBA, or analysis in general, that presents actual numbers, what changes the Board and staff define as successful changes to affordability, what such numbers indicate about plan functioning and patient services, ballpark expenditures for implementation and how the Board sees ongoing UPL and affordability efforts as the means to achieve those changes would be significantly more meaningful and facilitate trust in the current process from the public and the legislature.

Presently, there is no clear path for the implementation of a UPL or overall cost containment measures. Thus, since there is no substantive analysis of how current systems, entities, and departments could be affected by a UPL, moving forward with rulemaking is questionable.

Legislative and Regulatory Policy Recommendations

We support the patient inclusion early in the process of affordability examination, as presented in the Board's 2024 Activities Summary Report Draft. The draft states, "The Board recommends the General Assembly consider revising section 10-16-1406(1), C.R.S. to allow for consumers to identify prescription drugs for consideration for affordability reviews, recognizing that some parameters regarding this process could and should be established, either in law or in regulation." Patients do not define affordability utilizing WAC or other arbitrary measures. What patients deem as unaffordable is a more effective indicator of where energy should be directed.

Conclusion

The costs of prescription drugs and health care in general are significant issues facing Coloradans. However, "affordability" is a system, not a number. Systems theory requires examination of the interconnectedness of all parts of a system, not just individual parts. Patient financial burden, patient access, the drug supply chain, safety-net provider infrastructure, state expenditures, and more are all parts of the affordability system. Presently, there is no precise analysis of how a UPL would affect any of those things, good or bad; nor a declaration of what specific effects the Board wants to see as a result to define success.

Respectfully submitted,

Sincerely,
Ranier Simons
Director of State Policy, PDABs

Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
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May 21, 2025

SUBMITTED VIA EMAIL
Colorado Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202
Email: dora_ins_pdab@state.co.us.

RE: Upper Payment Limit Rulemaking Process

Dear Board:

On behalf of the **Global Healthy Living Foundation (GHLF)** and the chronically ill patients we represent across the country and in Colorado, we thank you for the opportunity to comment on the rulemaking process for the Upper Payment Limit (UPL) as part of the state's prescription drug affordability efforts. We submit this in advance of the May 23rd Colorado Prescription Drug Affordability (PDAB) Meeting.

At GHLF, we are committed to improving access to care and ensuring that policies designed to reduce costs do not have unintended consequences that harm patients. We recognize and appreciate the Board's transparency in disclosing concerns about flawed data used in prior cost reviews. This acknowledgment demonstrates accountability and integrity. However, we strongly urge the Board to **pause any UPL proceedings** until the affordability reviews can be re-evaluated using accurate, complete, and patient-centered data.

Many of the patients we serve rely on these life-changing therapies to manage serious and chronic illnesses. Their health depends not just on the theoretical affordability of medications but on timely, uninterrupted access to them. Unfortunately, we remain deeply concerned that the implementation of UPLs—as currently structured—may not improve patient out-of-pocket costs and could in fact create new barriers to access.

UPLs may reduce what insurers or public programs pay for medications, but they do **not lower** the amount patients pay at the pharmacy counter. Without clear mechanisms to ensure that any cost reductions flow through to patients, UPLs may offer **limited or no benefit to those who need help the most**.

Additionally, we worry about unintended disruptions to care. UPLs could prompt insurers to reconfigure formularies, impose new prior authorization steps, or require patients to "fail first" on alternative treatments. These tactics may delay treatment, restrict provider flexibility, and increase

administrative burden—outcomes that **undermine the very goals of affordability and equitable access**.

There are also open questions about how manufacturers, pharmacies, and providers will respond to a state-specific pricing model. Reduced reimbursement could affect product availability in Colorado or discourage provider participation in certain therapies, especially in smaller or rural practices. We urge the Board to carefully assess these potential ripple effects and consult directly with stakeholders who deliver and receive care on the ground.

Most importantly, we urge the Board to **prioritize patient engagement** at every step of this process. Chronic illness patients bring essential lived experience that should inform how affordability is defined, measured, and achieved. We encourage the Board to collaborate with patient advocacy organizations to design listening sessions, community forums, and surveys that capture the real-world impact of affordability policies. This input is critical—not supplementary—to fair and effective rulemaking.

We appreciate the Board's mission to make prescription drugs more affordable in Colorado. That goal is one we share. But cost containment must never come at the expense of access, continuity, or health outcomes. We stand ready to work with you to ensure that affordability efforts center the needs, voices, and well-being of Colorado patients.

