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: Ongoing UPL Development

Dear Honorable Members of the Colorado Prescription Drug Affordability Board,

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

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

Clarity On How A UPL Can Adversely Affect Access

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

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

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

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

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

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

Monitoring remains unclear

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

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

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

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

Respectfully submitted,

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Community Access National Network (CANN)

On behalf of
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