Report to
The Vermont Legislature

Wholesale Importation Program for Prescription Drugs Legislative Report

In Accordance with
Act 133 . Sec.1 An Act Relating to the Wholesale Importation of Prescription Drugs into Vermont

Submitted to:	**House Committee on Health Care** **House Committee on Ways and Means** **Senate Committee on Finance** **Senate Committee on Health and Welfare**
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VERMONT
AGENCY OF HUMAN SERVICES

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Executive Summary

Act 133 of 2018, *An act relating to the wholesale importation of prescription drugs into Vermont,* required the Agency of Human Services (AHS) to design a wholesale prescription drug importation program, to the extent that funds were made available or appropriated. Such a program must comply with federal requirements regarding safety and cost savings, as assessed through an application to the Secretary of the U.S. Department of Health and Human Services (HHS). The National Academy for State Health Policy (NASHP) Center for State Rx Drug Pricing provided free technical assistance and design expertise through a grant from the Laura and John Arnold Foundation. AHS is satisfying the legislative charge by submitting this report containing the preliminary design of a "Canadian Rx Drug Import Supply Program" and offering next steps for consideration should there be continued interest in a program of this kind.

Working with NASHP and stakeholders, AHS determined that participating Vermont commercial insurers could see savings of between $1-5 million dollars by purchasing prescription drugs imported from Canada. Such drugs would be made available through licensed Canadian drug suppliers and state-based, licensed wholesalers. The Office of Professional Regulation (OPR) Board of Pharmacy could oversee licensure for the two new categories of licensees only. Administering a program of this kind in its entirety is a role most appropriate for an Executive Branch agency, like the Agency of Human Services. Program licensure and program administration activities are described in more detail in the body of the report and are crucial for guaranteeing that imported prescription drugs pose no additional risk to health and safety. These activities likely come at substantial cost to the state, requiring upfront investment and appropriations. Before a program of prescription drug importation can be recommended, the state needs to determine the cost of operating such a program and whether that cost eclipses the savings for participating commercial payers. A program that costs more to operate than produces in savings is highly unlikely to meet the Secretary's criteria for certification.

Considerations for next steps include:

- Create detailed estimate of upfront and ongoing state expense to operate a program of prescription drug importation; such an estimate may require further contracted expertise.
- Estimate the total potential savings of a program of prescription drug importation relative to mark-ups, operating costs, and potential revenue.
- Establish a clear mechanism for assuring that savings from prescription drug importation accrue to consumers.
- Assess the interest of suppliers and wholesalers.
- Legislative action to assign the appropriate state agencies for operating the wholesale drug importation program and corresponding appropriation of funds.
- Legislative action enabling the OPR to create new license categories.
- Submit a successful application to the Secretary of Health and Human Services.

Background

Act 133 of 2018, *An act relating to the wholesale importation of prescription drugs into Vermont,* requires the Agency of Human Services to design a wholesale prescription drug importation program that complies with the applicable requirements of 21 U.S.C. § 384, including the requirements regarding safety and cost savings. The design of a wholesale prescription drug importation program was required only to the extent that funds were appropriated for the purpose or were otherwise made available. While the General Assembly did not appropriate funds for AHS to design a wholesale prescription drug importation program, the National Academy for State Health Policy (NASHP) and its Center for State Rx Drug Pricing provided free technical assistance and program design expertise to enable AHS to meet the legislative charge. NASHP's services were made available through the generosity of the Laura and John Arnold Foundation. This report provides a preliminary program design sketch and offers considerations for next steps. The following three sections detail:

1. Program design requirements and process.
2. Preliminary program design.
3. Considerations for next steps.

Section 1: Program Design Requirements and Process

Program Design Requirements: Federal Requirements

Any wholesale drug importation program must comply with the applicable requirements of 21 U.S.C. § 384, including the requirements regarding safety and cost savings. Under Federal Food Drug and Cosmetic Act (FDCA) Section 804, Congress permits importation and reimportation of prescription drugs[1] from Canada by a pharmacist or wholesaler, provided the drugs meet certain minimum standards and the Secretary of Health and Human Services (HHS) certifies to Congress that implementation of such a program will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer. This is not a waiver of existing law; rather, the Secretary may certify a program of importation if both safety and savings are assured. By law, prescription drugs may only be imported from Canada, laboratory testing is required, and there are prohibitions on the importation of a controlled substance, biological product, infused drug, intravenously injected drug, or a drug inhaled during surgery. If the Secretary so certifies, the law directs HHS to promulgate regulations as necessary to implement the program. Section 804 has never been used; approval for this kind of program has not yet been requested by any state.

