May 2, 2023

Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff;

We appreciate the opportunity to provide public comment on the Board's proposed regulations for identifying and selecting prescription drugs for cost review. With Maryland poised to be the first state to conduct an affordability review and take meaningful action to make prescription drugs more affordable, we look forward to how this process may pave the way for states around the nation to follow suit. As these regulations are likely to serve as a model, we are pleased to see the thoughtful considerations taken thus far and urge the Board to explicitly center health equity and patient perspective in all steps of this process.

Thank you for the work you do.

Catherine Kirk Robins
Deputy Director, Maryland Citizens' Health Initiative

Comments on Maryland Prescription Drug Affordability Board Draft Regulations

Title 14, Subtitle .01, Chapter .03, .01
Public Reporting of Drug Affordability Issues

We applaud the inclusion of direct patient/consumer feedback in the Board's process of determining which prescription drugs cause affordability issues. We encourage that the input collection form invites comment that offers perspective into the real-life consequences of unaffordable prescription drugs. Including: *what hard decisions have Marylanders had to make in order to afford their medicines? How many people have rationed or skipped treatment due to cost, and how has that impacted their life? Have Marylanders had to sacrifice their savings or stability in order to get the prescription drugs they need?*

Additionally, it is unclear exactly how this consumer input may be weighed in the identification, selection, and cost review processes and we would welcome additional clarification as to how this information may be used. We feel it would best serve as a tool in the selection process, helping the Board to narrow-down the list of eligible prescription drug products; however, we would also like for the Board to establish a more formal opportunity for direct consumer input during the cost review process for those who may use or prescribe the selected drugs.

Should the Board & Staff wish to speak with Maryland patients as these forms are created, we would be happy to connect you with consumers willing to provide feedback. Additional patient perspectives can be found in the 2020 and 2022 reports that summarize the Prescription Drug Affordability Forums our coalition hosted around the state.

Title 14, Subtitle .01, Chapter .03, .03
Selecting Drugs for Cost Review

We are cognizant of the likelihood that the review parameters detailed in the statute will lead to a considerable number of eligible drugs in the identification step, particularly since the new median price of drugs that come to market exceeds $200,000—well above the $30,000 threshold established in the 2019 law. In order to maximize the time of the Board, its Staff, and the Stakeholder Council, we feel that additional metrics to help focus the list of drugs that should be prioritized be added. These include:

1. Consideration of health equity data. Communities of color, low-income, and uninsured individuals are disproportionally impacted by the high cost of prescription drugs; thus, it is critical that the products that most frequently serve these populations be considered a priority for Board review. The Board may be able to utilize data from the Maryland Department of Health Office of Minority Health and Health Disparities to concentrate its focus on prescription drug products that are used to treat conditions with the highest rates of disparity in our state.

2. Estimates of patient non-adherence for the prescription drug product. Recent polling indicates that nearly a quarter of Marylanders have rationed, skipped, or left a prescription unfilled due to cost. If there are particular drugs for which this is occurring regularly (as reported by pharmacies and/or patients and providers), we would encourage that those are prioritized for review.

3. Reviewing tier placement on health plans during this selection process (not just during the request for information/cost review stage), as this is a likely indicator of what drugs may still be out of reach for those with health coverage.

4. Prioritizing review of products with partial orphan drug designation. A study published in 2021 in Health Affairs shows that in 2018 more than 70% of the money spent on top-selling partial orphan drugs went to the treatment of common diseases, meaning that these extended patent lives are driving up costs for patients using otherwise commonly prescribed medications. We would encourage orphan drug designation and patent thicketing to be weighed when considering which prescription drugs will undergo a cost review.

Other considerations:

1. The Board may consider removing prescription drugs that have a set Medicare Fair Price (or are in the midst of the federal negotiation process) from the list of potential drugs to be reviewed so that Board time is optimized to focus on products that are not under federal review. If feasible, instead create a streamlined process to decide whether to adopt Medicare Fair Price as an upper payment limit in the state. The Center for American Progress recently determined 22 of the prescription drug products most likely to be included in the first ten drugs negotiated under the Inflation Reduction Act using the proposed methodological guidance published by CMS.

2. There is also opportunity to include use of the patient feedback forms in the selection process, perhaps prioritizing eligible prescription drug products that meet a Board-established threshold for input.

2600 St. Paul Street Baltimore, MD 21218
www.healthcareforall.com
Phone (410)235-9000 Fax (410)235-8963

Title 14, Subtitle .01, Chapter .03, .04
Request for Information for Cost Review

We feel there is opportunity for more patient-centric input collection in this process. Beyond looking at prices for the product, rebates, and copay/coinsurance amounts, it would be beneficial for the Board to hear directly from patients who use the prescription drug product. We would encourage that the process includes a public hearing that is *specifically* designed to help the Board engage with patients, providers, and advocacy groups regarding the prescription drug product, beyond the standard open meeting.

Title 14, Subtitle .01, Chapter .03, .05
Cost Review

Similar to the selection process, it is important that there are additional metrics considered that prioritize health equity during the cost review process. In addition to data on general epidemiology and total number of patients using the drug, we would encourage that the Board be presented with data that specifically examines the demographics of populations with the condition or disease indicated for use for the prescription drug product, the source of health coverage that most commonly provides the drug, and the percentage of the served population that is likely uninsured. These specific data points would strengthen the Board's efforts to complete an assessment of the impact of the prescription drug product's cost to access by priority populations and impact on equity.

Other Considerations

The Board's work offers a unique opportunity to view a complete landscape of the affordability challenges high-cost prescription drugs cause the Maryland health care system and patients. Understanding that there may be a significant number of prescription drug products that are ultimately eligible for review, we would encourage that a truncated list of prescription drug products that meet multiple review/eligibility parameters (regardless of whether or not the product is chosen for a cost review) be published at regular intervals so that Marylanders are able to access this information. If feasible, a published list of *all* eligible prescription drug products may help to illuminate the scope of the issue, as well.

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