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: Comments Concerning Ongoing Rulemaking

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.

Today, we write with exceptional concerns regarding current methodologies, interpretations of concepts used to arrive at certain conclusions, and the overall conceptual presentation of the Upper Payment Limit (UPL) as a policy tool for cost containment/savings.

Prominent tenet utilization based on incomplete information

A significant part of ongoing Board deliberation involves discussion of Wholesale Acquisition Cost (WAC) as it is one of your UPL cost metrics. Moreover, in your materials put together by staff it is described as the list price set by manufacturers made available to wholesalers or direct purchasers. Unfortunately, this description is too simplistic and does not present the full description of the reality. The recent Federal Trade Commission complaint filed against several of the major PBMs explains that while manufacturers may offer clinically identical high and low WAC versions of the same medications, PBMs often select the higher WAC medications because it enables them to have a higher rebate retention, increasing their profits and increasing the overall or average WAC.

Therefore, the ongoing discourse of methodologies of rulemaking involving WAC borderlines on conjecture, at best, when the whole reality of WAC is not **considered.**

This is important since the impetus of price manipulation is the PBM, not the manufacturer, who seems to be the Board's current focus.

Patient Engagement Remains a Weakness

The Board continues to emphasize its desire to gather better data from patients in terms of policy for affordability review. Yet, there is a reoccurring sentiment of concern about bias from patient advocacy groups. Like the Board, patient advocacy groups exist for the betterment of the lives of patients. The Board does not have a robust direct pipeline to patients, yet it questions the information provided by advocacy groups that do. As the Board continues to research ways to create appropriately constructed surveys that ***effectively*** ask the questions of patients that ***need to be asked***, we encourage the Board to place equal scrutiny on the entities they consult and partner with, including those they utilize for data collection in general. Additionally, we encourage the Board and staff to reach out to local doctors and physician groups that have daily interactions with patient populations who need to be reached to facilitate a better pipeline to the direct data the Board desires.

Furthermore, even in the instance where the Board might wish to remain skeptical of the expertise patient advocacy groups provide, staff have failed to engage existing State agencies that possess the ability and reach to directly engage patients, providers, and pharmacists. In spite of this lack of engagement, which the Board cites as necessary to obtain adequate data for "affordability reviews" and other Board endeavors, the Board *continues* to move forward. This presents as the Board viewing patient, provider, and pharmacist engagement and associated data as "optional." If such data is critical to developing a holistic view and sourcing sufficient data, absent that engagement and data, the Board must acknowledge it does not *currently* have sufficient means to diagnose 'affordability' nor institute a UPL. To insist otherwise defies logic and will ultimately be pointed out in adversarial litigation. All of which is entirely foreseeable and avoidable.

Failure to Sufficiently Consider Effects on the State

Indispensable information concerning data from the state's Medicaid and other public health entities has not been obtained despite actual years' worth of requests for said data from engaged patient advocacy organizations, which weakens the quality of the Board's decision-making. The risk of adverse unintended outcomes is significant; saying so is not "fear-mongering." UPLs could reduce funding structures, reduce patient access, and decrease the stability of Colorado's independent, non-chain pharmacy network, a critical resource in reaching impoverished, rural, and otherwise marginalized at-risk patient communities.

Oregon's PDAB enlisted the assistance of Medicaid consultants Stauffer-Meyer to investigate the effects on their programs. Those findings include an unknown but largely anticipated impact of reduced rebate values for the Medicaid program and 340B safety net providers. The most measurable anticipated outcome noticed by Stauffer & Meyer includes a less than half a million dollar "savings" in the state's $36 billion Medicaid program due singularly to rebate value reductions. Stauffer & Meyer encouraged Oregon's PDAB to request information from safety net provider entities regarding the impact of 340B value reduction on services and the scope of the program's reach, as such financial changes would be significant.

Indeed, this very impact is one CANN pointed out in previous public comments both in broad terms and in specific terms relative to the Board's "affordability" review of Genvoya. The Board's conclusion, when faced with the undeniable reality of public health funding systems and specified programs, such as Ryan White, was to admit efforts to address "affordability" would not be served by additional review or a UPL. The case remains true with all medications utilized in the federal 340B program and Colorado's Medicaid.

The people of Colorado would benefit from a thorough analysis of a UPL's possible fiscal outcomes. It is essential to know how the potential savings compare to the expenditures spent to maintain Colorado PDAB operations in combination with possible additional appropriations that would be required as a result of financial losses to 340B providers, SDAP, and Medicaid. Moving forward with such a glaring paucity of information/data is not reasonable or responsible. Doing so confirms the perception that the Board does not actually appear concerned with achieving the Colorado Legislature's goals of addressing "affordability" either for patients or the state, but rather "doing something, anything" that achieves the Governor's desired outcomes, as described in comments from the Governor's appointee, Kim Bimestefer, on July 13, 2023, to "punish" certain manufacturers.

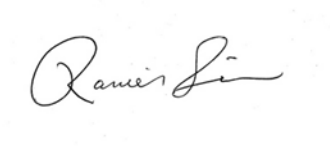
CANN is readily aware of budget-related concerns regarding Colorado's Medicaid program. Similar concerns have been raised by Indiana's Legislature, now facing a billion-dollar short fall and having to assess programmatic cuts. As a result, Indiana's Legislature began investigating the state's Medicaid Managed Care Organizations (in the commercial space, Pharmacy Benefit Managers) and their justification for increased costs. What lawmakers in Indiana found was that the state had overpaid the PBMs and was being inappropriately billed by the PBMs to the tune of $1.6 billion. We would suggest similar oversight might prove significantly more beneficial to Colorado than the imposition of a UPL.

A UPL Offers Limited to No "Savings" with Unacceptable Risks

Data from CMS indicates that any cost savings achieved by a UPL would only be due to cost-shifting. A UPL is in the same vein as the Inflation Reduction Act's Maximum Fair Price (MFP). The CMS National Health Expenditure Projections explain that instituting the MFP will reduce government spending by only cost-shifting and will simultaneously increase patient out-of-pocket costs. In the same manner, a UPL could result in the same shift, increasing patient costs, which actually reduces patient affordability and access.

We have thus far asserted our belief that the Board has the best interests of patients and the infrastructure that supports their well-being in mind. That belief is being challenged as the Board and staff continue moving forward with decisions that are plainly contraindicated by the data or lack thereof. As the Board and staff continue to work through solidifying metrics of affordability and pinpointing the specific problems they are attempting to solve we encourage the Board to consider the aforementioned concerns we have raised.

Respectfully submitted,



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Community Access National Network

On behalf of

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