**Instructions to respondents for the completion of Exhibit A-4:**

All respondents to this solicitation shall utilize **Exhibit A-4**, Submission Requirements and Evaluation Criteria Components (Technical Response), for submission of its response and shall adhere to the instructions below for each Submission Requirement Component (SRC).

Respondents **shall not** include website links, embedded links and/or cross references between SRCs.

Each SRC contains form fields. Population of the form fields with text will allow the form field to expand and cross pages. There is no character limit.

Attachments are acceptable for any SRC but must be referenced in the form field for the respective SRC and located behind each respective SRC response. Respondents shall name and label attachments to refer to respective SRCs by SRC identifier number.

Agency evaluators will be instructed to evaluate the responses based on the narrative contained in the SRC form fields and the associated attachment(s), if applicable.

Each response will be independently evaluated and awarded points based on the criteria and points scale using the Standard Evaluation Criteria Scale below unless otherwise identified in each SRC contained within **Exhibit A-4**.

|  |
| --- |
| **STANDARD EVALUATION CRITERIA SCALE** |
| **Point Score** | **Evaluation** |
| 0 | The component was not addressed. |
| 1 | The component contained significant deficiencies. |
| 2 | The component is below average. |
| 3 | The component is average. |
| 4 | The component is above average. |
| 5 | The component is excellent. |

The SRCs in **Exhibit A-4** may not be retyped and/or modified and must be submitted in the original format.

Failure to submit, **Exhibit A-4**, may result in the rejection of response.

**Exhibit A-4** is available for respondents to download at:

[http://ahca.myflorida.com/procurements/index.shtml](http://ahca.myflorida.com/Procurements/index.shtml).

**Respondent Name:**

**SRC #1: Table of Contents**

The respondent shall include a Table of Contents in its response. The Table of Contents shall contain section headings and subheadings along with corresponding page numbers. The Table of Contents shall be provided as an attachment.

**Score:** No points will be awarded for the Table of Contents.

**SRC #2: Executive Summary**

The respondent shall include an executive summary that indicates a thorough understanding of the overall need for and purpose of the services described in this solicitation, and adequately summarizes its approach to delivering these services according to the specifications of this solicitation and Section 381.02035, Florida Statutes (F.S.).

**Response:**

**Score:** No points will be awarded for the Executive Summary.

**SRC #3: Organizational Structure and History**

The respondent shall describe its organizational structure and history as it relates to the performance of the requirements of the Program. The description shall include, at a minimum:

1. A detailed description of the respondent’s organizational structure, history, legal structure, ownership, affiliations, and location(s).
2. A copy of the respondent’s organizational chart, including the total number of employees and the respondent’s corporate qualifications. Evidence shall be clear that the respondent has necessary and sufficient personnel employed to carry out all tasks for which the successful respondent is responsible.

**Response:**

**Evaluation Criteria:**

The respondent shall demonstrate its capability to provide the services described in this solicitation by describing its organizational structure and history.

1. The adequacy of the respondent’s ability to provide the services described in this solicitation based on its organizational structure, history, legal structure, ownership, affiliations, and location(s).
2. The adequacy of the respondent’s staffing levels for this project based on the organizational chart and the respondent’s corporate qualifications.

**Score:** This section is worth a maximum of **10** raw points with each of the above components worth a maximum of 5 points each.

**SRC #4: Florida Presence**

The respondent shall provide information regarding whether each of its operational functions will be based in the State of Florida, and the extent to which operational functions will be conducted by staff in-house or through contracted arrangements, located in the State of Florida. This includes:

1. Specifying the location of the respondent’s corporate headquarters.
2. Indicating whether the respondent is a subsidiary of, or a joint venture with, any other entity whose principal office will not be located in the State of Florida.
3. Identifying the number of full-time staff, by operational function that will be located in the State of Florida and out of state.
4. A detailed description of the respondent’s proposed physical business locations, in or outside the State of Florida, and how those locations will be utilized to effectively provide the services required by this solicitation.

**Response:**

**Evaluation Criteria:**

1. Whether the respondent’s corporate headquarters will be located in Florida (if it is not a subsidiary of, or a joint venture with, any other entity whose principal office will be located outside Florida).
2. 5 points for corporate headquarters in Florida and no parent or joint venture organization outside Florida;
3. 0 points if no relevant corporate headquarters in Florida.
4. The extent to which operational functions will be performed in the State of Florida.

5 points will be awarded for each of the following operational functions performed in Florida.

Documentation and Recordkeeping;

Prescription drug laboratory testing;

Prescription drug storage;

Repackaging and relabeling; and

1. Prescription Drug Distribution.

**Score:** This section is worth a maximum of **35** raw points. Each of the above components is worth a maximum of 5 points each, for a total of 30 points. Five (5) additional points will be awarded if the respondent meets Items 1(a) and 2(a) above.

**SRC #5: Contract Performance**

The respondent shall state whether, in the past five (5) years from date of solicitation issuance as noted in **Attachment A.**, Instructions and Special Conditions, Section A.1., Instructions, Sub-section A., Overview, Item 4., Date of Issuance, it has:

1. Voluntarily terminated all or part of a drug importation or distribution contract;
2. Had such a contract partially or fully terminated before the contract end date (with or without cause); and
3. Withdrawn from a contracted state or other service area; or has requested any reductions in its responsibilities under the terms of the contract.

