AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

June 25th, 2025

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

RE: Board request for additional data and information from stakeholders for their consideration of Enbrel's UPL

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

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases who is also representing the 3,400 plus people in Colorado who are currently prescribed Enbrel. As people living with diseases that are treated with drugs like Enbrel, we understand the cost of our drugs are high and share Board concerns about affordability for Colorado consumers. We thank the Board for this opportunity to provide additional information, as requested, in conjunction with the Data Submission Guide (DSG) and the Enbrel Upper Payment Limit (UPL) hearing.

Duality of Interest. AiArthritis is an organization who relies on support from various entities, including pharmaceutical companies - and Amgen - to implement our patient-identified issues and patient-infused solution projects (see "How we do it" section of our About Us website page). As an organization led by patients and whose programs are a result of our own reported needs, it is against our ethical standards to permit any funder to influence our work. All research and data presented in this submission is 100% conducted by AiArthritis patient leaders and free from collaboration, advice, or commentary from pharmaceutical company supporters. We welcome the Board to view all our projects, 90% which are funded by pharmaceutical companies and 70% which focus on education, awareness, and research and not public policy.

Impact to Persons with Disabilities

The Americans with Disabilities Act defines a person with a disability as a "person who has a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such an impairment, or a person who is perceived by others as having such an impairment" Whether a condition is considered a disability can depend on severity of the disease, how long someone has had the condition,and other factors that might only be identified through the lived experience of an individual diagnosed with the condition. *Staff recommend the Board review stakeholder input regarding whether the prescription drug*

impacts individuals with a disability. We thank Staff for this opportunity to explain the various levels of disability associated with AiArthritis disease - which ranges from mild to severe - and due to the extreme heterogeneity of our conditions why it is vital that no actions by the board negatively impact patient access to these treatments.

AiArthritis diseases, like **rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, juvenile arthritis - all conditions treated by Enbrel -** are complex diseases that require close monitoring using a Treat-to-Target (T2T) approach to achieve low disease activity, potential remission, and the best opportunity to avoid comorbidities. ***Continuity of care is vital for patients, yet because insurance companies view that it is acceptable to cite therapeutic alternatives as a reason to non-medically switch patients to options that cost less for them, patients with our diagnosis struggle to ever achieve remission.***

While it is recommended to initiate treatment within six months of disease onset to increase the probability of remission, it takes several years to get an accurate diagnosis for a majority of patients. Due to several factors, including clinical trials that do not represent real world populations, comorbidities, and disease heterogeneity, only 40-60% respond well to existing treatments. It is estimated that as many as 70% of patients develop comorbidities (including dual diagnosis and conditions such as heart disease or Alzheimer's).The standard arthritis treatment approach of trial-and-error further complicates therapy response.

Regarding how this drug is used for the disease treated by each disease, we would like to take this opportunity to point out that within each **AiArthritis disease diagnosis, there is a spectrum of disease that is dependent on many confounding factors, such as:**

- **Age of the person when onset originates.** While the average age of onset for AiArthritis diseases is 20 to 40 in adults, and any age in children (even at birth), onset can happen at any age.

- **The window of opportunity: Duration of onset to diagnosis, initial treatment, treatment that works for the patient**. The American College of Rheumatology (ACR) recommends early intervention with disease modifying agents as early as 6 months after onset for the best opportunity to achieve remission in people diagnosed with AiArthritis diseases. However, diagnosing these diseases rarely occurs within this time frame for a variety of factors including, but not limited to: 1) delay in detection 2) delay in referral to a specialist 3) access to specialists (health equity, lack of specialists, rural areas).

  The average time to diagnose these diseases varies, but ranges between 1 and 9 years. Fixing the issue of early diagnosis and therapy will increase rates of remission and enable many patients to discontinue use of expensive therapies, like biologics.

- **Mild, Moderate, Severe**. There are also varying degrees of disease severity. Biologics are used largely to treat moderate to severe disease, which is most common. Those with severe disease are most prone to worse outcomes and comorbidities, especially if their treatment is disrupted or they are not matched with the best therapy for their unique needs early on.

- **Comorbidities/Older Individuals.** An estimated 70% or more of people with one AiArthritis disease will develop at least one more autoimmune/autoinflammatory disease, which happens when inflammation is uncontrolled.[1]Uncontrolled inflammation is also responsible for potentially developing heart disease, interstitial lung disease, Alzheimer's disease, and dementia.[2] [3]

- **Disease complexity**. AiArthritis cannot express enough that a diagnosis does not dictate how a disease manifests in any one condition. For example, Etanercept- Juvenile Idiopathic Arthritis often involves inflammation of the eyes (uveitis), but may not be present in all. Choosing a biologic, in this case, may be dependent on which demonstrates higher efficacy and safety in people with uveitis. The American College of Rheumatology (ACR), the governing scientific authority on determining disease therapeutic recommendations, revised their recommendations for treating Rheumatoid Arthritis in 2021.

Therapeutic Alternatives and Cost Economic Assessments

We understand the Board's consideration of Therapeutic Alternatives is not the same as a payer's viewpoint that drugs with the same mechanism of action (MoA) (in this case TNF-inhibitors) are interchangeable and that the Board is tasked only to understand why a drug with the same MoA is priced higher than another. ***However, we must point out that by setting a UPL on a retail drug price that no matter which scenario plays out, some patients will be exposed to utilization management (specifically non-medical switching) because of this decision. Here's why:***

- Setting a UPL is not a direct cost savings for patients.The drug will still then go to the insurance companies and PBMs for the 100's of different plans in the state and they will,

[1] "Autoimmune Registry." How Likely are You to Have More than 1 Autoimmune Disease? Autoimmune Registry, 26 July 2022, www.autoimmuneregistry.org/newsletters/how-likely-are-you-to-have-more-than-1-autoimmune-disease. Accessed 2 Oct. 2023.
[2] Sangha, Pritpal S et al. "The Link Between Rheumatoid Arthritis and Dementia: A Review." Cureus vol. 12,4 e7855. 27 Apr. 2020, doi:10.7759/cureus.7855
[3] Abou-Raya, Anna, and Suzan Abou-Raya. "Inflammation: a pivotal link between autoimmune diseases and atherosclerosis." Autoimmunity reviews vol. 5,5 (2006): 331-7. doi:10.1016/j.autrev.2005.12.006

like always, choose which drug goes on their formulary. So, in the case of Enbrel, it is ruled unaffordable and let's say the Board chooses to continue forward setting a UPL.

- The UPL on the retail price of Enbrel is set, the PBMs for the 100's of different health plans in the state have a decision whether or not to put it on their formulary. PBM's are known to not choose the least expensive drug option because they will lose profit, but let's say they are fine with their profit and it is the drug they prefer to save system costs. *Keep in mind, it is also up to them how much out of pocket the patient pays, which has nothing to do with capping the retail price.*
- Depending on the percentage of profit the PBM takes and the rebates they set for reimbursement for those who prescribe, stock, and administer these drugs, this will determine access to the drug. If the reimbursement results in a financial loss to them, they cannot prescribe it or administer it. *We already see this happening with biosimilars, which is why our country does not have the success in savings as others do*.
- Let's say there is enough reimbursement and, in turn, those 3,000 people in Colorado on Enbrel do not have to worry about losing access. Given those the PDAB can help (largely commercial insurance) already pay $0-$50 out of pocket a month, the savings goes to (not sure.. PBM? State?)
- ***But, wait! PBMs view any drug with the same MoA as Enbrel as a Therapeutic Alternative. So that means for the 10's of thousands of people with the diagnosis of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, juvenile arthritis in Colorado - all conditions treated by Enbrel - will get non-medically switched to Enbrel. For this reason, their is no positive outcome from setting a UPL. The PBMs still will dictate who gets what drug and who pays what for the drug, and patients will continue fighting for access to the drug that works best for them.***

Impact to Older Adults

"Older adults are defined in the PDAB Policy 05 as individuals aged 65 and older. Board staff will present APCD data regarding utilization and payment amounts for older adults. Board staff will also compile stakeholder input related to a drug's impact on older adults, including input on the specific drug and/or the indications the drug treats."

We respectfully remind the Board that most individuals over the age of 65 will access their treatments through Medicare, which is not under the Board statute to address.

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Copay Assistance Programs and Other Patient Assistance Programs (PAPs)

Thankfully, the large majority of people in Colorado using Enbrel and who have the type of insurance the board can address pay $0 - 25 out of pocket a month due to manufacturer copay assistance programs. Amgen, the manufacturer of Enbrel, also has a Patient Assistance Program for those uninsured and underinsured, which also helps patients afford this medication. Unfortunately, we find those on Medicare - which is not covered by the work of the PDAB - are the Coloradians who have the most issues with high out of pocket costs (as demonstrated in your patient-facing survey, 2024):

- Of the 38 respondents, 16 were on Medicare and 3 were on Medicaid/Health 1st (a total of 50%) - *all of which are ineligible for manufacturer assistance programs. Additionally, according to the CO PDAB Upper Payment Limit Policy and Procedures (Policy Number 05) document, section 10-16-1407, C.R.S. states that Medicare/Medicaid programs are not subject to the policies of the board, including applying an Upper Payment Limit.*[4]
- Also in the Enbrel review, because Medicare respondents were not stratified as a separate cohort in analysis, it is clear to see they are the Coloradian's who also struggle with affordability because the commercial insurance copay assistance programs are not usable with their healthcare plans. Excerpt published in the Enbrel affordability review dossier:

> Assistance Programs
>
> Patients were asked if they use copay assistance programs, discount cards, or savings provided by prescription drug manufacturers or non-profit organizations to help with out-of-pocket costs. Of 267 national patients, 49 did not use manufacturer assistance programs. 216 of 267 patients reporting using patient assistance, and 61 still had trouble affording Enbrel despite assistance.
>
> Of the 38 Colorado respondents, four patients did not use assistance programs, and one did not answer. Of the 33 of 38 Colorado patients who use assistance programs, 10 patients still had trouble affording Enbrel despite assistance.

- *This statement is the result of group analysis, including Medicare patients, as AiArthritis reviewed the data and determined that 7 were on Medicare/Medicaid and 2 reported trouble affording Enbrel when they stated their monthly payment was $0-$50. Therefore, the CO PDAB data shows copay assistance programs for Enbrel do make this prescription affordable, with exception of those whose personal situations make $0-50 a month unaffordable.*

In a pilot study conducted by the Patient Inclusion Council (PIC) in 2024, they confirmed the same findings as the CO PDAB - Medicare patients represent those with the most prescription drug affordability challenges:

[4] CO PDAB Policy and Procedures -URL and Medicare/Medicaid

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Medicare patients struggle with affordability

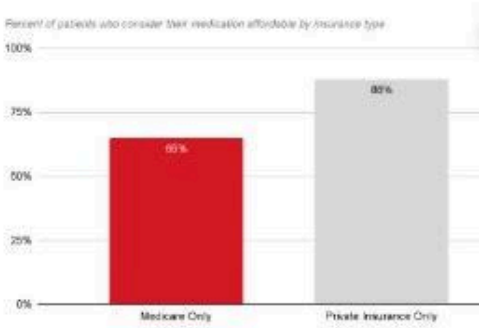
"Medicare **patients do NOT qualify for discounts**"

"Once I lose my employer coverage and go to Medicare **the pharma company will not give [me co-pay] assistance.** [A] Tier 5 Drug on Medicare costs $1000's."

"I am in the 'doughnut hole'. When I filled the medication last time it was $141 now it is $648"

"If you are on Medicare most copay assistance programs from drugs go away. It's ridiculous."

"I had a copay card when I had commercial insurance and I could afford it. Then **I switched to Medicare and cannot afford it.** I don't understand why copay cards can't be used on any of these meds for Medicare"



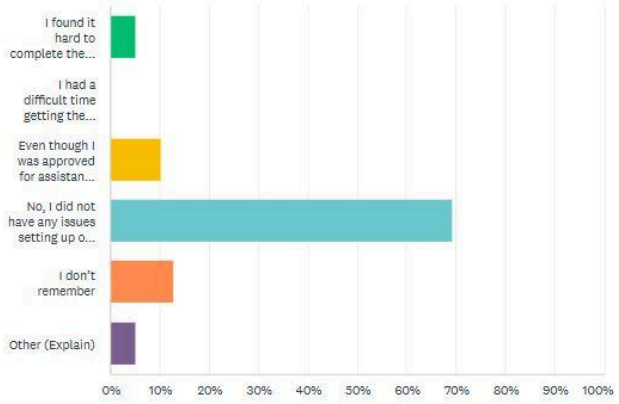
Clarification of Terms and Confusion Among the Patient Community. In response to the RFI regarding assistance programs, first we would like to take this opportunity to educate the Board about the terminology and, in turn, the differences in benefits and processes associated with applying for and implementing such a program.

