20100320D

HOUSE BILL NO. 1404

Offered January 8, 2020

Prefiled January 8, 2020

A BILL to amend the Code of Virginia by adding in Chapter 3 of Title 32.1 an article numbered 2.1, consisting of sections numbered 32.1-78.1 through 32.1-78.9, relating to the establishment of the Canadian Prescription Drug Importation Program.

Patrons—Leftwich and McNamara

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 Chapter 3 of Title 32.1 an article numbered 2.1, consisting of sections numbered 32.1-78.1 through 32.1-78.9, as follows:

Article 2.1.

Canadian Prescription Drug Importation Program.

§ 32.1-78.1. Definitions.

As used in this article, unless the context requires a different meaning:

"Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.

"Designated entity" means (i) the Department, the Commissioner, or any other agency or officer of the Commonwealth; (ii) a licensed drug wholesaler; or (iii) a nonprofit, nonstock corporation established by the Department under Chapter 10 (§ 13.1-801 et seq.) of Title 13.1 as a public instrumentality exercising public and essential governmental functions, that is designated by the Commissioner, upon becoming licensed as a prescription drug wholesaler, as the entity that will, upon obtaining federal approval and certification, import prescription drugs into the Commonwealth pursuant to the Program.

"Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Drug Quality and Security Act, 21 U.S.C. § 351 et seq.

"Health carrier" means an entity subject to the insurance laws and regulations of the Commonwealth and subject to the jurisdiction of the State Corporation Commission, including an insurer licensed to sell accident and sickness insurance, a health maintenance organization, or a health services plan, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of services for the diagnosis, prevention, treatment, cure, or relief of a health condition, illness, injury, or disease.

"Pharmacist" and "pharmacy" have the meanings ascribed to those terms in § 54.1-3300.

"Prescription drug" has the meaning ascribed thereto in 21 U.S.C. § 384(a)(3).

"Program" means the Canadian Prescription Drug Importation Program established pursuant to this article.

"Track-and-trace" means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in the federal Drug Supply Chain Security Act, 21 U.S.C. § 351 et seq.

"Wholesale prescription drug importation list" means the list of prescription drugs prepared by the Department pursuant to subdivision A 17 of § 32.1-78.2, as amended from time to time.

§ 32.1-78.2. Design of the Canadian Prescription Drug Importation Program; review by Commissioner; legislative review.

A. By July 1, 2021, the Department shall develop a proposed design for the Canadian Prescription Drug Importation Program. Upon obtaining federal approval and certification, the Program shall authorize the designated entity 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 proposed design shall provide for the establishment and operation of the Program that will:

1. Comply with the applicable requirements of 21 U.S.C. § 384, including requirements regarding safety and cost savings;

2. Establish conditions and requirements pursuant to which the Commissioner shall designate the designated entity pursuant to subsection B;

3. Provide for the use of one or more Canadian suppliers that are regulated under the laws of Canada or of one or more Canadian provinces, or both;

4. Require that only prescription drugs meeting the U.S. Food and Drug Administration's safety, effectiveness, and other standards shall be imported by the designated entity;

5. Import only those prescription drugs that are on the wholesale prescription drug importation list;

6. Comply with applicable track-and-trace procedures and requirements;

7. Prohibit the distribution, dispensing, or sale outside the Commonwealth's borders of prescription drugs imported pursuant to the Program;

8. Propose a procedure by which the Commissioner will establish a charge per prescription or another method of support to ensure that the Program is funded adequately in a manner that does not jeopardize significant consumer savings;

9. Provide that the designated entity shall contract with one or more Canadian suppliers to acquire prescription drugs on the wholesale prescription drug importation list at the lowest cost it is able to negotiate, for the purpose of distributing the prescription drugs to participating pharmacists and pharmacies for dispensing to eligible residents of the Commonwealth in accordance with the terms of the Program;