Program Design Requirements: State Requirements

Act 133 of 2018 specifies that a wholesale prescription drug importation program in Vermont must:

- Designate a State agency that shall either become a licensed drug wholesaler or contract with a licensed drug wholesaler in order to seek federal certification and approval to import safe prescription drugs and provide significant prescription drug cost savings to Vermont consumers;
- Use Canadian prescription drug suppliers regulated under the laws of Canada or of one or more Canadian provinces, or both;

[1] "Prescription Drug" is defined in 21 U.S.C. § 384(a)(3)

- Ensure that only prescription drugs meeting the U.S. Food and Drug Administration's safety, effectiveness, and other standards shall be imported by or on behalf of the State;
- Import only those prescription drugs expected to generate substantial savings for Vermont consumers;
- Ensure that the program complies with the tracking and tracing requirements of 21 U.S.C. §§ 360eee and 360eee-1 to the extent feasible and practical prior to imported drugs coming into the possession of the State wholesaler and that it complies fully after imported drugs are in the possession of the State wholesaler;
- Prohibit the distribution, dispensing, or sale of imported products outside Vermont's borders;
- Recommend a charge per prescription or another method of support to ensure that the program is funded adequately in a manner that does not jeopardize significant consumer savings; and
- Include a robust audit function.

Process

Along with its contractor, FDAImports.com, LLC (FDAImports), NASHP convened four meetings with the Agency of Human Services and stakeholders identified by AHS: The Office of Professional Regulation Pharmacy Board, the Office of the Vermont Attorney General, Blue Cross and Blue Shield of Vermont, MVP Health Care, and the Department of Vermont Health Access. NASHP and FDAImports traveled to Vermont in October for an in-person meeting; Representative Norm Thurston of Utah was also a participant.

Timeline:

- NASHP convened an in-person focus group with supply chain experts, Washington, DC – 7/31/18
- Call with NASHP & VT state officials - 8/1/18
- NASHP convened an in-person technical assistance workshop with Vermont state officials and commercial payers, Williston, VT – 10/3/18
- Call with NASHP & VT state officials – 11/30/18
- Call with NASHP, VT state officials and commercial payers – 12/17/18

Section 2: Preliminary Program Design

Relative to federal requirements for a potential program of wholesale prescription drug importation from Canada, AHS and stakeholders needed to determine whether wholesale drug importation from Canada could provide a savings to Vermont consumers. The Department of Vermont Health Access (DVHA), determined that drug importation from Canada would not provide net savings to the state or individuals because Medicaid's existing prescription drug rebate program already yields substantial savings. There would be minimal if any benefit to Medicaid members as their copays are limited to $1, $2, and $3 dollars, and a significant number have no copays. However, DVHA believes there may be a small number of specific drugs that may be more cost-effective through Canada for a limited period-of-time. Vermont stakeholders then chose to explore whether drugs imported from Canada could provide savings to commercial health insurers. To make this determination, an analysis of participating commercial insurers' drug spend was conducted in tandem with NASHP/FDAImports' program design sketch and identification of supply chain costs and opportunities for mark-ups. The program design sketch did not include dollar amounts for the cost of a state-operated prescription drug importation program.

Determining Savings from Wholesale Drug Importation from Canada

The National Academy of State Health Policy (NASHP) prepared two worksheets for commercial payers in Vermont in order to: 1) Determine drug candidates for importation, and 2) estimate savings from a wholesale importation program from Canada.

