AHCA CONTRACT NO. MED214
AMENDMENT NO. 2

THIS CONTRACT, entered into between the **STATE OF FLORIDA, AGENCY FOR HEALTH CARE ADMINISTRATION**, hereinafter referred to as the "**Agency**" and **LIFESCIENCE LOGISTICS, LLC**, hereinafter referred to as the "**Vendor**," is hereby amended as follows

1. **Standard Contract**, the lead paragraph is hereby amended to now read as follows:

THIS CONTRACT is entered into between the State of Florida, **AGENCY FOR HEALTH CARE ADMINISTRATION**, hereinafter referred to as the "**Agency**", whose address is 2727 Mahan Drive, Tallahassee, Florida 32308, and **LIFE SCIENCE LOGISTICS, LLC**, hereinafter referred to as the "**Vendor**", whose address is 3100 Olympus Boulevard, Suite 100, Dallas, Texas 75109, to provide services necessary for the implementation, operation, and management of the Canadian Prescription Drug Importation Program.

2. **Standard Contract**, **Section III.,** THE VENDOR AND AGENCY HEREBY MUTUALLY AGREE, **Sub-Section B.,** Contract Managers, **Item 2.,** is hereby amended to now read as follows:

2. The Vendor's Contract Manager's contact information is as follows:

Chris Mizener
LifeScience Logistics, LLC
3100 Olympus Boulevard
Suite 100
Dallas, Texas 75109
(469) 844-5721

3. **Attachment I**, Scope of Services, is hereby deleted in its entirety and replaced with **Attachment I-A**, Scope of Services – Update: August 1, 2021, attached hereto and made a part of this Contract. All references in this Contract to **Attachment I**, Scope of Services, shall hereinafter refer to **Attachment I-A**, Scope of Services – Update: August 1, 2021.

All provisions not in conflict with this Amendment are still in effect and are to be performed at the level specified in this Contract.

This Amendment and all its attachments are hereby made a part of this Contract.

This Amendment cannot be executed unless all previous Amendments to this Contract have been fully executed.

IN WITNESS WHEREOF, the Parties hereto have caused this fifty-seven (57) page Amendment to be executed by their officials thereunto duly authorized. This Amendment is not valid until signed and dated by both Parties.

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AHCA CONTRACT NO. MED214
AMENDMENT NO. 2

LIFESCIENCE LOGISTICS, LLC		STATE OF FLORIDA, AGENCY FOR HEALTH CARE ADMINISTRATION	
SIGNED BY:	DocuSigned by: Richard Beeny 4FB00D9F3D844C1...	**SIGNED BY:**	DocuSigned by: Simone Marstiller D7DBA2C36BC64B3...
NAME:	Richard Beeny	**NAME:**	Simone Marstiller
TITLE:	CEO	**TITLE:**	Secretary
DATE:	9/10/2021	**DATE:**	9/10/2021

List of Attachments included as part of this Amendment:

Specify Type	Number	Description
Attachment	**I-A**	Scope of Services – Update August 1, 2021 (55 Pages)

ATTACHMENT I-A
SCOPE OF SERVICES
Update August 1, 2021

Table of Contents

ATTACHMENT I-A
SCOPE OF SERVICES
Update August 1, 2021

I. Service(s) to be Provided

A. Background

During the 2019 Florida Legislative session, Governor Ron DeSantis signed into law House Bill 19/Senate Bill 1528 that creates section (§) 381.02035, Florida Statutes (F.S.) establishing the Canadian Prescription Drug Importation Program (Program) within the Agency for Health Care Administration (Agency). The law requires the Agency to contract with a vendor that will assist with overseeing the importation of specific prescription drugs from eligible Canadian suppliers. Eligible importers are limited to pharmacists or wholesalers providing services to individuals on behalf of State programs including pharmacies enrolled in Florida Medicaid, pharmacies or wholesalers employed or contracted with the Department of Corrections, county health departments, developmental disability centers, and treatment facilities as defined in s. 394.455, F.S. Consistent with the requirements in the Medicare Modernization Act of 2003 (21 United States Code (U.S.C.) § 384), the law defines the prescription drugs that are eligible for importation, including those that are excluded (e.g., controlled substances, biologic drugs, etc.).

B. Overview/Purpose

The purpose of this contract is to specify requirements for a Vendor to provide services necessary for the implementation, operation, and management of the Program.

The Vendor shall perform duties as specified in this Contract and in accordance with all applicable State (Chapter 499, F.S. and Chapter 61N, F.A.C.) and federal (Title II of the Drug Quality Security Act (DQSA) (Pub. L. No. 113-54), the Federal Drug Supply Chain Security Act (DSCSA)) rules and statutes.

The Agency will retain ultimate responsibility for ensuring that the Vendor operates consistently with all federal rules and regulations related to the importation of prescription drugs. The Agency will maintain active oversight and monitoring functions over Vendor operations and will actively collaborate with DHHS and DOH to ensure success under the Program.

II. Manner of Service(s) Provision:

A. Services Provided by the Agency

The Agency will provide the following information and services:

1. Establishing standards and requirements to ensure receipt of complete and accurate data for program administration.

2. Establishing Vendor requirements for receiving orders and invoicing state agencies that will purchase imported prescription drugs under the Program.

3. Providing information related to federal and State requirements related to the provision of services under this Contract and expectations of the Vendor.

4. Collaborate with the Vendor on identifying prescription drugs eligible for importation that yield the highest potential for cost savings.

5. Monitoring and evaluating the Vendor's compliance with the requirements of this Contract. The Agency reserves the right to request additional information in support of monitoring the Vendor's performance to ensure compliance with the requirements of this Contract.

6. Executing inter-agency agreements with other State agencies that will receive imported prescription drugs to determine quantities needed of each drug and delivery locations for prescription drug shipments.

7. Reviewing all deliverables submitted by the Vendor in a timely manner. The Agency reserves the right to approve, deny, or require revision to any submitted deliverables.

8. Determining whether the Vendor has violated a contractual obligation and assessing liquidated damages or monetary sanctions, when necessary.

9. Providing contract management of this Contract in good faith, with the best interest of the State and persons it serves being the prime consideration. The Agency shall make all clarification of policy and contractual requirements as needed or as requested by the Vendor. The Vendor may seek a formal interpretation of the Contract from the Agency by submitting a written request to the Agency's Deputy Secretary for Medicaid at the following mailing address:

Deputy Secretary for Medicaid
Agency for Health Care Administration
Prescription Drug Importation Request for Contract Interpretation, Mail Stop 8
2727 Mahan Drive, MS#8
Tallahassee, FL 32308

10. Performing at least one (1) on-site readiness review of the Vendor during the implementation of this Contract. The readiness review process shall include additional on-site and virtual meetings as needed and required by the Agency.

11. Meeting with the Vendor in person or virtually after execution of this Contract to discuss the Vendor's proposed implementation plan, anticipated time frames, and to determine information and other resources needed to complete the final implementation plan.

12. Ensuring that the Vendor has the necessary data and information from the State agencies involved in the Program to fulfill the requirements of this Contract.

B. Services Provided by the Vendor

The Vendor shall facilitate the implementation, management, and operational duties of importing prescription drugs into Florida from Canadian Suppliers. The Vendor, at a minimum, shall be responsible for the following:

1. General Responsibilities

a. The Vendor shall:

1) Comply with all State and federal laws related to the importation of prescription drugs from Canada, including the federal Title II of the DSCSA; § 381.02035, F.S.; Chapter 499, F.S.; and Chapter 61N-1, Florida Administrative Code (F.A.C.).

2) Be licensed, minimally, as a prescription drug wholesale distributor through the Florida Department of Business and Professional Regulation (DBPR).

3) Ensure that Canadian prescription drugs purchased and imported under the Program have equivalents manufactured by a United States (U.S.) Food and Drug Administration (FDA) approved manufacturer.

4) Purchase eligible prescription drugs from Canadian suppliers as approved by the Agency.

5) Make available publicly registration data connected with drug labeler codes to identify FDA-approved manufacturers for qualifying prescription drugs.

6) Submit pre-import requests to the FDA as required by Title 21 CFR § 251.5.

7) Ensure that imported prescription drugs enter into the U.S. through a U.S. customs and border patrol free trade zone.

8) Establish a process for distributing imported prescription drugs and receiving orders and delivery information from State agencies that will receive imported prescription drugs.

9) Identify and enter into agreements with Canadian suppliers and manufacturers that are in full compliance with relevant Canadian federal and provincial laws and regulations and

who have agreed to export drugs at prices that will provide cost savings to the State.

10) Be responsible for directly reimbursing the Canadian manufacturer(s) or Canadian wholesaler(s) for imported prescription drugs. Copies of remittance notifications must be made available to the Agency upon request.

11) Assume ownership and liability of imported prescription drugs until ownership and custody of the imported prescription drugs are in the possession of the State.

12) Contract with a qualifying laboratory(s) that has ISO 17025 accreditation to perform statutorily required testing on selected samples of imported prescription drugs to verify authenticity.

13) Maintain documentation that sample testing of the prescription drugs occurred at a qualified laboratory, as required by 21 U.S.C. 384.

14) Maintain documentation that the imported prescription drug is approved for marketing in the United States, has not been adulterated or misbranded, and meets all labeling requirements under state and federal law.

15) Lease or purchase a facility in Florida that has adequate space, security, and environmental conditions necessary for the storage of imported prescription drugs.

16) Ship and distribute imported prescription drugs from the Canadian manufacturer(s) or wholesaler(s) to the receiving State agency(s) or its designee(s).

17) Maintain additional information and documentation from Canadian suppliers as specified in § 381.02035, F.S.

18) Assist the Agency in the preparation of an annual legislative report on the efficacy of the Program.

19) Complete quarterly reports required for submission to the U.S. FDA in accordance with Title 21 CFR § 251.19.

20) Acknowledge all Agency inquiries within twenty-four (24) hours and respond to them on the next business day. Responses due on a weekend or State holiday shall be submitted to the Agency no later than the next business day.

21) Meet with Agency staff both face-to-face and via conference call throughout the term of this Contract period concerning

any issues as needed and required to fulfill the responsibilities of this Contract.

22) Develop, manage, maintain, and modify an electronic system and database specific to the requirements of this Contract.

23) Support the exchange of data with necessary partners, as approved by the Agency, in the required formats as is necessary to support this Contract.

24) Develop, deliver, and comply with all reporting requirements established by the Agency, including ad hoc reporting, as applicable, at no additional cost to the Agency. Reports due on a weekend or State holiday shall be submitted to the Agency no later than the next business day.

25) Create and deliver an implementation plan within ten (10) calendar days of the execution of this contract.

26) Provide outreach and communication to other state agencies regarding use of the online platform for ordering and invoicing prescription drugs purchased under the Program as approved and directed by the Agency.

27) Deliver training to pharmacies, Agency staff, and other state agencies as identified in this Contract or otherwise directed by the Agency.

28) Provide for any equipment necessary for the operation and distribution of imported prescription drugs necessary for the performance of duties specified in this Contract at a location within the State of Florida.

29) Provide sufficient qualified staff to meet the requirements of this Contract.

