COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

Jen Laws
Phone: (313) 333-8534
Fax: (646) 786-3825
Email: jen@tiicann.org

April 9, 2025

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

RE: Cost Investigation and Data Validation

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.

Today, we write with concerns regarding cost evaluation and data validation efforts.

Budget Impacts Have Still Not Been Examined

Given the delays in the commencement of rulemaking proceedings in the setting of a UPL, we are concerned that staff has yet to investigate costs effectively. In the steps leading up to the affordability reviews that deemed Enbrel unaffordable for Coloradans, many different cost metrics related to drug pricing were examined from multiple viewpoints. Statue-defined factors to be used to set a UPL also discuss many different pricing factors such as carrier paid amounts and public healthcare fee schedules. However, there has not been equal thoroughness in evaluating the implementation costs, either direct or indirect.

Implementation of a UPL for one or multiple drugs requires additional labor utilization to monitor and ensure compliance, process required reporting by affected plans, and solicit and analyze data generated regarding the outcomes of UPL setting. Moreover, as evidenced by Orgeon's cost research conducted by an independent consulting group, a UPL can result in costs to the state Medicaid program and safety-net entities due to lost revenue. Although Oregon has not instituted a UPL, they sufficiently completed an analysis that indicated additional adverse costs to the state coupled with meager savings that did not warrant the potential for access challenges and the fiscal instability of finances associated with the state budget.

Effective consulting with state entities already in existence can facilitate an accurate picture of the true costs of a UPL on one or many drugs without a de novo data undertaking. Cost does not just pertain to the price of drugs but applies to the financial effects of implementation for patients and multiple stakeholders. One cannot explore actions to take regarding setting drug pricing, assuming that things will work out while ignoring the fiscal ramifications of cost-setting. Moreover, without a budgetary target of desired savings in any form, it is impossible to forecast if the desired savings can be achieved when all necessary costs are not accounted for.

We would encourage more substantive cost investigation to be undertaken, especially with data already readily available, such as staffing and consulting costs and additional appropriations needed to shore up lost funding as a result of a UPL of one drug or many, before attempting to set a UPL for one or more drugs.

Data Validation Starts with a Flawed Foundation

Agenda items for the April meeting include APCD data validation overviews for Enbrel, Cosentyx, and Stelara. It is important to note that regarding data validation, we are concerned that the foundation of any affordability discourse remains fatally flawed. During the affordability review phase, the Board did not ensure clean and applicable data acquisition since the Board did not ensure patient survey responses were Colorado-specific. The survey solicitations were across multiple states. This does not coincide with Board statutory directives or limitations of Colorado law. Additionally, there was no verification that the respondents were **not** Medicare beneficiaries. The experiences of Medicare beneficiaries are valuable. However, assessments of "affordability" and the implementation of cost-containment activities cannot include Medicare data, given that the state of Colorado cannot enact a UPL on Medicare claims.

APCD Data is Insufficient

APCD data does not consider claims denials or utilization management. Both increase patient and system costs financially and in regard to the effort required to navigate the processes associated with denials and utilization management. Dealing with both can be adversely burdensome to patients and caregivers, resulting in suboptimal care, including treatment abandonment, which is not reflected in APCD metrics.

The last meeting briefly touched on the desire to include some sort of denial and utilization management inquiry in the data submission guide. However, that guide has not yet been finalized.

Lastly, Board affordability discourse surrounding UPLs and supply chain elements has had a substantial focus on various aspects of drug rebates. A recent communication issued by the Center for Improving Value in Healthcare (CIVHC) analyzes drug rebate data for Colorado's top 15 most commonly rebated drugs. It is crucial to note CIVHC explains that in spite of rebates, drug costs for patients and payers continue to

increase. Proper affordability data analysis requires detailed, fully explanatory, properly filtered, and documented data. Without robust and properly informed data, including the multifocal costs of implementing policies, there is the risk of misinterpretation of data to support a pre-determined conclusion.