1. The first worksheet asked payers to identify their top spend drugs for the second quarter of 2018, excluding drugs not eligible for importation according to federal law. (Ineligible drugs are narcotics, biologics, drugs inhaled during surgery, IV and infused drugs.) Top spend was determined by multiplying the net cost of each drug by utilization. NASHP compared the lists across participating payers and compiled a list of 17 drugs occurring across all payers' lists. The final list included National Drug Codes (NDCs), unique identifiers for drug products. NASHP located Canadian prices for those drugs on the Quebec Public Drug Program List, converted them to US dollars using a rate of $0.75 CAD to $1 USD, and shared the resulting list with payers.
2. The second worksheet asked payers to calculate net savings from importation. In order to do so accurately, NASHP added a conservatively-high estimated mark-up for program administration of 45% on top of the Canadian price. (The 45% mark-up allows for 20% profit along the supply chain, as well as costs to the supply chain such as repackaging, relabeling, testing, record keeping, and recall management.) To determine savings, plans were asked to determine their net spend (i.e. net of rebates) on 17 high-spend drugs for the second quarter of 2018, and to compare that total to the would-be net spend for the same drugs if imported from Canada with a 45% mark-up.

Results: Even with the conservatively-high mark-up of 45%, participating plans reported savings in the range of $2.61-$2.82 per member per month, or $1-$5 million per year. These savings for commercial payers, post mark-up, do not take into consideration the State's costs in operating a program of wholesale prescription drug importation.

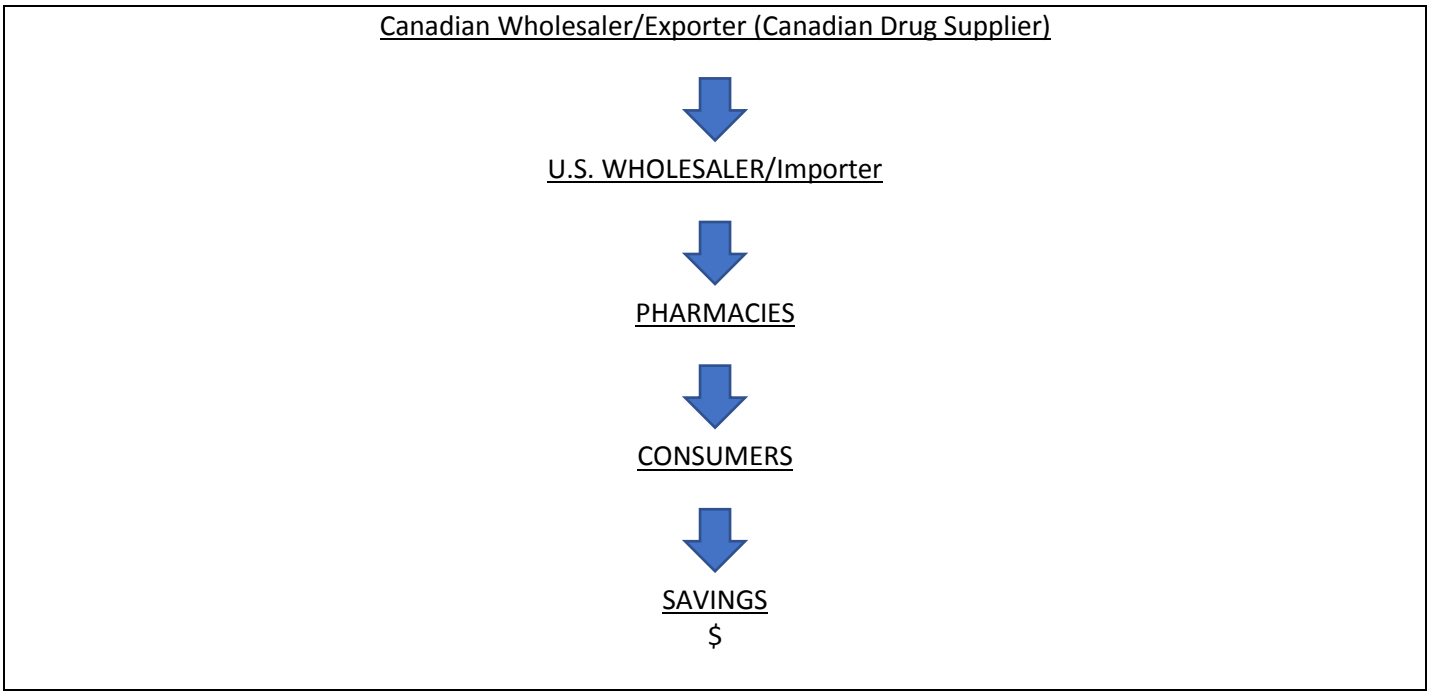
How Would Wholesale Prescription Drug Importation from Canada Work?

