

SECRETARY

June 30, 2020

Prospective Vendor(s):

Subject: Solicitation Number: AHCA ITN 008-19/20

Title: Canadian Prescription Drug Importation Program (CPDIP)

This solicitation is being issued by the State of Florida, Agency for Health Care Administration, hereinafter referred to as "AHCA" or "Agency", to select a vendor to provide Canadian Prescription Drug Importation Program services. The solicitation package consists of this transmittal letter and the following attachments and exhibits:

| Attachment | Α          | Instructions and Special Conditions                        |
|------------|------------|--|
| Exhibit    | <b>A-1</b> | Questions Template   |
| Exhibit    | A-2        | Transmittal Letter   |
| Exhibit    | A-3        | Required Certifications and Statements                     |
| Exhibit    | A-4        | Submission Requirements and Evaluation Criteria Components |
|            |            | (Technical Response)                                       |
| Exhibit    | A-5        | Cost Proposal  |
| Exhibit    | A-5-a      | Detailed Budget  |
| Exhibit    | A-6        | Summary of Respondent Commitments                          |
| Exhibit    | A-7        | Certification of Drug-Free Workplace Program               |
| Exhibit    | A-8        | Standard Contract  |
| Attachment | В          | Scope of Services  |
| Exhibit    | B-1        | Deliverables and Performance Standards                     |

Your response must comply fully with the instructions that stipulate what is to be included in the response. Respondents shall identify the solicitation number, date and time of opening on the package transmitting their response. This information is used only to put the Agency mailroom on notice that the package received is a response to an Agency solicitation and therefore should not be opened but delivered directly to the Procurement Officer.



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The designated Agency Procurement Officer for this solicitation is the undersigned. All communications from respondents shall be made in writing and directed to my attention at the address provided in **Attachment A**, Instructions and Special Conditions, **Section A.1.**, Instructions, **Sub-Section A.**, Overview, **Item 5.**, Procurement Officer, unless otherwise instructed in this solicitation.

The term "Proposal", "Response" or "Reply" may be used interchangeably and mean the respondent's submission to this solicitation.

Section 120.57(3)(b), Florida Statutes and Section 28-110.003, Florida Administrative Code require that a Notice of Protest of the solicitation documents shall be made within seventy-two hours after the posting of the solicitation. Failure to file a protest within the time prescribed in Section 120.57(3), Florida Statutes, shall constitute a waiver of proceedings under Chapter 120, Florida Statutes.

Sincerely,

Crystal S Demott

Procurement Officer,
Agency Procurement Director
Bureau of Support Services

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#### A.1. Instructions

#### A. Overview

#### 1. Solicitation Number

AHCA ITN 008-19/20

### 2. Solicitation Type

Invitation to Negotiate

### 3. Solicitation Title

Canadian Prescription Drug Importation Program

#### 4. Date of Issuance

June 30, 2020

#### 5. Procurement Officer

Crystal Demott
Agency for Health Care Administration
2727 Mahan Drive
Mail Stop #15

Tallahassee, FL 32308-5403

Email: solicitation.questions@ahca.myflorida.com

### 6. Solicitation Timeline

The projected solicitation timeline is shown in **Table 1**, Solicitation Timeline, below (all times are Eastern Time). The Agency for Health Care Administration (Agency) reserves the right to amend the timeline in the State's best interest. If the Agency finds it necessary to change any of the activities/dates/times listed, all interested parties will be notified by addenda to the original solicitation document posted on the Vendor Bid System (VBS) (<a href="http://myflorida.com/apps/vbs/vbs www.main menu">http://myflorida.com/apps/vbs/vbs www.main menu</a>).

