October 1st, 2025

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

RE: Draft Proposed Rule 4.3 Upper Payment Limit for Enbrel (Etanercept)

Dear Chair Mizner and Members of the Prescription Drug Affordability Board:

The undersigned organizations appreciate this opportunity to comment on the upper payment limit rulemaking for Enbrel and **support draft proposed rule 4.3.** 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.

CMS Max Fair Price

The CMS Max Fair Price (MFP) is a federally negotiated and overseen pricing standard. These negotiations include considerations across the entire drug chain as well as direct conversation with drug companies and input from Medicare enrollees, providers, caregivers, and additional experts.[1] As a state board with significantly less capacity than federal CMS and with the charge to address multiple high cost medications, we support you leveraging federal work and resources to ease the upper payment level (UPL) decision making process. Moreover, we firmly agree with the decision made in the August meeting to use the best data available for any given drug when considering what UPL to set and believe it is clear that the CMS MFP is the best data for Enbrel. Similarly, we support an annual adjustment to the UPL in order to match the most recent federally negotiated MFP.

Projected Savings from MFP UPL

When compared to the current Average Plan Paid PPPY, the CMS Max Fair Price represents an over 40% in savings.[2] Since PDAB legislation does indeed assert savings from a UPL *must be passed on directly to consumers*,[3] such cost reductions could significantly decrease out-of-pocket

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[1] https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026

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

[3] "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

costs[4] and premiums for Coloradans.[5] Elementary projections utilizing 2023 APCD data show a potential for $32.8 million in savings for Coloradans.[6] We look forward to additional modeling from DOI staff but remain encouraged by these early estimates. Our state is currently facing massive premium increases,[7] threats to Health First Colorado coverage,[8] and the devastating reality that many will become uninsured due to increased cost of coverage.[9] 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.

UPL Enforcement

In response to comments made during the August Board meeting we would like to highlight the enforcement mechanisms that were created in the enacting PDAB legislation and regulation for ensuring pass-through savings reach consumers. All carriers and state entities that offer health coverage plans in Colorado and make reimbursements for a drug with an UPL will be required to submit an annual report to the PDAB detailing the effects of any UPL(s). These reports include calculations of claims[10] and cost-sharing[11] savings as well as details on utilization, cost sharing amounts, total allowed paid claims, and narrative explanation of estimated effects of a UPL.[12] These reports will be submitted to you, the Board, for review. Additional enforcement actions may be made through the Attorney General's Office. We strongly encourage the board to consult

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THAT ISSUES THE HEALTH BENEFIT PLAN TO REDUCE COSTS TO CONSUMERS, PRIORITIZING THE REDUCTION OF OUT-OF-POCKET COSTS FOR PRESCRIPTION DRUGS"

[4] 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).

[5] 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).

[6] Calculated using patient count (1445) at Average Plan Paid ($53,049) vs patient count at CMS MFP. ($30,346)

[7] 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.

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

[9] 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

[10] "Claims savings are calculated and reported by determining the difference between utilization and cost of a prescription drug with a UPL compared to the estimated utilization and cost of the prescription drug without the UPL." (Code of Colorado Regulations 3 CCR 702-9 page 18.)

[11] "Cost-sharing savings and premium savings are calculated and reported in a manner that demonstrates how carriers utilized any savings generated for a health benefit plan from a prescription drug's UPL to reduce costs to consumers, prioritizing the reduction of out-ofpocket costs." (Code of Colorado Regulations 3 CCR 702-9 page 18.)

[12] See Code of Colorado Regulations 3 CCR 702-9 pages 17 - 20.

with the Attorney General Office to gain further clarity into these processes and their approach to enforcement.

Continued Support for the PDAB and Upper Payment Limits

As always, we appreciate the work of the Board. We recognize and appreciate that the PDAB and PDAB staff are fulfilling their statutory obligations to the people of Colorado, particularly to Coloradans who experience the greatest barriers to seeking the healthcare they need and want. We have seen the board staff and members take seriously the need to deliberate and proactively engage with stakeholders across the entire supply chain. Board staff have shown efforts to be fully transparent and accountable to the public despite the immense intricacies of pharmaceutical supply chains.

Coloradans are behind you in this work. 2021 bipartisan polling showed overwhelming support for the creation of the board and necessity for Colorado to take action on rising prescription costs through the implementation of upper payment limits. Three years later, this support has persisted. Polling from 2024 demonstrated the continued need for affordable medication and reaffirmed broad support for direct action.[13] Respondents supported setting standard prices for drugs in order to make them affordable (91%), setting out-of-pocket caps on life-saving medicine (92%), barring drug companies from charging more in the U.S. than abroad (89%), and *establishing a PDAB to set evidence based upper payment limits (86%).*

Thank you for this opportunity to provide comments. The use of CMS Max Fair Price as outlined in **Draft Proposed Rule 4.3 Upper Payment Limit for Enbrel (Etanercept)** 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. We believe setting this upper payment limit will meaningfully reduce prescription drug costs for Coloradans.

Sincerely,

Sophia Hennessy
Policy and Research Coordinator
Colorado Consumer Health Initiative

Nikita Valdez
Organizing Manager
Centennial State Prosperity

[13] Colorado Survey Respondents Worry about High Drug Costs; Support a Range of Government Solutions *HEALTHCARE VALUE HUB*

Lori Copani
Campaign manager
Committee to Protect Health Care

Laura Packard
Founder
Voices of Health Care Action

Mark Longshore
Executive Director
Colorado Nurses Association

Bethany Pray
Chief Legal and Policy Officer
Colorado Center on Law and Policy

Hunter Nelson
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Via Electronic Submission

September 29, 2025

Gail Mizner, MD
Colorado Prescription Drug Affordability Board Chair
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202
dora_ins_pdab@state.co.us

Dear Dr. Mizner:

Johnson & Johnson Innovative Medicine ("J&J") writes to share comments on the PORTAL "Presentation on STELARA Biosimilars," ("PORTAL Presentation"), which was placed on the July 11, 2025 and August 22, 2025 agendas for the Colorado Prescription Drug Affordability Board ("PDAB" or "Board") meetings. J&J respectfully reiterates our request that the Board cancel plans to move forward with an upper payment limit ("UPL") rulemaking for STELARA® (ustekinumab).

A. STELARA's UPL rulemaking should be cancelled because biosimilars are available.

As previously noted, when selecting drugs for affordability review, the Board initially ranked HUMIRA® first on its list of eligible drugs but ultimately excluded HUMIRA due to the availability of biosimilars.[1] Similarly, as communicated in our July 9, 2025 letter, the FDA has approved at least seven ustekinumab biosimilars and an unbranded ustekinumab biologic since the PDAB's affordability reviews began.[2] In response to our request for consistent treatment of STELARA and HUMIRA, the PDAB added the PORTAL Presentation to the July 11, 2025 and August 22, 2025 Board meeting agendas, although time constraints prevented its discussion.[3] We respectfully emphasize that the existence of FDA-approved ustekinumab biosimilars should be sufficient to cancel STELARA's UPL rulemakings based on the PDAB's previous actions with HUMIRA. Continuing with STELARA rulemaking would be inconsistent and arbitrary.

If the Board does review the PORTAL Presentation at an upcoming meeting, it is important to note that the Presentation arbitrarily distinguishes between STELARA and HUMIRA. The

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[1] CO PDAB 2023 Eligible Drug Dashboard, Tableau, https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/2_PrioritzedSummaryList (last visited June 20, 2025).

[2] FDA, *Purple Book: Database of Licensed Biological Products, Keyword "Ustekinumab,"* https://purplebooksearch.fda.gov/ (last visited June 20, 2025).

[3] CO PDAB, Prescription Drug Affordability Board Meeting Agenda, Friday, July 11, 2025 from 10:00 am – 1:00 pm, chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://doi.colorado.gov/sites/doi/files/documents/July%2011%20Draft%20Agenda.pdf (last visited July 8, 2025).

PORTAL Presentation does not contain any data or analysis of HUMIRA to justify why the two drugs would be treated differently by the PDAB in assessing which drugs to select for affordability review. Additionally, the Presentation contains inaccurate generalizations, such as claiming that ustekinumab biosimilar coverage is currently limited. Yet, the "Formulary Coverage" chart contained within the Presentation shows up to 83% of commercial and exchange plans and up to 69% of Managed Medicaid plans cover at least one, if not multiple, ustekinumab biosimilars as of July 1, 2025.

As of October 1, 2025, Health First Colorado's Preferred Drug List shows that all seven ustekinumab biosimilars, unbranded Ustekinumab, and STELARA are covered for psoriatic arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis; however, all nine products, including STELARA, are non-preferred.[4] The prior authorization requirements to access STELARA are the most stringent.[5] This trend to restrict STELARA access is consistent with recent analysis of 2026 formularies, which shows that PBMs are beginning to place STELARA on exclusion lists and cover multiple biosimilars instead.[6]

B. STELARA'S UPL hearings should be cancelled because the "verified" data shows significant decreases in spending over time.

We reiterate that the "Addendum to the 2023 Affordability Review Summary Report: STELARA" supports cancelling any planned UPL rulemakings. These "verified" numbers show significant reductions in spending across all categories (total paid, average paid per person, total patient paid, average out of pocket) (see image below).