If so, describe the contract, the month and year of the contract action, the reason for termination, withdrawal, or reduction of responsibilities, the parties involved, and the name, address, and telephone number of the authority for the client or other party.

If the contract was terminated based on the respondent’s performance, describe any corrective action taken to prevent future occurrence of the problem leading to the termination.

Include information for the respondent as well as the respondent’s affiliates and subsidiaries and its parent organization and that organization’s affiliates and subsidiaries.

**Response:**

**Evaluation Criteria:**

1. The extent to which the respondent has requested reductions in responsibilities or voluntarily terminated all or part of a contract.
2. The extent to which the respondent had contracts terminated due to performance.
3. The extent to which the respondent had terminations for performance issues related to drug importation or distribution operational functions rather than administrative concerns.
4. The extent to which the respondent had terminations for performance issues related to administrative or solvency concerns.

**Score:** This section is worth a maximum of **20** raw points with each of the above components worth 5 points each as described below.

For Item 1:

1. 5 points for no voluntary termination of all or part of a contract, no requests for reductions in responsibilities, and no withdrawals from service areas.
2. 0 points for any voluntary terminations, requests for reductions in responsibilities, or withdrawals from service areas.

For Item 2:

1. 5 points for no involuntary terminations.
2. 0 points for any involuntary termination based on performance.

For Item 3:

1. 5 points for no contract terminations due to issues with operational functions.
2. 0 points for any contract terminations due to issues with operational functions.

For Item 4:

1. 5 points for no contract terminations due to issues with administrative functions.
2. 0 points for any contract terminations due to issues with administrative functions.

**SRC #6: Drug Importation / Distribution Experience (National)**

The respondent, including the respondent’s parent, affiliate(s) and subsidiary(ies), hereinafter referred to as the respondent, shall provide a list of all of its current and/or recent (within two (2) years) of the issue date of this solicitation as noted in **Attachment A.**, Instructions and Special Conditions, Section A.1., Instructions, Sub-section A., Overview, Item 4., Date of Issuance, contracts for pharmaceutical importation and distribution.

The respondent shall provide the following information for each identified contract:

1. The name and address of the client;
2. The name of the contract;
3. The specific start and end dates of the contract;
4. A brief narrative describing the role of the respondent and the scope of work performed, including the contract’s goals and objectives;
5. The use of administrative and/or delegated subcontractor(s) and their scope of work;
6. The annual contract amount (payment to the respondent) and annual payment amounts;
7. The scheduled and actual completion dates for contract implementation;
8. Barriers encountered that hindered implementation (if applicable) and the resolutions; and
9. Performance metric and evaluation outcomes under the contract.

In addition, the respondent shall describe its experience working with state agencies in general and with agencies included in the Program in particular.

For this SRC, the respondent may include experience provided by subcontractors for which the respondent was contractually responsible, if the respondent plans to use those same contractors for Florida’s Canadian Prescription Drug Importation Program.

**Response:**

**Evaluation Criteria**

1. The extent of the respondent’s experience providing drug importation and distribution services.
2. The extent of the respondent’s subcontractors’ experience in providing drug importation and distribution services.
3. The extent to which the barriers to implementation experienced by the respondent have clear resolutions outlined/described.
4. The extent to which the respondent has listed performance metric and evaluation outcomes applicable to this solicitation.
5. The extent to which the respondent’s state agencies served are similar to the services required in this solicitation.
6. The extent to which the respondent has existing contracts in the State of Florida.

**Score:** This section is worth a maximum of **30** raw points with each of the above components worth a maximum of 5 points each.

**SRC #7: Eligible Foreign Seller**

The respondent shall specify its current registration status with the United States Food and Drug Administration (FDA) and licensure with Health Canada.

**Response:**

**Evaluation Criteria:**

Evidence that the respondent has:

1. Current and active registration, in good standing, as a Canadian Supplier with the United States Food and Drug Administration.
2. A current and active drug establishment license, in good standing, as a wholesaler from Health Canada.

**Score:** This section is worth a maximum of **10** raw points with each of the above components worth a maximum of 5 points each.

**SRC #8: Contracts and Agreements**

The respondent shall list any proposed subcontractors and associates to which it will delegate any function within the supply chain. The respondent shall describe how it will oversee and monitor the performance of subcontractors and associates in general, as well as any specific oversight planned for certain subcontractors and associates. The respondent shall include in its response the schedule and type of monitoring and how findings are reported, remediated, and used for process improvements.

**Response:**

**Evaluation Criteria:**

1. The extent to which the respondent provides a list of subcontractors and associates it proposes to use under the Program for the delegation of work described in this procurement.
2. The adequacy of the respondent’s oversight structure, including the extent of executive level staff participation.
3. The adequacy of the respondent’s approach to monitoring the quality of work performed by subcontractors and associates, including the frequency and type of monitoring.
4. The adequacy of the respondent’s processes for addressing performance issues, including the triggers for increase monitoring activities, interventions, and compliance actions.
5. The extent to which the respondent provides monitoring activities it will use to ensure the financial stability of the subcontractor and associate, including the required financial reporting frequency for subcontractors and associates.

