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

November 11, 2025

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

RE: UPL Next Steps

Dear Honorable Members of the Colorado Prescription Drug Affordability Board,

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

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

Responsibility for Unintended Consequences is Questionable

The Board acknowledges that non-medical switching, adverse tier adjustments, and formulary exclusions are potential outcomes of unfavorable UPL selection. However, the Board's sentiment is to urge stakeholders to reach out to legislators, since actions such as ensuring drugs assigned a UPL are not removed from formularies by plans require legislative protection. This presents as an abdication of responsibility for potentially adverse outcomes. These issues have been raised several times in the past, giving the Board ample time to inform the legislature of them. In addition to the responsibility of exploring non-UPL solutions, raising awareness of the absence of safeguards to protect stakeholders is also a responsibility of the Board's General Assembly reporting.

Extension of Time to Implementation is a Good Decision

The adopted rule states that the UPL will not take effect until January 2027. We support this, especially since, as of the last meeting, staff at this stage are trying to figure out the monitoring and implementation details. It is encouraging that energy is now being dedicated to determining which data and metrics should be measured for monitoring and implementation. However, as mentioned multiple times in the past, data points such as monitoring metrics should have been established much earlier in Board processes. Indeed, monitoring metrics would have emerged from a proper cost-benefit analysis.

Methodology Remains Unclear

A methodology is a planned and structured procedure for solving a problem or achieving a predefined goal. A practical methodology is one described in a way that allows peers and others to repeat the process to achieve the same outcome. The Board has expressed that it is not possible to set forth a concrete methodology because all drugs are different. However, regardless of the drug in question, any methodology requires defining the problem, explaining the drivers causing the problem, defining the desired outcome, and explaining how the stated solution specifically addresses that definition.

There does not appear to be a fleshed-out methodology for the Enbrel UPL that is repeatable and explainable. Relying on the CMS MFP for Enbrel as a convenient number is not a methodology.

A benchmark is a standard or a point of reference against which things may be compared or assessed. There is no evidence of analysis or research into multifactorial baseline data across multiple affordability aspects, where the outcomes of other potential UPLs were compared with the MFP. Additionally, rounding up the UPL to $600.00, which is just a few dollars above the actual MFP for no other reason than to ensure it is not colored as being directly linked to the MFP or to allow a margin of adjustment as MFP changes, is not an evidence-based methodology.

Presenting plan-payer APC data amounts and then stating that using the MFP would result in lower costs is not an evidence-based methodology. ***It is simply stating two different numbers where one is lower than the other***.

We also wish to reiterate our previously voiced concern about the overreliance on APC data, which is essentially flawed, not reflecting patient experience, which directly impacts patient affordability and access via benefit design. Similarly, APC data does not reflect profit-driven PBM motives in the tier structures that define patient cost-sharing amounts. Simply put, APC data is not a sufficient basis upon which to rely to define "affordability". Regardless of the PDAB's repeated use of this metric, APC remains a poor substitute for actual data gathering, accessibility metric monitoring, and policy-making.

There has been a repeated Board sentiment that manufacturers would not have agreed to MFP if it were financially harmful for them. Several stakeholders have pointed out that the MFP mechanisms were not a mutual negotiation process in which two parties of equal footing sat down at the negotiating table. CMS required manufacturers to agree to the terms before knowing them, with penalties of being locked out of the Medicare system if they did not agree. Most importantly, there is little explanation of how CMS arrived at the MFP number it settled on. With no framework for understanding how CMS arrived at Enbrel's MFP, and without proper analysis of Colorado's status quo, what methodology leads to the belief that the CMS MFP is what Colorado needs?

It is worth noting that medications selected for price caps by CMS are in their first stages of plan design changes, which this Board has not had the chance to review. Upon information and belief, CANN expects patients to be adversely affected by adverse tier changes, increasing patient costs.

Adopting the MFP as the basis for the UPL, without analyzing or modeling actual system and stakeholder needs, is not an evidence-based methodology. It is latching onto a convenient number and hoping for the best.

A UPL Does Not Operate in the Same Manner as an MFP

The CMS MFP program operates in a manner that attempts to make providers and pharmacies whole. Pharmacies and providers are required to pay manufacturers' acquisition costs while only being reimbursed at the MFP rate. Subsequently, claims are filed, and manufacturers pay pharmacies and providers the difference. A state UPL does not provide that attempt at financial saliency. A UPL set below the acquisition cost leaves purchasers at a loss. Currently, there has been no mention of suggesting additional appropriations to make up for that loss. A UPL is not a negotiated contract of acquisition prices. This is especially true for out-of-state wholesalers from where many pharmacies source medications.

The last meeting indicated that, now that a UPL has been set, staff is drafting letters as part of the manufacturer inquiry process to give manufacturers, such as Amgen, the opportunity to indicate whether they will make Enbrel available in Colorado at the UPL price. However, that description of inquiry is overly simplistic. Clarity on the inquiry letter details is needed, especially if the answer to the inquiry is 'no'. Because there is no evidence-based methodology for the current UPL's selection, what will the Board use as a foundation for offering another number?

As a non-patient issue, it is simply bad business to seek manufacturer agreement *after* issuing a mandate and during active litigation. It is neither reasonable nor rational to seek manufacturer agreement for a UPL at this late stage. It does, however, prove a tacit admission on the Board's part that a UPL is explicitly designed to pick winners and losers, or to otherwise coerce a private entity with complete humanitarian disregard for patients who might otherwise be negatively affected by losing access. From the patient perspective in observing this potential approach, the Board appears to be leveraging patient access (otherwise considered a potential consumer pool) as hostages in a business negotiation.

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.

We appreciate the time and effort the Board has put into this endeavor. Unfortunately, we are concerned that this UPL and the process leading up to it are irresponsible ways to simply put something in motion and hope for the best.

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