Over the last year as AiArthritis has participated in every PDAB meeting (including other states), and worked tirelessly to help improve patient-facing data collection processes, we have realized the term "Patient Assistance Programs", or PAP's, are used broadly to inquire patient experience with them. ***However, PAP is the term largely related to helping patients on Medicare or without insurance***. Using the term broadly to inquire about all types of assistance programs blends all experiences with all plans into one analysis bucket. Like we saw in the original CO PDAB analysis of Enbrel (which included all Medicare patients), lack of stratification will result in observations that lack context.

In the PIC pilot survey referenced previously, this issue became obvious that patients were reporting their experiences with different types of assistance plans (i.e., copay assistance programs for commercial insurance that take about 2 minutes to apply for online vs. patient assistance programs that require a significant amount of paperwork):

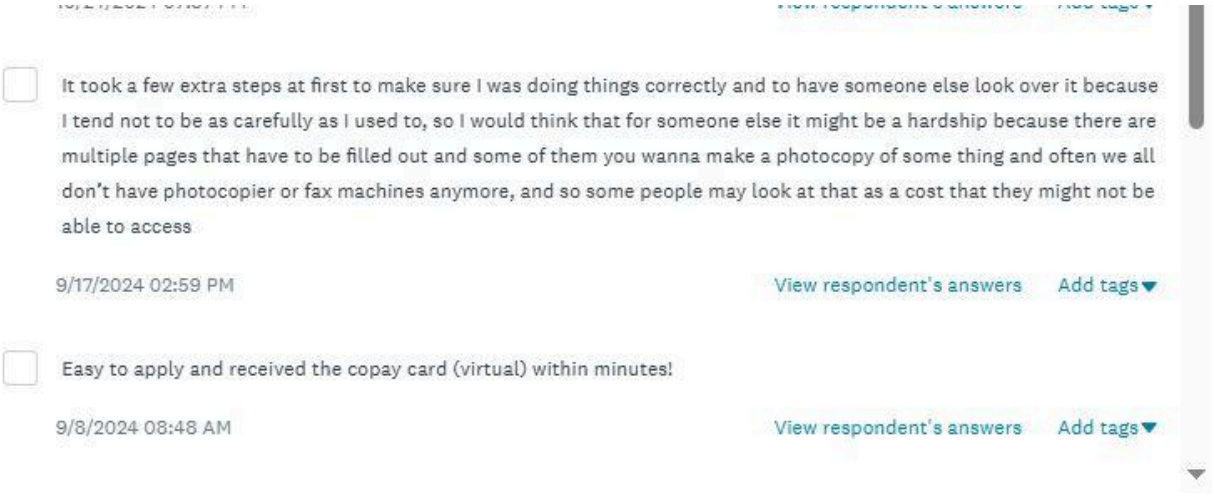
Did you find it difficult to apply for or set up the assistance program(s)? Select all that apply.

Answered: 39 Skipped: 103



ANSWER CHOICES	RESPONSES	
I found it hard to complete the initial application form.	5.13%	2
I had a difficult time getting the insurance company to add the assistance plan to my account.	0.00%	0
Even though I was approved for assistance the insurance company/specialty pharmacy still sent me a bill for the drug.	10.26%	4
No, I did not have any issues setting up or applying an assistance program to my insurance plan.	69.23%	27
I don't remember	12.82%	5
Other (Explain)	5.13%	2
Total Respondents: 39		

Of the two who did find it hard to complete, because of the open ended response option, the PIC was able to determine the patients were describing applying for Patient Assistance Programs and not manufacturer copay assistance programs:



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Comment on the top is a Patient Assistance Program, comment on the bottom is a manufacturer copay assistance program.

We bring this to your attention because there have been several conversations among Board members where they have stated with confidence that copay assistance programs are challenging to sign up for, but in reality, we feel they may have been referring to the Patient Assistance Programs - which are only applicable to those who do not qualify for the manufacturer copay assistance programs.

Out of pocket costs with copay assistance programs. The CO PDAB is tasked with helping identify how to lower costs of prescription drugs for a certain demographic of patients in Colorado (those on commercial insurance, Medicaid, uninsured).

The PAPs are available for those uninsured. When I was uninsured I was thankful to have paid $0 out of pocket for my biologic because of these types of plans. They do not help the other expenses I endured as a non-insured person, but the cost of my medication was not an issue. In saying this, over the past year AiArthritis has made a concerted effort to join more online discussion communities and, as a result, have identified an alarming percentage of patients who have no idea about any type of assistance programs - whether insured or not - which is causing them to be in debt or forego their treatments altogether. *For this reason, and thanks in part to the work we've been asked to do to help the PDABs, we have identified this vital issue around lack of education and awareness of assistance programs - as well as how to navigate them since there are many different types with similar names - and we plan to lead efforts to work with manufacturers and our community to ensure those who need these programs use them*.

Thank you again for this opportunity, we look forward to continuing to be a resource and trusted collaborator to the Board and staff throughout this process. Please do not hesitate to reach out with any questions.

Sincerely,

Tiffany Westrich-Robertson

Tiffany Westrich-Robertson
Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
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St. Louis, MO 63109

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

June 26, 2025

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

RE: Request for Input via the Data Submission Guide on Enbrel

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

The Ensuring Access through Collaborative Health (EACH) Coalition is a network of national and state patient organizations and allied groups that advocate for treatment affordability policies that consider patient needs first.

We appreciate the opportunity to provide additional input in response to the Data Submission Guide on Enbrel for the Upper Payment Limit (UPL) rulemaking process. We thank you for your efforts to improve the affordability of prescription drugs in Colorado and for your attention to the concerns outlined below.

Impact of Chronic Conditions Varies Broadly Across Patients

Members of our Patient Inclusion Council have shared firsthand accounts of their individual struggles, underscoring how important it is to recognize that each patient's journey is unique. We urge the board to consider patients as individuals with distinct experiences rather than as data points in an aggregate.

Impact to Persons with Disabilities

The effects of chronic autoimmune conditions like those treated by Enbrel can differ dramatically from one patient to another. Some individuals may experience relatively mild symptoms and respond well to readily available treatment options. For others, the impact can be profoundly debilitating—preventing them from working, participating in family life, or fulfilling caregiving responsibilities due to ongoing pain or medication side effects. These challenges are often compounded when a patient is managing more than one chronic condition, which is a common occurrence.

Impact to Older Adults

Similarly, health complexities typically increase with age and older adults are more likely to have comorbidities that require individualized care plans comprised of multiple treatments. Further, research has shown that early interventions with the right biologic for each person's disease can result in earlier remission. Therefore, unmitigated access to a broad spectrum of medications early in life is critical to health in later years.

Note on Older Adults: While we understand the statute requires special consideration for older adults, those over the age of 65 are most likely to be covered by Medicare, which we respectfully remind the board does not fall under the jurisdiction of the PDAB.

Medicine Is Not One-Size-Fits-All

The course of treatment for each patient is as unique as the individual and their disease. Once diagnosed with a chronic condition, each patient starts an often life-long journey to identify the correct treatments and regimen to successfully manage their symptoms and improve their health. Many will also face multiple chronic conditions or need medications to treat specific symptoms or even side effects of their preferred treatment. For these reasons, patients with chronic conditions often rely on a complicated and personalized course of treatment that is not easily altered.

For these patients, therapeutic alternatives may not be alternatives at all. Very often drug interactions or other health conditions would prevent individual patients from being able to switch to an alternative medication that, on paper, seems like it would be an appropriate treatment. Further, patients with chronic conditions can build up a tolerance to medications over time, so they must retain access to all treatments in a class of drugs to prolong their treatment.

Patient Access Cannot Be Compromised

Ultimately, chronic conditions are incredibly complex to treat. Each patient will face a unique experience and should be able to work with their doctor to identify the treatment that works best for them. Substituting or requiring patients to change drugs based on cost considerations instead of medical needs can disrupt continuity of care and result in complications and higher overall medical costs. We urge this board to seriously consider the unique circumstances faced by these patients and work diligently to ensure that access to all treatments is protected.

As patient advocates, we are concerned that upper payment limits (UPL) will only exacerbate these risks. While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications Patients could see reduction in access to medications in the future due to unforeseen consequences of UPLs, like increased utilization management within drug classes or limits on treatment options due to reduced reimbursement rates for doctors.

This is not a hypothetical concern.

As you know, the Centers for Medicare and Medicaid Services is actively implementing maximum fair prices (MFP) within the Medicare program. In their May 3, 2024 Guidance on Medicare Drug Price Negotiation CMS noted that, “CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs.”

Further, a white paper released by the Partnership to Fight Chronic Disease based on interviews and data from Avalere outlined that “77% of health plan payers surveyed believe that UPLs would disrupt patient access to prescription drugs due to changes in coverage, tiering, cost sharing, or broader supply chain issues, such as pharmacies not stocking products with UPLs” and 73% “expressed concerns that UPLs could lead to shortages of critical medicines.”

Broadly, the decision of the board to implement a UPL does not happen in a vacuum, but instead in an increasingly complicated marketplace that already does not appropriately take patient needs and concerns into consideration. Therefore, we strongly urge the board and staff to acknowledge this potential impact and the resulting negative effect it would have on patient access to medications. Furthermore, we urge the board to utilize its authority to fully explore

with all healthcare stakeholders how upper payment limits will be implemented and identify in advance any adverse impact to patients.

We remain committed to working alongside the board to ensure that the cost review and UPL processes promote affordability without compromising access or health outcomes for patients. Questions about any of the information contained in our submission, can be directed to:

Tiffany Westrich-Robertson
Founder and Project Manager for the EACH/PIC Coalition
tiffany@aiarthritis.org
(310) 295-7369
St. Louis, MO 63109

Sincerely,

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

EACH PIC COALITION

July 9, 2025

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

RE: Public Comments on the Upper Payment Limit Rulemaking for Enbrel

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

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

On behalf of the patients we represent, the undersigned groups urge the Colorado PDAB to decline to implement a UPL on Enbrel in the state. Broadly, we are concerned that a UPL will not result in any lowered costs for patients but could put their access to Enbrel or other drugs in the therapeutic class at risk in the future.

Upper Payment Limits Don't Necessarily Translate to Patient Savings

Assuming that UPLs directly translate to lowered costs for patients ignores the complicated nature of our healthcare system. Establishing a UPL will place a ceiling on what insurers or the state may pay for a medication, not a cap on the amount a patient must pay at the pharmacy counter.

The board does not have the authority to set limits on patient out-of-pocket costs, nor can it require insurers to adjust cost-sharing arrangements in line with a UPL. Without a mechanism to ensure that savings are passed along to patients, UPLs may offer little to no benefit to those who rely on the medications under review.

Upper Payment Limits Could Compromise Patient Access to Medications

Further, UPLs could add complexity to an already fragmented drug coverage landscape. Setting a UPL for a specific medication may prompt insurers to make changes—such as reshuffling formularies, adding prior authorization requirements, or implementing step therapy protocols. Each of these measures can delay or restrict access to needed treatments.

Additionally, insurers and PBMs may place drugs subject to UPLs on higher tiers of the formulary. This could ultimately lead to higher out-of-pocket costs for patients who could face higher copay or coinsurance rates to retain access to that drug or alternatively be forced to switch to a more expensive drug that results in higher profits to their pharmacy benefit manager (PBM).

Providers may also face challenges, as reduced reimbursement rates could affect their ability to purchase, administer, or dispense certain drugs. These disruptions can result in treatment delays, increased administrative burden, and poorer health outcomes for patients.

EACH/PIC COALITION

Upper Payment Limits Are Untested and Unproven

Importantly, we do not yet know how insurers, manufacturers, or pharmacies will respond to a state-specific pricing model. Limiting reimbursement for certain products could reduce their availability in states with UPLs, narrowing treatment options and limiting access for patients.