30) Maintain Agency-approved procedures for all aspects of the work performed under this Contract.

31) Maintain a structured complaint process that includes tracking and escalation of issues. The Vendor shall develop a performance dashboard for this process, as specified and approved by the Agency.

32) Develop and submit internal quality control (IQC) assurances that ensure appropriate administration of Vendor responsibilities specified under this Contract.

33) Obtain approval from the Agency prior to any delegation of responsibilities related to this Contract.

34) Submit all policies and procedures to the Agency in accordance with an Agency-approved implementation plan and as otherwise specified in this Contract.

b. If the Vendor fails to comply with the requirements of this Contract, the Vendor may be subject to liquidated damages and/or sanctions pursuant to **Section IV.,** Method of Payment, **Sub-Section D.,** Financial Consequences as Liquidated Damages, and as outlined in **Exhibit A-1,** Deliverables and Associated Payments.

2. General Requirements

a. The Vendor shall perform duties related to the importation of prescription drugs as described in this Contract.

b. The Vendor shall perform the following duties:

1) Purchase and import prescription drugs from Canada on behalf of the following Florida State agencies: the Agency and its Medicaid managed care plans, the Agency for Persons with Disabilities (APD), the Department of Children and Families (DCF) mental health treatment facilities, the Department of Corrections (DOC), and the Department of Health (DOH) county health departments.

2) Serve as an intermediary between the Canadian Supplier or manufacturers and the State.

c. The Vendor shall maintain all required and current licenses, permits, and/or registrations in good standing for the duration of this Contract. The Agency reserves the right to sanction or terminate the Vendor if the Vendor is found by its regulating body to be in violation of Florida laws or rules or if the Vendor receives disciplinary action.

3. Eligible Canadian Supplier

a. The Vendor shall perform the following duties:

1) Identify an eligible Canadian Supplier(s) or manufacturer(s) that is in compliance with relevant Canadian federal and provincial laws, received eligible prescription drugs from an FDA-approved manufacturer, and can obtain the eligible prescription drugs to be imported under the Program.

2) Negotiate and execute agreements with an eligible Canadian Supplier(s) or manufacturer(s), who has agreed

to sell prescription drugs under the Program. The Vendor shall ensure that each agreement has been reviewed and approved by the Agency prior to execution with the Canadian Supplier(s).

3) Provide the Agency with copies of all agreements negotiated with Canadian Supplier(s) within ten (10) days of their signing by the Vendor and Supplier or manufacturer. The Vendor must submit any modifications or changes to these agreements to the Agency upon completion of these changes.

4) Ensure that the Canadian Supplier or manufacturer provides the Vendor with all of the following for each batch of imported prescription drugs:

(a) Proprietary or established product name;

(b) Formulation;

(c) Strength and dosage;

(d) Container size;

(e) Number of containers;

(f) Lot number of product;

(g) Serial identifier for each package and homogenous case or product;

(h) Dates of shipment and transaction;

(i) Business names and addresses of the Canadian Supplier and importer;

(j) Business name and addresses of person associated with importer and foreign seller from whom ownership is being transferred; and

(k) Canadian drug identification number.

5) Be responsible for directly reimbursing the Canadian Supplier for imported prescription drugs.

b. The Agency shall make all payments associated with this Contract in accordance with the Performance Standards and Liquidated Damages (**Table 2-A**) and Payment Schedule (**Table 4-A)** listed in this Contract.

4. Prescription Drugs Eligible for Importation

a. The Vendor shall:

1) Collaborate with the State to identify the list of prescription drugs that can be imported under the Program.

2) Collaborate with the Agency to ensure that the listed prescription drugs have the highest potential for cost savings to the State.

3) Provide the Agency with the actual amount(s) paid to Canadian supplier(s) or manufacturer(s) for prescription drug(s) imported under this Program and maintain a process for updating the Agency with information on the entry of lower-priced products into the market.

4) Report to the Agency any price changes and product additions or deletions within five (5) business days of the manufacturer price change or manufacturer product addition(s) or deletion(s).

5) Ensure all products designated for importation to the U.S. maintain the same formulation as FDA-approved products.

6) Import prescription drugs that are not "donated or otherwise supplied at no charge by the manufacturer of the prescription drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country." See 21 U.S.C. § 384(i).

7) Ensure that imported prescription drugs are manufactured by a facility designated by the FDA as an approved facility and be an FDA-registered manufacturer.

8) Ensure that prohibited prescription drugs (as defined in federal law (21 U.S.C. § 384(a)(3)) are not imported under the Program.

9) Exclude generic products if the importation of the products would violate U.S. patent laws applicable to U.S.-branded products.

10) Ensure that eligible prescription drugs are initially purchased either from an FDA-approved manufacturer or from their authorized distributors, and that secondary and unauthorized products do not enter the Program supply chain.

11) Submit Section 804 Pre-Import Requests to a U.S. Customs and Border Patrol port of entry or to the U.S. Customs and Border Patrol's Automated Commercial Environment system at least thirty (30) calendar days prior to the scheduled date of arrival of an imported prescription drug shipment.

12) On a quarterly basis, provide the Agency with an updated list of prescription drugs eligible for importation that have the highest potential for cost savings to the State, including prescription drugs for which there are shortages, specialty prescription drugs, and high-volume prescription drugs.

5. Ownership and Liability

a. The Vendor shall assume ownership for imported prescription drugs under this Program upon the transfer of title(s) from the Canadian Supplier(s) or manufacturer(s) and delivery to its facility in the U.S.

b. The Vendor shall obtain and maintain insurance for imported prescription drugs due to loss, theft, security breach, accident, contamination, adulteration, mis-delivery, or other factors that have direct responsibility for the reduction of the quantity and quality, as applicable, at all points of in the chain of custody, including:

1) While the imported prescription drugs are in the Vendor's or its delegate's possession. Such policy must cover at a minimum (**$5,000,000.00**) per occurrence and (**$10,000,000.00**) annual aggregate.

2) While imported prescription drugs are in transit either from the Canadian manufacturer or wholesaler to the Vendor's facility or from the Vendor's facility to the ordering state agency or its designee. Such policy must cover at a minimum (**$2,000,000.00**) per occurrence and (**$4,000,000.00**) annual aggregate.

All amounts are in U.S. currency.

6. Wholesaler and Distribution Requirements

a. The Vendor shall be responsible for the importation and storage of imported prescription drugs under the Program.

b. The Vendor shall comply with all applicable State and federal regulations related to the storage and distribution of prescription drugs.

c. The Vendor shall submit an application within thirty (30) days of the execution of this Contract for a Florida Prescription Drug Wholesale Distributor license and shall not initiate distribution operations in Florida until license is obtained.

d. The Vendor shall purchase or lease (for a minimum of twelve (12) months with the option to renew) a facility in Florida that meets the FDA (Title 21 CFR § 205) and state (Chapter 499, F.S.) requirements for the storage of prescription drugs within sixty (60) calendar days of the execution of this Contract. This facility shall meet the following requirements:

1) Be geographically situated to allow for the timely delivery of imported prescription drugs.

2) Be clean and maintain cleanliness standards sufficient to prevent contamination of imported prescription drugs.

3) Have adequate space and environmental conditions available for the safe storage of imported prescription drugs.

4) Have sufficient space that can be environmentally controlled (i.e., refrigerated) to prevent degradation and maintain potency of imported prescription drugs.

5) Have areas designated for the quarantine of imported prescription drugs in accordance with Section 499.0121(5), F.S.

6) Have secure loading and unloading areas appropriate for vehicles used for the shipping and transportation of imported prescription drugs.

7) Have security measures sufficient to prevent theft, tampering, or damages to imported prescription drugs.

e. The Vendor shall ensure that its facility located in Florida is staffed and fully operational on or before May 15, 2021.

f. The Vendor shall ensure daily environmental conditions related to temperature, and humidity are tracked in the storage facility through conducting minimum twice-daily recordings and controls.

g. The Vendor shall ensure that the space in its storage facility designated for the Program is not allocated for other purposes or clients.

h. The Vendor shall ensure it does not distribute drugs with a shelf life expiration date of less than six (6) months.

i. The Vendor shall have 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. The Vendor shall make all policies and procedures available to the Agency upon request.

j. The Vendor shall develop and maintain a written 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.

k. The Vendor shall develop and maintain a written procedure to 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.

7. Ordering and Invoicing

a. The Vendor shall establish an electronic online system to receive orders from State agencies for eligible prescription drugs under the Program. The Vendor shall ensure that the system allows for the immediate receipt of orders and needs to capture the following information:

1) Name of product and product description (e.g., active pharmaceutical ingredients);

2) Quantity needed of the imported prescription drugs;

3) Strength and dosage;

4) Imported prescription drug form (e.g., tablet);

5) NDC number of each product;

6) Identity of requester; and,

7) Billing and shipping addresses.

b. Upon the receipt of an order(s), the Vendor shall notify the requestor within twenty-four (24) hours whether the order can be completely or partially fulfilled.

c. The Vendor shall have a system in place to receive orders via telephone in the event its electronic system is unavailable to take orders.

d. The Vendor shall only process orders for prescription drugs imported under the Program received from State agencies or individuals or entities designated by a State agency.

e. The Vendor shall have a process or mechanism for verifying that orders originated from a State agency or its authorized designee.

f. The Vendor shall have a process and mechanism in place for invoicing each State agency for imported prescription drug orders. The Vendor invoices shall include the following:

1) Date order was placed;

2) NDC number of each product;

3) Product name and product description;

4) Quantity(s) ordered;

5) Strength and dosage;

6) Imported prescription drug form;

7) FDA-approved U.S. and Canadian manufacturer(s);

8) FDA-approved U.S. equivalent(s) prescription drug(s);

9) Payment amount due;

10) Requestor billing and shipping addresses; and,

11) Vendor's billing address and method for payment.

The Vendor shall ensure the Agency has access to all invoices sent to State agencies for purchases under the Program.

g. The Vendor shall make staff available to provide technical assistance via telephone with the ordering and invoicing process from 8:00 AM (EST) to 5:00 PM (EST), Mondays through Fridays, excluding State holidays.

h. The Vendor shall process and ensure shipping of all complete orders received prior to 2:00 PM (EST) on the following business day. Orders received after 2:00 PM (EST) will be shipped on the second business day following the date of the order.

i. If the Vendor is unable to completely fill an order, it shall notify the requesting State agency or its designee within twenty-four (24) hours of receiving the order.

j. If the Vendor is unable to fill an order within the timeframe specified in Part II.B.10.i (Shipping and Delivery) and has not provided notice to the requester within twenty-four (24) hours of receipt of the order, it shall assume responsibility for obtaining the prescription drugs from an FDA-approved U.S. manufacturer. The Vendor cannot invoice the State for the difference in price between the imported prescription drug's cost and that of the U.S. FDA-approved equivalent prescription drug.

