EACH PIC COALITION

August 20, 2025

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

RE: Public Comments on the Final UPL Rulemaking for Enbrel

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.

Upon review of the board's agenda for the upcoming meeting, we were alarmed but unfortunately not surprised that the board already lists "UPL Implementation" as a discussion item to take place in the latter half of the meeting. This agenda item is included before the final hearing on the Enbrel UPL has been held or a vote has been taken to implement a UPL.

If this was not the board's intent, we encourage the board to be more judicious in the documents that are being released publicly and the messages they convey.

In the meantime, we remain concerned with the implications of implementing a UPL on Enbrel and offer the below input, urging the board to take specific steps to protect patients from unintended harm before proceeding with a final vote.

Patient Benefit Will Be Limited, If Realized At All

We remain unconvinced that a UPL will result in meaningful savings for patients, including the uninsured, who have been cited in board discussions as a key beneficiary. By design, a UPL caps what insurers and the state may pay for a drug, not what patients pay. The board does not have the authority to reduce out-of-pocket (OOP) costs, which means patients could see little to no change in what they are charged.

Even when savings are realized at the plan level, there is no guarantee they will be passed on to patients. Historically, insurers and PBMs typically retain similar savings, leaving patients exposed to the same cost-sharing structures and barriers that already exist.

Uninsured Coloradans will remain particularly vulnerable. Any UPL the board sets will still be priced far beyond what individuals without coverage can reasonably afford outright, especially since the board has indicated that rates will be set at levels that avoid driving manufacturers out of the market. Instead, uninsured patients will remain reliant on state and manufacturer support programs to afford their drugs. These programs are also not directly impacted by a UPL, further negating the intent of the board.

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Affordability, as patients themselves report, is determined less by the drug's list price and more by insurance design and access to assistance programs. Our Patient Experience Survey: Prescription Drug Affordability and Unaffordability pilot project confirms that affordability hinges on each individual's unique life circumstances, health burdens, insurance plans, and financial responsibilities, including cumulative costs for all healthcare needs. Results show:

- 20 percent of patients paying as little as $0–$10 per month still described their medication as unaffordable, citing cumulative prescription costs, annual income, and insurance changes or accumulator programs that undermined their access.
- 100% of patients who said they stopped taking a drug due to affordability cited insurance-related reasons: denials, prior authorizations, step therapy, or exclusion of copay assistance on Medicare.
- 75% of patients who skipped or stretched doses also reported at least one instance of care disruption due to insurance delays, not price.

In short, a UPL does not address the real problems patients identify. Instead of layering a new and untested pricing mechanism onto a system already stacked against patients, the board should focus on reforms that tackle these systemic drivers of unaffordability directly.

Addressing the Likelihood of Increased Utilization Management

We were initially encouraged by the discussion around the risks of non-medical switching and the increased likelihood of it happening to patients on therapeutic alternatives if a UPL is applied to Enbrel. However, while the acknowledgement that this potentially harmful practice by payers is commonplace, our concerns were largely dismissed as being 'hypothetical situations.'

We were further discouraged by the Board's recommendation that we take our concerns about non-medical switching "to the legislature", since they have the authority to change it. This eschews the responsibility of the board to ensure that the actions taken by the PDAB do not make the current system worse. Merely acknowledging utilization management or non-medical switching as a concern - and furthermore, is likely to continue - is not enough.

Patients cannot afford to be caught in a cycle where affordability efforts intended to help them actually heighten the barriers they face. Given the board's platform and statutory authority to recommend alternative policy solutions to the legislature, we urge you to advocate protections that will protect patients from measures that could disrupt their care and contribute to patient hardship.

Conduct Basic Due Diligence Before Implementing Potentially Harmful Policies

UPLs remain untested and unproven. No state has yet demonstrated that they can lower patient costs without creating harmful downstream effects. What is clear, however, is that insurers and PBMs will play a decisive role in how a UPL is implemented, and these stakeholders have been largely absent from the visible portion of the UPL consideration process in Colorado.

EACH/PIC COALITION

To address this, during the last meeting the board made a commitment to conduct outreach to insurers and PBMs. We are eager to hear the results of these conversations, but we are cautiously optimistic given this is coming so late in the UPL process. From this time forward, the board should utilize its statutory authority to secure input in advance from all healthcare stakeholders, including insurers, PBMs, and manufacturers, regarding how they will respond if a UPL is implemented. Also, any input collected should prioritize concerns expressed by patients and result in a clear understanding how a UPL will be applied to benefit them.

Patients cannot accept "we don't know" as an adequate answer from officials when access to life-sustaining medications hangs in the balance. At a minimum, due diligence requires the board to demand evidence from payers and PBMs on formulary placement, tiering, and utilization management changes, and integrate this information into a transparent monitoring process *before any UPL is finalized*.

Promises of Monitoring and Safeguards Are Not Sufficient

Monitoring the effects of a UPL after implementation is still "flying the plane while building it," which cannot be a substitute for proactive protections. Patients will bear the immediate consequences of insurer and PBM responses, while any corrective action from the board could take months or years.

Furthermore, the board should, at a minimum, design and publish for public comment their plan for an accountability and monitoring framework in advance to ensure even the most basic of safeguards are in place before any UPL is implemented.

In addition, we strongly urge the board to advocate for legislative measures to be passed to create protections that can be implemented alongside a UPL. *These should extend across the full therapeutic class, not just the drug subject to the UPL alone.* These protections should:

- Prohibit insurers and PBMs from altering formulary placement of UPL-affected drugs.
- Bar the imposition of new prior authorization or step therapy requirements.
- Prevent non-medical switching of patients who are stable on treatment.

Without these guardrails, patients risk losing access not only to Enbrel, but to other biologics in its class that they may depend on.

Conclusion

The EACH/PIC Coalition shares the board's commitment to improving drug affordability. But affordability must be defined by whether patients can actually obtain and adhere to their prescribed treatments, not whether insurers pay less for them. We urge the Colorado PDAB not to finalize a UPL on Enbrel until it has:

- Obtained concrete commitments from insurers and PBMs on how they will administer coverage.
- Finalized a robust and transparent monitoring framework with patient input.

- Advocated for legislative safeguards that prevent insurers from undermining patient access through utilization management and formulary changes.

Without these steps, a UPL risks compounding patient challenges rather than solving them. We stand ready to partner with the board to ensure patient perspectives and lived experiences remain at the center of this critical work.

Sincerely,

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Ensuring Access through Collaborative Health (EACH) Coalition Lead

Vanessa Lathan
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Patient Inclusion Council (PIC) Coalition Lead

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August 20, 2025

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

RE: UPL Setting Concerns

Dear Honorable Members of the Colorado Prescription Drug Affordability Board,

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

Patients Need to Be Protected - Patients are NOT Protected as of yet

Despite significant conversation among Board members during the July 11, 2025, Rulemaking Hearing, there is *no* requirement within the Board's enacting statute which offers patients any "appeal", should they be denied access to any medication subject to an Upper Payment Limit. Indeed, by design, the appeals process outlined within the statute is limited to 60 days after a UPL is set. However, a UPL is not to be imposed until six months after being set, creating a legal structure that necessarily limits the ability for any entity to qualify for legal standing in litigation while also functionally preventing any standing within the designated appeals process. This effectively denies any entity or patient any ability to seek remedy. Furthermore, the Board's lack of a defined process for post-implementation information gathering (as discussed in more detail below), paints the Board's motivations as disinterested in meaningful access to care. **If the Board does not wish to be viewed under the light of being politically motivated, serving the interests which funded both the model legislation and the Board's contracted analysts, the Board should, at the very least, consider the significant issues of concern *and address them*.**

Before any UPLs are set, formal safeguards for patients must be in place. Potential patient access issues resulting from a UPL would take some time after the UPL is established to come to light, and outside of the designated appeals process within the statute. Thus, there needs to be a formalized process for patients to seek and be granted a swift remedy for any adverse changes to their financial or formulary access to their medications as a result of a UPL.