As a measure of basic due diligence, we urge the board to obtain concrete information from all sectors of the healthcare marketplace—manufacturers, insurers, PBMs, and providers—regarding how they will respond to the implementation of a UPL.

The decisions of any one of these actors could influence whether patients continue to have access to critical medications. If even one stakeholder responds by limiting availability or access due to the constraints of a UPL, the result could be disruptions to continuity of care and increased burdens on patients and providers alike.

Integrate Public Input and Address Patient Needs

As we continue to note in our outreach to the board, meaningful participation from patients, caregivers, and patient advocacy organizations is critical to ensuring that board actions appropriately address patient needs. While we are encouraged that the board has committed to holding three rulemaking hearings on each drug, we were discouraged that time was not better managed during the first hearing to allow for public input.

We again raise concerns about the limitations of the board's patient survey and the data it collected on Enbrel. As noted in previous letters, the low response rates, problematic question design, and inadequate analysis of the survey undermine the validity of the findings. As a result, the data is insufficient for drawing meaningful conclusions about patient experiences and should prompt further patient outreach and engagement efforts.

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

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

Sincerely,

Ensuring Access through Collaborative Health/Patient Inclusion Council (EACH/PIC Coalition)
Advocates for Compassionate Therapy Now
AiArthritis
American Behcet's Disease Association
Autoimmune Association

EACHPIC COALITION

Caring Ambassadors Program
Community Liver Alliance
Cystic Fibrosis United
Derma Care Access Network
Epilepsy Foundation of America
GAAPP
Global Healthy Living Foundation
Health Hats
Infusion Access Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Colorado
Multiple Sclerosis Foundation
National Infusion Center Association
Partnership to Fight Chronic Disease
Partnership to Improve Patient Care
Rare Access Action Project
The Headache & Migraine Policy Forum
Virginia Society of Rheumatology

VIA Electronic Delivery July 9, 2025

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

Re: CO PDAB UPL Rulemaking Written Testimony

Dear Prescription Drug Affordability Board Members and Staff:

The Biotechnology Innovation Organization (BIO) and the Colorado BioScience Association (CBSA) appreciate the opportunity to provide written testimony for the Colorado Prescription Drug Affordability Board's (PDAB's or Board's) second rulemaking hearing for the draft proposed Upper Payment Limit (UPL) Rule, 3 CCR 702-9, Part 4.3: Upper Payment Limit for Enbrel ("Draft Proposed Rule"), on July 11, 2025.

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

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

In addition to our ongoing concerns about the constitutionality of the Colorado PDAB statute and the legality of the Board's implementation of the statute, BIO and CBSA have serious, continuing concerns about UPLs as a tool to accomplish the PDAB's goals and, more specifically, about the lack of a concrete methodology for determining UPLs in a clear, consistent manner. As we have discussed in our previous comments,[1] there is still a dire need for procedural safeguards and thorough, objective analyses of the likely impacts of UPLs, since none of the Board's work, including the UPL Cost-Benefit Analysis,[2] has contained such an analysis.

[1] CBSA and BIO Cost-Benefit Analysis Comment Letter. May 8, 2025.
[2] Colorado PDAB UPL Cost-Benefit Analysis (3 CCR 702-9 Part 4). April 1, 2025.

Above all, it is critical to highlight the voices of patients. Patient groups and other stakeholders continue to express concerns about UPLs as a tool for addressing the affordability of and access to prescription drugs and emphasize that UPLs are a proposed solution that will not improve what patients actually pay for their medicines. As patients represented by the Ensuring Access through Collaborative Health (EACH) Coalition and Patient Inclusion Council (PIC) have underscored, "A UPL is a ceiling on what insurers or the state may pay for a medication, not a cap on the amount a patient must pay at the pharmacy counter. The board does not have the authority to set limits on patient out-of-pocket costs, nor can it require insurers to adjust cost-sharing arrangements in line with a UPL. Without a mechanism to ensure that savings are passed along to patients, UPLs may offer little to no benefit to those who rely on the medications under review."[3]

Furthermore, EACH PIC Coalition wrote that they "are concerned that UPLs could further complicate the already fragmented drug coverage landscape. Setting a UPL on a specific medication could trigger changes by insurers—such as reshuffling preferred drug lists, instituting new prior authorization requirements, or requiring patients to try other drugs first—all of which may delay or restrict access to the treatments patients need. Providers may also be impacted, as lower reimbursement rates could limit their ability to purchase, administer, or dispense certain medications. These disruptions can lead to care delays, increased administrative burdens, and diminished health outcomes."[4]

The EACH PIC Coalition also emphasized that "we do not yet know how insurers, manufacturers, or pharmacies will respond to a state-specific pricing model. Limiting reimbursement for certain products could result in reduced availability in states where UPLs are implemented, further limiting access and choice for patients." A Patient Sign On Letter representing eleven different patient organizations also echoed these concerns, calling attention to how "the Board continues to be unable to gather assurances from all members of the supply chain that imposing a UPL will not disrupt patient access to needed medications. Until the Board and patients have this assurance, we plead with you to pause this process where the risks simply outweigh any possible rewards."[5]

More specifically, with regard to the UPL-setting methodology, the Patient Sign On Letter highlights concerns with "the lack of transparency and consistency in the UPL-setting process," calling attention to the fact that there "are currently no clear standards outlining how key categories are weighed or how decisions will be applied consistently across drugs and therapeutic classes. This lack of clarity undermines confidence in the Board's decisions and the overall process."[6]

BIO and CBSA also want to reiterate the concerns we have previously raised in written and oral comments and which have been raised by a variety of other stakeholders about meaningful data errors impacting the PDAB's selection and review of drugs, how consideration of patient input has fallen short, and other critical issues. These problems and key, outstanding questions must be addressed before the Board presses forward with setting UPLs. As said in the aforementioned Patient Sign On Letter, the "Board has an immense responsibility to get this process right," and must do so to "demonstrate [its] commitment to evidence-based decision-making and meaningful patient engagement."

As the Cost-Benefit Analysis for the Draft Proposed Rule acknowledged, the PDAB has the option "to not adopt this regulation and not establish an Upper Payment Limit for Enbrel." Instead, "the

[3] Ensuring Access through Collaborative Health (EACH) Coalition and Patient Inclusion Council (PIC). Public Comments to Colorado PDAB on the Upper Payment Limit Rulemaking Process. May 21, 2025.
[4] EACH PIC Coalition. Ibid.
[5] Coalition of 11 patient organizations. Patient Sign On Letter to Colorado PDAB on Enbrel Rulemaking. May 21, 2025.
[6] Coalition of 11 patient organizations. Ibid.

Board could provide payer- and payment-focused recommendations" to the General Assembly, which "could include co-payment caps for [ostensibly] unaffordable prescription drugs, limits on utilization management, etc." We strongly urge the PDAB to pause before setting any UPLs and make sure it has taken all of the appropriate steps before moving forward with this first-of-its-kind UPL rulemaking.

***

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

Sincerely,

/s/

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

/s/

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

COMMUNITY ACCESS NATIONAL NETWORK

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July 9, 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.

Concern with Staff Collaborating Across States; Contractor Conflict of Interest

We are deeply concerned with the Colorado PDAB staff expressly stating a "collaboration" with staff serving other states' PDABs. CANN wishes to be clear: the Colorado PDAB and its staff have an obligation to serve Coloradans, not import the staff perspective of other states or the policy or political motivations of private actors. If the Colorado Board is interested in the posture of the Oregon Board, when there is a conflict in report from public participants and staff, it is incumbent upon the Colorado Board to solicit information from the Oregon board Chair, not relay messages of conflicting content through staff.

Additionally, we would sincerely encourage the Board to examine the background of entities such as PORTAL and ICER in the same manner as advocacy groups and other organizations, with their motivations and funding being scrutinized.

The Connecticut legislature released a report examining questions surrounding PORTAL (also attached), the Harvard Program on Regulations, Therapeutics, and Law. The report indicates that its relationships include a wide range of associations, including direct involvement with organizations such as Arnold Ventures, NASHP, and RePo4EU.

Directly, NASHP's PDAB project and model legislation discloses project funding from Arnold Ventures. NASHP testified in favor of similarly structured legislation initiating this Board in the Colorado legislature. PORTAL, now contracted as the data analysts for this Board, is also funded by Arnold Ventures, as is ICER, and certain groups purporting to be representative of patients.

It is incumbent upon both the Board and staff of the Colorado PDAB to serve the interests of Coloradans, not import the pre-determined outcomes and motives (political or otherwise) of outside interests. The funding source, which both initiates the legislation and seeks a contract to serve the Board, presents an exceptional conflict of interest. The Board is responsible for reviewing the ethical implications and conclusions of such contracts. Put directly, if specific funding is pushing both for specific legislation and funding the consultant entity being contracted to advise the Board established by the legislature, is the Board truly "independent" rather than a governmental arm of a private actor? If the answer is "no" then the Board is obligated to halt all associations with entities funded by that private actor and seek immediate review of any materials, conclusions, and decisions guided by those entities funded by that outside actor and report those findings as appropriate to either the legislature, the Attorney General, the Governor, and the public writ large.

Clarification of CANN's Allusion to Oregon Report

During the May 23, 2025 meeting, staff expressed concerns with how CANN commented on and relayed the posture of the Oregon independent consulting analysis report regarding Upper Payment Limits. CANN has referred to this report on multiple occasions. The reasoning for this particular allusion was in reference to the paucity of information provided in Colorado's cost-benefit analysis prepared by staff. Many questions were left unanswered in the cost-benefit analysis, with the explanation that because a UPL had not yet been set, it was not possible to give a more specific analysis of the potential effects of a UPL. CANN referred to the Oregon report because although no UPL has been set since Oregon doesn't currently have the authority to set one, their independent consulting firm was still able to provide a more detailed and informed analysis than Colorado's cost-benefit analysis with quantifiable data of a UPL's potential effects to stakeholders, including numerical data, such as the Medicaid program.

Given previous staff, Lila Cummings', December 2024 staff hours response of "We won't be doing that", when a member of the public informally requested a comparable cost-benefit analysis, and the sheer absence of any sufficiently comparable analysis as Oregon's, a reasonable conclusion this Board should be concerned with is staff never intended to provide a meaningful cost-benefit analysis. If this Board wishes to maintain the public trust, it must consider not only the obvious data failings outlined in this meeting's agenda, but also the actual statements and chronological order of facts as they've occurred.

We are in support of the General Assembly Recommendations

We support the recommendation of allowing consumers to identify prescription drugs for consideration for affordability review since it directly empowers patients to express what they deem as affordability challenges. This is tangentially related to another of the Board's recommendations which is reducing the threshold for identified brand name drugs to below the current 30,000/yr threshold. List prices do not directly translate into affordability. Targeting high-cost drug prices results in a prejudicial selection of therapies that affect many vulnerable populations without many options for treatment, who often are not having issues with affordability for their medications. Lowering the threshold coupled with allowing consumers to report what they deem as unaffordable seems to be a more patient-centered course of operations to benefit Coloradans. We are also in support of suggesting the legislature address the pros and cons of adding a consumer advocate/representative to the board. Since the board expressed concerns about the expertise and abilities of such a member, it would be helpful to include the Board's suggestions in that recommendation.

Methodology still unclear

A vast amount of information is being requested from various stakeholders through data submission guides as well as data sourced by staff. Because there is not currently a working interpretation of what the Board would consider to be a successful outcome of a UPL, what kind of savings would be worth the fiscal expenditure of implementation once implementation is defined, and other questions, it is unclear how the Board will use the data collected to determine what an effective UPL would be. It also remains unclear how a UPL would directly benefit patients at the pharmacy counter. This is especially true in light of, as mentioned during the last meeting, that patient out-of-pocket expenses have increased over time, possibly as a result of shifting benefit plans.

We Encourage the Board to Ensure Its Goals Stay at the Forefront

The Board has been tasked with the noble and arduous task of effectuating positive change to improve affordability for Coloradans. This requires the utilization of staff, including the solicitation of information from various subject matter experts, a range of consulting services, and multiple categories of data sources and interpretations. Moreover, in the national PDAB landscape, states are looking to one another to find ways to best assist their constituents.

