By: Senator(s) Wiggins

To: Medicaid

COMMITTEE SUBSTITUTE
FOR
SENATE BILL NO. 2733

AN ACT TO CREATE THE MISSISSIPPI WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM; TO PROVIDE THAT THE DIVISION OF MEDICAID SHALL ESTABLISH THE PROGRAM TO PROVIDE PRESCRIPTION DRUGS AVAILABLE OUTSIDE OF THE UNITED STATES TO CONSUMERS IN THE STATE AT A LOWER COST; TO REQUIRE THE DIVISION TO CONTRACT WITH ONE OR MORE PRESCRIPTION DRUG WHOLESALERS AND CANADIAN SUPPLIERS TO IMPORT PRESCRIPTION DRUGS; TO REQUIRE THE DIVISION TO DEVELOP A REGISTRATION PROCESS FOR HEALTH BENEFIT PLANS; TO REQUIRE PROVIDERS AND PHARMACIES TO OBTAIN AND DISPENSE SUCH DRUGS; TO REQUIRE THE DIVISION TO COMPLY WITH CERTAIN FEDERAL LAWS REGULATING SUCH PROGRAMS; TO PROVIDE THAT A PRESCRIPTION DRUG MAY BE IMPORTED INTO THE STATE ONLY IF THE DRUG MEETS F.D.A. STANDARDS AND DOES NOT VIOLATE FEDERAL PATENT LAWS, AMONG OTHER REQUIREMENTS; TO REQUIRE THE DIVISION TO MONITOR ANY POTENTIAL ANTICOMPETITIVE ACTIVITIES AFFECTED BY THE PROGRAM; TO AUTHORIZE THE DIVISION TO IMPOSE A FEE ON EACH PRESCRIPTION DRUG SOLD UNDER THE PROGRAM; TO REQUIRE THE DIRECTOR OF THE DIVISION TO DEVELOP AUDITING PROCEDURES; TO REQUIRE THE DIVISION TO SUBMIT A REPORT ON THE PROGRAM TO THE LEGISLATURE AND GOVERNOR EACH YEAR; TO CREATE NEW SECTION 73-21-158, MISSISSIPPI CODE OF 1972, TO REQUIRE EACH DRUG MANUFACTURER TO SUBMIT A QUARTERLY REPORT TO THE COMMISSIONER OF THE DEPARTMENT OF INSURANCE WITH THE CURRENT WHOLESALE ACQUISITION COST INFORMATION FOR THE PRESCRIPTION DRUGS SOLD IN THE STATE BY THAT MANUFACTURER; TO SET CERTAIN OTHER REPORTING REQUIREMENTS, INCLUDING THE NAME OF THE DRUG AND AGGREGATE REBATE AMOUNTS; TO REQUIRE PHARMACY BENEFIT MANAGERS PROVIDING SERVICES FOR A HEALTH CARE PLAN AND EACH HEALTH INSURER TO SUBMIT CERTAIN REPORTS TO THE COMMISSIONER; AND FOR RELATED PURPOSES.

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

SECTION 1. This chapter shall be known and may be cited as the "Mississippi Wholesale Prescription Drug Importation Program."

SECTION 2. As used in this chapter, the following words and phrases have the meanings ascribed herein, unless the context clearly indicates otherwise:

(a) "Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy that is appropriately licensed or permitted under Canadian federal or provincial laws and rules to manufacture, distribute, or dispense prescription drugs.

(b) "Division" means the Mississippi Division of Medicaid.

(c) "Prescription drug wholesaler" means a person licensed as a wholesale distributor under Section 73-21-73 that contracts with this state to import prescription drugs under the program.

(d) "Program" means the wholesale prescription drug importation program established under this chapter.

SECTION 3. (1) The division shall establish the wholesale prescription drug importation program to provide lower cost prescription drugs available outside of the United States to consumers in this state at the lower cost.

(2) The division shall implement the program by:

(a) Contracting with one (1) or more prescription drug wholesalers and Canadian suppliers to import prescription drugs and provide prescription drug cost savings to consumers in this state;

(b) Developing a registration process for health benefit plan issuers, health care providers, and pharmacies to obtain and dispense prescription drugs imported under the program;

(c) Developing a list of prescription drugs, including the prices of those drugs, that meet the requirements of 21 USC 384 and publishing the list on the division website;

(d) Establishing an outreach and marketing plan to generate program awareness;

(e) Establishing and administering a telephone call center or electronic portal to provide information about the program;

(f) Ensuring the program and the prescription drug wholesalers that contract with this state under subsection (1) comply with the tracking, tracing, verification and identification requirements of 21 USC 360;

(g) Prohibiting the distribution, dispensing, or sale of prescription drugs imported under this chapter outside the boundaries of this state; and

(h) Performing any other duties the executive director determines necessary to implement the program.

(3) The division shall ensure that the program meets the requirements of 21 USC 384.

(4) In developing the program, the division may consult with interested parties.