|                             | TABLE 1        |   |  |  |  |  |  |  |  |  |  |  |  |
|-----------------------------|----------------|---|--|--|--|--|--|--|--|--|--|--|--|
| SOLICITATION TIMELINE       |                |   |  |  |  |  |  |  |  |  |  |  |  |
| ACTIVITY                    | DATE/TIME      | LOCATION  |  |  |  |  |  |  |  |  |  |  |  |
| Solicitation Issued by      | June 30, 2020  | Electronically Posted                           |  |  |  |  |  |  |  |  |  |  |  |
| Agency                      |                | http://myflorida.com/apps/vbs/vbs_www.main_menu |  |  |  |  |  |  |  |  |  |  |  |
|                             |                |   |  |  |  |  |  |  |  |  |  |  |  |
| Deadline for Receipt of     | July 21, 2020  | solicitation.questions@ahca.myflorida.com       |  |  |  |  |  |  |  |  |  |  |  |
| Written Questions           | 2:00 p.m.      |   |  |  |  |  |  |  |  |  |  |  |  |
| Anticipated Date for Agency | August 4, 2020 | Electronically Posted                           |  |  |  |  |  |  |  |  |  |  |  |
| Responses to Written        | -              | http://myflorida.com/apps/vbs/vbs_www.main_menu |  |  |  |  |  |  |  |  |  |  |  |
| Questions                   |                |   |  |  |  |  |  |  |  |  |  |  |  |

|                           | TABLE 1               |   |  |  |  |  |  |  |  |  |  |  |  |
|---------------------------|-----------------------|---|--|--|--|--|--|--|--|--|--|--|--|
|                           | SOLICITATION TIMELINE |   |  |  |  |  |  |  |  |  |  |  |  |
| ACTIVITY                  | DATE/TIME             | LOCATION  |  |  |  |  |  |  |  |  |  |  |  |
| Deadline for Receipt of   | September 29, 2020    | Crystal Demott                                  |  |  |  |  |  |  |  |  |  |  |  |
| Responses                 | 2:00 p.m.             | Agency for Health Care Administration           |  |  |  |  |  |  |  |  |  |  |  |
|                           |                       | 2747 Fort Knox Boulevard                        |  |  |  |  |  |  |  |  |  |  |  |
|                           |                       | Mailroom, Building 4                            |  |  |  |  |  |  |  |  |  |  |  |
|                           |                       | Tallahassee, FL 32308-5403                      |  |  |  |  |  |  |  |  |  |  |  |
| Public Opening of         | September 29, 2020    | 2727 Mahan Drive, Building 2                    |  |  |  |  |  |  |  |  |  |  |  |
| Responses                 | 2:30 p.m.             | Operations Conference Room, 2nd Floor, Room 200 |  |  |  |  |  |  |  |  |  |  |  |
|                           |                       | Tallahassee, FL 32308-5403                      |  |  |  |  |  |  |  |  |  |  |  |
| Anticipated Dates for     | November 9, 2020      | 2727 Mahan Drive, Building 2                    |  |  |  |  |  |  |  |  |  |  |  |
| Negotiations              | thru                  | Operations Conference Room, 2nd Floor, Room 200 |  |  |  |  |  |  |  |  |  |  |  |
|                           | December 4, 2020      | Tallahassee, FL 32308-5403                      |  |  |  |  |  |  |  |  |  |  |  |
| Anticipated Posting of    | December 14, 2020     | Electronically Posted                           |  |  |  |  |  |  |  |  |  |  |  |
| Notice of Intent to Award |                       | http://myflorida.com/apps/vbs/vbs_www.main_menu |  |  |  |  |  |  |  |  |  |  |  |

### 7. PUR 1000, General Contract Conditions

**PUR 1000**, General Contract Conditions, is incorporated by reference and is available for prospective respondents to download at:

https://www.dms.myflorida.com/content/download/2933/11777/PUR 1000 General Contract Conditions.pdf

### 8. PUR 1001, General Instructions to Respondents

**PUR 1001,** General Instructions to Respondents, is incorporated by reference and is available for prospective respondents to download at:

https://www.dms.myflorida.com/content/download/2934/11780/PUR 1001 General Instructions to Respondents.pdf

Unless otherwise noted, instructions in this **Attachment A** shall take precedence over the **PUR 1001**, General Instructions to Respondents.

## 9. Restriction on Communications

Respondents to this solicitation or persons acting on their behalf may not contact, between the release of the solicitation and the end of the seventy-two (72) hour period following the Agency posting the notice of intended award, excluding Saturdays, Sundays, and State holidays, any employee or officer of the executive or legislative branch concerning any aspect of this solicitation, except in writing to the Procurement Officer or as provided in the solicitation documents. Violation of this provision may be grounds for rejecting a response. See Section 287.057(23), Florida Statutes (F.S.).