The statute allows the Board to amend or cancel a UPL if it causes harm or fails to achieve its desired effects. In reality, the Board has to clearly define those desired effects (we are again, asking the Board to clearly answer "Lowering costs for whom?" and specify which cost metrics define "affordability") without defined metrics for consistent review or a formalized, timely process for public reporting of harm, and functional definition of "affordability", patient care can and, with reasonable inference from other areas of policy-making, *will* be compromised.

There has been some Board Member discussion on concerns about their perceived difficulties in patients accessing some of the patient assistance programs. If a patient and provider must navigate the appeals process of an insurance carrier denying coverage of a medication where coverage has changed as a result of a UPL, that would be an even more time-consuming and resource-intensive endeavor. Ultimately, a patient would be denied medication for a period of time, potentially significant amounts of time, that could be medically harmful during the dispute process, with no guarantee of a reversal of the denial. And this appeals process is between patients and their insurance providers, not this Board. **To put a more fine point on this issue, staff to the Board has readily acknowledged that denial of coverage and other utilization management barriers are *not* currently captured in data the Board considers.**

Relying on insurance appeals neglects patient needs and abdicates some of the most meaningful patient experience of "affordability".

Monitoring Methods Have Not Been Set; Removing Any Ability to Define "Success"

We would like to thank the Board for the discussion and emphasis on the importance of monitoring the consequences of a UPL at the July meeting. **However, there has been no discussion currently on the methodology for establishing monitoring activities, nor on the establishment of any baseline metrics.** CANN has been requesting such processes for nearly *two years* to no avail. As providers and healthcare professionals, you depend on scientific rigor in data gathering and monitoring methodologies to do your best in caring for your patient populations. Yet, after multiple requests from the public, these things are not in place to facilitate your work in making any decisions for Coloradans.

The cost-benefit analysis report published earlier this year did not provide any substantive data establishing a baseline of metrics for multiple aspects of the healthcare system, the fiscal impact on patients, or any definition of"affordability". We asked for these details both prior to the cost-benefit analysis and after, to no answer, or in the case of staff hours in December, staff explicitly saying "we won't be doing that". **It is not possible to monitor and interpret the outcomes of a UPL without a reference point for comparison, since without a baseline of metrics, there is nothing to systematically measure. Additionally, without an established baseline, there is no way to define what is deemed an acceptable successful outcome.** Without a definition of success, how are the best interests of Coloradans served?

Implementation Remains Unclear, Despite Years of Information Request

The statute states that if a UPL results in savings, those savings must be passed on to consumers. However, how exactly would that be guaranteed, and what is the administrative burden on the state and the manufacturer to ensure it happens? Additionally, a UPL will not suddenly make medications affordable for uninsured patients.

We are also concerned about the potential use of MFP as part of UPL development. Although the initial round of MFP pricing has not yet taken effect, its impacts are already being realized. Reporting has already shown that payors will increase the formulary tiers' cost-sharing for MFP negotiated medications or exclude them from formularies. A UPL stands to cause the same issue as a similar price cap.

There has been an overall sentiment during the board deliberations that any negative consequences of a UPL are speculative since UPLs have not yet been implemented. From a practical standpoint, any assumed "positive" impacts are equally as speculative, if not more so, since a multifactorial baseline has not been established.

While the PDAB is given the statutory tool of a UPL, the Board is not required to enact one. It would certainly not be wise to proceed with setting UPLs without sufficient data and safeguards to protect Coloradans from well-anticipated consequences. The Board can advise the legislature on other policy proposals and is statutorily obligated to include the consideration of alternative policy proposals in the final rule. Previous board commentary mentioned that there has been robust commentary provided about the problems with UPLs, but no other suggestions about ways to get manufacturers to lower prices. It is entirely possible that a more thorough baseline analysis of the system and patient impacts could reveal non-UPL changes that could be implemented.

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.

Respectfully submitted,

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

On behalf of
Jen Laws
President & CEO

August 20, 2025

Colorado Prescription Drug Affordability Board
Department of Regulatory Affairs
1560 Broadway
Denver, CO 80202

Dear Members of the Prescription Drug Affordability Board:

The Colorado Consumer Health Initiative (CCHI) appreciates this opportunity to comment on the Upper Payment Limit (UPL) rulemaking for Enbrel. CCHI is a nonprofit, consumer-oriented, membership-based health advocacy organization that ensures all Coloradans have equitable access to high-quality, affordable health care. We encourage the board to use the federally negotiated CMS Max Fair Price as your UPL benchmark for Enbrel. We will continue to weigh in on the implementation process to ensure the Board advances equitable, consumer-centered policies that make real strides to improve the affordability of medications for Coloradans with the highest barriers to care.

Using CMS Max Fair Price as an Upper Payment Limit for Enbrel

As the Board enters the final phase of rulemaking for an Upper Payment Limit (UPL) on Enbrel we encourage you to use the CMS negotiated Max Fair Price rate. This pricing standard has already been negotiated and implemented on the Federal level. As a state board with the charge to address multiple high cost medications we encourage you to leverage the guidance of federal work and resources to ease the UPL decision making process.

When compared to the current Average Plan Paid PPPY, the CMS Max Fair Price represents an over 40% in savings.[1] Since PDAB legislation states savings from a UPL must be passed on directly to consumers,[2] such cost reductions could significantly decrease out-of-pocket costs[3] and premiums for Coloradans.[4] Our state is currently facing massive premium increases,[5] threats to Health First Colorado coverage,[6] and the

[1] Average Plan Paid PPPY (APCD): $53,049 vs CMS Max Fair Price: $30,356

[2] "10-16-1410. Use of savings - report - rules. (1) ANY SAVINGS GENERATED FOR A HEALTH BENEFIT PLAN THAT ARE ATTRIBUTABLE TO THE ESTABLISHMENT OF AN UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD PURSUANT TO SECTION 10-16-1407 MUST BE USED BY THE CARRIER THAT ISSUES THE HEALTH BENEFIT PLAN TO REDUCE COSTS TO CONSUMERS, PRIORITIZING THE REDUCTION OF OUT-OF-POCKET COSTS FOR PRESCRIPTION DRUGS"

[3] The 2023 Affordability Review Summary Report cited 71% of surveyed patients said that cost affects their access to Enbrel (C-2). Unsurprisingly, 100% of patients who reported OOP costs of $100 or over said cost affects their access. Even patients with $50 or less in copay costs reported issues with affording Enbrel (28). Cost was even still a barrier for some patients who used *financial assistance* (24).

[4] The 2023 Affordability Review Summary Report for Enbrel indicates that the drug contributes to high health care costs for individuals and for the health care system more broadly. It is notable that half of carriers who reported to the APCD said that Enbrel was one of 15 prescription medications that raised premiums for all covered lives (2).

[5] Due to ACA marketplace cuts - including the expiration of enhanced premium tax credits which roughly 80% of Connect for Health Marketplace enrollees currently receive - most people on the individual market will face premium hikes of 170% or more.

[6] More Coloradans are predicted to churn on/off of Medicaid with more frequent redeterminations and work requirement barriers.

devastating reality that many will become uninsured due to increased cost of coverage.[7] It is imperative that Colorado use any tool it has available to keep health care accessible and affordable for those in our state. Setting a UPL at the CMS Max Fair Price is a clear opportunity to protect access to this vital medication.

