COMMUNITY ACCESS NATIONAL NETWORK

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

RE: UPL Setting Concerns

Dear Honorable Members of the Colorado Prescription Drug Affordability Board,

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

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

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

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

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

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

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

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

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

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

Implementation Remains Unclear, Despite Years of Information Request

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

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

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

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

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions.

Respectfully submitted,

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Community Access National Network (CANN)

On behalf of
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