8. Purchasing Imported Prescription Drugs

a. The Agency will be responsible for making payments to the Vendor for the cost of imported prescription drugs purchased on behalf of each State agency or its designee.

b. Each state agency or its designee will be responsible for placing orders with the Vendor for the purchase of imported prescription drugs.

c. The Vendor shall purchase prescription drugs from a Canadian Supplier(s) or manufacturer(s) in bulk and maintain at least a ninety (90)-day supply of imported prescription drugs at its facility in Florida. Inventory exceeding a ninety (90)-day supply require written approval by the Agency at least fifteen (15) days in advance.

d. The Vendor shall not charge state agencies or their designees any additional fees, percentages, or cost increases beyond the markup percentage specified in this Contract on imported prescription drugs under this program, except for fees for emergency orders.

e. The Vendor, when purchasing prescription drugs on behalf of the State, shall ensure sufficient quantity to account for the loss of product due to testing. The additional quantity for any single order shall not exceed two percent (2%).

f. In the event that the Vendor purchases the prescription drug at a lower cost than invoiced to the Agency, the Vendor will refund the difference or issue a credit toward a future purchase of imported prescription drugs as determined by the Agency.

g. In the event that the Vendor can only purchase the prescription drug(s) at a higher cost than invoiced to the Agency, the Vendor will notify the Agency within twenty-four (24) hours of determining the error and provide the Agency the option of paying the additional amount or receive a full refund or credit toward a future purchase of imported prescription drugs.

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9. Shipping and Delivery

a. The Vendor shall be responsible for the shipping of imported prescription drugs purchased under the Program from their point of origin in Canada to the delivery to their respective State agency(s) or designated recipient(s). The Vendor may delegate this responsibility to a subcontractor or commercial shipping entity with Agency approval.

b. If the Vendor does not perform shipping of imported prescription drugs, the Vendor shall identify its subcontractor or commercial shipping entity within thirty (30) calendar days of the execution of this Contract.

c. The Vendor shall only use its own vehicles or an Agency-approved subcontractor or commercial shipping provider for the transportation of imported prescription drugs.

d. The Vendor shall coordinate with the Agency, DOH, DCF, APD, and DOC or their designee(s) to identify the specific locations for the delivery of imported prescription drugs.

e. The Vendor shall ensure the safe transportation of all imported prescription drugs in accordance with Section 499.0121(12), F.S. by requiring the following for its vehicles or those of its subcontractor or selected commercial shipping provider:

1) Security measures sufficient to prevent theft, tampering, or damages to imported prescription drugs;

2) Maintaining environmental conditions as recommended by the manufacturer to prevent degradation and maintain potency;

3) Maintaining cleanliness standards to prevent contamination of imported prescription drugs; and

4) Processes to prevent mis-delivery or loss of imported prescription drugs.

f. The Vendor shall ensure that its shipping provider can track packages and provide estimated times of delivery.

g. The Vendor shall ensure that its shipping provider obtains delivery confirmations from its shipping provider for orders of imported prescription drugs.

h. The Vendor or its shipping provider shall have a process for addressing mis-deliveries or lost shipments that could cause a delay resulting in a shortage of the ordered prescription drug(s).

i. The Vendor shall ensure that ninety-eight percent (98%) of all orders for an imported prescription drug(s) are shipped from the Vendor's facility in Florida within seventy-two (72) hours of receiving the order.

10. Pricing Requirements

a. The Vendor shall negotiate prices with a Canadian Supplier(s) or manufacturer(s) for prescription drugs that render substantial savings to the State.

b. The Vendor shall be responsible for ensuring that prices for imported prescription drugs adhere to the following:

1) Provide a cost savings for all prescription drugs purchased across the Program in comparison to what the State paid in Calendar Year 2020 for same quantities, strengths, dosages, and forms of the FDA-approved equivalent prescription drugs. This percentage includes any markup from the Vendor added to the prices and is based on amounts after all rebates, discounts, and reductions.

2) Cost comparison(s) used to demonstrate savings between the imported prescription drug(s) shall be between an imported brand-name drug(s) and FDA-approved equivalent brand-name drug(s) or a generic imported drug(s) and generic FDA-approved drug(s).

3) Cost comparison(s) used to demonstrate savings shall be between prescription drugs that meet the following requirements:

(a) Have the same active pharmaceutical ingredient(s); and,

(b) Have the same quantities of active pharmaceutical ingredient(s).

c. The Vendor shall report a pricing change by the Canadian manufacturer(s) to the Agency within three (3) business days of its occurrence(s).

11. Supply Chain Quality Assurance

a. The Vendor shall:

1) Establish and maintain a quality assurance system for ensuring compliance with the federal DSCSA, federal Food,

Drug, and Cosmetic Act (FDCA), § 381.02035, F.S., and Chapter 61N-1, F.A.C.

2) Implement supply chain standards for Canadian manufacturers and wholesalers to ensure that prescription drugs manufactured outside of Canada are commercially exported to Canada by the manufacturer(s) and labeled for the Canadian market and sold directly to the Canadian Supplier.

3) Establish processes and procedures delineating the responsibilities of all parties within the pharmaceutical supply chain, delegation of responsibilities, authorization for release of products, inspection and certification of compliance with current industry standards for quality assurance systems, and continuous improvement through ongoing internal and third-party audits.

4) Maintain and ensure all products received from the time procured from the Canadian supplier until delivery to a designated State agency.

b. The Vendor shall implement all track and trace requirements as stated in the federal DSCSA.

12. Laboratory Testing

a. The Vendor shall:

1) As required by federal law (Title 21 CFR § 251.16), ensure testing is conducted on sample batches of imported drugs through a qualified laboratory. If approved by the FDA, the Vendor may satisfy the laboratory testing requirements if the certificate of analysis can be obtained by the manufacturer and demonstrates that all required testing was complete.

2) Identify at least two (2) qualifying laboratories that will be used to satisfy testing requirements immediately upon execution of this Contract.

3) Ensure testing as needed on samples collected randomly and representatively from each batch of the imported prescription drugs is performed in International Organization for Standardization (ISO) 17025 accredited laboratories (including third party laboratories).

4) Ensure that samples tested are sufficient to provide statistically valid analyses.

5) Ensure that the laboratory testing techniques used to evaluate imported prescription drugs consist of those recommended by the manufacturer sufficient to verify their authenticity.

6) Ensure that the prescription drug meets the active ingredient, identity, strength, purity, sterility, and quality standards of the federal Food, Drug, and Cosmetic Act (FDCA) (such that the prescription drug is not adulterated, counterfeit, damaged, tampered with, or expired) and ensure that it meets the parameters as purported by the labeling of the prescription drug or, where applicable, as established by the United States Pharmacopeia (USP) or other FDA-recognized compendia standards.

7) Provide documentation to the Agency specifying the tests performed on each batch or shipment of imported prescription drugs.

8) Comply with the frequency of testing as specified in 21 U.S.C. § 384 and shall maintain documentation of all testing that occurred.

9) Have policies and procedures of the steps the Vendor shall take if any of the drugs fail laboratory testing.

10) Document product traceability to the original manufacturer and the manufacturing site, the organization issuing the Certificate of Analysis, and describe the availability of the Certificate of Analysis and testing results when requested.

11) Provide copies of all contracts with qualifying laboratories to the Agency upon execution.

12) Create a contingency plan if the contracted laboratory is unavailable or cannot meet the established time frames.

13. Relabeling

a. The Vendor shall:

1) After importation, ensure prescription drugs are relabeled in accordance with federal and State statutes prior to distribution. The Vendor may delegate this responsibility to the supplier. (21 U.S.C. § 352; 61N-1.032, F.A.C.)

2) Ensure that the relabeler(s) is registered with the FDA and follow the FDA's unique prescription drug product identifier requirement governing prescription drugs distributed under the DSCSA (i.e., pharmaceutical serialization).

3) Provide information to the Agency regarding the facility where the relabeling will occur for all eligible prescription drug(s) including:

- The facility's unique facility identifier;
- The facility's name, address, and establishment identification number;
- The anticipated date the relabeling and any limited repackaging will be completed; and,
- Information about where the relabeled prescription drug will be stored pending distribution, including the FDA establishment identification number of the storage facility, if available.

4) Ensure that the relabeler(s) has appropriate environmental and climate storage controls and implements processes and procedures to prevent mix-ups, contaminations, and cross-allergenicities (e.g., penicillin reactions).

14. Immediate Suspension and Recalled Products

a. The Vendor shall comply with federal and State laws related to handling recalls and withdrawals of prescription drugs. The Vendor shall develop and maintain a written procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

1) Any action initiated at the request of the FDA or any other federal, State, or local law enforcement or other government agency.

2) Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or

3) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

b. The Vendor shall subscribe to the Consumer Product Safety News newsletter to monitor and manage any manufacturer recalls of acquired or targeted products.

c. The Vendor shall develop a procedure to ensure that any outdated prescription drugs are segregated from other drugs and returned to

the manufacturer or dispositioned. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

d. The Vendor shall have systems in place to respond appropriately to suspect or illegitimate products. For suspect or illegitimate products, the Vendor (in coordination with the Canadian Supplier) shall:

1) Quarantine the suspect or illegitimate products;

2) Investigate whether the prescription drugs are illegitimate products; and

3) Notify the FDA if the investigation finds that the prescription drugs are not suspect or illegitimate products.

e. If the investigation finds that the prescription drugs are illegitimate products, the Vendor shall (in coordination with Canadian Supplier):

1) Notify the FDA within twenty-four (24) hours of determining the illegitimate product status;

2) Quarantine the illegitimate products until dispositioned;

3) Dispose the illegitimate products through disposal or return of the prescription drug(s);

4) Provide a report to the Agency specifying the circumstances behind the illegitimate products and recourse to prevent future incidents.

5) Provide reasonable assistance for disposition to parties who have received the illegitimate products, including the payment of refunds as applicable; and,

6) Retain a sample for further physical examination and analysis.

f. The Vendor shall develop a procedure to coordinate the return of recalled imported prescription drugs from State agencies or their designated recipients that accepted delivery.

g. The Vendor shall accept the return of all recalled imported prescription drugs and store them at its facility in Florida until they are determined to be either resaleable or dispositioned.

h. The Vendor shall notify the Agency within seventy-two (72) hours of any recalled or suspended prescription drug(s) imported under the Program.

i. The Vendor, with approval from the Agency, may revoke the suspension of an imported prescription drug if, after investigating, it determines that the public is adequately protected from illegitimate or unsafe drugs being imported into the State.

j. The Vendor shall subscribe to the Consumer Product Safety News newsletter to monitor and manage any manufacturer recalls of acquired or targeted products.

15. Drug Shortages

a. The Vendor shall have policies and procedures for when manufacturers cannot supply drugs, whether it is because they are in backorder or the drugs have been discontinued.

b. Within thirty (30) calendar days of request by the Agency, the Vendor shall submit a contingency plan to the Agency that specifies actions it will take in the event of a Canadian prescription drug shortage(s).

c. The Vendor shall report all shortages of prescription drugs specified under the Program to the Agency within twenty-four (24) hours of becoming alerted to such shortages.

d. The Vendor shall submit a monthly report to the Agency forecasting availability of prescription drugs available under the Program, to anticipate any potential shortages or areas where need will have to be addressed.

e. The Vendor shall monitor prescription drug shortages in Canada and report to the Agency within twenty-four (24) hours of the addition or deletion of a prescription drug to Canada's Drug Shortages Homepage that is approved for importation under this Program.

