

Vermont's Canadian Wholesale Importation Program for Prescription Drugs

Concept Paper
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Executive Summary

This concept paper outlines Vermont's approach to fulfilling the cost-saving and safety requirements for a state wholesale importation program under Section 804 of the federal Food, Drug, and Cosmetic Act (FDCA), and is submitted as guidance for the Federal Department of Health and Human Services (HHS) as it drafts regulations for state importation programs. Vermont's program differs from the importation concept paper submitted by Florida; Vermont's program accrues saving through commercial plans, bringing savings to make coverage more affordable to Vermonters rather than through public programs, as Florida proposes.

Section 2 demonstrates annual savings from Canadian importation for Vermont are estimated at \$1-5 million. These were preliminary projections and additional analysis is currently underway to develop more precise savings projections. Savings will be passed on to consumers through health plans via lowered premiums, deductibles, and/or co-pays.

Section 3 demonstrates how Vermont would meet both Section 804 safety requirements as well as all other Federal Food, Drug, and Cosmetic Act (FDCA) requirements for importation, including the requirements of 2013 Drug Supply Chain Security Act (DSCSA).

Section 1: Background

Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) in 2003 (see 21 U.S.C. § 384). Under section 804 of the Federal Food, Drug, and Cosmetic Act (FDCA), the MMA created a pathway for wholesale state importation from Canada, subject to certification by the U.S. Secretary of Health and Human Services to Congress that implementation of such a program:

- 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**

In 2018, the Vermont General Assembly passed Act 133, *An act relating to the wholesale importation of prescription drugs into Vermont*. Act 133 requires Vermont's Agency of Human Services to design a wholesale prescription drug importation program that complies with all applicable requirements of 21 U.S.C. § 384, including the requirements regarding safety and cost savings.

On July 31, 2019, the U.S. Department of Health and Human Services (DHHS) and the U.S. Food and Drug Administration (FDA) released the *Safe Importation Action Plan*, including a notice of proposed rulemaking to promulgate regulations enabling importation through Section 804 of the Federal Food, Drug, and Cosmetic Act. To date, no state has submitted a formal wholesale importation program application to the U.S. Secretary of Health and Human Services for certification. However, Florida submitted a concept paper to DHHS outlining its approach on August 20, 2019, detailing its importation program concept to aid in the process of developing regulations.

Vermont's concept for an importation program entails some important differences from Florida's concept. For that reason, Vermont is submitting this concept paper to DHHS for additional guidance in the development of regulations as they pertain to Vermont and other states with similar approaches. The primary difference between the two importation program concepts relates to payer participation. Florida's legislation directs its Agency for Health Care Administration to import drugs for consumers served through public payers only, including Florida's Department of Health, Agency for Health Care Administration, Department of Corrections, Agency for Persons with Disabilities, and Department of Children and Families.

Vermont's importation concept would allow participation by consumers served by commercial health plans in the state, with the possibility of phasing in public payers after the launch of the program. This approach was selected following cost-savings analyses for Vermont which indicated the most significant savings for consumers would be garnered for those served by commercial plans (see Section 2). Aside from the important difference surrounding participating payers in Florida versus Vermont, both states share similar approaches to fulfilling the safety requirements outlined in Section 804 (see Section 3).

Vermont's work to design its concept has been informed through technical assistance from the National Academy of State Health Policy (NASHP) and its consultants at FDAImports.com, LLC. In May of 2019, NASHP began convening the four states with legislative mandates to pursue implementing wholesale importation from Canada (Vermont, Florida, Colorado, and Maine) for bi-weekly calls to collaborate on implementation as possible. Of these states, Florida's focus on public payers was unique, while Vermont, Colorado, and Maine, as well as a second, separate importation concept in Florida, focus on the commercial market.

Section 2: Fulfilling Section 804 Cost-Saving Requirements

To fulfill federal cost-savings requirements in Section 804 of the FDCA, Vermont sought to determine whether its wholesale importation program from Canada could provide significant savings to Vermont consumers. Vermont consulted with the National Academy of State Health Policy (NASHP) for technical assistance in estimating cost savings.

