

November 8, 2024

Maryland Prescription Drug Affordability Board 16900 Science Drive, Suite 112-114 Bowie, MD 20715

RE: Draft Proposed Regulations for Comment

Dear Members of the Board, Stakeholder Council, and Staff:

The Ensuring Access through Collaborative Health (EACH) Coalition is a network of national and state patient organizations and allied groups that advocate for treatment affordability policies that consider patient needs first.

On behalf of our national network of patient organizations, we would like to submit feedback on COMAR 14.01.05 (Policy Review, Final Action, Upper Payment Limits) which defines the process for establishing an Upper Payment Limit by the board.

.04 Policy Review - Information Gathering

We urge the board to put significant emphasis on gathering input from patients during the information gathering process. This will ensure that the board is appropriately identifying and addressing real patient problems and that patients' lived experiences are addressed by board proposed policy solutions.

To foster more robust patient input into the UPL process, the board should consider setting minimum thresholds for patient input. Additionally, the board should be required to hold meetings, focus groups, or other scheduled events at varied times and locations to ensure members of the public are given adequate opportunity to attend. Also, focus groups and surveys should have basic parameters for both structure and participant numbers to be considered representative of the viewpoints of the public.

Further, we recommend that the board work directly with patient organizations to better understand and attain patient perspectives. There are many proven methods patient organizations have used to collect meaningful, unaltered data from patients (including discussion sessions, surveys, etc.) that we could facilitate, acting as a bridge to enable more voices to be heard. We could combine these efforts with those conducted by the board, in a transparent way that ensures the raw patient data is untouched, thus increasing real-world evidence without any perceived bias of data submission.

.05 Policy Review—Preliminary Policy Recommendations

We applaud continued discussions and emphasis by the board and stakeholder council to consider alternative policy solutions along with UPLs. However, we continue to urge the board to seek authority to implement policy alternatives before proceeding with the UPL process.

The board currently has no authority to implement alternative policies nor has it outlined any alternatives under consideration. Proceeding with the UPL process without taking these important steps increases the likelihood that the board will resort to implementing UPLs simply



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because other policy solutions have not been explored and are therefore not available to implement.

Currently, the board simply does not have enough tools to address patient needs and lower drug costs. Therefore, we urge the board to suspend its ongoing cost reviews and dedicate board meetings and time to exploring other potential policy options.

.06. Policy Review - Process for Establishing a UPL

We urge the board to proceed with extreme caution when considering implementing reference prices within a therapeutic class of drugs. We fear that lowering prices for only some drugs within a therapeutic class could incentivize payers to implement utilization management or adverse tiering for some or all the drugs in the class. As a result, patients could face non-medical switching of their medications, increased costs, or decreased access to their preferred medication.

Patients with chronic conditions often rely on a complicated and personalized course of treatment that is not easily altered. For these patients, therapeutic alternatives may not be alternatives at all. Very often drug interactions or other health conditions would prevent individual patients from being able to switch to an alternative medication that, on paper, seems like it would be an appropriate treatment. Further, patients with chronic conditions can build up a tolerance to medications over time, so they must retain access to all treatments in a class of drugs to prolong their treatment.

.08 Establishing and Monitoring a UPL.

While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies. We appreciate the board's recognition that this could be a consequence of UPL implementation; however, we are disappointed that the board only intends to monitor for these changes after the UPL has been implemented.

Instead, we urge the board to work with the state legislature to put in place safeguards for patients prior to moving forward with UPL policies to protect patients from increased utilization management, compromised access to drugs under review, and other unintended consequences of the board's actions.

We look forward to continuing to engage with staff on the specifics of board policies and to provide testimony during board meetings. We invite any and all opportunities to speak directly with any board member who would be interested in more detailed perspectives from our national network of patient organizations and allied groups.

Sincerely,

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