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

October 20, 2023
**VIA Electronic Mail**
Michigan House of Representatives
House Committee on Insurance and Financial Services

**RE: SB483 – Patient Concerns on Process and Ultimate Savings, or Lack Thereof**

Dear Chair Carter and Honorable Members of the House Committee on Insurance and Financial Services,

**About Community Access National Network:** CANN is a 27-year-old national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis from the patient perspective. CANN's mission is to define, promote, and improve access to healthcare services and supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

Attached is CANN's written testimony to the Senate Finance, Insurance, and Consumer Protection Committee. Below, we detail additional concerns regarding Prescription Drug Affordability Boards from the patient perspective.

**Process Concerns:**

CANN has worked in support of patient advocates and people living with HIV (PLWH) in several other states which have passed similarly situated legislation. Colorado, for example, is a state which has advanced quite swiftly in selecting medications for "affordability" review and continues in that process today. Speaking directly to patient experiences with these boards and their processes, those patients engaged in Colorado are regularly and routinely frustrated at the Board's failure to adhere to the recommendations of the Advisory Council, failure to adequately and substantially engage with patients affected by "affordability" review selection and the potential impacts of imposing an upper price limit, and the failure to coordinate with state agencies with more substantial community connections – be it with patients or providers themselves. Additionally attached are CANN's most recent public comments to the Colorado PDAB outlining these process failures and highlighting the sheer frustration patients are experiencing in working to be adequately heard in an effort to afford Michigan Legislators an informed perspective as to how fraught these boards are. Should the Michigan House pass SB483 into law as currently written, Michigan patients will face similar problems.

## “Affordability” as Framed by SB483 Does Not Speak to Patient Experiences

The issue of “affordability” strictly from the end-user, or patient, perspective does not start or end with list prices or reimbursement rates of medications. Rather, these are issues related to industry stakeholder interests, particularly those of pharmacy benefit managers (PBMs), and their profit margins; “Affordability” especially within the frame of various rebate structures, most directly translates to how much a PBM makes off of any particular medication. Indeed, testimony provided to this very Committee on October 12, 2023, by Sean Stephenson of the Pharmaceutical Care Management Association (PCMA), page 10, described this structure in exact detail by stating that PBMs “get compensated” by “some combination of the following options” “1. Spread pricing, 2. Rebate retention, 3. Administrative Fee”. However, those rebates offered by pharmaceutical manufacturers are designed to reduce the costs of medication *to patients*, not pad the profit margins of PBMs or their vertically integrated mail-order or physical pharmacy locations.

Rather, patient experiences in accessible healthcare and treatment, particularly medication access, is far more complicated. Barriers to care begin with high deductible and high premium health plans and are complicated by issues of insufficient provider networks, patient steering in pharmacy selection, and utilization management practices which operate to allow health plans to disrupt the provider-patient relationship by way of administrative burdens. Compounding these concerns, consolidation in the provider, hospital, and pharmacy markets reduce the number of access points of care, with particular harm toward rural communities wherein accessing even an emergency room might leave patients in rural communities hours away from life-saving care.

## Actions to Protect Patients and Improve Access to Care and Treatments

The Michigan legislature is well positioned to address these barriers to care and meaningfully making care and treatment more meaningfully accessible to Michiganders by examining and addressing the role of these interests by any of the following actions, all of which work to provide protections to patient interests:

- Prohibiting unfair trade practices (particularly with regard to hospital consolidation and patient steering)
- Prohibiting spread pricing (wherein PBMs may not charge a patient or plan sponsor more than the cost of acquiring a medication)
- Prohibiting so-called “co-pay accumulator” or “co-pay maximizer” programs (wherein financial support from manufacturer patient assistance programs must be applied directly to a patient’s deductible and/or maximum-out-of-pocket limit)
- Prohibiting certain utilization management practices (such as prior authorizations or step therapy – adopting “provider prevails” program)
- Prohibiting patient steering (wherein patient choice of pharmacy is equally reimbursed and protected from vertically integrated entities which profit from the self-dealing nature of PBMs requiring patients to utilize mail-order or physical pharmacies owned by or associated with the PBM)

## Questions Remain, Michiganders Should Not Answer by way of Experimentation

Many questions remain regarding the potential negative impacts of a an upper price limit on programs and providers dependent upon revenues and savings generated from the 340B Drug Discount Program in order to provide life-saving and life-improving care for marginalized populations, particularly people living with HIV, rare diseases, disabilities, and chronic conditions. Ensuring safety-net providers are well supported in providing reduced cost and/or no cost care and treatment to the patients who need it most is critical to ensuring Michigan meets its highest ideals in caring for its residents. A UPL undermines these essential funding mechanisms.

