

Florida's Canadian Prescription Drug Importation Concept Paper



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I. Executive Summary



Pharmaceutical prices in the United States (U.S.) are rising at an astronomical rate and have been for the last decade. No reforms that have been implemented to date have had a significant impact in reducing costs. Americans spend 30%-190% more on prescription drugs when compared to other high-income developed nations (e.g., Switzerland, Germany, Canada, France, U.K., Australia, Norway, and Sweden)¹ and pay significantly more for the same drugs per capita (almost twice as much)². According to a poll conducted by the Kaiser Family Foundation in February 2019, 80% of respondents (of all political affiliations) feel that profits made by pharmaceutical companies is a major factor contributing to the price of prescription drugs.³ In spite of continuing efforts to effectively manage the increasing costs of prescription drugs, nothing has worked.

Prescription drug prices in Canada are significantly less than those paid in the U.S. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (the Act), which allows U.S. wholesalers and pharmacists to commercially import prescription drugs from Canada under certain circumstances (See 21 United States Code (U.S.C.) § 384, also known as Section 804 of the Federal Food, Drug, and Cosmetic Act (FDCA)). However, before importation of prescription drugs from Canada can take effect, the law requires the Secretary of the Federal Department of Health and Human Services (DHHS) to certify that the federal importation program will pose no additional risk to the public health and safety and will result in significant cost savings. While this law was passed more than fifteen (15) years ago, it has not been implemented to date.

During the 2019 Florida Legislative session, Governor Ron DeSantis signed into law a bill (House Bill 19/Senate Bill 1528) that creates section (s.) 381.02035, Florida Statutes (F.S.) establishing the Canadian Prescription Drug Importation Program (Program) within the Agency for Health Care Administration (Agency), the chief health policy and planning entity for the state of Florida. The purpose of the Program is to facilitate the commercial importation of prescription drugs into Florida from approved Canadian suppliers. The list of prescription drugs that are imported under the Program must have the greatest potential for savings to the State. House Bill (HB) 19 allows the importation of drugs that meet the United States Food and Drug Administration (FDA) standards related to safety, effectiveness, misbranding, and adulteration.

The Agency is required to contract with a Vendor that will manage and oversee all aspects of the Program and ensure Canadian suppliers and eligible importers comply with all federal and state law requirements. Eligible importers will be limited to wholesalers and pharmacists that are dispensing prescription drugs to consumers who are being served by certain state/government programs. Florida's Program must also comply fully with Title II of the Federal Drug Supply Chain

¹ Sarnak, D. (October 5, 2017). Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier? retrieved on February 20, 2019 from: <https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier>

² Kesselheim, A.S. (August 2016). The high Cost of Prescription Drugs in the United States. Journal of American Medical Association, retrieved on February 25, 2019 from <https://jamanetwork.com/journals/jama/article-abstract/2545691>

³ Kaiser Family Foundation. Retrieved from: <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

Security Act (DSCSA).

The State of Florida has prepared this concept paper, which is being submitted to DHHS to demonstrate the ability of a state to safely and effectively import prescription drugs into the U.S. (exceeding standards that are currently in place for domestic commerce). This concept paper provides detailed information about how the State of Florida has designed a commercial prescription drug importation program that will yield significant cost savings of over **\$150 million dollars** annually and would ensure compliance with 21 U.S.C. § 384, including:

1. Track and trace requirements for imported drugs;
2. Sampling of the purity, chemical composition, and potency of the imported drugs;
3. Reviewing laboratory records, including complete data derived from testing;
4. Reviewing labeling standards for prescription drugs; and
5. Ensuring that drugs are not imported that are identified in the Act as being excluded.

Based on the strength of the Program design articulated in this concept paper, the State of Florida is confident that Secretary Azar can certify to Congress that the implementation of a prescription drug importation program, consistent with 21 U.S.C. § 384, poses no additional risk to the public's health and safety and will result in cost savings. **Importantly, while this concept paper only discusses importation to state entities, Florida's new law does not and should not be interpreted to prevent importation from private wholesalers and pharmacies, which is the purpose of 21 U.S.C. § 384. The State of Florida welcomes and fully supports importation to private entities.**

The DHHS can use this concept paper to aid in the process of developing federal regulations that govern importation programs; it can also be used to develop parameters in which the states may pilot such programs in coordination and cooperation with the FDA. Regardless, it is time to try something different and bold – and begin the implementation of a law that the U.S. Congress passed over a decade ago.

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II. Background

In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (the Act), which allows U.S. wholesalers and pharmacists to commercially import prescription drugs from Canada (See 21 United States Code (U.S.C.) § 384). A key requirement in 21 U.S.C. § 384 is that the Secretary of the Federal Department of Health and Human Services (DHHS) certifies that the commercial importation program poses no additional risk to the public's health and safety and that the program will result in significant cost savings. While this law was adopted well over a decade ago, it has not been implemented to date.

Federal law allows individuals to import prescription drugs from outside of the U.S. (also referred to as personal importation) under the following circumstances⁴:

1. The drug is for use for a serious condition for which effective treatment is not available in the U.S.;
2. There is no commercialization or promotion of the drug to U.S. residents;
3. The drug is considered not to represent an unreasonable risk;
4. The individual importing the drug verifies in writing that it is for his or her own use and provides contact information for the doctor providing treatment or shows the product is for the continuation of treatment begun in a foreign country; and
5. Generally, not more than a three-month (3-month) supply of the drug is imported.

These restrictions significantly limit an individual's legal access to most prescribed drugs from outside of the U.S., as there are few drugs that meet the exceptions listed above.