Determining Savings from Wholesale Drug Importation from Canada

Private Payers

1. The first step of the savings analysis was to request that health plans identify a list of their top spend 35-40 prescription drugs. Top spend was determined by multiplying the net cost of each drug by utilization. The second quarter of 2018 was arbitrarily chosen to establish a consistent unit of time across plans for this analysis. Plans were instructed to exclude drugs ineligible for importation according to FDCA (See Section 3.11 for a list of ineligible drugs).
2. NASHP compared the lists across participating payers and compiled a list of 17 drugs occurring across payers' lists. The final list included common brand name prescription drugs for treating conditions including: chronic obstructive pulmonary disorder, diabetes, hepatitis C, HIV/AIDS, multiple sclerosis, arthritis, and blood clots.

NASHP located Canadian prices for those drugs on the Quebec Public Drug Program List, and converted them to US dollars using a rate of \$1 CAD to \$0.75 USD. NASHP then added a 45% mark-up to the Canadian price in order to reflect costs that will be incurred along the distribution supply chain.

The 45% mark-up breaks down as follows:

- an allowance of 20% profit for commercial entities within the supply chain
- repackaging/relabeling (15%)
- testing (5%)
- record keeping and recall management (5%)

The total amount of mark-up was determined with input from industry consultants. It was selected as an intentionally high mark-up, meaning that actual savings might accrue at levels even higher than estimated.

3. To determine savings, plans were asked to determine their net spend (i.e. net of rebates or other price concessions) on the 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 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.

Savings, even after mark-up, were as high as 60-70% for certain drugs.

The estimated savings from this initial analysis were sufficient impetus to keep Vermont moving forward with its program design (see Section 3). Vermont is currently updating its savings analysis using the second quarter of 2019 as the unit of time. Vermont will also ask health plans to exclude insulin from the analysis given the pending shift in classification of insulin to regulate it as a biologic, with the understanding that this would make insulin ineligible for importation. However, Vermont is intent on lowering insulin costs for its residents and would request consideration from HHS to import those needed drugs as we develop our final proposal.

Passing Savings to Consumers

Establishing savings to health plans is necessary, but not sufficient for ensuring those savings are passed on to consumers. In order to ensure the significant savings from importing certain prescription drugs wholesale from Canada would be passed on to consumers, Vermont would amend its annual rate review filing requirements for health plans doing business in the state. Health plans would be required to document savings from importation as well as how those savings were passed on to consumers. Options for passing savings to consumers include:

- lowering premiums
- lowering deductibles
- reducing or eliminating co-pays

In addition to the rate review process described above, the state would establish a transparent, public price list of the imported drugs in order to ensure that mark-up along the supply chain was not exceeding allowed amounts at the expense of consumer savings.

Public Payers & 340B Providers

The Department of Vermont Health Access (DVHA) determined that drug importation from Canada would not provide significant net savings to the state's Medicaid program because the existing Medicaid prescription drug rebate program already yields substantial savings. There would also 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 yield cost-savings through Canadian importation for a limited period of time. Though such drugs may be phased into Vermont's importation program at a later time, it is not envisioned. Medicaid would be part of the importation program upon its launch.

Payers that meet federal eligibility requirements for the 340B Drug Discount Program, similar to Medicaid, are not likely to see savings from Canadian importation because 340B drug pricing is so low. The importation program would be able to operate independently without impacting the 340B program, while importation would create a new pathway to increase drug affordability for consumers not served by Medicaid or 340B programs.

Section 3: Fulfilling Section 804 Safety Requirements

Having established significant savings for consumers from the importation of select, eligible prescription drugs, Vermont has taken steps to design a program to fulfill Section 804 safety requirements. The following section examines these requirements as laid out in Section 804 and demonstrates Vermont's plan for fulfilling those requirements.

I. The Program operates under both Federal Food, Drug, and Cosmetic Act (FDCA) Section 804 requirements and existing FDCA requirements to ensure no additional risk to health and safety.