In order to operate a program of wholesale prescription drug importation from Canada, a state agency should establish new prescription drug wholesaler licenses for VT importers and Canadian suppliers. These licenses could be established and issued by the Office of Professional Regulation (OPR) Board of Pharmacy, with legislative approval. The OPR would need to assure that the license numbers, class of activity, and locations are publicly available to facilitate verification of pedigrees by downstream importers, wholesalers and pharmacies. The Vermont Board of Pharmacy is established and governed by 26 V.S.A. §§ 2021 et seq. Its statutory composition includes seven total members, of whom five are experienced pharmacists and two are public members. No sitting member has any experience to speak of in respect to drug manufacturing, the wholesale distribution of legend drugs, or supply-chain security.

The Board meets once a month for approximately four hours. Its primary functions are: (1) Adjudication of disciplinary cases concerning its licensees, which are investigated and prosecuted by the Office of Professional Regulation, and (2) development and maintenance of administrative rules governing qualifications for licensure and pharmacy standards. Thus, the activities of verification via audit and international inspection would need to be performed by or guaranteed by the state agency administering the program--AHS. The licensed suppliers and wholesalers would then be authorized to import the qualifying prescription drugs, as determined by law and savings opportunities. Once the drugs have been imported to Vermont, they would be

available to be purchased by pharmacies and consumers. Legislative action is required to designate AHS as responsible for administering the importation program.

The sketch below, provided by NASHP/FDAImports, depicts the flow of prescription drugs from Canadian suppliers to consumers in Vermont, and broadly encompasses a program to be referred to as the "Canadian Rx Drug Import Supply Program."



Regulation

NASHP and FDAImports determined that the parties participating in the Canadian Rx Drug Import Supply Program should be subjected to (1) Vermont licensing requirements, and (2) inspection and audit requirements for obtaining and maintaining state licenses to participate. While the Office of Professional Regulation (OPR) can establish new license types and provide for licensure, it does not have the capacity to provide for international inspection or a program of auditing. The Agency of Human Services, or any other state agency deemed as the administrator of the program, would need to take responsibility for inspection and audit requirements. NASHP and FDAImports suggest the following licensing and FDA registration requirements apply to an importation program:

1. Establish two types of licenses: (1) "Rx Drug Importer-Wholesaler License," and (2) "Canadian Rx Drug Supplier License." These licenses will be new categories of the current VT Rx Drug Wholesale License regime.
2. VT-Licensed Rx Drug Importer-Wholesalers will import Qualifying Rx Drugs from suppliers that hold Canadian Rx Drug Supplier Licenses. Rx Drug Importers-Wholesalers will distribute the prescription drugs under the current Drug Supply Chain and Security Act ("DSCSA") requirements.[2] The VT program will extend the requirements of DSCSA to the Canadian Rx Drug Supplier and Rx Drug Importer

[2] 21 U.S. Code § 360eee–1 (Section 582 of the DSCSA).

Wholesaler, requiring pedigree and transaction histories back to the FDA-approved manufacturer (whether foreign or domestic) or the manufacturer's Authorized Distributor.