Canada has a regulatory system to manufacture and distribute prescription drugs that is considered an equivalent to the U.S. system. Health Canada, the equivalent to the U.S. FDA, has a program to conduct inspections of establishments to verify compliance with Good Manufacturing Practices (GMP) related to prescription drugs and health products. To the extent a prescription drug is manufactured in Canada, the U.S. can be assured that Health Canada has taken proactive steps to ensure that their products are safe, pure, and effective. Further, Health Canada requires that prescription drugs that are manufactured outside of Canada, but are imported into the country (Canada) for the sole purpose of exportation, undergo the same scrutiny and inspection as those prescription drugs that will be consumed in Canada.⁵ Furthermore, eighty percent (80%) of all active pharmaceutical ingredients and forty percent (40%) of all prescription drugs sold in the United States (U.S.) are actually manufactured in facilities overseas.

The Florida Legislature recently passed House Bill 19/Senate Bill 1528 that created section (s.) 381.02035, Florida Statutes (F.S.) establishing the Canadian Prescription Drug Importation Program (Program). The Program will be overseen by the Agency for Health Care Administration (Agency), through a contracted Vendor. The Program focuses exclusively on

⁴ The Food and Drug Administration, "Is it legally for me to personally import drugs?", retrieved on February 22, 2018 from: <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194904.htm>

⁵ Health Canada. Import and Export Policy for Health Products under the Food and Drugs Act and its Regulations (POL-0060). Retrieved on April 24, 2019 from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/policy-health-products-under-food-drugs-act-regulations-0060.html>

II. Background

commercial importation – not personal importation. Eligible importers will be limited to wholesalers and pharmacists that are dispensing prescription drugs to consumers who are being served by certain state/government programs, as described in Section IV of this concept paper. The State of Florida has prepared this concept paper to demonstrate the feasibility of compliance of 21 U.S.C. § 384 and the capability of a state to ensure adequate safeguards for consumers in implementing a commercial prescription drug importation program.

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III. Program Overview

The concept paper will address each component of the Program and requisite responsibilities of all participants. Included in this section is a brief overview of the key features of the Program, however, greater details are described later in the concept paper.

Since adopting the Medicare Modernization Act in 2003, the U.S. has made huge strides in passing additional legislation that will further ensure public health safety under any commercial drug importation program, specifically Title II of the Federal Drug Supply Chain Security Act (DSCSA), which added regulations for all participants in the supply chain and outlined critical steps towards building an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the U.S. Florida's wholesale drug importation program will leverage the FDA administered drug manufacturing inspection program and existing pharmaceutical distribution supply chain to import commercial quantities of select high-cost drugs from Canada into the U.S.⁶ Florida's adoption and implementation of the FDA's existing requirements and enforcement of DSCSA will serve as the basis for ensuring that health and safety risks associated with acquiring, distributing, wholesaling and importing a drug under the Program are no greater than those related to the drugs already circulating in domestic commerce.

Florida's legislation requires the Agency to procure a contract with a Vendor to handle the day-to-day operation of the Program and to ensure importers follow all state and federal laws related to importation of prescription drugs. The Agency will require that the Vendor be permitted, minimally, as a wholesale distributor through the Florida Department of Business and Professional Regulation (DBPR). The DBPR is responsible for administering and enforcing the Florida Drugs, Devices, and Cosmetics Act (DDCA), in accordance with state law and in concert with FDA requirements. This construct creates opportunities for additional oversight to ensure safety standards are met.

The Vendor will be responsible for identifying and maintaining a list of eligible Canadian suppliers that are in full compliance with relevant Canadian federal and provincial laws and executing agreements with Canadian suppliers who have agreed to export drugs under the Program. The Vendor will serve as an intermediary between the Canadian supplier and the eligible importers (wholesalers and pharmacists providing services on behalf of the state programs) – ensuring that these entities are qualified to participate in the Program, but also maintaining records (in coordination with the FDA) that demonstrates compliance with 21 U.S.C. § 384 as it relates to the supply chain documentation. The Vendor will also be responsible for developing a list of the prescription drugs that have the highest potential for cost savings to the state programs, including prescription drugs for which there are shortages and specialty prescription drugs.

Under Florida's Program, eligible prescription drugs **will** be the same with respect to active pharmaceutical ingredients, strength, purity and route of administration as the FDA-approved product, and will have been initially purchased from either an FDA-approved manufacturer or from their authorized distributors. The FDA already inspects and approves international drug manufacturing facilities before they can be used to produce drugs for U.S. consumers. These same FDA-approved facilities supply prescription drugs in other markets, including Canada.

⁶ National Association of State Health Policy, Center for State Rx Drug Pricing, retrieved on June 1, 2019 from: https://nashp.org/wp-content/uploads/2019/04/Final-updated-Importation-QA-4_1_2019.pdf

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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.). Further, the same freight companies, customs brokers, and trucking companies that currently provide the U.S. with most of its pharmaceuticals will transport these imported drugs.



Imported prescription drugs will be repackaged and relabeled prior to importation into the U.S. by FDA-registered repackagers and relabelers to ensure the drug labeling meets U.S. requirements. FDA regulates drug repackagers and relabelers as “manufacturers” for registration purposes, drug listing (and assignment of national drug code NDC), and the FDA’s regulation and oversight of the procedures, methods, processes and equipment used for such operations. Florida’s prescription drug importation program will leverage the same existing regulatory requirements, controls and safeguards as are employed currently by traditional drug repackaging and relabeling facilities.

Federal law requires that prescription drugs imported under the Program be tested at a qualified laboratory. Florida’s Program will ensure testing is performed by approved third party laboratories in the U.S. on samples collected randomly and representatively from batches or shipments, depending on the circumstances. This process will ensure that the drug meets the identity, strength, purity, and quality standards of the FDCA (such that the drug is not “adulterated”) and ensure that it meets the parameters as purported by the labeling of the drug or, where applicable, as established by the United States Pharmacopeia (USP) or other FDA-recognized compendia standards.