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

HealthHIV

1630 Connecticut Avenue, NW, Suite 500
Washington, DC 20009

202.232.6749 | healthhiv.org

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

RE: Follow-up on Regulatory Analysis for 3 CCR 702-9 (Upper Payment Limits Rule)

Thank You for posting the cost-benefit analysis (CBA) for 3 CCR 702-9. After reviewing the posted materials—and in light of our formal request submitted on December 30, 2024—I'd like to follow up with some context and concerns from our patient-focused perspective at HealthHIV.

As outlined in our original submission, the UPL rule carries significant implications for Colorado's HIV care infrastructure—particularly through its potential disruption of rebate-dependent programs like ADAP (HMAP), HIAP, Medicare Part D support, and community case management contracts. Unfortunately, the current CBA does not appear to fully consider these impacts or provide the comparative analysis of action, inaction, and alternative approaches required under §24-4-103(4.5). For the CBA, we were looking for additional and substantive engagement on the potential:

- Estimated revenue loss to the state's HIV ecosystem from diminished rebates (ADAP, 340B, and Medicaid)
- Increased administrative and transition costs for the Department and contracted providers
- Impact on continuity of care for people living with HIV
- Relevant learnings from other states, such as Oregon, where cost-savings were negligible while provider destabilization was significant

We are concerned that the posted CBA neither engages these questions in detail nor references outreach to affected stakeholders or agencies, including CDPHE or Medicaid. The assumption of "nominal" implementation costs is particularly difficult to reconcile with the complexity of the pharmaceutical supply chain and the known reliance on rebate spread revenue among HIV ecosystems and aligned (contractually or otherwise) safety-net programs.

We appreciate the opportunity to engage through formal rulemaking, but for the purposes of transparency and good governance—as envisioned by both state statute and legislative intent—we respectfully urge DORA and the PDAB to revisit this CBA to ensure it fully reflects the economic and public health dimensions raised by community and provider stakeholders.

Please don't hesitate to reach out if further clarification or collaboration would be helpful, and we again appreciate the important and exigent work of this Board.

Best Regards,

Scott D Bertani, MNM, PgMP
HealthHIV
scottb@healthhiv.org
720.250.6691

April 11, 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 your proposed UPL could unintentionally limit input from diverse stakeholders and restrict access to essential treatments—especially for patients with rare, chronic or complex conditions.

Coloradans and their elected representatives deserve recommendations grounded in thorough wide-ranging and inclusive stakeholder engagement. Physicians and patients are concerned that your current approach may overlook individual patient needs, while also disadvantaging certain populations.

Your existing structure for gathering stakeholder input presents significant data collection challenges. Patients are often hesitant to participate in advocacy or reluctant to publicly share their medical conditions. Furthermore, your board meetings, typically lasting four hours and held during workdays, make it unrealistic for many individuals to attend or contribute meaningfully. Patients join advocacy organizations just for these reasons: to represent their interests and provide a voice when they are unable to do so themselves. Limiting organizations' participation undermines your charge to gather diverse and meaningful input, something the board has already noted is a deficiency. These organizations' input is vital in ensuring that the Board's decisions are informed by the lived experiences of patients.

Many of my patients, including those with juvenile idiopathic arthritis or lupus, depend on specialized, innovative, and unfortunately, expensive therapies. The current affordability review and rulemaking process ~~o~~utline extensive information gathering about costs, utilization, and spending by "eligible governmental entities" but fail to capture the real-world metrics reflecting actual patient affordability or health outcomes.

Additionally, I am deeply concerned the current approach may fail to account for individual patient needs, potentially disadvantaging certain populations. Policy decisions must be shaped by those who live with their consequences and that is not possible without robust and comprehensive patient and clinician input. Moving forward, it is crucial that the board ensures a more comprehensive and inclusive review process is implemented to avoid rushed or ineffective policy decisions and predictable consequences.

I urge the Board to review and provide recommendations that include the roles of **all** players in the system, including payors, pharmacy benefit managers (PBMs), and others who influence both list prices and out-of-pocket costs. Without including the entire drug pricing, supply and distribution chain, improving access to affordable, life-saving drug is not possible. Effective solutions must focus on what patients actually pay, not inflated list prices.

Physicians and patients remain committed to working with you to ensure affordable medications for all Coloradans. Accomplishing this goal ~~will~~ requires a more thorough, comprehensive, and extensive consideration.

