COMMUNITY ACCESS NATIONAL NETWORK

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

Submitted for Public Comment: Colorado Prescription Drug Affordability Board Meeting, February 23, 2024

February 21, 2024
Colorado Prescription Drug Affordability Board
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

Madam Chair and Honorable Members of the Colorado Prescription Drug Affordability Board,

The Community Access National Network (CANN) thanks the Board and serving staff for continued engagement on a variety of issues related to its work.

While CANN is primarily focused on policy matters affecting access to care for people living with 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 each and every one of those health conditions.

Today, we wish to raise significant concerns regarding the Board's recent vote to consider Enbrel "unaffordable" and urge the Board to pause any adoption of final report, initiation of establishing an "upper payment limit", and any additional reviews until such time as the issues outlined below are sufficiently addressed and resolved.

LACK OF STANDARDIZED ASSESSMENT

Throughout the Board's review of Trikafta and Genvoya, patient experience testimony was given appropriate, significant weight. The Board has also recognized in previous meetings the barriers for patients to sufficiently engage and the limitations of staff in working to reach patients who may be affected by drug selection for "affordability reviews" or an "upper payment limit". We appreciate the thoughtfulness of this consideration.

Indeed, the Board so significantly understood this limitation that it directed staff to re-open patient experience surveys – of which we have previously noted concern due to design. While this was an excellent choice, which CANN applauds, the survey responses included seeking data from a national reach. The Board is not tasked with assessing anecdotal national impacts, rather it is solely empowered to assess a loosely defined issue of "affordability" in Colorado alone. While it is proper for the Board to direct staff to partner with multiple organizations more closely in touch with consumers in order to advertise the patient surveys, it is improper for the Board to solicit responses from outside of

the state of Colorado, as the Board does not hold any jurisdiction outside of the state of Colorado. The "affordability review" report of Enbrel only includes some 38 responses from patients from Colorado. According to the Board's data, staff were able to identify 3,406 patients in Colorado utilizing Enbrel – meaning the Board gained insight from just 1.1% of patients who depend on Enbrel. Data was voluntarily collected regarding patient out of pocket expenses with 19 respondents, more than half of total respondents, stating their out-of-pocket costs were between $0-$50 dollars. More than half of those stated this out-of-pocket range "affected access". This range encompasses the lowest out-of-pocket costs possible and are still being considered "unaffordable" by some patients. While the Board should absolutely consider that for many patients, regardless of health condition or medication, *any* out-of-pocket costs may "affect access", the lowest tier metric should not be weighted as the same as out-of-pocket cost exceeding $1000 per month. Yet, during the PDAB meeting convened on February 16, 2024 to discuss "affordability" of Enbrel, this lowest tier metric was as highly discussed as the highest with no particular discernment between the two. Additionally, *no* discussion as to how out-of-pocket costs exceeding $1000 per month were an issue of plan design utilizing "coinsurance" as a percentage of *list* price, rather than *net* or how a flat-rate copayment might provide patients greater protection from out-of-pocket cost exposures.

Indeed, this issue of out-of-pocket costs, however, would be unaffected by the establishment of an "upper reimbursement limit" as the statute does not require pass through of any "savings". The report does, though, specifically note, on page 67, "the majority of carriers place Enbrel on the highest two formulary tears [sic], meaning a higher potation of the drug is paid for by patients than prescription drugs on lower tiers (until the maximum out-of-pocket amount under the plan is paid by the patient)." This further demonstrates the need to evaluate the impact of plan design, rather than reimbursement rates, as the core issue of patient "affordability" and "access". The issue of patient out-of-pocket costs is an issue of plan design and an issue the Board would do well to more sufficiently investigate as an opportunity to advise the Legislature appropriately.

CONSULTANT CONFLICT OF INTEREST NOT DISCLOSED

In all draft "affordability review" reports, reports refer to consultation by any other name with outside entities receiving funding from numerous sources, including those with foundation supports tied to both drug manufacturers and interests proposing PDAB legislation. The Board's conflict of interest policies apply to Board members and the Board requests that those wishing to submit comment are also submit funding interest information. No similar mechanism is required for those consultations nor is any funding interest disclosed regarding these consultants.

The Board has an ethical obligation to stop *all* work until all conflicts are investigated and disclosed. The Board would do well to include in its annual report to the Legislature any conflict with contractors or consultants and the ethical concerns arising from it.