16. Implementation Plan

a. The Vendor shall develop and submit to the Agency a draft implementation plan, no-later-than ten (10) business days after Contract execution, outlining steps necessary for the Vendor to be operational by the implementation date as directed by the Agency.

b. The Vendor shall develop and deliver a comprehensive final implementation plan within five (5) calendar days of receiving Agency feedback on the draft implementation plan.

c. The Vendor shall detail the specific time frames, tasks, responsibilities, and key milestones in the final implementation plan that ensure a successful implementation.

d. The Vendor shall include, at a minimum, the following elements in the final implementation plan:

1) Tasks associated with the Vendor's establishment of project management tools such as Microsoft Project or similar tools that efficiently track changes to the plan and progress toward accomplishing the activities, goals, and objectives set out in the plan;

2) An itemization of activities that the Vendor shall undertake during the implementation period and the implementation of this Contract. These activities shall have established deadlines and time frames listed. These activities, at a minimum, shall include all information technology (IT) requirements;

3) A staffing plan including position types, number of staff per position type, and job description with roles and responsibilities. The staffing plan shall include the ramp-up and ramp-down phase of the implementation with on-boarding and off-boarding dates for temporary staff as well as details related to Operations staffing;

4) A communication and outreach plan which include communication modality and time frames;

5) A training plan that includes staff numbers by job type, training locations, proposed dates, training times, and training session descriptions;

6) Identification of interdependencies between activities in the implementation plan; and,

7) Identification of Vendor expectations regarding participation by the Agency and/or its agent(s) in the activities in the implementation plan, and dependencies between these activities and implementation activities for which the Agency and/or its agent(s) shall be responsible.

e. The Vendor shall implement the final implementation plan only after Agency approval.

f. The Vendor shall work with the Agency to develop a final implementation plan. Any changes to the final implementation plan, either increase or decrease of scope must be reviewed and approved with the Agency. Failure to do so may be regarded by

the Agency as a material breach and all remedies provided for in this Contract shall become available to the Agency, except where Agency approval has been provided in writing for reasons beyond the control of the Vendor.

g. The Vendor shall participate in both face-to-face meetings and conference calls with the Agency and relevant parties for purposes of coordinating implementation activities.

17. Outreach and Communications

a. The Vendor shall provide all services related to outreach and communications as identified by the Agency to include email communications, posting messages to the Vendor's web page, and performing call campaigns as needed to support the implementation and maintenance of the Program.

b. The Vendor shall develop and implement a draft Outreach and Communication plan to be delivered to the Agency within thirty (30) calendar days of execution of this Contract, which, at a minimum describes:

1) Methods and timing of outreach and communications; and

2) Reporting related to outreach and communications. The Vendor shall identify all outreach and communications activities and report, at a minimum monthly, identifying the subject of the outreach and communication, the modality, and the timing of each outreach and communication.

c. The Vendor shall develop and deliver a comprehensive final Outreach and Communication plan within five (5) business days of receiving Agency feedback on the draft Outreach and Communication plan.

d. The Vendor shall amend or update its outreach plan as directed by the Agency at no additional cost to the Agency.

e. The Vendor shall develop and deliver a draft training plan for Program participants, to the Agency, within seven (7) calendar days of execution of this Contract.

18. Corporate Capability/Office Location

a. The Vendor shall establish an office location(s) where U.S. based duties are fulfilled. The Vendor shall notify the Agency of any changes to the Vendor office location or when any of the Vendor Contractual obligations shall be performed at a different site other than the designated office location. The Vendor shall ensure that

staff are available at the designated office location on business days from the hours of 8:00 AM to 6:00 PM, EST.

19. Staffing Requirements

a. The Vendor shall be responsible for the administration and management of all aspects of this Contract, including all subcontracts, employees, agents, and services performed by anyone acting for or on behalf of the Vendor.

b. The Vendor shall have a centralized executive administration, which shall serve as the contact point for the Agency, except as otherwise specified in this Contract.

c. The Vendor shall maintain a sufficient number of staff at its storage and distribution facility in Florida to ensure the safety, timely receipt, and timely delivery of imported prescription drugs.

d. The Vendor shall maintain a sufficient number of qualified staff to comply with all terms of this Contract.

e. The Vendor shall meet all requirements for doing business in the State of Florida.

f. The Vendor shall submit a resume for any candidates to fill any key named position for Agency approval prior to hiring.

g. The Vendor shall ensure that key name positions are not vacant for more than thirty (30) calendar days.

h. The Vendor shall maintain the minimum level of staffing as required in this Contract. If minimum staffing levels fall below the requirements and remain below the minimum staffing levels in this Contract for more than sixty (60) calendar days, the Agency reserves the right to impose Liquidated Damages.

i. The Vendor shall submit a quarterly Organizational Chart by the fifth (5^{th}) calendar day of each reporting quarter. The Vendor shall identify in its Organizational Chart each person by position and shall attest that each employee meets the contract requirement for said position if applicable.

j. Key Staffing Positions:

1) The Vendor shall designate a Contract Manager to work directly with the Agency. The Vendor Contract Manager shall possess at least two (2) years of contract management experience. The Vendor Contract Manager shall be a full-time employee of the Vendor. The Vendor Contract Manager shall have the authority to administer the day-to-

day business activities of this Contract, including revising processes or procedures and assigning additional resources as needed to maximize the efficiency and effectiveness of services required under this Contract. The Vendor Contract Manager shall meet in person, or by telephone, at the request of Agency. The Vendor Contract Manager shall be located in the State of Florida. The Vendor shall have a Contract Manager upon execution of this Contract.

2) The Vendor shall designate a Compliance Officer to the Contract. The Vendor's Compliance Officer shall possess at least two (2) years of compliance monitoring experience in pharmaceutical distribution practices and inventory.

k. The Vendor shall notify the Agency in writing of any key staff resignations, dismissals, or personnel changes within five (5) business days of the occurrence and describe by whom and how the duties of the vacant key staff will be accomplished by an interim candidate until the position is filled. The Vendor shall provide information on the interim candidate, as approved by the Agency, within three (3) business days of the occurrence.

l. In the event the Agency determines the Vendor's staff or staffing levels are not sufficient to properly complete the services specified in this Contract, it shall advise the Vendor in writing. The Vendor shall address staff or staffing levels as directed by the Agency and in a timeframe approved by the Agency, in order to remedy all identified staffing deficiencies.

20. Operational Procedures

a. The Vendor shall develop and maintain up-to-date operational procedures for all aspects of this Contract.

b. The Vendor shall submit all operational procedures to the Agency prior to implementation in accordance with the Agency approved implementation plan. The Vendor shall obtain the Agency's approval prior to implementing any subsequent changes to any of its operational procedures.

c. The Agency reserves the right to direct the Vendor to amend or update any of the operational procedures at no additional cost to the Agency, within the time frame specified by the Agency.

d. The Vendor shall make each operational procedure available to the Agency at all times.

21. Complaints

a. The Vendor shall resolve all written and verbal inquiries or complaints as soon as possible, but no-later-than five (5) business days from initial receipt, with the exception of recalls from Canadian Suppliers or manufacturers.

b. The Vendor shall document any procedural action that occurred as a result of a complaint. The Vendor shall submit this documentation as part of the monthly complaint report. The Vendor shall have formal written and dated procedures regarding this process.

c. The Vendor shall maintain a log of all complaints that shall include the date, name, nature of complaint, and disposition.

d. The Vendor shall submit a monthly report to the Agency that includes details related to all complaints received, including the date the complaint was reported, nature of the complaint, disposition, and date of resolution. The Vendor shall develop an Agency-approved dashboard for this process.

22. Internal Quality Control Plan (IQC)

a. The Vendor shall develop and submit to the Agency a complete IQC plan and written procedures to ensure appropriate administration of all responsibilities specified in this Contract.

b. The Vendor shall submit its IQC plan in accordance with the Agency approved implementation plan.

c. The Agency reserves the right to direct the Vendor to make modifications and/or additions to the Vendor's IQC plan, as needed.

d. The Vendor's IQC plan, as approved by the Agency, shall become effective no later than thirty (30) calendar days following execution of this Contract.

23. Delegation of Responsibilities

a. The Vendor shall receive Agency approval for the delegation of any responsibilities under this Contract prior to delegating any such work/responsibilities. The Vendor shall ultimately be responsible and liable for the obligations and duties under this Contract and ensure that subcontracts reflect the requirements of this Contract. If the Vendor delegates any function of the administration or management of this Contract, the Vendor shall:

1) Ensure that the entity receiving such delegation adheres to all requirements set forth in State of Florida and federal requirements.

2) Request approval from the Agency no less than sixty (60) calendar days before such functions are delegated (full or partial delegation), specify what functions are delegated, identify the Vendor staff responsible for monitoring the delegated functions, and define how the Vendor shall accomplish monitoring of delegated functions.

3) Provide to the Agency the names, addresses, telephone numbers and roles of all subcontractors for this Contract and notify the Agency within two (2) business days of any changes.

24. Emergency Management Plan

a. The Vendor shall submit to the Agency in accordance with an Agency-approved implementation plan and by September 1st of each contract year, an emergency management plan specifying what actions the Vendor shall conduct to ensure the ongoing provision of services in a disaster.

b. The Vendor shall ensure that the emergency management plan includes a risk assessment, procedures to comply with this Contract during disasters, a communication plan during disasters, and training schedules for Vendor staff, to ensure the ongoing provision of services in a disaster as defined in § 252.34, F.S.

c. The Vendor shall submit a daily report to the Agency advising of any impact to its information management system(s) and/or providers using the system during any emergency or disaster period.

C. Deliverables

Deliverables are included as **Exhibit A-1,** Deliverables and Associated Payments, to this Attachment.

D. Reporting

1. General Reporting Requirements

a. The Vendor and Agency agree that specific reporting requirements may be more clearly defined or developed as a result of Contract negotiations.

b. The Vendor shall adhere to reporting requirements included in this **Section** in a manner and format specified by the Agency. The

Agency reserves the right to direct the Vendor to amend or update its reports and/or report formats in accordance with the best interests of the Agency and at no cost to the Agency. The Agency will notify the Vendor of such modification, in writing.

c. All electronic transmission of reports and supporting documentation containing Protected Health Information (PHI) as defined by the Health Insurance Portability and Accountability Act (HIPAA) shall be encrypted to meet the HIPAA privacy standards. Unless otherwise directed by the Agency, all electronic reports shall be formatted utilizing Microsoft Word or Excel, version 2013 or greater. Supporting documentation may be submitted in Adobe PDF format. The Vendor shall maintain the capability to upgrade its electronic report format as directed by the Agency.

d. Report formats shall be finalized and approved by the Agency no later than thirty (30) calendar days after execution of this Contract, unless otherwise agreed to by the Agency.

e. The Vendor shall develop reports, using formats approved in advance by the Agency, complying with the requirements established by the Agency. When reporting requirements are not established in this Contract, the Agency shall provide the Vendor with instructions and submission timetables. The Agency reserves the right to modify reporting formats and submission timetables resulting from changing priorities or management direction.

f. The Vendor shall provide the Agency with a monthly report by the 30th day of the month, stating the quantity of drugs shipped to each facility, provider, or subcontractor with detailed expenditures that lists amounts, per individual drug, for each individual shipment or batch.

g. All reports shall be developed, produced, and maintained at no cost to the Agency.