Similarly, no state has yet to answer the question of what happens when a UPL is imposed and the cost to acquire a particular medication is higher than the allowable reimbursement rate? Who pays? Will it be patients? If an exemption is allowed, what process burdens will patients face to get the treatments our providers have identified best suit our individual care needs?

Lastly, what are the costs to the “system” of care of ultimately denying access to the personalized care patients require to meet our health outcome goals? As one patient in Colorado recently stated during a stakeholder meeting, “Is it more costly to give me the medication I need now or is it more costly for me to end up in the hospital for three weeks, attempting to be stabilized?” These questions are very, very real, especially in the frame of medications selected for review by the Colorado PDAB – rare disease and antiretroviral medications are among those selected. PLWH and cystic fibrosis patients are quite familiar with what happens to us, our friends, and our families when our treatment access is disrupted – people die, families struggle through transplant waitlists, and higher viral loads due to disruptions in care mean new HIV diagnoses. That’s not an exaggeration. But is our fear.

## Conclusion

Ultimately, CANN respects the work and effort the Michigan Legislature is trying to achieve here. We well know you care about your constituents, your neighbors, and even your own families. And we know you want to address the complexities of our healthcare system which leave far too many patients behind. In these issues, we agree. A PDAB, especially one with the power to impose an upper price limit, is simply not the way to get there.

I am readily available to answer any questions you may have and look forward to future discussion on improving access to care for Michiganders. I can be reached at 313-333-8534 or by email at Jen@tiicann.org.

Yours in service,

Jen Laws
President & CEO
Community Access National Network

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

**National Programs**:

340B Action Center

HIV/HCV Co-Infection Watch

Hepatitis Education, Advocacy & Leadership (HEAL) Group

Industry Advisory Group (IAG)

National ADAP Working Group (NAWG)

Written Testimony, RE: SB483
Michigan Legislature
Senate Finance, Insurance, and Consumer Protection Committee
Committee Meeting 9/20/23

September 19, 2023
**VIA Electronic Mail**
Michigan Legislature
Senate Finance, Insurance, and Consumer Protection Committee
6500 Binsfield Office Building
P.O. Box 30036
Lansing, Michigan 48909-7536

**RE: SB483 Establishing a Prescription Drug Affordability Board neglects to require patient input or patient experience considerations; In opposition or, in the alternative, suggesting amendments affecting patient protections in process and implementation.**

Honorable Chairwoman, Senator Cavanagh, Honorable Vice Chairs, Senator Moss and Senator Huizenga, and Members of the Michigan Senate Finance, Insurance, and Consumer Protection Committee,

**About Community Access National Network (CANN):** CANN is a 27-year-old national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis from the patient perspective. CANN's mission is to define, promote, and improve access to healthcare services and supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

**SB483 Does not prioritize patient input, experiences, or outcomes above other entities.**

CANN is gravely concerned about SB483 and, more generally, the speed in which several states are adopting "Prescription Drug Affordability Boards", often neglecting to require patient input on each board, patient experience in required evaluative and monitoring measures, and failing to consider the unintended, but quite predictable, consequences of these boards.

A press release outlined Governor Whitmer's priorities in lowering barriers to care and making prescription medications more accessible and affordable for patients. However, Prescription Drug Affordability Boards, as described in SB483, do not consider patient experiences with payor (health insurer and pharmacy benefit manager) practices, like prior authorizations or step-therapy or other benefit design concerns patients face (including but not limited to insufficient provider and pharmacy networks or patient steering amounting to self-dealing by "vertically integrated" companies and their associated subsidiaries). Indeed, SB483 sponsor, Senator Camilleri stated directly the intent of the bill is help families, people with disabilities and chronic conditions, and those with limited incomes from feeling like they're "forced to choose between the medicine they need and basic necessities." As patients ourselves, we agree with this noble effort and the necessity of reducing cost and administrative burdens on patients and our healthcare providers.