As discussed in the July PDAB meeting, Patient Co-Assistance Programs are not a sustainable, universally accessible option for patients.[8] Even in the case of Enbrel, when such programs are available for those without insurance, the vast amount of paperwork is a tremendous barrier for many Colorands - especially those with multiple jobs, child care obligations, and/or for whom English is not their preferred language. Moreover, as we heard in July's hearing, Patient Co-Assistance Programs are subject to market powers and can be discontinued at the discretion of manufacturers. This is particularly concerning at a time when so much about the future of health care in Colorado is uncertain. Setting a UPL is an opportunity to increase universal and reliable access for consumers who need this vital prescription medication.

The CMS Max Fair Price rate offers a thoughtful option to the systemic and individual unaffordability of Enbrel in Colorado. It allows you, the board, to leverage federal processes to protect consumers at the state level. Furthermore, it helps insulate Coloradans from the unregulated and tedious bandaid Patient Co-pay Assistance Programs offer. We believe setting this upper payment limit will meaningfully reduce prescription drug costs for Coloradans. If you have any questions regarding our comments, please contact Sophia Hennessy, shennessy@cohealthinitiative.org.

Sincerely,

Sophia Hennessy
Policy and Research Coordinator
Colorado Consumer Health Initiative
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[7] By 2030, Colorado will lose $2 billion or more annually in Medicaid and ACA funding. Between ACA marketplace and Medicaid changes, at least 200,000 Coloradans expected to lose coverage, but estimates are likely undercounting.
https://c4-media.s3.amazonaws.com/wp-content/uploads/2025/08/11113423/ePTC-Preliminary-Rates-Analysis_081125.pdf
https://www.commonwealthfund.org/publications/issue-briefs/2025/may/medicaid-work-requirements-job-losses-harm-states

[8] https://cohealthinitiative.org/wp-content/uploads/2025/07/Website_Copay-Assistance-Policy-Brief_Kang_Georgetown_Final_.pdf

Infusion Access Foundation

Colorado Division of Insurance
1560 Broadway, Suite 850
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August 20th, 2025

Re: Enbrel Rulemaking

Dear Members of the Prescription Drug Affordability Board,

On behalf of the Infusion Access Foundation, thank you for your service to the people of Colorado and for your commitment to addressing the affordability of prescription drugs. As an organization dedicated to ensuring patients have access to the treatments they need, we appreciate the opportunity to provide input regarding your current rulemaking of Enbrel.

The Infusion Access Foundation is a nonprofit advocacy organization committed to protecting access to both infusion and injection therapies. We support patients across all disease states and advocate for policies that expand access to the treatments that help people live their best, healthiest lives. We also work directly with patients who face significant barriers to accessing prescribed medications.

We recognize the important role of the Colorado PDAB in evaluating drug affordability. However, we are concerned that establishing an Upper Payment Limit (UPL) for Enbrel could have unintended consequences for patient access.

Enbrel is a self-administered therapy that patients typically receive through a pharmacy benefit. While lowering costs is a critical goal, setting a UPL that is too restrictive could lead to challenges such as reduced manufacturer participation in the Colorado market, narrower distribution channels, or insurers removing Enbrel from formularies altogether. Each of these outcomes would limit the ability of patients with rheumatoid arthritis, psoriatic arthritis, and other serious autoimmune conditions to access the therapy their physician prescribed.

We share your goal of making prescription drugs more affordable, but we urge the Board to carefully consider how a UPL for Enbrel might affect availability and continuity of care. Affordability policies should not inadvertently make it harder for patients to obtain or stay on their medications. Ensuring that patients continue to have reliable

access to Enbrel in Colorado is critical to supporting disease stability, reducing long-term health care costs, and protecting quality of life.

Thank you for your consideration of this important issue. The Infusion Access Foundation stands ready to work with the Board to ensure affordability initiatives achieve their intended goals without reducing access to care. Please do not hesitate to reach out if additional information would be helpful.

Sincerely,

Alicia Barron, LGSW
Executive Director
Infusion Access Foundation

August 20,2025

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

Re: Concerns Regarding UPL Process and Patient Impact

Dear Chair Mizner and Members of the Board,

On behalf of Lupus Colorado and the patients we represent, I want to thank you for your commitment to addressing the challenges of drug affordability in Colorado. Your work carries profound implications for those living with complex chronic conditions, and we deeply value your willingness to weigh potential impacts carefully. With that in mind, we write to express serious concerns regarding the current UPL process, particularly as it relates to Enbrel.

Transparency and Public Trust
The recent decision to move public comment and testimony until after Board deliberation erodes transparency and undermines patient trust in this process. When patients' voices are heard only after decisions are already framed, the opportunity for meaningful engagement is lost. This discourages participation at precisely the moment when patient experience and lived reality should inform your decisions.

Scientific Rigor and the Absence of Monitoring
We appreciate the Board's acknowledgement that monitoring the effects of a UPL is important. However, no baseline data or methodology has been developed to measure those effects, despite years of requests from the patient community. As providers and scientists, you know that without rigorous data collection and monitoring systems, outcomes cannot be meaningfully assessed. Proceeding with a UPL absent these safeguards risks blind policymaking, implementing an experiment without the tools to measure results.

Speculation and Evidence
The Board has dismissed predicted harms to patients as "speculative," yet relies on equally speculative assumptions of benefit. In reality, supply chain stakeholders, especially health plans, have openly described how they anticipate adjusting to a UPL, and those adjustments overwhelmingly suggest reduced access for patients. By

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contrast, the potential benefits remain theoretical and unsupported by evidence. In the absence of metrics, privileging positive speculation over negative but credible stakeholder input defies logic and sound policy practice.

Perverse Incentives in Coverage and Design

These anticipated harms are not abstract, they are predictable consequences of how plans and PBMs respond to price caps:

- **Cost-Sharing:** If reimbursements are capped below plan assumptions, insurers may restructure cost-sharing (copays, coinsurance), often raising out-of-pocket costs by moving drugs into higher tiers.
- **Network Adequacy:** Reduced margins may lead to narrower provider or pharmacy networks, cutting off access to specialty providers and community pharmacies.
- **Benefit Adjustments:** Plans may redesign deductibles, out-of-pocket maximums, or specialty carve-outs to compensate for lost rebate structures.
- **Formulary Changes:** When rebates shrink under a UPL, preferred drug lists may be reshuffled, disadvantaging patients dependent on specific therapies.
- **Exclusion/Restriction:** Plans may exclude high-cost drugs altogether or layer on additional hurdles like prior authorization or step therapy.
- **Incentive Shifts:** Formularies may prioritize drugs offering non-price inducements, over those backed by strong clinical evidence, leading to coverage decisions that stray from best-practice care.

These are not speculative harms, they are consistent with how benefit design operates today.

Statutory Obligation and PBM Complications

Finally, we remind the Board of its statutory obligation under SB21-175, C.R.S. § 10-16-1406(3)(c):

“Any savings generated for a carrier as a result of an upper payment limit must be used by the carrier to reduce costs for consumers, so that the consumer benefits from the savings.”

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This requirement is directed at carriers, not PBMs. Yet because nearly all carriers contract with PBMs to administer drug benefits, PBM practices create a serious compliance challenge.

- **Rebate Contracts:** UPLs reduce list prices, diminishing rebate value and incentivizing formulary reshuffling away from UPL drugs.
- **Spread Pricing:** PBMs may preserve margins through contractual spread adjustments, limiting savings carriers can pass to patients.
- **Cost-Sharing Design:** Even if acquisition costs fall, PBM-driven formulary structures can sustain high out-of-pocket costs unrelated to the UPL price.

In short, while carriers remain legally responsible for ensuring savings reach patients, PBM contracts can obscure and dilute those savings. Without strict reporting and auditing requirements, the statutory obligation cannot be enforced.

