MISSISSIPPI LEGISLATURE REGULAR SESSION 2024

By: Representative Currie

To: Drug Policy; Public Health and Human Services

HOUSE BILL NO. 817

AN ACT TO REQUIRE THE STATE DEPARTMENT OF HEALTH TO ESTABLISH THE CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM; TO DEFINE CERTAIN TERMS FOR THE PURPOSE OF THE ACT; TO REQUIRE THE DEPARTMENT TO CONTRACT WITH A VENDOR TO FACILITATE WHOLESALE PRESCRIPTION DRUG IMPORTATION UNDER THE PROGRAM; TO SPECIFY THE RESPONSIBILITIES FOR THE VENDOR, INCLUDING THE PAYMENT OF A BOND; TO PROVIDE ELIGIBILITY CRITERIA FOR PRESCRIPTION DRUGS, CANADIAN SUPPLIERS, AND IMPORTERS UNDER THE PROGRAM; TO AUTHORIZE A CANADIAN SUPPLIER TO EXPORT DRUGS INTO THIS STATE UNDER THE PROGRAM UNDER CERTAIN CIRCUMSTANCES; TO PROVIDE ELIGIBILITY CRITERIA AND REQUIREMENTS FOR DRUG IMPORTERS; TO REQUIRE PARTICIPATING CANADIAN SUPPLIERS AND IMPORTERS TO COMPLY WITH SPECIFIED FEDERAL REQUIREMENTS FOR DISTRIBUTING PRESCRIPTION DRUGS IMPORTED UNDER THE PROGRAM; TO PROHIBIT CANADIAN SUPPLIERS AND IMPORTERS FROM DISTRIBUTING, DISPENSING, OR SELLING PRESCRIPTION DRUGS IMPORTED UNDER THE PROGRAM OUTSIDE OF THIS STATE; TO REQUIRE THE DEPARTMENT TO REQUEST FEDERAL APPROVAL OF THE PROGRAM AND REQUIRE THE REQUEST TO INCLUDE CERTAIN INFORMATION; TO REQUIRE THE DEPARTMENT TO BEGIN OPERATING THE PROGRAM WITHIN SIX MONTHS AFTER RECEIVING FEDERAL APPROVAL; TO PROVIDE FOR CERTAIN DOCUMENTATION REQUIREMENTS FOR VENDORS; TO REQUIRE THE DEPARTMENT TO SUSPEND THE IMPORTATION OF DRUGS IN VIOLATION OF THIS ACT OR ANY FEDERAL OR STATE LAW OR REGULATION; TO AUTHORIZE THE DEPARTMENT TO REVOKE THE SUSPENSION UNDER CERTAIN CIRCUMSTANCES; TO REQUIRE THE DEPARTMENT TO SUBMIT AN ANNUAL REPORT TO THE GOVERNOR AND THE LEGISLATIVE OFFICERS BY A SPECIFIED DATE AND PROVIDE REQUIREMENTS FOR SUCH REPORT; TO REQUIRE THE DEPARTMENT TO NOTIFY LEGISLATIVE OFFICERS UPON FEDERAL APPROVAL OF THE PROGRAM AND TO SUBMIT A PROPOSAL TO THE LEGISLATURE FOR PROGRAM IMPLEMENTATION AND FUNDING BEFORE A CERTAIN DATE; TO REQUIRE THE DEPARTMENT TO ADOPT RULES DEEMED NECESSARY TO IMPLEMENT THIS ACT; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. Program established. The State Department of Health shall establish the Canadian Prescription Drug Importation Program for the importation of safe and effective prescription drugs from Canada that have the highest potential for cost savings to the state.

SECTION 2. Definitions. As used in this act, the following terms shall be defined as provided in this section:

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

(b) "County health department" means a county department of health established under Section 41-3-43.

(c) "Department" means the State Department of Health.

(d) "Drug" or "prescription drug" has the same meaning as "prescription drug" in Section 73-21-73, but is limited to drugs intended for human use.

(f) "Federal act" means the federal Food, Drug, and Cosmetic Act, 21 USC Section 301 et seq.; 52 Stat. 1040 et seq., as amended by the federal Drug Quality and Security Act, 21 USC Section 351 et seq.