In order to achieve this goal, the means and process of getting there must center those who are supposed to benefit – patients and our families. SB483, as currently designed, fails to consider the most direct costs to patients and healthcare providers.

For these reasons, we urge members of the Senate Finance, Insurance, and Consumer Protection Committee to oppose SB483 in its current form.

If the Michigan legislature is committed to passing this legislation, please consider amendments which would re-center the activities and decisions of this board on patients and our experiences, rather than the for-profit entities which stand to benefit the most such as pharmacy benefit managers and managed care organizations. Attached, please find a summary of suggested "amendments in concept" which would move the board construction, considerations, and decision-making process, and ultimately, the outcomes of this board's decisions to benefit patients and our healthcare providers.

If the Committee or any sponsor of SB483 has any questions, CANN is ready and willing to answer at your convenience.

Yours in service,

J Laws

Jen Laws
President & CEO
Jen@tiicann.org

**Prioritizing Patients - Suggested Amendments in Concept: SB483**

Sec. 3 – add definition for "therapeutic alternative." (Sec. 11, C (4) (c))

Sec. 5 – relative to board conflicts of interest; In an effort to ensure no issue of bias or conflict of interest, language should be clarified. Either strike "manufacturer or trade association for a manufacturer or otherwise" and clarify what constitutes "personal or financial interest" to include any stakeholders ***OR*** add "pharmacy benefit manager, health insurer".

Secs. 5 & 9 – relative to board member affiliations or qualifications;

- Include "patient"
- Re: "The public"; specify "resident of Michigan"
- Re: "statewide organizations"; amend to "statewide or national organizations that advocates for…" in order to provide parity to labor unions, researchers, and other potential member types which might draw expertise from outside of the state of Michigan and/or from national associations, advocacy organizations included must also be able to draw expertise from outside of the state or from national associations.
- Include a member representing rare disease advocates
- Include a member with public health expertise
- Include a member associated with the Michigan Department of Public Health, Michigan Drug Assistance Program (MIDAP)
- Include a member associated with the Michigan Department of Public Health, Medicaid program

Sec. 11 – implementation; due to suggested amendments, should they be adopted and in order to provide sufficient time to complete data analysis, stakeholder input gathering, and mandated studies, consider amending implementation time to 24 months.

Sec. 11, paragraph 3 – considerations of "affordability" must be from the patient perspective and reflective of overall patient experiences;

- Add to "average patient cost share for each prescription drug product."
  - Market diversity and competition relative to subject prescription drug
  - Patient experiences in healthcare navigation (particularly burdens associated with utilization management)
  - Expected and potential impacts on patient experience and overall burdens (to include but not limited to administrative burdens associated with utilization management, narrowed pharmacy networks, and patient steering)
- Paragraph 4 – Considerations
  - In allowable considerations, include market diversity and competition
  - In mandated considerations, include:
    - Utilization management practices
    - Disruption of the patient-provider relationship; individualized care needs
    - Cost or administrative burdens shifting to providers and/or patients
    - Payor use of spread pricing prior to and after the event of implementing an upper payment limit
    - Provider or AIDS Drug Assistance Program use of 340B rebates
- Paragraph 5 – Considerations; insert a sections focused on measurable and monitorable patient experiences, potential cost and administrative burden shifts to patients and providers, payor estimates for premium or cost-sharing reductions as a result of UPL, impact among independent pharmacies in the instance of instituting upper payment limit, and public health considerations

Section 20. studies; In order to ensure the advisory boards and decision-making board has sufficient data and input from stakeholders and understanding of the ecosystem of care (including economic impacts and various public health funding mechanisms), studies should be mandated to conclude prior to all other board activities.

- Additional studies necessary for full consideration and prioritization of patients:
    - Patient experiences relative to utilization management practices, pharmacy network adequacy, and patient steering
    - Payor/PBM profit relative to various rebate programs and concessions, profit relative to enactment of an upper payment limit, expected policies and practices as a result of an upper payment limit
    - Provider and healthcare entity experiences relative to utilization management, cost and administrative burden shifts associated with these
    - Anticipated changes to programmatic revenues and support services for MIDAP

CANN
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

**Board of Directors:**

Kathie Hiers, Chair
Darnell Lewis, Secretary

Michelle Anderson
Hon. Donna Christensen, MD
Dusty Garner
Riley Johnson
Judith Montenegro
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

HIV/HCV Co-Infection Watch

Hepatitis Education, Advocacy & Leadership (HEAL) Group

Industry Advisory Group (IAG)

National ADAP Working Group (NAWG)

# Submitted for Public Comment: Colorado Prescription Drug Affordability Board Meeting, September 15, 2023

September 12, 2023
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,

Community Access National Network has and worked to represent the interests and voices of people living with HIV for 26 years. We do so again today.

