

Department of Planning and Budget

2022 Fiscal Impact Statement

1. Bill Number: HB 478

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: Subramanyam

3. Committee: Health, Welfare and Institutions

4. Title: Wholesale prescription drug importation program; Sec. of Health and Human Resources to establish

5. Summary: This legislation directs the Secretary of Health and Human Resources (SHHR) to establish a wholesale prescription drug importation program that complies with the requirements of federal law and provide an annual report. Specifically, the program must:

- Designate an agency or hire a contractor for the purpose of importing prescription drugs;
- Provide for the purchase of prescription drugs from suppliers regulated under the laws of Canada or a Canadian province;
- Ensure that imported prescription drugs comply with all requirements related to safety and effectiveness;
- Provide for importation of only those prescription drugs expected to result in significant cost savings for residents of the Commonwealth;
- Ensure compliance with all tracking and tracing requirements;
- Prohibit the distribution, dispensing, or sale of prescription drugs imported by the Commonwealth;
- Establish a charge per prescription or other mechanism for funding the program, which shall not significantly reduce savings to consumers resulting from the program;
- Monitor industries that would be affected by the program for anticompetitive behavior and take appropriate action in response to such anticompetitive behavior if identified; and
- Provide for robust audit and oversight of the program.

The bill also requires the SHHR to (i) convene a workgroup composed of relevant stakeholders to develop a plan for implementation of the wholesale prescription drug importation program and subsequently report the plan, and (ii) seek such federal approvals, waivers, exemptions, or agreements as may be necessary to enable all covered entities enrolled in or eligible for the federal 340B Drug Pricing Program to participate in the wholesale prescription drug importation program to the greatest extent possible without jeopardizing their eligibility for the 340B Drug Pricing Program by July 1, 2023.

6. Budget Amendment Necessary: Yes

7. Fiscal Impact Estimates: See Item 8.

- 8. Fiscal Implications:** Several states, including Florida, Vermont, Colorado, Maine, New Mexico, and New Hampshire have enacted laws establishing importation programs for prescription drugs from Canada. In order for any importation plan to go into effect, the federal Health and Human Services (HHS) Secretary must certify that it meets the safety and cost saving requirements set forth in Section 804 of the Federal Food, Drug, and Cosmetic Act. Under each state's respective laws to establish an importation program, they are required to submit a proposal to HHS to demonstrate how its program will meet those safety and cost saving requirements. Based on available information, it appears that no state plan has yet been certified.

In 2018, the Vermont Agency of Human Services (AHS) released draft estimates for legislation most similar to HB 478. AHS "testified that they lack the capacity, resources, and expertise to implement such a prescription drug importation program in Vermont" and released estimates ranging from \$645,000 to \$1,234,000 "for design, development, certification, and implementation costs." This estimated costs included hiring consultants with expertise in wholesale businesses and negotiations with federal partners. In addition, AHS assumed approximately six additional positions would be needed. No program operating costs were estimated. AHS expected the timeline for design, development, certification and implementation to be 18 to 24 months.

Again, there is not sufficient information available to make a reasonable estimate as to the ultimate cost of this legislation. Based on the Vermont experience, it is assumed that Virginia's SHHR would have immediate costs associated with developing the program and gaining federal approval. It is assumed that SHHR could require approximately \$1.2 to \$2.4 million to develop and implement the program. Note: The Vermont costs were adjusted to reflect inflation and greater complexity of the Commonwealth (i.e. Virginia's population is 92 percent larger than Vermont). Although the bill provides for the establishment of a 'charge per prescription' for funding the program, it is assumed that such revenue would not be available until the program is fully implemented. Therefore, the initial SHHR costs would need to be supported with general fund dollars. Once the program is authorized and implemented, it is assumed that it would generate sufficient revenue to cover all operating costs. However, even this assumption is not clear due to many unknowns. For example, general fund would be required if the program requires 'bridge' funding to get started or if the revenue generated is insufficient to cover costs and ensure consumer savings. It is likely that the General Assembly will need to re-examine the fiscal impact of this program once development has been completed.

- 9. Specific Agency or Political Subdivisions Affected:**
Secretary of Health and Human Resources

- 10. Technical Amendment Necessary:** No

- 11. Other Comments:** None