**Score:** This section is worth a maximum of **25** raw points with each of the above components worth a maximum of 5 points each.

**SRC #9: Track and Trace Requirements**

The respondent shall describe its use of an electronic system (or other Customs and Border Protection (CBP)-authorized electronic data interchange system) to collect and maintain transaction information as the prescription drug product(s) transition through the supply chain. The respondent shall describe its back-up systems to ensure, at a minimum, information is maintained on behalf of eligible importer(s). The respondent shall provide detailed information, where applicable, on documents relating to any activity involved in the supply chain, particularly how documents are designed, completed, reviewed, distributed, approved and amended.

**Response:**

**Evaluation Criteria:**

The respondent shall demonstrate its ability and approach to track and trace prescription drugs throughout the supply chain. The description shall be evaluated based on the following:

1. The extent to and frequency on which transaction information, transaction history, and transaction statements for prescription drugs is verified for accuracy.
2. The extent to which the respondent provides examples of documents that show product traceability to the original manufacturer and the manufacturing site, the results of statutory testing of statistically valid samples from the qualifying laboratory, the organization issuing the Certificate of Analysis (COA), and describe the availability of the COA and testing results when requested.
3. The extent to which the respondent documents agreements, contracts, and mechanisms to allow transfer of information, custody, or other functions in the supply chain.
4. The respondent maintains information on behalf of eligible importers and participating Canadian Suppliers as specified in **Attachment B**, Scope of Services.
5. The extent to which the respondent maintains records in accordance with industry standards and makes them available upon request.

**Score:** This section is worth a maximum of **25** raw points with each of the above components worth a maximum of 5 points each.

**SRC #10: Prescription Drugs Eligible for Importation**

The respondent shall describe how it will identify prescription drugs that demonstrate significant cost savings to the State of Florida. The respondent shall provide detailed information describing how it will ensure prescription drugs maintain the same formulations of FDA-approved drugs, how it will ensure that prescription drugs are eligible for importation in accordance with federal and State regulations, and how it will prevent prescription drugs that are not eligible for importation (e.g., donated drugs to charitable organizations, drugs not labeled for the Canadian market) from entering the United States (U.S.).

**Response:**

**Evaluation Criteria:**

1. The extent of the respondent’s ability to ensure imported prescription drugs will generate significant cost savings to the State that will result in continued federal approval of the program.
2. The adequacy of the respondent’s ability to ensure that imported prescription drugs will generate significant cost savings to the State that will result in continued federal approval of the program.
3. The extent to which the respondent can prevent prescription drugs that are not eligible for importation from entering the U.S.
4. The extent of the respondent’s capability to acquire prescription drugs from approved Canadian manufacturers.
5. The extent of the respondent’s ability to maintain transparent pricing information and communicate pricing changes to the Agency.

**Score:** This section is worth a maximum of **25** raw points with each of the above components worth a maximum of 5 points each.

**SRC #11: Supply Chain Quality Assurance**

The respondent shall describe how its processes and procedures for tracking and tracing imported prescription drugs conform to the Drug Supply Chain Security Act (DSCSA), including how it shall prepare and maintain transaction information, transaction histories, and transaction statements. The respondent shall provide detailed information outlining how it will ensure imported prescription drugs are safely transported beginning with the manufacturer and ending with the consumer.

**Response:**

**Evaluation Criteria:**

1. The adequacy of the respondent’s ability to ensure imported prescription drugs comply with the DSCSA.
2. The extent of the respondent’s capability to prepare and maintain all required documentation, including transaction information, transaction histories, and transaction statements.
3. The extent to which the respondent can identify the responsibilities of all parties involved in the pharmaceutical supply chain, including their delegation of responsibilities, inspections, and compliance with current industry standards.
4. The adequacy of the respondent’s ability to continuously monitor and improve upon their processes and procedures for supply chain quality assurance.

**Score:** This section is worth a maximum of **20** raw points with each of the above components worth a maximum of 5 points each.

**SRC #12: Laboratory Testing**

The respondent shall describe how it will meet laboratory testing requirements, including laboratory qualifications, sampling methodologies, and provide a flowchart, written description and other mapping of the process the respondent will utilize for handling prescription drugs not allowed under the program (e.g., counterfeit, expired), including identifying, tracking, and analyzing the outcomes of this process.

**Response:**

**Evaluation Criteria:**

1. The extent to which the respondent describes the how it will meet laboratory testing requirements, traceability, compliance with the Food, Drug, and Cosmetic Act (FDCA), policies and procedures for handling of drugs that fail laboratory testing.
2. The extent to which the respondent describes the handling of prescription drugs not allowed under the program in accordance with a procedure that ensures appropriate quarantine of the products and prevents their introduction or reintroduction into the market. This includes maintenance of records covering all activities, including destruction, disposal, return, and reclassification.
3. The extent to which the respondent describes how investigations are performed to determine the extent to which other batches are also affected. This includes the identification of corrective and preventive measures where necessary.
4. The extent to which the respondent describes the process for documenting the disposition of the material, including downgrading to other suitable purposes.