(g) "Free clinic" means a clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to low-income recipients.

(h) "Medicaid pharmacy" means a pharmacy licensed under the Mississippi Pharmacy Practice Act that has a Medicaid provider agreement in effect with the Division of Medicaid and is in good standing with the division.

(i) "Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy under the Mississippi Pharmacy Practice Act.

(j) "Program" means the Canadian Prescription Drug Importation Program.

(k) "Track-and-trace" means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the federal Drug Quality and Security Act, Drug Supply Chain Security Act, 21 USC Section 351 et seq.

(l) "Vendor" means the entity contracted by the department to manage specified functions of the program.

SECTION 3. Importation process. (1) The department shall contract with a vendor to provide services under the program.

(2) By December 1, 2024, and each year thereafter, the vendor shall develop a Wholesale Prescription Drug Importation List identifying the prescription drugs that have the highest potential for cost savings to the state. In developing the list, the vendor 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 (3) months to ensure that it continues to meet the requirements of the programs and may direct the vendor to revise the list, as necessary.

(3) The vendor shall 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 list at prices that will provide cost savings to the state. The vendor must 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.

(4) The vendor shall contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and Canadian suppliers, to import drugs under the program.

(5) The vendor shall maintain a list of all registered importers that participate in the program.

(6) The vendor shall ensure compliance with Title II of the federal Drug Quality and Security Act, 21 USC Section 351 et seq., by all suppliers, importers and other distributors, and participants in the program.

(7) The vendor shall assist the department in the preparation of the annual report required by Section 12 of this act, including the timely provision of any information requested by the department.

(8) The vendor shall provide an annual financial audit of its operations to the department as required by the department. The vendor shall also provide quarterly financial reports specific to the program and shall include information on the performance of its subcontractors and vendors. The department shall determine the format and contents of the reports.

SECTION 4. Bond requirement. The department shall require a bond from the vendor to mitigate the financial consequences of potential acts of malfeasance or misfeasance or fraudulent or dishonest acts committed by the vendor, any employees of the vendor, or its subcontractors.

SECTION 5. Eligible prescription drugs. Eligible importers as described in Section 7 of this act may import a drug from an eligible Canadian supplier as described in Section 6 of this act, if:

(a) The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;

(b) Importing the drug would not violate federal patent laws;

(c) Importing the drug is expected to generate cost savings; and

(d) The drug is not:

(i) A controlled substance as defined in 21 USC Section 802;

(ii) A biological product as defined in 42 USC Section 262;

(iii) An infused drug;

(iv) An intravenously injected drug;

(v) A drug that is inhaled during surgery; or

(vi) A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

SECTION 6. Eligible Canadian suppliers. A Canadian supplier may export prescription drugs into this state under the program if the supplier:

(a) Is in full compliance with relevant Canadian federal and provincial laws and regulations;

(b) Is identified by the vendor as eligible to participate in the program; and

(c) Submits an attestation that the supplier has a registered agent in the United States, including the name and United States address of the registered agent.

SECTION 7. Eligible importers. The following entities may import prescription drugs from an eligible Canadian supplier under the program:

(a) A pharmacist or wholesaler employed by or under contract with the department's central pharmacy, for distribution

to a county health department or free clinic for dispensing to clients treated in such department or clinic.

(b) A pharmacist or wholesaler employed by or under contract with a Medicaid pharmacy, for dispensing to the pharmacy's Medicaid recipients.

(c) A pharmacist or wholesaler employed by or under contract with the Department of Corrections, for dispensing to inmates in the custody of the Department of Corrections.

(d) A pharmacist or wholesaler employed by or under contract with a developmental disabilities center for dispensing to clients treated in such center.

(e) A pharmacist or wholesaler employed by or under contract with a treatment facility for dispensing to patients treated in such facility.

SECTION 8. Distribution requirements. Eligible Canadian suppliers and eligible importers participating under the program:

(a) Must comply with the tracking and tracing requirements of 21 USC Section 360eee et seq.

(b) May not distribute, dispense, or sell prescription drugs imported under the program outside of the state.

