PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

What They Are and Why They Matter to Patients

Wednesday, November 1st, 2023 | 2:00 PM ET - 3:30 PM ET

CANN
COMMUNITY ACCESS NATIONAL NETWORK

HealthHIV

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

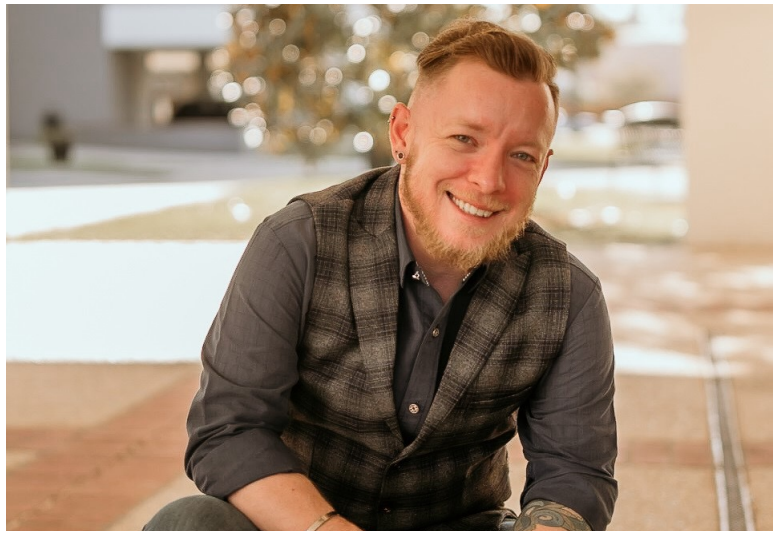
About CANN: The Community Access National Network (CANN) is a 27-year-old national non-profit patient advocacy organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking. Learn more at www.tiicann.org.

About HealthHIV: HealthHIV advances effective prevention, care, support, and health equity for people living with, or at risk for, HIV and hepatitis C—particularly with LGBTQ and other underserved communities—by providing education, capacity building, health services research, and advocacy to organizations, communities and professionals. Learn more at www.healthhiv.org.

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

COMMUNITY ACCESS NATIONAL NETWORK

Jen Laws



Scott Bertani

HealthHIV

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **What:**
- PDABs are state-level boards or commissions, typically situated within the Department of Insurance (or equivalent), tasked with:
  - Assessing “affordability” of prescription drugs
  - Setting “Upper Price Limits” (UPLs) for certain medications selected by each board as “unaffordable” – Note, note all PDABs have UPL powers
- **Where:**
- Colorado, Maine, Maryland, New Hampshire, New Jersey, Minnesota, Oregon, Washington (states that have proposed or tried to pass: Ohio, Virginia, Michigan)

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Who:**
- Mechanism of Action: In setting a UPL, a state is choosing to limit reimbursement, rather than direct price setting, by forbidding state-managed payors from reimbursing above a set dollar amount.
  - Medicaid, AIDS Drug Assistance Programs (ADAPs), etc.
- Disease states targeted (patients affected):
  - HIV
  - Behavioral health
  - Rare Diseases
  - Oncology

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Maryland:**
- **When (legislation passed): July 01, 2019**
- **What (powers/purpose):Purpose of Board**
- (b) The purpose of the Board is to protect State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products.
- The Stakeholder Council consists of 26 members, jointly **appointed** by the Speaker of the House, the President of the Senate, and the Governor.
- From among the membership of the Council, the Chair of the Board appoints two members to serve as co-chairs.
- A member's term is three years, with the initial members serving staggered terms as required under Md. Code Ann., Health-General § 21-2C-04.
- Entity Fees: An entity that is otherwise subject to assessment because it meets the definition of a qualifying entity under COMAR 14.01.01 and Health-General Article, § 21-2C-11(b)(1)
- **What (is going on):**
- **Analysis of the prescription drug product approval process**
  - The shifting conversation from upper payment limits to formulary designs and management.
  - Concerns about the board potentially delving into insurance product management. Observations and concerns about the scope and purpose of the board and its relation with insurance.
  - Emphasis on understanding the broader impact and not just focusing on individual affordability.
  - Emphasis on reducing both out-of-pocket costs and the overall price of drugs for insurance companies.
  - Importance of understanding the balance between premiums and actual out-of-pocket costs.

Proposed Methodology:

- Board's hesitation to lock into a specific tool, recognizing strengths and weaknesses.
- Caution against focusing solely on individual drug affordability.