**Score:** This section is worth a maximum of **20** raw points with each of the above components worth a maximum of 5 points each.

**SRC #13: Repackaging, Labeling, and Relabeling**

The respondent shall provide detailed information on its methods and processes relating to all activity involved in the supply chain, particularly how products are packaged, re-packaged, labeled, relabeled, and safely readied for lawful distribution under the program in accordance with 21 U.S.C. § 352; 61N-1.032, Florida Administrative Code (F.A.C.). The respondent shall provide a process map that demonstrates the series of processes through which prescription drugs are repackaged, labeled, and/or relabeled, as applicable.

**Response:**

**Evaluation Criteria:**

The respondent shall demonstrate its ability and approach to ensuring safe and accurate repackaging and relabeling in compliance with Title 21 U.S.C. § 352 and Rule 61N-1.032, F.A.C. The description shall be evaluated based on the following:

1. The extent to which the respondent’s description addresses minimum requirements of State and federal requirements.
2. The extent to which the respondent’s description identifies and demonstrates how the respondent proposes to exceed minimum standards to bring about operational efficiencies, provide extra assurance of product safety and integrity, and to assure the exclusion of prohibited practices identified in state and federal regulations
3. The extent to which the respondent provides a process map identifying the steps through which prescription drugs are repackaged and relabeled.

**Score:** This section is worth a maximum of **15** raw points with each of the above components worth a maximum of 5 points each.

**SRC #14: Prescription Drug Storage**

The respondent shall provide a detailed implementation and operating plan of authorized activities relating to the purchase, importation, receipt, security, storage, inventory, and distribution of products in the oversight and management of the prescription drug supply chain and the Florida Canadian Prescription Drug Importation Program. This includes:

1. The respondent’s use of the Automated Commercial Environment (ACE) or other U.S. Customs and Border Protection (CBP)-authorized electronic data interchange system; and
2. Written policies and procedures demonstrating compliance with state and federal regulations for the receipt, security, storage, inventory, and distribution of prescription drugs.
3. A flowchart, written description and other mapping of the process the respondent will utilize for dispatch and transport of prescription drug products, including identifying, tracking, and analyzing the outcomes of this process

**Response:**

**Evaluation Criteria:**

The response shall describe the respondent’s ability and approach to ensuring timely and accurate reporting to the Agency as specified in **Attachment B**, Scope of Services. The description shall be evaluated based on the following:

1. The extent to which the respondent’s description demonstrates compliance with Title II of the Federal DSCSA.
2. The extent to which the respondent’s description demonstrates compliance with Part I of Chapter 499, F.S. and rules promulgated by the Department of Business and Professional Regulation regarding the procurement, warehousing, and storage of prescription drugs.
3. The extent to which the respondent implements safety protocols that exceed the minimum standards of state and federal regulations in the procurement of prescription drugs.
4. The extent to which the respondent implements safety protocols that exceed the minimum standards of state and federal regulations in the warehousing of prescription drugs.
5. The extent to which the respondent implements safety protocols that exceed the minimum standards of state and federal regulations in the storage of prescription drugs.
6. The extent to which the respondent describes product safety protocols in its description of the processes for loading, unloading, and transporting prescription drugs in a manner that ensures the maintenance of controlled conditions where applicable (e.g. recommended storage temperature and/or humidity, protection from the environment).
7. The extent to which the respondent describes requirements for special transport of prescription drugs.
8. The extent to which the respondent’s processes and procedures assure proper cleaning and prevention of cross-contamination when products are transported.

**Score:** This section is worth a maximum of **40** raw points with each of the above components worth a maximum of 5 points each.

**SRC #15: Immediate Suspension and Recalled Products**

The respondent shall provide a workflow, written description and other mapping of the process the respondent will utilize for recalls, including identifying, tracking, and analyzing recalls and their outcomes. The respondent shall provide a written description of the process the respondent will utilize for returned products, including identifying, tracking, and analyzing returns and their outcomes.

**Response:**

**Evaluation Criteria:**

1. The extent to which the respondent describes a system for recalling promptly and effectively from the market, products known or suspected to be defective.
2. The extent to which the respondent describes a notification system to inform the Agency and points along the supply chain of a recall and the reason for the product to be returned.
3. The extent to which the respondent describes its procedures for any recall activity, including the frequency with which those procedures are regularly reviewed and updated.
4. The extent to which the respondent describes the measures to quarantine and store recalled products in a secure area while their disposition is decided.
5. The extent to which the respondent details the process for promptly informing consumers and authorities of any intention to recall prescription drug products in the event of serious or potentially life-threatening situations.
6. The extent to which the respondent describes its recordkeeping and documentation protocols and is able, upon request, to summon and provide sufficient information on products supplied to consumers (including imported products).
7. The extent and frequency with which the respondent regularly evaluates the effectiveness of the arrangements for recalls.
8. The adequacy of the respondent’s process for handling of returned products, including identifying and quarantining returned prescription drugs.
9. The extent to which the respondent describes the conditions under which returned goods are stored and shipped and the respondent’s process and frequency of evaluation of the quality of the returned goods.
10. The extent to which the respondent describes how internal quality control processes provide for a formal investigation process prior to the return of goods, and identifies the need for corrective and preventive actions where appropriate.

