



Wholesale Prescription Drug Importation Program Report

**As Required by House Bill 25,
88th Legislature, Regular Session, 2023**

**Texas Health and Human Services
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TEXAS
Health and Human
Services

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1. Executive Summary

The Wholesale Prescription Drug Importation Program Report for fiscal year 2023 is submitted in accordance with Health and Safety Code Section 444.007, as modified by House Bill (H.B.) 25, 88th Legislature, Regular Session, 2023, which requires the Health and Human Services Commission (HHSC) to submit an annual report to the Governor and the Legislature regarding the operation of the program during the preceding state fiscal year. The report must include:

- A list of the prescription drug and Canadian suppliers included in the program;
- The number of health benefit plan issuers, health care providers, and pharmacies participating in the program;
- The number of prescriptions dispensed through the program;
- 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;
- Information regarding the implementation of the audit procedures under Health and Safety Code Section 444.006; and
- Any other information:
 - ▶ The governor or the legislature requests; or
 - ▶ The commission considers necessary.

H.B. 25, the Wholesale Prescription Drug Importation Act, requires HHSC to establish a wholesale prescription drug importation program to provide lower cost prescription drugs available outside the US to Texas consumers at a lower cost.

This report outlines research, recommendations, and strategic planning to support implementation for the program, laying out a plan for a successful path forward.

Legislative appropriations were not provided for this Act. If the Wholesale Prescription Drug Importation program cannot be transferred under the authority of the Texas Pharmaceutical Initiative (TPI) agency/program as established by House Bill (H.B.) 4990, 88th Legislature, Regular Session, 2023, and as recommended in the Next Steps section of this report, then another alternative source of appropriations will need to be established.

2. Introduction

Wholesale Prescription Drug Importation refers to the practice of purchasing prescription medications from prescription drug wholesalers and Canadian suppliers to import prescription drugs and provide cost savings to Texas consumers. This practice has gained attention as a potential way to lower prescription drug prices in the United States, where medication costs can be higher than in Canada and other countries.

H.B. 25 allows Texas to import eligible prescription medications that meet the standards of the United States Food and Drug Administration (FDA) related to prescription drug safety, effectiveness, misbranding, and adulteration, and do not violate federal patent laws through their importation. Certain prescription drugs cannot be imported through the program, including controlled substances, biological products, infused drugs, intravenously injected drugs, drugs that are inhaled during surgery, or parenteral drugs.

Prior to program implementation, HHSC must receive approval from the FDA in accordance with [21 United States Code \(USC\) Part 251, Section 804 Importation Program](#) (SIP). Section 804 outlines the SIP proposal requirements to be submitted to the FDA for approval.

HHSC will need to enter into contracts with Texas licensed drug distributors, one or more state drug wholesalers, and contract with one or more Canadian suppliers. Implementation will also require contracts for marketing and an outreach campaign. HHSC Information Technology (IT) system contracts and costs are assumed to support the program, in particular in developing a data system for maintaining information to include in future annual reports to the governor and the Legislature. Examples of the data required may include, but are not limited to:

- The prescription drugs imported under the program;
- Canadian suppliers and eligible importers involved in the program;
- Prescriptions dispensed through the program;
- Estimated cost savings during each fiscal year and to date;
- Data coordination from manufacturers and wholesalers into data nexus; and
- Ongoing production support of program maintenance and reports post development.

HHSC will be responsible for the creation, review, and approval of newly written rules for the program in the Texas Administrative Code (TAC).

Following implementation, HHSC will report to the governor and the Legislature regarding the operation of the program during the previous year. Reporting will include, at a minimum:

- Details on the eligible prescription drugs and Canadian suppliers;

- The number of pharmacies, providers, and health insurance plans participating;
- The number of prescriptions dispensed;
- The estimated cost savings to consumers, health plans, employers, and the state of Texas;
- Information on audit plan procedures and implementation; and
- Correction plans for findings, if required.

To ensure best practices and operations in implementing a drug importation program, HHSC will review outcomes and recommendations from other states which have passed similar legislation, while weighing the benefits and risks to the state in drug importation. The background section of this report will provide more information on the endeavors of other states, as well as implementation recommendations.

3. Background

Several states have passed or are in the process of passing laws to implement policy allowing importing prescription drugs from Canada in an effort to lower drug prices; however, to date, no state has received necessary approval from the FDA. These states include:

- Colorado
- Florida
- Maine
- New Hampshire
- New Mexico
- Ohio
- Vermont

Progress in Other States

Colorado

Colorado was one of the first states to enact legislation establishing a wholesale Canadian drug importation program, with expected implementation in late 2023.¹ Colorado has made progress on contracting and development for supply and implementation needs and provided annual reports in 2021 and 2022 to their General Assembly.

