WEST VIRGINIA LEGISLATURE

2021 REGULAR SESSION

Introduced

House Bill 2284

FISCAL NOTE

BY DELEGATE BATES

[Introduced February 10, 2021; Referred

to the Committee on Health and Human Resources then

the Judiciary]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §16-63-1, §16-63-2, §16-63-3, §16-63-4, §16-63-5, and §16-63-6 all relating to creating a state-administered wholesale drug importation program monitored by the Bureau for Medical Services; defining terms; establishing criteria for program; duties of the Attorney General and the bureau; certification of the state's wholesale drug importation program; and annual report to the Legislative Oversight Commission on Health and Human Resources.

Be it enacted by the Legislature of West Virginia:

ARTICLE 63. STATE ADMINISTERED WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM.

§16-63-1. Definition.

The following terms are defined:

"Bureau" means the Bureau for Medical Services.

"Commission" means the Legislative Oversight Commission on Health and Human Resources.

"Importation program" means a state-administered wholesale importation program where the state is the licensed wholesaler, importing drugs from a licensed, regulated Canadian supplier, solely for distribution to voluntarily-participating, state-licensed, in-state pharmacies and administering providers for the exclusive purpose of dispensing to state residents with a valid prescription.

§16-63-2. Development of wholesale importation program; criteria.

The bureau shall design and establish a wholesale prescription drug importation program in consultation with relevant stakeholders and federal agencies that will meet relevant requirements of 21 U.S.C. § 384, including safety and cost savings. To establish this program,

the bureau shall designate a state agency to become a licensed wholesaler for the purpose of seeking federal certification and approval to import safe prescription drugs at low cost for West Virginia's consumers. The design and implementation of the program must conform to the following criteria:

(1) The program shall use Canadian suppliers regulated under the appropriate Canadian and provincial laws;

(2) The program shall have a process to sample the purity, chemical composition, and potency of imported products;

(3) The program shall only import those prescription pharmaceuticals expected to generate substantial savings for West Virginia's consumers;

(4) The program shall ensure imported products will not be distributed, dispensed, or sold outside of West Virginia's borders;

(5) Voluntary participant, state-licensed, pharmacies and administering providers shall only charge individual consumers and health plans the actual acquisition cost of the imported, dispensed product;

(6) The health plan payment of the product component of pharmacy and provider billing shall not reimburse more than the actual acquisition cost of the dispensed, imported product;

(7) The program shall ensure that participating health plans keep their formularies and claims payment systems up to date with the prescription drugs provided through the wholesale importation program;

(8) The program shall ensure that participating health plans base patient cost-sharing on no more than the actual acquisition cost of the dispensed, imported product;

(9) The program shall require participating health plans to demonstrate to the bureau how savings on imported drugs are reflected in premiums.

(10) The profit margin of any participating wholesaler and distributor of imported pharmaceutical products shall be limited to a specified amount established by the bureau;

(11) The program shall not import generic products that would violate U.S. patent laws on U.S. branded products;

(12) The program shall comply with the requirements of 21 U.S.C. §§ 581 and 582, pertaining to the track and trace requirements as enacted in Title II of the Drug Security and Quality Act (Pub. L.113-54) to the extent practical and feasible before imported drugs come into possession of the state wholesaler and shall comply fully after imported drugs are in the possession of the state wholesaler;

(13) The program shall be adequately financed through a fee on each prescription or other appropriate approach, but the size of the fee may not jeopardize significant consumer savings;

(14) The program shall include an audit function to ensure that:

(A) The bureau has a sound methodology by which to determine the most cost-effective products to include in the importation program on an ongoing basis;

(B) The bureau has processes in place to select Canadian suppliers of high quality, high performance, and in full compliance with Canadian law and regulation and at the option of the sponsor, state pharmacy, or wholesaler laws;

(C) Imported drugs under the state program are not shipped, sold, or dispensed outside the state once in the possession of the state;

(D) Imported products are pure, unadulterated, potent, and safe;

(E) Participating pharmacies and administering providers are not charging more than actual acquisition cost to any consumer or any participating health plan;

(F) Participating health plan formularies and claims processing systems remain up to date with all relevant aspects of the importation program;

(G) Participating health plans base patient coinsurance and other cost-sharing on the actual acquisition cost of covered, imported drugs;

(H) Participating health plans reimburse participating pharmacies and administering providers actual acquisition cost for imported, dispensed product;

(I) The program is adequately financed to support all administrative functions while generating significant consumer savings;

(J) The program does not put consumers at higher risk than if the program did not exist; and

(K) The program continues to provide West Virginia consumers with substantial savings on prescription drugs.

§16-63-3. Monitoring for Anti-Competitive Behavior.

The Attorney General shall assist the bureau to identify the potential for anticompetitive behavior in industries that would be affected by a program of importation.

§16-63-4. Submission of Request for Federal Certification and Approval.

The bureau shall submit a formal request to the Secretary of the U.S. Department of Health and Human Resources for certification of the state's wholesale drug importation program.

§16-63-5. Implementation/Additional Administrative Requirements.

Upon certification and approval by the Secretary of the US Department of Health and Human Resources, the bureau shall begin implementation of the wholesale importation program and have the program operational within six months of the date of the certification. As part of the implementation process the bureau shall:

(1) Become licensed as a wholesaler;

(2) Contract with a state-licensed distributor or distributors;

(3) Contract with a licensed, regulated, Canadian supplier or suppliers;

(4) Engage health plans, employers, pharmacies, providers, and consumers;

(5) Develop a registration process for health plans, pharmacies, and administering providers willing to participate;

(6) Create a publicly available source for listing prices of imported products that will be available to all participating entities and consumers;

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

(8) Create and staff a hotline to answer questions from any affected sector starting in the weeks before the program becomes operational that can address the needs and questions of consumers, employers, plans, pharmacies, and providers, among others;

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

(10) Conduct any other activities determined to be important to successful implementation as determined by the bureau.

§16-63-6. Report to the commission.

The bureau shall report to the commission annually by December 1st. The report to the commission shall include:

(1) The drugs covered in the wholesale importation program;

(2) The number of participating pharmacies, providers, and health plans;

(3) The number of prescriptions dispensed under the program in the period;

(4) The estimated savings to consumers, health plans, and employers that resulted from the program in the reporting period and to date;

(5) In the first three reporting periods, information on the implementation of the audit plan and, on an on-going basis, audit findings for the reporting period; and

(6) Any other information of importance as determined by the bureau.

NOTE: The purpose of this bill is to permit the state to designate a state agency, the Bureau for Medical Services, to become a drug wholesaler to import pharmaceuticals from Canada to provide cheaper drugs to West Virginians.

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