Thank you for your attention to this critical issue.

Sincerely,

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

Prescription Drug Affordability Cost Benefit Analysis
April 2, 2025
By Advocates for Compassionate Therapy Now
Concerns and Recommendations
Bridget Dandaraw-Seritt
719.357.2334
actnow4patients@gmail.com

In December of 2024, the Colorado Division of Insurance (DOI) was tasked with providing a cost benefit analysis (CBA) for their consideration of establishing an upper payment limit (UPL) on the prescription drug Enbrel. That report was released April 2025. This report was supposed to outline potential benefits and costs to make sure this process would be economical for Colorado's tax payers. Unfortunately, the main theme of the CBA is, "we don't know" and provides very little insight.[1]

Given the current budget dilemma Colorado is facing[2], it would be beneficial to pause or stop the program until further discussion of costs versus benefits happens in a more robust manner.

Cost Benefit Analysis

In the Division of Insurance's version of the CBA, it claims potential benefits would be job creation, economic growth, and increased economic competitiveness. It further discusses the intent of the UPL is to reduce out of pocket drug costs, reduced premiums, increased use of therapeutic alternatives, improved patient adherence rates, and improving affordability for the healthcare system as a whole. It then goes on to discuss why it's hard to know if those goals will be achieved.

1. **Patients are unlikely to see direct out of pocket savings.** The vast majority of patients use some form of insurance with uninsured rates between 4.6% and 6.5%.[3] Typically, out of pocket costs are based on

---

[1] PDAB_Cost-Benefit Analysis_Final CBA template.docx.pdf

[2] https://www.cpr.org/2025/03/14/education-coalition-urges-colorado-lawmakers-create-long-term-school-funding-plan/

[3] https://www.coloradohealthinstitute.org/research/colorado-health-access-survey-preview#:~:text=Health%20insurance%20coverage%20in%20Colorado,the%20federal%20continuous%20coverage%20provision.

Bridget Dandaraw-Seritt
719.357.2334
actnow4patients@gmail.com

insurance plan designs, with a set amount or percentage. According to patient reported data, most pay between $0-$50 each month for Enbrel.[4] A UPL would not directly impact set copays, and most patients will end up with no change in out of pocket costs. According to a Partnership to Fight Chronic Disease survey, insurance companies expect patient cost sharing to rise as much as 50%, while 70% expect to see therapeutic alternatives in the same class to increase costs. [5]

2. **Premiums are unlikely to be reduced.** A recent survey of regional payers showed 57% are expecting premium costs to continue to rise. One report expects employer sponsored health plan cost to rise between 8% and 9% this year due to inflationary pressures.[6] Between increased hospital costs, advances in treatment options (like GLP-1 drugs for diabetes), and increased mental health expenses, premiums will continue to rise.[7]
3. **A UPL does not increase market competitiveness.** Unfortunately, given the supply chain structure with rebates and incentives driving formulary coverage, a UPL actually disincentives a drug making it less competitive.[8] Without the back end rebates, many payers would completely remove Enbrel from their formularies leaving patients with little option. Non-medical switching to "therapeutic alternatives" is not considered a benefit since other drugs may not be as effective since autoimmune arthritis diseases are often very individualized.[9]

---

[4] Enbrel

[5] https://www.fightchronicdisease.org/latest-news/new-research-shows-prescription-drug-affordability-boards-will-not-benefit-patients

[6] https://www.shrm.org/topics-tools/tools/express-requests/health-care-costs-projections-2025#:~:text=The%20average%20cost%20of%20employer,to%20an%20analysis%20from%20Aon.

[7] https://www.pwc.com/us/en/industries/health-industries/library/behind-the-numbers.html

[8] https://pmc.ncbi.nlm.nih.gov/articles/PMC10441264/

[9] https://youtu.be/1jmOXWvwPx0?si=m-2e7ejq2YFeGIsT

Bridget Dandaraw-Seritt
719.357.2334
actnow4patients@gmail.com

4. **Outside of the Division of Insurance jobs, there is no indication the PDAB is a job creating program.** After extensively trying to find where jobs would be created, the only information we could find pointed to job loss. Reduction in profitability will cause job loss in bioscience, pharmaceutical development, and other related fields.[10] [11] [12] [13]

Rather than addressing the realities and complexity of the UPL impact, the Division of Insurance chose to take a stance of uncertainty without acknowledging many of their intended benefits will not be realized. In addition, no indication of actual costs involved in setting the UPL were included. The CBA contains no numbers.