10. Provide (i) any health carrier, (ii) the Department of Human Resource Management or its agent as administrator of any coverage issued pursuant to § 2.2-1204 or 2.2-2800, and (iii) the Department of Medical Assistance Services as administrator of the Medicaid program, with the opportunity to participate in the Program by allowing their in-network pharmacies or pharmacists to provide the imported prescription drugs to their covered individuals at the cost prescribed in or established pursuant to the participating health carrier's or agency's contract with the designated entity;

11. Require the Department to establish a website through which pharmacists or pharmacies that are in-network with a health carrier, administrator, or agency described in subdivision 10 may arrange to contract with the designated entity;

12. Prohibit the designated entity from setting the cost to participating pharmacies for the imported prescription drugs at an amount that exceeds the cost of acquiring the prescription drugs from the Canadian supplier and any charge for recovering the costs of establishing and administering the Program;

13. Establish requirements for an eligible pharmacist or pharmacy to register with the designated entity in order to participate in the Program, including reasonable requirements for a surety bond or other proof of financial responsibility;

14. Ensure that enrollees in the Medicaid program and the individuals covered under the state employee health benefit program under § 2.2-2800, the local choice program established under § 2.2-1204, or a health plan offered by a health carrier are given the option of purchasing prescription drugs imported under the Program from any participating in-network pharmacy;

15. Ensure that each health carrier passes on all savings resulting from participating in the Program to individuals covered under a health plan offered by a health carrier by reducing or eliminating prescription drug copayments or reducing premiums;

16. Ensure that no copayment is required to be paid by a covered individual for a prescription drug purchased through the Program that exceeds the copayment that would be required to be paid by the covered individual under the individual's health plan for the same prescription drug not purchased through the Program and that any permitted copayment shall count toward any applicable deductible under the individual's health plan;

17. Require the Department to develop a wholesale prescription drug importation list identifying the prescription drugs that have the highest potential for cost savings to the Commonwealth. In developing the prescription drug importation list, the Department shall consider, at a minimum, which prescription drugs will provide the greatest cost savings to state programs, including prescriptions drugs for which there are shortages, specialty prescription drugs, and high volume prescription drugs. The Department shall review the wholesale prescription drug importation list every three months to ensure that it continues to meet the requirements of the Program and may direct the designated entity to revise the prescription drug importation list as necessary. In addition, the Department shall be authorized to import a prescription drug from an eligible Canadian supplier only if (i) the drug meets the U.S. Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration and (ii) importing the prescription drug would not violate federal patent laws;

18. Require the Department to:

a. Identify Canadian suppliers that are in full compliance with relevant Canadian federal and provincial laws and regulations and the federal act and who have agreed to export drugs identified on the prescription drug importation list at prices that will provide cost savings to the Commonwealth;

b. Verify that such Canadian suppliers meet all of the requirements of the Program while meeting or exceeding the federal and state track-and-trace laws and regulations;

c. Contract with such eligible Canadian suppliers, or facilitate contracts between the designated entity and Canadian suppliers, to import drugs under the Program;

d. Maintain a list of all pharmacies that participate in the Program; and

e. Ensure compliance with federal Drug Supply Chain Security Act, 21 U.S.C. § 351 et seq., by the designated entity and other participants in the Program; and

19. Require the designated entity to provide an annual financial audit of its operations to the Department as required by the Department. The designated entity shall also provide quarterly financial reports specific to the Program. The Department shall determine the format and contents of the reports.

B. By December 1, 2021, the Commissioner shall complete a review the proposed Program and determine whether the proposed Program complies with the requirements of this article. If the Commissioner determines that the proposed Program does not comply with such requirements, the Commissioner, in consultation with the Department, shall make necessary amendments to the proposed Program. Upon approving the proposed Program or amending the proposed Program, as applicable, the Commissioner shall designate the designated entity and submit the proposed Program for review as required by § 32.1-78.3.

§ 32.1-78.3. Submission of proposed Program for review.

By January 1, 2022, the Commissioner shall submit the proposed Program, with any amendments thereto made pursuant to subsection B of § 32.1-78.2, to the Chairmen of the House Committee on Health, Welfare and Institutions, the House Committee on Appropriations, the Senate Committee on Finance, and the Senate Committee on Education and Health. The Chairmen may conduct hearings to determine if the proposed Program complies with the requirements of this article.