Sincerely,

Steven R. Newmark
Chief Officer, Legal & Policy Affairs

May 21, 2025

Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway
Denver, CO 80202

TO: Members of the Colorado Prescription Drug Affordability Board

As a pediatrician and pediatric rheumatologist with decades of experience caring for patients whose families often struggled to access and afford necessary medications, I am deeply concerned that your proposed UPL implementation could unintentionally limit and restrict access to essential treatments—especially for patients with rare or complex conditions.

Coloradans and their elected representatives deserve recommendations grounded in evidence and thorough, inclusive stakeholder engagement. Clinicians and patients are concerned that the current approach may overlook pharmaceutical equivalences, individual patient needs and thereby disadvantage certain populations.

Many of my young patients depend on specialized, innovative, and unfortunately, expensive therapies. The current affordability reviews and rulemaking outline extensive information gathering about costs, utilization, and spending by "eligible governmental entities", but fall short in capturing metrics that reflect total patient costs, true patient affordability or health outcomes. Further, they fail to take into account the consequences of imposing governmental price controls on private companies.

Any approach that imposes an Upper Payment Limit by definition cannot account for specific individual patient circumstances, needs and medical history. Medical treatment decisions are a result of intimate discussions between the clinician and patient that consider many factors - including cost - before a specific choice is made. If a substitution must be made due to sudden formulary changes, for example, we consider therapeutic equivalents, not therapeutic alternatives. It is critically important that the Board recognize and understand that not all therapeutic alternatives are therapeutically equivalent and correct this misinterpretation within its rulemaking. For policymakers to unilaterally designate certain medications as "therapeutic alternatives" is, in fact, a medical error and disrupts the clinician's ability to consider all the relevant factors or utilize their professional expertise when consulting with their patient. Patients with rare or complex chronic conditions require individualized, continuous care to successfully manage their conditions.

Even slight deviations in treatment and variations between drugs, even those within the same

therapeutic class, can have serious adverse consequences. Patients already endure multiple issues as they work with their physician to find the right course of treatment, and any changes often result in a loss of disease control. For chronic inflammatory conditions, such as rheumatoid arthritis, multiple sclerosis or inflammatory bowel disease, any loss of control caused by a delay or interruption in their treatment can lead to irreversible or even life threatening consequences. It may also result in not being able to return to the patient's original successful treatment. The Board cannot assume that even medications with a similar mode of action will result in similar outcomes. Forcing patients to abandon currently successful treatment regimens can easily result in unsatisfactory and potentially permanent outcomes.

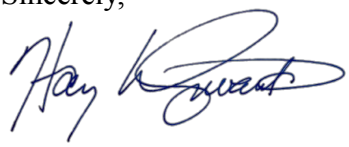
Moving forward, it is crucial the Board pursue a more comprehensive and inclusive review process utilizing the most current data to prevent making policy decisions that will result in predictable negative consequences. We strongly recommend that the Board adopt clinical practice standards recognizing that only therapeutic equivalents are clinically appropriate when considering medication substitutions, and if a medication is removed from a formulary due to the UPL, a therapeutic equivalent be available.

We also urge the Board to review and recommend that the legislature amend the its role so that it may include evaluating and including the impacts of all players in the system, including payors, pharmacy benefit managers (PBMs), and others who influence both list prices and out-of-pocket costs in the Board's affordability decisions. Without examining the entire drug pricing, supply and distribution ecosystem, achieving Colorado's goal of improving access to affordable drugs is not possible. Effective solutions must focus on patients' total and actual costs, not just inflated list prices.

Clinicians and patients remain committed to working with you to ensure affordable medications for all Coloradans, but to accomplish this goal will require a more thorough, comprehensive, and extensive consideration.

Thank you for your attention to this critical issue.

Sincerely,



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

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May 16, 2025

Colorado Prescription Drug Affordability Board
1560 Broadway, Suite 850
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Submitted via electronic mail: dora_ins_pdab@state.co.us

Re: Colorado Prescription Drug Affordability Board: Draft Proposed Upper Payment Limits Rulemaking

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 draft proposed Upper Payment Limits ("UPLs") Rule, 3 Colo. Code Regs. 702-9, Part 4: Upper Payment Limit for Enbrel ("Draft Proposed Rule"), which is scheduled to be discussed at the Board's May 23, 2025 meeting.[1] PhRMA has also incorporated comments below on the Draft Upper Payment Limit (UPL) Data Submission Guide ("Draft Data Submission Guide") and recent All Payer Claims Database ("APCD") data issues in this letter.[2] 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 appreciates the Board's ongoing work to implement and carry out its responsibilities under Part 14 of Article 16 of Title 10 of the Colorado Revised Statutes, as amended by HB 23-1225 and SB 24-203 (the "PDAB Statute"), but we continue to have significant concerns about the lack of concrete methodological elements in the Board's implementation of the PDAB Statute.[3] As noted in prior comments, PhRMA believes that additional clear guidelines are needed as to many critical details underlying the Board's methodology for determining the UPL.[4] Prior to continuing with any UPL-setting process, PhRMA urges the Board to adopt refinements and clarifications to its UPL-setting rule and procedures that incorporate additional procedural safeguards and legal protections as described below.