REPORT PAYOR METRICS DESERVE GREATER SCRUTINY

Furthermore, data regarding drug reimbursement contribution to premium costs and plan design deserves greater scrutiny than that provide within the All Payor Claims Database (APCD) due to the inherent and, now, well publicized conflict of interest for when a payor either owns or is owned by a Pharmacy Benefit Manager.

For context, the Patient Protection and Affordable Care Act established profit caps upon each qualifying plan. The profit cap rule, known as "medical loss ratio" or MLR, requires that each plan conform to a profit cap of 15 or 20%, depending on plan group size. Meaning either 80% or 85% of all collected premiums and deductibles must be utilized by a carrier for actual care provision (medical claims). The remaining 15% or 20% may be used for overhead expenses and applied as profit. The same rule, however, does not apply with regard to pharmacy benefits or pharmacy benefit managers.

Since the inception of the Patient Protection and Affordable Care Act, healthcare insurers have begun operating their own, purchasing pre-existing, or otherwise folding in Pharmacy Benefit Managers into their own operations. Sometimes this might even be by subsidiary, in an effort to feign a lack of mutual association and potential for fiduciary irresponsibility by the insurer, should pharmacy benefit claims be particularly high.

In fact, this is exactly what several states have begun to recognize as a self-dealing type of reality. In Ohio, Attorney General David Yost has pursued the largest PBMs in the country for anti-trust action because of the role they play in keeping drug costs high for patients, while still making better than the top 20 among *Fortune 500* companies in the United States based on revenue. The state of Louisiana is still in suit against Optum for this same type of action – particularly as an abuse of the state's Medicaid program. On the federal level, the Federal Trade Commission is also investigating the role PBMs play in inflating drug costs, including the costs they report to their associated healthcare plans.

All Payor Claims Databases are excellent as an anti-fraud tool, in order to identify concerning transactions but the data itself should not be viewed as particularly scrupulous in light of the aforementioned investigations.

NO ACCESS MONITORING METRICS

In addition to the concerns laid out above, the Board has established *no* means of monitoring overall access to any particular medication selected for review or which might be affected by an "upper payment limit". The Board has an ethical obligation to periodically review the impact of its work in order to ensure the work is achieving its intended goals and not otherwise harming access to care.

Indeed, because of the unproven nature of imposing an "upper payment limit" and its impacts to patient access to care and the specific nature of rare disease, orphan drug, and public health interest associated with particular medications, the Advisory Committee very specifically requested the Board *not* consider reviewing orphan drugs until the impact of access is more well understood. Despite this advice, the Board is now faced with reviewing and potentially imposing an access limiting "upper payment limit" to a medication that serves to better the lives of patients across Colorado.

The Board has an ethical obligation to establish monitoring metrics and the mechanism for withdrawing an "upper payment limit" should new information come to light as to the effects of an "upper payment limit" on patient access to care and systems affordability *prior* to imposing any "upper payment limit" on any medication.

In light of the extraordinary nature of the information contained within this letter, the voices of patients attending the Board's meetings repeatedly heard throughout the last year, and the very uncertain impact to access imposing an upper payment limit would cause, we again urge the Board to opt to **NOT** approve the "affordability review" report as-is and **NOT** move forward with establishing an upper payment for Enbrel.

Again, and we must emphasize this to the fullest, CANN believes the nature of the Board's work, the work of DOI staff, and intent of the Legislature is good-meaning and honest. None of the issues described above should be considered an attack on the character or intentions of Board members or DOI staff. ***AND***, in order to act from that place of intent, with eyes wide open, the Board must consider the unintended consequences of potentially limiting access to Enbrel for patients in Colorado, the weighted known interests of PBMs under the banner of not being required to pass along any particular savings, and to meaningfully disclose conflicts of interest among all parties involved in the Board's decision-making process.

Integrity is, after all, integrating our actions with the values we espouse as our guiding intentions. CANN

respectfully requests the Board uphold the integrity of the Legislature's intent and of each Board member, individually, by pausing all work to address the issues above, protect access to medications for patients, and properly advise the Legislature of more appropriate tools to address patient affordability than those currently allowed under statute.

Respectfully,

Jen Laws
President & CEO