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Oregon:**
- **When (legislation passed): Senate Bill 844, passed June 2023**
- **What (powers/purpose):**
- **Concerns on Confidentiality:** Vice Chair Bailey (2022) raised concerns regarding the confidentiality of sensitive information shared with third-party vendors. This issue relates to patient data protection and its misuse.
- **What (is going on):**
  - **Inadequate Data Skews the Board's Affordability Review Choices**
    - The Board, in its recent deliberations, has primarily depended on Drug Price Transparency (DPT) carrier reports.
    - Advise a meticulous examination of the DPT Carrier Reports
  - **Limited Data Use Misses Essential Drug Value and Affordability Factors**
  - **Prescription Drug Affordability and Utilization Management**
  - **UPL & Drug Pricing Complexity**:
    - **Net Price vs. List Price**:
    - **Recommendation**: PBMs - rebates and discounts directly to patients at POS .
    - **Issues with Utilization Management**:
    - **Prior Authorization Concerns**:
    - **Transformative Therapies**:
- While the board mainly discussed its functioning and procedures, there was a clear undercurrent of patient advocacy, especially regarding confidentiality and the financial burden of prescription drugs.
- The public comments particularly brought forward these patient-centric issues, urging the board to consider the larger impact of their decisions on Oregonians.

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Washington:**
- **When (legislation - WAC passed):** On March 24, 2022, Washington became the latest among six (at the time) states to form a Prescription Drug Affordability Board (PDAB) with Governor Inslee's endorsement of SB 5532, a bill proposed by (D) Sen. Karen Keiser.
- **WAC 182-52-0005 Prescription drug affordability board**—Purpose. The prescription drug affordability board conducts reviews of drug prices, performs drug affordability reviews, and sets upper payment limits for prescription drugs.
- **What (powers/purpose):**The PDAB will concentrate on high-priced brand name drugs: those with annual costs exceeding $60,000 or ones whose prices surged by 15% in the last year or 50% over three years. Some biosimilars and generics may also come under scrutiny.
  - Five governor-appointed members with expertise in health care economics or clinical medicine.
  - Members serve a five-year term once appointed.
  - Members cannot be: a. An employee of, board member of, or consultant to a prescription drug manufacturer. b. Pharmacy benefit manager. c. Health carrier. d. Prescription drug wholesale distributor. e. Trade association related to any entities in (a) to (d).
  - Representative Exception: Specific representatives may be part of an advisory group without conflict.
    - **Advisory Groups**:
      - Purpose: Establish groups of stakeholders for each drug affordability review.
      - Composition: Patients, patient advocates, and one prescription drug industry representative.
      - Immunity: Advisory group members are immune from civil liability for their official acts.

CANN COMMUNITY ACCESS NATIONAL NETWORK

HealthHIV

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Washington (Cont'd):**
- **What (is going on): October 20, 2023 the WA PDAB held its first meeting.**
  - Authority to Review Drug Prices
    - Review Factors: Including drug price factors, patient costs, therapeutic alternatives, and more.
    - Additional Review Factors: Life-cycle, market competition, projected revenue, and others.
  - Setting Upper Payment Limits
  - Use of Savings from Health Plans
  - Establishment of a Savings Formula and Annual Report

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Colorado:**
- **When (legislation passed):** SB 21-175
- **What (powers/purpose):** Authority to review prescription drug costs and evaluate their impact on Coloradans through affordability reviews of prescription drugs. The Board may then recommend ways to address those costs and may set an upper payment limit for certain prescription drugs.
  - PDAB: Senate Bill (SB) 21-175 introduced the PDAB, responsible for assessing prescription drug prices and determining maximum payment thresholds for select drugs.
    - SB 23-1225 introduces modifications to the board's evaluation method and permits the board to assess all prescription drugs. As of now, they are limited to examining 12 drugs. This change will take effect from January 1, 2025.
  - PDAAC: To provide stakeholder input on prescription drug affordability. All PDAAC members meet statutory requirements for composition, geographic representation, and subject matter expertise.
    - Overview of PDAB Work:
    - Dr. Gail Mizner, PDAB Chair
    - Anticipated 2024 PDAB Timelines
- **What (is going on):**

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Colorado (Cont'd):**
- In early August, PDAB selected five drugs for affordability evaluations – **Enbrel, Genvoya, Cosentyx, Stelara, and Trikafta.**
  - **Accessibility and Affordability**
  - **Treatment interruptions in HIV care: $850,557**
  - **Drug Utilization and Its Necessity**
  - **Data Limits**
  - **Wider Impact**
  - **Patient-Centric vs. System-Centric Approach**
- **What (is going on):**
- **Meaningful opportunity to participate in the decision-making process:**
    - **Affordability Reviews: Stakeholder Engagement & Guide.**
      - a. The utilization of the prescription drug by the safety net provider's patients,
      - b. Whether the safety net provider receives a 340B discount for the prescription drug,
      - c. Where the safety net provider does not receive a discount, whether access to the prescription
      - drug is impeded, and
      - d. Any other topics identified by safety net provider stakeholders for discussion.
  - PDAAC Recommendations for Selection Criteria Data (03/2023) Out of 15 PDAAC members, 9 submitted completed forms. The insights from the Advisory Council were crucial in shaping the Board staff's suggestions, which are outlined in the staff memo titled "**Affordability Reviews - Suggestions Regarding Selection Criteria Consideration & Data Details**."