SECTION 4. (1) A prescription drug may be imported into this state under the program only if the drug:

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

(b) Does not violate any federal patent laws through its importation;

(c) Is expected to generate cost savings for consumers; and

(d) Is not:

(i) Listed as a controlled substance under state or federal law;

(ii) A biological product;

(iii) An infused drug;

(iv) An intravenously injected drug;

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

(vi) A parenteral drug.

SECTION 5. The division shall identify and monitor any potential anticompetitive activities in industries affected by the program.

SECTION 6. In addition to money appropriated by the Legislature, the division may impose a fee on each prescription drug sold under the program or establish another funding method to administer the program.

SECTION 7. The executive director by rule shall develop procedures to effectively audit a prescription drug wholesaler participating in the program.

SECTION 8. (1) Not later than December 1 of each year, the division shall submit a report to the Governor and the Legislature regarding the operation of the program during the preceding state fiscal year, including:

(a) Which prescription drugs and Canadian suppliers are included in the program;

(b) The number of health benefit plan issuers, health care providers, and pharmacies participating in the program;

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

(d) The estimated cost savings to consumers, health plans, employers, and this state since the establishment of the program and during the preceding state fiscal year;

(e) Information regarding the implementation of audit procedures; and

(f) Any other information:

(i) The Governor or the Legislature requests; or

(ii) The division considers necessary.

SECTION 9. The following shall be codified as Section 73-21-158, Mississippi Code of 1972:

73-21-158. (1) Each drug manufacturer shall submit a report to the Commissioner of the Mississippi Department of Insurance no later than the fifteenth day of January, April, July, and October with the current wholesale acquisition cost information for the

prescription drugs sold in or into the state by that drug manufacturer.

(2) Not more than thirty (30) days after an increase in wholesale acquisition cost of forty percent (40%) or greater over the preceding five (5) calendar years or ten percent (10%) or greater in the preceding twelve (12) months for a prescription drug with a wholesale acquisition cost of Seventy Dollars ($70.00) or more for a manufacturer packaged drug container, a drug manufacturer shall submit a report to the commissioner. The report must contain the following information:

(a) Name of the drug;

(b) Whether the drug is a brand name or a generic;

(c) The effective date of the change in wholesale acquisition cost;

(d) Aggregate, company level research and development costs for the previous calendar year;

(e) Aggregate rebate amounts paid to each pharmacy benefits manager for the previous calendar year;

(f) The name of each of the drug manufacturer's drugs approved by the United States food and drug administration in the previous five (5) calendar years;

(g) The name of each of the drug manufacturer's drugs that lost patent exclusivity in the United States in the previous five (5) calendar years; and

(h) A concise statement of rationale regarding the factor or factors that caused the increase in the wholesale acquisition cost, such as raw ingredient shortage or increase in pharmacy benefit manager's rebates.

(2) The quality and types of information and data a drug manufacturer submits to the commissioner pursuant to this section must be the same as the quality and types of information and data the drug manufacturer includes in the drug manufacturer's annual consolidated report on Securities and Exchange Commission Form 10 K or any other public disclosure. A drug manufacturer shall notify the commissioner in writing if the drug manufacturer is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D Program.

(3) The notice must include a concise statement of rationale regarding the factor or factors that caused the new drug to exceed the Medicare Part D Program price. The drug manufacturer shall provide the written notice within three (3) calendar days following the release of the drug in the commercial market. A drug manufacturer may make the notification pending approval by the United States Food and Drug Administration if commercial availability is expected within three (3) calendar days following the approval.

(4) On or before April 1st of each year, a pharmacy benefits manager providing services for a health care plan shall file a

report with the commissioner. The report must contain the following information for the previous calendar year:

(a) The aggregated rebates, fees, price protection payments and any other payments collected from each drug manufacturer;

(b) The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from each drug manufacturer which were passed to health insurers;

(c) The aggregated fees, price concessions, penalties, effective rates, and any other financial incentive collected from pharmacies which were passed to enrollees at the point of sale;

(d) The aggregated dollar amount of rebates, price protection payments, fees, and any other payments collected from drug manufacturers which were retained as revenue by the pharmacy benefits manager; and

(e) The aggregated rebates passed on to employers.

(5) Reports submitted by pharmacy benefits managers under this section may not disclose the identity of a specific health benefit plan or enrollee, the identity of a drug manufacturer, the prices charged for specific drugs or classes of drugs, or the amount of any rebates or fees provided for specific drugs or classes of drugs.

(6) On or before April 1st of each year, each health insurer shall submit a report to the commissioner. The report must

contain the following information for the previous two (2) calendar years:

(a) Names of the twenty five (25) most frequently prescribed drugs across all plans;

(b) Names of the twenty five (25) prescription drugs dispensed with the highest dollar spend in terms of gross revenue;

(c) Percent of increase in annual net spending for prescription drugs across all plans;

(d) Percent of increase in premiums which is attributable to prescription drugs across all plans;

(e) Percentage of specialty drugs with utilization management requirements across all plans; and

(f) Premium reductions attributable to specialty drug utilization management.

(7) A report submitted by a health insurer may not disclose the identity of a specific health benefit plan or the prices charged for specific prescription drugs or classes of prescription drugs.

SECTION 10. This act shall take effect and be in force from and after July 1, 2024.