Finally, through the importation Program, the State would apply existing U.S. prescription drug wholesale track and trace requirements to the imported drug supply chain.

The Agency will retain ultimate responsibility for ensuring that the Program operates consistently with any federal rules and regulations that are ultimately adopted by DHHS. The Agency will maintain active oversight and monitoring functions over Vendor operations and will actively collaborate with DHHS to ensure success under the Program. Annually, the Agency will develop a report on the Program that can be provided to DHHS. The report will highlight the following:

1. A list of prescription drugs imported under the Program;
2. The number of participating entities;
3. The number of prescriptions dispensed through the Program;
4. The estimated cost savings during the previous state fiscal year and to date;
5. A description of the methodology used to determine which prescription drugs are included on the Wholesale Prescription Drug Importation List; and
6. Documentation demonstrating how the Program ensures that:
 - a. Canadian suppliers participating in the Program are of high quality, of high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations;
 - b. Prescription drugs imported under the Program are not shipped, sold or dispensed outside of the state once in the possession of the importer;
 - c. Prescription drugs imported under the Program are pure, unadulterated, potent and

III. Program Overview

- safe;
- d. The Program does not put consumers at higher health and safety risks than if the program did not exist; and
- e. The Program provides cost savings to the state on imported prescription drugs.

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IV. Eligible Importers

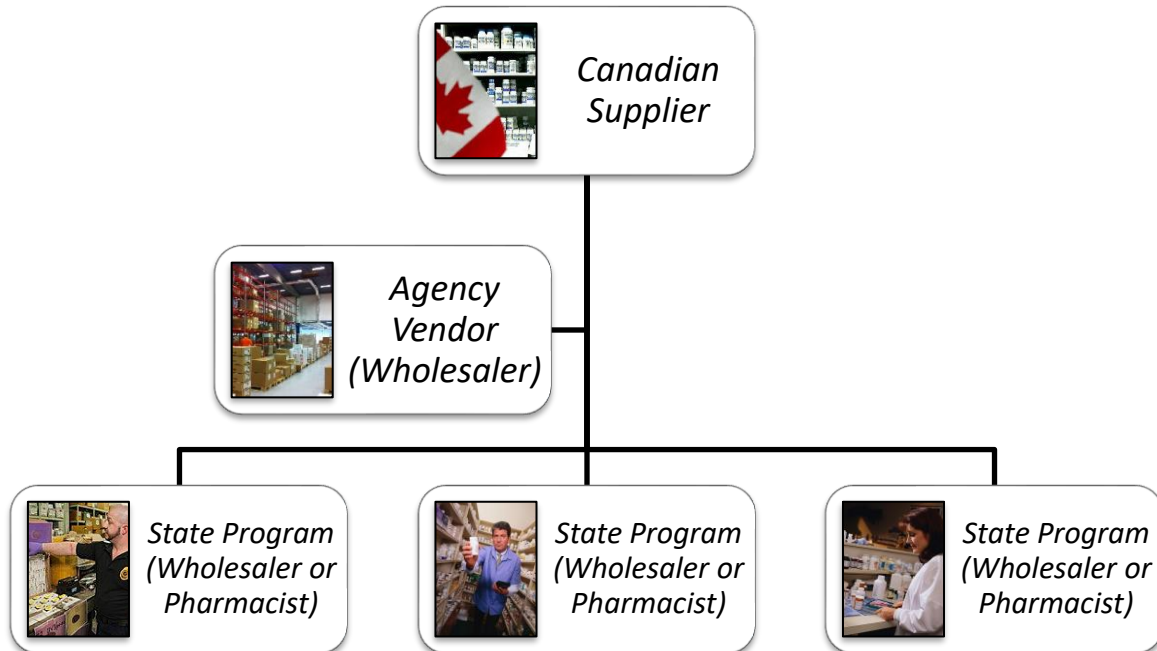
Florida's prescription drug importation program will have a heightened level of state government oversight and accountability. As established by Florida law, eligible importers will be limited to wholesalers or pharmacists dispensing prescription drugs to consumers served by these state/government programs:

- A wholesaler or pharmacist employed by or under contract with the **Department of Health's**⁷ central pharmacy, for distribution to a county health department or free clinic for dispensing to clients treated in such a department or clinic.
- A wholesaler or pharmacist employed by or under contract with a Medicaid pharmacy enrolled/registered with the **Agency for Health Care Administration**, for dispensing to Medicaid recipients.
- A wholesaler or pharmacist employed by or under contract with the **Department of Corrections**, for dispensing to inmates in custody of the Department of Corrections.
- A wholesaler or pharmacist employed by or under contract with a developmental disabilities center (as defined in s. 393.063, F.S. and licensed by the **Agency for Persons with Disabilities**), for dispensing to clients treated in such a center.
- A wholesaler or pharmacist employed by or under contract with a treatment facility (as defined by s. 394.455, F.S. and licensed/certified by the **Department of Children and Families**), for dispensing to patients treated in such a facility.

Wholesalers or pharmacists operating under the Program must be licensed/permitted in the state of Florida to dispense or distribute pharmaceuticals. A prescription drug wholesale distributor must be permitted through the DBPR; the permitting process requires entities to post a surety bond in an amount no less than \$25,000 and to undergo an on-site inspection. A pharmacist must be licensed through the Florida Board of Pharmacy managed by the Florida Department of Health. While each state program may have the ability to import prescription drugs directly from the Canadian suppliers, for administrative efficiencies and greater oversight, the Agency's contracted Vendor will serve as the primary importer, acting on behalf of these state programs. The Vendor may either warehouse and distribute the prescription drugs through the supply chain, or contract with a third-party logistics (3PL) provider (permitted by DBPR) to warehouse, distribute, and provide other logistical support. Below is a graphic representation of the potential relationship between the supplier, vendor, and the state programs.