I. Lack of Meaningful Standards and Processes for UPL-Setting

[1] Draft Proposed Rule (Dec. 2024), https://www.sos.state.co.us/CCR/Upload/NoticeOfRulemaking/ProposedRuleAttach2024-00610.doc; Colo. Dep't of Reg. Agencies, *Colorado Prescription Drug Affordability Review Board & Advisory Council,* https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board (last visited Jan. 7, 2025) ("Enbrel UPL rulemaking will begin during the January 17 PDAB meeting.").

[2] Draft UPL Data Submission Guide. Dated January 14, 2025. https://drive.google.com/file/d/14KBgRsVAxg8-fxpoWYFmX0PdVHRjW8Ii/view?usp=drive_link.

[3] PhRMA also continues to have concerns about the constitutionality of the Colorado PDAB Statute more generally, as well as the legality of the Board's implementation of said statute. In filing this comment letter requesting changes to the Draft Proposed Rule, PhRMA reserves all of its 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 (Nov. 28, 2024); Letter from PhRMA to Board (Oct. 16, 2024); Letter from PhRMA to Board (Nov. 14, 2022); Letter from PhRMA to Board (Aug. 17, 2022).

[4] *See, e.g.*, Letter from PhRMA to Board 2-3 (Nov. 28, 2024); Letter from PhRMA to Board 1-8 (Sept. 29, 2022).

PhRMA continues to have serious concerns about the lack of clear and meaningful standards for how the Board will conduct its UPL-setting process.[5] Critically, the Board has not set forth a concrete methodology that addresses how it intends to consider and weigh each of the categories of information reviewed in the UPL-setting process in a manner that is consistent across drugs and drug classes.[6] The lack of clear, binding standards for the UPL-setting process risks arbitrary and inconsistent decision-making in violation of the Colorado Administrative Procedure Act ("APA"). Consistent with our prior comments, PhRMA encourages the Board to revise its existing UPL methodology regulations to set forth clear standards and consistent standards that guide the Board's UPL decision-making.[7] These standards should provide detail as to how the Board will conduct this process in a manner that complies with applicable legal requirements and is consistent and transparent in how the Board determines proposed UPL amounts and other relevant details for each drug it considers.[8]

These concerns also extend to the Board's Draft Data Submission Guidance.[9] By its own description, the Draft Data Submission Guidance is "meant to provide guidance for stakeholders that are interested in submitting information to the [Board] consideration prior to a specific drug's upper payment limit (UPL) rulemaking," and outlines "[s]pecific data elements that may be helpful to the Board."[10] However, the Draft Data Submission Guidance does not provide any detail on how information received by the Board from stakeholders will be compiled, evaluated, and considered in a consistent manner. Prior to conducting any UPL-setting activities, PhRMA urges the Board to revise its Draft Data Submission Guidance and existing UPL rules to establish clear and binding standards for how it will consistently evaluate the data it intends to rely upon for UPL rulemaking.[11]

We also note that, in the form currently published, the Draft Proposed Rule does not contain a specific UPL proposal nor any explanation of how the Board will specifically reach a proposed UPL amount in the future.[12] Similarly, while the Cost-Benefit Analysis that accompanies the Draft Proposed Rule reiterates several times that the Board's UPL-setting process requires it to "review a significant volume of quantitative and qualitative data in determining whether to establish a UPL and what specific dollar amount the UPL should be," it does not provide any details regarding the Board's methodology for reviewing that data or the specific values the Board intends to propose with respect to the Draft Proposed Rule.[13] When the Board ultimately revises its Draft Proposed Rule to incorporate a UPL dollar amount and other relevant information, it must provide a detailed explanation as to how it determined those details based on its review. Failure to do so would raise serious concerns under the Colorado APA, as it

