ENVISIONING THE BENEFITS OF A PDAB

The possibilities, decision points, and potential savings a Prescription Drug Affordability Board can have for Colorado consumers.

Timeline of the Board

Board appointed by Oct 1, 2021

First meeting by Nov 12, 2021

Rulemaking on initial methodology*** must be done in public

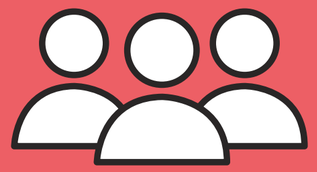
Rulemaking on savings by Nov 1, 2022

Board gets to work! Data collection, review & UPLs through rulemaking; Data reporting starts 2022

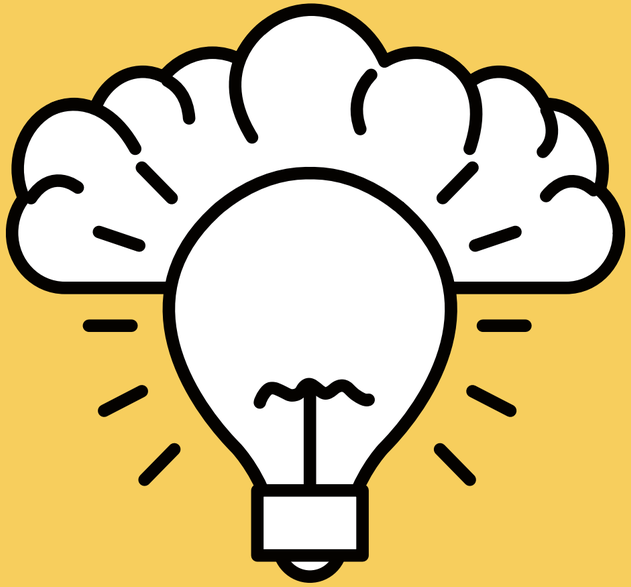
Annual reports on use of savings starts March 2023

Info published on website starting Jan 2022, annual reports to GA start July 2023

Stakeholder advisory council appointed by Jan 1, 2022



DOI manages hiring, budget + transparency info



What would the process for affordability reviews look like?

Options for PDAB Rulemaking

Steps:

1. Drug is triggered for review by criteria outlined in 10-16-1306 (1).
2. Board determines whether to conduct affordability review based on rules made in accordance with 10-16-1306 (2).
3. Board determines whether or not drug is unaffordable based on rules made in accordance with 10-16-1306 4, 6, 7.

What would the process for affordability reviews look like?

Important Aspects to Note:

1. **Board must consider availability & efficacy of therapeutic alternatives****
2. **Board must consider out of pocket costs and impact of availability & costs on health & financial wellbeing of patients**
3. **Decisions on whether to do an affordability review AND whether to deem drug unaffordable must be done in public meeting, with opportunity for public comment**

Steps:

1. Drug found unaffordable--Board MAY determine whether to set a UPL based on rules made in accordance with 10-16-1307(2).
2. Decisions regarding rulemaking process for UPL methodology MUST happen in public, with opportunity for public comment

What would the process for setting an Upper Payment Limit look like?

Options for PDAB Rulemaking & Processes

Demystifying the Upper Payment Limit

- UPLS are NOT price controls- does not affect list prices or ability to offer price concessions per standard business practice
- Intended only for drugs sold for use within state of Colorado- therefore no violation of the interstate commerce clause
- The UPL will likely face a legal challenge- but will likely be found to be legal
  - Bill has been vetted by Colorado Attorney General
  - PCMA vs Rutledge case resulted in unanimous decision from Supreme Court that states have full authority to establish payment regulation in an ERISA case
- UPLs are ubiquitous in healthcare- no one pays list prices, everyone sets their payment limits or reimbursement rates (think about your EOB)
- UPL uses the standard operating procedures of manufacturers and suppliers- negotiated discounts for different drugs for different payers and purchasers supplied by wholesalers

Adapted from Horvath Health Policy

UPLs, Continued

- **UPLs are better than a rebate pass through for the chronic disease community.** Rebating tends to happen with drugs that have true competition; many specialty drugs do not. UPLs bring relief to consumers who may not benefit from rebating. Pharmacists also overwhelmingly say they do not have the means to implement rebate pass through.
- **For high-priced drugs with rebating and a UPL, the rebate mechanism should no longer be necessary** because the deep discounts of the rebates would become transparent discounts at the pharmacy counter. A statewide upper payment limit for a drug would eliminate the need for rebates. However, the bill does not ban rebates.
- **The Board would work through affordability**, leaving clinical value to providers, patients, and health insurance carriers.
- Establishing UPLs is the only reasonable mechanism the State of Colorado can use to put downward pressure on Rx prices due to federal statute and case law.
- **UPLs can actually benefit Rx manufacturers**- manufacturers stand to make as much money from a lower-cost/higher-utilization approach as netted by a higher-price/lower-utilization strategy.

