By the Committee on Health Policy; and Senators Bean and Gruters

588-03459-19 20191528c1

A bill to be entitled

An act relating to the Canadian Prescription Drug Importation Program; creating s. 381.02035, F.S.; requiring the Agency for Health Care Administration to establish the Canadian Prescription Drug Importation Program; defining terms; authorizing a Canadian supplier to export drugs into this state under the program under certain circumstances; providing eligibility criteria and requirements for drug importers; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program; providing responsibilities for the vendor; providing eligibility criteria for prescription drugs, Canadian suppliers, and importers under the program; requiring participating Canadian suppliers and importers to comply with specified federal requirements for distributing prescription drugs imported under the program; prohibiting Canadian suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the program outside the state; providing certain documentation requirements; requiring the agency to suspend the importation of drugs in violation of this section or any federal or state law or regulation; authorizing the agency to revoke the suspension under certain circumstances; requiring the agency to request federal approval of the program; requiring the request to include certain information; requiring the agency to begin operating

the program within a specified timeframe after receiving federal approval; requiring the agency, in consultation with the vendor, to submit an annual report to the Governor and the Legislature by a specified date; providing requirements for such report; authorizing the agency to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.02035, Florida Statutes, is created to read:

381.02035 Canadian Prescription Drug Importation Program.—

(1) PROGRAM ESTABLISHED.—The Agency for Health Care Administration shall establish a program for the importation of safe and effective prescription drugs from Canada which have the highest potential for cost savings to the state.

(2) DEFINITIONS.—As used in this section, the term:

(a) "Agency" means the Agency for Health Care Administration.

(b) "Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.

(c) "Drug" or "prescription drug" has the same meaning as "prescription drug" in s. 499.003.

(d) "Federal Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351

et seq.

(e) "Importer" means a wholesale distributor, pharmacy, or pharmacist importing prescription drugs into this state under the program.

(f) "Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 465.

(g) "Program" means the Canadian Prescription Drug Importation Program.

(h) "Track-and-trace" means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the Drug Quality and Security Act, Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.

(i) "Vendor" means the entity contracted by the agency to manage specified functions of the program.

(3) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may export drugs into this state under the program if the supplier meets all of the following requirements:

(a) Complies fully with relevant Canadian federal and provincial laws and regulations.

(b) Complies fully with the Federal Act, including all other state and federal law and regulations relating to the track-and-trace requirements at the package level.

(c) Submits evidence at time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security

arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security arrangement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary. The purposes of the bond or other security arrangements for the program are to:

1. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the supplier fails to pay within 30 days after assessment;

2. Ensure performance of contractual and statutory obligations by the supplier through use of a bond or other comparable security arrangements to receive payment of any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the supplier is non-compliant with its contractual and statutory obligations. If the supplier is assessed a penalty under the program and fails to pay within 30 days after that assessment, the agency, the state, or an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

3. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the supplier's contract under the program has ended with the agency or the state, the supplier's license is no longer valid, or the program has ended, whichever occurs last.

A surety bond or other comparable security arrangement is required regardless of the time of bid or negotiation process

used by the agency or the type of final contract or agreement executed for services.

(d) Is identified by the vendor as eligible to participate in the program.

(e) Submits evidence at the time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security arrangement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary. The purposes of the bond or other security arrangements for the program are to:

1. Indemnify the supplier in the event that any civil or criminal legal action is brought by the state, the agency, any other state agency, or private individuals or entities against the supplier because of the supplier’s failure to perform under the contract, including, but not limited to, causes of actions for personal injury, negligence, and wrongful death;

2. Ensure payment by the supplier of legal judgements and claims that have been awarded to the state, the agency, other entities acting on behalf of the state, individuals, or organizations if the supplier is assessed a final judgement or other monetary penalty in a court of law for a civil or criminal action related to participation in the program. The bond or

comparable security arrangement may be accessed if the supplier fails to pay any judgement or claim within 60 days after final judgement; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to 1 year after the supplier's contract under the program has ended with the agency or the state, the supplier's license is no longer valid, or the program has ended, whichever occurs last.

(4) ELIGIBLE IMPORTERS.—

(a) The following entities or persons may import prescription drugs from a Canadian supplier under the program:

1. A wholesale distributor.

2. A pharmacy.

3. A pharmacist.

(b) An eligible importer must meet all of the following requirements at time of contract award and throughout the contract term:

1. Register with the vendor before importing drugs into the state under the program and be deemed in compliance with all requirements, including any relevant provisions of the Federal Act.