[5] *See, e.g.*, Letter from PhRMA to Board 2-3 (Nov. 28, 2024); Letter from PhRMA to Board 2-5 (Oct. 16, 2024); Letter from PhRMA to Board 1-5 (Nov. 14, 2022); Letter from PhRMA to Board 3-12 (Aug. 17, 2022).
[6] *See* CRS § 10-16-1407(2); 3 Colo. Code Regs. 702-9, § 4.1(C)(2); Board Policy Number 05: Upper Payment Limit Policy and Procedure 3-5.
[7] *See generally* 3 Colo. Code Regs. 702-9, § 4.1 (generally applicable UPL methodology regulations).
[8] CRS § 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).
[9] Board, "Upper Payment Limit Data Submission Guidance," https://drive.google.com/drive/folders/1dbDbYz_GBwE-UjFP1b3cGZVKoq3ulHq8.
[10] *Id.*, 1, 3.
[11] *See, e.g.*, Letter from PhRMA to Board 1-4 (Nov. 14, 2022); Letter from PhRMA to Board 1-8 (Sept. 29, 2022).
[12] https://www.sos.state.co.us/CCR/Upload/NoticeOfRulemaking/ProposedRuleAttach2024-00610.doc. As discussed in more detail below, the Draft Proposed Rule also currently has a series of placeholders for certain key details, including for the UPL amount. *See* Draft Proposed Rule § 4.3(E).
[13] Colorado Department of Regulatory Agencies (DORA). 3 CCR 702-9. PDAB Cost Benefit Analysis. https://www.dora.state.co.us/pls/real/SB121_Web.Show_Rule?p_rule_id=10523

demonstrates a clear risk of arbitrary decision-making.[14]

Below, PhRMA provides a non-exhaustive list of additional areas where the Board should implement appropriate standards and processes prior to engaging in any further UPL-setting activities:

- **Opportunities for Public Comment.** The Board's UPL-setting process is required to incorporate opportunities for meaningful public and stakeholder comment.[15] While PhRMA appreciates the opportunity to comment on the Draft Proposed Rule in advance of the Board's first rulemaking hearing, the draft notably omits the actual UPL amount contemplated, as well as the unit and relevant NDCs.[16] The lack of such information from the Draft Proposed Rule, limits the opportunity of stakeholders to meaningfully comment. PhRMA asks that the Board explicitly incorporate a separate round of notice-and-comment for a version of the Draft Proposed Rule, including a subsequent version that includes the actual UPL amounts, units, and National Drug Codes ("NDCs") under consideration. Further, we also request confirmation that, when the Board ultimately completes its draft and publishes an official proposed rule in the Colorado Register, there will be a separate and distinct opportunity for public comment on the proposed rule consistent with the requirements of CRS § 24-4-103, including with respect to the methodology for how the Board ultimately determined its proposed UPL amount and further information regarding how the Board intends to implement and apply the proposed UPL amount.[17]

- **UPL Reconsideration.** PhRMA is concerned that the Board has not implemented a process by which it will review, and potentially rescind, a UPL which may longer be appropriate for a particular drug. The Board must retain responsibility for the UPLs it may implement and should monitor at regular intervals whether a UPL continues to serve the purposes described in the PDAB Statute.[18] We ask that the Board establish, through notice-and-comment rulemaking, a process that requires any UPL to be revisited annually to reevaluate whether the UPL continues to be an appropriate policy measure.[19] Such a process should include an opportunity for public comment.

II. Inadequate Protections for Confidential, Proprietary, and Trade Secret Information

Consistent with our prior comment letters, PhRMA also emphasizes the importance of safeguards against

[14] *See Hoyl v. Babbitt*, 927 F. Supp. 1411, 1415 (D. Colo. 1996), *aff'd* 129 F.3d 1377 (10th Cir. 1997) (requiring the agency to have "examined the relevant data and articulated a rational connection between the facts found and the decision made" (quoting *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1574 (10th Cir. 1994)). In addition, an agency commits a "serious procedural error" if it fails to provide the technical basis of its proposal in sufficient time to allow for meaningful stakeholder input because such failure prevents meaningful notice-and-comment. *Conn. Light & Power v. NRC*, 673 F.2d 525 (D.C. Cir. 1982); CRS § 24-4-106(7)(b) (agency action is unlawful if "[u]nsupported by substantial evidence"); *see also See Barela v. Beye*, 916 P.2d 668, 677 (Colo. App. 1996) (looking to federal APA standards for arbitrary and capriciousness).

[15] *See* CRS 10-16-1404; 3 Colo. Code Regs. 702-9, § 4.1(C)(2)(c), (f).

[16] *See* Draft Proposed Rule § 4.3(E).

[17] PhRMA also emphasizes that the Colorado APA requires an agency to actually consider all comments submitted. CRS § 24-4-103(4); *see also Colorado-Ute Elec. Ass'n v. Pub. Utilities Comm'n of State of Colo.*, 760 P.2d 627, 648 (Colo. 1988) ("[I]n the absence of sufficient investigation into pertinent considerations, [agency action] is arbitrary, capricious, and invalid.").

