

Maryland Prescription Drug Affordability Board

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Issue

Describe Maryland's recently enacted law creating the Maryland Prescription Drug Affordability Board.

Summary

This year, the Maryland General Assembly passed [HB 768](#), which took effect July 1, 2019. The new law establishes a Prescription Drug Affordability Board to study and potentially reduce the cost of prescription drugs. Among other things, the board must identify brand name prescription drugs that (1) cost more than \$30,000 per year or course of treatment or increased in price by more than \$3,000 in the last year. It must also identify (1) generic prescription drugs costing more than \$100 or more per month or certain generics costing over \$100 per month that doubled in price over the last year and (2) biosimilars (i.e., generic versions of biologic drugs) that cost more than 85% of their reference drug. After identifying these drugs, the board may conduct a cost review to determine whether they pose affordability challenges to the state health care system or Maryland residents.

With additional legislative approval, the board may also set payment limits for all prescription drugs it identifies as posing affordability challenges for state, county, and local government programs. This authority to establish payment caps begins in 2022. The board must also conduct a pharmaceutical pricing policy study to gather best practices from other states.

An August 22, 2019, Washington Post [article](#) notes that Governor Hogan had not yet released the board's initial funding. According to the Maryland Department of Health, as of December 3, 2019, the board has not received its initial funding and no personnel have been allocated.

Prescription Drug Affordability Board

Members

The board has five members, one each appointed by the governor, Senate president, House speaker, and attorney general and one appointed jointly by the president and speaker. The jointly appointed member serves as the board's chair and must hire an executive director, general counsel, and board staff. Members serve five-year, staggered terms. The legislation also establishes a 26-member stakeholder council to advise the board. Council members must have knowledge in specified areas.

Pharmaceutical Pricing Study

By December 31, 2020, the board, in consultation with the stakeholder council, must study (1) Maryland's pharmaceutical distribution and payment system and (2) policies other states use to lower pharmaceutical prices, including payment caps, reverse auction marketplaces, and bulk purchasing.

The board must report its findings and any legislative recommendations to the Senate Finance and House Health and Government Operations committees. The board must also:

1. collect and review publicly available information on prescription drug manufacturers, health insurers, HMOs, wholesale distributors, and pharmacy benefit managers (PBMs), among others;
2. identify other states that require prescription drug cost reporting; and
3. enter into a memoranda of understanding with these states to improve data collection and transparency.

Based on the information collected, the board, in consultation with the stakeholder council, must adopt regulations to (1) establish additional data collection methods if necessary and (2) identify when the cost of a prescription drug created affordability challenges for patients and the state health care system.

Identifying High Cost Prescription Drugs

The board must identify brand name prescription drugs or biologics that, adjusted for inflation, have (1) an initial wholesale acquisition cost of \$30,000 or more per year or course of treatment or (2) a wholesale acquisition cost increase of \$3,000 or more in the last year or for a course of treatment.

It must also identify the following:

1. biosimilars that have an initial wholesale acquisition cost of 85% or more of the reference brand;
2. generic drugs that cost \$100 or more for a 30-or-fewer-day supply;
3. generic drugs that cost \$100 or more for one unit of the drug if the U.S. Food and Drug Administration (FDA) does not recommend a finite dose and the price increased by 200% or more in that last year; and
4. other drugs that may create affordability challenges for the state health care system and patients.

After identifying these drugs, the board must determine whether to conduct a cost review by considering the drug's average cost share and consulting with the stakeholder counsel. During a cost review, the board must determine whether use of the drug has or will lead to affordability challenges for the state health care system or high out-of-pocket costs for patients. In doing so, it must consider several factors, including the drugs wholesale acquisition cost and manufacturer discounts.

Price Caps

If the board finds, after conducting a cost review, that it is in the state's best interest to set an upper payment limit for prescription drugs, it must draft a plan of action. In doing so, it must consider drug administration and delivery costs, as well as any related administrative expenses. The board may then recommend an upper price limit for prescription drugs purchased by or on behalf of the following:

1. state and local governments or programs, including correctional facilities, state hospitals, and health clinics at state colleges and universities;
2. state or local health benefit plans; or
3. the Maryland state medical assistance program (i.e., Medicaid).

The board must submit its recommendations to the legislature, which has 45 days to approve it. If the legislature does not act, the board must submit the plan to the governor and attorney general,

who may approve the recommendations within 45 days. The board may not implement an upper payment limit without approval.

In general, drugs on the FDA shortage list are exempt from price caps. The law requires the board to (1) monitor the availability of a drug that has a price cap and (2) reconsider a price cap if there becomes a shortage.

Annual Report

Under the law, the board must annually submit to the legislature a report detailing prescription drug price trends, the number of prescription drugs that the board reviewed, and any legislative recommendations.

Funding Source

The board's initial funding comes from a General Fund appropriation. However, the board must independently raise its ongoing operating costs. As a result, the board must determine another source of funding and recommend it to the legislature by December 31, 2020. In doing so, it must consider, among other things, an assessment fee on manufacturers, insurers, distributors, or PBMs or using manufacturer rebates. In addition, the law requires the board to repay the General Fund for its initial funding.

Expansion

By December 1, 2023, the board must report to the legislature on (1) the legality, obstacles, and benefits of setting upper payment limits on all prescription drug purchases in the state and (2) whether the legislature should expand the board's authority to do so.

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