§ 32.1-78.4. Submission of proposed Program for federal approval.

Upon the later of 30 days following receipt of notice from the Chairmen of the Committees as provided in § 32.1-78.3 or July 1, 2022, the Department shall submit a request to the Secretary of the U.S. Department of Health and Human Services for approval and certification of the Program. The request shall:

1. Describe the Department's plan for operating the Program;

2. Demonstrate how the prescription drugs to be imported into the Commonwealth under the Program will meet the applicable federal and state standards for safety and effectiveness;

3. Demonstrate how the prescription drugs imported into the Commonwealth under the Program will comply with federal track-and-trace procedures and requirements;

4. Include a list of proposed prescription drugs that have the highest potential for cost savings to the Commonwealth through importation;

5. Estimate the total cost savings attributable to the Program;

6. Provide an estimate of the costs of program implementation to the Commonwealth; and

7. Include a list of potential Canadian suppliers from which the Commonwealth would import prescription drugs and demonstrate that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations as well as all applicable federal and state laws and regulations.

§ 32.1-78.5. Implementation plan; implementation of Program.

A. Following the submission of the proposed Program to the Secretary of the U.S. Department of Health and Human Services for approval and certification pursuant to § 32.1-78.4, the Department shall prepare, and submit to the Chairmen of the House Committee on Health, Welfare and Institutions, the House Committee on Appropriations, the Senate Committee on Finance, and the Senate Committee on Education and Health for review, an implementation plan that:

1. Identifies the prescription drugs on the initial wholesale prescription drug importation list;

2. Sets the amount of assessment per prescription at a level that covers ongoing program administrative costs;

3. Identifies procedures to ensure the quality of the prescription drugs imported;

4. Evaluates and addresses any data privacy concerns; and

5. Recommends any procedures and modifications necessary to effectively implement the Program.

B. The Department shall commence implementation of the Program in accordance with an approved implementation plan within six months after the last to occur of:

1. The enactment of any legislation required for the Commissioner's establishment of the charge or assessment per prescription or another method of financial support for the Program at a level that covers ongoing program administrative costs; and

2. The 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.

C. As part of the implementation process, the Department shall:

1. Develop a registration process for those entities that are willing to participate in the Program;

2. Create a publicly available source for listing the prices of imported prescription drug products that shall be made available to the public on a website maintained by the Department;

3. Create an outreach and marketing plan to generate public awareness of the Program;

4. Create and staff a hotline to answer questions and address the needs of consumers, employers,

health carriers, pharmacies, health care providers, and other affected persons;

5. Establish a two-year audit work-plan cycle; and

6. Conduct any other activities that the Commissioner determines to be important for successful implementation of the Program.

§ 32.1-78.6. Monitoring for anticompetitive behavior.

The Department shall 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.

§ 32.1-78.7. Coordination with federal drug pricing program.

The Department shall seek the appropriate federal approvals, waivers, exemptions, or agreements, or a combination thereof, as needed to enable all covered entities enrolled in or eligible for the federal 340B Drug Pricing Program to participate in the Program to the fullest extent possible without jeopardizing their eligibility for the federal 340B Drug Pricing Program.

§ 32.1-78.8. Suspension of authority to import prescription drugs.

The Department shall immediately suspend the importation of a specific prescription drug or the importation of prescription drugs by a specific importer if it discovers that any prescription drug or activity is in violation of this article. The Department may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe prescription drugs being imported into the Commonwealth pursuant to the Program.

§ 32.1-78.9. Annual reporting.

Annually on or before March 1 following the calendar year in which the Program is implemented, the Department shall report to the Governor and the General Assembly regarding the operation of the Program during the previous calendar year, including:

1. Which prescription drugs were included in the Program;

2. The number of participating pharmacies, pharmacists, and health carriers;

3. The number of prescriptions dispensed through the Program;

4. The estimated savings to consumers, health carriers, and the Commonwealth during the previous calendar year;

5. Information regarding implementation of the audit plan and audit findings; and

6. Any other information the Commissioner deems relevant.