CANN remains gravely concerned about the selection process for so-called “affordability review”, the insufficient nature of the PDAB’s “stakeholder engagement”, and the failure to seek public health expertise and insights.We write today to detail our concerns due to the board’s selection of Genvoya, an anti-retroviral treatment for HIV, being selected for “affordability review”.

The considerations used to calculate “affordability” singularly focus on the perspective of payors, rather than patients. With the sole exception of “out-of-pocket cost”, there is no consideration, measure, or monitoring metric which centers patient experience and even that calculation is based on amounts reported by payors, rather than patients. Patients experience a plethora of barriers to care beyond what a payor projects an out-of-pocket cost to be, but to be clear, that out-of-pocket cost is most directly influenced by the policies set by pharmacy benefit managers (PBMs), rather than manufacturers themselves. Indeed, PBM policies have significantly greater impact on patient access to care than any issue of those metrics considered in calculating the PDAB’s “affordability”. These include, but are not limited to, step-therapy (colloquially referred to as “fail-first”), prior authorizations, pharmacy steering and lack of network adequacy, mandatory mail-order, and discriminatory reimbursement policies adversely affecting independent pharmacies. Each of these hinder access to care and have a disproportionately negative impact among marginalized communities, patients, the economic ecosystem of care, and other stakeholders and yet, nothing in the monitored metrics or assessment of “affordability” or the PDAB’s stakeholder engagement survey address these issues. Nothing in continued monitoring metrics would seek to assess these impacts among people living with HIV in accessing their life-saving medications.

The state of Colorado *knows* these barriers to care present real and tangible threats to public health goals, including Ending the HIV Epidemic. This year, the Colorado legislature passed legislation prohibiting some of the PBM practices outlined above with regard to prior authorization requirements and step-therapy but the board’s selection of Genvoya will incentives that undermine these protections.

Beyond the tangible lack of patient-experience focused metrics, the process for stakeholder engagement is not meaningful and belies a pre-determined conclusion. HIV advocates across the country are quite familiar with required “needs assessments” as part of the Ryan White HIV/AIDS Program. These often take months to plan and several more months to implement and parse data – the entire process can take up upwards of a year. But the proposed process for collecting stakeholder engagement is precisely 21 days. No detail has been made about patient specific outreach, meanwhile each jurisdiction funded under the Ryan White program is required to maintain regular and sufficient patient and community meetings. For Colorado, this the Colorado HIV Alliance for Prevention, Care, and Treatment. Nor has any data been presented from the state’s Department of Public Health and Environment regarding potential impacts to Colorado’s State Drug Assistance Program (SDAP), which “provides services to help people living with HIV get access to medications and offers assistance with insurance premium payments and covered out of pocket medical costs”. Colorado’s SDAP is the state’s AIDS Drug Assistance Program (ADAP), a federally funded program by the Ryan White HIV/AIDS Program.  ADAPs are dependent upon rebate revenues and enjoy being the only non-provider covered entity in the 340B Discount Drug Program. Beyond that, the vast majority of providers serving people living with HIV and accessing Ryan White services do so through clinics and hospitals similarly dependent on these programmatic revenues in order to provide a wide variety of services which are critically necessary tools in meeting the needs of patients. And there is no evidence to date to reflect a request or provision of data on how an upper payment limit on any anti-retroviral might impact already marginalized patients struggling to get their care needs met.

Colorado is home to the most innovative and justice-oriented patient demand that’s ever existed: The Denver Principles. “Nothing About Us, Without Us.” And yet, the operation of this board to date shamefully moves against those principles. The board must pause, must assess barriers to care from the patient perspective, and prioritize us to have any positive effect on medication access in the name of patients.

Respectfully,

J Laws

Jen Laws
President & CEO