### 10. Respondent Questions

- a. The Agency will receive all questions pertaining to this solicitation no later than the date and time specified for written questions in Section A.1., Instructions, Sub-Section A., Overview, Item 6., Solicitation Timeline, Table 1, Solicitation Timeline.
- b. Prospective respondents must submit all questions by email at <u>solicitation.questions@ahca.myflorida.com</u>, utilizing **Exhibit A-1**, Questions Template. **Exhibit A-1**, Questions Template, is a Microsoft excel document and is available for prospective respondents to download at:

# http://ahca.myflorida.com/procurements/index.shtml.

- **c.** The Agency will not accept questions by telephone, postal mail, hand delivery or fax.
- d. The Agency's response to questions received will be posted as an addendum to this solicitation as specified in Section A.1., Instructions, Sub-Section A., Overview, Item 6., Solicitation Timeline, Table 1, Solicitation Timeline, and may be grouped as to not repeat the same answer multiple times.
- e. The Agency reserves the right to post an addendum to this solicitation in order to address questions received after the written question submission deadline. It is the sole discretion of the Agency to consider questions received after the written questions submission deadline.

#### 11. Solicitation Addenda

If the Agency finds it necessary to supplement, modify, or interpret any portion of this solicitation during this solicitation period, a written addendum will be posted on the VBS as addenda to this solicitation. It is the respondent's responsibility to check the VBS periodically for any information or updates to this solicitation. The Agency bears no responsibility for any resulting impacts associated with a prospective respondent's failure to obtain the information made available through the VBS.

### 12. Public Opening of Responses

Responses shall be opened on the date, time and at the location indicated in **Section A.1.**, Instructions, **Sub-Section A.**, Overview, **Item 6.**, Solicitation Timeline, **Table 1**, Solicitation Timeline. Respondents may, but are not required to, attend. The Agency will only announce the respondent(s) name at the public opening. Pursuant to Section 119.071(1)(b), F.S., no other materials will be released. Any person requiring a special accommodation because of a disability should contact

the Procurement Officer at least five (5) business days prior to this solicitation opening. If you are hearing or speech impaired, please contact the Agency by using the Florida Relay Service at (800) 955-8771 (TDD).

### 13. Type and Amount of Contract Contemplated

- a. The Contract resulting from this solicitation will be a fixed price contract and the Agency anticipates the Contract amount shall not exceed \$30,000,000.00.
- **b.** This will be a fixed price contract.
- **c.** The State of Florida's performance and obligation to pay under the Contract resulting from this solicitation is contingent upon an annual appropriation by the Legislature.

### 14. Term of Contract

- a. The anticipated term of the resulting Contract is three years from date of execution. The term of the resulting Contract is subject to change based on the actual execution date of the resulting Contract.
- b. In accordance with Section 287.057(13), F.S., the Contract resulting from this solicitation may be renewed for a period that may not exceed three (3) years or the term of the resulting original Contract period whichever is longer. Renewal of the resulting Contract shall be in writing and subject to the same terms and conditions set forth in the resulting original Contract. A renewal Contract may not include any compensation for costs associated with the renewal. Renewals are contingent upon satisfactory performance evaluations by the Agency, are subject to the availability of funds, and optional to the Agency.
- c. Respondents shall offer renewal year pricing in its response. The Agency will not evaluate renewal year proposals as part of the evaluation and scoring process. Proposed cost, as provided in Exhibit A-5, Cost Proposal, will be applied in the event the resulting Contract is renewed.
- d. If the resulting Contract is renewed, it is the Agency's policy to reduce the overall payment amount by the Agency to the successful respondent by at least five percent (5%) during the period of the Contract renewal, unless it would affect the level and quality of services.