Moreover, as this data is outdated, it does not reflect the current market. Across our portfolio, J&J's net prices have declined by a compounded 18.2% since 2016, and our rebates, discounts, and fees to middlemen, private insurers, and other entities continued to grow, reaching $47.8 billion in 2024.[7] These discounts, rebates, and fees accounted for 58% of every dollar in J&J's gross sales.[8] STELARA is no exception, and we would expect to see spending continue to decrease given robust biosimilar competition. Therefore, J&J respectfully urges the Board to cancel any future UPL rulemaking for STELARA.

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[4] *Colorado Department of Health Care Policy and Financing Preferred Drug List (PDL) Effective October 1, 2025*, Health First Colorado, https://hcpf.colorado.gov/sites/hcpf/files/10-01-25%20PDL%20V2.pdf (Sept. 30, 2025).
[5] *Id.*
[6] *The Stelara Biosimilar Price War: How PBM-Affiliated Private Labels Are Reshaping the Market*, Drug Channels (July 8, 2025), https://www.drugchannels.net/2025/07/the-stelara-biosimilar-price-war-how.html (last visited Sept. 29, 2025); Adam Fein, *Buh Bye Stelara! Hello, ESI's Private Label Play*, LinkedIn, https://www.linkedin.com/posts/adamjfein_pbm-activity-7373470406009167872-yE75/?utm_source=costcurve.beehiiv.com&utm_medium=newsletter&utm_campaign=it-s-formulary-season-and-early-analyses-suggest-big-changes-in-how-pbms-approach-biosims&_bhlid=1c2f29618da22fa2c2f981580fad0fb7bcf4aa9f (last visited Sept. 29, 2025).
[7] *Patient Access and Affordability: 2024 Johnson & Johnson Innovative Medicine U.S. Pricing Transparency Data*, (2025), https://policyresearch.jnj.com/2024transparencyreport (last visited Sept. 29, 2025).
[8] *Id.*

Annual Utilization and Expenditures (All Lines of Business/Pharmacy Claims)

Table 10 shows the percent change in the Annual Utilization and Expenditures for Stelara in 2019-2022.

	Percent Change			
	2019	2020	2021	2022
Patient Count	-2%	-3%	-5%	-5%
Total Paid	-1%	-12%	-30%	-28%
Average Paid Per Person	3%	-13%	-28%	-33%
Total Patient Paid	0.1%	0.1%	-2%	-15%
Average Out-of-Pocket (OOP)	-28%	-33%	-30%	-32%

As one of the nation's leading healthcare companies, J&J has a responsibility to engage with stakeholders in constructive dialogue to address gaps in affordability and access as well as protect our nation's leading role in the global biopharmaceutical innovation ecosystem. We know that patients are counting on us to develop, bring to market, and support access to our medicines. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives. We thank you in advance for taking our recommendations into account.

Sincerely,

Michael J. Valenta

Michael Valenta
Vice President, Value, Access & Pricing, Strategic Customer Group
Johnson & Johnson Healthcare Systems, Inc.

October 3, 2025

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

Re: Final Hearing on Upper Payment Limit for Enbrel
October 3, 2025

Dear Chair Mizner and Members of the Board,

On behalf of Lupus Colorado and the patients and families we serve, thank you for the opportunity to provide input during this final rulemaking hearing. We recognize the Board's mandate to address affordability, but we remain deeply concerned with the process and the proposed regulation before you today, specifically Part 4.3: Upper Payment Limit for Enbrel.

Transparency, Engagement, and Caution

Today's agenda allows witness testimony only after rule introduction, staff presentation, and deliberation. While procedurally efficient, this sequencing undermines transparency and meaningfully reduces the role of patient voices in shaping policy. For a Board designed to center consumers, this process does the opposite and sidelines them.

Equally troubling is the pattern this reflects. The PDAB continues to blaze forward with sweeping actions without the caution, intention, or thoughtfulness that the public deserves. Patient organizations, providers, and caregivers have repeatedly offered feedback and requested safeguards, yet these calls have been consistently minimized or deferred. A process intended to protect patients cannot succeed if it disregards their lived experience.

Lack of Baseline Data and Monitoring

Although the rule sets a binding ceiling on reimbursement, no baseline data or monitoring system exists to measure its real-world impact on patients. To implement a UPL without metrics is to run a policy experiment on Coloradans without evaluating outcomes. That is not science, it is assumption.

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Commentary on the Maximum Fair Price (MFP)

We note that Section 4.3(E) sets the UPL for Enbrel at **$583.59 per unit, equivalent to the current Maximum Fair Price (MFP)**. While the alignment of state UPLs with federal MFPs may appear efficient, there are several significant concerns:

- **Purpose Mismatch**: The MFP was designed under federal law (IRA, CMS negotiations) to govern Medicare pricing, not to function as a statewide ceiling across all payers, populations, and benefit designs. Repurposing it here applies a tool outside its intended scope.
- **Static vs. Dynamic Market**: MFPs are administratively set and updated annually. This rigid link risks tethering Colorado patients to federal calculations that may lag behind market realities or fail to reflect local needs.
- **Impact on Benefit Design**: Anchoring reimbursement to MFP levels may lead plans and PBMs to respond not with lower costs for patients, but by reshuffling cost-sharing, formulary placement, and network adequacy to protect revenues.
- **Compliance Risks**: Statute (§10-16-1406(3)(c)) requires that savings flow to consumers. Yet PBM contracts may dilute or divert those savings. Without strict auditing, the law's promise will remain unenforced.

In short, adopting the MFP as Colorado's UPL imports federal assumptions into a state system that lacks parallel oversight, creating risks for patients.

Predictable Patient Impacts of UPL Implementation

If the UPL for Enbrel is finalized as written, Colorado patients can expect:

- Higher out-of-pocket costs through tiering and formulary changes
- Narrower specialty networks, especially in rural areas
- Increased barriers like prior authorization and step therapy
- Disruptions to stable treatment regimens as formularies reshuffle
- Persistent opacity in PBM contracts that obscure whether savings ever reach patients

These are foreseeable harms, not speculative.

The Risk of Precedent

Enbrel is the first test case. If the Board finalizes this UPL without safeguards, it sets a precedent that expedience outweighs evidence, and that patient voices can be sidelined. That precedent would undermine public trust and damage the credibility of this Board's work for years to come.

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Conclusion

For these reasons, Lupus Colorado urges the Board to pause. The adoption of an MFP-based UPL for Enbrel without baseline data, transparent monitoring, and enforceable oversight risks harming the very people this process is designed to help.

The PDAB must slow down, listen to the people it is statutorily required to protect, and incorporate their feedback into both process and outcome. Only with caution, intention, and respect for lived experience can this work advance the Board's mission. Patients deserve more than an administratively convenient number. They deserve transparency, accountability, and access-centered policymaking.

Thank you for your service and for considering the voices of the people most affected.

Respectfully,

Kristy Kibler
CEO
Lupus Colorado

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Value of Care Coalition

October 1, 2025

Prescription Drug Affordability Board
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RE: ENBREL UPPER PAYMENT LIMIT RULEMAKING HEARING #4

Dear Chair and Members of the Board:

On behalf of the Value of Care Coalition, thank you for the opportunity for further comment on the Board's proposal to set an upper payment limit for Enbrel. As a broad coalition of advocacy organizations representing patients, caregivers and health care providers, we recognize the importance of lowering health care costs and appreciate the work of the Board toward that goal.

MFP REFERENCE PRICING FAILS PATIENTS

The name "Maximum Fair Price" suggests affordability. But in reality, the MFP is a list-price benchmark. Unfortunately, it does not address the actual drivers of patient cost or treatment delays related to benefit design like premiums, deductibles, copays and coinsurance, prior authorization, and step therapy. It also doesn't account for other costs of care like doctor visits, medical devices, imaging, surgeries or hospital stays. Focusing solely on list price while ignoring those other factors takes a too narrow view of a very complex health care system. It also does not guarantee meaningful patient savings or ensure patient access to their life-changing medications.

As the Value of Care Coalition noted in its comments to the Board dated July 9, 2025[1], federal experience with the setting of a MFP is already proving this point.

- Patient out of pocket costs have risen by an average of 32% for the first set of drugs subjected to the MFP.[2]
- A white paper from the University of Southern California details how Medicare Part D plans are responding to government price caps. The paper notes a "sharp increase in

[1] Value of Care Coalition, *Public Comments RE: ENBREL UPPER PAYMENT LIMIT RULEMAKING HEARING #,* July 2025, https://doi.colorado.gov/sites/doi/files/documents/7.11%20Written%20Testimonies.pdf#page=55
[2] Pioneer Institute. Key Findings to Date: The Inflation Reduction Act (IRA). May 2025. https://pioneerinstitute.org/the-inflation-reduction-act-ira-key-findings-to-%20date/

annual deductibles" paired with a sharp increase in plans that require co-insurance rather than co-pays, further shifting prescription drug cost burdens onto patients.[3]

- A survey by the National Community Pharmacists Association found that one third of independent pharmacies won't carry drugs subjected to Medicare's maximum fair price, and another 60% are considering not stocking those drugs.[4]

These are not abstract concerns—they are early warning signs of exactly how MFP reference pricing plays out when it meets the real world.

LOW LIST PRICES DO NOT EQUAL PATIENT SAVINGS OR PATIENT ACCESS

During last month's meeting, a common response emerged from the board regarding health plans' own statements that they will raise patient cost and decrease patient access because of upper payment limits. Each time it was mentioned, the Board asked: why?