Conclusion

For these reasons, Lupus Colorado urges the Board not to move forward with a UPL until monitoring systems, baseline data, and enforceable oversight mechanisms are in place. To proceed without them is to substitute assumption for science and risk worsening, rather than improving, access for patients. Patients deserve the same rigor, transparency, and care in policymaking that you apply in your clinical and professional practice.

Thank you for your attention and for your continued commitment to serving the people of Colorado.

Respectfully,

Kristy Kibler
CEO
Lupus Colorado

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August 20, 2025

Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway
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TO: Members of the Colorado Prescription Drug Affordability Board

As a physician with decades of experience caring for patients whose families often struggle to access and afford necessary medications, I continue to find the proposed implementation of Upper Payment Limits (UPLs) deeply troubling. Implementing a list price cap on Enbrel and future medications will predictably restrict access to essential treatments and deserves more input from the patients who would be most adversely affected and the clinicians who care for them.

Coloradoans and their elected representatives deserve recommendations grounded in thorough, inclusive and comprehensive stakeholder engagement. Clinicians and patients alike worry that the Board's current deliberations still lack this crucial diversity of real-world input, thereby diminishing individual patient needs and disadvantaging vulnerable populations.

Many Coloradoans depend on specialized, innovative, and - unfortunately - expensive therapies. The Colorado affordability reviews and rulemakings detail an extensive process for aggregating cost, utilization, and spending information by "eligible governmental entities," but fall short in capturing data reflecting actual patient affordability or health outcomes. Importantly, the Board has yet to detail any plans or metrics to measure the outcomes of its decisions. This fundamentally shortsighted approach undermines the entire mission: without an ongoing rigorous quantitative impact assessment of the Board's programs, how can Coloradoans feel confident in its decisions?

As the Board approaches its third and final proposed rulemaking hearing for Enbrel's UPL, we believe that the Board still lacks sufficient input before making its precedent-setting decision. There is no evidence supporting the Board's belief that UPLs will reduce patients' drug costs or increase accessibility to their critical medications. Rather, economics and history suggest that UPLs will create purchasing restrictions that threaten to limit patient access. If the purchase price is capped at a level where buyers - including independent physician practices, rural clinics and hospitals throughout the state - lose money, the product will not be available to the customers - in this case, Coloradoans who require these essential medications. This final hearing must address the fundamental market reality that UPLs will predictably restrict drug supply and clinician participation rather than lowering patient costs.

Focusing solely on list price UPLs as a mechanism to improve patient treatment costs is like pulling on a single thread in order to unravel a large quilt: targeting one narrow component of a multi-faceted drug pricing ecosystem is too myopic of an approach to address Coloradoans' high drug costs. Without factoring in the many players - and payors - within the health care system who influence drug prices and patient costs, the Board's strategy will inevitably fall short of its mandate to improve patient medication affordability.

The role of many middlemen, such as pharmacy benefit managers (PBMs), national and international group purchasing organizations (GPOs), and the unique cost structures for infusible or other administered medicines are among the many cost and pricing factors the Board is overlooking in its UPL deliberations. Only if the many buyers, including clinicians, can afford to purchase and sell or administer the drugs will they be accessible to patients. Further, your deliberations exclude the impact of 340B and other governmental and commercial discounts and price concessions. As a result, the Board's restrictive UPL price controls can only jeopardize drug availability within Colorado.

I fully appreciate the Board's difficult position. The enacted legislation only provides the Board with a single tool - UPLs - as a means to make drugs affordable. It does not empower the Board to consider other players' actions within the pharmaceutical pricing and supply chain. Given these limitations, I urge the Board to pause, review and provide legislative recommendations to expand its capacity so it may effectively address the roles of <u>all</u> players and influences within the drug pricing system. At a minimum it should include federal and state legislation, regulations, payors, PBMs, GPOs, wholesalers and others who influence all the drug prices with a focus on patient costs. Without examining <u>and</u> addressing the entire drug pricing,

supply and distribution chain, improving access to affordable, disease-modifying or life-saving drugs is not possible. Effective solutions must address what patients actually pay, not the much publicized inflated list prices. Furthermore, it is critical that the Board monitor, analyze and report on the impact of the policies it advances.

I implore the Board to pause and reconsider its UPL approach before Colorado becomes the first state implementing a policy that restricts access rather than improves affordability. State and national clinicians, patients and organizations are committed to working with you to ensure affordable medications are available for all Coloradoans through a more thorough, comprehensive, extensive and patient-focused evaluation process.

No policy is preferable to bad policy, and if a problem is predictable, it is potentially preventable.

Thank you for your attention to this critical issue.

Sincerely,

Harry L. Gewanter, MD, FAAP, MACR

Board Member, Let My Doctors Decide Action Network
Board Member, Coalition of State Rheumatology Organizations

PARTNERSHIP TO FIGHT CHRONIC DISEASE

August 20, 2025

Dear Members of the Prescription Drug Affordability Board:

The Partnership to Fight Chronic Disease (PFCD) appreciates the opportunity to share written testimony for your consideration. We recently completed research exploring perspectives of insurers on the implementation of the upper payment limits (UPLs) your efforts involve. As you know many experts on the importance of access to medicines, including people living with chronic conditions and their care partners, patient and consumer advocates, healthcare providers, and others have raised concerns about the unintended, negative consequences UPLs will have on access to medicines in the state, and ultimately, overall health outcomes. Those concerns include that UPLs will raise costs for patients on the medication as well as other consumers and increased barriers to access for the drug and others in the same class. People living with rheumatoid arthritis, psoriatic arthritis or other autoimmune conditions already face significant access barriers placed by insurers on Enbrel and other medications for these conditions.[1]

Since insurers are the decision-makers with the power to influence that access as well as what patient costs will be, we commissioned the research firm Avalere to ask insurers directly about the potential impacts on patient and consumer costs and medication access. The research included both in-depth-interviews and a survey of regional and national health plan executives on UPL implementation and the impacts on patients and providers.

As described in greater detail in the attached paper, their responses confirm and validate the concerns patients, care partners, providers and other advocates continue to raise: **patient costs will not decrease, but patient access will**.

- **77% of health plan payers** believe UPLs will **disrupt patient access** to prescription drugs due to coverage changes, tiering adjustments, increased cost-sharing, or supply chain complications, including pharmacies potentially refusing to stock medicines with UPLs.

[1] Let My Doctors Decide. National Health Insurer Scorecard Highlights Serious Medication Access Barriers Among People Living with Autoimmune Diseases, Jan. 2023. Available at https://letmydoctorsdecide.org/latest-news/2023/1/26/national-health-insurer-scorecard-highlights-serious-medication-access-barriers-among-people-living-with-autoimmune-diseases; Xcenda. Autoimmune Prior Authorization Survey Results. Feb. 2023. Available at https://static1.squarespace.com/static/59a55aa28dd041cc6f74be62/t/6400cd39682f995eb6058b53/1677774138385/Autoimmune+PA+Survey_Cover+slide_2023.02.28+%28SAS%29.pdf,

- **67% of payers** anticipate that **patient cost-sharing for UPL-designated drugs will not decrease and half believe cost-sharing will increase (50%)**, while **70%** expect **out-of-pocket (OOP) costs for drugs in the same class will not decline.**
- **57% of payers** foresee **increases in health insurance premiums** if a UPL is enforced.
- **50% of surveyed payers** indicated that **utilization management restrictions** on UPL-designated drugs **would likely increase**.
- **73% of respondents** expressed concerns that **UPLs could lead to shortages** of critical medicines, with **60%** believing pharmacies might be unable to stock these drugs.
- **57% of payers** agreed that **UPLs could result in providers receiving lower reimbursements** for administering affected drugs, potentially reducing availability for patients.