**Score:** This section is worth a maximum of **50** raw points with each of the above components worth a maximum of 5 points each.

**SRC #16: Drug Shortages**

The respondent shall describe its processes and procedures for addressing prescription drug shortages. The respondent shall provide detailed information specifying how it will work with the Canadian Supplier to obtain the required prescription drugs and how it will communicate information regarding drug shortages to the State.

**Response:**

**Evaluation Criteria:**

1. The adequacy of the respondent’s plan to respond to drug shortages, including how it will ensure imported prescription drug quotas are met.
2. The extent of the respondent’s ability to communicate timely to the State regarding shortages that could result in Floridians not receiving medically necessary prescription drugs.
3. The extent of the respondent’s ability to update the State on a monthly basis regarding prescription drug availability.

**Score:** This section is worth a maximum of **15** raw points with each of the above components worth a maximum of 5 points each.

**SRC #17: Implementation Plan**

The respondent shall demonstrate its capability to successfully meet the requirements of this solicitation and the resulting Contract by describing its capability to implement the prescription drug importation program as described in **Attachment B.,** Scope of Services, Section II., Manner of Service(s) Provision, Sub-Section B., Services Provided by the Vendor, Item 13., Implementation Plan. At a minimum, the response shall include the following:

* + - 1. Level of effort for the entire Program based on the detailed narrative description;
			2. Timeline for Project implementation that encompasses all phases of the Project;
			3. Milestones and anticipated completion dates for activities during all phases;
			4. Potential risks or barriers to timely implementation and proposed methods for overcoming them;
			5. Process for review, revision and approval of planning documents, testing processes, and other deliverables;
			6. Roles and responsibilities of proposed subcontractors in completion of implementation tasks;
			7. Assistance needed from the Agency; and
			8. The respondent’s proposed approach to ensuring interaction and communication with Agency staff and subcontractors during the implementation activities to ensure successful implementation of the Program.

The respondent’s entire response for this SRC must be provided within the respective response field below and up to two (2) attachments, as prescribed herein.

Attachments are limited to the following:

* Visual presentations of the implementation plan.
* Project Implementation Timeline, presented in both PDF and Microsoft Project formats.

**Response:**

**Evaluation Criteria:**

1. The adequacy of the respondent’s proposed implementation plan based on the identified level of effort for the entire Project.
2. The adequacy and viability of the respondent’s proposed implementation plan based on the timeline for Project implementation.
3. The adequacy of the respondent’s proposed implementation plan based on inclusion of all phases of the Project.
4. The adequacy and viability of the respondent’s proposed implementation plan based on the identified milestones and anticipated completion dates for activities during all phases.
5. The adequacy and viability of the respondent’s proposed implementation plan based on the identified potential risks or barriers to timely implementation and proposed methods for overcoming them.
6. The adequacy and viability of the respondent’s proposed implementation plan based on the identified process for review, revision and approval of planning documents, testing processes, and other deliverables.
7. The adequacy, viability and appropriateness of the respondent’s proposed implementation plan based on the identified roles and responsibilities of proposed subcontracts in completion of implementation tasks.
8. The adequacy and appropriateness of the respondent’s proposed implementation plan based on the identified assistance needed from the Agency.
9. The adequacy and viability of the respondent’s proposed approach to ensuring interaction and communication with Agency staff and subcontractors during implementation to ensure successful implementation of the Program.

**Score:** This section is worth a maximum of **45** raw points with each of the above components worth a maximum of 5 points each.

**SRC #18: Outreach and Communications**

The respondent shall submit a draft of its outreach and communication plan. The respondent shall provide detailed information explaining how it will communicate to participating state agencies, stakeholders, and providers.

**Response:**

**Evaluation Criteria:**

1. The extent to which the respondent is able to post updates to its webpage and send emails to notify state agencies, stakeholders, and providers of recalls or emergencies impacting prescription drug distribution or availability.
2. The adequacy of the respondent’s ability to report monthly on its communication and outreach activities
3. The extent to which the respondent is able to prepare a communications and outreach plan within seven (7) days of execution of the resulting contract.

**Score:** This section is worth a maximum of **15** raw points with each of the above components worth a maximum of 5 points each.

**SRC #19: Staffing Requirements**

The respondent shall demonstrate its capability to successfully meet the requirements of this solicitation and the resulting Contract by describing its capability to meet the staffing requirements as described in **Attachment B,** Scope of Services, Section II., Manner of Service(s) Provision, Sub-Section B. Services Provided by the Vendor, Item 16. Staffing Requirements. At a minimum, the description shall include the following:

