COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

Jen Laws
Phone: (313) 333-8534
Fax: (646) 786-3825
Email: jen@tiicann.org

June 1, 2026

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

RE: Cost Review Study Process Revisions

Dear Honorable Members of the Maryland Prescription Drug Affordability Board,

The **Community Access National Network (CANN)** is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions. State Prescription Drug Affordability Boards are of profound importance to our community.

Today, we write with comments on amendments to COMAR 14.01.04 - Cost Review Study Process. The proposed revisions to COMAR 14.01.04 Cost Review Study Process, in some ways, add clarity and detail to the process. However, some of the changes, and in some areas the lack of change, raise concerns and leave questions. What follows are notable areas of concern.

14.01.04.02 Identifying Drugs Eligible for Cost Review

This section lists multiple aspects of the MCDB to be used to identify drugs eligible for cost review. Since the submission of data from self-insured employer-sponsored health plans is not mandated due to the federal Employee Retirement Income Security Act (ERISA), a significant blind spot exists in the MCDB data. According to the Maryland Insurance Administration's 2025 "Number of Insured and Self-Insured Lives" report, roughly 32% of Maryland residents under age 65 with commercial health coverage were in self-insured employer-sponsored plans.

Additionally, the section states that eligible data sets will also include "the data obtained from governmental and commercial databases, other databases, and other data sets as available". Since the details about these specific other databases are not typically publicly disclosed, there is concern that knowledgeable stakeholders would not be able to voice issues regarding potential problems of their use. While we know that the Board and staff are well-intentioned, the opacity of other data being considered gives us pause.

We appreciate the change under the description of Patient Out-of-Pocket Costs to focus on the top 100 prescription drug products with the highest and highest average total patient out-of-pocket costs in the most recent calendar year. However, because this information is based on MCDB claims data, out-of-pocket costs are not fully captured, as various patient assistance avenues are not included in those numbers. Moreover, out-of-pocket costs that patients endure but that standard claims processes do not capture are also not included.

The inclusion criterion of "Any prescription drug product subject to the Medicare Drug Price Negotiation Program (MDPN), under the Inflation Reduction Act (IRA)" is also concerning. The MDPN is based on data not specific to Maryland's needs, and it has not yet generated substantive outcomes data to justify or inform its utility.

14.01.04.03 Selecting Drugs for Cost Review

We appreciate the detail added under part A, "Priority Setting and Development of Curated Eligible List". Concern remains with the lack of standardization. Priority setting and list curation lend themselves to being arbitrary and not a repeatable, systematic process, which we feel weakens the integrity and efficacy of the drug selection process.

14.01.04.04 Request for Information for Cost Review

The vast amount of information to be potentially requested regarding manufacturers' "documents and research explaining the relationship between the pricing of the prescription drug product and the cost of development, documents and research explaining the relationship between the pricing of the prescription drug product and the cost of development" appears to be logistically burdensome to produce. Additionally, it is unclear how this information would contribute to determining whether or not a drug poses an affordability challenge.

Under section B(1), the request for manufacturer information regarding state and national gross and net sales, profit margins, tax benefits from activities, and even direct-to-consumer marketing cost information is also puzzling. The requests present themselves as a focus on deciding what the Board would deem an acceptable revenue level for a manufacturer should be instead of examining patient and system affordability. This is particularly evident in B(1)(i) "The invoice and net price per unit for the prescription drug product charged to purchasers in the United Kingdom, Germany, France, and Canada, reported in U.S. dollars." As has been discussed repeatedly, pricing outside the U.S. involves many factors not relevant to the U.S. system and that are unchangeable by any PDAB statutory authority.

14.01.04.05 Cost Review Study

Section B(1)g) states that data elements derived from reports generated by foreign governmental and quasi-governmental agencies and foreign non-profit organizations may be considered. This inclusion is highly likely to lead to inadvertent backdoor use of QALY-paradigmatic insights, other discriminatory analyses, or the consideration of variables and systems that are not relevant to the U.S. The unambiguous purpose of cost reviews, drug selection, and the PDAB's work is cost containment. Maryland is prohibited by the ADA from utilizing pricing equations that include QALYs for the purposes of cost containment.

The current limited scope of UPL application which includes Medicaid, would go against CMS and HHS rules with the integration of QALY data. CMS and HHS expressed this explicitly in rules applying to § 84.57 [2024-09237 (89 FR 40066) and 2024-08711 (89 FR 37522)]:

"While the nondiscriminatory use of value assessment is an important tool for health care cost containment, the Department agrees that discriminatory usages of value assessment harm people with disabilities and provide unequal opportunities."

and

"That is, where a value assessment uses methods that penalize patients or groups of patients on a ground protected by section 1557 and where such methods then result in limiting access to an aid, benefit, or service, they may violate section 1557. In response to commenters, we note that value assessment tools cannot be used to, to deny or afford an unequal opportunity to qualified individuals with disabilities or on the basis of age with respect to the eligibility or referral for, or provision or withdrawal of any aid, benefit, or service, including the terms or conditions under which they are made available."

Section C(2)(e-iii) regarding the incremental costs associated with a therapeutic equivalent prescription drug product should be a factor considered in the cost review of all drugs, for cost review, not just therapeutic equivalents. "Including financial impacts to health, medical, or social services as can be quantified and compared to baseline effects of the standard of care" should be a major part of all affordability and cost reviews, given these things are all a part of patient out-of -pocket costs.

Overall, the cost review study process remains heavily focused on system spending and policing manufacturers' financial bottom lines, and it still lacks robust consideration of patient needs. Moreover, regarding system spending, the focus is on the amount of spending rather than the machinations of the system that support and result in it, beyond just the price of the medications in question.

Respectfully submitted,

Ranier Simons
Director of Patient-Centered Drug Pricing and Healthcare Access Policy
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network