2. Submit evidence at time of contract award and throughout the contract term of a surety bond or other comparable security arrangement from this state or any other state in the United States in the amount of $1 million. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security agreement such as an

irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangements for the program are to:

a. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the importer fails to pay within 30 days after assessment;

b. Ensure performance of contractual and statutory obligations by the importer through use of a bond or other comparable security arrangements to receive payment of any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the importer is non-compliant with its contractual and statutory obligations. If the importer is assessed a penalty under the program and fails to pay within 30 days after that assessment, the agency, the state, or an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

c. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the importer's contract under the program has ended with the agency or the state, the importer's license is no longer valid, or the program has ended, whichever occurs last.

A surety bond or comparable document is required regardless of the time of bid or negotiation process used by the agency or the type of final contract or agreement executed for services.

(c) Submits evidence at the time of contract award and throughout the contract term of a surety bond or comparable

security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security agreement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangements for the program are to:

1. Ensure participation of the supplier in any civil or criminal legal action by the state, the agency, any other state agency, or private individuals or entities against the supplier because of the supplier's failure to perform under the contract, including, but not limited to causes of actions for personal injury, negligence, and wrongful death;

2. Ensure payment by the supplier through the use of a bond or other comparable security arrangements of legal judgements and claims that have been awarded to the agency, the state, other entities acting on behalf of the state, individuals, or organizations if the supplier is assessed a final judgement or other monetary penalty in a court of law for a civil or criminal action under the program. The bond or comparable security arrangement will be accessed if the supplier fails to pay any judgement or claim within 60 days after final judgement; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to 1 year after the supplier's contract under the program

has ended with the agency or the state, the supplier's license is no longer valid, or the program has ended, whichever occurs last.

(5) IMPORTATION PROCESS.—

(a) The agency shall contract with a vendor to provide services under the program. The vendor must submit evidence of a surety bond with any bid or initial contract negotiation documents and maintain documentation of evidence of such a bond with the agency throughout the contract term of a surety bond from this state or any other state in the United States in the same amount of $1 million. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security agreement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangements for the program are to:

1. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the vendor fails to pay within 30 days after assessment;

2. Ensure performance of contractual and statutory obligations by the vendor through use of a surety bond or other comparable security arrangements to receive payment of any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the vendor is non-compliant with its contractual and statutory obligations. If the vendor is assessed a penalty under the program and fails to pay within 30 days after that assessment, the agency, the state, or

an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

3. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the vendor's contract under the program has ended with the agency or the state, the importer's license is no longer valid, or the program has ended, whichever occurs last.

A surety bond or comparable document is required regardless of the time of bid or negotiation process used by the agency or the type of final contract or agreement executed for services.

(b) Submits evidence at the time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security arrangement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which names the State of Florida as a beneficiary. The purposes of the bond or other security arrangements for the program are to:

1. Ensure participation of the vendor in any civil or criminal legal action by the state, the agency, any other state agency, or private individuals or entities against the vendor because of the vendor's failure to perform under the contract,

including, but not limited to causes of actions for personal injury, negligence, and wrongful death;

2. Ensure payment by the vendor through the use of a bond or other comparable security arrangements of legal judgements and claims that have been awarded to the agency, the state, other entities acting on behalf of the state, individuals, or organizations if the vendor is assessed a final judgement or other monetary penalty in a court of law for a civil or criminal action under the program. The bond or comparable security arrangement will be accessed if the vendor fails to pay any judgement or claim within 60 days after final judgement; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to 1 year after the vendor's contract under the program has ended with the agency or the state, the vendor's license is no longer valid, or the program has ended, whichever occurs last.

(c) The vendor shall provide all of the following services at a minimum:

1. Develop a list every 3 month of drugs that have the highest potential for cost savings to the state if imported from Canada. In developing the list, the vendor shall consider, at a minimum, which drugs will provide the greatest cost savings to the state, including drugs for which there are shortages, specialty drugs, and high-volume drugs. The agency may direct the vendor to revise the list, as necessary.

2. Identify Canadian suppliers that are in full compliance with relevant Canadian federal and provincial laws and regulations and the Federal Act and who have agreed to export

drugs identified on the list. The vendor must verify that such Canadian suppliers meet all of the requirements of the program and will export drugs at prices that will provide cost savings to the state while meeting or exceeding the track-and-trace federal and state laws and regulations.

3. Contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and Canadian suppliers, to import drugs under the program.

4. Maintain a listing of all registered importers that participate in the program.

5. Ensure compliance with Title II of the federal Drug Quality and Security Act P.L. 113-54 by all suppliers, importers and other distributors and participants in the program.

6. Assist the agency with the annual report as required in subsection (12) and provide any information requested by the agency for such report on a timely basis.

(d) The profit margin and administrative fees of any participating wholesaler, pharmacy, or pharmacist on imported drug products is limited to a maximum amount as specified annually in the General Appropriations Act.