The previously submitted survey of health plans, conducted by Avalere for the Partnership to Fight Chronic Disease, along with countless other publications, papers and articles found online, explains that complex negotiations between manufacturers of medicine and pharmacy benefit managers create this dynamic.

In fact, Maryland PDAB Board Member and policy expert Gerard Anderson has been clear about the supply chain dynamics, saying in an NBC News interview this summer:

> *PBMs "are looking for the drug that makes them the most money"…The deals are "a negotiation between the drug companies and the PBM. The drug company wants their drug on the formulary in a favorable position. The PBM wants to get the largest possible rebate."*[5]

The implication is clear: higher list prices allow for greater rebates, which in turn begets preferable formulary placement. With that in mind, our concerns become plainly understandable. If UPLs restrict the ability for reasonable negotiations between PBMs and manufacturers, coverage is likely to be reduced or eliminated.

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[3] USC Leonard D. Schaeffer institute for Public Policy & Government Service. Most Medicare Beneficiaries May Pay More for Drugs Under the IRA. June 2025. https://schaeffer.usc.edu/research/medicare-part-d-drug-costs-ira/

[4] National Community Pharmacists Association. *NCPA to CMS: A Third of Independent Pharmacies Won't Carry Drugs in the Negotiated Price Program, and 60 Percent More are Considering Dropping Out.* January 2025. https://ncpa.org/newsroom/news-releases/2025/01/27/ncpa-cms-third-independent-pharmacies-wont-carry-drugs-negotiated

[5] NBC News, *Parents sue over son's asthma death days after inhaler price soared without warning,* June 2025, https://www.nbcnews.com/health/health-care/asthma-death-prescription-price-pharmacy-lawsuit-rcna210075

In fact, we've seen this play out in the biosimilars market. When adalimumab biosimilars entered the U.S. market, some manufacturers introduced a low-list-price version, while others offered a high-list-price version with large rebates attached.[6] Instead of choosing the lower-list option, health plans overwhelmingly preferred the high-list, high-rebate version. A 2024 Medicare analysis found that while nearly every plan continued to cover Humira itself, only about half covered any biosimilar - and among those that did, the higher-priced biosimilars received broader coverage than the lower-priced ones. The authors wrote, "this study showed that higher-priced versions received greater formulary coverage."[7] Meanwhile, patients were left with little or no access to the low-list alternatives.

A hypothetical patient with rheumatoid arthritis might have thought her out-of-pocket costs would come down when lower priced options launched. Instead, data suggests her insurer may have only covered the high-list version to receive higher rebates. If her coinsurance was calculated on that list price, she would be worse off than if the low-list option had been available. The drug she needed existed at a lower price, but because of the way formularies were built, she would never see the benefit.

The Federal Trade Commission has now shown that this problem is widespread. In its lawsuit against the three dominant PBMs, the FTC alleged that they deliberately excluded low-list-price insulins from formularies in favor of higher-priced, highly rebated versions.[8]

In its follow-up report, the FTC documented how PBMs marked up specialty generic drugs by hundreds or even thousands of percent at their affiliated pharmacies.[9] Patients were steered away from the lower-cost versions and toward the higher-priced ones. These findings are not hypothetical - they are official allegations by the nation's top competition authority that the rebate-driven system actively disadvantages lower-cost drugs.

RECONSIDER USE OF AN UPPER PAYMENT LIMIT

Taken together, these examples show why adoption of MFP reference pricing is such a risky idea. It ties state reimbursement to a federal list-price benchmark without changing the underlying incentives that actually drive patient costs. It assumes that savings from lower list prices will flow to patients when all of the evidence shows the opposite. And it risks importing

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[6] Pharmacy Times, *What Went Wrong: How Formularies, Contracts, and Rebates Created a Headwind for Biosimilars,* November 2024, https://www.pharmacytimes.com/view/what-went-wrong-how-formularies-contracts-and-rebates-created-a-headwind-for-biosimilars

[7] JAMA, *Formulary Coverage of Brand-Name Adalimumab and Biosimilars Across Medicare Part D Plans,* June 2024, https://jamanetwork.com/journals/jama/fullarticle/2819471

[8] Federal Trade Commission, *FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Prices,* September 2024, https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices

[9] Federal Trade Commission, *FTC Releases Second Interim Staff Report on Prescription Drug Middlemen*, January 2025, https://www.ftc.gov/news-events/news/press-releases/2025/01/ftc-releases-second-interim-staff-report-prescription-drug-middlemen

to Colorado the same access problems we are already seeing at the federal level - pharmacies not stocking drugs, plans raising coinsurance, and patients paying more, not less.

We urge the Colorado Prescription Drug Affordability Board to reject this proposal. Patients deserve policies that deal with the real drivers of affordability: transparency in benefit design, safeguards against switching, delays and denials for care, and reforms that ensure savings flow directly to the pharmacy counter. A UPL based on the Maximum Fair Price does not meet these standards. Rather than a solution to patient affordability, it is an untested idea that risks patient access.

Respectfully submitted,

Derek Flowers
Executive Director
Value of Care Coalition

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October 1, 2025

Colorado Prescription Drug Affordability Board
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Submitted via electronic mail: dora_ins_pdab@state.co.us

Re: Colorado Prescription Drug Affordability Board: DRAFT Proposed UPL Rule for Enbrel

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

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the updates to the draft proposed Upper Payment Limits ("UPLs") Rule, 3 Colo. Code Regs. 702-9, Part 4: Upper Payment Limit for Enbrel (Etanercept) ("Draft Proposed Rule"), which is scheduled to be discussed at the Board's October 3, 2025, meeting.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

PhRMA recognizes the Board's ongoing work to carry out its responsibilities under Part 14 of Article 16 of Title 10 of the Colorado Revised Statutes, as amended by HB 23-1225 and SB 24-203 (the "PDAB Statute"). However, PhRMA continues to have significant concerns about the lack of clear and concrete standards and processes for UPL-setting.[2] These concerns have not been resolved in the updates to the Draft Proposed Rule, which instead exemplifies the lack of procedural clarity by failing to explain the Board's rationale for proposing to set the UPL for Enbrel at the Medicare Maximum Fair Price ("MFP")—an amount set by the Centers for Medicare & Medicaid Services ("CMS") pursuant to the Inflation Reduction Act ("IRA"). PhRMA is also concerned with the Board's mischaracterization of the MFP-setting process more generally.

I. Lack of Meaningful Standards and Processes for Determining Proposed UPL

PhRMA has previously raised concerns about the lack of meaningful standards and processes for conducting the UPL-setting process.[3] Those concerns are heightened now that the Board has proposed a

[1] Draft Proposed Rule (Aug. 22, 2025), https://doi.colorado.gov/sites/doi/files/documents/Draft%20Proposed%20UPL%20Rule_Updated_8.22.25.docx.pdf; 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 Sept. 18, 2025).

[2] 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. 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 (May 16, 2025); PhRMA to Board (Dec. 4, 2024); Letter from PhRMA to Board (Nov. 28, 2024); Letter from PhRMA to Board (Oct. 16, 2024); Letter from PhRMA to Board (June 21, 2024); Letter from PhRMA to Board (Nov. 22, 2023); Letter from PhRMA to Board (June 23, 2023); Letter from PhRMA to Board (May 2, 2023); Letter from PhRMA to Board (Jan. 12, 2023); Letter from PhRMA to Board (Nov. 14, 2022); Letter from PhRMA to Board (Oct. 6, 2022); Letter from PhRMA to Board (Sept. 29, 2022); Letter from PhRMA to Board (Aug. 17, 2022); Letter from PhRMA to Board (Feb. 1, 2022).

[3] *See* Letter from PhRMA to Board 1-3 (May 16, 2025).

UPL amount for Enbrel—without first addressing these fundamental procedural issues.

The PDAB Statute requires the Board to determine "by rule" the methodology for establishing a UPL.[4] The methodology must include, among other things, consideration of the cost of administering or dispensing the prescription drug and the cost of distributing it to Colorado consumers.[5] However, 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, let alone demonstrated that it has adhered to such a methodology in its decision to set a UPL for Enbrel in the Draft Proposed Rule.[6] Indeed, the Draft Proposed Rule fails to demonstrate how statutory factors were considered in the Board's decision to set the UPL, if at all.

The Board has stated that its 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."[7] Yet, the Draft Proposed Rule does not provide any explanation for the Board's proposal to set a UPL at the MFP. Instead, the Board appears to have relied on what it considered to be a "reasonable benchmark"—one established under a separate, federal statutory regime and that is the product of different considerations than those required under the PDAB Statute.[8] Adopting a "benchmark" is not a substitute for adopting and applying a concrete and consistent, statutorily mandated UPL-setting methodology or engaging in meaningful consideration of statutorily mandated UPL-setting factors. Moreover, the absence of any methodology or explanation of the Board's rationale for selecting the MFP as the proposed UPL restricts stakeholders' abilities to provide meaningful feedback. The continued lack of clear standards for the UPL-setting process risks arbitrary and inconsistent decision-making in violation of the PDAB Statute and the Colorado Administrative Procedure Act ("APA").[9]

Furthermore, while the Draft Proposed Rule states that the price per unit of the UPL will be reviewed and updated annually, the Board has not sufficiently explained how this review will occur or under what circumstances a UPL may be rescinded or revised.[10] PhRMA reiterates its request that the Board establish, through notice-and-comment rulemaking, a transparent process for periodic review of the continued propriety of a UPL and its alignment with statutory requirements.[11] Such a process should include clear criteria for reevaluation, a defined timeline, and meaningful opportunity for stakeholder input.