⁷ More information about each state program is included in Exhibit A.

IV. Eligible Importers



Through the normal course of business, Florida state agencies routinely enter agreements with each other to coordinate efforts related to shared populations. The Agency already has in place interagency agreements with most of the state agencies that would be involved in the importation Program. These agreements would be amended (or initiated if none exist) to reflect each party's responsibility for ensuring full compliance with state and federal requirements under the importation Program. The Agency would require the Vendor to have similar agreements/contracts in place with the state entities (including its wholesalers and/or pharmacists) for the purposes of operating the Program and sharing data.

With this approach, there would be a limited number of importers operating under the Program, allowing for greater controls and oversight, and further enhancing the State's ability to adapt quickly, as the need arises. The Department of Health and Human Services can be assured that there is a high degree of government accountability throughout all steps of the process, given the enhanced involvement from several state agency and regulatory bodies, which creates an ideal scenario for a pilot program.

It is important to note that though Florida's law limits importation to wholesalers and pharmacists providing services under certain state programs, the State fully supports importation to private entities.

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V. Eligible Canadian Suppliers

V. Eligible Canadian Suppliers

Upon contracting with the Agency, the Vendor will determine what Canadian suppliers are interested in participating in the Program. Eligible Canadian suppliers may export prescription drugs into the state under the Program if the supplier is in full compliance with relevant Canadian federal and provincial laws and regulations and is identified by the Vendor as eligible to participate in the Program. The supplier must have a registered agent in the U.S., in accordance with 381.02035, F.S.

One additional safeguard that the State is considering is requiring the Canadian supplier to be permitted through the DBPR (the State's Devices, Drugs, and Cosmetic Acts enforcement agency). The Florida Legislature recently passed legislation that enables the DBPR to create a new permitting type for non-resident wholesaler distributors. This permit would afford additional protections under the Program. The supplier would not only have to meet Canadian laws and other U.S. regulatory requirements but would also have to comply with Florida law as well.

The Agency has not executed a contract with a Vendor but has obtained a list of potential Canadian suppliers. These entities will be contacted to determine their interest in participating in the Program; those that are interested will be thoroughly vetted to ensure compliance with the requirements stated in the preceding paragraph. A copy of the list is included with the proposal under Exhibit B.

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VI. Qualifying Prescription Drugs

As defined in 21 U.S.C. § 384, a prescription drug eligible for importation is a drug subject to 353(b) of the FDCA. Qualifying prescription drugs imported from Canada must meet the following parameters:

1. Must be the same formulation as FDA-approved products.
2. Must not have been “donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.” See 21 USC. § 384(i).
3. Must be manufactured by a facility designated by the FDA as an approved facility and be an FDA registered manufacturer.
 - a. The State will request from the FDA a list of FDA-approved manufacturing facilities outside of the U.S. for those drugs on the qualifying prescription drugs list.
 - b. The State will also rely upon publicly available registration data connected with drug labeler codes to identify FDA-approved manufacturers for qualifying prescription drugs.

Some of the opponents of prescribed drug importation argue that certain drugs, such as controlled substances, intravenous products, and biologics are highly susceptible to counterfeiting on the global market. Under the Florida Program and consistent with federal law (21 USC § 384(a)(3)), the following prescription drugs will be excluded from importation:



1. Controlled substances;
2. Biological products;
3. Infused and parenteral (administered via route other than the gastro-intestinal tract) drugs;
4. Intravenously injected drugs; and
5. Drugs inhaled during surgery.

The State will import qualifying prescription drugs through bulk orders/shipments. However, the program will only import a limited number of prescription drugs that yield the most cost savings. Again, this presents an ideal scenario if DHHS were interested in piloting the program with a state where the participants and number of imported drugs are limited in nature.

The State has identified a preliminary list of prescription drugs that meet all of the above requirements (in varying dosage form) to demonstrate the potential savings that could be yielded under the Program if it were implemented today (see Table A). The Vendor will be responsible for identifying all drugs that are eligible for importation under the Program; the list will be updated at a minimum on a quarterly basis (or more frequently if needed). This initiative is market-based and assumes Canadian supply will meet demand. If demand becomes a concern at any time, the State can implement the program on a smaller scale.

VI. Qualifying Prescription Drugs

A sample of the list of qualifying drugs are as follows:

Brand Name	Indications
Atripla	HIV
Aubagio	Multiple Sclerosis, Relapsing
Complera	HIV
Diclegis Dr	Nausea and Vomiting Prevention in Pregnancy
Epclusa	Hepatitis C
Genvoya	HIV
Ibrance	Allergic Rhinitis
Isentress	HIV
Nasonex	Allergic Rhinitis
Odefsey	HIV
Prezista	HIV
Pulmicort	Chronic Obstructive Pulmonary Disease
Sabril	Epilepsy
Stribild Tablet	HIV
Tecfidera Dr	Multiple Sclerosis, Relapsing
Tivicay	HIV
Triumeq	HIV
Truvada	HIV
Vimpat	Epilepsy

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VII. Costs and Cost Savings

The State has adopted a comprehensive methodology to determine the most cost-effective products to include in the importation Program.