SECTION 9. Federal approval. By July 1, 2025, the department shall submit a request to the United States Secretary of Health and Human Services for approval of the program under 21 USC Section 384. The department shall begin operating the program

within six (6) months after receiving such approval. The request must, at a minimum:

(a) Describe the department's plan for operating the program;

(b) Demonstrate how the prescription drugs imported into this state under the program will meet the applicable federal and state standards for safety and effectiveness;

(c) Demonstrate how the drugs imported into this state under the program will comply with federal tracing procedures;

(d) Include a list of proposed prescription drugs that have the highest potential for cost savings to the state through importation at the time that the request is submitted;

(e) Estimate the total cost savings attributable to the program;

(f) Provide the costs of program implementation to the state; and

(g) Include a list of potential Canadian suppliers from which the state would import 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.

SECTION 10. Prescription drug supply chain documentation.

(1) The vendor shall ensure the safety and quality of drugs imported under the program. The vendor shall:

(a) For an initial imported shipment of a specific drug by an importer, ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the federal act;

(b) For every subsequent imported shipment of that drug by that importer, ensure that a statistically valid sample of the shipment is tested for authenticity and degradation in a manner consistent with the federal act;

(c) Certify that the drug:

(i) Is approved for marketing in the United States and is not adulterated or misbranded; and

(ii) Meets all of the labeling requirements under 21 USC Section 352;

(d) Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section; and

(e) Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications.

(2) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(3) The vendor shall maintain information and documentation submitted under this section for a period of at least seven (7) years.

(4) A participating importer must submit all of the following information to the vendor:

(a) The name and quantity of the active ingredient of the drug;

(b) A description of the dosage form of the drug;

(c) The date on which the drug is received;

(d) The quantity of the drug that is received;

(e) The point of origin and destination of the drug; and

(f) The price paid by the importer for the drug.

(5) A participating Canadian supplier must submit the following information and documentation to the vendor specifying all of the following:

(a) The original source of the drug, including:

(i) The name of the manufacturer of the drug;

(ii) The date on which the drug was manufactured; and

(iii) The location (country, state or province, and city) where the drug was manufactured;

(b) The date on which the drug is shipped;

(c) The quantity of the drug that is shipped;

(d) The quantity of each lot of the drug originally received and the source of the lot; and

(e) The lot or control number and the batch number assigned to the drug by the manufacturer.

(6) The department may require that the vendor collect any other information necessary to ensure the protection of the public health.

SECTION 11. Immediate suspension. The department shall immediately suspend the importation of a specific drug or the importation of drugs by a specific importer if it discovers that any drug or activity is in violation of this section or any federal or state law or regulation. The department may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe drugs being imported into this state.

SECTION 12. Annual report. By December 1 of each year, the department shall submit a report to the Governor, the Speaker of the House of Representatives and the Lieutenant Governor on the operation of the program during the previous fiscal year. The report must include, at a minimum:

(a) A list of the prescription drugs that were imported under the program;

(b) The number of participating entities;

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

(d) The estimated cost savings during the previous fiscal year and to date attributable the program;

(e) A description of the methodology used to determine which drugs should be included on the Wholesale Prescription Drug Importation List; and

(f) Documentation as to how the program ensures the following:

(i) That Canadian suppliers participating in the program are of high quality, high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations as well as all federal laws and regulations and state laws and rules;

(ii) That prescription drugs imported under the program are not shipped, sold, or dispensed outside of this state once in the possession of the importer;

(iii) That prescription drugs imported under the program are pure, unadulterated, potent, and safe;

(iv) That the program does not put consumers at a higher health and safety risk than if the consumer did not participate; and

(v) That the program provides cost savings to the state on imported prescription drugs.

SECTION 13. Notification of federal approval. Upon receipt of federal approval of the program, the department shall notify the Speaker of the House of Representatives and the Lieutenant

Governor and the relevant committees of the Senate and the House of Representatives. After approval is received and before the start of the next regular session of the Legislature in which the proposal could be funded, the department shall submit to all legislative parties a proposal for program implementation and program funding.

SECTION 14. Rulemaking. The department shall adopt rules deemed necessary to implement this act.

SECTION 15. This act shall take effect and be in force from and after July 1, 2024.