Finally, consistent with our previous comments, PhRMA asks the Board to confirm that, when it finalizes the Draft Proposed Rule and publishes an official proposed rule in the Colorado Register, there will be a distinct opportunity for public comment on the official proposed rule, consistent with the requirements of CRS § 24-4-103.[12]

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[4] *See* CRS § 10-16-1407.
[5] *See id.* § (2); *see also id.* §§ (3)-(4) (additional methodological requirements).
[6] *See id.* § (2); 3 Colo. Code Regs. 702-9, § 4.1(C)(2); Board Policy Number 05: Upper Payment Limit Policy and Procedure 3-5; *see also* Letter from PhRMA to Board 2 (May 16, 2025).
[7] Board, Regulatory Analysis - Proposed Rule # 3 CCR 702-9 Part 4.3 Upper Payment Limit for Enbrel 3, https://doi.colorado.gov/sites/doi/files/documents/Regulatory%20Analysis%20%20%282%29.pdf.
[8] Upper Payment Limit Rulemaking Hearing (Aug. 22, 2025).
[9] *See* CRS § 10-16-1407; CRS § 24-4-101 *et seq*.
[10] Draft Proposed Rule § 4.3(E).
[11] See Letter from PhRMA to Board 3 (May 16, 2025). 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).
[12] *See* Letter from PhRMA to Board 3 (May 16, 2025).

II. Improper Characterization of MFPs as "Negotiated" Prices

The Board has previously characterized MFPs as the results of "negotiations between the manufacturer and CMS."[13] Additionally, during its August 22, 2025, UPL rulemaking hearing, Board members repeatedly justified the Board's decision to set the UPL at MFP by asserting that the MFP was a "negotiation" between manufacturers and CMS.[14] These statements misrepresent the MFP-setting process.

Under the IRA and CMS's implementing guidance, the process for establishing an MFP is not a "negotiation" in any traditional sense of the word.[15] In fact, CMS has the unilateral, nearly unconstrained authority to both set any price it wishes (below a statutory ceiling) and impose severe penalties on manufacturers who do not agree to the CMS-set price (or even engage in the process), with little-to-no transparency on how CMS reached this price in the first place. If a manufacturer does not agree to "negotiate" or agrees to negotiate but does not agree with the MFP that CMS sets, the manufacturer must withdraw *all* of its products from Medicare and Medicaid—which account for approximately 45 percent of nationwide retail prescription drug spending.[16] Manufacturers' only alternative is to accept an excise tax of up to 1,900 percent and, in some circumstances, civil monetary penalties. Such penalties and taxes command acquiescence, rather than true negotiation.[17] Furthermore, CMS dictates MFP terms through a rigid, non-negotiable framework. Manufacturers are required to sign the agreement with CMS before knowing the final price, cannot revise terms, and are denied legal recourse or transparency into CMS's decision-making process.[18]

As discussed above, PhRMA remains concerned about the Board's UPL-setting process. Such procedural concerns are compounded by the Board's fundamental mischaracterization of MFP, against which it seeks to benchmark the Enbrel UPL.

* * *

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

Sincerely,

Katelin Lucariello
Deputy Vice President, State Policy

Alexandra Hussey
Senior Director, Law

[13] Board, Board Staff Memo, Upper Payment Limit Benchmarks - Cost & Price Metrics and Data Details (Nov. 22, 2024).
[14] Upper Payment Limit Rulemaking Hearing (Aug. 22, 2025).
[15] *See* Decl. of Patrick Costello, *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-00707-DII (W.D. Tex. Aug. 10, 2023), ECF 35-6 at ¶¶ 12-14, 20 (describing the MFP-setting process and indicating that, "[a]bsent a legal compulsion to do so, Amgen would not agree to these prices.")
[16] Congressional Budget Office ("CBO"), Prescription Drugs: Spending, Use, and Prices (January 2022), https://www.cbo.gov/publication/57772.
[17] In fact, the CBO score for the IRA presumes that the excise tax will not generate any revenue independent of its effects on Medicare drug pricing through imposition of the government's MFP. *See* CBO, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14 at 5 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.
[18] *See* Inflation Reduction Act of 2022, Pub. L. 117-168, §§ 11001(c), 11002(c) (lack of notice-and-comment rulemaking); 42 U.S.C. § 1320f–7, Social Security Act § 1198 (lack of judicial review).

EACH PIC COALITION

September 30, 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) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

We remain concerned with the implications of setting an upper payment limit (UPL) for Enbrel in Colorado at the Medicare Maximum Fair Price (MFP). We offer the below input and urge the board not to proceed with establishing a UPL for Enbrel due to the potential unintended consequences for patients.

UPLs Do Not Address Patient-Reported Obstacles

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:

- Patients facing out-of-pocket costs at all levels (from $10-250+) still described their drugs as unaffordable due to insurance barriers, low income, cumulative costs, and inability to access financial assistance.
- 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.
- No individual drug emerged as singularly creating hardship; instead, affordability and access were more directly impacted by insurance coverage and personal life circumstances.

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.

Promises of Monitoring and Safeguards Are Not Sufficient

We remain deeply concerned that the board is considering moving forward with a UPL before establishing any safeguards or even a framework for monitoring and accountability. 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, we have been discouraged by the lack of due diligence that the board has taken so far in obtaining assurances from insurers and PBMs that UPLs will be implemented into existing plans in a way that will not lead to increased utilization management. The board’s inability to gather even basic feedback from plans and PBMs does not lend confidence in the board’s ability to access the information and input it will need in the future to effectively monitor for negative patient outcomes as a result of UPL implementation.

At a minimum, the board should design and publish for public comment their plan for an accountability and monitoring framework 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.

Absent these measures, patients will be subject to the risks of an untested and unproven policy experiment.

Concerns with Application of MFP

We are also troubled by the Board’s reliance on the Medicare MFP as a benchmark. The Medicare population and benefit structure differ significantly from those of Colorado’s commercial and Medicaid populations, making the MFP an inappropriate proxy for state-level affordability. Moreover, the first MFP rates will not take effect until 2026, and their outcomes remain unknown. Defaulting to the MFP avoids the difficult work of establishing an appropriate price for Colorado’s system and patient needs.

Conclusion

The EACH/PIC Coalition shares the board’s commitment to improving drug affordability. We respectfully call on the Colorado PDAB not to move forward with a UPL on Enbrel until more is known about its impacts and until safeguards, monitoring processes, and patient protections are in place.

The board has heard, but so far failed to heed, repeated warnings from patients, patient organizations, hospitals, pharmacies, and providers of potential unintended consequences of implementing a UPL in Colorado. Patients must not bear the burden of policies that are untested, inadequately monitored, and unlikely to address the affordability barriers they actually face.

EACH PIC COALITION

We thank you for your commitment to drug affordability and stand ready to work with you to design reforms that prioritize patient access and real affordability solutions.

Sincerely,

Tiffany Westrich-Robertson
tiffany@aiarthritis.org
Ensuring Access through Collaborative Health (EACH) Coalition Lead

Vanessa Lathan
vanessa@aiarthritis.org
Patient Inclusion Council (PIC) Coalition Lead

COMMUNITY ACCESS NATIONAL NETWORK

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October 1, 2025

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

RE: Ongoing UPL Development

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.

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.

Clarity On How A UPL Can Adversely Affect Access

Payers, whether private insurers or government programs, finance or reimburse the cost of health services. In this case, the focus is on prescription drugs. Health plans vary in structure regarding how and what kind of specific coverage they provide. Unlike MFP negotiations, a UPL is a reimbursement cap. It is not a direct negotiation with a manufacturer for the acquisition price of a drug. A UPL is only a reimbursement cap on what payers in a state are allowed to pay for a medication.

If a UPL is set too low, pharmacies would operate at a financial loss, as the acquisition cost of a drug would be higher than the reimbursement from the health plan. Wholesalers, where pharmacies source their medication, are outside of the state, thus not beholden to any UPL statute. Thus, if they are not going to be paid appropriately, pharmacies can't realistically be expected to purchase the medication.

Reimbursement comes from the PBM. As has been established, PBM contracting and rebates are convoluted, complex, and opaque. It is also understood that PBMs link their compensation to the price of a drug. A secondary issue is that if a UPL is set too low, it could mean that a PBM would be unable to obtain contracting with a manufacturer because the manufacturer would be unwilling to accept payment terms for a drug as a result of the terms a PBM would create for its own financial benefit based on the potential for profit at the UPL. Therefore, a plan would have to remove a drug from the formulary, thereby removing patient access.

In a different scenario, a UPL that is set too low might actually get utilized by a plan. However, to offset the cost, the formulary would be adjusted to move the drug to a higher cost-sharing tier to increase the financial burden on the patient and lower the financial risk to the plan. This is another way a UPL could adversely affect patient access, by increasing cost-sharing to patients. There are already instances where patient cost share exceeds the plan's spend for a drug. And this is precisely why CANN has attempted to educate this body on plan design concerns as they directly impact both patients and plan sponsors (i.e. the state and state programs).