Identifying Costs



In conducting the cost analysis, the State began by identifying the common costs/expenses that need to be accounted for in spite of any savings that may be derived from up-front, lower cost alternative prices offered by Canadian suppliers. The expectation for this Program is that it will operate within the normal global prescription drug supply chain and under the existing federal/state regulatory requirements. Most of the expenses of the Program can be covered by the margins between the cost

of sourcing the drug and delivering it for a profit while retaining a significant reduction in the cost of the eligible drugs. Supplier and wholesaler profit were contemplated when conducting the cost analysis, as this is an important element to attract participation in the Program. The State has built in a markup of forty-five percent (45%) above the original Canadian price to account for all third-party costs, as illustrated in Table A.

The following factors were considered as a part of the cost analysis:

- Sourcing;
- Repackaging;
- Relabeling;
- Testing laboratories; and
- Vendor costs

Sourcing: The State has already identified the preliminary list of qualifying prescription drugs, along with the Canadian equivalent formulation, and potential pricing information. The State has also already identified a potential list of Canadian suppliers. The Vendor will be required to identify which eligible suppliers are able to obtain the qualifying prescription drugs. This cost will be included in the contract with the Vendor. The costs associated with the suppliers acquiring the needed prescription drugs from eligible manufacturers will be negotiated freely among trading partners and was accounted for in the markup amount reflected in the cost analysis, which is discussed later in this section.

Repackaging and Relabeling: The costs associated with repackaging and relabeling will be borne by the commercial participants in the Program (i.e., the FDA-approved manufacturer or authorized distributor, the Canadian supplier, and/or the U.S. Vendor) and will be negotiated by parties to the various transactions in the supply chain. The State has factored enough markup to account for these additional negotiated costs, which is discussed later in this section.

Testing: The costs associated with testing the drugs at an FDA-qualified laboratory will be borne by the commercial participants in the Program (i.e., the FDA-approved manufacturer or authorized distributor, the Canadian supplier, and/or the U.S. Vendor) and will be negotiated by parties to the various transactions in the supply chain. FDA-approved manufacturers are already required to conduct testing on its products in accordance with

VII. Costs and Cost Savings

Current Good Manufacturing Practice requirements. The Agency will make every effort to partner (through the Canadian suppliers) with manufacturers that are already using (or willing to use) FDA-qualified laboratories for their testing that comply with the requirements of 21 U.S.C. § 384. This will avoid duplicative testing efforts and reduce overall costs by avoiding unnecessary markups for added steps as drugs proceed through the supply chain.

Vendor Costs: The State will have to enter into a contract with the Vendor for purposes of assisting with administration of the Program. These costs will be offset by savings from the Program, but initially will require an upfront appropriation from the State Legislature to fund the activities performed by the Vendor.

Cost Savings

The first step to ensure cost savings is to identify the common set of drugs that will save the largest amount of money among participating agencies. The State collected information from each participating state agency on the amount spent on all prescription drugs in Quarter 2 of calendar year 2018. The State compared the unit cost of each drug to its Canadian equivalent formulation. Because many of the state programs already benefit from deep discounts through other government programs (e.g., 340B covered entities, Medicaid supplemental rebate program requirements, etc.), the State removed drugs that were already deeply discounted and would not yield any greater savings or were ineligible for inclusion due to other restrictions. The State is projecting to save over **\$150 million** dollars annually when the Program is fully operational. Table A presents an example of the analysis conducted to determine the potential cost savings under the Program using a sample of drugs used to treat HIV/AIDS (the data represents utilization and costs for one quarter of 2018).

Table A: Example of Predicted Savings

Brand Name	Utilization	Net Unit Cost	Total Spend/Actual Spend	Canadian Unit Cost *	Potential Spend	Estimated Difference
Atripla Tablet	48,513	\$ 87.90	\$ 4,264,305	\$ 42.25	\$ 2,049,674	\$ 2,214,618
Complera Tablet	15,477	\$ 85.66	\$ 1,325,757	\$ 42.65	\$ 660,094	\$ 665,666
Genvoya Tablet	225,815	\$ 94.98	\$ 21,448,515	\$ 47.63	\$ 10,755,568	\$ 10,692,340
Isentress 400 Mg Tablet	104,607	\$ 24.15	\$ 2,525,748	\$ 12.51	\$ 1,308,634	\$ 1,217,625
Odefsey Tablet	66,699	\$ 86.46	\$ 5,766,699	\$ 42.66	\$ 2,845,379	\$ 2,921,416
Prezista 800 Mg Tablet	71,933	\$ 51.09	\$ 3,675,303	\$ 21.26	\$ 1,529,296	\$ 2,145,761
						\$ 19,857,428
<i>*includes 45% markup</i>						

The markup amount could be considerably less, which would result in an even greater amount of cost savings. However, given the uncertainty of the outcome of negotiations, the State is taking a more conservative approach.

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VIII. Supply Chain Safety Requirements

The Program will leverage the current supply chain that is managing the importation of millions of annual drug shipments into the U.S. Under federal law, in an importation program, the first foreign recipient of a qualifying drug to be imported into the U.S. must be able to document it has purchased the drug from an FDA-authorized manufacturer or distributor, and that the drug was lawful in the first purchaser's foreign country. Additionally, through the Program a Canadian exporter would be required to register with the FDA and to appoint a U.S. agent to comply with established regulations. When the first foreign recipient and the Canadian supplier are the same entity, importation would follow the same basic supply chain as any other prescription drugs imported into the U.S., except there will need to be a re-packaging and/or re-labeling step prior to export from Canada. All imported drugs will be sampled and have batches submitted to a qualified laboratory for testing. This process of testing in the importation Program is more robust than that of current drug importation requirements. The graphic below provides a high-level overview of the process that may be used.