In accordance with FDCA section 804, Vermont's Canadian drug importation program ("Vermont's Program" or "the Program") has safeguards in place to ensure that the qualifying prescription drugs imported under Vermont's Program are FDA-approved, not adulterated, not misbranded, and that they pose no additional risk to the public's health and safety.

Drugs imported under the Program would be subject to all U.S. laws that apply to prescription drugs marketed in the U.S. related to their approval, formulation, manufacturing, packaging, labeling, importation, and distribution, as well as additional FDCA section 804 requirements (such as testing by qualified labs for authenticity and degradation). FDCA section 804 and the supplemental oversight by the State of Vermont add two additional layers of public health protection to ensure that the qualifying prescription drugs imported under Vermont's Program pose no additional risk to the public's health and safety.

The only FDCA provision with which prescription drugs imported under Vermont's Program *do not* have to comply is FDCA section 801(d)(1), which ordinarily prohibits reimportation of prescription drugs by anyone other than the manufacturer and importation of foreign-made prescription drugs by anyone without the authorization of the manufacturer. Prescription drugs imported in accordance with FDCA section 804 are expressly exempt from FDCA 801(d)(1).

A. Drugs imported under the Program must be FDA-approved, not adulterated, and not misbranded.

Qualifying prescription drugs imported under Vermont's Program must be the same as the drug originally intended for the U.S. market with respect to key factors such as active pharmaceutical ingredient (API), strength, purity, and route of administration. Further, such drugs must be made in the FDA-approved facility and must have been initially purchased from either the FDA-approved manufacturer or from their authorized distributor (or foreign equivalent).

Any differences in the original packaging and labeling of a drug obtained from Canada compared to U.S. marketed product will be cured under Vermont's Program by duly FDA-registered, licensed, and regulated repackagers and/or relabelers, as currently permitted by the FDCA and FDA regulations. Repacking and relabeling of qualifying prescription drugs under Vermont's Program would be performed prior to importation of the drugs into the U.S. (in Canada), to ensure no misbranded or unapproved drugs enter the U.S. under the Program.

B. Drugs imported under the Program must comply with the FDCA registration and listing requirements and the Drug Supply Chain Security Act.

The Drug Supply Chain Security Act (DSCSA), which was enacted in 2013, addresses and resolves many of the concerns about importing drugs from Canada that existed when FDCA section 804 was enacted in 2003. Compliance with FDCA registration and listing requirements, and the Drug Supply Chain and Security Act under Vermont's Program, particularly when in combination with the additional FDCA section 804 protections discussed below, will ensure the accountability of the supply chain back to the FDA-approved manufacturer or its authorized distributor.

1. Registration, listing, and licensing requirements for supply-chain participants

Under the FDCA (including the DSCSA), all parties in the prescription drug distribution chain – drug manufacturers, wholesale distributors, repackers, relabelers, third-party logistics providers, and dispensers (pharmacies for the most part), whether foreign or domestic – must hold various registrations, licenses, and/or permits from appropriate federal and/or State authorities, and must maintain certain records establishing a pedigree, ownership, and distribution history for each lot of prescription drug sold, purchased, received, stored, and distributed. All federally required FDA-registrations and drug listings (connecting relevant National Drug Code (NDC) numbers) will be required for Vermont's Program.

Note that the NDC declared on the drug label need not be that of the repacker or relabeler, but may be a Private Label Distributor's NDC. The Vermont Office of Professional Regulation (OPR) can impose additional State requirements, as needed, to satisfy any FDA concerns regarding the repacking or relabeling of drugs under the Program.

2. DSCSA requirements for supply chain documentation and track-and-tracing

Supply chain participants under Vermont's Program will comply with transaction document requirements under the DSCSA and Vermont law to ensure transparency of the supply chain. In accordance with the DSCSA, prescription drug wholesalers under Vermont's Program would have to ensure that the prescription drugs received from Canadian suppliers are accompanied by adequate documentation reflecting the drug originated at the FDA-approved manufacturer or its distributor as well as the drug transaction information and transaction statement. This information would include:

- adequate documentation reflecting the drug originated at the manufacturer or its distributor;
- the proprietary / established name of the prescription drug;
- the strength and dosage of the prescription drug;
- the NDC for the prescription drug as marketed in the United States;

- the container size, number of containers, and the lot number of the prescription drugs;
- the transaction date;
- the shipment date (if shipped more than 24 hours after transaction);
- the business name and the address of the person shipping the prescription drug; and
- the business name and the address of the person receiving the prescription drug.