It is too simplistic a view, especially since UPL implantation is currently unclear, to assume that a UPL would immediately, or ever, result in a reduction in patient out-of-pocket costs, regardless of the decrease in PBM spend. It is important to note that plan spend and PBM spend are two different things. PBMs bill plans for medications and services. Thus, instead of passing any savings onto health plans PBMs would increase their overall fees billed to plans to absorb any savings as profit. UPL statute focuses on plan spend, not PBM spend, thus not capturing any drug-specific fiscal improvement.

Moreover, in the MFP negotiations, pharmacies and providers are required to be made whole by manufacturers paying the difference between the negotiated MFP and the actual acquisition costs. A UPL does not provide that. **Loss would simply be loss**. A UPL does not create an agreement for a pharmacy to acquire medication at the UPL. Additionally, regarding implementation, it was expressed in the last meeting that the Colorado Department of Insurance would be the party to enforce and monitor compliance with the direct pass-through of plan savings directly to patients. That is an additional administrative procedure that has to be created but for which no clear process has been established, raising doubts as to DOI's ability to enforce.

Monitoring remains unclear

During the last meeting, staff indicated that they are developing ways to monitor various aspects of a UPL's effects on the system, pharmacies, providers, institutions, and patients. Monitoring methodology needs to be thoroughly articulated *before* a UPL is implemented to ensure an established baseline. This is the most basic scientific method for testing untested actions. Additionally, the planned monitoring methodology should be posted to allow the public to review and provide comments. There are also many concerns regarding implementation that need to be addressed. For example, carriers can appeal by identifying that a particular UPL is unacceptable. How will the appeal process work? In terms of monitoring after a UPL is implemented, part of the information will come from complaint investigation, but **no process for complaint by a patient losing access has been clearly articulated**. A complaint implies that a harm has been done. Contingency plans should be in place to protect aggrieved parties from harm before it actually occurs. Whether it is policy or the appropriation of funds, safety nets need to be established *before* implementation, as a complaint indicates some kind of adverse access. Aggrieved parties cannot wait for a lengthy resolution regarding patient care. **Care delayed is care denied.**

Also, now that a potential UPL has been identified, is there an analysis being conducted to examine the change in current system spending levels that would occur at that price point? As indicated by the lack of sufficiency and completeness of APCD data used in the affordability review process, APCD data monitoring is simply not sufficient in this respect either. Is there an established goal of acceptable savings that subsequently identified change can be compared to? Change for the sake of change is not beneficial if the expenditure of various resources (time, money, administrative burden, policy creation, etc) to implement change does not justify the result.

Lastly, at the last meeting, there was consensus that setting a UPL at an MFP is a good price point because a manufacturer would not have agreed to an MFP if it was not financially acceptable. We question that rationale since MFP and UPL are operationally different in terms of reimbursement, and a state does not have the same volume of sales as the federal government, among other distinct concerns articulated above.

We appreciate all your ongoing efforts and encourage further development from multiple angles before any UPL is finalized. Now that a potential UPL has been suggested, it is vital to analyze the potential fiscal and patient access impacts associated with that price point.

Respectfully submitted,

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

On behalf of
Jen Laws
President & CEO
Community Access National Network

Bridget Dandaraw-Seritt

Founder, Advocates for Compassionate Therapy Now

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Advocates for Compassionate Therapy Now
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30 SEPTEMBER 2025

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

Dear Members of Colorado Prescription Drug Affordability Board,

Hello members of the Board,

I'm writing again to express concerns that not all outcomes of an upper payment limit are being considered, and that we are potentially placing patients into situations where access will be impeded or taken away altogether.

- **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.
- **Local pharmacies may choose not to stock drugs with UPLs because reimbursement is too risky.** As you know, outside the Front Range, Colorado is a pharmacy desert. Independent pharmacies are closing at alarming rates making access to care even harder. There does not appear to be a back up plan to help local pharmacies guarantee proper reimbursement so they can continue providing for their communities.
- **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.
- **There is no patient representation on the Board.** We understand the Board feels patients would not be able to comprehend information outside their specific conditions, but we disagree. You all are learning as you go and a patient is just as capable of doing the same. There have been several times it's appeared that you all don't have a full grasp on what impacts the

UPL will have, with multiple comments being made about helping uninsured and Medicare. You've also mistakenly suggested Trikafta had therapeutic alternatives. You've learned as the process has progressed, and a patient is just as capable as you of doing the same thing. We bring a perspective you cannot have unless you are in our shoes and could help make sure that our experiences are at the forefront of each decision.

- **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.
- **Despite statute requiring payers to show how they saved Coloradans money, we have serious doubts that Coloradans will see savings in any form.** There is research suggesting that UPLs will increase barriers to access like non-medical switching, preauthorization tactics, and will choose medications based on back end rebates rather than choose cost effective alternatives. These concerns were blown off because we already have to deal with them. The Board made it seem like these are no big deal and easily appealed, and this is not the case. These appeals take **months** and cause us additional stress. Increasing these delay tactics place our health at risk.

We look forward to working with the Board to address these issues before further reviews happen.

Sincerely,

Bridget Dandaraw-Seritt

AIMEDALLIANCE

September 24, 2025

Via Electronic Correspondence

Dr. Gail Mizner
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

RE: Concerns About the Enbrel UPL Rulemaking Process

Dear Chair Mizner:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the Colorado Prescription Drug Affordability Board's ("PDAB" or "Board") commitment to addressing the rising cost of prescription drugs for Colorado patients. As the Board continues to move forward with the upper payment limit (UPL) rulemaking process for Enbrel, Aimed Alliance urges it to proceed with caution, carefully evaluating potential unintended consequences and ensuring that patient feedback is meaningfully prioritized during the process.

I. Exercise Caution as the Board Proceeds with the UPL Rulemaking Process and Consider Unintended Consequences

Aimed Alliance appreciates the inherent challenges and complexity of conducting affordability reviews. However, we are concerned by the Board's accelerated timeline and recent challenges in data collection and interpretation. Therefore, we urge the Board to proceed with caution and diligence to ensure the Board has the opportunity to consider and mitigate potential unintended consequences of a potential UPL, without the quality of the Board's decisions and the public's confidence in its work.

Aimed Alliance is particularly concerned given the recent issues with data accuracy during the affordability review process. During the April 2025 meeting, the Board acknowledged that data submitted by a pharmacy benefit manager (PBM) had been mischaracterized, creating confusion between Medicare and commercial data sets. Although the Board claimed this error would not affect its affordability reviews, it remained unclear to advocates and consumers how this mischaracterized data would not negatively influence the review process. Ultimately, the Board decided to proceed without fully addressing the public's concerns, jeopardizing public trust in this process.

Now, as the Board moves through the UPL rulemaking process for Enbrel, Aimed Alliance is concerned by the potential for significant unintended consequences. Data show that 57 percent of surveyed health plans expect both UPL-targeted drugs and their therapeutic alternatives to face formulary changes, and half anticipate increased utilization management.[1] Thus, there is a strong

[1] Avalere Health, *Update: Health Plans' Perceptions of PDABs and UPLs* (Mar. 28, 2025), https://advisory.avalerehealth.com/insights/update-health-plans-perceptions-of-pdabs-and-upls.

likelihood that PBMs may choose to exclude Enbrel from formularies or subject patients to non-medical switching once a UPL is implemented.

While the Board acknowledged that non-medical switching already occurs, it is important to recognize that this practice is harmful to consumers who have spent months or years testing, trying, and failing on alternative treatments before identifying a treatment that works for them. For these patients, non-medical switching jeopardizes their health and all their hard-earned progress. Furthermore, when patients are currently stable on a treatment and forced to change medication, this risks disease flares, reduced treatment effectiveness, and higher downstream medical costs that could erase any short-term savings derived from a UPL.

Moreover, the Board's recognition that non-medical switching is an existing practice should not be considered an endorsement of this tactic in health insurance or a reason for the Board to dismiss how this practice may be expanded by a UPL. It is the job of policymakers, like this Board, to mitigate or prevent bad practices, not to perpetuate them.

Establishing a UPL is likely to intensify, not merely maintain, this practice. As such, the Board has an obligation to identify how it will ensure that consumers who are stable on their current treatments are not non-medically switched due to the implementation of a UPL. While the Board has recognized these potential unintended outcomes, the Board has only indicated that it could address this issue by withdrawing a UPL, if necessary. While Aimed Alliance appreciates the Board considering solutions to potential access challenges, this raises critical process questions regarding implementation. For example, what will be the threshold for establishing sufficient harm for a UPL to be withdrawn; can the harm only be to consumers, or will provider-harm be included as well; what data sources will be used; and how will it be collected and measured? Aimed Alliance believes these are all critical questions that must be answered, and without a clear, enforceable mechanisms to monitor patient impact, the ability to withdraw a UPL provides minimal protection.

Aimed Alliance does not intend for a slower process to halt, change, or alter the intent of the Colorado Board to develop upper payment limits for selected prescription drugs. However, considering the approach adopted and implemented by the Board will be replicated by the Board in future reviews, and potentially by other state PDABs, we urge the Board to develop a thoughtful process that ensures a meaningful way for consumers to engage the Board if a UPL establishes an access challenge.

Ultimately, Aimed Alliance urges the Board to exercise caution as it advances the rulemaking process and ensure a credible, meaningful, replicable, and sustainable process is developed that includes a mechanism to address unintended consequences. This will promote public trust in the process and ensure better outcomes for patients, providers, and caregivers in the long-term.