We encourage the Board to be mindful of ensuring its desires are explicitly acted upon and that its endeavors are not inadvertently steered by influences not clearly beneficial to Coloradans. Various state PDABs have their own challenges they are working through, including fleshing out how the extraordinarily complex drug supply chain, payer mechanics, and entities providing care to patients all interact. What the PDAB is tasked with is new, very necessary, but cautiously speculative in the effects decisions may impart.

It is essential to ensure that every consideration is based on meaningful data and analysis and approached with an open mind to the nuances involved. There is independent data that explains the very real possibility of cost-control decisions resulting in increased costs to patients. Consistently evolving data includes direct commentary from payers. When advocacy groups and individual patients raise various concerns, those concerns are valid.

The pharmaceutical industry is not a monolithic big bad wolf. High-cost interventions are still valuable because of their significant benefits, just as some lower-cost interventions are not as valuable or effective. Analysis indicating how improper affordability actions can affect Medicaid and other programs is real.

The best interests of Colorado citizens regarding affordability are at the forefront of concern.While affordability concerns are universal, the needs of Coloradans are specific. The inquiries you desire and the discourse you generate should remain under your guidance and not be inadvertently improperly informed.

We thank you for all of your ongoing hard work and thoughtful deliberations.

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

OFFICE OF LEGISLATIVE RESEARCH
Objective Research for Connecticut's Legislature
ResearchReport

Program on Regulations, Therapeutics, and Law (PORTAL)

By: James Orlando, Chief Attorney
July 29, 2024 | 2024-R-0123

Issue

This report answers several questions about the Harvard Program on Regulations, Therapeutics, and Law (PORTAL). We contacted PORTAL for information on several of these questions, as noted below.

Who/what is the Harvard Program on Regulations, Therapeutics, and Law (PORTAL)?

PORTAL is a research core within the Division of Pharmacoepidemiology and Pharmacoeconomics at Harvard Medical School and Brigham & Women's Hospital. According to its website, PORTAL:

> bring[s] together concerned researchers, analysts, and trainees from the fields of medicine, law, epidemiology, and health policy to critically evaluate emerging issues on the regulation, use, and reimbursement of therapeutics (prescription drugs and medical devices). We are interested in how laws and regulations influence the development, utilization, and affordability of therapeutics, as well as the ethical questions that current and proposed policies raise for patients, physicians, policymakers, and payors. Particular areas of focus include drug and device regulation, intellectual property, cost-effectiveness, and comparative effectiveness.

Among other things, the website states that the goals of PORTAL's research "include its publication in major medical, legal, and health policy journals; dissemination through the lay media and

international, national, regional, and local professional meetings; and interaction with key decision-makers in the public and private sectors to ensure translation into actionable health care policy."

Currently, PORTAL includes four core faculty members (all from Harvard Medical School) and a research team consisting of several research fellows, research assistants, and students in a range of disciplines. Their website also lists affiliated faculty and researchers from various other institutions.

Who and where does their funding come from? Is any of that funding from health insurers or pharmacy benefit managers?

According to its website, PORTAL's funding sources include the following private entities:

- Arnold Ventures: a philanthropy organization focused on evidence-based policy solutions
- CeBIL — Centre for Advanced Studies in Biomedical Innovation Law, Novo Nordisk Foundation: a research initiative, based at the University of Copenhagen, focused on "legal challenges and rapid developments in the health and life science area," funded in part by the Novo Nordisk Foundation, an independent Danish enterprise foundation focused on medical research and affiliated with the pharmaceutical company, Novo Nordisk
- The Commonwealth Fund: a private foundation that supports independent research on health care issues, with a focus on improved equity in health care access
- Elevance Health: a health insurance company, formerly known as Anthem, Inc.
- Gary and Mary West Foundation: a private foundation focused on addressing the needs of vulnerable seniors
- The Greenwall Foundation: a private foundation with a mission "to expand bioethics knowledge to improve clinical, biomedical, and public health decision-making, policy, and practice"
- National Academy for State Health Policy (NASHP): a nonpartisan organization focusing on "developing and advancing state health policy innovations and solutions"
- Kaiser Permanente Institute for Health Policy: an organization with a mission "to shape policy and practice with evidence and experience from the nation's largest private integrated health care delivery and financing organization," and affiliated with Kaiser Permanente, an insurer
- RePo4EU (an organization developing an online platform for precision drug repurposing)

The website also states that PORTAL receives funding from the Massachusetts Health Policy Commission and the U.S. Food and Drug Administration.

How many states does PORTAL work with?

According to PORTAL, "[w]e currently have a grant from NASHP to advise a cohort of seven states on implementing prescription drug affordability boards (PDABs) -- Colorado, Maine, Maryland, Minnesota, New Hampshire, Oregon, and Washington. You can see some of the output here. We have also been consultants for the Massachusetts Health Policy Commission."

How many states does PORTAL have a contract with and what is the contract amount?

PORTAL reports that "[s]eparate from the NASHP grant (see above) we have contracts with Colorado, Oregon, and Washington to support the more technical operations of their PDABs."

What is PORTAL's relationship to NASHP, the Institute for Clinical and Economic Review (ICER), and the Arnold Foundation?

PORTAL reports that "[o]ur government and foundation funders include the FDA, NIA, Arnold Ventures, Commonwealth Fund, and the Greenwall Foundation, among others. We have no formal relationship with the Institute for Clinical and Economic Review (ICER)."

Does PORTAL have any patient representation or input?

PORTAL reports that "[w]e do not have patient representatives working within PORTAL, but we often connect with patient groups and understanding the patient impact of high drug costs is a key research area."

Does PORTAL have any direct drug industry expertise or is it only academic?

PORTAL reports that it "is an academic group at Brigham and Women's Hospital and Harvard Medical School, and no one in PORTAL accepts any personal financial support from pharmaceutical or medical device companies."

Does PORTAL have any contracts with Connecticut's Office of Health Strategy (OHS) or have they presented to OHS?

We contacted OHS for this information and their representative was unfamiliar with PORTAL. It appears that PORTAL has no affiliation with OHS.

JO:co

Bridget Dandaraw-Seritt

Founder, ACTnow

Vice-Chair, Cystic Fibrosis United

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9 July 2025

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

Dear Members of the Board,

Thank you for taking the time to hear our concerns regarding upper payment limits for any drug, including Enbrel. Upper payment limits can have negative impacts on medication accessibility, and not enough precautions are in place to prevent issues. Surveyed insurance companies indicated there will be **impacts such as increased prior authorization requests, non-medical switching, more step therapy, changes in formularies, and cost impacts throughout the entire class of drugs**. Stakeholders have also expressed multiple concerns about process integrity during the affordability reviews and UPL process including **skewed statistics, discriminatory data sets, and inconsistent interpretation.** These concerns have been raised for well over a year, without seeing action to mitigate these issues. We strongly feel that unless the concerns mentioned are fixed, there is no way the Board can make a valid decision on an upper payment limit.

Patient Engagement

Patient engagement has been chronically low and does not create a complete and accurate picture of affordability for Coloradans. Very little effort has been made by the Board or Division of Insurance to improve community awareness, effectively placing the burden of engagement directly on the patient.

- **The Division of Insurance has been asked to utilize community partners, including pharmacists, doctors, and major health systems like Denver Health and UCHealth.** To date, none of this has been done and enormous segments of our community are being missed. There has been little attempt to partner directly with clinics that utilize these drugs or the pharmacists that dispense them. Patient groups like ours have contacted them only to be told they are waiting on direction from the DOI or the Board.
- **No advertising or awareness campaigns have been utilized.** The Division of Insurance has not used any of its funding to raise patient or provider awareness, yet seems to have the funding to send staff to conferences like NORD to promote the concept of upper payment limits. In addition, Board members have suggested the lack of patient engagement is the fault of patient groups who “didn’t bring their people”. (Cathy Harshbarger, last meeting). As an org with zero funding, we did increase the engagement significantly for Enbrel, but only after diverting

resources we do not have. We stopped after that, since promoting engagement is 100% the job of paid employees of the Division of Insurance. It is ***not*** our job to create social media campaigns, speak at patient groups, or contact the major health systems.

- **Patients that do participate are dismissed and have even been called names like "fear mongers", creating a hostile environment.** Some Board members have even gone so far as to accuse patients of working for pharmaceutical companies. The verbiage and hostility need to stop because it's hard to encourage patients to engage if they will be mistreated.
- **Upcoming survey periods are short and not announced with enough time to solicit meaningful information.** Announcements that feedback periods were open have only been 2 weeks at most and some even just days before. No social media material has been provided, and it isn't advertised on state social media for us to share. This leaves little time to make sure the appropriate stakeholders are informed.

<u>Data Integrity</u>

Problems with the data have not been rectified, which means all the data used to determine affordability is compromised.

- **Data interpretation has not been consistent.** For example, in the Trikafta and Genvoya reviews, patient assistance programs were praised and one of the reasons that they were deemed affordable. In the reviews for the rest of the drugs, these same assistance programs were disparaged. There is also a major concern that for each set of reviews, evaluation criteria can change. This means the process is completely subjective to the whims of the Board. They can decide to evaluate for state affordability one time then decide to evaluate for premium savings the next. It's the responsibility of the Board and The Division of Insurance to develop set criteria for which ***all*** drugs will be evaluated. It is up to you to develop standards like ***how much does patient assistance weigh*****,** and to uphold set standards so integrity is maintained.
- **Medicare data was included in the affordability reviews which resulted in highly skewed information.** Knowing that the UPL would not impact healthcare plans like Medicare and TriCare, that data should have been omitted from analysis. Those plans often do not have access to traditional assistance programs inflating out of pocket costs. Nearly ***half*** the patient data on Enbrel includes Medicare statistics.
- **No standard of "affordable" was set.** Many who responded to Enbrel's survey said they paid $50 or less. They also indicated having debt or trouble paying bills. Context is missing here, because patients have multiple contributing factors to both the medical debt and paying bills. Was the debt a result of multiple things associated with the medicine like required labs or time off work for tests/appointments?
- **The use of Quality Adjusted Life Year data during the**

affordability process is discriminatory and encourages distrust between the public and the board. There are plenty of data sources less controversial than quality adjusted life year data. While they aren't directly being used in the upper payment limit process, the board members have already seen those data sets. Their use during the affordability/cost assessment phase absolutely will impact UPL decisions, as they have impacted affordability/cost decisions.

- **There are no guardrails in place to prevent Coloradans from losing access to working medications.** No formal appeals process is in place, and no guarantee that medications covered now will continue to be accessible. While Enbrel has similar therapies, these medications are not interchangeable. The Board has been made aware that non-medical medication switching could result in rejection of the original drug if the other is not effective. It's not uncommon for someone to stop Enbrel (or any biologic) and find it no longer works upon restarting. Over time, this would increase the risk of damage causing the patient to be unable to work, need more surgeries, and be put on more expensive medications.

Until these issues are addressed, the Board cannot possibly make an informed and objective recommendation for an upper payment limit. There has not been enough data to accurately reflect true affordability and this **has** to be fixed. It's important for The Division of Insurance to get this done properly. The healthcare access implications on hard working Coloradans is at stake, and the entire country is watching you. Please pause and make sure these concerns are addressed before moving forward.

Sincerely,

Bridget Dandaraw-Seritt
Founder, ACTnow
Vice-Chair, Cystic Fibrosis United

amgen.com

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

July 9, 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)
1560 Broadway, Suite 850
Denver, CO 80202

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

On behalf of Amgen Inc., its wholly-owned subsidiary Immunex Corporation, and its indirect wholly owned subsidiary Amgen Manufacturing, Limited (collectively "Amgen"), we respectfully continue to object to the inconsistent, undisclosed, and otherwise ambiguous processes and procedures employed by the Colorado Prescription Drug Affordability Board (PDAB or Board). This approach extends to the proposed rule itself, which provides nothing of substance to which stakeholders may respond and consequently prevents meaningful participation in the Board's rulemaking process. Reflecting the lack of substance in the proposed rule, the Board's cost-benefit and regulatory analyses do not adequately address the statutorily mandated factors for those analyses. Furthermore, we again raise legal concerns regarding the Board's authority and approach, among other matters.

Amgen is committed to improving the lives of patients by discovering and developing medicines for serious diseases. Amgen understands that the cost of prescription drugs is a concern for many Coloradans, and Amgen has programs in place to ensure affordability while minimizing access hurdles from pharmacy benefit managers (PBMs) and others. Amgen is committed to the responsible pricing of our medicines, and we price products based on the value they deliver, while aiming to employ flexible pricing approaches to ensure patient access.