1. A staff organization chart for the staff that will provide services for this Project that identifies proposed key staff by name and position title;
2. Proposed staffing levels;
3. The respondent’s proposed approach to ensure staff conduct all components of the Contract resulting from this solicitation in a timely, efficient, productive, consistent, courteous, and professional manner as representatives of the State;
4. The respondent’s proposed approach to ensure all staff are familiar with and have a general knowledge of all components of the Contract resulting from this solicitation;
5. A description of key staff positions, including the decision-making authority within the organization and the percentage of time each key staff employee will spend on this Project;
6. Resumes for key staff listed below, demonstrating their education and experience as required by this solicitation. If the position will need to be filled, indicate the qualifications that must be met by the applicants:
	1. Contract Manager;
	2. Customer Service Supervisor; and
	3. Compliance Officer.
7. The respondent’s proposed approach to ensure it employs a sufficient number of qualified staff to provide the services required in this solicitation and the resulting Contract;
8. The respondent’s proposed approach to ensure it employs sufficient Information Technology staff to respond timely to all reporting elements in this Contract;
9. The respondent’s proposed approach to ensure the capability of its Contract Manager to meet with Agency staff, both face-to-face and via conference call throughout the resulting Contract period;
10. The respondent’s proposed approach to ensure staff communicate all contract issues to the designated Agency Contract Manager as the single point of contact;
11. The respondent’s proposed approach to ensure a sufficient number of staff who are fluent in both English and Spanish, and how interpreter services will be provided to consumers and providers whose primary language is not English, and meet the additional service requirements described in this solicitation;
12. The respondent’s proposed subcontracting plan must be void of conflicts of interest and include the identification of any current or anticipated subcontracts the respondent will use in operating the Program. The respondent’s description shall include at a minimum, the name of the subcontracted organization(s); the services to be provided; and the qualifications of the subcontracted organization(s); and
13. The respondent’s proposed approach to coordinate and communicate with any proposed subcontractors and the Agency to ensure effective integration of services.

The respondent’s entire response for this SRC must be provided within the respective response field below and up to six (6) attachments, as prescribed herein.

Attachments are limited to the following:

* Staff organization chart, including proposed staffing levels;
* Key staff position descriptions;
* Proposed Contract Manager resume or required qualifications if position is to be filled;
* Proposed Customer Service Manager or required qualifications if position is to be filled;
* Proposed Compliance Officer or required qualifications if position is to be filled; and
* Qualifications of key subcontractors the respondent intends to utilize for this program (if applicable).

**Response:**

**Evaluation Criteria:**

1. The adequacy of the respondent’s organizational structure based on its proposed staff organization chart.
2. The adequacy of the respondent’s proposed staffing levels to meet the requirements of this solicitation and the resulting Contract.
3. The adequacy of the respondent’s proposed approach to ensure staff conducts all components of the Contract resulting from this solicitation in a timely, efficient, productive, consistent, courteous, and professional manner as representatives of the State of Florida.
4. The adequacy of the respondent’s proposed approach to ensure all staff are familiar with and have a general knowledge of all components of the Contract resulting from this solicitation.
5. The adequacy of the respondent’s proposed decision-making authority for key staff positions.
6. The adequacy of the respondent’s proposed allocation of dedicated staff time.
7. The adequacy of the respondent’s proposed Contract Manager based on their resume or the proposed required qualifications of the Contract Manager position if the position must be filled.
8. The adequacy of the respondent’s proposed Customer Service Supervisor based on their resume(s) or the proposed required qualifications of the Education/Customer Service Manager position(s) if the position(s) must be filled.
9. The adequacy of the respondent’s proposed approach to ensure it employs a sufficient number of Information Technology staff to perform duties outlined in this solicitation and the resulting Contract.
10. The adequacy of the respondent’s proposed approach to ensure the Contract Manager’s availability to meet with Agency staff, both face-to-face and via conference call throughout the implementation period and the duration of the resulting Contract period.
11. The adequacy of the respondent’s proposed approach to ensure staff communicates all contract issues to the designated Agency Contract Manager as the single point of contact.
12. The adequacy of the respondent’s proposed approach to ensure a sufficient number of staff who are fluent in both English and Spanish are available.
13. The adequacy of the respondent’s proposed approach to provide interpreter services to consumers and providers whose primary language is not English and meet the additional service requirements described in this solicitation.
14. The adequacy and appropriateness of the respondent’s proposed subcontracting plan as evidenced by the delegation of services for the Prescription Drug Importation Program to proposed subcontractors and the adequacy of the respondent’s proposed approach to coordinate and communicate with proposed subcontractors.

**Score:** This section is worth a maximum of **70** raw points with each of the above components worth a maximum of 5 points each.

**SRC #20: Customer Service**

The respondent shall describe its customer service call center located in the state of Florida. The respondent shall provide information on the number of call center staff and their training.

**Response:**

**Evaluation Criteria:**

The respondent shall demonstrate its capability to provide the services described in this solicitation by describing its customer service functions.

1. The extent to which the respondent has adequate staff trained to handle inquiries regarding prescription drug importation.
2. The extent to which the respondent’s Florida locations will have staff available during business days from 8:00 AM to 5:00 PM EST.
3. The extent to which the respondent’s call center can answer ninety percent (90%) of all calls received during normal business hours within thirty (30) seconds.

**Score:** This section is worth a maximum of **15** raw points with each of the above components worth a maximum of 5 points each.

