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: Affordability Review Rulemaking and Ongoing Policy Activities

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.

Today, we write with comments on the Board's current rulemaking considerations.

Analysis of Specific Rulemaking Redline Updates to 10/9/24 Draft

Section D Subsection 5: "Consideration of whether the prescription drug has an approved orphan drug designation for one or more rare diseases and no other indications. If the prescription drug has an approved orphan drug designation for one or more rare diseases and no other indications, then the Board will consider input from consumers and the Colorado Rare Disease Advisory Council created in section 25-1-1503, C.R.S."

This verbiage seems to indicate that this category of Orphan Drug could still be eligible for consideration for affordability review if the Board considers input from consumers and the RDAC. We would urge that drugs with Orphan Drug status for one or more rare diseases and no other indications should not be considered at all.

Section E Subsection 2(c): We support the expounding that states, "To the extent the data is available, the Board may consider the impact of the drug's price on insurance premiums and out-of-pocket costs, the impacts of formulary placement on access, and the extent to which rebates are shared with patients purchasing the drug."

The FTC complaint points out that PBMs manipulate the average WAC with a preference for high WAC offerings. One of the instances where this is emphasized is the following direct statement from the FTC filing:

"144. The PBM Respondents, however, were not indifferent between the high WAC and low WAC insulin versions. Instead, they methodically disfavored the low WAC insulin products on their flagship commercial formularies, preferring only the high WAC versions, with high rebates and fees."

Regarding rebates being shared with patients, the FTC complaint also states:

"51. PBMs also handle the flow of rebate payments from drug manufacturers to the commercial payers. PBMs claim they pass on the vast majority of the drug rebates to their payer clients, though almost never directly to the patients."

Section E Subsection 2(d-ii): This section states that the Board may use literature that uses QALY analysis or similar measures that discount the value of life because of an individual's disability or age as a basis to evaluate financial effects but not to determine a U.P.L. or other cost containment measures. This is akin to an individual stating they smoked but did not inhale. QALY analysis should not be used in any form. Any usage of it poisons the entire analysis. QALY consideration is forbidden by the statute. Consideration is in **direct violation** of the advisory board statutory language.

Section E Subsection 2(e-iv): We thank you for specifying formulary placement as a data point in the rulemaking. Formulary placement significantly impacts the direct costs to patients, which ties into the significance of PBM control of plan design, which raises patient and system costs. Formulary placement is directly tied to issues outlined by the FTC complaint and reflective of controls negatively impacted by a PBM. The Board would be better served by analysis and reporting to the legislature where a UPL does not effectively address PBM abuses and would be an ineffective mechanism to correct the issue.

Section E Subsection 2(h): The availability of therapeutic alternatives is mentioned twice and comes up often during Board deliberations. We are inquiring as to why? How are therapeutic alternatives influential on actions aimed at cost reduction endeavors such as a U.P.L.? How does the exploration of therapeutic alternatives help determine the price of a U.P.L.? Additionally, does the exploration of the availability of therapeutic alternatives indicate a desire to institute other changes that do not involve a U.P.L., and would those possible actions be within the current statutory power of the Board, or would it require additional legislation?

Section E Subsection 3(b-iii): We discourage the Board from seeking drug pricing information from other countries. It would be comparing apples to oranges, providing no translatable correlation, and thus should not be used for any price-setting calculations. Additionally, other countries' pricing methodologies include QALYs and other discriminatory designs. Thus, utilizing drug pricing information from other countries is a 'backdooring' of prohibited metrics.

Section E Subsection 4(b): The section states: "Failure of an entity to provide pricing information to the Board for an affordability review does not affect the authority of the Board to conduct the affordability review, as described in this section."

We inquire as to how informed decision-making can occur without receiving the required information?

Section E Subsection 5(c & d): The verbiage indicates a broad ideation of 'unaffordable' where it is possible a particular drug could be deemed unaffordable for the system even if it is not unaffordable for Coloradans who utilize and depend on it. Thus, possible cost-reduction measures, while reducing system costs by some desired defined amount, could result in patient access issues.

Barriers to Effective Continued Cost Analysis

We urge you to consider that as you work through reporting for the legislature for next year and continue to work through affordability review rulemaking, the information you currently use is contaminated and does not adequately look at the issues at hand.

For example, the previous survey design used through the last round of reviews was inappropriate. There wasn't significant enough information among patient consumers for them to understand how the list cost of a drug is not necessarily reflective either in their coinsurance, deductibles or premiums. This was emphasized in the recent F.T.C. complaint filed against PBMs in the following paragraph:

"225. Additionally, many plan documents are confusing, unclear, or elusive about the extent of the patient cost-sharing obligations. Thus, patients in deductible and coinsurance plans may be unaware that their "share" of the dmg cost far exceeds the amount implied by their plan documents and may, in fact, exceed the payer's entire net cost."

There are other factors not being considered as well regarding deceptive W.A.C. practices, as delineated here:

"226. The substantial injury to consumers is not outweighed by any countervailing benefits to consumers or to competition. The PBM Respondents' systematic practice of excluding a low W.A.C. drug in favor of an identical high W.A.C. alternative from the same manufacturer does not lower net prices for the high W.A.C. drug. While some rebates may serve to lower premiums across patients in a health plan, not all rebates are used to lower patient premiums. Some rebates are retained by the PBMs and G.P.O.s, and the majority of the remaining rebates are retained by the commercial payer. For insulin patients forced to pay coinsurance and deductible payments based on the list price, dramatically higher out-of-pocket costs for insulin are significantly more harmful than the possibility of slightly lower premiums."

W.A.C. impropriety is damaging since the discussion of W.A.C. metrics is a central tenet of your affordability review analysis.

We will be sending you an extensive analysis of the F.T.C.'s complaint against PBMs, which outlines how they control and manipulate the market, including patient out-of-pocket costs, system costs, rebates, etc.

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.

Respectfully submitted,

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On behalf of
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