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Colorado (Cont'd):**
- **Public approaching Legislature once again**
- **What (is going on):**
- **Intersection of the Denver Principles** with PDABs, several key points arise:
  - **Right to Comprehensive Medical Treatment**: One of the core tenets of the Denver Principles is that PWAs have the right to "as full and satisfying sexual and emotional lives as anyone else."
  - **Self-Empowerment and Autonomy**: The Denver Principles emphasize the autonomy and self-empowerment of PWAs.
  - **Equity and Non-Discrimination**: The Denver Principles insist on the rights of PWAs to be treated with dignity and respect, without discrimination.
  - **Informed Decision-Making**: The principles advocate for PWAs' right to be informed and make autonomous decisions about their treatment.
  - **Holistic Well-being**: The well-being of PWAs isn't just about managing the virus but also about ensuring a comprehensive quality of life.
  - **Patient Advocacy and Representation**: In line with the Denver Principles, any decision-making body, including PDABs, should involve representation from the affected communities.

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Michigan:**
- **When (legislation passed):** SB483 (proposed)
  - Passed Senate Committee, Full Senate with amendment to include “health equity” – ill-defined.
- **What (powers/purpose):**
  - “Affordability” review
  - UPL
- **What (is going on):** Currently “stalled” in House Committee. Unexpected to pass this year, concerns related to impacts on patient access and benefit (or lack thereof) to patients. **Advocates continue to engage.**

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Ohio:**
- **When (legislation passed):** RS. Sec. 125.95 (2019), Prescription Drug Transparency and Affordability Advisory Council
- **What (powers/purpose):** The Advisory Council issued a report in 2020, making a series of recommendations for the legislature to consider.
  - "Combined purchasing power" of a variety of state agencies obligated to paying for medications. The idea here being to leverage a "larger" purchase pool for bulk discounting.
  - "Reverse auction" designed with an automated bidding process set up in "rounds" between bidders, with guard rails of an opening price.
  - Establish a single formulary to serve all covered purchasing entities.
  - "Find additional ways to benefit consumers":
    - Expand options for use of copayment programs; speaking to addressing co-pay accumulator and "maximizer" programs established by payers.
    - Establishing a "minimum" formulary in which certain medications must be provided as covered without necessity for a consumer to reach their deductible first (addressing limited access by way of "high deductible plans".
    - "Allow" plans to apply rebates to members/enrollees at the point of sale to reduce out of pocket burden.
  - Consider health equity in developing prescription drug policies; meaning considerations of how systems changes impacts might disproportionately impact patients of marginalized identities, patients with chronic conditions, and patients with rare diseases.
  - Require clarity and accountability in PBM contract terms; among other recommendations this section very specifically sought to recommend the allowance of plan sponsor auditing of claims in order to generate transparency.
- **What (is going on):** RS. Sec. 125.95 was amended in 2021, establishing an effective termination date of advisory council

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Looking Forward:**
- Michigan
- Virginia
- Minnesota
- New Hampshire
- Illinois
- Other states?

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **How (to engage):**
- Stakeholders can engage in a variety of ways:
  - Legislative testimony
  - Patient letters
  - Coalition building
  - Patient education
  - Manufacturer informational meetings/submissions
  - Public comment during board/advisory board meetings

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Problems:**
- Is it worth it?
- Not patient-oriented
- Conflicted consultants
- Lack of coordination among state agencies
- Lack of meaningful engagement with patients
- Rebate impact unknown
- Pre-determined conclusions (bias)
- Who pays the difference?

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- **Elevating Patients:**
- Defining “access” beyond payor “affordability”
- Leveraging existing coalitions
- Considering ecosystem of care impacts (340B, support services, access for needy patients)
- Unlikely partners – Hospitals, independent pharmacies, FQHCs
- Offer pathways that improve patient access
  - Patient protections (addressing step-therapy, prior authorization, other payor-based barriers)
  - Prohibition on Spread Pricing
  - Assessing consolidation
  - Prohibitions on patient steering, protecting independent pharmacies and patient choice

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

QUESTIONS???

PRESCRIPTION DRUG AFFORDABILITY BOARDS (PDABs)

- Jen Laws
  President & CEO, CANN
  Jen@tiicann.org

Scott Bertani
Director of Public Policy, HealthHIV
ScottB@HealthHIV.org