

WEST VIRGINIA LEGISLATURE

2022 REGULAR SESSION

Introduced

Senate Bill 483

BY SENATORS BALDWIN, ROMANO, WOELFEL, AND

CAPUTO

[Introduced January 25, 2022; referred
to the Committee on Health and Human Resources;
and then to the Committee on Finance]

FISCAL NOTE

1 A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article,
2 designated §16-5DD-1, §16-5DD-2, §16-5DD-3, §16-5DD-4, §16-5DD-5, and §16-5DD-6,
3 all relating to creating the Wholesale Prescription Drug Importation Program; setting
4 requirements for the design of the program; setting certain deadlines for the
5 implementation of the program; requiring monitoring for anticompetitive behavior; ensuring
6 compliance with federal law; requiring a plan for program financing to be provided to the
7 Joint Committee on Government and Finance; authorizing the proposal of emergency and
8 legislative rules; providing for certain implementation requirements; and requiring annual
9 reporting to the Legislature.

Be it enacted by the Legislature of West Virginia:

ARTICLE 5DD. WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM.

§16-5DD-1. Wholesale importation program design.

1 (a) The Secretary of the Department of Health and Human Resources, in consultation with
2 the state health officer, interested stakeholders and appropriate federal officials, shall design a
3 wholesale prescription drug importation program that complies with the applicable requirements
4 of 21 U.S.C. §384, including the requirements regarding safety and cost savings. The program
5 design shall:

6 (1) Designate a state agency or division of the department that shall either become a
7 licensed drug wholesaler or contract with a licensed drug wholesaler in order to seek federal
8 certification and approval to import safe prescription drugs and provide significant prescription
9 drug cost savings to West Virginia consumers;

10 (2) Use Canadian prescription drug suppliers regulated under the laws of Canada or of
11 one or more Canadian provinces, or both;

12 (3) Ensure that only prescription drugs meeting the U.S. Food and Drug Administration's
13 safety, effectiveness, and other standards shall be imported by or on behalf of the state;

14 (4) Import only those prescription drugs expected to generate substantial savings for West

15 Virginia consumers;

16 (5) Ensure that the program complies with the tracking and tracing requirements of 21
17 U.S.C. §360eee and §360eee-1 to the extent feasible and practical prior to imported drugs coming
18 into the possession of the state wholesaler and that it complies fully after imported drugs are in
19 the possession of the state wholesaler;

20 (6) Prohibit the distribution, dispensing, or sale of imported products outside West
21 Virginia's borders;

22 (7) Recommend a charge per prescription or another method of support to ensure that the
23 program is funded adequately in a manner that does not jeopardize significant consumer savings;
24 and

25 (8) Include a robust audit function.

26 (b) On or before September 1, 2022, the secretary shall submit the proposed design for a
27 wholesale prescription drug importation program to the Joint Committee on Government and
28 Finance.

§16-5DD-2. Monitoring for anticompetitive behavior.

1 The Department of Health and Human Resources shall consult with the Office of the
2 Attorney General to identify the potential, and to monitor, for anticompetitive behavior in industries
3 that would be affected by a wholesale prescription drug importation program.

§16-5DD-3. Federal compliance.

1 (a) On or before December 31, 2022, the Department of Health and Human Resources
2 shall submit a formal request to the Secretary of the U.S. Department of Health and Human
3 Services for certification of the State's Wholesale Prescription Drug Importation Program.

4 (b) The department shall seek the appropriate federal approvals, waivers, exemptions, or
5 agreements, or a combination thereof, as needed to enable all covered entities enrolled in or
6 eligible for the federal 340B Drug Pricing Program to participate in the State's Wholesale
7 Prescription Drug Importation Program to the fullest extent possible without jeopardizing their

8 eligibility for the 340B Program.

§16-5DD-4. Program financing; rule-making authority.

1 The Department of Health and Human Resources may not implement the Wholesale
2 Prescription Drug Importation Program until the Joint Committee on Government and Finance
3 reviews the proposed charge per prescription or another method of financial support for the
4 program. After review and approval in concept by the Joint Committee on Government and
5 Finance of the financing method, the department shall promulgate emergency rules pursuant to
6 the provisions of §29A-3-15 of this code and shall propose corresponding rules for legislative
7 consideration pursuant to the provisions of §29A-3-1 et seq. of this code to implement the
8 financing method.

§16-5DD-5. Implementation provisions.

1 After the financing method is approved pursuant to §16-5DD-4 of this code and the
2 Secretary of the U.S. Department of Health and Human Services has certified and approved the
3 program, the Department of Health and Human Resources shall begin implementation of the
4 Wholesale Prescription Drug Importation Program and shall begin operating the program within
5 six months. As part of the implementation process, the department shall, in accordance with state
6 purchasing laws:

7 (1) Become licensed as a wholesaler or enter into a contract with a West Virginia-licensed
8 wholesaler;

9 (2) Contract with one or more West Virginia-licensed distributors;

10 (3) Contract with one or more licensed and regulated Canadian suppliers;

11 (4) Engage with health insurance plans, employers, pharmacies, health care providers,
12 and consumers;

13 (5) Develop a registration process for health insurance plans, pharmacies, and
14 prescription drug-administering health care providers who are willing to participate in the program;

15 (6) Create a publicly available source for listing the prices of imported prescription drug

16 products that shall be made available to all participating entities and consumers;

17 (7) Create an outreach and marketing plan to generate program awareness;

18 (8) Starting in the weeks before the program becomes operational, create and staff a
19 hotline to answer questions and address the needs of consumers, employers, health insurance
20 plans, pharmacies, health care providers, and other affected sectors;

21 (9) Establish the audit function and a two-year audit work-plan cycle; and

22 (10) Conduct any other activities that the department determines to be important for
23 successful implementation of the program.

§16-5DD-6. Annual reporting.

1 Annually on or before December 15, the Department of Health and Human Resources
2 shall report to the Joint Committee on Health and the Joint Committee on Finance regarding the
3 operation of the Wholesale Prescription Drug Importation Program during the previous fiscal year,
4 including:

5 (1) Which prescription drugs were included in the wholesale importation program;

6 (2) The number of participating pharmacies, health care providers, and health insurance
7 plans;

8 (3) The number of prescriptions dispensed through the program;

9 (4) The estimated savings to consumers, health plans, employers, and the state during
10 the previous calendar year and to date;

11 (5) Information regarding implementation of the audit plan and audit findings; and

12 (6) Any other information the secretary of the department deems relevant.

NOTE: The purpose of this bill is to allow West Virginia residents to purchase prescription drugs from Canada in order to generate cost savings to consumers.

Strike-throughs indicate language that would be stricken from a heading or the present law, and underscoring indicates new language that would be added.