WEST VIRGINIA LEGISLATURE

2024 REGULAR SESSION

Introduced

House Bill 4170

By Delegate Young

[Introduced January 10, 2024 ; Referred

to the Committee on Health and Human Resources]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §9-11-1, §9-11-2, §9-11-3, §9-11-4, and §9-11-5, all relating to the wholesale importation of prescription drugs.

Be it enacted by the Legislature of West Virginia:

ARTICLE 11. WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM.

§9-11-1. Authorization.

The Wholesale Prescription Drug Importation Program referred to in this article is established to provide for the wholesale importation of prescription drugs from Canada by or on behalf of the state. The program must be designed in accordance with the requirements of this article. The program may not be implemented unless the state obtains approval and certification from the United States Department of Health and Human Services pursuant to 21 U.S.C. § 384(l).

§9-11-2. Definitions.

As used in this article:

"Department" means the West Virginia Department of Health and Human Resources.

"Program" means the Wholesale Prescription Drug Importation Program.

§9-11-3. Design of program.

(a) *Design requirements*. —The department, in consultation with appropriate federal and other state agencies, other states and interested parties, shall design the program to comply with the applicable requirements of 21 U.S.C. § 384, including requirements regarding safety and cost savings. The program design must:

(1) Provide that the department become a licensed drug wholesaler or contract with a licensed drug wholesaler in order to seek federal certification and approval, pursuant to 21 U.S.C. § 384, to import safe prescription drugs and provide cost savings to consumers in the state;

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

(3) Ensure that only prescription drugs meeting the federal Food and Drug Administration's

safety, effectiveness and other standards are imported by or on behalf of the state;

(4) Import only those prescription drugs expected to generate substantial cost savings for consumers in the state;

(5) Ensure that the program complies with the transaction and tracing requirements of 21 U.S.C. §§ 360eee and 360eee-1 to the extent feasible and practical prior to imported prescription drugs coming into the possession of the licensed drug wholesaler and that the program complies fully with those federal requirements after imported prescription drugs are in the possession of the licensed drug wholesaler;

(6) Consider whether the program may be developed on a multistate basis through collaboration with other states;

(7) Prohibit the distribution, dispensing or sale of imported prescription drugs outside of the state;

(8) Recommend a charge per prescription or another method of financing to ensure that the program is adequately funded in a manner that does not jeopardize significant cost savings to consumers, including adequate funding for the initial start-up costs of the program;

(9) Apply for and receive funds, grants or contracts from public and private sources; and

(10) Include an audit function.

(b) *Rules.* —The department shall propose rules for legislative approval pursuant to §29B-3-1 *et seq.*, of this code to design the program in accordance with the requirements of subsection (a) of this section no later than September 1, 2024.

(c) *Request for federal approval and certification.* —The department shall submit a request for approval and certification of the program to the United States Department of Health and Human Services no later than April 1, 2025.

§9-11-4. Implementation.

(a) *Implementation; operation.* — Upon receipt of federal approval and certification under 21 U.S.C. § 384, the department shall implement the program as required in subsection (b). The

program must begin operating no later than six months following receipt of federal approval and certification.

(b) *Requirements.* — Prior to operating the program, the department shall:

(1) Become a licensed drug wholesaler or enter into a contract with a licensed drug wholesaler in the state;

(2) Contract with one or more distributors licensed in the state;

(3) Contract with one or more licensed and regulated prescription drug suppliers in Canada;

(4) Consult with health insurance carriers, employers, pharmacies, pharmacists, health care providers, and consumers;

(5) Develop a registration process for health insurance carriers, pharmacies and health care providers, authorized to prescribe and administer prescription drugs, that are willing to participate in the program;

(6) Create a publicly accessible website for listing the prices of prescription drugs to be imported under the program;

(7) Create an outreach and marketing plan to generate public awareness of the program;

(8) Provide a telephone hotline to answer questions and address needs of consumers, employers, health insurance carriers, pharmacies, health care providers, and others affected by the program;

(9) Develop a two-year audit work plan; and

(10) Conduct any other activity determined necessary to successfully implement and operate the program.

§9-11-5. Annual reporting.

Beginning December 1, 2024, and annually thereafter, the department shall report to the Legislative Oversight Commission on Health and Human Resources Accountability regarding the implementation and operation of the program during the previous calendar year, including:

(1) *Prescription drugs included*. —The prescription drugs included in the program;

(2) *Participation.* —The number of participating pharmacies, health care providers and health insurance carriers;

(3) *Prescriptions dispensed.* —The number of prescription drugs dispensed through the program;

(4) *Estimated savings.* — The estimated cost savings to consumers, health insurance carriers, employers and the state during the previous calendar year and to date;

(5) *Audit findings*. — Information regarding implementation of the audit work plan and audit findings; and

(6) *Other relevant information.* — Any other information the department considers relevant.

NOTE: The purpose of this bill is to establish the Wholesale Prescription Drug Importation Program for the purpose of importing drugs from Canada on behalf of the state. The program will operate in compliance with the federal Department of Health and Human Services (HHS) regulations governing importation of prescription drugs and with approval of the secretary of HHS.

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