FDA has implemented most of the DSCSA already, and through the year 2023 will continue phase-in of DSCSA requirements, standards, and an electronic system for product tracing through the year 2023. Supply chain participants under Vermont's Program will continue to comply with DSCSA tracking and tracing requirements as they are established and implemented by the FDA, and to the extent practical should incorporate existing and available supply chain track-and-trace technology (e.g., practical, feasible, and effective blockchain applications).

3. Handling of suspect and illegitimate products

Manufacturers, wholesale distributors, dispensers, and repackagers of drugs under the Program must also establish and implement systems for verification and handling of suspect or illegitimate product, as required by the DSCSA. If a manufacturer, wholesale distributor, dispenser, or repackager has reason to believe that a drug is potentially illegitimate (e.g., potentially counterfeit, diverted, or otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans) it must:

- quarantine the suspect products;
- investigate whether the prescription drugs are illegitimate products and notify FDA regardless of the outcome of the investigation; and
- if the investigation finds that the prescription drugs are illegitimate products, take certain corrective measures including appropriately disposing of the product and providing reasonable assistance for disposition to parties who have received the illegitimate product.

C. Prescription drugs imported under Vermont's Program are subject to FDA-examination at the border

Importation of prescription drugs from Canada to the U.S. under Vermont's Program will occur under the ordinary course of business utilizing international logistics companies and customs brokerage services under existing Customs and Border Protection (CBP) and FDA import laws and regulations. The importer of any prescription drug must submit comprehensive information

about the product to CBP and FDA for their review prior to importation of the product. Such information submitted under the Program would include the information currently required for importation of prescription drugs (see, e.g., 21 CFR Part 1 Subpart D) and any additional information FDA would require to be submitted in accordance with FDCA section 804. FDA exercises broad discretion to examine and sample essentially any prescription drug offered for import, and FDA can detain and refuse admission of any prescription drug that appears to be violative (e.g., that appears to be adulterated, misbranded, unapproved, or manufactured in an unregistered facility).

II. Drugs imported under Vermont's Program would be subject to FDCA section 804 safeguards

In addition to the safeguards applicable to all prescription drugs, as discussed above, prescription drugs imported under Vermont's Program would be subject to requirements under FDCA section 804. In conformity with section 804, the following types of drugs will not be imported under VT's program:

- controlled substances,
- biological products,
- infused drugs,
- intravenously injected drugs,
- parenteral drugs that the FDA determines pose a threat to the public health, and
- drugs that are inhaled during surgery.

The importer of a prescription drug under Vermont's program will submit additional information about each shipment to FDA, including documentation from the foreign seller specifying the original source of the prescription drug and documentation of the lot or control number that was assigned to the prescription drug by the manufacturer of the prescription drug. Each batch or shipment (depending on the circumstances) of the prescription drug will be subjected to testing for authenticity and degradation by a qualified laboratory at various points in the supply chain. At a minimum, a qualified laboratory under Vermont's Program will be independent and accredited to the ISO/IEC 17025:2017 standard. Importers will submit documentation of this testing to FDA, including the complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards, and the documentation demonstrating that the testing was conducted at a qualified laboratory.

FDCA Section 804 requires manufacturers to make available, at no cost, written authorization for the wholesalers and pharmacies importing drugs under Vermont's Program to use the approved labeling for the qualifying prescription drug. This will help ensure the prescription drugs imported under the Program are not unintentionally misbranded (e.g., that they feature the most up-to-date label and labeling).

HHS/FDA has authority under FDCA section 804 to immediately suspended importation of a specific prescription drug or importations by a specific importer on discovery of a pattern of importation of drugs that are counterfeit or that are in violation of any requirement of FDCA section 804.

Additionally, in accordance with FDCA section 804 no drugs may be imported under the Program if they were donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (e.g., to the United Nations) or to a government of a foreign country.