3. An Rx Drug Importer-Wholesaler Licensee must be physically located in the U.S. but need not be physically located in the State of Vermont provided the Licensee is registered and inspected by the appropriate regulatory unit of the Licensee's home-state regulatory agency. All participating Rx Drug Importer-Wholesalers are subject to VT license and audit requirements irrespective of location.
4. The OPR will establish a "Canadian Rx Drug Supplier License" for Canadian third parties who export Rx Drugs to Rx Drug Importer-Wholesaler. Canadian Rx Drug Supplier Licensees must be physically located in and ship/export drugs from Canada.
5. All Canadian Rx Drug Suppliers and VT Rx Drug Importer-Wholesalers must pass an inspection/audit conducted by the State of Vermont or third-party contractor or another U.S. state or a Federal regulatory agency to obtain the appropriate VT License; such inspections and audits would not be conducted by the licensing entity, OPR, but rather the state's program administrator, AHS. Periodic audits will also be required to maintain the license. VT will establish the minimum standards for any accredited third-party inspectors as well as the inspection/audit components and documentation.
6. The VT-Licensed Canadian Rx Drug Supplier must register with FDA as Foreign Rx Drug Seller and identify the name and place of business of its establishment and the name of its U.S. Agent (agency is for FDA).
7. Canadian and US- registered third parties may perform the repacking/relabeling for Canadian Rx Drug Supplier sellers/exporters as well as enter into contracts for third parties to perform pick & pack/warehousing/freight-forwarding logistics services. Similarly, such third-party service providers may support VT Rx Drug Importer-Wholesalers. Any party performing repacking and/or relabeling operations must be registered with FDA as Drug Establishments. The repacking and relabeling obligations applicable to the Program are identical to the federal requirements.
8. VT may establish sub-categories of licenses for some third-party contract service providers that do not take ownership of a Qualifying Rx Drug but perform only third party receiving, warehousing, forwarding, logistics services, the agency administering these sub-category licenses may also need to be licensed through the OPR.

Posing no additional risk to public health and safety

In determining how a program of importation would guarantee no additional risk to the public's health and safety, NASHP and FDAImports base their recommendations on the premise that any regulation, requirement, or commercial practice that is recognized as good enough for the US market is also good enough for the Vermont importation program. What follows are NASHP/FDAImports' proposal for ensuring public health and safety in an importation program, based on current US regulations, requirements, and recognized commercial practices.

Relevant factors related to risk to the public's health and safety are:

1. Public health and safety risks related to the active pharmaceutical ingredient (API), strength, purity, quality and route of administration of the drug.

The FDA's new drug approval process is the primary guarantor that health and safety risks associated with API, strength and route of administration of a drug imported under the Vermont importation program are no

greater than those related to the drug already circulating in domestic commerce. The secondary guarantor will be the testing regime required by Section 804.

Many drugs approved by FDA today are made in foreign facilities that the FDA has inspected and approved to manufacture the drugs. Those same facilities manufacture the same drugs for other markets, however, the packaging may be different (e.g., blister packs instead of plastic bottles) and the labeling will be different in many respects (e.g., foreign language, warnings, indications for use, etc.). Provided the drugs consist of the same APIs in the same strengths, and they are administered by the same route (*e.g.,* solid oral dose tablets), it is irrelevant with respect to health and safety risks whether the drugs were originally intended by the manufacturer for sale in Europe or Canada or Asia or USA.

Qualifying prescription drugs (drugs that can be imported under federal law) must be the same with respect to API, strength, purity and route of administration as the FDA-approved product, made in the FDA-approved facility, and must have been initially purchased from either the FDA-approved manufacturers or from their Authorized Distributors (or foreign equivalent).[3] The pedigree requirements, therefore, must trace back to the initial transaction.

Section 804 also requires testing of the Qualifying Rx Drugs imported under the program. A VT program needs to adopt the statutory testing regime. The testing regime would need to be performed by third party laboratories in the USA on samples collected randomly and representatively from batches or shipments, depending the circumstances. Ensuring a drug meets the identity, strength and purity and quality standards of the FDCA (such that the drug is not "adulterated" under the Act[4]) amounts to ensuring it meets those parameters as purported by the labeling of the drug or, where applicable, as established by the United States Pharmacopeia (USP) or other FDA-recognized compendial standards. USP monograph and strength, purity and quality testing is routinely performed by accredited third-party testing laboratories.

The importer of a Qualifying Rx Drug is required to maintain sampling and testing records related to the drug and to be able to produce the records. This gives VT and the FDA the ability to evaluate Qualifying Rx Drugs imported under the program in real time (upon importation) or when conducting program or supply chain audits.