2. Monthly Reporting

a. The Vendor shall submit monthly reports. At a minimum, monthly reports shall include the following:

1) Information on each shipment of prescription drugs that were imported from Canada, including:

- Name and quantity of the active ingredient;
- Description of the dosage;
- Date received;

- Quantity received;
- Point of origin and destination; and,
- Price paid.

2) Forecast of availability of prescription drugs available under the Program, to anticipate any potential shortages or areas where need will have to be compensated.

3) Pricing reports on each imported prescription drug to track cost savings and determine when a prescription drug is to be removed from the list of those imported.

b. Monthly reports shall be due on the fifteenth (15th) of each month following the reporting month.

3. Annual Reporting

a. The Vendor shall submit an annual report to the Agency, compiling all quarters' data from the most recent, complete contract year. At a minimum, annual reports shall include the following:

1) A list of prescription drugs imported under the Program;

2) The quantity, lot number, and name of each drug distributed to each State agency participating in the Program.

3) The number of participating entities;

4) The number of prescriptions dispensed through the Program;

5) The estimated cost savings during the previous State fiscal year and to date by drug and drug class based on the current cost of the same or like drug using the same NDC code;

6) A description of the methodology used to determine which prescription drugs were included for the year;

7) Documentation demonstrating how the Program ensures:

- Canadian Supplier participating in the Program are of high quality, of high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations and U.S. federal and state laws and rules;

- Prescription drugs imported under the Program are not shipped, sold or dispensed outside of the State once in the possession of the importer;

- Prescription drugs imported under the Program are pure, potent and safe, and not adulterated, counterfeit, damaged, tampered with, or expired; and,

- The Program does not put consumers at higher health and safety risks than if the Program did not exist.

8) The Program provides cost savings to the State on imported prescription drugs.

b. Annual reports shall be due forty-five (45) calendar days following the end of each resulting contract year.

4. Adverse Event Reporting

a. The Vendor shall be responsible for completing and filing the following reports to the FDA when appropriate following the occurrence of an adverse incident(s) or quality issue(s):

1) Field alert reports

2) Adverse event reports

3) Expedited Individual Case Safety Reports (ICSRs)

4) Follow-up reports to ICSRs

5) Non-expedited ICSRs

b. The Vendor shall be responsible for identifying the type of report necessary and appropriate for each incident(s) for submission to the FDA.

c. The Vendor shall submit reports in accordance with the timeframes specified in Title 21 of the Code of Federal Regulations (CFR) § 251.18

5. FDA Quarterly Reports

a. The Vendor shall compile all documentation and components as specified in Title 21 CFR § 251.19 and submit to the Agency within ten (10) calendar days of the end of each calendar quarter.

b. The Vendor shall prepare the necessary documentation and components in a report format as prescribed by the Agency in

accordance with FDA guidelines as specified in Title 21 CFR § 251.19.

c. The Vendor shall make any corrections or provide missing information as specified to the Agency within five (5) calendar days of receiving feedback on the report.

d. The Vendor shall submit the quarterly report to the FDA within three (3) calendar days of receiving approval from the Agency via the FDA's Electronic Submissions Gateway (ESG).

6. Ad Hoc Analysis and Reports

a. The Agency reserves the right to request the Vendor to conduct ad hoc analyses and provide ad hoc reports. In such instances, the Agency will make the request in writing and will establish a deadline for submission.

b. Ad hoc analyses and reporting shall be provided at no additional cost to the Agency.

c. The Vendor shall provide ad hoc reports on an as needed basis at no additional cost to the Agency. Ad hoc reports may be requested on any aspect of the data collected by the Vendor.

d. Ad hoc reports shall be submitted to the Agency within fourteen (14) calendar days from the time of the request, unless the Agency directs the Vendor to provide the data or information in less than fourteen (14) calendar days.

At the Agency's request, the variables calculated as part of ad hoc reports may be required for inclusion in standard reports.

E. Monitoring

1. General Monitoring Provisions

a. The Agency may conduct, or have conducted, performance and/or compliance reviews, reviews of specific records or other data as determined by the Agency. The Agency may conduct a review of a sample of analyses performed by the Vendor to verify the quality of the Vendor's analyses. Reasonable notice shall be provided for reviews conducted at the Vendor's place of business.

b. Reviews may include, but shall not be limited to, reviews of procedures, computer systems, laboratory records, track and trace records, relabeling and repackaging records, accounting records, and IQC reviews. The Vendor shall work with any reviewing entity selected by the Agency.

c. During this Contract period, these records shall be available at the Vendor's office at all reasonable times. After this Contract period and for ten (10) years following, the records shall be available at the Vendor's chosen location subject to the approval of the Agency. If the records need to be sent to the Agency, the Vendor shall bear the expense of delivery. Prior approval of the disposition of the Vendor and subcontractor records shall be requested and approved by the Agency. This obligation survives termination of this Contract.

d. The Vendor shall comply with all applicable federal requirements pertaining to procurement, including but not limited to Chapter 2 of the CFR and any other final or interim rules with respect to audit requirements of federal contracts administered through State and local public agencies.

e. At a minimum, the Vendor's financial documents, invoices, dispensing records relevant to this Contract will be subject to audits by the Agency. The Vendor shall be responsible for its own costs associated with any audits.

f. In accordance with § 20.055, F.S., the Vendor and its subcontractors shall cooperate with the Office of the Inspector General (OIG) in any investigation, audit, inspection, review or hearing; and shall grant access to any records, data or other information the OIG deems necessary to carry out its official duties.

g. The Vendor shall ensure that Canadian suppliers and all subcontractors (e.g., laboratories, relabelers, etc.) comply with Contractual requirements.

III. Method of Payment:

This Contract includes a combination of fixed price and cost-plus deliverables. The Agency shall pay the Vendor, in arrears, upon the completion and acceptance of deliverables in accordance with the deliverable schedule specified in **Exhibit A-1,** Deliverables and Associated Payments.

- Fixed Price: The Agency will use a fixed price approach to pay the Vendor for implementation deliverables and a fixed monthly price for ongoing Program operations, as specified in **Exhibit A-1,** Deliverables and Associated Payments.

- Cost Plus: The Agency will use a cost reimbursement approach, plus a fixed percentage rate, to compensate the Vendor for purchasing prescription drugs from the Canadian Supplier(s) or manufacturers. In accordance with **Table 1-A,** Fixed Percentage Rates for Cost Plus Reimbursement, below.

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TABLE 1-A FIXED PERCENTAGE RATES FOR COST PLUS REIMBURSEMENT		
Percentage Rate – Original Term		
Year 1	**Year 2**	**Year 3**
7%	6.5%	6.25%
Percentage Rate – Renewal Term		
Year 4	**Year 5**	**Year 6**
6.25%	6.25%	6.25%

- The Agency will only reimburse the Vendor for the cost of prescription drugs that were acquired by the Vendor during the billing month. To receive reimbursement, the Vendor shall provide a monthly invoice with documentation sufficient for the Agency to determine the types and quantities of prescription drugs purchased, and subsequently delivered, for the billing month. The documentation must include copies of original invoices from the Canadian Supplier(s) showing the actual amount(s) for which the Vendor paid for prescription drugs and is seeking reimbursement from the Agency. If sufficient documentation and an acceptable invoice are provided by the Vendor, the Agency will reimburse the Vendor for the total amount of prescription drugs purchased and delivered for the billing month, and pay a fixed rate percent (of the total amount of the monthly invoice). The Agency shall not pay more than the reimbursable amount plus the fixed percentage rate for any billing month.

- The Vendor will order one hundred and four percent (104%) of the predetermined requested drug(s) invoiced. The additional inventory will be allocated for laboratory testing or loss. The Agency and the Vendor will conduct a "true up" within sixty (60) days of the end of the contract year.

A. Invoicing

1. Invoices and all supporting documents shall be submitted on the Vendor's letterhead to the Agency's designated Contract Manager within fifteen (15) calendar days of completion and Agency approval of deliverable(s).

Invoice(s) shall include, at a minimum:

a. Invoice date;

b. Invoice number;

c. Agency's Contract number;

d. Description of the services rendered;

e. Date(s) on which services were rendered;

f. Payment remittance address; and,

g. Other supporting documentation as requested by the Agency.

2. The Vendor shall not charge the State for any travel expenses related to any portion of this Contract.

3. Payments will be authorized only for services that are in accordance with the terms and conditions of this Contract.

4. Appropriate documentation as determined by the Agency shall be submitted to support invoices.

5. Invoices shall not be approved for payment by the Agency until reports and deliverables from the Vendor are received as specified in this Contract.

B. Late Invoicing

If the Vendor is unable to meet the invoice submission deadlines specified in this Contract, the Vendor shall notify the Agency in writing prior to the deadline explaining the circumstances and requesting an extension to the deadline.

C. Financial Consequences as Liquidated Damages

1. Performance Standards and Liquidated Damages

a. The Vendor shall comply with all requirements and performance standards set forth in the Contract.

b. The Agency's Contract Manager will monitor the Vendor's performance in accordance with the monitoring requirements of the Contract. Failure by the Vendor to meet the established minimum performance standards may result in the Agency, in its sole discretion, finding the Vendor to be out of compliance, and all remedies provided in this Contract and under law, shall become available to the Agency.

c. The Agency reserves the right to impose liquidated damages upon the Vendor for failure to comply with the performance standard requirements set forth in **Table 2-A**, Performance Standards and Liquidated Damages, below and as outlined in **Exhibit A-1,** Deliverables and Associated Payments.

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TABLE 2-A **PERFORMANCE STANDARDS AND LIQUIDATED DAMAGES**	
Performance Standard Requirement	**Liquidated Damages to be Imposed**
Performance Bond	
A performance bond in the amount of ten percent (10%) of the total annual amount of the Contract shall be furnished to the Agency by the Vendor within thirty (30) calendar days after execution of the Contract and prior to commencement of any work under the Contract.	**$500.00** per calendar day for each calendar day after the due date until an acceptable performance bond is furnished to the Agency.
A performance bond shall be furnished on an annual basis, thirty (30) calendar days prior to the new contract year and be in the amount of ten percent (10%) of the current annual Contract amount.	**$500.00** per calendar day for each calendar day after the due date until an acceptable performance bond is furnished to the Agency.
Performance Measures	
The Vendor must provide documentation demonstrating negotiations and or pricing from wholesalers or manufacturers accounting for sixty-five percent (65%) of the prescription drugs in two (2) separate drug classes as listed in the SIP proposal by June 1, 2021, or as otherwise specified by the Agency.	**$5,000.00** for every one percent (1%) short of the required ninety percent (90%) the Vendor fails to obtain.
The Vendor must show evidence of negotiations and or maintain agreements with sixty-five percent (65%) of the prescription drugs that the Vendor and Agency have jointly identified as meeting the savings requirements outlined in the SIP proposal by June 1, 2021, or as otherwise specified by the Agency.	**$2,500.00** per month for every one percent (1%) short of the required ninety percent (90%) the Vendor fails to obtain.
The Vendor must ensure eighty-six percent (86%) of all imported prescription drugs meet the following requirements: • Delivered within forty-eight (48) hours of having been ordered. • Delivered complete and correct, without missing or incorrect items. • Delivered without damage resulting in any of the prescription drug(s) being rendered un-consumable. • Delivered with accurate documentation.	**$1,000.00** per month per every one percent (1%) short of the required eighty-six percent (86%) the Vendor fails to meet.
The Vendor must maintain an adequate inventory of imported prescription drugs at its Florida facility.	**$500.00** per occurrence that the Vendor is unable to fill an order for a State agency or its designee.