III. Licensing eligible participants

Vermont will establish new prescription drug importer-wholesaler licenses for Vermont pharmacies, Vermont wholesale distributors, and Canadian suppliers. These licenses will be issued and maintained by OPR and the Vermont Board of Pharmacy. OPR will ensure that the license numbers, class of activity, and establishment locations are publicly available, to facilitate verification of pedigrees by downstream importers, wholesalers, and pharmacies.

Prescription drug importer-wholesalers under the Program must also certify to OPR, for each shipment of qualifying prescription drugs that they import, that the shipment complies with FDCA section 804 requirements and other key requirements of the Program.

In accordance with FDCA section 804, Vermont would not allow any drug to be imported under the Program from any Canadian supplier who has not registered with HHS/FDA the name and place of business of the establishment and the name of the U.S. agent for the establishment.

Verification via audit and international inspection of Canadian prescription drug supplier licensees and Vermont prescription drug importer licensees would be performed by or guaranteed by the state agency administering the program. Inspections and audits may be conducted by other states (e.g., for Pharmacy Drug Importer-Wholesalers located in and permitted by other states), by Health Canada, by the appropriate Canadian provincial authority, or by qualified third-party contractors. A successful inspection or audit of a program applicant will be required for them to obtain a Vermont license under the Program. Periodic audits will be performed to assess whether the licensee continues to meet the requirements for the license. Reports of these audits will be shared with FDA, enabling FDA to evaluate whether a particular prescription drug or its importer should be suspended from the Program.

Prescription drug importer-wholesaler licensees and Canadian prescription drug supplier licensees will annually report to FDA their state licensure information for each facility, contact information for each facility, and any significant disciplinary actions taken by a State or the federal government, as required by the DSCSA. The Vermont licensees involved in the Program will file a similar report with OPR as a condition of maintaining their licenses.

IV. Unique NDC for Vermont as Private Label Distributor

Vermont would obtain from FDA its own FDA "Private Label Distributor" (PLD) labeler code, which would identify Vermont as the private labeler for all qualifying prescription drugs imported under the Program. Vermont would also list each qualifying prescription drug with FDA using Vermont's labeler code. As part of this process Vermont will obtain a valid NDC code for each qualifying

prescription drug under the Program. This is consistent with current contract drug manufacturing, repacking and relabeling regulations and practice under the FDCA and FDA review in the international drug supply chain.

The qualifying drug label reflecting Vermont's PLD NDC will enhance visibility within the supply chain and ensure Vermont's and FDA's ability to connect a specific package of a qualifying prescription drug under the Program with that specific drug's supply chain. Because the product identifiers must be both human-readable and machine-readable, repacked and relabeled qualifying prescription drugs will be immediately identifiable. This will also help ensure that no drugs imported under the Program are distributed, dispensed, or sold outside of Vermont's borders.

The Vermont PLD NDC will be included in the third-party payment system utilized currently to ensure proper coding for reimbursement.

V. Recordkeeping & Reporting

Participants in the Program, whether Canadian suppliers, prescription drug Importers-Wholesalers, or other entities registered and/or licensed with the Vermont's OPR and/or FDA, will establish and maintain records to document compliance with the Program. Such documentation will include, for example, identification of the testing conducted and the applicable DSCSA-related records. In all cases, Vermont will attempt to add few new record keeping obligations but will require access to records that are already necessary to comply with existing federal and State programs. Some records will be unique to the Program, such as the prescription drug importer-wholesaler certification of compliance. Audits of participants in the Program may include review of relevant records.

VI. Recall Management

The mechanics of handling recalls of qualifying prescription drugs imported under the Program will follow the ordinary FDA-established process. Furthermore, as noted above, under the DSCSA manufacturers, wholesale distributors, dispensers, and repackagers of drugs must investigate suspect products, and if the product is unfit for distribution such that the product would result in serious adverse health consequences or death to humans, they must quarantine and dispose of the product and provide reasonable assistance for disposition to parties who have received the illegitimate products. Vermont would cooperate with FDA to help facilitate any recalls under the Program.