The Vermont administrative agency charged with the Canadian Rx Drug Import Supply Program should require sampling and testing records be maintained electronically in a standardized format and in a password-protected and digitally-encrypted account-based database enabling market participants to securely upload data and to designate who may access the data through their own secure credentials.

2. Safety risks related to packaging and labeling of the drug

[3] In the U.S. Rx drug supply, manufacturers designated Authorized Distributors (Ads) for distribution into the market place. These ADs act as reset points for Rx drugs obtained from third party wholesalers. Every Rx drug pedigree must trace the drug back to either the manufacturer or one of its ADs to satisfy the requirements of the DSCSA. Although foreign markets have similar distribution schemes, they may not designate any particular commercial entity as an "AD" *per se*. Nevertheless, tracing a drug back to the manufacturer or the foreign equivalent of an AD (as that term is used in the U.S.) provides an adequate level of confidence that the drug's supply pedigree is reliable.

[4] *See* 21 U.S.C. 352(a).

The FDA's new drug approval process represents the primary guarantee that health and safety risks associated with the packaging and labeling of a drug imported under the Vermont importation program are no greater than those related to the drug already circulating in domestic commerce. The secondary guarantor will be the FDA's drug repackaging and relabeling registration regulations, and the FDA's current manufacturing practices, governing the repacking and relabeling operation.

Many FDA-approved drugs are repacked and relabeled by third parties that do not hold FDA-approved new drug applications (NDAs) for the final repacked and relabeled drugs. FDA regulates drug repackers and relabelers as "manufacturers" for the purposes of establishment registration, drug listing (and assignment of NDCs). The agency also regulates the procedures, methods, processes and equipment used for repacking and relabeling. The importation program will leverage the existing regulatory requirements, controls and safeguards as are employed by traditional drug repacking and relabeling facilities today. The only difference will be that the repacking and relabeling under the VT importation program will be performed prior to importation into the USA.

3. Safety risks related to distribution/storage of the drugs

Vermont's adoption and implementation of the FDA's existing regulations, requirements and enforcement of the Drug Supply Chain Security Act of 2013 (DSCSA) will serve as the basis for ensuring that health and safety risks associated with acquiring, distributing, wholesaling and importing a drug under the Vermont importation program are no greater than those related to the drug already circulating in domestic commerce. The secondary guarantor will be the State of Vermont's existing prescription drug wholesaler licensing program, which will be expanded to include Canadian Rx Drug Exporters and VT Rx Drug Importers.

Currently, prescription drugs are routinely purchased, distributed, warehoused and supplied to pharmacies by secondary prescription drug wholesalers, which operate under a robust federal and state regulatory regime. The DSCSA requires drug wholesalers to obtain, maintain and provide pedigree traceability for each lot and quantity of prescription drugs purchased and sold in the USA. The pedigree must be able to trace each drug quantity, by original manufacturer lot number, back to the manufacturer or back to one of the manufacturer's Authorized Distributors. In this way, later purchasers of the drug have assurance that it is authentic, was not previously illegally diverted, and originated at the FDA-approved manufacturer's facility or, minimally, at a distributor authorized by the FDA-approved manufacturer to distribute the drug. This reduces the risk that the drug may be misbranded, unapproved or counterfeit.

Under the Vermont program, each participant in a Qualifying Rx Drug's supply chain must similarly be able to trace the Qualifying Drug back to the FDA-approved manufacturer or its Authorized Distributor (or foreign equivalent). The requirements for the Canadian Rx Drug Supplier and the VT Rx Drug Importer-Wholesaler will be the same as those that currently apply to U.S. secondary Rx drug wholesalers, ensuring no greater risks to health and safety are posed by the VT Rx Drug Importation Program.

4. Safety risks related to authenticity of the drug

Section 804 requires that if the importer performs the required laboratory testing (described in the previous section), that the manufacturer must provide to the importer information "needed" for the importer to authenticate the drug being tested. *See* 21. U.S.C. 384(e)(2). If, however, the drug was obtained from the FDA-approved manufacturer or its Authorized Distributor, the drug may be properly authenticated by commercial documentation demonstrating that transaction because no further information is "needed" by the importer.