TABLE 2-A **PERFORMANCE STANDARDS AND LIQUIDATED DAMAGES**	
Performance Standard Requirement	**Liquidated Damages to be Imposed**
This supply must be sufficient to fill orders from State agencies or their designees for ninety (90) days, barring a shortage of the drug to be imported or disaster that would impact importation of sufficient inventory.	
The Vendor must ensure that no more than four percent (4%) of the quantity of purchased prescription drugs is added to an order for the purpose of laboratory testing or loss.	**$1,000.00** per occurrence that the Vendor adds more than four percent (4%) of purchased prescription drugs to an order for the purpose of laboratory testing or loss.
The Vendor must report current and accurate data on its inventory through a dashboard accessible to the Agency at any time.	**$500.00** per occurrence of a verified inaccuracy.
The Vendor must ensure that the rate of return of imported prescription drugs due to errors or negligence by the Vendor from state agencies or their designees is no more than two percent (2%) per month for all orders the Vendor fills, ships, and delivers.	**$1,000.00** per month per every one percent (1%) above the five percent (5%) that the Vendor is unable to meet.
The Vendor must make its online portal available twenty-four (24) hours per day/seven (7) days per week for placing orders for imported prescription drugs with the exception of scheduled maintenance.	**$100.00** per occurrence that the portal has an unscheduled shutdown that lasts for sixty (60) minutes or longer.
The Vendor will ensure that imported prescription drugs distributed to state agencies or their designees are authentic, potent, and safe to consume.	**$500.00** per occurrence for prescription drugs deemed non-consumable due to labeling errors. **$1,000.00** per occurrence for prescription drugs deemed non-consumable due to expiration, lack of potency, adulteration, or contamination that would not result in harming individuals if consumed. **$10,000.00** per occurrence for prescription drugs that would cause mild harm (i.e., not result in hospitalization or death) if consumed. **$50,000.00** per occurrence for prescription drugs that would result in severe harm (i.e., hospitalization or death) if consumed.

TABLE 2-A **PERFORMANCE STANDARDS AND LIQUIDATED DAMAGES**	
Performance Standard Requirement	**Liquidated Damages to be Imposed**
HIPAA	
The Vendor shall comply with provisions of HIPAA / Health Information Technology for Economic and Clinical Health (HITECH).	**$500.00** to **$5,000.00,** per incident, per occurrence, depending upon the severity. In addition, Federal penalties may apply in accordance with the HIPAA Act of 1996.
The Vendor shall not inappropriately release PHI.	**$500.00** to **$5,000.00,** per incident, per occurrence, depending upon the severity.
Records	
The Vendor shall comply with public records laws, in accordance with § 119.0701, F.S.	**$5,000.00** for each incident in which the Vendor does not comply with a public records request.
Background Screening	
Complete initial and renewal background screenings within required timeframes.	**$500.00** per occurrence.
Submit policies and procedures within thirty (30) calendar days of Contract execution.	**$250.00** per calendar day beyond the due date.
The Vendor shall ensure that all workers and subcontracted workers providing services under this Contract are in compliance with the required background screening prior to providing services under this Contract.	**$5,000.00** for each incident in which the Vendor allows a worker and/or worker of a subcontractor who failed the required background screening and who does not meet one of the exemptions to provide services under this Contract.
Security Rating Score	
Annually maintain a top tier security rating score from the Agency's selected information security rating service.	**$5,000.00** per occurrence and **$250.00** per calendar day, if the Vendor does not improve to a top tier security rating score within three (3) months after its initial failure notification by the Agency, to annually obtain a top tier security rating score.
Service Organization Controls (SOC) 2 Type II Audit	
Annually submit the SOC 2 Type II audit report by April 30th of each contract year.	**$1,000.00** per calendar day for each calendar day beyond the due date.
Services	
Implement the approved Corrective Action Plan (CAP) by the Agency specified date.	**$500.00** per calendar day for each calendar day that the approved CAP is not implemented to the satisfaction of the Agency.
Quarterly by the fifth (5th) calendar day of the quarter, submit an Organizational Chart identifying each person by position and attesting	**$100.00** per calendar day for each calendar day beyond the due date.

TABLE 2-A PERFORMANCE STANDARDS AND LIQUIDATED DAMAGES	
Performance Standard Requirement	**Liquidated Damages to be Imposed**
that each employee meets the contract requirement for said position as applicable.	

2. Sanctions

a. In the event the Agency identifies a violation of or other non-compliance with the Contract (to include the failure to meet performance standards), the Agency may sanction the Vendor pursuant to § 409.912(4), F.S. The Agency may impose sanctions in addition to any liquidated damages imposed pursuant to the Contract.

b. For purposes of this **Item**, violations involving individual, unrelated acts shall not be considered arising out of the same action.

c. If the Agency imposes monetary sanctions, the Vendor shall pay the monetary sanctions to the Agency within thirty (30) calendar days from receipt of the notice of sanction, regardless of any dispute in the monetary amount or interpretation of policy which led to the notice. If the Vendor fails to pay, the Agency, at its discretion, reserves the right to recover the money by any legal means, including but not limited to the withholding of any payments due to the Vendor. If the Deputy Secretary determines that the Agency should reduce or eliminate the amount imposed, the Agency will return the appropriate amount to the Vendor within sixty (60) calendar days from the date of a final decision rendered.

3. Disputes

a. To dispute the imposition of a corrective action plan, liquidated damages, sanctions and/or contract interpretations, the Vendor shall request that the Agency's Deputy Secretary for Medicaid or designee, hear and decide the dispute.

b. The Vendor shall submit a written dispute directly to the Deputy Secretary, listed below, or designee by U.S. mail and/or commercial courier service (hand delivery will not be accepted). This submission shall be received by the Agency within twenty-one (21) calendar days after the issuance of a corrective action plan, liquidated damages, sanctions and/or Contract interpretations and shall include all arguments, materials, data, and information necessary to resolve the dispute (including all evidence, documentation and exhibits). The Vendor submitting such written requests for appeal or dispute as allowed under the Contract by U.S. mail and/or commercial courier service, shall submit such appeal or dispute to the following mailing address:

Deputy Secretary for Medicaid
Agency for Health Care Administration
Prescription Drug Importation Medicaid Appeals/Disputes, Mail Stop 8
2727 Mahan Drive
Tallahassee, FL 32308

Regardless of whether delivered by U.S. mail or commercial courier service, appeals or disputes not delivered to the address above will be denied.

c. The Vendor waives any dispute not raised within twenty-one (21) calendar days of issuance of liquidated damages, sanctions and/or contract interpretations. It also waives any arguments it fails to raise in writing within twenty-one (21) calendar days of receiving the corrective action plan, liquidated damages, sanctions and/or Contract interpretations, and waives the right to use any materials, data, and/or information not contained in or accompanying the Vendor's submission submitted within the twenty-one (21) calendar days following its receipt of the liquidated damages, sanctions and/or Contract interpretations in any subsequent legal, equitable, or administrative proceeding (to include Circuit Court, Federal court and any possible administrative venue).

d. The Deputy Secretary or his/her designee will decide the dispute under the reasonableness standard, reduce the decision to writing and serve a copy to the Vendor. This written decision will be final.

e. The exclusive venue of any legal or equitable action that arises out of or relating to the Contract, including an appeal of the final decision of the Deputy Secretary or his/her designee, will be Circuit Court in Leon County, Florida. In any such action, the Vendor agrees to waive its right to a jury trial, and that the Circuit Court can only review the final decision for reasonableness, and Florida law shall apply. In the event the Agency issues any action under F.S. or F.A.C. apart from the Contract, the Agency will notice the Vendor of the appropriate administrative remedy.

IV. Financial Requirements

A. General Provisions

The Vendor shall meet all financial requirements established by this Contract and report financial information, including but not limited to quarterly and annual financial Statements, in accordance with Section D., Reporting Requirements. The Vendor shall certify that information it submits to the Agency is accurate, truthful, and complete, under penalty of perjury [42 CFR § 438.606 (a) and (b); § 457.1201(o)].

1. Inspection and Audit of Financial Records

The State or branches within the Department of Health and Human Services may inspect and audit any financial records of the Vendor or its subcontractors, as well as financial records from parent companies relating to corporate or administrative charges included on financial reports submitted by the Vendor to the Agency.

2. Financial Reporting

a. The Vendor shall submit annual audited and quarterly unaudited financial Statements that are specific to the processes of the Vendor rather than to a parent or umbrella organization.

b. The Vendor shall submit all financial reports to the Agency in accordance with Section D., Reporting Requirements.

c. The Vendor shall submit their audited reports in accordance to the timeline in the Financial Report template.

V. Attorney's Fees

In the event of a dispute, each party to this Contract shall be responsible for its own attorneys' fees, except as otherwise provided by law.

VI. Legal Action Notification

The Vendor shall give the Agency, by certified mail, immediate written notification (no later than thirty (30) calendar days after service of process) of any action or suit filed or of any claim made against the Vendor by any subcontractor, vendor, or other party that results in litigation related to this Contract for disputes or damages exceeding the amount of **$50,000.00**. In addition, the Vendor shall immediately advise the Agency of the insolvency of a subcontractor or of the filing of a petition in bankruptcy by or against a principal subcontractor.

VII. Failure to Implement Contract Requirements

If the Vendor fails to establish an agreement(s) with a Canadian manufacturer(s) or Canadian wholesaler(s) that would result in the acquisition of imported prescription drugs at prices that would yield significant savings to the State, such an event will result in the dissolution of this Contract and release both parties from any further payments, obligations, responsibilities, duties, and deliverables specified in this contract.

VIII. Damages for Failure to Meet Contract Requirements

In addition to remedies available through this Contract, in law or equity, the Vendor shall reimburse the Agency for any Federal disallowances or sanctions imposed on the Agency as a result of the Vendor's failure.

IX. Corrective Action Plan (CAP)

A. If the Agency determines that the Vendor is out of compliance with any of the provisions of this Contract, the Agency may require the Vendor to submit a Corrective Action Plan (CAP) within a specified timeframe. The CAP shall provide an opportunity for the Vendor to resolve deficiencies without the Agency invoking more serious remedies, up to and including contract termination.

B. The Vendor shall respond by providing a CAP to the Agency within the timeframe specified by the Agency.

C. The Vendor shall implement the CAP only after Agency approval.

D. The Agency may require changes or a complete rewrite of the CAP and provide a specific deadline.

E. If the Vendor does not meet the standards established in the CAP within the agreed upon timeframe, the Vendor shall be in violation of the provisions of this Contract and shall be subject to liquidated damages.