Table 1. Colorado: Timeline for Importation

Year	Action	Description
2018	State Legislation	Legislation passed in Colorado to establish a wholesale Canadian Drug Importation Program. ²
2019	State Legislation	Colorado passes law identifying the Department of Health Care Policy and Financing to design a program to allow for wholesale prescription drug importation from Canada.

¹ <https://hcpf.colorado.gov/drug-importation#:~:text=The%20Department%20estimates%20that%20the,which%20is%20located%20in%20Canada>.

² <https://leg.colorado.gov/bills/sb19-005>

Year	Action	Description
2020	Ongoing Research and Development	Colorado drafts SIP proposal and program rules.
2021	Continued Development	Colorado passes law allowing for importation from other nations beyond Canada.
2021	Contracts and Development	Colorado posts and closes Invitation to Negotiate (ITN), through which vendors were identified for the program.
2022	Contracts and Development	Colorado executes contracts with supply chain partners.
2022	Submission of Section 804 Importation Program (SIP) Proposal	Colorado submits formal SIP proposal to FDA.
2023	Ongoing	Colorado Department of Health Care Policy and Financing hosted stakeholder meeting ³ with anticipated program implementation late this year.

Florida

The state of Florida is awaiting the outcome of a lawsuit filed by the state against the FDA to continue to move forward with its plans for importation.⁴

Table 2. Florida: Timeline for Importation

³<https://hcpf.colorado.gov/sites/hcpf/files/Drug%20Importation%20Public%20Stakeholder%20Meeting%20-%2010-2023.pdf>

⁴<https://www.flgov.com/2022/08/31/governor-ron-desantis-announces-lawsuit-against-biden-administrations-reckless-delay-of-canadian-prescription-drug-importation-program/>

Year	Action	Description
2019	State Legislation	Legislation passed in Florida to establish a wholesale Canadian Drug Importation Program. ⁵
2020	Submission of Section 804 Importation Program (SIP) Proposal	(July) Florida submits its drug importation proposal to the U.S. Department of Health and Human Services (HHS) for review. The proposal outlines the types of drugs to be imported and the safety measures to be put in place.
2020	Preliminary Approval	(December) Florida received preliminary approval to move forward with its drug importation program.
2021	Opposition	Pharmaceutical Research and Manufacturers of America (PhRMA), Partnership for Safe Medicines (PSM), and the Council for Affordable Health Coverage (CAHC) file a citizen petition to reject plan based on safety concerns.
2021	Draft Rules and Public Comment	(March) Florida releases draft rules outlining the specifics of how the importation program would operate within the state. The public is invited to provide comments on the draft rules.
2021	Continued Development	Throughout the first half of 2021, Florida continues to finalize its importation program. This involves addressing concerns from stakeholders, refining program details, and making any necessary adjustments to comply with federal regulations.
2022	Delays	Governor Ron DeSantis announces lawsuit against the FDA to allow the state to move forward with importation without further delay.

⁵http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=03-00-0399/0381/Sections/0381.02035.html

Year	Action	Description
Ongoing	Federal Review Process	<p>Florida's drug importation program remains subject to a thorough review process by the federal government, including the FDA and the Centers for Medicare & Medicaid Services (CMS). The program must demonstrate that it can ensure the safety and cost-effectiveness of imported drugs. In an August 2023 letter to Florida, the FDA responded with a new requirement for a secured warehouse within thirty miles of an "authorized port of entry" for prescription drugs in Canadian importation programs. Currently, the only authorized port of entry is Detroit, Michigan. The FDA also stated Florida's proposal did not adequately describe how Florida would "assure drug supply chain security for products imported" under the program and that the state had not adequately explained how the program "will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs..."⁶</p> <p>UPDATE: The federal government delayed its decision on whether to authorize Florida's Canadian drug importation program, according to an update by Safe Medicines. The October 31, 2023, deadline will not be met, based on a status report filed by government attorneys on October 20, 2023, because Florida did not adequately address the issues identified in the FDA's August 14, 2023, request for information. Per the status report, the "FDA anticipates that it will be able to render a decision on Florida's SIP proposal within 60 days after receiving the new information."⁷</p>

Maine

Maine's Department of Health and Human Services continues to collect input from stakeholders and research program design and implementation.