II. Prioritize the Patient Voice During the UPL Rulemaking Process

Aimed Alliance appreciates the Board's commitment to incorporating the patient voice into the cost review process. Patients are the individuals most directly impacted by affordability

determinations, yet their perspectives are far too often underrepresented in healthcare decision-making.

For example, a recent patient-led study found that prescription drug affordability was complex and varied between individuals.[2] Importantly, the survey found that access and affordability are often conflated, with 75% of respondents stating they skipped or stretched doses at least once due to insurance delays, not price. While less than 15% reported skipping or missing doses solely due to price.[3] As such, Aimed Alliance urges the Board to not only engage with patients through information surveys and public comment periods, but to also meaningfully integrate and reconcile patient-reported feedback and data with its final affordability determinations. Reconciling decisions with feedback informs consumers on how their information was helpful and encourages consumers to continually engage with these processes.

Moreover, reconciliation of feedback and decision-making can provide greater clarity to regulators, policymakers, and legislators on the types of supplemental reforms that may be necessary to better and more directly address consumer affordability. For example, if a primary reason consumers report a drug as unaffordable is out-of-pocket costs resulting from delays in prior authorization—rather than the actual price of the drug—it is important to reconcile why the Board would pursue a UPL for a drug whose unaffordability is not driven by its cost. However, insights like this may not be adequately derived from survey questions that are not designed with patients, caregivers, and healthcare consumers in mind. Therefore, Aimed Alliance urges the Board to center patient experience throughout its affordability reviews to adequately understand the factors that make a prescription drug "unaffordable."

III. Conclusion

In conclusion, Aimed Alliance commends the Board for its commitment to addressing the rising cost of prescription drugs for Colorado patients. However, we urge the Board to proceed with caution, carefully evaluating potential unintended consequences and ensuring that patient feedback is meaningfully prioritized during the process. Aimed Alliance looks forward to continued engagement as the Board conducts its affordability reviews. If you have any questions or wish to discuss these matters further, please contact us at policy@aimedalliance.org.

Sincerely,

Olivia Backhaus
Staff Attorney

[2] EACH/PIC Coalition, *EACH/PIC Releases Results from Patient-Led Survey on Drug Affordability* (Aug. 4, 2025), https://eachpic.org/each-pic-releases-results-from-patient-led-survey-on-drug-affordability/.
[3] *Id*.

September 30, 2025

Prescription Drug Affordability Board
c/o Sophie Thomas, Prescription Drug Affordability Director
Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

Re: Comments on Draft Proposed Rule – Upper Payment Limit for Enbrel (Etanercept)

Dear Members of the Board:

On behalf of the Colorado Association of Health Plans (CAHP), which represents health insurers covering more than 2.5 million Coloradans, we appreciate the opportunity to comment on the draft regulation establishing an Upper Payment Limit (UPL) for Enbrel (Etanercept).

We remain supportive of efforts to reduce the high cost of prescription drugs in Colorado. However, we are deeply concerned that the **proposed implementation timeline—set to take effect as soon as six months following adoption—is insufficient** for carriers to meaningfully operationalize a UPL, particularly for a specialty biologic such as Enbrel.

Concerns Regarding Implementation Timeline
Carriers operate under a tightly regulated environment with numerous statutory and contractual obligations that make quick implementation of a UPL nearly impossible without triggering compliance risks or consumer disruption. Specifically:

- **Formulary design and tiering decisions** are made well in advance of each plan year, and must be submitted to the Division of Insurance (DOI) as part of rate filings.
- Many carriers contract with **Pharmacy Benefit Managers (PBMs)** under multi-year agreements that limit unilateral changes to pricing arrangements or drug access mid-contract.
- **Changes to formularies during the plan year** are restricted under both state and federal law, including **HB22-1370** and **ACA requirements** related to formulary stability and midyear cost-sharing changes.
- The UPL may necessitate a **new formulary tier or drug-specific copayment**, which could affect a plan's **actuarial value** and compliance with standardized plan requirements, such as those required for the **Colorado Option**.
- If a carrier cannot comply via formulary tier adjustment, it may need to engage **utilization management tools** to remain under the UPL—which triggers a separate set of compliance obligations.

Given these constraints, we urge the Board to adopt a **longer implementation horizon—no less than 18 to 24 months—**to allow for appropriate planning, actuarial analysis, contract renegotiation, regulatory filings, and consumer notifications.

Regulatory and Statutory Compliance Considerations

We respectfully remind the Board that health plans are subject to a wide array of existing state and federal requirements that govern how medications are covered, accessed, and managed. These include, but are not limited to:

Statutes:

- § 10-16-103 - Proposal of mandatory health-care coverage provisions
- § 10-16-103.4 - Essential health benefits - requirements – rules
- § 10-16-103.6 - Copayment-only prescription payment structures - required inclusion in health benefit plans – rules
- § 10-16-112 - Private utilization review - health-care coverage entity responsibility – definitions
- §-16-112.5 - Prior authorization for health-care services - disclosures and notice - determination deadlines - criteria - limits and exceptions - enforcement - definitions - rule
- § 10-16-122, C.R.S. – Requirements on prior authorization and step therapy for prescription drugs.
- § 10-16-145, C.R.S. – Step therapy--limitations--exceptions--definitions--rules
- **§** 10-16-156 - Prescription drugs - rebates - consumer cost reduction - point of sale - study - report - rules – definitions
- **§** 10-16-168 - Carriers - health care - price transparency - rules - legislative declaration - definitions
- Affordable Care Act § 156.122 – Coverage of essential health benefits, including prescription drugs, and related formulary standards.

Regulations:

- Amended Regulation 4-2-81- Concerning Colorado Option Standardized Health Benefit Plans
- Amended Regulation 4-2-17 Prompt Investigation of Health Claims Involving Utilization Review and Denial of Benefits and Rules Related to Internal Claims and Appeals Processes
- Amended Regulation 4-2-21 External Review Of Benefit Denials Of Health Coverage Plans
- Amended Regulation 4-2-42 Concerning Essential Health Benefits
- Regulation 4-2-94 Concerning Health Insurer Reporting Of Prescription Drug Rebates and Discounts
- New Regulation 4-7-3 Standards for Health Maintenance Organizations

We encourage the Board to closely coordinate with the Division of Insurance to ensure that any final UPL implementation is feasible within these overlapping frameworks.

As written, the proposed rule risks placing carriers in an untenable position—held to a new price ceiling without sufficient time, authority, or supply chain leverage to adjust plan designs accordingly. We urge the Board to extend the implementation timeline and to consider aligning any future UPLs with the standard regulatory planning cycle for health insurance carriers.

Thank you for your continued engagement and transparency. We stand ready to assist the Board in evaluating the operational impact of UPL implementation and remain committed to working collaboratively toward drug affordability solutions that are actionable, equitable, and patient-centered.

Sincerely,

Kevin M. McFatridge
Executive Director
Colorado Association of Health Plans

amgen.com

Amgen Inc.
1 Amgen Center Drive
Thousand Oaks, CA 91320 USA
(805) 447-1000

October 1, 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

Re: **Proposed Upper Payment Limit for Enbrel® (etanercept)**

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 object to the Board's proposed upper payment limit (UPL) for Enbrel®.

I. The Proposed UPL Would Not Result in Any Patient Paying Less for Enbrel

Amgen is driven by its mission to serve patients and committed to improving lives by discovering and developing treatments and cures for serious diseases. Amgen understands that the cost of prescription drugs is a concern for many Coloradans, but these concerns will only increase if the Board proceeds to set a UPL for Enbrel and ignores patients' voices.

The Board's rulemaking proceedings have underscored the Board's lack of focus on the many Colorado patients who use Enbrel. As patient advocates have pointed out, the proposed UPL would not provide any direct benefit to patients, because there is no evidence that any patient currently pays more than the proposed UPL out-of-pocket for Enbrel. This is due to a combination of insurance and Amgen's generous patient assistance programs. The Board has largely ignored Amgen's patient assistance programs in its assessment of "affordability," except to insist that Amgen has a "public obligation[]" to continue providing assistance at the same level even as the UPL would dramatically alter the payment and reimbursement landscape in ways not yet acknowledged by the Board. Consequently, any cost savings from a UPL will go not to patients, but to insurance companies.

Board members have not disputed this. Instead, they have emphasized that insurers are required to use any savings from a UPL to "reduce costs to consumers" in general, not to Enbrel patients specifically. The Board,

however, has made no effort to determine whether and to what extent a UPL on Enbrel would reduce insurance premiums or co-pays.

Moreover, this justification for a UPL—that it will reduce costs for insurers, which may or may not translate into marginally lower costs for commercial insurance—is utterly disconnected from the Board's putative reasons for subjecting Enbrel to a UPL. The Board determined that Enbrel was "unaffordable for Colorado consumers" based on claims that "the cost of Enbrel has made it difficult to access the drug" and that patients in Colorado "had trouble affording Enbrel." Yet the Board now acknowledges that a UPL will do nothing to make Enbrel more affordable for patients or improve access.