X. Performance Bond

A. A performance bond in the amount specified in **Table 3-A,** Performance Bond Requirements, below, shall be furnished to the Agency by the Vendor for the specified Contract term.

TABLE 3-A
PERFORMANCE BOND REQUIREMENTS

Contract Term	"Estimated" Annual Contract Amount	Performance Bond Amount (10%)
Year 1: Contract execution – June 30, 2021	**$9,825,200.00**	**$982,520.00**
Year 2: July 1, 2021 – June 30, 2022	**$14,496,000.00**	**$1,449,600.00**
Year 3: July 1, 2022 – June 30, 2023	**$14,496,000.00**	**$1,449,600.00**

B. Performance Bond Requirements

1. The initial performance bond shall be furnished to the Agency's Procurement Office within thirty (30) calendar days after execution of this Contract and prior to commencement of any work under this Contract.

2. Thereafter, the performance bond shall be furnished on an annual basis, thirty (30) calendar days prior to the new contract year.

3. The initial performance bond shall be in the amount of ten percent (10%) of the current annual Contract amount and shall be submitted to the Agency's Procurement Office at:

Procurement Office
Agency for Health Care Administration
2727 Mahan Drive, Mail Stop 15
Tallahassee, FL 32308

4. A copy of all performance bonds shall be submitted to the Agency's Contract Manager.

5. The performance bond shall not contain any provisions that shorten the time for bringing an action to a time less than that provided by § 95.03, F.S.

6. No payments will be made to the Vendor until an acceptable performance bond is furnished to the Agency. The performance bond shall remain in effect for the full term of this Contract, including any renewal period. The Agency shall be named as the beneficiary of the Vendor's bond. The bond shall provide that the insurer(s) or bonding company(s) pay losses suffered by the Agency directly to the Agency.

7. The cost of the performance bond will be borne by the Vendor.

8. Should the Vendor terminate this Contract prior to the end of this Contract period, an assessment against the bond will be made by the Agency to cover the costs of selecting a new Vendor. The Vendor agrees that the Agency's damages in the event of termination by the Vendor shall be considered to be for the full amount of the bond. The Agency need not prove the damage amount in exercising its right of recourse against the bond.

XI. Contract Transition

A. At the time of this Contract's completion, the Vendor shall cooperate with the Agency in transitioning responsibilities of this Contract to the Agency or another vendor.

B. Prior to the ending or termination of this Contract, the Vendor shall coordinate with the Agency to develop and implement a wind down strategy to utilize current drug inventory and minimize the total amount of products that must be transferred to State custody by the end of the Contract.

C. The Vendor shall deliver to the Agency, or its authorized representative, all Contract-related records and data in a format specified by the Agency, within sixty (60) calendar days from the expiration or termination of this Contract. This obligation survives termination of this Contract.

D. Prior to the ending or termination of this Contract, the Vendor shall meet with the new vendor or the Agency's designated representative(s) to develop a HIPAA compliant, written agreement that sets forth how the entities will cooperate to ensure an effortless transition. The agreement shall be approved by the Agency prior to execution and shall include at a minimum, the following:

1. Designated point of contact for both entities;

2. A calendar of regularly scheduled meetings;

3. A detailed list of data that will be shared;

4. A mechanism and timeframe for transmitting records and data from the Vendor's system;

5. A mechanism and timeframe for transmitting documents produced under this Contract, as requested by the Agency;

6. A clear description of the mutual needs and expectations of both entities; and,

7. Identification of risks and barriers associated with the transition of services to a new vendor and solutions for overcoming them.

XII. System Functionality

A. The Vendor shall have the capacity (hardware, software, and personnel) sufficient to access and generate all data and reports needed for this Contract.

B. The Vendor shall comply with HIPAA and the HITECH Act.

C. The Vendor shall have protocols and internal procedures for ensuring system security and the confidentiality of state agency or designee identifiable data.

D. The Vendor shall ensure an annual SOC 2 Type II audit is performed on the application hosting center. The Vendor shall provide a copy of the most recent audit report to the Agency.

XIII. Information Technology

A. The Vendor shall have the necessary IT resources needed to fully manage the product required in this Contract.

B. The Vendor shall develop an online platform to allow state agencies or their designees to place orders and receive invoices for orders of imported prescription drugs. The online platform shall comply with the following:

1. Be accessible only to state agencies or their designees via a password protected portal;

2. Be user friendly and require minimal clicks for navigating;

3. Have security measures in place to maintain confidentiality of state agency or designee information;

4. Allow state agencies or their designees to upload all information required in **Section II.,** Manner of Service(s) Provision, **Sub-Section B.,** Services Provided by the Vendor, **Item 8.,** Ordering and Invoicing;

5. Provide digital invoices that contain all information required in **Section II.,** Manner of Service(s) Provision, **Sub-Section B.,** Services Provided by the Vendor, **Item 8.,** Ordering and Invoicing;

6. Provide up-to-date information on the types, quantities, strengths, dosages, and forms of imported prescription drugs available for purchase; and,

7. Maintain a list of employed or contracted staff who have made changes or updates to the online platform.

C. The Vendor shall make updates within ninety (90) days of Agency notification to its online platform as necessary in the event of policy, procedural, or technological changes by state agencies that affect requirements for the placing of orders or receiving invoices for orders of imported prescription drugs.

D. The Vendor shall have a system capable of storing all information as required by the FDA, State of Florida, and this Contract.

E. The Vendor shall ensure that the Customer Service Call Center, IT help desk or any other type of customer support provided directly under this Contract, shall be located only in the forty-eight (48) contiguous United States.

F. The Vendor shall conform to current and updated publications of the principles, standards, and guidelines of the Federal Information Processing Standards (FIPS), the National Institute of Standards and Technology (NIST) publications, including but not limited to Cybersecurity-Framework and NIST.SP.800-53r4.

G. The Vendor shall employ traffic and network monitoring software and tools on a continuous basis to identify obstacles to optimum performance.

H. The Vendor shall employ traffic and network monitoring software and tools on a continuous basis to identify email and Internet spam and scams and restrict or track user access to appropriate websites.

I. The Vendor shall employ traffic and network monitoring software and tools on a continuous basis to identify obstacles to detect and prevent hacking, intrusion, and other unauthorized use of the Vendor's resources.

J. The Vendor shall employ traffic and network monitoring software and tools on a continuous basis to prevent adware or spyware from deteriorating system performance.

K. The Vendor shall employ traffic and network monitoring software and tools on a continuous basis to update virus blocking software daily and aggressively monitor for and protect against viruses.

L. The Vendor shall employ traffic and network monitoring software and tools on a continuous basis to monitor bandwidth usage and identify bottlenecks that impede performance.

M. The Vendor shall conduct all activities in compliance with 45 CFR § 164 Subpart C to ensure data security, including, but not limited to encryption of all information that is confidential under Florida or Federal law, while in transmission and while resident on portable electronic media storage devices. Encryption is required and shall be consistent with FIPS, and/or the National Institute of Standards and Technology (NIST) publications regarding cryptographic standards.

N. In order to enable the Agency to effectively measure and mitigate the Vendor's security risks, Agency may conduct an initial IT security rating score scan on the Vendor, as well as periodic or continuous security monitoring through an information security rating service, at the Agency's expense, to enable the Agency to effectively measure and mitigate the Vendor's security risks. The Vendor will work with the Agency's Security Rating Score Provider to define the relevant Vendor assets providing Agency services. If the Vendor does not maintain a top tier security rating score, the Agency will impose liquidated damage(s) and/or other applicable sanction(s).

XIV. Disaster Recovery

A. The Vendor shall develop and maintain a disaster recovery plan for restoring the application of software and current master files and for hardware backup in the event the production systems are disabled or destroyed. The disaster recovery plan shall limit service interruption to a period of twenty-four (24) clock hours and shall ensure compliance with all requirements under this Contract. The records backup standards and a comprehensive disaster recovery plan shall be developed and maintained by the Vendor for the entire period of this Contract and submitted for review annually by the anniversary date of this Contract.

B. The Vendor shall maintain a disaster recovery plan for restoring day-to-day operations including alternative locations for the Vendor to conduct the requirements of this Contract. The disaster recovery plan shall limit service interruption to a period of twenty-four (24) clock hours and shall ensure compliance with all requirements of this Contract.

C. The Vendor shall maintain database backups in a manner that shall eliminate disruption of service or loss of data due to system or program failures or destruction.

D. The disaster recovery plan shall be finalized no later than thirty (30) calendar days prior to this Contract effective date. The Agency shall review the Vendor's disaster recovery plan during the readiness review.

E. The Agency, at its discretion, reserves the right to direct the Vendor to amend or update its disaster recovery plan in accordance with the best interests of the Agency and at no additional cost to the Agency.

F. The Vendor shall make all aspects of the disaster recovery plan available to the Agency at all times.

G. The Vendor shall conduct an annual Disaster Recovery Plan test and submit results for review to the Agency in the annual plan submitted in compliance with **Section XII.,** Disaster Recovery, **Sub-Section A**.

XV. Agency Contract Management

A. The Agency shall be responsible for management of this Contract. Contract management shall be conducted in good faith, with the best interest of the State and the residents it serves being the prime consideration. The Agency shall make all statewide policy decisions via issuance of a Policy Transmittal or Contract Interpretation, which shall be included in the next amendment.

B. The Vendor shall submit all procedures to the Agency as required by this Contract. Unless specified elsewhere in this Contract, procedures required by this Contract shall be submitted to the Agency at least seventy-five (75) days before the proposed effective date of the policy and procedure or change. Other procedures related to this Contract shall be submitted to the Agency upon request. If the Agency has requested procedures, the Vendor shall notify the Agency of any subsequent changes in such materials.

C. The Vendor may seek an interpretation from the Agency of any Contract requirement. When an interpretation of this Contract is sought, the Vendor shall submit a written request to the Agency's Deputy Secretary for Medicaid in a format prescribed by the Agency.

D. The terms of this Contract do not limit or waive the ability, authority or obligation of the OIG, its contractors, or other duly constituted government units (State or federal) to audit or investigate matters related to or arising out of this Contract.

E. This Contract shall be amended only as follows (unless specified elsewhere in this Contract):

1. The parties cannot amend or alter the terms of this Contract without a written amendment and/or change order to this Contract.

2. The Agency and the Vendor understand that any such written amendment to amend or alter the terms of this Contract shall be executed by an officer of each party, who is duly authorized to bind the Agency and the Vendor.

3. The Agency reserves the right to amend this Contract within the scope set forth in the procurement (to include original Contract and all Attachments) in order to clarify requirements or if it is determined by the Agency that modifications are necessary to better serve or provide covered services to the eligible population.