Table 3. Maine: Timeline for Importation

Year	Action	Description
2019	State Legislation	Legislation passed in Maine to establish a wholesale Canadian Drug Importation Program. ⁸

⁶ <https://news.wfsu.org/state-news/2023-09-01/florida-feds-tangle-over-drug-importation-plan>
⁷ [FL-v-FDA-Defendants-Second-Supplemental-Status-Report-2023-10-20.pdf \(safemedicines.org\)](#)
⁸ [Title 5, Chapter 168: WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM \(maine.gov\)](#)

Year	Action	Description
2019	Continued Development	Maine’s Department of Health and Human Services (DHHS) released a proposed rule laying out a process to design a program for the wholesale importation of prescription drugs from Canada.
2020	Continued Development	Maine DHHS releases “State of Maine Canadian Drug Importation Program: Considerations” Memorandum
2020	Submission of Section 804 Importation Program (SIP) Proposal	Maine submits formal SIP proposal to FDA. ⁹

New Hampshire

Along with establishing a wholesale Canadian Drug importation program, New Hampshire’s law also established a prescription drug affordability board, a prescription drug competitive marketplace and other measures aimed at lowering prescription costs for its residents.¹⁰

Table 4. New Hampshire: Timeline for Importation

Year	Action	Description
2020	State Legislation	Legislation passed in New Hampshire to establish a wholesale Canadian Drug Importation Program.
2021	Submission of Section 804 Importation Program (SIP) Proposal	New Hampshire submits formal SIP proposal to FDA. ¹¹
2022	Delays	FDA rejected application because the Canadian wholesaler was not identified in the application.

⁹ [Maine Section 804 Importation Program Application_0.pdf](#)
¹⁰ <https://www.governor.nh.gov/news-and-media/governor-chris-sununu-signs-prescription-drug-bill-law>
¹¹ <https://khn.org/wp-content/uploads/sites/2/2022/12/New-Hampshire-Application.pdf>

New Mexico

In addition to the importation legislation, New Mexico’s Governor established a prescription drug task force to improve affordability for residents of the state. ¹²

Table 5. New Mexico: Timeline for Importation

Year	Actions	Description
2020	State Legislation	Legislation passed in New Mexico to establish a wholesale Canadian Drug Importation Program. ¹³
2020	Ongoing Research and Development	Progress Report released on the New Mexico’s Wholesale Prescription Drug Importation Act. ¹⁴
2020	Submission of Section 804 Importation Program (SIP) Proposal	New Mexico Submits formal SIP proposal to FDA. ¹⁵
2021	Opposition	phRMA, PSM and CAHC filed petition to reject plan based on safety concerns.
2022	Ongoing	Prescription drug task force is established.

Ohio

H.B. 715 was introduced in the Ohio Legislature (Establish Canadian Prescription Drug Importation Program) on August 31, 2022, with no further action following referral of the bill to committee. On March 7, 2023 (135th General Assembly) H.B. 92 was introduced to the Ohio Legislature (House Chamber). The bill can be found [here](#).

¹² [Gov. Lujan Grisham establishes prescription drug price task force | Office of the Governor - Michelle Lujan Grisham \(state.nm.us\)](#)

¹³ [SB0001 \(nmlegis.gov\)](#)

¹⁴ [PowerPoint Presentation \(state.nm.us\)](#)

¹⁵ [nmhealth.org/publication/view/meeting/6418/](#)

Table 6. Ohio: Timeline for Importation

Year	Action	Description
2023	State Legislation	The Enact Save Ohio Prescription Act introduced in the House ¹⁶
2023	State Legislation	Referred to the House Committee

Vermont

In 2018, Vermont’s legislature became the first in the nation to approve importation of prescription drugs from Canada.¹⁷ Their Legislative Report on Wholesale Importation Program for Prescription Drugs is available [online](#).

Table 7. Vermont: Timeline for Importation

Year	Action	Description
2018	State Legislation	Legislation passed in Vermont to establish a wholesale Canadian Drug Importation Program ¹⁸
2019	State Legislation	Establishes that the Vermont Agency of Human Services is responsible for program implementation and administration; requires the application be submitted before July 2020. ¹⁹
2019	Continued Development	Submits concept paper ²⁰ to the federal government’s Office of Management and Budget to be assistive in federal regulation development and differentiate the VT program from FL (similar to requirements that would be included in SIP proposal submission).

¹⁶ [House Bill 92 | 135th General Assembly | Ohio Legislature](#)

¹⁷ <https://nashp.org/vermont-first-in-the-nation-to-approve-rx-drug-importation-from-canada/#:~:text=Vermont%20is%20the%20first%20state,175>.