This is not surprising, because Enbrel is already affordable for patients. As Amgen explained in its October 2, 2023, submission, "roughly two-thirds, or 67 percent, of prescriptions nationally, including those where the Enbrel® Co-Pay Card was used, cost $10 or less per month. The remaining one-third of prescriptions cost an average of $341 per month. Overall, only 14 percent of prescriptions cost more than $100 per month." In concluding that Enbrel was nonetheless "unaffordable" for patients in Colorado, the Board relied on a handful of comments during public meetings and survey responses from 38 Colorado residents—amounting to, at most, roughly 1.5% of the 2,500+ patients who use Enbrel in Colorado each year. The Board never made any effort to determine whether the information it gleaned from this tiny sample was representative of patients' experiences with Enbrel, and it plainly was not.

In sum, the Board's determination to establish a UPL for Enbrel is a solution to a supposed affordability problem that does not exist and would not be helped by a UPL if it did exist. Moreover, Board members have repeatedly acknowledged that they have no clear understanding of whether a UPL will harm patients, with one member insisting that "no one can predict exactly what will happen" if a UPL is established. This uncertainty also reflects the Board's failure to provide any details about how a UPL will be implemented – the absence of which has been raised as a key concern by representatives of critical components of the delivery system, such as the Colorado Pharmacists Society[1] and Healthcare Distribution Alliance[2]. Rather than rush to impose a UPL on Enbrel with no idea what the consequences may be, the Board should listen to stakeholders, such as patients, caregivers, and advocacy groups, who have repeatedly warned the Board of the unintended negative consequences of a UPL.[3]

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[1] *See* Verbal Testimony of Emily Zadvorny, Executive Director of the Colorado Pharmacists Society to the Colorado Prescription Drug Affordability Review Board (Aug. 23, 2025).

[2] *See* Written and Verbal Testimony of Leah Lindahl, Vice President, State Government Affairs, Healthcare Distribution Alliance, to the Colorado Prescription Drug Affordability Review Board (May 23, 2025).

[3] *See also* Written Testimony from Kathy Sherman, Associate Vice President, State and International Government Affairs, Amgen, to the Colorado Prescription Drug Affordability Review Board (Aug. 20, 2025),

II. The Proposal to Adopt the Federal MFP as the State UPL for Enbrel Is Improper

The Colorado legislature required the Board, before establishing any UPLs, to "determine by rule the methodology for establishing an upper payment limit." As Amgen has pointed out many times (with no response from the Board), the Board violated that legislative mandate by holding rulemaking hearings to set a UPL for Enbrel without ever establishing a methodology for setting UPLs. The lack of a clear methodology has made it impossible for Amgen and other stakeholders to participate meaningfully in the rulemaking process.

The Board's failure to establish a mandated methodology culminated in the Board's proposal, at the third Enbrel UPL rulemaking hearing on August 22, 2025, to set the UPL for Enbrel at a price that the Board deemed equivalent to the federal "maximum fair price" (MFP). The Board did not perform any independent analysis to determine whether the federal MFP would be appropriate as a UPL in Colorado. Instead, Board members stated that they could avoid the difficulty of determining an appropriate UPL by simply adopting the MFP. As one Board member stated: "I know a lot of people are concerned. How are you going to come up with that price? What is the calculation? Where's the research? Well, in this instance, it was already done at that level." This is improper for several reasons.

First, the Board members' comments show that the Board fundamentally misunderstands the federal MFP. Board members repeatedly suggested that Amgen's participation in the so-called "negotiation" process required by the federal Inflation Reduction Act (IRA) implies that Amgen "agreed to" or was "amenable to" the MFP. That is wrong.

Regarding a drug's federal MFP as a "negotiated" price to which the drug's manufacturer has voluntarily "agreed" is deeply misleading. As Amgen and other drug manufacturers have explained, the IRA does not provide for any meaningful negotiations. Instead, after an exchange of offers bounded by an already drastically low statutory ceiling price, the MFP is unilaterally dictated by the Centers for Medicare and Medicaid Services (CMS). A manufacturer that does not "agree" to the price CMS demands faces a massive, punitive "excise tax" that quickly rises to 19 times the manufacturer's total revenue for the drug. The manufacturer's only alternative is to withdraw all its drugs from Medicare and Medicaid, which together account for nearly half of the national market for prescription drugs. Such withdrawal would cause severe financial harm to the manufacturer and deprive patients nationwide of access to critical medicines.

CMS uses these overwhelming threats to force drug manufacturers to "agree" to the government's price even when it is far below a level that the

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https://doi.colorado.gov/sites/doi/files/documents/August%2022%20Written%20Testimonies.pdf.

manufacturer considers fair and reasonable. Amgen thus had no choice but to adopt the MFP dictated by CMS. To be clear, Amgen strongly disagrees that the MFP is the "maximum fair price" for Enbrel—it is not even *a* fair price. Amgen would never agree to sell Enbrel for this price in a genuine negotiation.[4]

Second, an MFP regulates only the price charged for a drug in sales to individuals and entities participating in Medicare. It is not intended to be, and cannot logically be repurposed as, a price cap for sales made in the private market.

When CMS establishes an MFP, it is well aware that the MFP will not apply to private sales, which account for roughly half of the national market for prescription drugs. CMS is thus able to set the MFP for sales to Medicare at an extremely low level while assuming that sales in private markets will continue to provide a return on the manufacturer's investment and incentivize further innovation.

There is no evidence that CMS concluded the Enbrel MFP would be an appropriate price cap for all transactions for Enbrel across both public Medicare and private markets. Nor is there any basis to assume that CMS would have set the MFP for Enbrel at the same low level if it had been charged with establishing a price cap for private as well as public Medicare transactions.

For its part, the Board has not explained why extending the MFP to private markets is appropriate. Among other things, it has not performed any analysis to show that extending the MFP to private sales would not harm patients and destroy incentives for manufacturers to invest in developing innovative prescription drugs.

In this regard, it is significant that federal law requires Medicare Part D prescription drug plans to cover MFP drugs. This requirement prevents PDPs from dropping an MFP drug from their formularies because the capped price does not allow for the same level of manufacturer rebates.[5] Colorado law does not include any similar requirement, and the Board has not performed any analysis to determine whether the proposed UPL would result in PBMs/insurers dropping Enbrel from their formularies, leading to reduced patient access. Indeed, despite ostensibly being on the cusp of adopting a UPL, the Board has failed to even develop the details on how the UPL would

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[4] For these reasons, Amgen supports the constitutional challenge to the IRA brought by the Pharmaceutical Research and Manufacturers of America (PhRMA), of which Amgen is a member. That challenge is pending in the U.S. Court of Appeals for the Fifth Circuit. *See Nat'l Infusion Ctr. Ass'n v. Kennedy*, No. 25-50661. Regardless of the outcome of that case, the simple fact is that Amgen had no meaningful choice but to accept the MFP dictated by CMS.

[5] *See* 42 U.S.C. § 1395w-104(*l*).

be effectuated across eligible private transactions to individuals within the state of Colorado.

Third, contrary to suggestions made by Board members, there is no evidence that the federal MFP reflects a reasoned analysis of the factors that are relevant to establishing a UPL under Colorado law.

CMS did not provide any meaningful explanation of how it arrived at the MFP. While CMS has published a document purporting to explain how the MFP was determined, that document states only that CMS "considered certain negotiation factors" and "took into account all data in totality." CMS's process for establishing the MFP is a black box: CMS claims to have considered various factors and data (not all of which is public), but it is impossible to know how CMS weighed the factors or how it used the data to calculate the MFP.

For the Board to simply adopt this black-box MFP as the UPL, without conducting any independent analysis of whether the MFP represents a fair and reasonable price for Enbrel, would abdicate the Board's statutory responsibility for setting UPLs. This abdication is made even more problematic by the fact that CMS is not even required to consider the same factors as the Board. For example, the legislature directed the Board to consider "the impact [of a UPL] to older adults and persons with disabilities," but no similar requirement applies to CMS. Adopting the MFP as the UPL is also contrary to the Board's own regulations, which state the MFP is one of numerous factors the Board may consider in setting a UPL, but which do not allow the Board to rely on the MFP to the exclusion of all other factors.

Accordingly, while it might be appropriate to consider the MFP as a *lower bound* on any UPL (since Congress instructed CMS to "achieve the lowest maximum fair price for each selected drug"), it is improper for the Board to set the UPL at the same level as the MFP without independent analysis. The Board cannot refuse to do its job under Colorado law just because that job is difficult.

Conclusion and Path Forward

Amgen is driven by its mission to serve patients. We recognize concerns about prescription drug affordability, but a UPL as currently proposed would discourage pharmaceutical innovation and substantially increase access risks for Coloradans, including patients who rely on Enbrel®, particularly vulnerable pediatric populations. The scope of such risks can only be exacerbated by the absence of appropriate independent analyses and of critical implementation details.

We respectfully request that the Board pause the current rulemaking timeline; address stakeholders' concerns, including those discussed above; and pursue non-UPL efforts and recommendations that will reliably and meaningfully benefit patients.

Regards,
/s/ Kathy Sherman

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

Chronic Care Policy Alliance | State Advocates Working Together to Bridge the Gaps in Chronic Care

September 30, 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 Chronic Care Policy Alliance (CCPA) works with state and regional chronic care policy networks to further good public policy on behalf of patients with chronic illnesses.

Dedicated to achieving better access to quality, affordable health care, CCPA brings together advocates who share common goals and lends its experience in legislative action and public policy creation to support statewide and regional networking development.

