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H.B. 92
135th General Assembly

Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. T. Young and Santucci

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SUMMARY

- Requires the State Board of Pharmacy to develop a program for the importation of prescription drugs from Canada, in particular, those expected to generate cost savings for consumers.
- Requires the Board to contract with a third-party entity to establish and administer the program.
- Appropriates $2 million to the Board for fiscal year 2024 for the program's operation.
- Also authorizes the same third-party entity, on behalf of state agencies, to negotiate prices and directly purchase from drug manufacturers any prescription drugs, including insulin and epinephrine.
- Names the act the Save Ohio Safe Rx Act.

DETAILED ANALYSIS

Canadian Prescription Drug Importation Program

H.B. 92 requires the State Board of Pharmacy to develop a program for the importation of prescription drugs from Canada, to be known as the Canadian Prescription Drug Importation Program.[1] The bill describes the program as an effort to generate substantial cost savings for prescription drug consumers in Ohio.

[1] R.C. 4729.71(A)(1).

Third-party entity

The Board must contract with a third-party entity to develop, establish, and administer the required program.[2] To be eligible to contract with the Board, the entity must have previously assisted one or more other states in developing, establishing, or administering a prescription drug importation program.

Program development

The bill establishes responsibilities that the third-party entity must meet when developing the program. These include the following:

- Identifying wholesalers for the importation of prescription drugs from Canada;
- Identifying prescription drug suppliers regulated under the laws of Canada, its provinces, or both;
- Identifying the drugs expected to generate substantial cost savings for Ohio consumers;
- Establishing measures for importing only prescription drugs that (1) satisfy federal Food and Drug Administration (FDA) safety and effectiveness standards and (2) are expected to generate substantial cost savings for Ohio consumers;
- Ensuring that the program has the ability to comply with the transaction and tracing requirements established under federal law;
- Recommending a charge per prescription or another method of financing to ensure adequate funding for the program.[3]

Federal approval

The bill requires the third-party entity to submit to the U.S. Department of Health and Human Services (HHS) a request for program approval and certification.[4] The third-party entity must do this not later than four months after the bill's effective date. If HHS approves and certifies the program, the third-party entity must then establish and administer the program within six months of the approval and certification.

Note on federal law

Federal law generally prohibits the importation of foreign drugs unless the FDA has approved the drug for the U.S. market and it is being introduced into the U.S. by the drug's original manufacturer. However, a state may import prescription drugs from Canada under a Section 804 Importation Program, or SIP, which requires federal approval.[5] A state seeking to

[2] R.C. 4729.71(A)(2).

[3] R.C. 4729.71(B).

[4] R.C. 4729.71(C).

[5] 21 Code of Federal Regulations (C.F.R.) 251.

do so must submit to the FDA (an agency within HHS) a proposal that includes the drugs to be imported and the names of the program's Canadian drug suppliers and wholesalers. In its proposal, the state also must demonstrate how the program will not pose a risk to the public health or safety, will result in significant cost savings, and will satisfy testing and supply chain requirements.

Program establishment and administration

In establishing and administering the program, the third-party entity must do all of the following:

- Comply with federal law as well as any conditions specified by HHS in its program approval and certification;
- Enter into a contract with a wholesaler identified during the program's development;
- Enter into contracts with one or more of the drug suppliers identified during the program's development;
- Enter into contracts with one or more entities located in Ohio for the distribution of the imported prescription drugs;
- Consult with health plan issuers, employers, pharmacies, pharmacists, health care providers, and consumers;
- Develop a process by which health plan issuers, pharmacies, and health care providers may register to participate in the program;
- Establish and periodically update the list of prescription drugs to be imported under the program and make that list available to the Board;
- Ensure that prescription drugs imported under the program are dispensed, sold, or distributed only in Ohio;
- Periodically provide to the Board information identifying the prices of prescription drugs imported under the program and the locations where the drugs are dispensed, sold, or distributed;
- 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;
- Conduct a program audit on an annual basis and share audit findings with the Board;
- Make available to the Board any information necessary to prepare the Board's report to the General Assembly (see "**Report**," below);

- Conduct any other activity required by Board rule.[6]

Entity compensation

The bill requires the third-party entity to negotiate with the Board its fee for administering the program. The fee must 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 (DAS).[7]

Board of Pharmacy duties

After the program is established, the bill requires the Board to make available on its website the following information: (1) the prescription drugs imported under the program, (2) the drugs' prices, and (3) the locations where they are dispensed, distributed, or sold. The Board also must update its website periodically to reflect any changes to the foregoing information and engage in activities generally to improve public awareness of the program.[8]

Report

Not later than 18 months after the bill's effective date and every year thereafter, the Board must submit to certain members of the General Assembly a report regarding the program's administration for the previous year.[9] The General Assembly members include the Senate President, Speaker of the House of Representatives, and chairpersons of the standing committees primarily responsible for considering health issues.

Each submitted report must include the following details:

- The prescription drugs included under the program;
- The number of participating pharmacies, health care providers, and health plan issuers;
- The number of prescriptions for which drugs were dispensed through the program;
- The estimated cost savings to consumers, health plan issuers, employers, and Ohio over the previous year;
- The findings of any audits conducted over the previous year;
- Any other information required by Board rule.

[6] R.C. 4729.71(D)(1)(a).

[7] R.C. 4729.71(D)(1)(b).

[8] R.C. 4729.71(E)(1).

[9] R.C. 4729.71(E)(2).

Rulemaking

The bill requires the Board to adopt rules as necessary to implement its provisions. In adopting the rules, the Board must comply with the Administrative Procedure Act.[10]

Appropriation

The bill appropriates to the Board $2 million for the program's operation. The appropriation is for fiscal year 2024 only.[11]

Drug price negotiations and purchases for state agencies

In addition to its duties under the Canadian Prescription Drug Importation Program, the third-party entity may, on behalf of state agencies, negotiate prices for and directly purchase any prescription drugs from their manufacturers. This is to occur on the Board's request, in consultation with DAS.[12] The drugs may include insulin, epinephrine, biological products, and interchangeable biological products and must be FDA-approved for use in the U.S.

The bill requires the negotiations and purchases to be conducted according to the same terms and conditions as negotiations and purchases are conducted under the Canadian Prescription Drug Importation Program. The third-party entity is to be compensated for such negotiations and purchases in the same amount as it is compensated for administering the program.

HISTORY

Action	Date
Introduced	03-07-23

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[10] R.C. 4729.71(F); R.C. Chapter 119, not in the bill.

[11] Section 3.

[12] R.C. 4729.71(D)(2).