

Maryland's Prescription Drug Affordability Board Bill Set to Take Effect

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In the ongoing public dialogue about prescription drug affordability, Maryland seems poised to lead the way for states considering a new way to rein in drug spending: drug affordability boards. This spring, the Maryland General Assembly passed a [drug pricing bill](#) to establish a 5-member "Prescription Drug Affordability Board" which could, among other things, cap certain drug prices. The bill is set to become law without Governor Larry Hogan's signature, as he indicated last week that he will not sign or veto the bill.

In addition to the Board, the bill will also create a "Prescription Drug Stakeholder Council" which will offer stakeholder input to guide the Board's decision-making. The Council will consist of members from various backgrounds and associations, including representatives of pharmacists, biotechnology companies, physicians, and hospitals; a labor union representative; representatives of brand name and generic drug corporations; and a representative of pharmacy benefit managers (PBMs).

The bill charges the Board with working in consultation with the Council to collect, study, and report on information relating to the pharmaceutical distribution and payment system in Maryland and policy options used outside of Maryland to lower drug list prices. The Board will adopt regulations to, among other things, identify circumstances under which a drug's cost has created or may create affordability challenges for patients or Maryland's health care system. Using the information it collects, the Board will identify drugs that may present such affordability challenges, including:

- Brand name drugs or biologics that have a launch wholesale acquisition cost (WAC) of \$30,000 or more per year or course of treatment;
- Brand name drugs or biologics that have a WAC increase of \$3,000 or more in any 12-month period (or course of treatment if less than 12 months); and
- Generic drugs that have a WAC that increased by 200% or more during the prior 12 months.

The Board will then determine whether to conduct a cost review of such drugs. The cost review would assess whether use of the drug (in accordance with its FDA-approved labeling or standard medical practice) has led or will lead to affordability challenges for patients or Maryland's health care

system. In making this determination, the Board could consider a variety of factors, including:

- The WAC and other relevant prescription drug indices for the drug sold in Maryland;
- The average price concession, discount, or rebate the drug manufacture offers to health plans in Maryland or is expected to provide to health plans in Maryland, as reported by health plans and manufacturers;
- The total amount of the price concession, discount, or rebate the manufacturer provides to each PBM operating in Maryland, as reported by PBMs and manufacturers;
- The impact on patient access resulting from the cost of the drug relative to insurance benefit design; and
- The average patient copay or other cost-sharing for the drug in Maryland.

The Board will be required to annually submit to specified committees a report identifying prescription drug pricing trends, the number of prescription drugs that were subjected to cost review by the Board, and any recommendations the Board has for legislation necessary to make prescription drugs more affordable in Maryland. The Board will be authorized to draft a process for setting payment caps for those drugs that it has determined are likely to or have caused affordability challenges for Maryland patients or the state's health care system. The Board's proposed plan will be submitted to the General Assembly's Legislative Policy Commission for approval. If the commission rejects the plan, the Board would then have to seek approval from the Governor and the Attorney General.

If the proposal is timely approved, the Board could begin setting payment limits in January 2022 for prescription drugs that are: (i) purchased or paid for by (or by an organization on behalf of) a unit of state or local government; (ii) paid for through a health benefit plan on behalf of a unit of state or local government; or (iii) purchased for or paid for by the Maryland State Medical Assistance Program. This limited application is a notable departure from the bill's original scope, which would have impacted all payors, including commercial plans.

Legislation involving drug pricing boards or similar measures has been introduced in a number of other states, including [Illinois](#), [Maine](#), [Nevada](#), and [New Jersey](#), but Maryland's bill is the first to make it this far. That may not be surprising given that the state has long had a [hospital rate-setting and review board](#) aimed in part at containing costs and improving access to care. Given the continued scrutiny of prescription drug pricing by both federal and state legislatures, Maryland may be setting an example for other states to follow in their efforts to lower drug spending.

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National Law Review, Volume IX, Number 148

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