A. Repackaging/Relabeling of Drugs

Prescription drug repackaging and relabeling is already a recognized practice under U.S. law, as no prescription drug product can enter the U.S. without meeting the proper labeling requirements. Currently, FDA regulations require both domestic and foreign drug repackagers to be registered with the FDA. Drug repackaging and relabeling operations are subject to FDA established current good manufacturing practice regulations and FDA inspection. The importation of prescription drugs is regulated and enforced by FDA and U.S. Customs and Border Protection. These regulatory requirements already exist and will govern all sourcing, repackaging, relabeling, distribution, importation, and wholesaling of the drugs that will be approved by the

VIII. Supply Chain Safety Requirements

Agency's Vendor under the Program.

Prescription drugs are repackaged and/or relabeled prior to being shipped into the U.S. for a variety of reasons, including repackaging tablets and capsules from larger bulk containers into smaller containers or blister packs, as an example; or ensuring the labeling information is in English. Manufacturers and distributors are accustomed to these requirements and incorporate them into their day-to-day operations. Arguments that the repackaging and relabeling process will be cost prohibitive and significantly reduce any savings under the Program are simply unfounded as these steps are incorporated into the supply chain currently, regardless of whether a drug is manufactured for the U.S., Europe, Asia, or Canada. While there will be increased cost associated with these activities, it should not be substantially more than is already charged for drugs consumed in Canada when a manufacturer or distributor has to repackage or relabel a product for consumption in that market. The Vendor will be required to negotiate with Canadian suppliers and/or manufacturers who are willing to perform these functions, as they do now. In cases where a negotiated agreement cannot be reached, the Vendor will assume the responsibility (either directly or by contract).

The Agency's Vendor will ensure the Program is in compliance with all state and federal laws. The Vendor will ensure that repackagers are registered with the FDA. The Vendor will ensure that repackagers follow the FDA's unique prescription drug product identifier requirement governing prescription drugs distributed under the DSCSA (i.e., pharmaceutical serialization). This will be accomplished by the Vendor registering with the FDA as a private label distributor in order to obtain its own labeler code and obtain a valid National Drug Code (NDC) number for the drugs imported under the Program. Florida will also list the imported prescription drugs with the FDA. Because the product identifiers must be human and machine readable, repacked and relabeled imported drugs will be immediately identifiable.

These existing requirements along with the drug sampling testing requirements will ensure the imported prescription drugs distributed and dispensed in Florida are approved, not adulterated, and not misbranded.

B. Compliance with Federal Track and Trace Requirements

Through the importation Program, the State would apply existing U.S. prescription drug wholesale track and trace requirements to the imported drug supply chain. The DSCSA was enacted by Congress on November 27, 2013. The process of tracking and tracing ensures that information about the present location of a prescription drug product can be collected and managed throughout the life cycle of the supply chain, and the history of the manufacturing and distribution of the product can be stored and retained.

Title II of the DSCSA outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S. This enhances the FDA's ability to help protect consumers from exposure to drugs that may be adulterated, counterfeit, stolen, contaminated, or otherwise harmful. The system improves detection and facilitates removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers. The deadline for the deployment of these interoperable systems take effect in 2023. DSCSA requires a manufacturer, with each transaction or transfer of product, to provide the subsequent owner with complete

VIII. Supply Chain Safety Requirements

transaction information, transaction history, and a transaction statement which captures the complete product transaction history information.

The Florida Program will require imported prescription drugs be in their finished dosage form for administration and accompanied by documentation to ensure each transaction is traced from manufacturer to dispensing. For each transaction, the following documentation would be required:

1. Transaction information such as:
 - Proprietary or established name or names of the product;
 - Strength and dosage form of the product;
 - NDC number of the product;
 - Container size;
 - Number of containers;
 - Lot number of the product;
 - Date of the transaction;
 - Date of the shipment, if more than twenty-four (24) hours after the date of the transaction;
 - Business name and address of the person from whom ownership is being transferred; and
 - Business name and address of the person to whom ownership is being transferred.
2. Transaction history, including the transaction information for each prior transaction going back to the manufacturer of the product.
3. Transaction statement, a statement in paper or electronic form, that the entity transferring ownership in a transaction:
 - Is authorized as required under the DSCSA;
 - Received the product from a person that is authorized as required under the DSCSA;
 - Received transaction information and a transaction statement from the prior owner of the product;
 - Did not knowingly ship suspect or illegitimate product;
 - Had systems and processes in place to comply with verification requirements; and
 - Did not knowingly provide false transaction information or alter the transaction history.

Given the impending 2023 deadline for all participants in the supply chain, the FDA initiated a pilot project in which manufacturers, repackagers, and other stakeholders can pilot the use of innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the U.S. Pilots have already commenced and yielded positive results related to the use of blockchain technology pertaining to food manufacturing and distribution, which allows data to be distributed along a network while enabling each participant to maintain a record of the entire process. Similar track and trace innovative technology is being piloted related to the pharmaceutical supply chain

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among companies such as Merck, Walmart, KPMG, and IBM.⁸ Results from the pharmaceutical pilots are expected in late 2019. These initiatives demonstrate that companies have already invested in technological advances related to electronic track and trace processes that address historical concerns about the feasibility of ensuring the safety of drugs as they travel through the supply chain under a Canadian commercial drug importation program.

One of the criteria the Agency will review when selecting a Vendor to participate in the Program is their technological capabilities with respect to ensuring that all transactions are recorded electronically and that all participants in the Program (supplier, importer, manufacturer, etc.) have access to its electronic system. As an added enhancement, the State will be seeking vendors that want to pilot an electronic track and trace system (which must comply with the DSCSA) sooner than the 2023 deadline.

C. Testing of Drugs by Qualified Laboratories



All FDA-registered and approved facilities must comply with CGMP. As a part of CGMP, manufacturers routinely test a sample of a batch to ensure that it meets quality, strength, purity, and validate the identity of the drug product. The FDA has laboratories across the country that test drugs to standards set by the USP. The Program will require testing of qualifying prescription drugs. The batch testing must be conducted by FDA-

qualified laboratories, as defined under 21 U.S.C. § 382.