Any information required for an importer (or VT) to authenticate the drug product being tested as being that of the FDA-approved manufacturer must be provided by the manufacturer to the importer.

Given that the legal standard in section 804 is that drugs imported under the program pose no *additional* risks to public health and safety, and neither the FDCA nor FDA regulations require secondary wholesalers to ensure drugs they distribute are authentic by any means other than inspection of the labeling or pedigree documentation, drugs under the VT importation program should comply with the same regulations to satisfy the authentication step. Rather, DSCSA requires prescription drug wholesalers to inspect for and develop procedures to handle "suspect" and "illegitimate" prescription drugs the wholesaler receives, inventories or distributes. Only when more information is "needed" to authenticate the drug is authentic (made by the FDA-approved manufacturer) does section 804 mandate that the manufacturer provide such information.

Identification of Program Costs

The new or existing costs identified by NASHP and FDA Imports (to any part of the supply chain) to participate in a State wholesale importation program include:

Regulation

1. Costs of Licensure and Auditing:

- Application Fees, Licensing Fees, Inspection/Audit Fees will cover the application process, licensing, record review, and inspection/audit fees. These operations can be outsourced to third parties to obtain efficiency. The Office of Professional Regulation charges licensing fees only. Fees for other activities would need to be charged by the Agency of Human Services. The State may also rely on audits performed by other states, Health Canada, FDA, WHO or other appropriate public or commercial auditing organizations provide the audits meet VT's minimum standards registration -- not commercial -- purposes). Costs for establishing and maintaining the list of licensed participants should be covered by the licensing fees paid by the participants.
- New classes or types of licenses for importers, exporters. Typically, the licensee supports the cost of the administration, including audits, through license fees.

2. Costs of Ensuring No Risk to Health and Safety:

- Batch testing by federally recognized laboratories. Laboratory recognition by accreditation is now a well-established process and for other FDA-regulated commodities, FDA has begun the process of creating a third-party accreditation program. Most commercial laboratories already hold accreditations from international and U.S. third party accreditors such as American Association for Laboratory Accreditation (A2LA) and National Cooperation for Laboratory Accreditation (NCLA). Between these two bodies alone, hundreds of commercial laboratories in the U.S. have been accredited to ISO 17025 standards. New costs for testing imported drugs can be supported by the wholesaler and will be covered by the margins between reduced sourcing and distribution for a profit.
- Current Laboratory Information Management Systems (LIMS), which are deployed by most (if not all) nationally accredited private laboratories will suffice but may require adaptation. NASHP/FDAImports expect the commercial participants will bear the costs of making necessary adaptations to existing data systems for this functionality at no additional cost to VT.

Upfront Funding Requirements

- Appropriations for the Agency of Human Services to build, operate, and regulate prescription drug importation program, including ongoing monitoring of savings opportunities and updating of the drugs-for-importation-list.
    - The VT legislation requires VT to establish and staff a "hotline" for consumers, third-party payers, service providers, pharmacists, and other potential commercial participants to call with questions or concerns prior to and after initial implementation of the Program. This expenditure will be a part of the overall budget for the state administrative agency, such as AHS.
- Potential investment in the Office of Professional Regulation to create and administer new license types.
- Cost of the purchase of the first shipment of imported products. This cost would be handled by the wholesaler just the way it is handled in the US supply chain. The wholesaler makes the purchase and then sells the product to lower tiers of the supply chain and recoups the initial cost. New costs supported by the commercial participants in supply chain and covered by the margins between reduced sourcing and distribution for a profit.