¹⁸ <https://legislature.vermont.gov/Documents/2020/WorkGroups/House%20Health%20Care/Prescription%20Drugs/W~Ena%20Backus~Wholesale%20Prescription%20Drug%20Importation%20from%20Canada-%20%20State%20of%20Vermont%20and%20Federal%20Efforts,%20Corrected%20Copy~1-23-2020.pdf>

¹⁹ <https://legislature.vermont.gov/Documents/2020/WorkGroups/House%20Health%20Care/Prescription%20Drugs/W~Ena%20Backus~Wholesale%20Prescription%20Drug%20Importation%20from%20Canada-%20%20State%20of%20Vermont%20and%20Federal%20Efforts,%20Corrected%20Copy~1-23-2020.pdf>

²⁰ [vt-submittal-to-omb-12-3-2019.pdf \(nashp.org\)](#)

Year	Action	Description
2020	Continued Development	Vermont's Agency for Human Services provided an update to the House Committee on Health Care on the state's work and laid out next steps for the state's importation plans.

4. Recommendations

The following recommendations are a result of our review of progress made in other states related to drug importation programs, the needs of the applicable agencies charged with implementing similar programs and are designed to establish a successful program as envisioned in H.B. 25.

Expertise Assistance

The agency will need to issue a solicitation to work with a consultant with extensive knowledge and experience of the FDA SIP process to allow HHSC to leverage their expertise in developing and preparing a SIP application in a timely manner and avoiding potential delays in the application process due to incomplete or missing information.

Thereafter, HHSC will need to develop a solicitation with requirements for the services providers (wholesaler, importer, repackager, etc.). Contracts should be established, along with required documentation necessary, to submit the SIP application.

Additional requirements will include:

- Development of a registration process for health benefit plan issuers, health care providers, and pharmacies to obtain and dispense imported drugs;
- Development and publication of a list of prescription drugs including pricing for drugs approved through this program;
- Establishment of an outreach and marketing plan for program awareness;
- Establishment and administration of a call center or electronic portal to provide the public with program information; and
- Oversight to ensure program and prescription drug wholesalers under contract comply with federal tracking, tracing, verification, and identification requirements.

While the FDA does not provide a timeframe for review of a Section 804 proposal, it anticipates providing feedback within six months from the submission. This is dependent upon the inclusion of all necessary requirements of the SIP proposal.

Resource Needs

The agency continues to review resource needs to effectively implement H.B. 25. As this bill was recently passed, more time is needed to identify the implementation costs. Some costs may include:

- Procuring expertise to assist with authoring the SIP proposal;

- Procuring a wholesaler;
- Procuring an importer;
- Procuring a warehouse;
- Procuring a distributor;
- Financing the cost to purchase pharmacy drugs;
- Financing the management and monitoring of the program; and
- Procuring a lab to test and certify the drugs

Other states we have reviewed (in above sections) have identified similar resource needs.

As an example of an implementation cost, Florida will expend \$38 million for the administration and operation of their program, which does not include the cost to purchase the drugs.²¹

Consolidation of Similar Programs

HHSC recommends consolidating the Wholesale Prescription Drug Importation Program under the authority of Texas Pharmaceutical Initiative (TPI). H.B. 4990, 88th Regular Session, created TPI to provide cost-effective access to prescription drugs and other medical supplies for employees, dependents, and retirees of public higher education systems and institutions; Employees Retirement System of Texas members; Teacher Retirement System of Texas members; persons confined by Texas Department of Criminal Justice or the Juvenile Justice Department; and individuals served by programs operated or administered by HHS system.

The similarities between the Wholesale Prescription Drug Importation Act and the TPI established by H.B. 4990 would allow for both programs to be successfully implemented and provide consistent policy development and oversight from the Advisory Council, Board Members and Executive Director. The legislature provided the TPI with its own appropriation which could be utilized to address resource needs necessary to implement the Wholesale Prescription Drug Importation Act.

²¹ [MED214 CPDIP New-Contract 12.29.2020 Redacted.pdf \(khn.org\)](#)

5. Conclusion

In the United States, there has been ongoing debate about the high cost of prescription drugs and efforts to find solutions to make medications more affordable. Efforts to improve access to affordable prescription medications continue to be a topic of discussion and policy consideration at the state and national levels, including drug importation.

Feasibility and impact of drug importation vary depending on the specific medications, regulations, and supply. While importing drugs from Canada might offer potential cost savings, it also raises important questions about safety, quality, and long-term sustainability.

HHSC will continue to track the progress of other states going through this process to learn how to implement this program with approval from the FDA.