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HOUSE BILL 1022

By Potts

AN ACT to amend Tennessee Code Annotated, Title 4; Title 53; Title 68 and Title 71, relative to prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 68, Chapter 1, is amended by adding the following as a new part:

68-1-2601. Short title.

This part is known and may be cited as the "Safe, Low-Cost Prescription Drugs Program Act."

68-1-2602. Part definitions.

As used in this part:

(1) "Commissioner" means the commissioner of health;

(2) "Department" means the department of health;

(3) "Employer":

(A) Means any person or entity that employs one (1) or more employees; and

(B) Includes the state and its political subdivisions and instrumentalities;

(4) "Health insurance plan" means health insurance coverage as defined in § 56-7-109;

(5) "Healthcare provider" means healthcare professionals, establishments, or facilities licensed, registered, certified, or permitted pursuant to title 63 or this title and regulated under the authority of either the department of

health or any agency, board, council, or committee attached to the department of health; and

(6) "Prescription drug" means a drug that under federal or state law is required to be dispensed only pursuant to a prescription order or is restricted to use by prescribers and that under federal law must be labeled with either the symbol "Rx only" or the statement "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian".

68-1-2603. Wholesale importation program for prescription drugs—Design.

(a) The department, in consultation with interested stakeholders and appropriate federal officials, shall design a wholesale prescription drug importation program that complies with the applicable requirements of 21 U.S.C. § 384, including the requirements regarding safety and cost savings. The program design must:

(1) Designate a state agency to either become a licensed drug wholesaler or contract with a licensed drug wholesaler in order to seek federal certification and approval to import safe prescription drugs and provide significant prescription drug cost savings to Tennessee consumers;

(2) Use Canadian prescription drug suppliers regulated under the laws of Canada or of one (1) or more Canadian provinces, or both;

(3) Ensure that only prescription drugs meeting the United States food and drug administration's safety, effectiveness, and other standards are imported by or on behalf of this state;

(4) Import only those prescription drugs expected to generate substantial savings for Tennessee consumers;

(5) Ensure that:

(A) The program complies with the tracking and tracing requirements of 21 U.S.C. §§ 360eee and 360eee-1 to the extent feasible and practical prior to imported drugs coming into the possession of the state wholesaler; and

(B) The state wholesaler complies fully after imported drugs are in the possession of the state wholesaler;

(6) Prohibit the distribution, dispensing, or sale of imported products outside the borders of this state;

(7) Recommend 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; and

(8) Include a robust audit function.

(b) On or before January 1, 2022, the commissioner shall submit the proposed design for a wholesale prescription drug importation program to the health committee of the house of representatives, the health and welfare committee of the senate, and the finance, ways and means committees of the house of representatives and the senate.

68-1-2604. Monitoring for anticompetitive behavior.

The department shall consult with the office of the attorney general and reporter to identify the potential, and to monitor, for anticompetitive behavior in industries that would be affected by a wholesale prescription drug importation program.

68-1-2605. Federal compliance.

(a) On or before July 1, 2022, the commissioner shall submit a formal request to the secretary of the United States department of health and human services for certification of this state's wholesale prescription drug importation program.

(b) 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 state wholesale prescription drug importation program to the fullest extent possible without jeopardizing their eligibility for the 340B program.

68-1-2606. Program financing.

The department shall not implement the wholesale prescription drug importation program until:

(1) The general assembly enacts legislation establishing a charge per prescription or another method of financial support for the program; or

(2) Another source of program funding is in place.

68-1-2607. Program implementation.

Upon the last to occur of the general assembly enacting a method of financial support pursuant to § 68-1-2606 and receipt of certification and approval by the secretary of the United States department of health and human services, the department shall begin implementation of the wholesale prescription drug importation program and shall begin operating the program within six (6) months. As part of the implementation process, the department shall, in accordance with state procurement and contract laws, rules, and procedures, as appropriate:

(1) Become licensed as a wholesaler or enter into a contract with a state-licensed wholesaler;

(2) Contract with one (1) or more state-licensed distributors;

(3) Contract with one (1) or more licensed and regulated Canadian suppliers;

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

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

(6) Create a publicly available source for listing the prices of imported prescription drug products that must be made available to all participating entities and consumers;

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

(8) No less than thirty (30) days before the program becomes operational, create and staff a hotline to answer questions and address the needs of consumers, employers, health insurance plans, and pharmacists;

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

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

68-1-2608. Annual report.

Annually, on or before January 15, the department shall deliver a report to the health committee of the house of representatives, the health and welfare committee of the senate, the finance, ways and means committees of the house of representatives and the senate, and the legislative librarian regarding the operation of the wholesale prescription drug importation program during the previous calendar year, including:

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

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

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

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

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

(6) Other information the department deems relevant.

SECTION 2. The department of health is authorized to promulgate rules to effectuate the purposes of this act. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 3. The headings to sections in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 4. This act takes effect upon becoming a law, the public welfare requiring it.