[18] *See, e.g.*, CRS § 10-16-1407(2) (authorizing the Board to establish a UPL for a prescription drug "to protect consumers from the excessive cost of prescription drugs and ensure they can access prescription drugs necessary for their health").

[19] Recognizing that potential issues may arise with respect to a previously set UPL, the PDAB Statute requires the Chair of the PDAB to present to certain committees of the Colorado House of Representatives and Senate regarding "any prescription drug for which the board established an upper payment limit during the preceding calendar year," and allows the members of those committees to pursue legislation to "discontinue the upper payment limit for any prescription drug for which the board established an upper payment limit." CRS § 10-16-1414(3).

the disclosure of confidential information.[20] In addition to the requirements of confidentiality imposed by federal law,[21] the PDAB Statute itself imposes stringent confidentiality requirements, including a legal obligation on the Board to maintain the confidentiality of trade secret, confidential, or proprietary information.[22] These requirements apply to each stage of the affordability review and UPL-setting processes contemplated under the PDAB Statute.[23]

PhRMA remains concerned that, despite these requirements, the Board has not yet adopted concrete guidelines regarding how trade secret, confidential, and proprietary information will be maintained, stored, and used. Given the Board's confidentiality obligations, it is critical that the Board develop and implement specific mechanisms to protect all confidential information received or used by the Board as part of the affordability review process and during its UPL-setting activities. Such mechanisms should provide safeguards to prevent and mitigate unauthorized disclosures of trade secret, confidential, and proprietary information (and discussions of such information) by the Board, staff, or qualified independent third parties (where permitted by state law),[24] whether intentional or inadvertent. In addition, such mechanisms should be explicitly incorporated into guidance produced by the Board regarding the process by which manufacturers may provide information for the Board's consideration, including the Board's Data Submission Guide, and should specify how manufacturers can share trade secret, confidential, and proprietary information with the Board while maintaining its protection from improper disclosure.

III. Inappropriate and Underdeveloped Pricing Metrics

a. Maximum Fair Price

PhRMA also remains concerned about the Board's potential reliance on inappropriate pricing metrics, such as the federal Maximum Fair Price ("MFP"), in its UPL-setting activities.[25] Implementation of MFP by the federal Centers for Medicare & Medicaid Services ("CMS") is still at an early stage, with significant effectuation issues still unaddressed in CMS's high-level guidance,[26] and MFPs for the first set of selected drugs will only go into effect in 2026.[27] Because MFP implementation is incomplete, its impact on patients and other stakeholders cannot yet be evaluated, and the potential savings to patients from MFP pricing

[20] *See*, *e.g.*, Letter from PhRMA to Board 3 (Nov. 28, 2024); Letter from PhRMA to Board 4 (May 26, 2023); Letter from PhRMA to Board 5-7 (Nov. 14, 2022); Letter from PhRMA to Board 8-11 (Sept. 29, 2022).

[21] As PhRMA has explained in more detail in its prior comments to the Board, federal law incorporates numerous protections 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).

[22] CRS § 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"). *See also* CRS § 10-16-1407(7).

[23] *Id. See also* CRS § 10-16-1405(3)(b).

[24] *See id.* (qualified independent third parties contracted with the Division of Insurance must be subject to a nondisclosure agreement prohibiting disclosure of such information).

[25] 3 Colo. Code Regs. 702-9, § 4.1(C)(2)(a)(ix) (permitting the Board to consider Medicare's MFP when establishing a UPL). *See, e.g.*, Letter from PhRMA to Board 2 (Dec. 4, 2024); Letter from PhRMA to Board (Nov. 14, 2022).

[26] *See* Letter from PhRMA to CMS at Appendix B (July 2, 2024), *available at* https://pink.citeline.com/-/media/supporting-documents/pink-sheet/2024/07/phrma-comments-on-effectuation-of-the-maximum-fair-price.pdf?rev=b0d6355afe5543e68afdb1984ea4633b&hash=FCC0529BB97F82130C450B42613F643A.