CCPA has been monitoring the development and actions of Prescription Drug Affordability Boards (PDABS) throughout the country with an eye toward public policies that benefit and promote affordable patient access to medications they and their providers agree are needed for successful and effective medical care. Patient affordability of their needed medications is a factor in a patient's ability to access the care they need.

We understand that the Colorado PDAB wishes to move quickly to embrace an Upper Payment Limit for the medication, Embrel. However, CCPA believes patient guardrails need to be in place first to protect the financial ability for patients to access medications for their care and not face the barriers that currently are in place.

We are concerned that the institution of UPL caps without or before guardrails protecting patients are in place, will ultimately make access to medications less rather than more accessible and affordable. We and most patient groups have already seen the barriers payers and PBMs have erected which in essence ration care. Moving medications to higher cost formulary tiers, prior authorization policies, step therapy policies are a few examples of barriers to access to care. Another barrier that is currently erected and is probable with UPLs is that formularies will be restrictive where only one medication per class will be available. It is well documented that one medication does not necessarily fit all. In fact, some patients can be on one drug for many years and suddenly find that the drug doesn't work anymore. If payers and PBMs

have only one MFP approved drug per class on their formulary, what timely recourse does a patient have?

No matter what, guardrails need to be in place before UPLs are set. Patients need to be financially and medically protected. Before UPLs are adopted, it is imperative that insurance plans state plainly how they intend to address barriers to care which do not reduce patient out-of-pocket costs, promote non-medical switching, encourage copay accumulators and other barriers.

Thank you for your attention to these concerns. We urge the Colorado Prescription Drug Affordability Board to prioritize patient protection promoting both patient affordability and access to care before ruling on UPLs of medications like Embrel.

Sincerely,

Elizabeth Helms
CEO and Founder

October 1, 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 physician with decades of experience caring for patients whose families often struggle to access and afford necessary medications, I continue to find the Board's proposed implementation of Upper Payment Limits (UPLs) deeply troubling. Implementing a list price cap on Enbrel and future medications will predictably restrict access to these essential treatments and deserves more input from the patients with rare or complex conditions who would be most adversely affected and the clinicians who care for them.

As the Board approaches its final rulemaking hearing for Enbrel's UPL, we believe that the Board still lacks sufficient input and data before making a precedent-setting decision. There remains no evidence supporting the Board's belief that UPLs will reduce patients drug costs or increase accessibility to their critical medications. Rather, historical and economic history suggest that UPLs will create purchasing restrictions that threaten to limit patient access. If the purchase price is capped at a level where the buyer - be it independent physician practices, rural clinics or PBMs - loses money, the product will not be available to the patients who require these essential medications. This final hearing must address the fundamental market reality that UPLs will predictably restrict supply and provider participation rather than lowering patient costs.

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. Further, the Board has yet to detail any plans or metrics to measure the outcomes of your potential decisions. Given its access to significant data, I have also not seen the Board present any predictive modeling demonstrating the potential success of its actions.

If the Board insists on moving forward with this unprecedented policy against the counsel of practicing clinicians, their patients and multiple organizations, then it must establish accountability measures to ensure this untested theory actually achieves its intended outcomes.

This should include at least publishing a detailed implementation timeline, proposing necessary technical amendments to the PDAB legislation that address the complex realities of drug procurement and distribution, and committing to comprehensive tracking and reporting mechanisms that will measure real-world patient access and affordability outcomes.

Notably absent from the Board's rulemaking are any exceptions for Coloradoans who have tried and failed other medications and respond only to Enbrel. What happens to the patient whose disease is controlled exclusively by this medication? What recourse exists when their rheumatologist can no longer offer it because the economics make it impossible? The Board's current approach offers no answers to these predictable scenarios.

I fully understand the Board's difficult position, as 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 actions addressing the multiple cost drivers from other players within the pharmaceutical pricing and supply chain. Given your limitations, it would behoove the Board to pause, review and provide legislative recommendations that its role be expanded so it may include the roles of all 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 drug prices - at least the list, net and out-of-pocket costs. Without examining and addressing the entire drug pricing, supply and distribution chain, improving access to affordable, life-saving drugs is not possible . Effective solutions must focus on what patients actually pay, not inflated list prices. Furthermore, it is critical that the Board monitor, analyze and report on the impact of the policies it has advanced.

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

October 1, 2025

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

Dear Members of the Colorado Prescription Drug Affordability Board,

We write to express our deep concern regarding the Board's decision to adopt an Upper Payment Limit (UPL) for Enbrel. Patients across Colorado are disheartened by this decision. While we share the Board's goal of addressing high prescription drug costs, the evidence presented does not support the conclusion that UPLs will lower patients' out-of-pocket expenses. Instead, research strongly suggests that UPLs will increase barriers to access and disrupt patient care.

Throughout this process, patients and pharmacists offered clear, consistent testimony warning of the risks UPLs pose to affordability, access, and continuity of care. Unfortunately, these voices appear to have been discounted. By moving forward despite this testimony, the Board has signaled that patient, insurer and pharmacist experiences—the perspectives most directly impacted—were not given the weight they deserve.

Colorado has now forged ahead as the first state in the nation to impose an Upper Payment Limit. Other states, faced with the same evidence, have exercised caution, recognizing the

unresolved risks to patients. By pressing forward where others have shown restraint, Colorado has effectively embarked on a reckless policy experiment with serious implications for patient access and continuity of care.

The central assumption of UPLs—that capping reimbursement will reduce costs for patients—lacks supporting data. Avalere Health's analysis of health plan perspectives confirms that payers do not expect UPLs to yield savings at the pharmacy counter[1]. Similarly, Oregon's PDAB proceedings documented broad stakeholder concerns that UPLs add complexity and uncertainty without proven benefits[2]. The National Alliance of State Pharmacy Associations (NASPA) has further emphasized that reimbursement caps place unsustainable financial strain on pharmacies, undermining, rather than improving, affordability[1].

Taken together, this evidence reveals a troubling reality: while UPLs may serve as a symbolic response to high drug prices, they do not achieve the intended outcome of lowering patients' out-of-pocket costs. Instead, they amount to a risky experiment with consequences that will be borne by patients.

Moreover, research and testimony shared throughout this process make clear that UPLs jeopardize access. When acquisition costs exceed reimbursement rates, pharmacies and infusion centers must either dispense at a financial loss or deny patients their prescribed therapies. This risk is particularly acute for biologics such as Enbrel. Oregon's PDAB materials acknowledged these supply chain dangers, with pharmacies warning that reimbursement below acquisition cost would directly impede their ability to serve patients[2]. These disruptions will not remain theoretical—they will be felt at the pharmacy counter or infusion center when patients cannot obtain their medications.

Equally concerning is the predictable response from insurers. Avalere's findings indicate that health plans expect to respond to UPLs by altering benefit designs and formularies, relying more heavily on prior authorization, step therapy, and non-medical switching[3]. These tactics undermine the patient-provider relationship, delay care, and force patients with chronic

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[1] National Alliance of State Pharmacy Associations (NASPA). *Prescription Drug Affordability Boards Resource Center.* (2023). Available at: [https://naspa.us/resource/pdab/](https://naspa.us/resource/pdab/

[2] Oregon Division of Financial Regulation, Prescription Drug Affordability Board. *PDAB Document Package.* (October 16, 2024). Available at: https://dfr.oregon.gov/pdab/Documents/20241016-PDAB-document-package.pdf

[3] Avalere Health. *Update: Health Plans' Perceptions of PDABs and UPLs.* (2023). Available at: https://advisory.avalerehealth.com/insights/update-health-plans-perceptions-of-pdabs-and-upls

conditions into treatments not chosen by themselves or their physicians. For Coloradans already managing complex health challenges, these hurdles will create additional suffering, not savings.

Given these risks, we respectfully request clarity on what actions the Board will take over the next six months to protect patients from these foreseeable consequences. Specifically, we ask:

- What specific assurances can the Board provide that patients will not lose access to their prescribed medications as a result of the UPL for Enbrel?
- How will the Board prevent supply chain disruptions so pharmacies are not forced to choose between dispensing at a loss or denying patients their medications?
- What safeguards will be implemented to protect patients from increased utilization management, non-medical switching, or other insurer-driven changes prompted by UPL adoption?

We are deeply disheartened that the Board has adopted a policy tool with no demonstrated ability to reduce patient costs and with such significant risks to access. By disregarding the consistent testimony of patients and pharmacists, the Board has missed an opportunity to craft policy grounded in lived experience.

As you move forward with UPLs for Enbrel and potentially other medications, we urge you to reconsider the evidence and testimony provided throughout this process. Patients cannot afford to be collateral damage in a well-intentioned but reckless experiment.

We respectfully call on the Board to explain what concrete actions will be taken to mitigate these consequences and to ensure patients maintain access to their prescribed therapies. Without such assurances, this decision will be viewed not as a step toward affordability, but as a barrier to care.

Sincerely,
ACT Now
ALS Association
Community Access National Network
Cystic Fibrosis United
Biomarker Collaborative
Exon 20 Group
The Infusion Access Foundation
ICAN, International Cancer Advocacy Network
Lupus and Allied Diseases Association, Inc.
Lupus Colorado
Mamas Facing Forward
MET Crusaders
National Bleeding Disorders Foundation Colorado Chapter
National Infusion Center Association
PDL1 Amplifieds
Rare Access Action Project
SOCO Special Needs Families

Infusion Access Foundation

Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

October 3rd, 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