

# Considerations and Implications of PDABs and Their Impact on 340Bs

## EXECUTIVE SUMMARY

Prescription Drug Affordability Boards (PDABs) are designed to help reduce the costs of prescription medications. Although the scope of PDABs varies, they typically conduct affordability reviews of medications deemed ‘unaffordable’—to patients, the state’s healthcare budget, or both. Certain states further set Upper Payment Limits (UPLs) for specific drugs. But, UPL measures might unnecessarily limit formulary (medication or plan benefit design) options, affecting patient choice and reimbursement rates for some interconnected drug discount programs like 340B.

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### Why Are PDABs Being Created?

PDABs were created to address the rising cost of prescription drugs (in the public and, in some states, private sectors) and shortcomings in state drug price transparency laws. This marks a strategic move by states to improve healthcare affordability and access.

### How Do PDABs Work?

Each state’s PDAB and UPL determination process can vary. In short, PDABs may conduct “Affordability Reviews” of selected high-cost medications to evaluate their impact on patients and state budgets.

### What Factors Do PDABs Consider?

PDABs are meant to make drug price increases sustainable by recommending more “affordable” alternatives or setting price caps. However, balancing affordable drug costs with the need for personalized patient care remains an ongoing challenge.

### What Are Upper Payment Limits (UPLs)?

State-established UPLs define the maximum payment for specified drugs by state-regulated buyers and insurance plans to manage healthcare expenses more effectively.

Criteria for setting UPLs can vary and include factors such as:

- » The drug’s wholesale acquisition cost (WAC)
- » The financial impact on state healthcare budgets
- » Considerations related to drug availability or shortages as indicated by the FDA

Currently, PDABs in Colorado, Maryland, Minnesota, Washington, and Oregon can implement UPLs, which may prompt payers to adjust their cost-sharing policies and formulary tiering accordingly, potentially affecting patient access to medications under said UPLs.

PDAB initiatives should center on patient protection and incorporate their feedback—ensuring that efforts to control costs do not compromise the availability of choices and the standard of care patients receive.

## **Are Patient Assistance Programs (PAPs) Key to Understanding PDABs' Goals?**

Patient Assistance Programs (PAPs) are integral to PDABs' UPL determination processes. PAPs offer strategic discounts on medications in hopes of reducing out-of-pocket costs. They work to balance affordability with access.

## **What Are Manufacturer or Managed Rebates?**

Manufacturer or Managed Rebates constitute a negotiated discount on the price of a drug between manufacturers and payers, which lowers drugs' acquisition cost. Collectively, Manufacturer or Managed Rebates and PAPs aim to lower drug costs (for both patients and state health programs). Considering the interconnected nature of these programs is the key for PDABs to effectively evaluate the real-world drug affordability and out-of-pocket costs of given drugs.

## **Why Do Manufacturers Offer Rebates to Begin With?**

Rebates allow manufacturers to adjust drug prices dynamically in response to market competition and payers' negotiating power.

## **What is the Medicaid Drug Rebate Program (MDRP)?**

The Medicaid Drug Rebate Program (MDRP) mandates that manufacturers offer rebates to Medicaid, ensuring lower drug prices and enhancing affordability for beneficiaries.

## **Do All Manufacturers (Have to) Participate in the MDRP or Offer Rebates?**

Manufacturers are not required to participate in the MDRP, but many still offer rebates or discounts through other means to support drug affordability.

## **How Does the Medicaid Prescription Drug Rebate Program Make Medications More Affordable?**

The Medicaid Prescription Drug Rebate Program reduces medication costs for (state) Medicaid (programs) through manufacturer rebates. This broadens access to affordable prescriptions.

## **How Does the 340B Program Fit Into This?**

The 340B program further enables healthcare providers (Covered Entities) to buy drugs at reduced prices for vulnerable groups. Savings are then reinvested back into the community or system. Policies like UPLs may influence its effectiveness.

## **How Do the 340B and Medicaid Drug Rebate Programs Impact Drug Prices and Access?**

The 340B program's discounted prices are meant to match the prices Medicaid gets after rebates (Ceiling Price). But, it is crucial (HRSA mandated) to ensure manufacturers do not pay twice (the discount) for the same drugs given to Medicaid patients. Changes in these pricing metrics could significantly affect Medicaid's best price calculations and the 340B drug pricing program, influencing overall drug cost dynamics and access.

Coordination between the 340B program and the Medicaid Drug Rebate Program highlights the complexity of drug pricing and access in the healthcare system.

## **Who Oversees the 340B Program?**

The Health Resources and Services Administration (HRSA) oversees the 340B program—offering flexibility for what's known as covered entities to use their savings as additional funding to address their community's unique healthcare.

## Who Are Some Covered Entities in the 340B Drug Pricing Program?

Covered Entities (CEs) in the 340B Drug Pricing Program include a variety of healthcare organizations that are eligible to purchase discounted medications. Examples include:

- » Federally Qualified Health Centers (FQHCs)
- » FQHC Look-Alikes
- » Ryan White HIV/AIDS Program Providers
- » State AIDS Drug Assistance Programs (ADAPs)
- » Children’s Hospitals
- » Critical Access Hospitals (CAHs)
- » Disproportionate Share Hospitals (DSHs)
- » Rural Referral Centers (RRCs) and Sole Community Hospitals (SCHs)
- » Cancer Hospitals

## What Factors Drive Variations in 340B Compliance?

340B compliance varies because each healthcare provider type has its own rules, and audits focus on different aspects, like hospitals’ financials or clinics’ patient checks—this illustrates how the program adjusts to meet various healthcare needs.

## What Is the Connection Between the 340B Program and State AIDS Drug Assistance Programs (ADAP)?

The 340B program helps state ADAP programs get discounted HIV medicine, making it easier for people who need it to afford their treatments.

## What is the Potential impact of UPLs on this Relationship?

Implementation of UPLs could disrupt the pricing structure within the 340B program, leading to increased drug costs for ADAPs and challenging their ability to effectively provide comprehensive medication access to PWH.

## Can the 340B Program Sustain AIDS Drug Assistance Programs’ Mission in the Face of UPL Challenges?

New payment rules, like Upper Payment Limits, may test the 340B Program’s ability to continue providing affordable HIV medicine through the state AIDS Drug Assistance Program, highlighting a need for increased dialogue between ADAPs and PDABs.

## How Does “Patient Choice” Apply?

“Patient Choice” emphasizes informed treatment decisions made in collaboration between and in consultation with individual healthcare providers and patients. This further highlights how financial factors, like those addressed by PDABs, can impact healthcare choices (for better or worse).

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## Conclusion

PDABs are meant to make prescription drugs cheaper, but their actual impact on what people pay in the real world can vary. This highlights the need to balance cost-cutting carefully, keeping healthcare choices open while supporting critical programs like 340B.

To make prescription drugs more affordable, PDABs must carefully consider and balance their cost-reduction efforts with real-world issues and person-first experiences of patient access and choice in consultation and collaboration with their provider(s).

PDABs must work to ensure that their policies do not unnecessarily restrict the full complement of available treatments. Recent advocacy insights also underscore PDABs' need to commit to continuous quality improvement, regularly evaluating and adapting their strategies to effectively address emerging challenges and prioritize patients' well-being and preferences.



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