We share the goal of promoting greater affordability for patients in accessing recommended care, including prescribed medications. To do that, understanding what affordability means **from the patient perspective** is paramount. We urge you to consider the recently released Patient Experience Survey: Prescription Drug Affordability and Unaffordability that actually documents the real life medication affordability challenges patients face and the sources of those barriers to access. If the true purpose of the PDAB is to address affordability for medicines, this survey should guide those efforts.

While these research studies demonstrate that UPLs miss the opportunity to improve medication affordability for the people relying on medicines for their health, there are several reforms that would improve patient access and affordability for medicines. We urge you to consider recommending the following actions:

- Pursue affordability measures with a greater impact on reducing patient costs, while also supporting medication adherence, such as capping copayments, banning copay accumulator and maximizer policies by insurers, and requiring rebates on prescription drugs be passed along to consumers at the pharmacy counter.
- Prioritize patient engagement and testimony in the UPL rulemaking and decision processes. Frustration with criticism over PDAB efforts will ease once policy efforts are directed to the affordability problem for patients.
- Work more closely with stakeholders that a UPL could affect, including pharmacies and providers who purchase and/or administer medications to appreciate the impact of additional financial risks on access that arise with UPL implementation.
- Define value from a patient-focused societal perspective and include benefits relating to alleviating caregiving assistance needs, improved health status and well-being, enhanced independence and productivity, better quality of life, increased life

expectancy, and reductions in disability in addition to changes in health care utilization in the short and longer term.

- Reject value assessments that discriminate against people living with disabilities, people living with chronic conditions, or people with shorter life expectancies, including the QALY or similar measures; and
- Focus patient affordability on including the availability of patient assistance programs. Payer costs should be net spending, inclusive of manufacturer rebates and discounts, instead of gross spending or list price.

We appreciate the opportunity to provide these comments. As you move forward, we urge you to consider the risks to patient access that advocates have raised that attached study confirms. Working more closely with concerned stakeholders will help to refine both goals and intended outcomes of your efforts and assure affordability and better health outcomes for people living with autoimmune conditions and other chronic illnesses in Colorado.

Sincerely,

Candace DeMatteis

Candace DeMatteis, JD MPH
Vice President, Policy
Partnership to Fight Chronic Disease

Attachment: *Payer Perspectives Confirm UPLs Will Likely Raise Costs and Hinder Patient Access to Medicines*

August 20, 20025

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

Dear Members of the Prescription Drug Affordability Board,

On behalf of the undersigned organizations, we are writing to share the following letter, which we previously submitted to members of the Colorado General Assembly in June. The letter conveys the patient perspective on the PDAB's process and outlines significant concerns that remain unresolved as Colorado moves closer to implementing upper payment limits.

Our intent in sharing this with you directly is to ensure that the Board has a full and accurate understanding of patient perspectives as you carry out your statutory responsibilities. Patients and caregivers have engaged diligently throughout this process, and we remain deeply concerned that key issues around data accuracy, implementation planning, and real-world patient savings have not yet been addressed.

We respectfully urge the Board to take these perspectives into account, and we stand ready to work with you toward evidence-based solutions that truly lower costs without compromising access to essential medications.

Thank you for your attention and for your continued service to the people of Colorado.

Sincerely,

Biomarker Collaborative

The Bonnell Foundation: Living with Cystic Fibrosis

CANN

Epilepsy Foundation of CO & WY

Exon 20 Group

Global Coalition on Aging

ICAN, International Cancer Advocacy Network

Lupus and Allied Diseases Association, Inc.

Lupus Colorado

Mamas Facing Forward

MET Crusaders

National Infusion Center Association

PDL1 Amplifieds

Spondylitis Association of America

- ***Patient letter to the Colorado General Assembly included on the next page -***

July 29, 2025

Dear Members of the Colorado General Assembly,

On behalf of Colorado Patients Taking Action, we are writing to share the patient perspective on the implementation of the Colorado Prescription Drug Affordability Board (PDAB).

Colorado is on the cusp of becoming the first state to set upper payment limits (UPLs) on prescription medications. While we support all efforts to lower the cost of health care, we are deeply concerned that the PDAB's current process will fail to deliver savings for Coloradans, and worse, may restrict access to critical medications.

We have closely followed the PDAB's work over the years and have participated in all PDAB meetings. While stakeholder input is permitted, **patient concerns have been consistently overlooked** - with one important exception.

Last year, after repeatedly raising the issue that patients felt their concerns were not being heard, Board Member Dr. Sam Diab proposed adding a **patient voting member** to the PDAB (PDAB Meeting, April 2024). His proposal met resistance and was completely excluded from the PDAB's 2024 report to the legislature. We appreciate that Dr. Diab renewed this call in May 2025, citing the widespread inclusion of patients in clinical review processes. The Board ultimately included a modest recommendation that the General Assembly "consider the pros and cons" of adding a consumer representative (PDAB Meeting, May 2025).

We strongly urge you to act on this recommendation and ensure that patients have a real seat at the table.

Following another year of diligent patient engagement, we remain alarmed by persistent issues with the PDAB's process. We have raised — and continue to raise — serious, unresolved concerns that must be addressed before any upper payment limit is implemented. We respectfully submit these concerns for your thoughtful consideration and timely action:

I. No Evidence of Patient Savings

There is currently **no evidence** that a UPL will lower what patients pay at the pharmacy counter.

- In April 2025, the Colorado Division of Insurance released a cost-benefit analysis on applying a UPL to Enbrel. It included **no quantifiable data** and admitted the benefits were "difficult to quantify" due to pharmaceutical supply chain complexity and the absence of a set UPL.[1]
- In March 2025, Avalere Health published findings from interviews with senior health plan executives, warning that UPLs could actually **increase patient costs**, disrupt access, and strain benefit design.[2]
- Importantly, Oregon's own exploration of this policy space included a meaningful and comprehensive analysis — the Stauffer-Meyer report — demonstrating that a thorough cost-benefit assessment is not only possible but necessary.[3]
- Oregon's Stauffer-Meyer report identified significant risks to safety-net providers through the potential erosion of 340B savings and flagged the destabilizing impact that UPLs could have on the Medicaid Drug Rebate Program (MDRP) — which provides critical funding for the state's Medicaid program. Specifically, they noted reduced MDRP value, which is considered the state's share of cost offsets, and

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[1] Colorado Division of Insurance, *PDAB Cost Benefit Analysis* (April 2025), https://doi.colorado.gov/sites/doi/files/documents/Cost%20Benefit%20Analysis%20%281%29.pdf.
[2] Michael Matthews and Sarah Chen, "Update: Health Plans' Perceptions of PDABs and UPLs," *Avalere Health Advisory*, March 2025, https://advisory.avalerehealth.com/insights/update-health-plans-perceptions-of-pdabs-and-upls.
[3] Oregon Prescription Drug Affordability Board, *Upper Payment Limit (UPL) Analysis: Oregon Educators Benefit Board (OEBB) and Public Employees' Benefit Board (PEBB), Medicaid FFS and CCO*, prepared by Myers & Stauffer LC (Nov. 2024), included in PDAB Document Package for October 16, 2024 meeting, https://dfr.oregon.gov/pdab/Documents/20241016-PDAB-document-package.pdf.

concluded that such unintended consequences could outweigh any theoretical benefit.

Recommendations: Before implementing any UPL, the General Assembly should require:

- A meaningful, evidence-based analysis of expected outcomes.
- Assurances from supply chain stakeholders that patient access will not be disrupted.

II. Decisions Based on Flawed and Incomplete Data

We have serious concerns about the data and methodology PDAB is using to make affordability decisions and set public policy.

