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HOUSE BILL NO. 478

Offered January 12, 2022

Prefiled January 11, 2022

A *BILL to amend the Code of Virginia by adding in Article 6 of Chapter 2 of Title 2.2 a section numbered 2.2-214.1:1, relating to Secretary of Health and Human Resources; wholesale prescription drug importation program.*

Patrons—Subramanyam and Helmer

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Article 6 of Chapter 2 of Title 2.2 a section numbered 2.2-214.1:1 as follows:

§ 2.2-214.1:1. Wholesale prescription drug importation program.

A. *The Secretary of Health and Human Resources shall establish a wholesale prescription drug importation program that complies with the requirements of 21 U.S.C. § 384, including provisions related to safety and cost savings. Such wholesale prescription drug importation program shall:*

1. *Provide for designation of a state agency that shall (i) become a licensed wholesaler for the purpose of importing prescription drugs in accordance with this section or (ii) enter into a contract with a licensed wholesaler for the purpose of importing prescription drugs in accordance with this section;*

2. *Provide for the purchase of prescription drugs for importation to the Commonwealth from suppliers regulated under the laws of Canada or a Canadian province;*

3. *Ensure that prescription drugs purchased from suppliers described in subdivision 2 and imported into the Commonwealth comply with all requirements related to safety and effectiveness and any other requirements adopted by the U.S. Food and Drug Administration;*

4. *Provide for importation of only those prescription drugs expected to result in significant cost savings for residents of the Commonwealth;*

5. *Ensure compliance with the tracking and tracing requirements of 21 U.S.C. §§ 360eee and 360eee-1 to the greatest extent possible prior to and after importation of prescription drugs into the Commonwealth;*

6. *Prohibit the distribution, dispensing, or sale of prescription drugs imported by the state agency described in subdivision 1 or licensed wholesaler with whom the state agency has entered into a contract pursuant to subdivision 1 outside of the Commonwealth;*

7. *Establish a charge per prescription or other mechanism for funding the program, which shall not significantly reduce savings to consumers resulting from the program;*

8. *Provide for monitoring of industries that would be affected by the program for anticompetitive behavior and appropriate action to be taken in response to such anticompetitive behavior if identified; and*

9. *Provide for robust audit and oversight of the program.*

B. *The Secretary (i) shall make information about the wholesale prescription drug importation program established pursuant to subsection A available to the public; (ii) establish a process for registration of health plans, pharmacies, and health care providers that dispense or administer prescription drugs that wish to participate in the program; and (iii) make information about the price of prescription drugs imported through the program available to all participating health plans, pharmacies, and health care providers and to the public.*

C. *The Secretary shall report annually by October 1 to the Governor and the Chairmen of the House Committees on Appropriations and Health, Welfare and Institutions and the Senate Committees on Finance and Appropriations and Education and Health on the wholesale prescription drug importation program established pursuant to this section, including, for the previous year, (i) the prescription drugs imported through the program; (ii) the number of participating health plans, pharmacies, and health care providers; (iii) the number of prescriptions dispensed through the program; (iv) the estimated savings to health plans, pharmacies, health care providers, and consumers resulting from the prescription drug importation program; and (v) information about any audit undertaken and the results and findings of such audit.*

2. That the Secretary of Health and Human Resources (the Secretary) shall convene a workgroup composed of relevant stakeholders to develop a plan for implementation of the wholesale prescription drug importation program established pursuant to this act, which shall include recommendations for any statutory, regulatory, budgetary, or policy changes necessary to

INTRODUCED

HB478

59 implement the program. The Secretary shall report the plan to the Governor and the Chairmen of
60 the House Committees on Appropriations and Health, Welfare and Institutions and the Senate
61 Committees on Finance and Appropriations and Education and Health by December 1, 2022.
62 3. That the Secretary of Health and Human Resources shall (i) submit a formal request for
63 certification of the Commonwealth's wholesale prescription drug importation program established
64 pursuant to this act to the U.S. Department of Health and Human Services and (ii) seek such
65 federal approvals, waivers, exemptions, or agreements as may be necessary to enable all covered
66 entities enrolled in or eligible for the federal 340B Drug Pricing Program to participate in the
67 wholesale prescription drug importation program established pursuant to this act to the greatest
68 extent possible without jeopardizing such entities' eligibility for the 340B Drug Pricing Program by
69 July 1, 2023.