Adapted from Horvath Health Policy

What could the methodology look like?

PDAB in CO prohibited from using QALY or discriminatory measures based on disability status or age

British National Formulary Information

US: Institute for Clinical and Economic Review Methodology Consultations

Quebec: Factors for drug review & formulary listing

Themes across the world:

- *Evaluation of public documents & information on pricing provided by manufacturers*
- *Comparison within countries & internationally*
- *Most countries separate out pharmacy reimbursement for bona fide service fees*

What would the savings to Coloradans be?

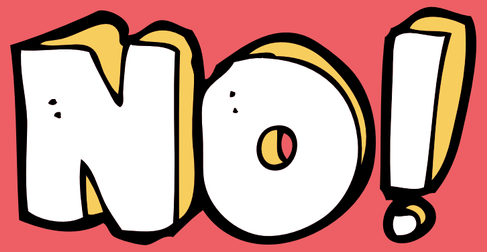
Possibilities for savings across ALL insurance type

1. No consumer in Colorado *regardless of insurance type* could pay more than UPL at the pharmacy counter for the drug (potential for bona fide service fee)
2. For state regulated plans and opt in plans, Board must establish a savings formula for insurers
    a. Amendment to be introduced on floor that states OOP for Rx must be prioritized in this formula

AMENDMENT LANGUAGE TO BE INTRODUCED ON FLOOR (draft)

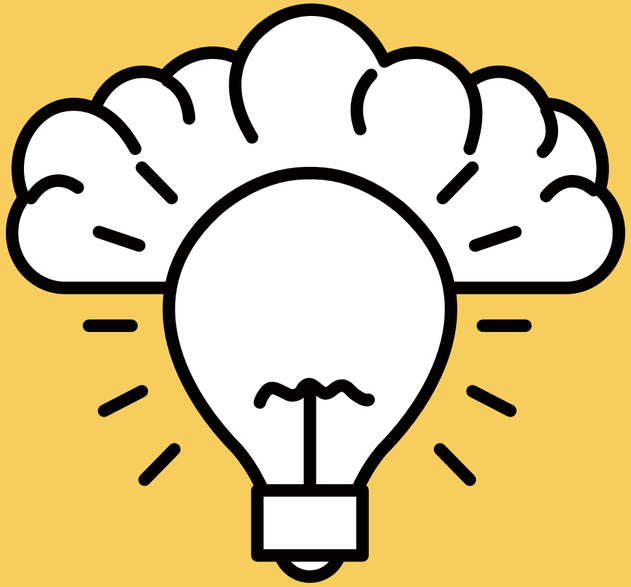
pg. 27, line 13, strike “CONSUMERS.” and substitute “CONSUMERS, PRIORITIZING THE REDUCTION OF OUT OF POCKET COSTS FOR PRESCRIPTION DRUGS.”

Can insurers absorb all of the savings as profits?



Rationale:

1. Medical Loss Ratio
2. Requirement for savings use transparency & reporting in SB 175 with focus on OOP for Rx.



What could the savings formula look like?

Options for PDAB Rulemaking

1. 10-16-1310 outlines requirement to demonstrate use of savings yearly to Commissioner of Insurance, amendment to focus on OOP for Rx
2. Board promulgates rules by Nov 2022 to this effect.
3. *Options could include:*
    a. *Fixed or lower percentage of member contribution to total spend for drugs w/ UPL, based on historical APCD data*
    b. *Lowering Rx co-payment/co-insurance*
    c. *Any ideas the CCC wants to present in public comment!*

Potential Example of what a UPL could look like: Gilenya (MS Drug)

	Avg cost per unit per patient	Total Spend	Carrier	Member	% Savings to Members
2019 Data from CO APCD	199.21	$17,642,837	$15,419,157	$523,630	--
Projection with Quebec Formulary	63.87	$3,743,356.83	$3,631,056.13	$112,300.70	79%
Projection with Quebec Formulary + Markup	92.6115	$5,427,867.40	$5,265,031.38	$162,836.02	69%

Uninsured/ cash customers could NOT be charged more than UPL**

***Assumptions: Board decides to allow reference pricing considerations in UPL methodology, ensures in savings formula that % of member contribution to drug expenditure must remain the same or lower