All Payer Claims Database Inaccuracies: At its April 2025 meeting, the Board acknowledged errors in the **All-Payer Claims Database (APCD)** dating back to 2022.[4] These errors affected approximately 7% of claims and skew metrics such as:

  - Patient counts
  - Average Wholesale Acquisition Cost (WAC)
  - Average Paid Per Person Per Year (APPY)
  - Total payer and patient costs
- The application of inaccurate data calls into question the validity of the unaffordability determinations for Enbrel, Cosentyx, and Stelara.
- The APCD also fails to include denied claims and utilization management barriers which significantly affect patient costs, delays in care, and therapy abandonment.

Flawed Survey Design: As raised by Tiffany Westrich-Robertson of the EACH Coalition and Patient Inclusion Council in written testimony to the PDAB, the Board's patient survey design used in affordability reviews is deeply flawed and inaccurate [5]:

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[4] Partnership for Safe Medicines. "PDAB Activity – April 2025 Update." *SafeMedicines.org*, April 2025. https://www.safemedicines.org/2025/04/pdab-activity-apr-2025.html.

[5] Colorado Division of Insurance, *Written Testimonies to the Prescription Drug Affordability Board*, May 23, 2025, https://doi.colorado.gov/sites/doi/files/documents/Written%20Testimonies_5.23.25.pdf.

- Responses included non-Colorado residents, violating the statutory requirement for Colorado-specific input.
- Medicare beneficiaries were included, despite the fact that UPLs do not apply to Medicare-covered drugs. Colorado cannot legally impose UPLs on Medicare plans, as they are federally regulated under the Centers for Medicare & Medicaid Services (CMS). Any attempt to do so risks federal preemption and legal challenge — and highlights the need for PDAB to distinguish clearly between state-regulated commercial plans and federally regulated Medicare coverage.
- As a result, the data does not reflect the real affordability landscape for the population PDAB is meant to impact.

Ongoing Use of Discriminatory QALYs: Despite clear statutory and federal prohibitions, PDAB continues to reference **Quality Adjusted Life Years (QALYs)** in its evaluations.

- QALYS measures inherently devalue the lives of people with disabilities or chronic illnesses and violate the General Assembly's directive that such methodologies not be used in affordability decisions.

Recommendations: Halt implementation of UPLs until the Board can:

- Demonstrate that their decisions are based on complete, reliable, Colorado-specific data.
- Employ a transparent, and evidence-based process.
- Redesign patient surveys to exclude Medicare data and out-of-state responses and reanalyze prior surveys with corrected methodology.
- Strengthen and enforce the prohibition on QALYs in all PDAB decisions.

III. Lack of Implementation Planning:

We are deeply concerned that the Board has not conducted a meaningful implementation analysis. Specifically:

- How are supply chain actors — including pharmacies, PBMs, and insurers — supposed to distinguish between commercial and Medicare claims in order to comply with a UPL?

- The PDAB has failed to adopt any monitoring metrics to evaluate whether UPLs impact patient access or affordability post-implementation.
- Without tracking outcomes, the Board cannot credibly claim to be protecting patient interests — or even measure whether its actions are having any effect at all.

Recommendations: Prior to implementing UPLs, require the PDAB to:

- Provide a detailed implementation plan that clarifies compliance pathways for supply chain actor.
- Commit to measuring and reporting on patient access and affordability outcomes after a UPL is implemented.

IV. No Results After $2 Million Spent

On July 1, PDAB issued an 11-page report claiming Colorado is "leading the nation" in addressing drug affordability. As patient stakeholders, we challenge that assertion. Over the past four years, the Board has cost taxpayers more than $2 million and has not saved patients a single dollar at the pharmacy counter.

This year we watched as you, our legislators, struggled to cut $1.2 billion dollars in spending to address Colorado's budget deficit. As you know, these cuts will affect school meals, early intervention for children with disabilities, and transportation safety. At a time when we are cutting vital health and safety services, it is irresponsible to continue spending on a board that has failed to deliver on its core promise to make prescription drugs more affordable.

The State of New Hampshire recognized this failure and not only cut all funding for the state's PDAB, they repealed the Board entirely.[6] Colorado should consider doing the same.

Recommendation: We urge you to stop funding a failed experiment and instead invest our limited public dollars in programs that produce measurable results for Coloradans.

Sincerely,

Biomarker Collaborative

The Bonnell Foundation: Living with Cystic Fibrosis

CANN

[6] New Hampshire Medical Society. *Legislative Updates – May 27, 2025*. https://www.nhms.org/news/legislative-updates-52725

Epilepsy Foundation of CO & WY

Exon 20 Group

Global Coalition on Aging

ICAN, International Cancer Advocacy Network

Lupus and Allied Diseases Association, Inc.

Lupus Colorado

Mamas Facing Forward

MET Crusaders

National Infusion Center Association

PDL1 Amplifieds

Spondylitis Association of America

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August 20, 2025

Via email (*dora_ins_pdab@state.co.us*)

Colorado Department of Regulatory Agencies
Division of Insurance
ATTN: Colorado Prescription Drug Affordability Review Board (PDAB or Board)
1560 Broadway, Suite 850
Denver, CO 80202

Re: Enbrel Upper Payment Limit (UPL) Rulemaking: Process and Substantive Issues

Re: **Proposed Upper Payment Limit for Enbrel® (etanercept)** — Request for Specific Notice, Transparent Methodology, Implementation Details, and Correction of Record

Dear Members of the Board:

On behalf of Amgen Inc., its wholly owned subsidiary Immunex Corporation, and its indirect wholly owned subsidiary Amgen Manufacturing, Limited (collectively, "Amgen"), we submit these comments to continue our objection to the Board's inconsistent, undisclosed, and ambiguous processes and procedures regarding the proposed upper payment limit (UPL) for Enbrel®. We also reiterate significant legal concerns with the Board's authority and approach.

Before taking any further action on a UPL for Enbrel®, the Board should:

1. **Clarify aspects of UPL implementation**: provide greater clarity around how covered transactions are identified, which programs and entities are excluded (e.g., federal programs), how self-funded plans may opt into a UPL, enforcement mechanisms, and any safe harbors.
2. **Address UPL information flows and any requisite infrastructure changes**: specify how UPL applicability will be communicated across the supply chain (e.g., identifiers, coding, data fields, and timing) so participants can reliably determine where and when to apply the UPL, including how self-funded plans' UPL opt-in decisions will be communicated.
3. **Correct and document the data record**: adequately reconcile patient counts, utilization, and other data across phases of the review process, as requested by Amgen since early 2024; and provide access to the corrected underlying data, detailed methodologies, and data dictionaries so stakeholders can validate and replicate results.
4. **Recognize and incorporate patient assistance**: adequately reflect the material impact of Amgen's co-pay and patient support programs in any evaluation of out-of-pocket costs.
5. **Hold at least one additional hearing and technical session** to walk stakeholders through the methodology, datasets, calculations, and

implementation mechanics of the UPL prior to any vote to adopt a UPL figure.

The lack of detailed information about UPL implementation has hindered the ability for key stakeholders to provide information sought by the Board in its data submission guide (DSG). Information must flow through the system to indicate where a UPL has been applied, and, given that such a UPL will be a novel administrative challenge to key stakeholders, doing so will require necessary changes in systems, and potentially infrastructure as well, that could take longer than six months to become fully operational.

The following provides greater detail on our continued objections, many of which have been raised in prior letters from Amgen to the Board:

I. The Rule Provides No Meaningful Notice or Methodology

Although the Board is now at its final planned rulemaking hearing, the Enbrel® UPL proposed rule remains essentially a blank template—announcing an intent to set a UPL but omitting both the proposed level or range and any process, method, or criteria for selecting a UPL figure. Restating statutory factors and listing "metrics the Board may consider" does not constitute a methodology and deprives stakeholders of the specificity required by the Colorado Administrative Procedure Act and due process.