(6) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers may import a drug from an eligible Canadian supplier if:

(a) The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;

(b) Importing the drug would not violate the patent laws of the United States;

(c) Importing the drug is expected to generate cost savings; and

(d) The drug is not:

1. A controlled substance as defined in 21 U.S.C. s. 802;

2. A biological product as defined in 42 U.S.C. s. 262;

3. An infused drug;

4. An intravenously injected drug;

5. A drug that is inhaled during surgery; or

6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(7) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers and importers participating under the program:

(a) Must comply with the tracking and tracing requirements of 21 U.S.C. ss. 360eee et seq.

(b) May not distribute, dispense, or sell drugs imported under the program outside of the program or outside of this state.

(8) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

(a) The vendor shall ensure the safety and quality of drugs imported under the program. The vendor shall:

1. For an initial imported shipment, ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the Federal Act.

2. For any subsequent imported shipment, ensure that a statistically valid sample of the shipment was tested for authenticity and degradation in a manner consistent with the Federal Act.

3. Certify that the drug:

a. Is approved for marketing in the United States and is

not adulterated or misbranded; and

b. Meets all of the labeling requirements under 21 U.S.C. s. 352.

4. Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

5. Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the Federal Act and any other applicable federal and state laws and regulations governing laboratory qualifications.

(b) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the Federal Act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(c) The vendor shall maintain information and documentation submitted under this section for a period of at least 7 years.

(d) A participating importer must submit the all of following information to the vendor:

1. The name and quantity of the active ingredient of the drug.

2. A description of the dosage form of the drug.

3. The date on which the drug is received.

4. The quantity of the drug that is received.

5. The point of origin and destination of the drug.

6. The price paid by the importer for the drug.

(e) A participating Canadian supplier must submit the following information and documentation to the vendor specifying

all of the following:

1. The original source of the drug, including:

a. The name of the manufacturer of the drug.

b. The date on which the drug was manufactured.

c. The location (country, state or province, and city) where the drug was manufactured.

2. The date on which the drug is shipped.

3. The quantity of the drug which is shipped.

4. The quantity of each lot of the drug originally received and from which source.

5. The lot or control number and the batch number assigned to the drug by the manufacturer.

(f) The agency may require that the vendor collect any other information necessary to ensure the protection of the public health.

(9) IMMEDIATE SUSPENSION.—The agency shall immediately suspend the importation of a specific drug or the importation of drugs by a specific importer if it discovers that any drug or activity is in violation of this section or any federal or state law or regulation. The agency may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe drugs being imported into the state.

(10) FEDERAL APPROVAL.—By July 1, 2020, the agency shall submit a request to the United States Secretary of Health and Human Services for approval of the program under 21 U.S.C. s. 384(l). At a minimum, the request must do all of the following:

(a) Describe the agency's plan for operating the program.

(b) Demonstrate how the drugs imported into the state under

the program will meet the applicable federal and state standards for safety and effectiveness.

(c) Demonstrate how the drugs imported into the state under the program will comply with federal tracing procedures.

(d) Include a list of proposed drugs that have the highest potential for cost savings to the state through importation at the time that the request is submitted.

(e) Estimate the total cost savings attributable to the program.

(f) Provide the costs of program implementation to the state.

(g) Include a list of potential Canadian suppliers from which the state would import drugs and demonstrate that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations as well as all applicable federal and state laws and regulations.

(11) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of federal approval of the program, the agency shall notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives. The program may not be implemented until the Legislature approves the program as authorized by the federal government. As part of its review process for implementation approval, the Legislature shall consider the estimated cost savings to the state and whether the program has met the required safety standards.

(12) ANNUAL REPORT.—By December 1 of each year, the agency shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the

operation of the program during the previous fiscal year. The report must include, at a minimum:

(a) A list of the drugs that were imported under the program;

(b) The number of participating entities;

(c) The number of prescriptions dispensed through the program;

(d) The estimated cost savings during the previous fiscal year and to date in the program;

(e) A description of the methodology used to determine which drugs should be included; and

(f) Documentation of how the program ensures the following criteria:

1. Canadian suppliers participating in the program are of high quality, high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations as well as all United States and Florida laws and regulations;

2. Drugs imported under the program are not shipped, sold, or dispensed outside of the state or the program once in the possession of the importer;

3. Drugs imported under the program are unadulterated, potent, and safe;

4. The program does not put consumers at a higher health and safety risk than if the consumer did not participate; and

5. The program provides cost savings to the state.

(13) RULEMAKING.—The agency may adopt rules necessary to implement this section.

Section 2. This act shall take effect July 1, 2019.