21 U.S.C. 384(d)(J) identifies minimum laboratory testing requirements for batches based upon whether the Canadian exporter is the first foreign recipient of the qualifying prescription drug being imported. The importer must maintain and provide access to documentation, outlined below.

In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

1. Documentation demonstrating that the prescription drug was received by the first foreign recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.
2. Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.
3. In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.
 - a. In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

⁸ <https://www.prnewswire.com/news-releases/ibm-kpmg-merck-and-walmart-to-collaborate-as-part-of-fdas-program-to-evaluate-the-use-of-blockchain-to-protect-pharmaceutical-product-integrity-300866751.html>

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- b. In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

The Vendor shall ensure that the Canadian supplier provides documentation that either the manufacturer or supplier has tested the drugs in a qualified laboratory. If the manufacturer/supplier has not tested the drug in a qualified laboratory, the Vendor shall have the appropriate batch sample sent to a qualified laboratory for testing. Documentation of the testing should be included with the track and trace documentation before an imported drug can enter Florida. This step will also allow U.S. Customs Agents to confirm the integrity of the full shipment of the drug before it enters the U.S.

D. Record Keeping and Reporting

The Program will require compliance with the FDCA, which is intended to protect public health, safety, and welfare and to prevent fraud, adulteration, and misbranding in the preparation, manufacturing, repackaging, or distribution of drugs. As previously stated, the State intends to require the contracted Vendor to maintain an electronic system that will be used to collect and maintain transaction information as the prescription drug product(s) transition through the supply chain. The Vendor will be required to have back-up systems to ensure at the minimum the following information is maintained on behalf of eligible importer(s):

- Name and quantity of the active ingredient;
- Description of the dosage;
- Date received;
- Quantity received;
- Point of origin and destination; and
- Price paid.

Participating Canadian suppliers must submit the following documentation to the Vendor regarding the original source of the drug:

- The name of the manufacturer of the drug;
- The date on which the drug was manufactured;
- The location (country, state or province and city) where the drug was manufactured;
- The date on which the drug was shipped;
- The required laboratory testing results;
- The quantity of each lot of the drug originally received and the source of the lot;
- The lot or control number and the batch number assigned to the drug by the manufacturer; and
- The expiration date.

In addition to complying with federal documentation requirements, all eligible importers must also comply with Florida's Drug, Devices, and Cosmetic Act requirements (codified in Chapter 499, Florida Statutes and enforced by DBPR), which requires that they maintain specific business records and make them available for inspection by the State

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upon request. The Agency intends to ensure that DBPR has access to the Vendor's electronic system and all transaction information. This will serve as an added safeguard. The State is willing to provide the FDA with access to the system as well.

In addition to any electronic or hardcopy data that is maintained related to the supply chain documentation, eligible importers will have to make available upon request to DBPR all written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale distributors must include in their written policies and procedures:

1. A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.
2. A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:
 - a. Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency.
 - b. Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or
 - c. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.
3. A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency occurs.
4. A procedure to ensure that any outdated prescription drugs are segregated from other drugs and returned to the manufacturer or repackager or destroyed. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for two (2) years after disposition of the outdated drugs.

E. Immediate Suspension

The State will have systems in place to respond appropriately to suspect and/or illegitimate products.

Suspect products refer to prescription drugs for which there is a reason to believe that the prescription drugs are:

- Potentially counterfeit, diverted, or stolen;
- Potentially adulterated, such that the prescription drug would result in serious adverse health consequences or death to humans; or
- Potentially the subject of a fraudulent transaction and appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Illegitimate products refer to prescription drugs for which credible evidence shows that the prescription drugs are:

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- Counterfeit, diverted, or stolen;
- Intentionally adulterated, such that the prescription drug would result in serious adverse health consequences or death to humans; or
- The subject of a fraudulent transaction and appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

For suspect products, the Agency's Vendor, eligible importer, or Canadian supplier must:

- Quarantine the suspect products;
- Investigate whether the prescription drugs are illegitimate products; and
- Notify the FDA if the investigation finds that the prescription drugs are not suspect products.

If the investigation finds that the prescription drugs are illegitimate products, the Agency's Vendor, eligible importer, or Canadian supplier must:

- Notify the FDA within twenty-four (24) hours of determining the illegitimate product status;
- Quarantine the illegitimate products until dispositioned;
- Disposition the illegitimate products through disposal or return of the prescribed drug;
- Provide reasonable assistance for disposition to parties who have received the illegitimate products; and
- Retain a sample.

If the Agency's Vendor, eligible importer, or Canadian supplier are notified by the FDA or another party of the illegitimate products, they must follow the quarantine and disposition procedures described above. The Agency's licensed Vendor will immediately suspend the importation of a specific drug or drugs by a specific importer if it discovers that any drug or activity is in violation of any federal or state law or regulation.

The Agency's licensed Vendor may revoke the suspension if, after investigating, it determines that the public is adequately protected from counterfeit or unsafe drugs being imported into the state. Additionally, federal law requires a specific notification process. The Vendor will require all entities to comply within the mandated twenty-four hours after determining a product is illegitimate.

F. Product Recall

Recalls are mainly done voluntarily by the manufacturer or distributor of the drug. The mechanics of handling recalls of qualifying prescription drugs imported under the program will follow the standard FDA established process. The FDA has jurisdiction over drugs to monitor product recalls and maintains a website of products that have been recalled.

In addition, the Vendor (permitted in accordance with Florida law) must comply with all state laws, specifically Chapter 499.0121, F.S. Wholesale distributors are required to

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have a procedure to be followed for handling recalls and withdrawals of prescription drugs.