[27] *See* CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 128, 160 (Oct. 2, 2024), *available at* https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf (explaining that MFPs for initial price applicability year 2026 go into effect on January 1, 2026).

remain speculative.[28] Nevertheless, the Medicare Drug Price Negotiation Program is already beginning to disrupt and reduce Medicare Part D beneficiaries' access to medicines as Part D plans reduce coverage and signal narrower formularies and as many independent pharmacies indicate they may not stock medicines subject to price controls.[29] A January 2025 National Community Pharmacists Association ("NCPA") poll of independent pharmacy owners found that that 93.2 percent of respondents have decided not to or are considering not stocking MFP drugs as a result of the imposition of the MFP.[30] Price controls such as MFP could cause plans and pharmacies to limit patient access to medicines, which in turn could shift incentives for research and development away from many diseases and illnesses, including those such as diabetes, heart disease, and certain cancers that disproportionately affect underserved communities. [31]

The PDAB Statute sets forth clear requirements for criteria that must be considered in conducting affordability reviews and establishing UPLs, and the Board has not provided an explanation as to how it intends to consider MFP in its UPL-setting activities in a manner that is consistent with these requirements.[32] Further, consideration of MFPs prior to being able to analyze their impact on patients' access to drugs raises concerns that the Board will engage in arbitrary UPL-setting that is unsupported by evidence.[33] For these reasons, PhRMA strongly cautions the Board against unduly relying upon MFP as a consideration in its UPL-setting activities.

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[28] According to one recent analysis of the impact of the IRA on Medicare beneficiaries: "For seven of the ten selected drugs, Medicare beneficiaries will not likely see a significant change in their cost as a result of the Medicare Drug Negotiation Program (MDNP)." Kirsten Axelsen, et al., DLA Piper, *Medicare Drug Price Negotiation: Saving Money for Medicare, But What About Patients?* (Mar. 22, 2024), *available at* https://www.dlapiper.com/en/insights/publications/2024/03/medicare-drug-price-negotiation-saving-money-for-medicare-but-what-about-patients#6. Patients already pay fixed copayments for these drugs due to their favorable placement on the formularies of Part D plans. *Id.* Compared to what would occur in the absence of price-setting, the 3.5 million Part D patients who take drugs subject to price-setting are expected to see out-of-pocket costs increase in 2026, with average annual patient costs estimated to *increase* by 14 percent (or $83), driven by copayments for selected drugs. Madeleine Cline et al., Milliman, *Expected Impact of Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program on Medicare Part D Beneficiary Out-of-Pocket Costs* 1 (June 25, 2024), *available at* https://www.milliman.com/en/insight/ira-mdpnp-impact-on-beneficiary-oop.

[29] *See, e.g.*, Magnolia Market Access, *Inflation Reduction Act Payer Insights Report, Chartbook: Summary of Key Findings* 5 (2024), *available at* https://www.magnoliamarketaccess.com/wp-content/uploads/MMA_IRA-Payer-Insights-Survey-4.0_Chartbook_2024.07.31.pdf (survey finding that 78 percent 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, inclusive of the additional rebates they anticipate seeking in response to price negotiations); Nat'l Cmty. Pharmacists Ass'n, Press Release, *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 ("An informal National Community Pharmacists Association (NCPA) poll of community/LTC pharmacy owners and managers in October 2024 finds that 92 percent of them are considering not stocking maximum fair price (MFP) drugs as a result [of the imposition of the MFP].").

[30] National Community Pharmacists Association (NCPA). Comments to the Centers for Medicare and Medicaid Services (CMS) proposed rule: Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly [CMS–4208–P] https://ncpa.org/sites/default/files/2025-01/1.27.2025-NCPA.comments.to_.CMS-PartD.Final_.pdf.

[31] 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[.]").

[32] For example, the PDAB Statute requires that a UPL "ensure [consumers] can access prescription drugs necessary for their health." CRS § 10-16-1407(2). The PDAB Statute also directs the Board to consider state-specific factors when determining UPLs but relying on a national pricing metric like MFP risks failing to account for statutorily required considerations and setting UPLs that ultimately harm Coloradans. *See, e.g.*, *id.* § 10-16-1407(2)(b) (requiring the Board's UPL methodology to include consideration of the cost of distributing a drug "to consumers in the state").

[33] *See generally id.* § 24-4-106(7)(b)(VIII) (providing for invalidation of agency action that is "[u]nsupported by substantial evidence"); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (explaining that agency action must be "based on a consideration of the *relevant* factors" (emphasis added)); *Freedom Colo. Info., Inc. v. El Pasto Cnty. Sheriff's Dep't*, 196 P.3d 892, 903 (Colo. 2008) (explaining that a reviewing court must "determine whether the agency considered the relevant factors and made a reasonable choice") (quoting *Bd of Cnty. Comm'rs of Cnty. of Adams v. Isaac*, 18 F.3d 1492, 2497 (10th Cir. 1994)).

b. Data Quality Concerns

PhRMA continues to have significant concerns that the Board lacks adequate processes and safeguards to verify the data used in its Affordability Reviews and the UPL-setting process. PhRMA has previously cautioned that, with respect to the All Payer Claims Database ("APCD") and other data sources, failure to account for certain limitations of the data increases the risk of potential errors and negative impacts on access for Colorado patients.[34]

This risk is highlighted by an error in the APCD data, which was brought to the Board's attention at its April 11, 2025 meeting.[35] As this error in the APCD data dates back to 2022, it is clear that this mistake affected multiple steps in the Board's processes, including initial eligibility assessments, selection of drugs for affordability review, and affordability reviews of selected drugs. However, despite the implications of this error on other aspects of the Board's work, at its April 11, 2025 meeting, the Board only reviewed the impacts of this error on the data for those drugs already determined by the Board to be UPL-eligible and decided that it would move forward with UPL-rulemaking on those drugs without implementing any processes to review for and correct similar data errors that may occur in the future.