- It's estimated that Colorado has spent over $2,000,000 to date with costs around $700,000 in its first year alone.[14] Tax payers are paying for the DOI to research over 600 drugs each time the Board decides to choose new medications to review, rather than working off a singular developed list.[15]. This process is wasteful and expensive.

---

[10] https://www.brookings.edu/articles/the-long-term-economic-scars-of-job-displacements/#:~:text=A%20step%20and%20lasting%20negative,persist%20even%20a%20decade%20later.

[11] https://www.npcnow.org/resources/new-primer-highlights-unanswered-questions-and-unintended-consequences-state-prescription

[12] https://bio.news/latest-news/colorado-pdab-upl-drug-price-affordability/

[13] https://healthhiv.org/wp-content/uploads/2024/04/PDABs-and-UPLs-Impact-on-Patients-Drug-Pricing-and-Innovation.pdf

[14] https://dcjournal.com/the-failed-experiment-of-state-drug-affordability-boards/#:~:text=Four%20states%20are%20prime%20examples,in%20taxpayer%20costs%20to%20date.

[15] https://drive.google.com/file/d/1UivSMZngQH2aBHjTWcQntOtAICfnIwPn/view?usp=drivesdk

Bridget Dandaraw-Seritt
719.357.2334
actnow4patients@gmail.com

- Colorado has also spent over $150,000 on litigation fighting a lawsuit from Amgen, which most likely will be appealed.[16]
- Even further litigation could arise from the Board's insistence on using data that has been federally banned for devaluing the lives of elderly, disabled, and chronically ill.[17] [18] [19]
- According to the affordability report on Enbrel, 3,406 Coloradans utilized the drug in 2022 (most current available data). It cost $46,772 annually per person. It was not listed how much came back in rebates and 340B discounts. This is about $3,897.66 per month. Enbrel's list price is $7,106.00. Colorado is already paying significantly less than the list price. CMS negotiated a monthly rate of $2,355.00 which will become the new maximum fair price for Medicare and will most likely be adopted by Medicaid, saving an additional $1,542 per month. That means Colorado will already be saving over $5,000,000 per month without the help of the PDAB. Medicare has significantly more patients than Colorado, a relatively small market, so the chances of the PDAB improving on this is little to none. It should also be noted that the majority used manufacturer assistance programs making the drug affordable for most, thus lowering costs even more. This total does not include general rebates or 340B rebates making the true costs of Enbrel difficult to determine.[20]

---

[16] https://www.safemedicines.org/wp-content/uploads/2019/09/PDAB-update-3.12-1-1.pdf

[17] https://www.federalregister.gov/documents/2024/05/09/2024-09237/nondiscrimination-on-the-basis-of-disability-in-programs-or-activities-receiving-federal-financial

[18] https://youtu.be/q9EvKGUdkJ4?si=oN9ZPWvCc6lRKZNd

[19] https://drive.google.com/file/d/1UivSMZngQH2aBHjTWcQntOtAICfnIwPn/view?usp=drivesdk

[20] https://drive.google.com/file/d/17aAVEzICU5inUHz1LCu8ukYzb5sD6lqx/view?usp=drivesdk

- **The PDAB is doing redundant work creating government waste.** Two of the drugs being considered for a UPL have already been negotiated on a federal level, making the UPL and affordability process redundant and obsolete. Stelara and Enbrel already have signed contracts with The Centers for Medicare and Medicaid that will impact the maximum fair price allowed in Medicaid.[21]. There is no reason Colorado should be wasting taxpayer money on a similar process that actually does not impact manufacturer prices. One of the reasons the Amgen lawsuit was dismissed was because a UPL was not seen as impacting what the manufacturer could charge.[22]

The Division of Insurance touted several potential benefits that we now know will most likely not be realized. They, however, forgot to detail the potential harm that enacting a UPL could bring which will raise costs to Coloradans.