**SRC #21: Complaints**

The respondent shall provide a flowchart, written descriptions and other mapping of the process the respondent will execute for its complaint system, including identifying, tracking, and analyzing consumer complaints regarding defective products, issues with access to the system, issues with distribution, tracking, tracing, and all other aspects of the Program. The respondent shall include in the description details how the data resulting from the complaint system are used to improve the operational performance of the respondent.

**Response:**

**Evaluation Criteria:**

1. The extent to which the respondent’s documentation describes the process for the review of complaints and how complaint outcome information is utilized in the Internal Quality Control (IQC) process.
2. The extent to which the respondent’s documentation identifies the action to be taken and specifies the criteria on which a decision to recall a product is based, as well as how records of complaints are retained and evaluated for trends at defined intervals.
3. The extent to which the respondent’s description reflects how complaints are recorded and thoroughly investigated to identify the origin or reason for the complaint (e.g., the repackaging procedure or the original manufacturing process), as well as how corrective and preventive actions are taken where appropriate and recorded.
4. The extent to which the respondent gives consideration to whether other batches are checked if a defect in a pharmaceutical starting product is discovered or suspected.
5. The extent to which the respondent’s documentation reflects appropriate follow-up action, possibly including a recall, is taken after investigation and evaluation of the complaint.
6. The extent to which the respondent informs the manufacturer(s) and consumers if action is needed following possible faulty manufacturing, packaging, deterioration or any other serious quality problems with a prescribed drug product.

**Score:** This section is worth a maximum of **30** raw points with each of the above components worth a maximum of 5 points each.

**SRC #22: Internal Quality Control Plan**

The respondent shall describe its quality assurance system, and how that system is utilized to implement, maintain, and improve lawful trade and distribution practices. The description shall address, but not be limited to, 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. The respondent shall include in the description details of how the data resulting from these systems are used to assure product safety and improve the operational performance of the respondent.

**Response:**

**Evaluation Criteria:**

The respondent shall demonstrate its ability and approach to implementing a quality assurance system to implement, maintain, and improve lawful trade and distribution practices. The description shall be evaluated based on the following:

1. The extent to which the respondent has an infrastructure or “quality system” encompassing the organizational structure, procedures, processes, functions and resources, as well as the size, structure, and complexity of the prescription drug wholesale distributor and its activities are taken into consideration.
2. The extent to which the respondent has an independent quality unit (or designee), which is responsible for all quality-related matters.
3. The extent to which the respondent has an IQC plan to foster a systematic process for the assessment, control, communication and review of risks to the quality of the product.
4. The extent of application of the IQC system should reflect the operations performed.
5. The extent to which the respondent has a validation/qualification system to ensure that the product meets the requirements of the Program.
6. The extent to which the respondent has policies and procedures necessary to ensure confidence that a product (or function) and relevant documentation will satisfy given requirements for quality.
7. The extent to which the respondent has a clearly documented procedure for selecting, approving, disqualifying, and re-approving sellers of pharmaceutical products and services.
8. The extent of evidence from the respondent that it ensures prohibition of Canadian Suppliers and importers from distributing, dispensing, or selling prescription drugs for purposes other than those intended under the Program.

The extent of evidence from the respondent that it ensures prohibition of Canadian Suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the Program outside of the state of Florida.

1. The extent to which the respondent has mechanisms to ensure that quality is continually assessed and maintained. These include a consumer notification where appropriate.
2. The extent to which the respondent has a system ensuring traceability of products and associated documentation throughout the entire supply chain.

**Score:** This section is worth a maximum of **55** raw points with each of the above components worth a maximum of 5 points each.

**SRC #23: Reporting**

The respondent shall describe its ability and approach to ensuring timely and accurate reporting to the Agency as described in **Attachment B.**, Scope of Services. At a minimum, the description shall include:

1. The respondent’s approach to compiling information to include in its monthly, quarterly, and annual reports.
2. How the respondent shall ensure accurate and timely reporting of all deliverables as required by **Attachment B.**, Scope of Services, Section II., Manner of Service(s) Provision, Sub-Section D., Reporting.
3. A description of the data systems and software that will be used to submit reports as required by **Attachment B.**, Scope of Services, Section II., Manner of Service(s) Provision, Sub-Section D., Reporting.

**Response:**

**Evaluation Criteria:**

The response shall describe the respondent’s ability and approach to ensuring timely and accurate reporting to the Agency as specified in **Attachment B.**, Scope of Services, Section II., Manner of Service(s) Provision, Sub-Section D., Reporting. The description shall be evaluated based on the following:

1. The adequacy of the respondent’s approach to identifying metrics reflective of information to include in its monthly status report.
2. The adequacy of the respondent’s approach to ensuring accurate and timely reporting to the Agency.
3. The adequacy of the respondent’s description of the data systems and software that will be used to submit electronic work papers and the final report.

**Score**: This section is worth a maximum of **15** raw points with each of the above components worth a maximum of 5 points each.