This situation further underscores the need to ensure processes are in place to review the accuracy of data the Board is relying upon for its activities.[36] Given the potential impact of UPL-setting on patients, providers, and other health care stakeholders in Colorado, it is crucial that the Board takes action to review this data carefully and prevent any potential errors or other data accuracy issues from impacting the outcomes of its UPL-setting analyses.

* * *

On behalf of PhRMA and our member companies, thank you for your consideration of our comments. Although PhRMA has concerns with the Draft Proposed Rule and the lack of clarity surrounding the Board's UPL-setting methodology, we stand ready to be a constructive partner in this dialogue. Please contact me at klucariello@phrma.org with any questions.

Sincerely,

_____/s/_____

Katelin Lucariello
Deputy Vice President, State Policy
PhRMA

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[34] Letter from PhRMA to Board 3 (Dec. 4, 2024); Letter from PhRMA to Board 1-3 (June 23, 2023).

35 As reported by Board staff, a PBM reporting to the APCD miscategorized their commercial and Medicare claims data, which impacted 6.9 percent of total APCD pharmacy claims. The mistake was reflected in APCD-related utilization and expenditure data, which included Patient Count, Average WAC per Course of Treatment, Average Paid per Person per Year (APPY), APPY-Plan Paid, APPY-Out-of-Pocket, Total Paid, and Total Patient Paid Amounts.

[36] Such processes should include an opportunity for manufacturers to review and provide confidential feedback on data the Board intends to rely upon for its affordability review and UPL-setting activities. *See* Letter from PhRMA to Board 6 (Dec. 4, 2024).

May 21, 2025

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

Dear Members of the Colorado Prescription Drug Affordability Board,

On behalf of the undersigned organizations, we respectfully urge you to **postpone the decision to set an Upper Payment Limit (UPL) for Enbrel** at your upcoming meeting on May 23, 2025.

At your April 11 meeting, PDAB staff disclosed significant errors in the All-Payer Claims Database (APCD) that directly impacted the data used to support the selection of Enbrel for a UPL determination. Specifically, inaccuracies were found in commercial and Medicare claims data, affecting approximately 7% of total claims and leading to misrepresented metrics, including:

- Patient count
- Average Wholesale Acquisition Cost (WAC) per course of treatment
- Average Paid per Person per Year (APPY) for both plan-paid and out-of-pocket costs
- Total paid amounts (payer and patient)

These data errors date back to 2022 and directly compromise the foundation upon which the Enbrel “unaffordability” determination is based. Proceeding under these conditions risks making decisions that are not only flawed but potentially harmful to patients and other healthcare stakeholders.

We urge the Board to put safeguards in place to verify the integrity of the data before proceeding with any further UPL discussions. Given the far-reaching impact UPL decisions may have on access, affordability, and patient care, it is critical that decisions be based on accurate and validated data.

We also remain concerned about the **lack of transparency and consistency in the UPL-setting process**. There are currently no clear standards outlining how key categories are weighed or how decisions will be applied consistently across drugs and therapeutic classes. This lack of clarity undermines confidence in the Board's decisions and the overall process.

Moreover, the procedures for **patient engagement continue to fall short**. Patients do not yet have adequate opportunities to provide meaningful input to the Board, particularly during the affordability review phase. While public comment is allowed on the Draft Proposed Rule, the absence of a specific proposed UPL amount severely limits stakeholders' ability to provide informed feedback.

We strongly believe the process should allow for comments from all patients living with the condition in question—including those who have previously used the drug, those who were prescribed it but could not access it, and those who may need it in the future—not just those currently prescribed the medication. Additionally, research shows that changes are likely for all medications in that tier, not simply the medication with a UPL.

Finally, the Board continues to be unable to gather assurances from all members of the supply chain that imposing a UPL will not disrupt patient access to needed medications. Until the Board and patients have this assurance, we plead with you to pause this process where the risks simply outweigh any possible rewards.

