

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

Board of Directors:

Darnell Lewis, Chair Riley Johnson, Secretary Dusty Garner, Treasurer

Michelle Anderson Hon. Donna Christensen, MD Kathie Hiers Kim Molnar Judith Montenegro Amanda Pratter Trelvis D. Randolph, Esq Cindy Snyder

Director Emeritus:

William E. Arnold (in Memoriam) Jeff Coudriet (in Memoriam) Hon. Maurice Hinchey, MC (in Memoriam) Gary R. Rose, JD (in Memoriam)

National Programs:

340B Action Center

PDAB Action Center

Transgender Leadership in HIV Advocacy

HIV/HCV Co-Infection Watch

National Groups:

Hepatitis Education, Advocacy & Leadership (HEAL) Group

Industry Advisory Group (IAG)

National ADAP Working Group (NAWG)

September 4, 2024

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

RE: Ongoing Affordability Review and 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.

As an engaged patient stakeholder group, we appreciate all of the Board's ongoing work. We write today with comments on the Board's current activities involving UPL development.

Budgetary Impacts Not Yet Considered

According to August 2024 data from the Kaiser Family Foundation, Colorado has 1,174,868 Medicaid enrollees. Approximately 22% of the Colorado population is low-income (defined as less than 200% FPL), and Medicaid/CHIP covers 18% of the Colorado population. A proposed UPL will not necessarily benefit out-of-pocket costs for patients, particularly those utilizing Medicaid, as most medications used by Medicaid beneficiaries do not have any out-of-pocket expenses to consider. However, UPLs could increase Colorado's "system costs" by adversely affecting its Medicaid spending. Half of Colorado's traditional Medicaid spending is paid for by the federal government. The amount of federal dollars allocated to the state to help pay for Medicaid services is based on Federal Medical Assistance Percentages (FMAPs). FMAPs determine the matching federal funds based on the state expenditure. If UPLs drastically affect Medicaid expenditures, Colorado would receive fewer federal matching dollars, thus requiring increased state spending on Medicaid services.

If the Board has not already done so, the Board should solicit guidance and analysis from the state's Medicaid program concerning the budgetary or fiscal impacts of imposing a UPLs prior to imposing any UPL. Notably, the Board should focus on understanding and integrating information concerning potentially reduced rebates or reduced federal matching dollars into the program. Moreover, the Board should explore programmatic changes that may be necessary because of potential funding reductions. Addressing potential budgetary shortfalls due to unintentional gaps in funding could require legislative appropriation. These things should be considered before the implementation of any UPL.

What problem does the UPL solve?

Plan design, which includes formulary placements and cost sharing, control patients' out-of-pocket costs. Thus, a proposed UPL will not necessarily benefit patients' out-of-pocket costs. How specifically does a UPL improve patient "access" or "affordability"? Does the Board have a consensus on what the differing lenses of affordability look like for various stakeholders? Also, does the Board have defined goals and endpoints of how issuing a UPL will improve the Board's selected parameters of affordability of all stakeholders' needs? Additionally, is the board considering contingency plans for potential unintended consequences of UPLs, such as medication deserts or pharmacy underreimbursement?

Previous Board discussions and the Board's legislative report indicate the Board recognizes that PBMs are abusive and play a role in increased patient costs. Governor Polis signed HB23-1201 into law, eliminating the practice of spread pricing by PBMs in the state. However, PBM compensation includes things such as spread pricing, administrative fees, and rebate retention. Eliminating spread pricing may simply mean a business practice shift toward PBMs utilizing a greater share of rebate retention to maintain their profit margin. A UPL is a reimbursement cap that would essentially reward PBMs by encouraging more rebate retention. The status quo of the financial benefit of rebates not being passed through to the consumer and increased system costs to payers would be exacerbated.

A recent <u>report</u> from the Pennsylvania Auditor General found that PBM spread pricing designs had adversely affected the state's expenditures, patient access to care, and is likely driving independent pharmacies out of business. Whether the issue of predatory PBM practices manifests as spread pricing or rebate retention, regardless of practice moniker, the unfortunate reality is the Board has not sufficiently investigated these issues as drivers to lack of "affordability", increased system costs, or other harm to access to care for Coloradans. The Board must make adequate effort to fully understand the role these issue play in harming patient access to care and care affordability. While good work has been done by this Board, the Board has not yet considered these factors in determining actual "affordability" of any medication, nor has it considered what policy solutions might more adequately address "affordability" concerns.

Data Gathering and Information Solicitation

While CANN remains opposed to establishing a UPL based upon our previously voiced concerns on access and appropriate policy solutions regarding benefit design, if the Board were to pursue establishing a UPL, it must also ensure to do so in such a fashion that does not perpetuate discrimination against older patients or patients with chronic illnesses. Presently, it is unclear what tools and metrics the Board is considering or eliminating from consideration for usage in determining values of UPLs to set.

There are many ways to explore price setting. A way various parties examining drug pricing issues consider is comparing U.S. prices to international prices by using a tool such as International Reference Pricing (IRP). Firstly, we'd like to emphasize that drug prices paid in other countries should not be considered. Other countries' markets are very different from those in the U.S., including those with a single-payer system and vastly different means of price control. However, what is more important is that IRP is a backdoor integration of QALYs in pricing data determination. We urge the board not to consider weighing IRP or any other metric which might include a QALY backdoor.

QALY methodology (i.e., Cost Effective Analysis) is built upon subjective value judgments. QALYs disadvantage people with disabilities as well as those with chronic health conditions because these populations will never be able to achieve what is defined as the "highest quality of life." Drugs treating these populations would be considered of lower priority and value because their potential of returning patients to perfect health is much lower than the potential of ideal health offered by medications utilized by younger people and those in better health states. Congress has already banned the use of QALY theory in cost-effective reviews in the Medicare program.

As part of continued Board efforts to gain robust stakeholder feedback, we would also encourage the Board to seek in-depth, detailed dialogue with the Rare Disease Advisory Council concerning the ramifications of UPLs and other measures.

Continuous Monitoring to Ensure Access to Care

Most notably, the Board has not considered what metrics and methods for continuous monitoring of medication access and affordability, should it impose a UPL. This is particularly troubling because any proposed policy solution to a problem must also have active monitoring metrics to prove its concept – has the policy provided the solution it sought? If, as we and others have suggested, imposing a UPL hurts rather than improves access to care, the state's Medicaid budget, or independent pharmacies, how would the Board know? If, as we and others have suggested, the imposition of a UPL harms patients, would the Board consider revoking a UPL ruling? The Board must consider the full "life cycle" of policy implementation prior to imposing any UPL.

Conflict of Interest in Consultants Must be Addressed

The Board must consider conflicts of interest in pursuing any data analysis consulting agreements. Particularly, the Board should consider those entities funded by the same funding interests that presented authorizing legislation as necessarily conflicted and prohibit contracting with those entities.

We thank you for the ongoing opportunity to provide feedback. We respectfully ask that you consider all the concerns raised and welcome dialogue concerning any questions you may have regarding our comments.

Sincerely,

Ranier Simons

Ramin Li

Director of State Policy

Community Access National Network (CANN)