**SRC #24: Cost Analysis**

The respondent shall describe the methodology it will utilize to determine the costs for operating the Program, as well as to determine the cost savings to the State attributable to the Program. The respondent shall utilize the list of drugs and other applicable information defined in recent legislation and in Agency materials and complete a cost analysis to demonstrate costs and ongoing savings. The respondent’s methodology must provide transparency into its cost analysis by addressing:

* 1. The utilization of each eligible drug.
	2. The net unit cost and total cost of each eligible drug.
	3. The unit cost and total cost of each eligible U.S. manufactured drug to the unit cost and total cost of its Canadian equivalent.
	4. The estimated difference between the total cost of each eligible U.S. manufactured drug and the total cost of its Canadian equivalent.
	5. The extent to which seller and wholesaler profit and the amount of markup for each drug.
	6. The costs associated with repackaging and relabeling.
	7. Costs associated with testing the drugs at an FDA-qualified laboratory.
	8. The amount of vendor costs that are offset by savings from the Program.
	9. The extent to which the respondent included pharmacy benefits administrators and managers.

**Response:**

**Evaluation Criteria:**

**Score:** No points will be awarded for the Cost Analysis.

**SRC# 25: System Functionality Requirements**

The respondent shall demonstrate its capability and approach to provide the System Functionality Requirements described in **Attachment B**, Scope of Services, Section XI., System Functionality.

**Response:**

**Evaluation Criteria:**

1. The adequacy of the respondent’s capability and approach to have the capacity (hardware, software, and personnel) sufficient to access and generate all data and reports needed for the Contract resulting from this solicitation.
2. The adequacy of the respondent’s capability and approach to comply with the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH) Act.
3. The adequacy of the respondent’s capability and approach to have protocols and internal procedures for ensuring system security and the confidentiality of recipient identifiable data.

**Score:** This Section is worth a maximum of **15** raw points with each of the above components being worth a maximum of 5 points each.

**SRC# 26: Information Technology Requirements**

The respondent shall demonstrate its capability and approach to provide the Information Technology Requirements described in **Attachment B**, Scope of Services, Section XII., Information Technology.

**Response:**

**Evaluation Criteria:**

The adequacy of the respondent’s capability and approach to meet the Information Technology Requirements described in **Attachment B**, Scope of Services, Section XII., Information Technology.

**Score:** This Section is worth a maximum of **5** raw points with each the above component being worth a maximum of 5 points.

**SRC# 27: Security Rating Score Requirements**

In accordance with **Attachment B,** Scope or Services, Section XII., Information Technology, Sub-Section T., the Agency shall conduct an initial IT security risk score scan on the respondent, 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 successful respondent’s security risks. The respondent will work with the Agency’s Security Rating Score Provider to define the relevant respondent assets providing Agency services.

**Response:**

### **Evaluation Criteria:**

The adequacy of the respondent’s security rating score by determining whether the respondent has received:

* 1. A score in the top 90-100% of submitters;
	2. A score in the top 80-89% of submitters;
	3. A score in the top 70-79% of submitters;
	4. A score in the top 60-69% of submitters;
	5. A score in the top 50-59% of submitters; or
	6. A score in the lower 0-49% of submitters.

**Score: This Section is worth a maximum of 5 raw points as outlined below:**

1. 5 points for a score in the top 90-100% of submitters;
2. 4 points for a score in the top 80-89% of submitters;
3. 3 points for a score in the top 70-79% of submitters;
4. 2 points for a score in the top 60-69% of submitters;
5. 1 point for a score in the top 50-59% of submitters; or
6. 0 points for a score in the lower 0-49% of submitters.

**SRC# 28: Disaster Recovery Requirements**

The respondent shall demonstrate its capability and approach to meet the requirements described in **Attachment B,** Scope of Services, Section XIII., Disaster Recovery.

**Response:**

**Evaluation Criteria:**

1. The adequacy of the respondent’s proposed approach and capability to 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.
2. The adequacy of the respondent’s proposed approach and capability to ensure the disaster recovery plan limits service interruption to a period of twenty-four (24) clock hours and ensures compliance with all requirements under the resulting Contract.
3. The adequacy of the respondent’s proposed approach and capability to ensure the records backup standards and a comprehensive disaster recovery plan shall be developed and maintained by the Vendor for the entire period of the resulting Contract and submitted for review annually by the anniversary date of the resulting Contract.
4. The adequacy of the respondent’s proposed approach and capability to ensure it maintains a disaster recovery plan for restoring day-to-day operations including alternative locations for the Vendor to conduct the requirements of the resulting Contract.
5. The adequacy of the respondent’s proposed approach and capability to ensure it maintains database backups in a manner that shall eliminate disruption of service or loss of data due to system or program failures or destruction.
6. The adequacy of the respondent’s proposed approach and capability to ensure the disaster recovery plan is finalized no later than thirty (30) calendar days prior to the resulting Contract effective date.
7. The adequacy of the respondent’s proposed approach and capability to ensure it amends or updates its disaster recovery plan in accordance with the best interests of the Agency and at no additional cost to the Agency.
8. The adequacy of the respondent’s proposed approach and capability to ensure it makes all aspects of the disaster recovery plan available to the Agency at all times.
9. The adequacy of the respondent’s proposed approach and capability to ensure it conducts an annual Disaster Recovery Plan test and submits the results for review to the Agency.

**Score:** This Section is worth a maximum of **45** raw points with each of the above components being worth a maximum of 5 points each.