



Are PDABs Getting Good Guidance?

PORTAL Guidance Causes Concern for Patients and Providers

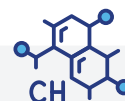
The Program on Regulation, Therapeutics, and Law, or PORTAL, guides prescription drug affordability boards' processes and decisions.

But their recommendations may have unintended consequences for patients. Here's what patients & providers may find concerning.

Recommendation: PORTAL suggests that prescription drug affordability boards assess drug affordability at the active moiety level.

Reality: This one-size-fits-all approach can overlook clinically meaningful differences between drug formulations, not considering:

- Different versions of a drug are not always interchangeable.
- Specialized patient populations need different forms of treatment. For example, a patient with Parkinson's may require a dissolvable or liquid form of a medication due to swallowing difficulties.



ACTIVE MOIETY LEVEL:

Active moiety is the part of a drug that is responsible for the drug's pharmacologic effect, and may not account for different clinical uses and dosage forms.

Recommendation: PORTAL recommends prescription drug affordability boards use clinical practice guidelines and unpublished studies for determining therapeutic alternatives to drugs.

Reality: This can have unintended consequences because:

- Guidelines may not account for real-world patient differences and can lag behind the development and availability of new treatments.
- Unpublished studies have not undergone full peer review and may not provide evidence on a drug's long-term safety or efficacy.
- PDAB board members may lack clinical expertise, meaning real-world treatment considerations may be left out.

Recommendation: PORTAL encourages combining clinical and economic evaluations during the affordability review process.


Reality: This can harm patients by:

- Discriminating against patients with chronic illness and disabilities by using metrics like the quality-adjusted life year.
- Prioritizing short term cost considerations over long-term health outcomes.
- Undervaluing real-life impacts to patients and caregivers such as ability to work, care for family, and take part in community activities.



QUALITY-ADJUSTED LIFE YEAR:

This metric is used by economists to place a value on patients' health by determining whether a medication is worth its cost.



Decisions made by prescription drug affordability boards impact individual patients. That's why patient and provider voices must be included in conversations about a drug's value.