

Department of Planning and Budget

2020 Fiscal Impact Statement

1. Bill Number: HB1404

House of Origin	<input checked="" type="checkbox"/> Introduced	<input type="checkbox"/> Substitute	<input type="checkbox"/> Engrossed
Second House	<input type="checkbox"/> In Committee	<input type="checkbox"/> Substitute	<input type="checkbox"/> Enrolled

2. Patron: Leftwich

3. Committee: Health, Welfare and Institutions

4. Title: Canadian Prescription Drug Importation Program established.

5. Summary: Establishes the Canadian Prescription Drug Importation Program, pending federal approval and certification from the Secretary of the U.S. Department of Health and Human Services. Under the Program, the Commissioner of Health is required to designate the Department of Health, the Commissioner, or another agency or officer of the Commonwealth; a licensed drug wholesaler; or a nonprofit, nonstock corporation established by the Department as a public instrumentality exercising public and essential governmental functions to (i) import prescription drugs from Canadian suppliers and (ii) distribute the imported prescription drugs to pharmacies or pharmacists in the Commonwealth that contract with the designated entity to make the imported prescription drugs available to residents of the Commonwealth at the cost prescribed in the contract. The measure provides that only prescription drugs that have the highest potential for cost savings to the Commonwealth shall be identified for importation. The Program will authorize the designated entity to purchase prescription drugs from a Canadian supplier and distribute the prescription drugs to pharmacists and pharmacies that are in-network under a health plan provided by a health carrier, state employee health plan or local choice plan, and the Medicaid program. Contracts between the pharmacist or pharmacy and the designated entity will set the price at which the prescription drugs are to be provided to covered individuals. The measure requires the Commissioner, by December 1, 2021, to review the proposed Program and, if the proposed Program is approved, to submit the proposed Program for federal review. The Department is also required to prepare an implementation plan, which is to be put into effect six months after the last to occur of (a) the enactment of any legislation required for the establishment of the charge or assessment to finance the Program and (b) receipt of notice that the proposed Program has been approved and certified by the Secretary of the U.S. Department of Health and Human Services.

6. Budget Amendment Necessary: Indeterminate.

7. Fiscal Impact Estimates: See item #8.

8. Fiscal Implications: The total fiscal impact this bill would have on the Commonwealth cannot be determined. The bill provides that VDH shall implement the program within six

months of an enactment of legislation required for the Commissioner's establishment of the charge per prescription or another method of financial support for the program at a level that covers ongoing program administrative costs or if the proposed program was approved by the Secretary of the U.S. Department of Health and Human Services (HHS). The bill provides that VDH shall create a publicly available list of the prices of the prescription drugs to be imported, however, it is unknown which prescription drug products this entails. Additionally it cannot be determined costs associated with the potential of Canadian importation fees or potential negative impacts to currently available manufacturer drug rebates.

The Department has estimated that there would be costs for the design of the program and to obtain federal approval and certification. VDH indicates that these costs and other implementation costs are likely to be significant, including the costs to hire contractual staff to develop and submit the program design to the appropriate authorities and meet the submission deadline to the legislative committees. It is estimated VDH would need a pharmacist during the design phase the program at a rate of \$149,928. VDH would also require attorney services, at an estimated cost of \$130,000, with an expertise in import and export law, and pharmacy practice, safety, and quality. They would also need a position with an expertise in procurement policy at a rate of \$85,000. These positions would only be necessary through the design phase of the program. It is likely other resources will be necessary to maintain program operations, however, this cannot be determined at this time.

The Office of the Attorney General has stated that if the federal FDA rule is finalized that would allow states and certain other non-governmental entities to submit proposals for importing prescription drugs wholesale from Canada, the proposed bill sets out the procedure by which the Virginia Commissioner of Health can designate the Virginia Department of Health (VDH) and others as the entities to import and distribute these drugs in the Commonwealth. Health Services has asked the Antitrust Unit to review the bill because proposed Section 32.1-78.6 of the bill requires VDH to "consult with the Office of the Attorney General to identify the potential, and to monitor, for anticompetitive behavior in industries that would be affected by the Program."

The time and other resources needed to fulfill this provision is unknown. For comparative purposes, the agency refers back to the Certificate of Public Need Program's development. For the Certificate of Public Need system developed in Va. Code Section 15.2-5384.1, the OAG was merely required to consult with the Commissioner of Health about whether the certificate should be granted, but has no ongoing monitoring requirement under the statute. In addition, this statute was limited to evaluating a hospital system in a specific region of the state. The OAG hired an economic expert that cost over \$500,000 (for which the OAG was reimbursed because of a provision in another statute, then-Section 55-532). HB1404 is much broader because it encompasses the entire state and more than one type of industry, as well as requiring ongoing monitoring. Without a means to recoup the costs of continuing economic analysis, the cost to the Office could be very large. The OAG estimates this will likely require at least two attorneys and an in-house economist.

Any impact to the Department of Human Resource Management and the State Health Insurance Plan is indeterminate since the pricing is unknown.

The fiscal impact of this bill on Department of Medical Assistance Services, (DMAS) programs is indeterminate. Currently the importation of drugs from Canada (and other foreign countries) is not permitted under federal law. DMAS is unable to provide an estimate of impact for this bill until the proposed plan for the importation program is developed.

This bill would not have an impact on the State Corporation Commission.

9. Specific Agency or Political Subdivisions Affected: Department of Health, the Department of Medical Assistance Services, the Office of the Attorney General, the Department of Human Resource Management, and the State Health Insurance Plan.

10. Technical Amendment Necessary: No.

11. Other Comments: None.