The Board has an immense responsibility to get this process right. We ask you to pause and correct course before finalizing a UPL for Enbrel or any other product. Doing so will demonstrate your commitment to evidence-based decision-making and meaningful patient engagement.

Thank you for your attention to these critical issues.

Sincerely,

Advocates for Compassionate Therapy NOW

Biomarker Collaborative

The Bonnell Foundation

Colorado Springs and Southern Colorado Area Special Needs Families

Cystic Fibrosis United

Exon 20 Group

ICAN, International Cancer Advocacy Network

Lupus Colorado

MET Crusaders

Patients Rising

PDL1 Amplifieds

Pharmacists United for Truth & Transparency

5/21/2025

Members of the Colorado Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

Re: Concerns Regarding Upper Payment Limits for Enbrel, Stelara, and Cosentyx—Impacts on Patient Access and Provider Viability

Dear Members of the Colorado Prescription Drug Affordability Board,

Thank you for your efforts to address the rising cost of prescription drugs. As pharmacists and independent pharmacy owners, PUTT fully supports the Colorado Board's mission to ensure affordability. However, **we write today to express deep concern regarding the potential consequences of implementing Upper Payment Limits (UPLs)** on Enbrel, Stelara, and Cosentyx—three high-cost biologic medications used to treat serious autoimmune and inflammatory conditions.

While the intent of UPLs is to lower costs for patients and the system, if implemented without adequate safeguards, these policies risk disrupting access, punishing providers, and creating opportunities for pharmacy benefit managers (PBMs) to game the system to their financial advantage.

Enbrel, **Stelara**, and **Cosentyx** are not easily substituted medications. Treatment is highly individualized. Patients often cycle through several therapies before finding the right biologic. Disruptions can result in disease flares, irreversible joint damage, or hospitalization.

These biologics often cost $4,000–$12,000 per dose, depending on the formulation and wholesaler contract. Pharmacies and providers must front these costs and carry the risk. **A UPL set below acquisition costs leaves pharmacy providers with an impossible choice: fill the prescription at a loss, or deny access to the patient.**

Community and independent pharmacies do not receive manufacturer rebates or administrative fees the way PBMs do. They operate on fixed margins and cannot absorb such losses.

We are deeply concerned that PBMs will manipulate UPLs in ways that undermine patient access and distort the intent of the policy, including:

- **Restrictive Prior Authorizations**: PBMs may weaponize the prior authorization process to steer patients away from medications subject to UPLs. These delays can lead to disease progression or treatment abandonment, especially for vulnerable or elderly patients.

- **Formulary Manipulation**: PBMs may drop UPL-affected drugs from preferred status, replacing them with more profitable options that are *not* subject to a UPL. This allows them to maintain spread pricing, extract higher rebates, and shift patients without regard for clinical outcomes.

- **Exclusive Mail-Order Requirements**: PBMs may restrict patient access to these drugs by

requiring fulfillment through a PBM-owned specialty pharmacy, further removing care from the provider-patient relationship and cutting off local access and consultation.

These commonly-used tactics reduce the transparency and effectiveness of UPLs and concentrate power in the hands of PBMs, the intermediaries whose pricing games have inflated costs for years. One of the most concerning consequences of UPLs is that none of these outcomes reduces the cost to patients. The unintended consequences could be limited patient access and health equity. If independent pharmacies and smaller clinics cannot afford to dispense these drugs, and PBMs steer patients through narrow, mail-order-only channels, patients will experience:

- Longer wait times
- Reduced one-on-one clinical counseling
- Limited assistance with injection techniques and adherence
- Greater risk of treatment failure due to administrative burdens

This disproportionately affects rural communities, the elderly, and patients with limited health literacy or online access.

As the Board evaluates UPLs for Enbrel, Stelara, and Cosentyx, we urge you to:

- **Set UPLs above acquisition cost thresholds** used by Colorado pharmacies and providers.
- **Establish enforcement guardrails** to prevent PBMs from altering coverage, formulary tiering, or prior authorization processes in response to UPLs.
- **Require PBMs and insurers to pass savings from UPLs directly to patients**, not pocket them through back-end rebates.
- **Engage stakeholders from independent pharmacy, specialty care providers, and patient advocacy groups** before finalizing any affordability policy.

Addressing drug affordability is critical, but reforms must be balanced, comprehensive, and shielded from manipulation by entrenched middlemen. True savings and equity cannot come at the expense of access, provider viability, or patient outcomes.

Thank you for your consideration and your service to the people of Colorado. We welcome the opportunity to discuss any concerns further as the Board deliberates.

Sincerely,

Brandi Chane
PUTT Board of Directors
Pharmacists United for Truth and Transparency
brandi@truthrx.org