As Introduced

134th General Assembly
Regular Session
2021-2022

H. B. No. 715

Representatives Lipps, Young, T.

A BILL

To enact section 4729.71 of the Revised Code to establish the Canadian Prescription Drug Importation Program and to make an appropriation.

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

Section 1. That section 4729.71 of the Revised Code be enacted to read as follows:

Sec. 4729.71. (A)(1) In an effort to generate substantial cost savings for consumers of prescription drugs in this state, the state board of pharmacy shall develop a program for the importation of safe and effective prescription drugs from Canada, which shall be known as the Canadian prescription drug importation program.

(2) The board shall contract with a third-party entity to perform on behalf of the board the duties described in divisions (B) to (D) of this section. To be qualified to contract with the board, a third-party entity must have assisted one or more other states in developing, establishing, or administering, in accordance with section 804 of the "Federal Food, Drug, and Cosmetic Act," 21 U.S.C. 384, a prescription drug importation

program.

(B) In developing the program, the third-party entity shall do all of the following:

(1) Identify wholesalers for the importation of prescription drugs from Canada;

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

(3) Identify the drugs expected to generate substantial cost savings for consumers in this state;

(4) Establish measures for importing only the following prescription drugs:

(a) Drugs that satisfy federal food and drug administration safety and effectiveness standards;

(b) Drugs that are expected to generate substantial cost savings for consumers in this state.

(5) Ensure that the program has the ability to comply with the transaction and tracing requirements of sections 581 and 582 of the "Federal Food, Drug, and Cosmetic Act," 21 U.S.C. 360eee and 360eee-1;

(6) 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.

(C) Not later than four months after the effective date of this section, the third-party entity shall submit to the United States department of health and human services, in accordance

with section 804 of the "Federal Food, Drug, and Cosmetic Act," 21 U.S.C. 384, a request for approval and certification of the program developed under division (B) of this section.

If the United States department of health and human services approves and certifies the program, not later than six months after receipt of the approval and certification, the third-party entity shall establish and administer the program.

(D)(1) In establishing and administering the program, both of the following apply:

(a) The third-party entity shall do all of the following:

(i) Comply with the requirements of 21 U.S.C. 384 as well as any conditions specified by the United States department of health and human services in its approval and certification of the program;

(ii) Enter into a contract with a wholesaler identified under division (B)(1) of this section;

(iii) Enter into contracts with one or more of the drug suppliers identified under division (B)(2) of this section;

(iv) Enter into contracts with one or more entities located in this state for distribution of the imported prescription drugs;

(v) Consult with health plan issuers, employers, pharmacies, pharmacists, health care providers, and consumers;

(vi) Develop a process by which health plan issuers, pharmacies, and health care providers may register to participate in the program;

(vii) Establish and periodically update the list of

prescription drugs to be imported under the program and make the list available to the board;

(viii) Ensure that prescription drugs imported under the program are dispensed, sold, or distributed only in this state;

(ix) Periodically provide to the board information identifying the prices of prescription drugs imported under the program and the locations where the prescription drugs are dispensed, distributed, or sold;

(x) Establish a toll-free telephone line to answer questions and address the needs of consumers, employers, health plan issuers, pharmacies, health care providers, and others impacted by the program;

(xi) Conduct on an annual basis an audit of the program and share audit findings with the board;

(xii) Make available to the board any information necessary for the board to prepare the report required by division (E)(2) of this section;

(xiii) Conduct any other activity required by the board in rules adopted under this section.

(b) The third-party entity shall negotiate with the board the fee to be paid to the entity for administering the program. The amount of the fee shall be either a markup of the drugs purchased or a percentage of the savings achieved under the program, as calculated by the board in consultation with the department of administrative services.

(2) On the request of the board, acting in consultation with the department of administrative services, the third-party entity may, on behalf of state agencies, negotiate prices for

and directly purchase any prescription drugs, including drugs such as insulin, epinephrine, and, as defined in section 3715.01 of the Revised Code, biological products and interchangeable biological products, from manufacturers whose drugs have been approved for use in the United States by the federal food and drug administration. Such negotiations and purchases shall be conducted according to the same terms and conditions as negotiations and purchases are conducted under the Canadian prescription drug importation program and the third-party entity shall be compensated for such negotiations and purchases in the same amount as described in division (D)(1)(b) of this section.

(E)(1) With respect to the information described in divisions (D)(1)(a)(vii) and (ix) of this section, the board shall make the information available to the public on the internet web site maintained by the board. The board shall periodically update the web site to reflect any changes in the information.

The board also shall engage in activities to generate public awareness of the program.

(2) Not later than eighteen months after the effective date of this section and every year thereafter, the board shall submit to the president of the senate, the speaker of the house of representatives, and the chairpersons of the standing committees of the house of representatives and senate that are primarily responsible for considering health issues a report regarding the administration of the program during the previous year. Each submitted report shall include all of the following:

(a) The prescription drugs included under the program;

(b) The number of pharmacies, health care providers, and

health plan issuers participating in the program;

(c) The number of prescriptions for which drugs were dispensed through the program;

(d) The estimated cost savings to consumers, health plan issuers, employers, and this state over the previous year;

(e) The findings of audits conducted over the previous year;

(f) Any other information required by the board in rules adopted under this section.

(F) The board shall adopt rules as necessary to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

Section 2. All items in this act are hereby appropriated as designated out of any moneys in the state treasury to the credit of the designated fund. For all operating appropriations made in this act, those in the first column are for fiscal year 2022 and those in the second column are for fiscal year 2023. The operating appropriations made in this act are in addition to any other operating appropriations made for the FY 2022-FY 2023 biennium.

Section 3.

1	2	3	4	5
A		PRX STATE BOARD OF PHARMACY		
B	General Revenue Fund			

C	GRF	887403	Prescription Drug Importation Program	$0	$2,000,000
D	TOTAL GRF General Revenue Fund			$0	$2,000,000
E	TOTAL ALL BUDGET FUND GROUPS			$0	$2,000,000

PRESCRIPTION DRUG IMPORTATION PROGRAM

The foregoing appropriation item 887403, Prescription Drug Importation Program, shall be used for the Canadian Prescription Drug Importation Program, in accordance with section 4729.71 of the Revised Code.

Section 4. Within the limits set forth in this act, the Director of Budget and Management shall establish accounts indicating the source and amount of funds for each appropriation made in this act, and shall determine the form and manner in which appropriation accounts shall be maintained. Expenditures from operating appropriations contained in this act shall be accounted for as though made in H.B. 110 of the 134th General Assembly. The operating appropriations made in this act are subject to all provisions of H.B. 110 of the 134th General Assembly that are generally applicable to such appropriations.