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IX. Conclusion

Based on the strength of the Program design articulated in this concept paper, the State of Florida is confident that Secretary Azar can certify to Congress that the implementation of a prescription drug importation program poses no additional risk to the public's health and safety and will result in cost savings. The State of Florida urges Secretary Azar to do so and to begin to develop regulations that would allow for the commercial importation of lower cost drugs into the U.S. **Importantly, while this concept paper only discusses importation to state entities, Florida's new law does not and should not be interpreted to prevent importation from private wholesalers and pharmacies, which is the purpose of 21 U.S.C. § 384. The State of Florida welcomes and fully supports importation to private entities.**

DHHS may wish to consider initiating a pilot to test new programs in order to determine the best regulatory framework in which to proceed. The DHHS can use this concept paper to develop parameters in which states may pilot commercial importation prescription drug programs in coordination and cooperation with the FDA.

Americans are very concerned about prescription costs. It is time to try something different and innovative that maximizes opportunities for cost savings – one way is to leverage the wisdom that Congress had 16 years ago when passing legislation that created a pathway to obtaining lower cost prescription drug alternatives from Canada. The State urges DHHS to act swiftly and boldly amidst new interest in the development of a regulatory construct that fully implements 21 U.S.C § 384.



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Exhibit A: Additional Information About Each State Agency

Department of Health



The Florida Department of Health (DOH) is the public health agency in the State of Florida and oversees a myriad of public health programs for the State, including providing health care services in county health departments throughout the state. County health departments provide (directly or by contract) prenatal care, immunization services, screening and treatment for sexually transmitted disease, family planning services, and basic sick care services. Florida's county health departments provide services to approximately one million consumers each year. The Bureau of Public Health Pharmacy within DOH is responsible for the procurement of prescribed drugs, which are shipped to county health departments. Annually, DOH spends \$138 million on prescribed drugs through its county health departments.

Agency for Health Care Administration



The Agency for Health Care Administration (Agency) is the chief health policy and planning entity for the state of Florida. The Agency serves as the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act. The Florida Medicaid program serves approximately 3.9 million Medicaid recipients at a cost of over \$25 billion annually and has over 100,000 actively enrolled service providers. During state fiscal year 2017-2018, the Agency spent over \$3 billion dollars on prescribed drugs through the Florida Medicaid program.

Florida Department of Corrections



The Florida Department of Corrections (FDC) is the third largest state prison system in the country with a budget of \$2.4 billion, approximately 96,000 inmates incarcerated and nearly 166,000 offenders on active community supervision (probation). FDC has one hundred forty-three (143) facilities statewide, including fifty (50) major institutions, seventeen (17) annexes, seven (7) private facilities (contracts for the private facilities are overseen by the Florida Department of Management Services (DMS)), thirty-four (34) work camps, three (3) re-entry centers, two (2) road prisons, one (1) forestry camp, one (1) basic training camp, twelve (12) FDC operated work release centers along with sixteen (16) more work release centers operated by various private vendors (FDC oversees these contracts). FDC dispenses and administers more than 1.5 million prescriptions per year to inmates. FDC pharmacy staff dispenses the medications, while the health care contractor administers or distributes the medications directly to the inmates.

Agency for Persons with Disabilities



The Agency for Persons with Disabilities (APD) works in partnership with local communities and private providers to assist people who have developmental disabilities and their families. APD also provides assistance in identifying the needs of people with developmental disabilities for supports and services. APD's yearly expenditures for prescribed drugs during 2017-2018 fiscal year was approximately \$700,000.

Department of Children and Families



The mission of the Department of Children and Families (DCF) is to work in partnership with local communities to protect the vulnerable, promote strong and economically self-sufficient families, and advance personal and family recovery and resiliency. DCF has a number of responsibilities including serving as the state mental health authority, regulating certain licensed mental health treatment facilities, determining eligibility for Medicaid and other cash assistance programs for low-income families, managing the state's child welfare and adult protective services programs, and operating other programs that address the needs of vulnerable Floridians. During the 2017-2018 fiscal year DCF served 3,384 individuals at the state hospitals and spent approximately \$9 million on prescribed drugs.

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Exhibit B: List of Potential Canadian Suppliers

Familiprix, Inc. 6000, rue Armand-Viau Québec (Québec) G2C 2C5	McKesson Distribution Spécialisée Inc. 8449 Lawson Road, Unit 102 Milton (Ontario) L9T 9L1
LE Groupe Jean Coutu (PJC) Inc. 530, Rue Bériault Longueuil (Québec) J4G 1S8	Andrew and David Wholesale Ltd. 3330 Ridgeway Drive, Unit12 Mississauga, Ontario LL 5Z9
Mcmahon Distributeur Pharmaceutique Inc. 12225, Boul. Industriel, Suite 100 Montréal (P.A.T.) Québec H1B 5M7	
McKesson Services Pharmaceutiques 8290, Boul Pie-IX Montréal (Québec) H1Z 4E8	
Amerisource Bergen Canada 10600, Boul. du Golf Anjou (Québec) H1J 2Y7	
Kohl & Frisch Limited 7622, Keele Street Concord (Ontario) L4K 2R5	
Shoppers Drug Mart Limited 243, Consumers Road North York (Ontario) M2J 4W8	
Distributions Pharmaplus Inc. 2905, Rue de Celles # 102 Québec (Québec) G2C 1W7	
Innomar Strategies Inc. 3450, Harvester Road Burlington (Ontario) L7N 3M7	
GMD Distribution Inc. 1215, North Service Road W. Oakville (Ontario) L6M 2W2	
PharmaTrust Med Services Inc. 2880 Brighton Road, Unit 2 Oakville (Ontario) L6H 5S3	