- In the Partnership to Fight Chronic Disease study, 77% of health plan payers believe UPLs could disrupt patient access due to coverage changes, tiering adjustments, increased plan cost sharing, and supply chain complications.[23] Disrupting access could be extremely costly for both the patient and the state and lead to more enrollment in welfare programs like TANF, SNAP, Medicaid, and Section 8. This truly could cost someone their ability to provide for themselves and their families.
- Since the UPL does not change the manufacturer list price, pharmacies are expecting shortages since they won't be able to stock medications

---

[21] https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf

[22] https://litigationtracker.law.georgetown.edu/wp-content/uploads/2024/03/Amgen_2025.03.28_MEMORANDUM-OPINION-AND-ORDER.pdf

[23] https://www.fightchronicdisease.org/latest-news/new-research-shows-prescription-drug-affordability-boards-will-not-benefit-patients

Bridget Dandaraw-Seritt
719.357.2334
actnow4patients@gmail.com

at a loss. This would disproportionately impact local independent pharmacies who are already struggling.[24]

- The impact of a UPL on critical 340B rebates could be catastrophic causing increased healthcare disparities in our most marginalized communities.[25]

Given the very real need to cut drug costs, other potential solutions should be considered. These alternatives have been presented multiple times to the Division of Insurance, but were not mentioned in their CBA. Instead they doubled down claiming a UPL was the only way Coloradans could access drugs at lower costs. We disagree with this statement and offer the same potential solutions we brought to the DOI.

- **Pharmacy Benefit Manager reform would have a bigger impact on lowering costs, both out of pocket and in premium savings.** You have HB25-1094 in front of you that would delink profits from list prices, encouraging PBMs to actually do their job and negotiate lower costs.[26] [27] [28]. In addition, CIVHC recently released rebate data suggesting that rebates could be driving up the costs of medication. "Nine of the eleven drugs that appear on the top 15 list for both highest volume and highest total

[24] https://naspa.us/blog/resource/pdab/

[25] https://transparencyreport.janssen.com/influence-of-pdabs#:~:text=If%20a%20UPL%20were%20to,the%20effects%20of%20the%20IRA.

[26] https://leg.colorado.gov/bills/hb25-1094

[27] https://drugchannelsinstitute.com/files/2025-PharmacyPBM-DCI-Overview.pdf

[28] https://www.wvinsurance.gov/Portals/0/pdf/pol_leg/IB_25-01_Prescription_Drug_Rebate_Impact_to_Commercial_Health_Insurance.pdf#:~:text=The%202021%20updates%20to%20the%20PAIA%20generally%20went%20into%20effect%20on%20January%201%2C%202022.&text=Any%20rebate%20calculated%20by%20a%20pharmacy%20benefit,plan%20to%20reduce%20the%20cost%20of%20premiums.

Bridget Dandaraw-Seritt
719.357.2334
actnow4patients@gmail.com

rebate amount have generic alternatives, which suggests that rebates could be driving increased use of higher cost brand and specialty drugs."[29]

- **Negotiating more effective plan benefit design.** Making sure preventative care is available to marginalized populations, creating an affordable copay structure, and decreasing costly utilization management like step therapy can significantly decrease healthcare costs.[30]
- **Making sure all copays and assistance goes toward deductibles and out of pocket maximums.** This would prevent PBMs and drug manufacturers from "double dipping" and increasing costs to both taxpayers and patients.[31]

In light of Colorado's budget shortfalls, it is recommended that the Prescription Drug Affordability Reviews be discontinued so that Coloradans can focus on truly reducing costs without sacrificing access to care. Doing so could save the state millions that could be more productive in other areas like education or Medicaid. We hope you all consider cancelling this wasteful program and seek other solutions to our healthcare crisis.

---

[29] https://civhc.org/2025/04/01/new-drug-rebate-data-identifies-colorados-top-15-most-commonly-rebated-drugs/

[30] https://www.actuary.org/sites/default/files/2023-08/health-brief-benefit-design-overview.pdf

[31] https://allcopayscount.org/