Wholesale Prescription Drug Importation Program Report

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

Texas Health and Human Services
December 1, 2024

TEXAS
Health and Human Services

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1. Executive Summary

The Wholesale Prescription Drug Importation Program Report for fiscal year 2024 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.

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 United States to Texas consumers at a lower cost.

Legislative appropriations are needed to implement 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 recommendations section of this report, then another alternative source of appropriations will need to be established to move forward with implementation.

2. Progress

Without a source of funding, HHSC is unable to procure the necessary resources to begin working on the Section 804 Importation Programs (SIP) proposal and the other federally required actions necessary to implement H.B. 25. Prior to program implementation, HHSC must receive approval from the FDA in accordance with 21 CFR Part 251 - Section 804 Importation Program (SIP). Section 804 outlines the SIP proposal requirements to be submitted to the FDA for approval. Additional federal requirements are outlined in the recommendations section of this report.

Despite the funding limitations, HHSC has gathered a list of high-cost drugs for Texas citizens and attended meetings with other states (Florida and Colorado) and interest groups (NASHP and NCSL[1]).

Lessons Learned from Other States:

Florida

HHSC met with Florida representatives, and they have provided the following recommendations:

- Hire a consultant to assist with SIP creation.
- Limit the list of drugs to no more than 10-15.
- Start identifying a manufacturer early.
- 3.5 full-time positions were appropriated; however, Florida relies on consultants for the bulk of the tasks and activities involved in the SIP creation and implementation process.
- Create a dedicated team of internal staff who assist with the project as needed.
- Use one vendor as much as possible. Florida used one vendor for their wholesaler, distributor, and importer.
- The vendor used for Florida procured a Canadian vendor to be their foreign seller.
- Florida contracted with multiple labs to assist with drug testing.

[1] National Academy for State Health Policy and the National Conference of State Legislatures

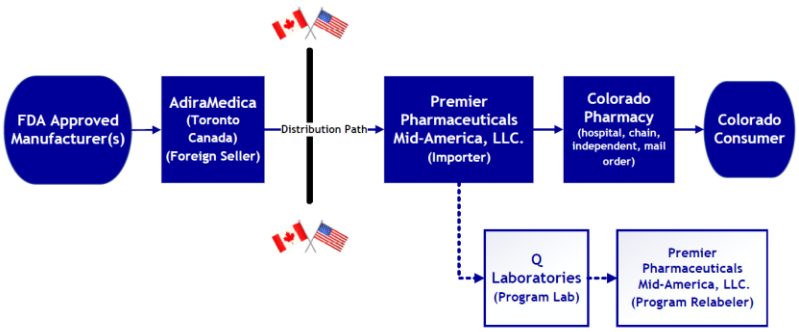
- Use an actuarial firm for cost savings analysis.
- Start thinking about your distribution model early.
- Engage with the federal agencies consistently as some changes may not be communicated timely.
- The approval process of the SIP can be lengthy, so structuring vendor payments based on deliverables rather than time and materials ensures that vendors are incentivized to meet specific milestones.
- Learn the FDA's "Final Rule" in detail and give the FDA all information that you have. The "Final Rule" refers to the FDA's regulations governing the importation of prescription drugs. Understanding and complying with these regulations is essential for SIP approval.
- Hired a turnkey contractor to implement their approved SIP with an estimated cost of $38M.

Colorado

HHSC met with Colorado representatives, and they provided the following recommendations:

- Request an exception from state procurement rules. With an exception in place, Colorado was able to directly contract with vendors without going through lengthy procurement cycles.

Importation Program High Level Drug Movement



- Contract with a vendor to help with compliance to assist with SIP creation.
- Use one vendor as much as possible for the tasks involved in the SIP process. Colorado used one vendor for their wholesaler, distributor, and importer. Please see the diagram above
- Set up your own marketplace.

- Contract with a law firm.
- Gauge interest from manufacturers in participating in the SIP and supplying drugs.

3. Recommendations

The following recommendations were included in the last annual report and remain relevant to this current report.

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.

HHSC will need to develop additional solicitations 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. Some costs may include:

- Procuring expertise to assist with authoring the SIP proposal;
- Procuring a wholesaler;
- Procuring an importer;
- Procuring a warehouse;
- Procuring a distributer;
- 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.

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.

4. Conclusion

HHSC will monitor legislative activity during the upcoming 89th Legislative Session, and determine next steps based on legislative direction.