II. The Board Must Define Where, How, and by or to Whom a UPL Applies

Based on the Board's statements and the State's representations in litigation, we understand the Board intends a UPL to apply to "downstream" transactions for drugs dispensed or administered to individuals in Colorado by any means, excluding federal programs and payors. As we have previously noted, stakeholders cannot assess compliance costs or access risks without, for instance, clear rules for determining applicability at the time of transaction, including for opt-in/opt-out ERISA plans, which constitute a substantial portion of the commercially insured market, and cross-border transactions. For example, where a medicine is acquired outside Colorado at a cost above the contemplated UPL, capping in-state payments below acquisition cost would predictably reduce provider willingness to stock the product, threatening patient access. We share other stakeholders' concerns that sites of care could become unable or unwilling to stock Enbrel®.

III. A UPL Threatens Significant Harm, and Implementation Details May Exacerbate that Harm

A UPL creates concrete, near-term risks across the drug supply chain and healthcare delivery system, and the details of how a UPL will be implemented may exacerbate those risks:

- **Patients.** Applying a UPL could drive formulary removals, less favorable tiering, or tighter utilization management for UPL drugs, while patients may still be charged cost-sharing based on static co-pays or coinsurance based on unadjusted rates. These are critical considerations given the Board's goal of reducing costs for patients. Key questions include:

    - How exactly drug availability impacts will be evaluated in a timely manner, and how the Board plans to monitor harmful effects caused by a UPL, such as an increase in non-medical switching;
    - The extent to which the Board views a UPL potentially triggering adverse formulary or utilization management (UM) changes; and
    - The extent to which patients may continue paying unadjusted out-of-pocket rates despite a UPL.
- **Providers.** Questions about UPL applicability, such as whether a particular self-funded plan has opted in, create uncertainty in reimbursement and acquisition costs, with potential cash-flow challenges that could discourage stocking UPL-priced drugs, among other considerations. Key questions include:
    - How providers will manage reimbursement and acquisition uncertainty;
    - What safeguards will prevent cash-flow disruptions when UPL applicability is unclear; and
    - How financial risks disincentivizing stocking will be mitigated.
- **Payers.** Colorado payers could reimburse transactions at normal, unadjusted rates for drugs acquired at UPL prices, misaligning payment with acquisition and leaving patient cost-sharing unchanged. Key questions include:
    - How payers may be aware a drug has been UPL-acquired; and
    - How out-of-state or pass-through dynamics will be addressed to avoid inappropriate spillover and cost-sharing distortions.

Any assertions that a UPL will not lead to significant negative consequences are unsupported absent a detailed and adequately vetted blueprint for implementation, eligibility signaling, claims adjudication, monitoring, auditing, enforcement, and subsequent UPL adjustment, among other critical considerations. The immediate risks are significant, and the Board lacks the information necessary to cast an informed vote.

IV. Unresolved Data Irregularities Preclude Informed Comment

Despite the Board's June 14, 2024, commitment to address questions Amgen has raised now for more than a year, there has been no response on key data aberrations and undisclosed methodologies. Recently disclosed PBM data miscategorizations (affecting roughly 7% of pharmacy claims) underscore the problem. Even basic figures have shifted materially across phases for the 2021 data year: 2,279 utilizers at eligibility/selection; 3,692 at affordability review (+62%); and 2,744 at UPL rulemaking (–25.7%). Without access to the Board's data and methods, stakeholders cannot validate these changes or understand the extent to which they have been corrected. The Board should publish a reconciliation memo, release relevant datasets or extracts, and allow technical review before proceeding.

VI. The Record Continues to Understate Manufacturer Assistance and Patient Impact

While Amgen detailed its support programs in an October 2, 2023, submission, this information appears only in Appendix K (p. 501 of 534) of the affordability report and has been largely discounted in subsequent meetings, including during the July 11, 2025, meeting. Reliance on Colorado APCD out-of-pocket data without incorporating key information on manufacturer assistance as it relates to the out-of-pocket data presented mischaracterizes patient costs. Any balanced UPL analysis must fully account for these programs when weighing patient out-of-pocket considerations alongside access risks.

VII. Legal Concerns

Proceeding toward a UPL in the absence of a previously adopted, transparent methodology, and without specific notice of the proposed level or analytical approach, is inconsistent with the Colorado Administrative Procedure Act and principles of due process. At a minimum, after development and adoption of a UPL implementation plan, the Board must re-notice the rule with the elements outlined herein (e.g., a proposed UPL amount and complete methodology, including data sources, weights, adjustments, exclusions, and decision criteria) and allow a meaningful opportunity for comment within the context of a detailed effectuation plan.

Conclusion and Path Forward

Amgen is driven by its mission to serve patients. We recognize concerns about prescription drug affordability, but an ill-defined UPL—adopted without transparent methods, reliable data, or functional information-sharing infrastructure, among other things—would increase access risks for Coloradans, including patients who rely on Enbrel®, particularly vulnerable pediatric populations.

We respectfully request that the Board pause the current rulemaking timeline, correct and document the data record, and shift focus to resolving UPL effectuation. Once UPL implementation can be understood by stakeholders, the Board should then re-notice the rule with the substantive information included necessary for stakeholders to assess the feasibility and risks of any UPL figure.

Regards,
/s/ Kathy Sherman

Kathy Sherman
Associate Vice President, State and International Government Affairs
Global Government Affairs & Policy

Bridget Dandaraw-Seritt

Founder, Advocates for Compassionate Therapy Now

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Advocates for Compassionate Therapy Now
2530 Farragut Ave.
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719.357.2334
ACTnow4patients@gmail.com

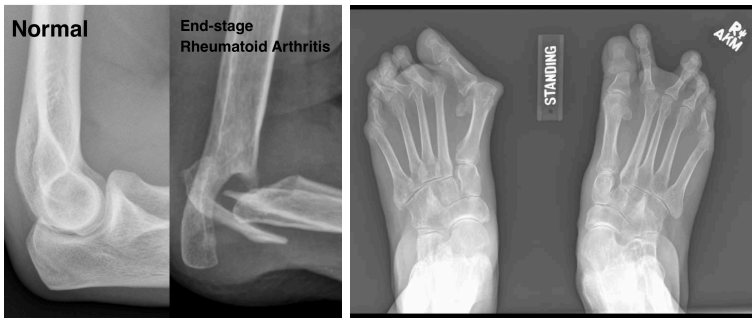
19 AUGUST 2025

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

Dear Members of Colorado Prescription Drug Affordability Board,

Thank you for taking the time to consider our concerns with how upper payment limits will impact patient access to critical medications. Enbrel is a first line therapy for many autoimmune arthritis conditions and one of the few approved for pediatric use. There are no generic options, and while other drugs in the class are similar, they are not interchangeable. This creates a potentially dangerous situation where access could be negatively impacted. Without their specific working therapy, Coloradans could face costly consequences like increased hospitalizations, more invasive surgeries, and lowered ability to work. These impacts could significantly raise costs to the state and federal government with more needing to depend on government programs like SNAP, Medicaid, and housing assistance. It will also raise premiums of public and private insurance. The availability of these resources is declining and existing programs are strapped.

Changes in access have impacted me personally, which is why I am so heavily involved in advocacy. In 2017, I lost access to the only working medication that keeps my rheumatoid arthritis contained. In 4 short years, I went from being able to hike miles to being bed ridden. I had irreversible damage to numerous areas of my body. As a result, I needed multiple surgeries including wrist fusions, knee and shoulder replacements, and reconstructive surgeries on both feet. My sudden decline meant that I could no longer work, play with my grandchildren, or even dress myself without help. Finally, at the end of 2021, I was able to restart my working medication. Thank goodness it still is effective and I've been able to slowly improve. While much of my damage is permanent, I'm able to work and participate in life again. Below are xrays that show some of my extensive, permanent damage.



