

Department of Planning and Budget 2023 Fiscal Impact Statement

1. **Bill Number:** HB1596

House of Origin Introduced Substitute Engrossed
Second House In Committee Substitute Enrolled

2. **Patron:** Delaney

3. **Committee:** Commerce and Energy

4. **Title:** Prescription Drug Affordability Board and Fund established; drug cost affordability review.

5. **Summary:** Establishes the Prescription Drug Affordability Board for the purpose of protecting the citizens of the Commonwealth and other stakeholders within the health care system from the high costs of prescription drug products.

The bill directs the Governor to appoint the members and alternate members of the Board and requires the Board to meet in open session at least four times annually, with certain exceptions and requirements enumerated in the bill. Members of the Board are required to disclose any conflicts of interest, as described in the bill. The bill also creates a stakeholder council for the purpose of assisting the Board in making decisions related to drug cost affordability. The bill tasks the Board with identifying prescription, generic, and other drugs, as defined in the bill, that are offered for sale in the Commonwealth and, at the Board's discretion, conducting an affordability review of any prescription drug product. The bill lists factors for the Board to consider that indicate an affordability challenge for the health care system in the Commonwealth or high out-of-pocket costs for patients. The bill also provides that any person aggrieved by a decision of the Board may request an appeal of the Board's decision and that the Attorney General shall have authority to enforce the provisions of the bill.

The bill also creates the Prescription Drug Affordability Fund to be used for funding the operations of the Board and reimbursing state agencies for implementing the provisions of the bill. The bill requires the Board to report its findings and recommendations to the General Assembly twice annually, beginning on July 1, 2024, and December 31, 2024.

Provisions of the bill shall apply to state-sponsored and state-regulated health plans and health programs and obligate such policies to limit drug payment amounts and reimbursements to an upper payment limit amount set by the Board, if applicable, following an affordability review. The bill specifies that Medicare Part D plans shall not be bound by such decisions of the Board.

Finally, the bill contains a severability clause and has a delayed effective date of January 1, 2024.

6. **Budget Amendment Necessary:** Yes, item 292.
7. **Fiscal Impact Estimates:** Preliminary.
8. **Fiscal Implications:** The provisions of this legislation would have a fiscal impact on the Virginia Department of Health (VDH) to establish a Prescription Drug Affordability Board (the Board). The Board will be comprised of five (5) members appointed by the Governor. These members may receive compensation as a member of the Board in accordance with the state budget of the Commonwealth and are entitled to reimbursement for expenses authorized by travel regulations promulgated pursuant to § 2.2-2823. The Board is required to meet in open session at least four times annually to review prescription drug product information. Additionally, they may meet in closed session to discuss proprietary data and information.

The cost of five Board members attending at least four meetings per year comes roughly to \$7,300. This is based on \$115 for mileage, \$150 for lodging, \$50 for incidentals, and then \$50 for compensation per member per meeting. Any additional meetings for members would increase the costs by the amounts above per board member.

The chair of the Board shall hire an executive director, general counsel, and staff to support the Board's activities and Board staff shall receive a salary as provided in the budget of the Board. It is unknown how many staff members will be needed to support the board's activities and the anticipated salaries. Using other boards and commissions to derive an estimate, the Behavioral Health Commission, which was established in FY22, was provided \$348,774 for staff and associated office-related costs that were phased-in over the year to reflect the timing necessary to startup the Commission. The Behavioral Health Commission currently has four staff: an Executive Director, Chief Policy Analyst, Associate Policy Analyst, and an Office Manager/ Executive Assistant.

Virginia Health Information (VHI) is currently under contract to VDH to administer the prescription drug pricing transparency data collection program referenced in this bill. If the amount of analytical support needed from VHI is expected to drastically increase by the creation of this Board, additional costs may be incurred.

The bill also provides that the Office of the Attorney General may pursue any appropriate available remedy under state law in enforcing the provisions of this article. The cost for VDH to hire of an Assistant Attorney General I to handle enforcement of the bill is \$138,000 annually including salary and fringe benefits. Hiring an assistant attorney general is consistent with Prescription Drug Affordability Boards (PDAB) established by Maryland and Colorado, which have allocated up to \$250,000.

The National Academy for State Health Policy (NASHP), a nonpartisan organization which provides model legislation and technical assistance to legislators and executive agencies

interested in prescription drug affordability boards (PDABs), Washington State and Colorado have implemented PDABs with similar responsibilities and approaches to what is outlined in HB1596 as it relates to the board's authority to set upper pay limits, the types of prescription drugs that the board is authorized consider for an affordability review, and who will benefit from any upper pay limits set (all consumers in the state). A breakdown of comparable PDAB from other states is below:

- Colorado
 - \$730,711 was appropriated for PDAB implementation in FY21-FY22.
 - The Board is staffed by two FTEs and two part-time Assistant Attorneys General
 - \$250,000 was allocated for additional contractors as needed.
- Washington
 - \$1,460,000 was appropriated for the PDAB from the general fund and \$31,000 from the insurance commissioner's regulatory account.
 - This amount includes staffing for 4 FTEs.
- Maryland
 - Operating with a \$1 million annual budget based on projected collected annual fees on manufacturers, pharmacy benefit managers, carriers, and wholesale distributors that sell prescription drugs in the state
 - Estimated start-up costs of the PDAB were \$831,900 in FY 2020. PDAB activities are staffed by 5 FTEs and 1 part-time Assistant Attorney General.
 - Like Colorado, the state allocated \$250,000 for additional contractors as needed.

It is currently unclear as to how the upper payment limit amount established by the Board would impact medical assistance programs administered by the Department of Medical Assistance Services (DMAS). DMAS is currently determining to what extent the provisions of this bill would apply to agency programs. Moreover, there is no way to know what drugs would be subject to an upper payment limit and how such limits would interplay with items such as managed care and pharmacy rebates. As such, the fiscal impact on medical assistance services is indeterminate at this time.

9. Specific Agency or Political Subdivisions Affected: Virginia Department of Health and the Department of Medical Assistance Services.

10. Technical Amendment Necessary: No.

11. Other Comments: SB957, introduced by Senator Petersen, is a companion bill.