Potential Revenue Sources

Fees for Supplier and Wholesale Licensees

- Initial App Fee: $5000
- Annual Reg Fee: $1000
- Annual Audit Fee: $1500
- Per prescription Fee (TBD, may add administrative complexity)

Section 3: Considerations for Next Steps in Determining Benefit of Prescription Drug Importation from Canada

Together with FDAImports, NASHP has provided the state of Vermont with a preliminary plan for prescription drug importation from Canada, primarily detailing the potential savings for commercial payers and focusing on how to ensure no additional risk to public health and safety from imported drugs. Moving forward, Vermont needs to determine the benefit of such a plan to the state, to complete a more detailed explanation of the work and cost of a state operated importation program, and to better define the need for legislative action relative to an application to the Secretary of Health and Human Services to certify a program of prescription drug importation.

Due to changes in prescribing patterns, the introduction of new drugs to market, participation of additional purchasers of imported drugs, and changes in the value of US and Canadian currency, a state agency operating a prescription drug importation program will need to provide for ongoing analysis of the savings opportunities with respect to imported drugs and maintain and updated list of drugs for importation; this work is in addition to the necessary activities to ensure public health and safety. The AHS will need to acquire, develop, or repurpose expertise in monitoring the trends identified above and making transparent the opportunities for savings, in addition to securing expertise in inspection and audits necessary to guarantee the safety of

imported Canadian prescription drugs. Before a program of prescription drug importation can be recommended, Vermont needs to determine the absolute cost of operating such a program and whether that cost eclipses the savings for participating commercial payers. A program that costs more to operate than produces in savings is highly unlikely to meet the Secretary's criteria for certification.

The following considerations for next steps have been identified:

1. Determining benefit to Vermonters:
    - Create detailed estimate of upfront and ongoing state expense to operate a program of prescription drug importation; such an estimate may require further contracted expertise.
    - Estimate the total potential savings of a program of prescription drug importation relative to mark-ups, operating costs, and potential revenue.
    - Establish a clear mechanism for assuring that savings from prescription drug importation accrue to consumers.
2. Steps Necessary to Facilitate Program Implementation
    - Assess the interest of suppliers and wholesalers.
    - Submit a successful application to the Secretary of Health and Human Services.
    - Enabling legislation and appropriations for the state agencies to operate the prescription drug importation program.

Consideration	Options	Rationale	Recommendation
Appropriate State Agency to Administer Wholesale Drug Importation	Agency of Human Services (AHS): Program Administration. Office of Professional Regulation: Licensure	AHS has limited but potentially applicable experience with the Universal Vaccine Program. Expertise in prescription drugs for the Medicaid program exists within the agency, but additional expertise would need to be acquired through personnel or contract. OPR has expertise in licensure.	Further exploration is necessary to understand full scope of administering a prescription drug importation program and the state resources required to do so.
Estimates of Program Costs	AHS, working with contracted expertise, would need to produce estimates of the actual cost of program administration.	Absent an estimate of costs to operate and regulate a program of wholesale prescription drug importation, balanced against potential revenue, Vermont cannot assess the actual savings to tax payers and health care consumers.	AHS propose operating budget and necessary appropriation for a wholesale prescription drug importation program.
Re-Estimate Program Savings relative to operational costs	After operational costs are clearly established, re-visit savings potential.	Vermont cannot assess the savings to tax payers and health care consumers. Furthermore, Vermont's savings estimates are based on participation of two payers. With further exploration of a program, additional payers may have interest in participation thereby increasing savings estimate.	AHS, working with contract expertise, analyze potential savings for consumers in-light-of program costs.
Establish mechanism for ensuring that savings accrue to consumers	• Rate review showing impact on commercial and state employee premiums. • Reduced co-pay, • Reduced coinsurance, or no deductible for the imports. • Savings to public payers or purchasers or Rx patient assistance program for uninsured residents.	Vermont should consider the appropriate mechanism for ensuring savings to consumers. Mechanisms that force commercial coverage plan design changes will have added complexity and implications for other covered services.	Stakeholder workgroup to include commercial payers, Green Mountain Care Board, Department of Vermont Health Access should be established to develop mechanisms for ensuring savings to consumers.
Assessment of Willing Participants as Suppliers or Wholesalers	Consider an RFI to determine interest in participating as a supplier or wholesaler.	An application for a wholesale drug importation program may be strengthened by clear interest in participation from suppliers and wholesalers.	Develop RFI for participation as Suppliers or Wholesalers.