We encourage the Board to carefully consider ***all*** potential impacts of

upper payment limits, not just desired outcomes. We understand the goal is to lower healthcare costs for Coloradans, but there is a strong probability patients will experience consequences like increased utilization management, insurance formulary changes across the entire class, and even complete loss of access to the drug. Mitigating these potentially catastrophic barriers is the responsibility of the Board and Division of Insurance. Our immediate concerns include:

- **There is no process for waiving the UPL for those who cannot use any other medication.** Alternative therapies and biosimilars are not interchangeable for most chronic illnesses. Each medication works in a specific way, and biosimilar drugs are just that - similar. There is strong evidence to suggest that upper payment limits will impact formularies and access. The PDAB and Division of Insurance has not created a process where patients can seek relief from the UPL should it interfere with access to their working therapy.
- **While QALY data was not used in the upper payment determination, the Board was given this information during the adorability review. We feel strongly that the Board cannot unsee data using QALYs. That contaminates the entire process and is discriminatory against the elderly, disabled, and chronically ill.** QALY data has no place in affordability and pricing decisions since it favors cures and perfect health. This metric does not include actual quality of life information, and is decided by what non-patients feel is our "quality of life". This data has been banned in Medicaid affordability decisions, and the UPL impacts Medicaid.
- **The process was plagued with multiple concerns with data and its collection.** Several issues with the patient/caregiver surveys have been raised, there were errors in the All Payer Claims Data used, and the Board has shown serious bias to which feedback weighs the most. These open biases have cast a huge shadow over the work and intentions of this Board. Until a more comprehensive survey with context is created, community outreach is significantly increased, and data (including financial) is more appropriate and transparent, the Boards work lacks credibility. We were hoping to see those issues rectified before the UPL process, and have serious concerns as a result.

Fixing these issues is critical for a successful program. Colorado needs to be a leader in compassionate healthcare equity, not an example of "what not to do". We all are working towards affordable and equitable healthcare, which is why we have such grave concerns about the impacts of a UPL. Unfortunately, healthcare is an ecosystem and rash change in one area could ripple to other areas causing increased barriers to getting care. Please consider our concerns and work to resolve very clear problems.

Sincerely,

Bridget Dandaraw-Seritt

VIA Electronic Delivery August 20, 2025

Colorado Department of Regulatory Agencies
Division of Insurance
ATTN: Colorado Prescription Drug Affordability Board
1560 Broadway, Suite 850
Denver, CO 80202

Re: CO PDAB UPL Rulemaking Written Testimony

Dear Prescription Drug Affordability Board Members and Staff:

The Biotechnology Innovation Organization (BIO) and the Colorado BioScience Association (CBSA) appreciate the opportunity to provide written testimony for the Colorado Prescription Drug Affordability Board's (PDAB's or Board's) rulemaking hearing on August 22, 2025.

CBSA champions Colorado's life sciences ecosystem and the patients it serves. CBSA's members include more than 720 life sciences companies and organizations employing more than 40,000 people in Colorado. Our life sciences community drives global health innovations that improve and save lives, from concept to commercialization. CBSA represents biotechnology and pharmaceutical, medical device and diagnostics, digital health, ag-bio and animal health, academic and research institutions, and the service provider companies that support the work of our ecosystem. CBSA remains committed to advancing affordability solutions that correct market failures, increase competition, and lower costs for patients while preserving patient access and supporting medical innovation.

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector. Learn more at bio.org.

BIO and CBSA continue to have serious concerns with the Board's rulemaking approach, particularly given the lack of any transparent and consistent methodology for setting upper payment limits (UPLs), which introduces significant uncertainty and risks for patients. As we have discussed in our previous comments,[1] the Board must provide a predictable framework for the implementation of UPLs and allow stakeholders the opportunity to provide feedback on the methodology and weighting that the Board will utilize for determining UPLs. Without important implementation details clarified and assurances received, patients are left vulnerable to the negative downstream effects of UPLs, which will likely impact patient access to treatments (see Appendix: "Access Issues Regarding State UPL Effectuation").

[1] CBSA and BIO Written Testimony on CO PDAB UPL Rulemaking. July 11, 2025.

Setting UPLs targets the most innovative medicines, disproportionately impacting patients with diseases for which there is a high unmet need and for which low-cost treatment options are not available (e.g., rare diseases), running counter to the aims of personalized medicine and risking the availability of new treatments. Further troubling, the arbitrary nature of UPLs ignores the value that an innovative therapy can have to an individual patient—especially one who may have no other recourse—or the societal impact innovative technologies can have, including increased productivity and decreased overall healthcare costs (e.g., due to fewer hospitalizations, surgical interventions, and physicians' office visits).

Please note that, in addition to our unaddressed concerns regarding UPL implementation, we also have more fundamental issues with price controls as a mechanism for addressing affordability challenges, and our position remains that the Board should not move forward with UPL rulemaking. As we have stated in previous comments, BIO and CBSA have serious and ongoing concerns regarding the constitutionality of the Colorado PDAB statute and the legality of the Board's implementation of the statute.

Finally, it is critical that the Board be reminded that the PDAB is not obligated to adopt this regulation nor to establish a UPL. Under its governing statute, the PDAB retains the discretion to forego setting a UPL and instead channel its efforts toward other policy recommendations. As the Cost-Benefit Analysis for the Draft Proposed Rule acknowledged, "the Board could provide payer- and payment-focused recommendations" to the General Assembly, which "could include…limits on utilization management, etc."

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BIO and CBSA appreciate the opportunity to provide feedback to the Colorado PDAB on the Draft Proposed Rule and the PDAB's work more generally. We look forward to continuing to work with the Board to ensure Colorado residents can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact us at pcastro@bio.org and agoodman@cobioscience.com.

Sincerely,

/s/

Primo J. Castro
Director
State Government Affairs – Western Region
BIO

/s/

Amy B. Goodman
VP and Counsel
for Policy + Advocacy
CBSA

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Access Issues Regarding State UPL Effectuation

Unknown implementation details leave patients vulnerable to negative downstream effects of UPLs, which will impact patient access to treatments.

LET MY DOCTORS DECIDE Action Network

"Any approach that imposes an Upper Payment Limit by definition cannot account for specific individual patient circumstances, needs and medical history."

"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, and greater risk of treatment failure due to administrative burdens."

Pharmacists United for Truth & Transparency

"... there is nothing to stop the plan from...requiring patients to "step through" much more expensive drugs before they can access the UPL medication. This type of formulary design manipulation will severely limit patient access to the drugs selected by the Board, minimizing the Board's influence in making medication more affordable.

CSRO Coalition of State Rheumatology Organizations

Stakeholder Impacts

Patients: Patients' out of pocket costs are determined based on their health plan. Without guidance on implementation, it is unclear whether the UPL will result in any cost savings, and if so, whether cost savings will be passed on to patients. UPL products may also be completely removed from formularies and subject to additional coverage restrictions.

Hospitals: Depending on the UPL amount and how it is applied to hospital reimbursement for affected medications, lower hospital reimbursement may create medication access issues or otherwise risk negatively impacting patient care.

Physician Practices: UPLs could lower reimbursement for physician practices, threatening financial stability and forcing physicians to limit access to certain therapies or stop offering them altogether.

Health plans/PBMs: UPL products are likely to see increased utilization management including step therapy and prior authorization, and potential removal of UPL drugs from formularies

Pharmacies: Depending on how pharmacy reimbursement will be decided, pharmacies may not be able to supply the medications in a financially viable manner, which may lead pharmacies to not stock or dispense drugs subject to the UPL

The PDAB was established to ensure that patients have greater access to drugs. Setting a UPL will undermine that promise to patients.