Accurate Assessment of a UPL's Impact Necessitates Clarity on Where and How a UPL Applies

Based on the Board's statements and the State's representations in litigation, we understand that the Board intends a UPL on Enbrel® to apply to all "downstream" transactions (*i.e.*, excluding sales to wholesalers and distributors) involving a drug that is dispensed or administered in Colorado, but excluding transactions involving federal programs and payors. As Amgen has explained, it is clear that such a UPL will harm Amgen and deprive it of the benefits it is entitled to under the federal patent system. But a more detailed assessment of the costs of a UPL, including compliance costs and harms to patient access, is impossible without greater clarity about how the Board intends to apply a UPL.

The Board has not explained how it would determine whether a UPL applies to particular transactions. For example, despite the Board's intent that a UPL not apply to certain transactions—such as those that involve a drug that is ultimately dispensed or distributed outside of Colorado—it will often be difficult or impossible to determine *at the time of a transaction* whether the UPL applies. Moreover, if a drug is acquired outside of Colorado at a cost exceeding the UPL, capping the payments and reimbursements to in-state providers below the acquisition cost will have a detrimental impact on access. Providers' uncertainty over whether they will be properly reimbursed will reduce their willingness to stock these medications. We share the concerns voiced by other stakeholders[1] that this dynamic could result in sites of care across Colorado being unable or unwilling to stock Enbrel®.

Without clarity on which specific transactions are subject to a UPL and how participants in the supply chain will be able to distinguish those transactions and medicines from their UPL-ineligible counterparts, both within the state and beyond its borders, stakeholders cannot accurately assess or provide responsive comments on what exactly a UPL means for their operations and, most importantly, for patient and provider access to medicines.

Beyond Stating the Board's Intent to Adopt a UPL, the Board Has Provided Nothing Meaningful for Amgen and Other Stakeholders to Comment On

Even though the Board is about to hold the second of just three planned rulemaking hearings, the proposed UPL rule remains little more than a blank template. As Amgen has explained in past comments, both the Colorado Administrative Procedure Act and due process require the Board to provide stakeholders with reasonably specific notice of what the agency is proposing to do, including enough factual detail and rationale to permit interested parties to comment meaningfully on the proposal. The Board has not provided such notice regarding the proposed UPL rule.

The proposed Enbrel® UPL rule lacks any meaningful substance for Amgen to respond to. It states only that the Board intends to establish a UPL for Enbrel®. It does not specify the level at which—or even a range within which—the Board is proposing to set the UPL. Nor does it disclose anything about the process, method, or criteria the Board will consider in determining the UPL.

The Board's other rules and guidance do not provide clarity, either. Importantly, the Board was supposed to "determine by rule the methodology for establishing an upper payment limit" in advance; the Board is not allowed to make up the methodology as it goes along.[2] But the Board has not disclosed anything resembling a methodology for setting upper payment limits. The Board's rule purporting to establish a methodology does no such

[1] Healthcare Distribution Alliance (HAD), Letter to the Chair Mizner and Members of the Colorado Prescription Drug Affordability Board, included in May 23, 2025, Board Meeting Materials.

[2] C.R.S. § 10-16-1407(2) (emphasis added).

thing: Instead, it simply (i) restates the statutory factors the Board is required to consider and those it is prohibited from considering, and (ii) lists ten different "price and cost metrics" that the Board "may consider," without specifying how the Board will use that information to establish an upper payment limit.[3] The Board's non-binding guidance adds nothing of substance: Like the rule, it lists ten different price and cost metrics that staff "may compile … for the Board's review" but does not specify what the Board will do with that information.[4]

The Board's first rulemaking hearing and its Data Submission Guide, which was not finalized until after that hearing, have done nothing to fill in these gaps. At the first rulemaking hearing, Board staff presented the Board with a slew of data purporting to reflect the various price and cost metrics listed in the rule that the Board "may consider" when setting a UPL. But the Board did not provide any guidance about how it would utilize that data or what methodology it would follow when establishing a UPL. Similarly, the Data Submission Guide requests a wide range of quantitative and qualitative information from manufacturers and other stakeholders, but it does not shed any light on what the Board is proposing to do with that data or how the data will influence the Board's selection of a UPL.

It appears that the Board is attempting to rush through the rulemaking process without disclosing any of the information that is crucial to allowing Amgen and other stakeholders to comment intelligently on the proposed UPL. This dynamic has put stakeholders in the precarious and unfair position of attempting to provide meaningful input on a proposal that is utterly undefined and open-ended.

A proposed rule should not put stakeholders in the position of both creating and responding to their own hypotheticals at the same time they are expected to help the Board understand the general issue landscape and perspectives on a host of critical issues. This not only violates the Colorado Administrative Procedure Act; it also deprives Amgen and other stakeholders of the meaningful opportunity to be heard that is the core of due process.

Questions of Data Accuracy and Ambiguous or Undisclosed Methodologies Remain as We Approach the Third UPL Rulemaking Hearing for Enbrel®

Amgen has been requesting further information on data irregularities and undisclosed methodologies for more than a year. Despite committing to a response addressing Amgen's questions regarding data aberrations and unknown methodologies at the June 14, 2024, Board meeting[5], neither the Board nor staff has ever provided such a response.

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[3] 3 CCR 702-9, Part 4.1.C.

[4] PDAB Policy 05: Upper Payment Limit Policy and Procedure (Jan. 13, 2023).

[5] Amgen verbal comments to the Board at the June 14, 2024, Board meeting, requesting clarification on how data for the same year could change substantially, including details on the standards, methodologies, and data used in each phase, and asking for assurances from the Board that any unsupported changes in the data had not unduly influenced Board assessments and deliberations.

The significance of these unanswered data and methodology questions has been underscored by the recently disclosed data miscategorization by a pharmacy benefit manager (PBM). For instance, even basic data categories, such as the number of patients utilizing Enbrel®, have changed in each phase of the Board's assessments. For the 2021 data year, the number of Enbrel® utilizers cited by the Board went from 2,279 utilizers during the eligibility and selection phase, to 3,692 utilizers during the affordability review phase (+62%), and to 2,744 utilizers during the UPL rulemaking phase (- 25.7%).

While we understand this latest round of changes to the reported Enbrel data was due to the purported data miscategorization impacting roughly 7% of pharmacy claims in the database, we have no means to better understand these new figures, assess their accuracy, or evaluate the extent to which they have been "corrected"[6] without access to the data before the Board and without transparent, evidence-based processes and methodologies.

By Emphasizing APCD Data on Patient Out-of-Pocket Costs, the Board Continues to Ignore Amgen's Efforts to Promote Access and Affordability

The out-of-pocket costs commercially insured patients pay for Amgen medicines, like Enbrel®, have changed very little over the decades. Through Amgen's co-pay card programs, out-of-pocket expenditures for our advanced medicines are significantly reduced—to as little as $0 out-of-pocket for each dose—with no income eligibility requirements. In fact, roughly two-thirds, or 67 percent, of Enbrel® prescriptions, 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.

Although Medicare beneficiaries are not eligible for co-pay cards, approximately three-quarters, or 76 percent, of Enbrel® prescriptions for Medicare beneficiaries cost $50 or less out-of-pocket per month, and the remaining quarter, or 24 percent, of prescriptions cost an average of $395 per month. For Medicaid beneficiaries, 93 percent of prescriptions cost $10 or less out-of-pocket per month, and the remaining 7 percent of prescriptions cost an average of $293 per month.

We also recognize that many uninsured and vulnerable patients need extra help affording their medicines. For that reason, Amgen established the Amgen Safety Net Foundation to provide access to Amgen medicines at no cost to qualifying patients in the U.S. (including Puerto Rico) who have a financial need and are uninsured or have an insurance plan that excludes the prescribed Amgen medicine. Since 2008, the Amgen Safety Net Foundation has provided nearly $13 billion worth of Amgen medicines to help hundreds of thousands of qualifying patients gain access to their therapy in the United States.

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[6] Addendum to the 2023 Affordability Review Summary Report: Enbrel (May 6, 2025).

The above information was provided to the Board in Amgen's submission dated October 2, 2023, but has only been reflected in the Board's affordability report at Appendix K, on page 501 of 534 pages. In subsequent Board meetings, the significant impact for patients of Amgen's co-pay card programs has been largely dismissed by the Board. The Board routinely cites data on patient out-of-pocket costs from the Colorado All Payer Claims Database without acknowledging that these figures do not reflect the beneficial impact of Amgen's patient assistance programs. If the Board sincerely intends to understand and balance the impact of any UPL on out-of-pocket costs to patients against risks to patient access, an appropriately thorough assessment and balanced discussion of manufacturer programs assisting patients must be part of the UPL rulemaking process.

* * *

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 access to prescription drugs is a concern for many Coloradans, but these concerns will only increase if the Board adopts an ill-considered UPL rule that may limit access to Enbrel® without providing stakeholders sufficient notice of and a meaningful opportunity to comment on the actual substance of the proposed rule. We look forward to the opportunity to hear fair and open Board discussion about the proposed UPL rule, and we thank you for your attention to the aforementioned issues.

Regards,
/s/ Kathy Sherman

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

Arthritis Foundation®

July 8th, 2025

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

Dear Chair Mizner and Members of the Board,

On behalf of the Arthritis Foundation and the nearly one million individuals we represent in Colorado living with arthritis, we appreciate the opportunity to share our perspective as you continue deliberations around setting a UPL for Enbrel.

We recognize and share your commitment to addressing prescription drug affordability.
While we understand that a UPL intends to lower patient costs, we are concerned that this approach could jeopardize access to the full range of treatment options that patients and providers rely on. Even if a UPL results in lower pricing at the retail level, downstream consequences, such as insurers or pharmacy benefit managers preferring the lower cost product such that they restrict coverage or require treatment switches among patients stable on a different therapy.

There are many reasons a patient may be on a specific TNF-inhibitor, such as a need or preference for a specific route of administration. The complexities of autoimmune disease and the experiences and needs of patients on these medications must be taken into account when considering therapeutic alternatives.

The Arthritis Foundation supports efforts to lower out-of-pocket costs, but policies must be carefully designed to preserve access and avoid unintended consequences that could undermine patient care. We would also caution that establishing a UPL will not necessarily make a drug more affordable for a patient. Insurance design and employer benefit packages are such that even if you set a UPL that is half the current list price, insurance will still make that drug unaffordable to most patients without some form of cost-sharing assistance. We urge the Board to continue focusing decision making on how a UPL will affect the patient experience.

Thank you for your continued efforts and for considering the voices of the arthritis community in this critical process.

Robert Nolan
Arthritis Foundation
State Affairs Coordinator | Department of Advocacy and Access

Children's Hospital Colorado
Here, it's different.

July 8, 2025

Sophie Thomas, MPH Prescription Drug Affordability Director
Gail Mizner, MD, FACP, AAHIVS, Board Chair
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

RE: PDAB Enbrel Upper Payment Limit Hearing

Dear Director Thomas, Chair Mizner, and members of the Colorado Prescription Drug Affordability Board:

Thank you for accepting public comments on the work of the Prescription Drug Affordability Board (PDAB) and the Prescription Drug Affordability Advisory Council (PDAAC). **We write to urge the Board and Council to carefully consider the impacts on accessibility for pediatric patients when considering an upper payment limit (UPL) on Enbrel.**

Children's Hospital Colorado (Children's Colorado) is one of the leading not-for-profit pediatric healthcare providers in the country, as well as the largest provider of Medicaid services for children in the state of Colorado. We care deeply about the health and well-being of children in our state and in the broader seven-state region from where our patients come for their specialty care. We desire to preserve and expand their access to care.

We understand the need to examine the high cost of prescription drugs and appreciate the PDAB and PDAAC's directive. We also believe it is critical to advocate for the medical needs of the patients and families we serve and, as such, we have identified potential areas of risk that we feel the Board should consider with regard to pediatric patients.

