November 11, 2026

Chair Cullison and Members of the Board
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
Submitted via comments.pdab@maryland.gov

Re: November 2026 Board Comments: Emergency Regulation COMAR 14.01.05.10, Appeals of Upper Payment Limit Determinations

Dear Chair Cullison and Members of the Board:

Patients Rising is a national nonprofit that represents patients living with chronic and life-threatening conditions, including many Marylanders. We write to comment on the emergency regulation at COMAR 14.01.05.10, which sets the scope, form, and procedure for appeals of upper payment limit determinations under Health-General Article § 21-2C-15.

We begin from a shared interest. Maryland's upper payment limits are designed to lower what the State and local governments pay for prescription drugs, and we expect the State shares our view that those savings should not come at the cost of patients' access to their treatments. We do not object to an orderly appeals process with clear filing rules and a defined timeline. Our concern is narrower and more practical: as written, the regulation leaves no route for the one kind of evidence patients are most likely to have, which is evidence that a limit is affecting their ability to get and stay on treatment.

The regulation limits an appeal to showing that a determination failed to follow the statute or the Board's own criteria and methodologies. Section A(2) then excludes generalized policy, economic, or market objections, along with any new clinical, financial, or economic data that was not submitted during the cost review and public comment period. Filing an appeal does not delay a limit unless the Board grants a stay, and appeals are decided on the written record with no live testimony.

Taken together, these provisions create a timing gap. The harms patients worry about most can only appear after a limit takes effect: a pharmacy or infusion site that stops stocking a treatment, a plan that changes how a medicine is covered, or a delay while a patient is moved to a different therapy. That evidence cannot exist during the cost review, so under Section A(2)(c)

it can never support an appeal. The Board's statute allows it to reconsider a limit when a drug becomes a current shortage, but many access problems fall well short of a formal shortage and would go unaddressed.

The statute allows any person aggrieved by an upper payment limit to request an appeal, and the Board's own definitions in COMAR 14.01.01.01 describe an aggrieved person broadly, as anyone who has suffered or is exposed to potential loss or injury to a legitimate interest. Because Maryland's upper payment limits apply to drugs purchased or paid for by state and local governments, including through county, municipal, and other public employee health plans, the patients most directly affected are the Marylanders those plans and facilities serve. They plainly have a legitimate interest in whether their treatment remains available.

The emergency regulation does not say whether patients may file, and its requirements, including a formal titled petition of up to 20 pages, strict formatting rules, and exhibits limited to the administrative record, are written for parties with legal counsel. A patient whose pharmacy stops filling a prescription is unlikely to clear those hurdles within 30 days.

We respectfully ask the Board to make four changes before this regulation is finalized.

1. **Create a post-implementation patient access review.** The monitoring regulation also on the November 16 agenda, COMAR 14.01.06.04, asks governmental entities to report spending, net cost, formulary placement, and units once a year. It collects nothing from patients and is not tied to any path for reconsidering a limit. We ask the Board to add a public channel for patients, caregivers, clinicians, and pharmacies to report access problems after a limit takes effect, and to review those reports alongside the annual data with a clear path to reconsider or adjust the limit. Evidence of access harm that arises after the effective date should be expressly excepted from the bar in Section A(2)(c).
2. **Confirm that patients may appeal, and give them a usable path.** State in the final regulation that patients, caregivers, and organizations acting on their behalf may file as aggrieved persons, and provide plain-language instructions and a simplified form for patient filers.
3. **Adopt the permanent rule through standard notice-and-comment rulemaking.** A rule that defines the only check on upper payment limit decisions deserves a full comment period, and the comments received now should be addressed in the permanent version.
4. **Strengthen patient input during the cost review.** Because this regulation makes the cost review record decisive, patients need a real chance to contribute to it. We thank the Board

for publishing the dossier for one of the two biologics selected for cost review this summer, and we ask that the Board make this standard practice, with a defined comment period on each dossier before any preliminary affordability determination.

These steps would not weaken the Board's authority or slow its work. They would give the Board better information and show Marylanders that a limit set in their name will be watched for its effect on the patients who depend on these treatments. We would be glad to help connect the Board with Maryland patients and clinicians.

Yours in Advocacy,

Terry Wilcox

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