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XVI. Disputes

A. To dispute an interpretation of this Contract, the Vendor must request that the Agency's Deputy Secretary for Medicaid hear and decide the dispute. The Vendor must submit a written dispute of this Contract interpretation directly to the Deputy Secretary; by U.S. mail and/or commercial courier service (hand delivery shall not be accepted); this submission must be received by the Agency within twenty-one (21) days after the interpretation of this Contract and shall include all arguments, materials, data, and information necessary to resolve the dispute (to include all evidence, documentation and exhibits). The Vendor shall submit such written requests for appeal or dispute as allowed under this Contract by U.S. mail and/or commercial courier service, shall submit such appeal or dispute to the following mailing address:

Deputy Secretary for Medicaid
Agency for Health Care Administration
Attn: Prescription Drug Importation Program, MS 1
2727 Mahan Drive Bldg. 3
Tallahassee, FL 32308

Regardless of whether delivered by U.S. mail or commercial courier service, appeals or disputes not delivered to the above address will be denied. The Vendor waives any dispute not raised within twenty-one (21) days of receiving a notice of this Contract interpretation. It also waives any arguments it fails to raise in writing within twenty-one (21) days of receiving a Contract interpretation, and waives the right to use any materials, data, and/or information not contained in or accompanying the Vendor's submission submitted within the twenty-one (21) days following its receipt of the notice of this Contract interpretation in any subsequent legal, equitable, or administrative proceeding (to include circuit court, federal court and any possible administrative venue).

B. The Deputy Secretary or his/her designee shall decide the dispute under the reasonableness standard, reduce the decision to writing and serve a copy to the Vendor. This written decision shall be final.

C. The exclusive venue of any legal or equitable action that arises out of or relating to this Contract, including an appeal of the final decision of the Deputy Secretary or his/her designee, shall be Circuit Court in Leon County, Florida; in any such action, the Vendor agrees to waive its rights to a jury trial, and that the Circuit Court can only review the final decision for reasonableness, and Florida law shall apply. In the event the Agency issues any action under Florida Statutes or Florida Administrative Code apart from this Contract, the Vendor shall receive notice of the appropriate administrative remedy.

XVII. Definitions and Acronyms

A. Definitions

Active Ingredient – As defined in 21 CFR § 210.3.

Ad Hoc – A report designed for a specific purpose, case, or situation.

Agency – State of Florida, Agency for Health Care Administration (Agency), its employees acting in their official capacity, or its designee.

Agency Information Technology (IT) Enterprise – Any interconnected system(s) or subsystem(s) or equipment that is used in the automatic acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the Agency.

Batch – As defined in Title 21 CFR § 210.3.

Business Day – Traditional workday, including Monday, Tuesday, Wednesday, Thursday, and Friday. State holidays are excluded.

Calendar Day – All seven days of the week. A twenty-four (24) hour period between midnight and midnight, regardless of whether or not it occurs on a weekend or holiday.

Calendar Year – A twelve (12) month period of time beginning on January 1 and ending on December 31.

Canadian Supplier – As defined in Section 381.02035, F.S.

Contract – The written agreement between the Agency and the Vendor comprised of the Contract, any addenda, appendices, attachments, or amendments thereto.

Contract Amendment – Any written alteration in the specifications, delivery point, rate of delivery, Contract period, price, quantity, or other Contract provisions of any existing Contract.

Contract Manager – An individual designated to act as liaison between the Agency and the Vendor and is responsible for the management of this Contract.

Contract Year – A twelve (12) month period of time beginning with the month of contract execution and ending on the last day of the twelfth month following, and each twelve (12) month period thereafter.

Importer – The entity designated by the State to arrange for the transport of prescription drugs from Canada to the U.S. through a port of entry.

Interoperability – The ability of a system to work with or use the parts or equipment of another system and characterized by seamless coordination and integration with other systems.

Manufacturer – A Canadian entity that produces prescription drugs approved by Canada's Health Products and Food Branch intended for sale to the Canadian market.

Prescription Drug – As defined in Section 381.02035, F.S.

Prescription Drug Class – A group of prescription drugs approved by the FDA and Canadian HPFB for the treatment of the same disease(s) or health condition(s).

Program – As defined in Section 381.02035, F.S.

Representative Sample – As defined in 21 CFR § 210.3.

Top Tier Security Rating – A vendor information security rating service (e.g., BigSight Technologies, Security Scorecard, CORL Technologies) that rates vendor information security.

Track and Trace – As defined in Section 381.02035, F.S.

Vendor – The entity that contracts directly with the Agency for the work specified within this Contract.

Willful Misconduct – Conduct committed with an intentional or reckless disregard for the safety of others.

Wholesaler – As defined in Section 499.003(49), F.S.

B. Acronyms

APD	Agency for Persons with Disabilities
Apps	Applications
BAA	Business Associate Agreement
CAP	Corrective Action Plan
CFR	Code of Federal Regulations
DCF	Department of Children and Families
DOC	Department of Corrections
DOH	Department of Health
DPPA	Driver Privacy Protection Act
DQSA	Drug Quality Security Act
DSCSA	Drug Supply Chain Security Act
EEO	Equal Employment Opportunity
FAC	Florida Administrative Code

FDA	U.S. Food and Drug Administration
FIPS	Federal Information Processing Standards
F.S.	Florida Statutes
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health
IQC	Internal Quality Control
ISM	Information Security Manager
ISO	International Organization for Standardization
IT	Information Technology
NDC	National Drug Code
NIST	National Institute for Standards and Technology
PHI	Protected Health Information
PII	Personally Identifiable Information
PL	Public Law
SIP	Section 804 Importation Program Proposal
SOC	Service Organization Controls
URL	Uniform Resource Locator
U.S.	United States
U.S.C.	United States Code
W3C	World Wide Web Consortium

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EXHIBIT A-1
DELIVERABLES AND ASSOCIATED PAYMENTS

	Table 4-A Payment Schedule			
#	**State Fiscal Year - SFY**	**Deliverable / Service Description**	**Unit Cost**	**Number of Units**
Year One Operations (Readiness) (December 30, 2020 through June 30, 2021)				
1	SFY 20/21 (December)	The Vendor shall conduct implementation activities as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.,** Services Provided by the Vendor, **Item 18.**, Implementation Plan. The Vendor must provide all of the following to receive payment: • Detailed Implementation plan and timeframes for completion of steps in development and implementation of the Program • Description of operational framework for importation of prescription drugs • Identification of key staff • Identification of a Canadian drug product and proposed labeling for FDA review • Copies of inspection history • Copies of disciplinary history	**$2,127,000.00**	1
2	SFY 20/21 (January)	The Vendor shall conduct implementation activities as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.**, Services Provided by the Vendor, **Item 18.**, Implementation Plan. Vendor must provide all of the following to receive payment: • Proof of submission for completed application for Florida prescription drug wholesaler and distributor license • Description of build design for online platform • Organizational chart and resumes of key staff • Completion of face-to-face meeting and conference calls with the Agency and relevant parties for purposes of	**$2,127,000.00**	1

		coordinating implementation activities		
3	SFY 20/21 (February)	The Vendor shall conduct implementation activities as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.**, Services Provided by the Vendor, **Item 18.**, Implementation Plan. The Vendor must provide all of the following to receive payment: • Copies of all site permitting • Copy of agreement with a repackager • Completion of face-to-face meeting and conference calls with the Agency and relevant parties for purposes of coordinating implementation activities required reports and submissions are the supporting documentation the Agency will use to verify the completion of implementation activities.	**$2,127,000.00**	1
4	SFY 20/21 (March)	The Vendor shall conduct implementation activities as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.**, Services Provided by the Vendor. Vendor shall submit all of the following to receive payment: • Provide evidence of active Florida prescription drug wholesaler and distributor license application • Provide copies of executed agreements with the shipping provider(s) that will transport, ship and distribute imported prescription drugs • Provide copies of executed agreements with Canadian manufacturers or wholesalers for the purchase of eligible prescription drugs • Completion of face-to-face meeting and conference calls with the Agency and relevant parties for purposes of	**$861,050.00**	1

		coordinating implementation activities.		
5	SFY 20/21 April	The Vendor shall conduct implementation activities as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.**, Services Provided by the Vendor. The Vendor shall submit all of the following to receive payment: • Provide evidence of completed training with: o Pharmacies o Agency staff o Other State agencies • Provide evidence of completion of remaining Phase II milestones as specified in the Vendor's implementation plan • Completion of face-to-face meeting and conference calls with the Agency and relevant parties for purposes of coordinating implementation activities	**$861,050.00**	1
6	SFY 20/21 May	The Vendor shall conduct implementation activities as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.**, Services Provided by the Vendor. The Vendor shall submit all of the following to receive payment: • Provide copy of final certificate of occupancy for warehouse • Provide evidence of completion of Phase II milestones as specified in the Vendor's implementation plan • Completion of face-to-face meeting and conference calls with the Agency and relevant parties for purposes of coordinating implementation activities	**$861,050.00**	1
7	SFY 20/21 June	The Vendor shall conduct implementation activities as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section**	**$861,050.00**	1

		B., Services Provided by the Vendor. The Vendor shall submit all of the following to receive payment: • Provide evidence of completion of successful testing of online platform • Completion of face-to-face meeting and conference calls with the Agency and relevant parties for purposes of coordinating implementation activities		
Year Two Operations (July 1, 2021 through June 30, 2022)				
8	SFY 21/22 (July-June)	The Vendor shall provide prescription drug importation services as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.**, Services Provided by the Vendor. The required reports are the supporting documentation the Agency will use to verify the completion of services.	**$1,208,000.00** (Not to exceed **$14,496,000.00**)	12
Year Three Operations (July 1, 2022 through June 30, 2023)				
9	SFY 22/23 (July- June)	The Vendor shall provide prescription drug importation services as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.**, Services Provided by the Vendor. The required reports are the supporting documentation the Agency will use to verify the completion of services.	**$1,208,000.00** (Not to exceed **$14,496,000.00**)	12
Year Four Operations (If Renewed) (July 1, 2023 through June 30, 2024)				
10	SFY 23/24 (July-June)	The Vendor shall provide prescription drug importation services as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.**, Services Provided by the Vendor. The required reports are the supporting documentation the Agency will use to verify the completion of services.	**$1,208,000.00** (Not to exceed **$14,496,000.00**)	12

EXHIBIT A-1
DELIVERABLES AND ASSOCIATED PAYMENTS

Year Five Operations (If Renewed) (July 1, 2024 through June 30, 2025)				
11	SFY 24/25 (July- June)	The Vendor shall provide prescription drug importation services as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.,** Services Provided by the Vendor. The required reports are the supporting documentation the Agency will use to verify the completion of services.	**$1,208,000.00** (Not to exceed **$14,496,000.00**)	12
Year Six Operations (If Renewed) (July 1, 2025 through June 30, 2026)				
12	SFY 25/26 (July- June)	The Vendor shall provide prescription drug importation services as described in **Attachment I-A,** Scope of Services – Update August 1, 2021, **Section II.,** Manner of Service(s) Provision, **Sub-Section B.**, Services Provided by the Vendor. The required reports are the supporting documentation the Agency will use to verify the completion of services.	**$1,208,000.00** (Not to exceed **$14,496,000.00**)	12

Note: Failure by the Vendor to provide the deliverables in accordance with the requirements of Attachment I-A, Scope of Services – Update August 1, 2021, shall be subject to the performance measures and liquidated damages provided in Section III., Method of Payment, Sub-Section C., Financial Consequences as Liquidated Damages.

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