Enbrel is the preferred drug for treating children with juvenile idiopathic arthritis (JIA). JIA is an autoimmune condition that affects children as young as one year old and typically presents with swollen joints, pain and mobility limitations. If left untreated, a child can have permanent joint damage and altered growth resulting in lifelong physical disabilities. At Children's Colorado, 87% of our patients with this condition are prescribed Enbrel. E**nbrel is a preferred treatment for pediatric patients with JIA because it allows for precise weight-based dosing, it is an at home-administered medication, it does not require concurrent medications with additional monitoring requirements (e.g., methotrexate + adalimumab), and it effectively treats the condition so that affected children can participate in daily activities, avoid disability and have a higher quality of life.**

The therapeutic alternatives to Enbrel that the PDAB included in their analysis are based on adult populations who have access to over 20 FDA-approved therapeutic agents for inflammatory arthritis, whereas there are only 12 FDA-approved options for pediatric patients. Among the alternative therapies to Enbrel that are available for the treatment of JIA, many of these require intravenous administration rather than subcutaneous injection. This not only increases healthcare costs but also poses access challenges for pediatric patients since this requires a higher level of medical care. Additionally, recurring infusion appointments require time off school for the child and often time off work for the parent/guardian, further impacting families both practically and financially. In-home infusion services, free-standing infusion centers, and adult-focused infusion centers are generally not equipped to support the unique safety needs of pediatric patients, leaving higher cost hospital-based infusion centers as the primary option for these patients.

Treatment with adalimumab, another subcutaneous alternative, is frequently associated with the development of anti-drug antibodies which block the effectiveness of the medication. To prevent this complication, therapy with adalimumab typically requires patients to be on a concurrent immunosuppressant, such as methotrexate. Given the risk of toxicity associated with methotrexate, the addition of this immunosuppressant requires more frequent lab monitoring. Due to its unique molecular structure and mechanism of action, Enbrel does not trigger antidrug antibody development. As a result, it does not require concurrent immunosuppression or the additional laboratory monitoring. **These characteristics make Enbrel the preferred therapeutic option for children with JIA since our treatment goals include minimizing risks, reducing excessive testing and enhancing overall quality of life.**

Turning to affordability, JIA patients seen at our institution have an average patient out-of-pocket cost of $0 due to financial assistance resources made available by the drug manufacturer, either through traditional copay cards or direct manual reimbursement. From the PDAB analysis, the majority of patients prescribed Enbrel had higher monthly average out-of-pocket costs (between $0-$50), likely reflecting the predominantly adult populations surveyed. There is concern that implementation of an UPL could lead to manufacturers restricting financial assistance programs for patients on Enbrel. This, in turn, could have the unintended consequence of increasing the out-of-pocket costs for patients who are therapeutically responding to Enbrel or force them to switch to an alternative, less desirable therapeutic option simply because of cost. This approach is not ideal for disease management, particularly in pediatric patients, where there are fewer FDA-approved treatment options for JIA compared to adult rheumatoid arthritis.

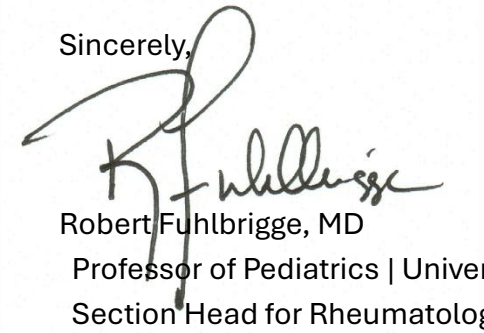
Children's Hospital Colorado
Here, it's different.

Additionally, switching medications for any reason may compromise disease control. **We recommend the Board include these and other factors contributing to the cost of Enbrel, including the roles of intermediaries in the supply chain and industry pricing dynamics, as part of your assessment of affordability.**

Another significant concern is the potential for restricted access to Enbrel by insurers following the establishment of an UPL. At present, Enbrel is included in the formulary for all (or nearly all) payers, often as a preferred agent for the treatment of JIA. However, some payers have indicated that they may respond to the implementation of a UPL by removing Enbrel from their formularies or lowering its tier status. Such changes would make Enbrel inaccessible to patients who are currently stable on the medication or for whom Enbrel is the most appropriate initial therapy. Insurers could also expand the use of utilization management strategies such as prior authorizations or step therapy requirements to restrict access.[1] In a related development, a recent article published in *Arthritis & Rheumatology,* titled "*The Inflation Reduction Act and Etanercept*", highlights that although the Centers for Medicare & Medicaid Services (CMS) and Amgen agreed on a Maximum Fair Price (MFP) for Enbrel, this pricing will not be binding for commercial payers. As a result, not all Americans – in particular, children covered under commercial insurance - will benefit from the MFP. [2]

Given our multi-payer system and drug patent protections in the United States, we are concerned that upper payment limit legislation may not result in lower direct medication costs for Coloradans as the PDAB intends. **We implore the Board and the Council to consider the unique needs of pediatric patients and proceed with caution as you assess a UPL for Enbrel and to judiciously avoid taking any actions that would risk limiting access to a drug that is so critical to the care of children in Colorado.** If you have any questions or need more information, please contact Erica Pike, Policy and Advocacy Specialist at Erica.Pike@childrenscolorado.org.

Sincerely,



Robert Fuhlbrigge, MD
Professor of Pediatrics | University of Colorado
Section Head for Rheumatology | Children's Hospital Colorado

[1] https://advisory.avalerehealth.com/insights/update-health-plans-perceptions-of-pdabs-and-upls
[2] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.43153

CSRO
Coalition of State Rheumatology Organizations

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June 24, 2025

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

Re: CO PDAB – Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel

Members of the Colorado Prescription Drug Affordability Board:

The Coalition of State Rheumatology Organizations (CSRO) appreciates the opportunity to comment on the Board's second hearing regarding *Rule 3 CCR 702-9: Part 4.3: Upper Payment Limit for Enbrel*. CSRO serves the practicing rheumatologist and is comprised of over 40 state rheumatology societies nationwide with a mission of advocating for excellence in the field of rheumatology and ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease.

Rheumatologic disease is systemic and incurable, but innovations in medicine over the last several decades have enabled rheumatologists to better manage these conditions. With access to the right treatment early in the disease, patients can generally delay or even avoid damage to their bones and joints, as well as reduce reliance on pain medications and other ancillary services, thus improving their quality of life.

Enbrel (etanercept) is a biologic therapy that plays a critical role in the treatment of several chronic and systemic rheumatologic conditions, including rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. It works by targeting tumor necrosis factor (TNF), a key driver of inflammation—helping to control disease progression, prevent joint damage, and improve patient function and quality of life. For many patients, Enbrel has made the difference between long-term disability and independence.

As the Board continues its evaluation of Enbrel (etanercept) under the affordability review process, we hope it will keep in mind the importance of protecting patient access to therapies that are essential to effective disease management in rheumatology. We respectfully offer the following comments and recommendations for your consideration.

Therapeutic Alternatives are Not Appropriate Substitutions

As the Board evaluates Enbrel (etanercept), CSRO urges the Board to recognize that not all therapeutic alternatives are therapeutically equivalent for this medication, having drastically different clinical outcomes for patients. When healthcare providers are evaluating medication substitutions, they typically consider therapeutic *equivalents* – not alternatives. Therefore, we strongly recommend that the Board recognize that only therapeutic equivalents to Enbrel (etanercept) are clinically appropriate to consider for substitution.

Deeming medications "therapeutic alternatives" is a one-size fits all approach that disrupts the physician's ability to exercise their medical expertise in concert with their patient. Patients that suffer from complex chronic conditions, such as rheumatoid arthritis and other rheumatologic diseases, require continuity of care to successfully manage their condition. Patients may spend months or years of trial and error, working with their physician to find a treatment regimen that properly manages their condition. The resulting course of treatment must carefully balance each patient's unique medical history, co-morbid conditions, and side-effect balancing drug interactions. For example, Enbrel (etanercept), which is a soluble tumor necrosis factor (TNF) receptor works differently than Humira (adalimumab) which is an anti TNF monoclonal antibody. While both are biologic agents studies have highlighted how patients at high risk for certain infections (TB, histoplasmosis, coccidioidomycosis) should receive Enbrel (which is unique in its mechanism of action) over Humira (adalimumab) or other anti-TNF monoclonal antibodies, such as infliximab.[i] Studies have also shown that Enbrel elicits fewer anti-drug antibodies (ADA) giving a clear advantage of Enbrel (etanercept) over the monoclonal antibodies (infliximab and adalimumab).

Even slight deviations in treatment and variations between drugs, even those in the same therapeutic class, can cause serious adverse events. Aside from the needless suffering endured by the patient as they work with their physician to find the right course of treatment, any disease progression caused by a delay in appropriate treatment can be irreversible, life threatening, and cause the patient's original treatment to lose effectiveness. The Board cannot assume that a treatment that works for one patient will work for every patient. These considerations are critical as the Board evaluates whether an Upper Payment Limit (UPL) on Enbrel (etanercept) could shift utilization toward less costly but non-equivalent alternatives.

Real World Impacts of a UPL for Enbrel (etanercept)

CSRO strongly encourages the Board to study the real-world impact of establishing UPL for Enbrel (etanercept). In particular, we urge the Board to monitor whether these medications remain accessible to patients following implementation. While a UPL may limit the list price for medications and reimbursement for health care providers, it fails to ensure that health plans will continue to cover the medication on their formularies. Limiting the payment for a medication often makes it less profitable for health insurance companies and their pharmacy benefit managers (PBM), which may reduce their incentive to place the drug on a preferred formulary tier.

Even if health plans include the selected drugs on their formularies, there is nothing to stop the plan from placing the medication on a fourth tier, requiring patients to "step through" much more expensive drugs before they can access the UPL medication. This type of formulary design manipulation will severely limit patient access to the drugs selected by the Board, minimizing the Board's influence in making medication more affordable.

In addition, we urge the Board to study the impact of the UPL on Enbrel (etanercept) and any future medications and how that may influence patient access. We urge the Board to conduct a comprehensive analysis of whether:

(1) The drug products subject to the UPL remained on formulary; whether formulary placement or plan design changes made the product more difficult for patients to access; whether insurance plans preferred a non-UPL product over a UPL-subject product;
(2) Medical practices, that administer these mediations to their patients at in-office infusion suites, are able to acquire the medication at a price sufficiently below the UPL to cover the acquisition costs and other overhead associated with storage of the drug (if reimbursement (payment) to the practice does not cover those costs, the patient will be referred to a higher cost of care (i.e., hospital) or lose access to the medication altogether);
(3) Prescription drug product shortages or other supply disruptions occurred following or as a result of the UPL's implementation;

(4) The distribution and delivery of specialty medications from out-of-state specialty pharmacies to providers, pharmacies, or directly to patients was impacted;
(5) Cost differences resulting from the UPL affected patients or providers, and who ultimately bore those costs; and
(6) The UPL was associated with increases or decreases in actual patients out-of-pocket costs for the prescribed medication.

Since Colorado will be the first state to implement an Upper Payment Limit on medications, the state also bears the responsibility to evaluate the effectiveness of this untested policy. CSRO welcomes the opportunity to work with the Board throughout this evaluation and provide feedback on how the UPL on Enbrel (etanercept) and other future medications impacts access to care.

On behalf of practicing rheumatologists throughout Colorado, we thank you for your consideration and are happy to further detail our comments to the Board upon request.

Respectfully,

Aaron Broadwell, MD, FACR
President
Board of Directors

Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs
Board of Directors

[i] https://www.tandfonline.com/doi/full/10.1080/14712598.2017.1340453

July 9, 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 am deeply concerned that the Board's process for selecting medications and conducting affordability reviews will leave Colorado patients without access to necessary medications.

I am a board-certified pediatrician and pediatric rheumatologist who spent my career caring for young people with chronic or disabling conditions. Many of my patients, such as those with juvenile idiopathic arthritis and lupus, rely on specialized, innovative, expensive therapies. My primary focus is always ensuring the well-being of my patients, but I fear that the Board's decisions do not reflect this same mandate.

The Board's search for "therapeutic alternatives" is fundamentally misguided and dangerous for patients for whom substitution is not clinically appropriate due to unique medical conditions or treatment needs. The criteria for selecting these so-called "alternatives" often fail to account for the complexities of individual patient care. Unilaterally designating certain medications as "therapeutic alternatives" fundamentally disrupts the physician's ability to exercise their medical expertise in concert with their patient. Healthcare providers like myself consider therapeutic equivalents when considering medication substitutions as a matter of standard practice, but therapeutic alternatives are not therapeutic equivalents. Patients with complex chronic conditions, such as rheumatoid arthritis or other rheumatologic diseases, require continuity of care to successfully manage their conditions. Policymakers should not make blanket policies overriding their doctor's prescribing recommendations.

The issue of using of "therapeutic alternatives" rather than "therapeutic equivalents" is evident in your decision to consider Enbrel "unaffordable" and therefore eligible for setting an Upper Payment Limit (UPL). While Enbrel is in the class of TNF-alpha inhibitors, its specific mode of action is unique within that class, resulting in specific differences in its pharmacological effects.

For example, while not as effective as other class members in treating uveitis or inflammatory bowel disease, it also has a lower risk of contracting tuberculosis than the other TNF-alpha inhibitors. For specific patients, its unique mode of action and other characteristics may result in better outcomes; how will your UPL decisions impact those patients?

Further, I find the lack of consideration of the real-world consequences of a UPL problematic. We have seen that the creation of the Maximum Fair Price (MFP) within the Inflation Reduction Act has resulted in a 32% increase in out-of-pocket costs to patients.[1] Since a UPL creates a similar situation to the MFP, there is no reason not to expect a similar consequence within Colorado. Similarly, NCPA has reported that many of its member pharmacies will not be carrying the medications with a MFP because they cannot afford to do so. This too is likely to occur in Colorado. We also know that insurers and PBMs will likely adjust their formularies if the UPL reduces their profits by shifting such a medication to a higher tier or excluding it from the formulary; what will be the Board's response to such actions?

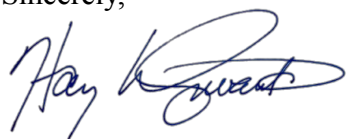
The opaque evaluation process of collected data further undermines confidence in the affordability review process. Without detailed definitions, methodologies or standards for assessing "therapeutic alternatives" and other critical factors, the Board risks making decisions that do not adequately reflect real-world patient experiences or clinical realities. Establishing clear, consistent processes and ensuring transparency in decision-making are essential steps toward improving access to affordable medications for those who depend on them.

The proposed list of potential therapies for affordability review is extensive and could significantly impact Colorado patients across a wide range of disease states. I am deeply concerned about the potential unintended consequences of such evaluations, especially when conducted under short timelines and without sufficient public input.

I share your goal to lower prescription drug costs, but the current process risks limiting access to essential medications. Physicians and patients are eager to collaborate with the Board to ensure affordability decisions reflect real-world patient needs on a more thoughtful, patient-centered approach. As it stands now, the Board's actions could inadvertently restrict access to medications for those who need them most in Colorado.

Thank you for your attention to this critical issue.

Sincerely,



Harry L. Gewanter, MD, FAAP, MACR
Board Member, Let My Doctors Decide Action Network[1]

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[1] https://pioneerinstitute.org/the-inflation-reduction-act-ira-overview/

Dear PDAB Members,

As someone deeply involved in healthcare along the Front Range, I see every day how hard it can be for Coloradans to get the care they need. Fewer local providers and limited access to specialists are just part of the challenge. That's why I'm writing to express concern about the potential consequences of setting upper payment limits (UPLs) on certain prescription drugs.

The intent—making medications more affordable—is something we all support. But the way UPLs are being considered raises important questions about transparency, access, and patient impact.

To date, the board has not issued clear guidelines or standards on what pricing data will be used to determine the UPL. There has also been no indication of what a UPL might actually look like for any specific medication. This lack of information is hampering true public input. In order for stakeholders to provide meaningful feedback, the board should disclose examples or ranges of potential UPLs to allow the public a full understanding of the impact.

As we've said repeatedly, there have been no concrete assurances that a UPL will not disrupt the supply of medications or restrict patient access. The imposition of a UPL represents a substantial risk to pharmacy reimbursements, which could lead to reduced availability of certain drugs, especially if manufacturers respond by limiting or pulling products from the Colorado market. This would ultimately harm the very people these policies are meant to help.

There's also no clear evidence that government-imposed price ceilings will lower out-of-pocket costs for patients. Meanwhile, the potential for unintended consequences—fewer treatment options, delayed access, and market disruption—is real.

There are better, more patient-centered ways to reduce drug costs. Simplifying insurance processes, capping out-of-pocket costs, and holding pharmacy benefit managers accountable would offer more targeted and effective relief—without putting access at risk.

I urge the board to proceed with greater transparency and caution. Lowering drug costs is an important goal, but it must be done in a way that protects both affordability and access for patients across Colorado.

Thank you for your commitment to this critical issue.

Sincerely,

Jennifer Churchfield, Chair

Front Range PharmaLogic

www.copharmalogic.org

jennifer.churchfield@gmail.com

June 27th, 2025

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

Dear Members of the Prescription Drug Affordability Board:

The undersigned organizations appreciate this opportunity to comment on upper payment limit rulemaking for Enbrel. We will continue to weigh in on the implementation process to ensure the Board advances equitable, consumer-centered policies that make real strides to improve the affordability of medications for Coloradans with the highest barriers to care.

Continued Support for the PDAB and Upper Payment Limits

The purpose of the Prescription Drug Affordability Board (PDAB), as expressed in the legislative declaration, is to reduce drug costs for Coloradans who struggle to afford medications with an equity lens.[1] In addition to assessing affordability and intervening to lower costs when affordability challenges are identified, the Board is charged with using its powers to bring more transparency and accountability to the pharmaceutical supply chain.

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. A broad and diverse coalition of community partners and organizations supported the passage of SB21 175 in response to growing concerns about drug costs from Coloradans across the state, from patients, health care providers, small businesses, and other concerned parties.

Three years later, this support has persisted. Polling from 2024 demonstrated the continued need for affordable medication and reaffirmed broad support for direct action.[2] 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%). Lastly, respondents attributed high healthcare costs writ large to the high costs charged by drug companies.[3] Such public sentiment speaks to an understanding that drug prices are not solely an individual prescription access issue but threaten affordability of care broadly.

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[1] "Excessive drug costs...Pose a threat to the health and safety of all Coloradans but disproportionately harm people of color and Coloradans with low incomes" C.R.S. Title 10, Art. 16, Pt. 14

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

[3] "In fact, out of fifteen options, the most frequently cited reasons for high health care costs were: Drug companies charging too much money (79% of respondents)"

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 to understand the complexities inherent to this work. Board staff have shown efforts to be fully transparent and accountable to the public.

With these obligations in mind, we want to highlight that the Board's work is designed to increase accountability and shed light on the unfair business practices along the pharmaceutical supply chain and most importantly, increase access to the highest cost drugs in our state. We acknowledge that this process is not perfect and we are operating in a complex system. However, the upper payment limit mechanism is the only tool that Colorado has to address the root cause of the high cost of prescription drugs and we believe that it must be seriously and thoroughly explored to understand the real benefits that it could provide to patients and the health care system alike.

We would also like to call out that uncertainty at the federal level and looming threats of funding cuts to affordable health care programs makes state driven solutions even more crucial. While Enbrel is one of the 15 drugs selected for Medicare Part B and Part D price caps beginning in January of 2026, we urge the board to continue with our state-level timeline that began in 2021 when the legislation that established the PDAB was passed.

Enbrel Upper Payment Limit

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). Even with carriers paying almost 90% of total costs for Enbrel across the private market, consumers with insurance are still struggling to access this medication due to high out-of-pocket costs--let alone those who are uninsured. The most recent APCD data reaffirms these trends showing Enbrel cost over $83 Million in 2023 commercial sales with an average out of pocket cost of $4,538 for Coloradans.[4]

Alarmingly, Enbrel's price has increased 36 times since introduction, resulting in an over 1500% increase in price thus far (2023 Affordability Review Summary Report, 24). Most recently, Enbrel's average out-of-pocket cost for Coloradans *increased 54% between 2021 and 2022*.[5] Given this history, it is reasonable to assume that this deeply concerning trend will continue

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[4] https://docs.google.com/spreadsheets/d/1KoAKUS1gIH6ssgGwJH2hZlF0IgL4tf4E/edit?gid=631693394#gid=631693394

[5] As reported by the All Payers Claim Database in 5/23/2025 PDAB Public Meeting Slides

through the course of Enbrel's patents, the last of which is set to expire in 2039 (C-11). Additionally, Enbrel's current patent protection from biosimilar competition, which lasts until 2029 (25), will continue to limit choice for Coloradans who deserve relief—both from the symptoms that their condition causes and the high price of Enbrel.

In understanding the need for an upper payment limit, we urge you to consider if any given prescription medication is universally and reliably accessible to those who need it.

We acknowledge that consumer stakeholding has been a difficult process for Enbrel. However, we would like to call attention to the cited 71% of surveyed patients who 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. Notably, even patients with $50 or less in copay costs reported issues with affording Enbrel (28). Relatedly, the report's detailing of patients struggling to afford Enbrel *even with financial assistance* (24) confirm concerns that we have previously raised regarding the reliability and accessibility of manufacturer patient assistance programs for all patients.[6, 7, 8] Furthermore, we elevate the systemic difficulty in capturing many of the folks who face the most barriers to health care[9] and applaud the board's determination to improve consumer input during future iterations of this process.

As a Board, you have looked at the findings and found Enbrel to be unaffordable - both in 2024 and with the corrected APCD data on May 23, 2025. The drug's high across the board costs and startling year-over-year price growth paints a picture of both individual and system-level unaffordability. You all have been diligent and heard from consumers, patients, manufacturers, and others. Now, the undersigned organizations encourage you, the PDAB, to embrace the full intent of legislation and set an upper payment limit for Enbrel. We believe setting upper payment limits will meaningfully reduce prescription drug costs for Coloradans.

Signed,

Mannat Singh
Executive Director
Colorado Consumer Health Initiative

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[6] A 2019 JAMA study found that nearly all patient assistance programs require consumers to be insured.
[7] A 2025 integrative review of patient assistance programs for oral oncolytics found numerous eligibility and accessibility barriers including "insurance status, income ceilings, OOP costs, and prescription to initiation timeline delays."
[8] A 2022 Health Affairs study found that "the "solution" [to affordability challenges] offered in the form of manufacturer-supported patient assistance programs is likely to worsen the affordability of prescription drugs for the health care system overall."
[9] The U.S. Census Bureau notes racial and ethnic minorities, people who speak languages other than English, low-income populations, undocumented immigrants, people with disabilities, and people who do not live in traditional housing are among those most difficult to capture in census surveys.

Austin Blumenfeld
Executive Director
Centennial State Prosperity

Lori Copani
Campaign Manager
Committee to Protect Health Care

Hunter Nelson
Colorado Director
Small Business Majority

Melanie Kesner
Rocky Mountain Regional Director
Young Invincibles

Dennis Dougherty
Executive Director
Colorado AFL-CIO

Laura Packard
Executive Director
Voices of Health Care Action

Mark Longshore
Executive Director
Colorado Nurses Association

Sammi Kerley
Senior Director
Small Business For America's Future

Andrea Wilkins
Legislative Liaison
League of Women Voters Colorado

Lydia McCoy
CEO
Colorado Center on Law and Policy

Neal Walia
Director of Policy and Government Relations
Colorado Academy of Family Physicians

From: Jennifer Churchfield

To the Members of the Prescription Drug Affordability Board,

I urge you to carefully consider the real human impact of setting an upper payment limit on medications like Enbrel.

My sister-in-law lives with rheumatoid arthritis, and I have seen firsthand the toll this disease can take. Before receiving access to medications, she spent most of her days confined to a recliner, relying on heating pads and the constant help of her husband—my brother. Daily life was a struggle. After finally gaining approval for the medication she needed, everything changed. Today, she's able to function more normally. She still experiences pain, but she's active again, and I know she would tell you she's grateful to have her life back.

I worry that government price setting—no matter how well intended—could threaten access to life-changing medications like this. If manufacturers pull these drugs from the market or reduce availability in Colorado, patients like my sister-in-law could lose the progress they've fought so hard for.

I understand the concern about high drug prices and the role of middlemen who contribute to cost inflation. But please consider whether this approach will truly help patients, or whether it might unintentionally harm them by limiting access. There must be a better way to reduce costs without putting critical treatments out of reach.

At your July 11 meeting, I respectfully ask that you think of people like my sister-in-law. This decision isn't just about numbers on a page—it's about people's lives.

Sincerely,

Polly Page

Aurora, CO

Dear Members of the Prescription Drug Affordability Board,

As someone with deep roots on the West Slope, I've grown increasingly concerned about how policy decisions made at the state level could impact people in our region—especially older adults and families who already face challenges accessing care.

The Colorado Prescription Drug Affordability Board is currently considering capping prices on certain medications. While the idea may sound like it would help patients, the reality could be very different. These price controls may not actually lower what patients pay, but they could create serious barriers—like drug shortages or reduced access in smaller communities like ours.

I think about how this could affect my own grandmother, and so many others across the West Slope. People here can't afford to lose options when it comes to their health. We already deal with fewer providers and longer travel for care. If certain medications are pulled from the market or no longer supplied to our area, it could have real consequences.

If we truly want to make prescriptions more affordable, we should focus on reducing out-of-pocket costs and fixing the insurance system. Bureaucratic pricing decisions should not put access to life-saving medicine at risk.

I respectfully urge PDAB to postpone this action and consider the broader impact it could have on families and patients across rural Colorado.

Sincerely,
Keanan Garnes
Grand Junction, CO

July 8, 2025

Subject: Urging Indefinite Postponement of Prescription Drug Price Controls

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

We, the undersigned Colorado businesses and organizations, urge the PDAB to indefinitely postpone its proposed July 11 action to impose prescription drug price controls.

Over the past four years since the passage of Senate Bill 21-175, the Prescription Drug Affordability Board has failed to demonstrate that such measures will improve patient outcomes or reduce costs in a meaningful or sustainable way. Instead, the process has lacked transparency, patient representation and real-world pharmaceutical pricing expertise.

Economic conditions, federal drug pricing reforms, and marketplace changes continue to evolve rapidly. Attempting to fix prices in one of the most complex sectors of the economy risks unintended consequences—most notably reduced access to critical medications and increased healthcare costs for patients and employers alike.

We are deeply concerned about the precedent PDAB is setting. Today, it's prescription drugs. Tomorrow, could it be automobiles, food, or clothing? Government price setting is not the solution. Market prices are determined by cost, supply, demand, and innovation—not by unelected boards.

We respectfully call on PDAB to halt further pricing action and instead focus on solutions that truly lower patient costs—such as improved insurance coverage, reduced out-of-pocket expenses and addressing PBM (Pharmacy Benefit Manager) practices that inflate prices.

Continued on next page

Thank you for your attention and consideration.

Sincerely,

Jennifer Churchfield, Front Range Pharmalogic Chair
Beau Flores, West Slope Pharmalogic Co-Chair
https://www.copharmalogic.org/

Organizations
Front Range PharmaLogic
West Slope PharmaLogic
Jefferson County Economic Development Corporation
Adams County Regional Economic Partnership
Fruita Area Chamber of Commerce
South Metro Denver Chamber of Commerce
Grand Junction Area Chamber of Commerce

Testimony in Support of Setting an Upper Payment Limit on Enbrel

Dr. Megan Purdy, emergency medicine physician in Denver, CO

Dear Members of the Colorado Prescription Drug Affordability Board,

Thank you for the opportunity to provide testimony, and more importantly, thank you for your continued work to make health care more affordable for Coloradans.

My name is Dr. Purdy, and I'm an Emergency Medicine physician practicing in Denver and Aurora. I care for many patients living with autoimmune diseases such as rheumatoid arthritis and plaque psoriasis–patients for whom medications like Enbrel are not optional. They're essential to managing pain, controlling inflammation, preventing disease progression, and preserving quality of life.

Thanks to the Board's work, we now have a clearer picture of the burden Enbrel's price places on patients and the broader health system. The data clearly show the scope of the challenge ahead: Coloradans spend more than $83 million a year on Enbrel. The average patient pays over $4,600 annually out of pocket–even with insurance. That's not sustainable. In fact, 71% of surveyed Coloradans reported that the cost of Enbrel makes it difficult to access. That means nearly three in four people are struggling to afford a medicine their doctor prescribed to keep them healthy.

I've seen the human impact of those numbers. Patients skip doses, try to stretch their prescriptions, or forgo Enbrel altogether–knowing their symptoms will worsen–because they simply can't afford it. As a physician, it's heartbreaking, especially knowing that it puts their long-term health at risk. We do everything we can to keep people healthy, but no treatment plan can succeed if patients can't afford the medicine.

Some argue that manufacturer discounts and rebates cushion the impact of price hikes but the evidence tells a different story. Even after accounting for those discounts, net prices of TNF-inhibitors like Enbrel still rose an average of nearly 10 percent per year. If there is credible evidence that contradicts this, I enthusiastically encourage those opposing a UPL to share it with the Board–because decisions this important should be grounded in facts.

Until that evidence is brought forward, here's the reality my patients face: These discounts are not protecting patients, they're just softening the blow. The fact is, my patients' pain is being exploited for monetary gain. But it doesn't have to be this way.

The Board's designation of Enbrel as "unafforable" was a vital first step. The high price of Enbrel didn't happen by accident. Enbrel's manufacturer, Amgen, has repeatedly raised the price over the years–more than 140% from 2011 to 2020, and another five percent last year. Meanwhile, their profits from this one drug have exceeded $70 billion.

The facts are on the Board’s side–and on the patients' side. Now, you have the opportunity to deliver real, tangible relief. Setting a strong upper payment limit on Enbrel would not only make this critical drug more accessible, it would reaffirm Colorado’s commitment to putting patients before profits.

I urge you to move forward with setting an upper payment limit that reflects what Coloradans can reasonably afford. Because prescription drugs don’t work if people can’t access them–and thanks to your leadership, Colorado is on the path to change that.

Thank you for your thoughtful work and your dedication to health care affordability in our state.

Sincerely,

Dr. Megan Purdy

Value of Care Coalition

July 9, 2025

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

RE: ENBREL UPPER PAYMENT LIMIT RULEMAKING HEARING #2

Dear Members of the Board:

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. We also recognize that no discussion of prescription drug affordability is complete without consideration of value, and that value is best defined by patients who receive the life-changing benefit of these treatments and by clinicians who weigh individual risks, comorbidities, and long-term outcomes of these treatments.

Unfortunately, the Board discussion during the May 23, 2025 rulemaking hearing did not account for that meaning of value. As the Board discussed setting an upper payment limit for Enbrel, it did so without once mentioning the value the drug provides to patients or health care providers, or the impact to actual patient cost or patient access at various hypothetical upper payment limits.

Instead of focusing on value, much of the discussion focused on Medicare's maximum fair price (MFP) as a potentially meaningful benchmark price. As such, VCC feels it important to acknowledge the already-apparent unintended consequences of the MFP on Medicare patients.

Medicare's Maximum Fair Price may cause community pharmacies to not stock certain drugs, resulting in diminished patient access

A recent 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.[1] Expanding MFP or similar pricing

[1] 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

beyond the Medicare program has potential to exacerbate challenges facing community pharmacies, and by extension, further diminish patients' ability to access the drugs they rely on.

Medicare patients are paying more for drugs subjected to the Maximum Fair Price

The Pioneer Institute recently released a report showing out-of-pocket costs have increased – not decreased – for Medicare patients for most drugs subjected to the Maximum Fair Price, with the average increase being 32%.[2] The report also noted, "all four of the largest PBMs increased out of pocket costs for six of the seven medicines with cost increases; one medication had out of pocket increases from only three of these PBMs," further highlighting that a focus on manipulating topline prices takes a too-narrow view of a complex health care system.

Additionally, a white paper from the University of Southern California further details how Medicare Part D plans are responding to government price caps. They note a "sharp increase in 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]

Clinician concerns about upper payment limits remain high

The Value of Care Coalition recently commissioned a white paper surveying specialists' (endocrinologists, rheumatologists, and HIV specialists/infectious diseases specialists) views on prescription drug affordability boards and upper payment limits in four states, including Colorado, where boards are operational. The board may find it valuable to consider a few key data points ahead of the release of the full report:

- Almost universally, physicians (93%) report a lack of sufficient knowledge-sharing between PDABs and clinicians
- Physicians (93%) are also concerned PDABs unaffiliated with a state medical board will make decisions that may affect medication access
- Clinicians surveyed (96%) were very or somewhat concerned that UPLs may lead to non-medical switching
- All specialists surveyed (100%) are concerned that additional administrative burdens related to PDABs will cut into office staff time and patient care

[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/

[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/

Conclusion

As the board continues the rulemaking process for Enbrel and future treatments under consideration for upper payment limits, it should carefully note the impact that MFPs set at the federal level are already having on patient costs and patient access. The board should also seek greater communication and collaboration with those who know best the value of the treatments being discussed – the patients who rely on them and the specialists tasked with caring for those patients. Thank you for your work on this important issue.

Derek Flowers
Executive Director
Value of Care Coalition

Dear Members of the Prescription Drug Affordability Board,

As Chair of the West Slope PharmaLogic Steering Committee and an advocate for healthcare access in our region, I've seen firsthand how access to reliable, affordable healthcare is already a challenge in Western Colorado. We face fewer providers, longer drives to care, and limited access to specialists. When statewide policy decisions are made that could affect medication availability, it is critical that we fully understand what is at stake.

PDAB's current proposal to consider price caps on certain prescription medications, including those relied on by Coloradans managing chronic conditions, raises serious concerns. While the goal of lowering costs is widely shared, we must ask whether these controls will truly benefit patients or unintentionally limit access, particularly in rural and underserved areas like ours.

At present, there is no clear evidence that government-mandated pricing will lower out-of-pocket costs for patients at the pharmacy counter. However, there is significant concern that these measures could reduce availability as manufacturers withdraw products or redirect supply away from smaller markets. These disruptions tend to affect rural communities first and most severely.

There are more effective ways to address high prescription drug costs by reducing insurance red tape, capping out-of-pocket expenses, and reforming the practices of pharmacy benefit managers, whose role in driving up prices remains largely unchecked.

Affordable medications are essential, but so is access. The West Slope cannot afford to be an afterthought in these decisions. I urge the Board to consider the broader impact of its actions and prioritize solutions that protect both affordability and availability for all Coloradans.

Thank you for your time and consideration.

Sincerely,
Beau Flores
Chair, West Slope PharmaLogic Steering Committee
Grand Junction, CO

Dear PDAB members-

As someone deeply involved in healthcare in the Front Range, I see every day how hard it can be for Coloradans to get the care they need. Fewer local providers and limited access to specialists are just part of the challenge. That's why it's crucial we pay attention to statewide decisions that could impact which medications are available and affordable. The Colorado Prescription Drug Affordability Board (PDAB) is currently considering setting upper price limits on certain prescription drugs, including medications that many rely on to manage chronic conditions. The intent—making medications more affordable—is something we all want. But we need to ask: will these proposed price caps actually help patients, or could they unintentionally do more harm than good? There's no solid evidence yet that government-set price ceilings will lower out-of-pocket costs for patients. However, there is real concern that they could reduce access if manufacturers respond by pulling certain medications from the Colorado market. That would leave patients with fewer options and could worsen existing access gaps. There are smarter, patient-focused solutions we should be exploring first: simplifying insurance processes, capping out-of-pocket costs, and addressing the role of pharmacy benefit managers— middlemen who often contribute significantly to high prices. Lowering drug costs is important, but it shouldn't come at the expense of access. Let's make sure we're protecting both affordability and access.

Jennifer Churchfield

Englewood, CO

Email from: Jennifer Churchfield

To the Members of the Prescription Drug Affordability Board,

As a patient living with a chronic condition, I know how important it is to have reliable access to the medications that keep me healthy and able to live my life. That's why I'm deeply concerned about an upcoming decision by the Board which is considering setting a government-mandated price on Enbrel—a medication that many Coloradans rely on for conditions like rheumatoid arthritis.

While lowering drug costs is a goal we can all support, I worry that this approach may do more harm than good. There's no clear evidence that these price caps will actually lower what patients pay at the pharmacy. But there is a real risk that drug companies could respond by pulling important medications from the Colorado market—leaving patients like me with fewer options or no options at all.

We've already seen how hard it can be to access care, adding more barriers won't help. There are better ways to reduce drug costs—like capping what patients pay out-of-pocket and increasing transparency around middlemen who drive prices up.

Our voices matter, and decisions about our care should never be made without us.

Lisa Elder

lmelder@live.com
Westminster, CO