### B. Response Preparation and Content

### 1. General Instructions

- a. The instructions for this solicitation have been designed to help ensure that all responses are reviewed and evaluated in a consistent manner, as well as to minimize costs and response time. Information submitted in variance with these instructions may not be reviewed or evaluated.
- b. The Agency has established certain requirements with respect to responses submitted to competitive solicitations. The use of "shall", "must", or "will" (except to indicate futurity) in this solicitation, indicates a requirement or condition from which a material deviation may not be waived by the Agency. A deviation is material if, in the Agency's sole discretion, the deficient response is not in substantial accord with this solicitation's requirements, provides a significant advantage to one respondent over another, or has a potentially significant effect on the quality of the response or on the cost to the Agency. Material deviations cannot be waived. The words "should" or "may" in this solicitation indicate desirable attributes or conditions, but are permissive in nature. Deviation from, or omission of, such desirable features will not in and of itself cause rejection of a response.
- **c.** Respondents shall not retype and/or modify required forms and must submit required forms in the original format. Required forms are available for respondents to download at:

http://ahca.myflorida.com/procurements/index.shtml.

# FAILURE TO SUBMIT EACH REQUIRED FORM IN ITS ORIGINAL FORMAT MAY RESULT IN REJECTION OF THE RESPONSE.

- d. A respondent shall not, directly or indirectly, collude, consult, communicate or agree with any other respondent as to any matter related to the response each is submitting. Additionally, a respondent shall not induce any other respondent to submit or not to submit a response.
- **e.** The costs related to the development and submission of a response to this solicitation is the full responsibility of the respondent and is not chargeable to the Agency.
- f. Joint ventures and legal partnerships shall be viewed as one (1) respondent. However, all parties to the joint venture/legal partnership shall submit all mandatory attachments and documentation required by this solicitation from respondents, unless otherwise stated. Failure to submit all required

documentation from all parties included in a joint venture/legal partnership, signed by an authorized official, if applicable, may result in the rejection of a prospective vendor's response.

g. Pursuant to Section 287.133(2)(a), F.S., a person or affiliate who has been placed on the convicted Vendor list following a conviction for a public entity crime may not submit a Bid, Proposal, or Reply on a contract to provide any goods or services to a public entity; may not submit a Bid, Proposal, or Reply on a contract with a public entity for the construction or repair of a public building or public work; may not submit Bids, Proposals, or Replies on leases of real property to a public entity; may not be awarded or perform work as a contractor, supplier, subcontractor, or consultant under a contract with any public entity; and may not transact business with any public entity in excess of the threshold amount provided in Section 287.017, F.S. for category two for a period of thirty-six (36) months following the date of being placed on the convicted Vendor list.

### 2. Mandatory Response Content

The respondent shall include the documents listed in this Item with the submission of the Original Response. Violation of this provision may result in the rejection of a response.

#### a. Exhibit A-2, Transmittal Letter

The respondent shall complete and submit **Exhibit A-2**, Transmittal Letter, as part of its response in accordance with the instructions contained therein.

#### b. Exhibit A-3, Required Certifications and Statements

The respondent shall complete and submit **Exhibit A-3**, Required Certifications and Statements, as part of its response in accordance with the instructions contained therein.

# c. Original Proposal Guarantee

- The respondent's Original Response must be accompanied by an Original Proposal Guarantee payable to the State of Florida in the amount of \$3,000,000.00. The proposal guarantee is a firm commitment the respondent shall, upon the Agency's acceptance of its response, execute such contractual documents as may be required within the time specified.
- 2) The respondent must be the guarantor. If responding as a joint venture/legal partnership, at least one party of the joint venture/legal partnership shall be the guarantor.

- The proposal guarantee shall be in the form of a bond, cashier's check, treasurer's check, bank draft or certified check. The Agency will not accept a letter of credit in lieu of the Proposal Guarantee.
- 4) The Agency will not accept a copy of the Proposal Guarantee.
- Proposal Guarantees will be returned upon execution of the legal Contract with the successful respondent and receipt of the performance bond required under this solicitation (See Section A.1., Instructions, Sub-Section D., Response Evaluation, Negotiations and Contract Award, Item 9., Performance Bond).
- 6) Proposal Guarantees may be returned to respondents not considered responsive and responsible prior to execution of the legal Contract if the respondent is not participating in an administrative challenge regarding this solicitation.
- 7) Proposal Guarantees will be returned to the Official Contact Person at the address listed in **Exhibit A-2**, Transmittal Letter.
- 8) If the successful respondent fails to execute a contract within ten (10) consecutive calendar days after a contract has been presented to the successful respondent for signature, the proposal guarantee shall be forfeited to the State.
- 9) The proposal guarantee must not contain any provisions that shorten the time from bringing an action to a time less than that provided by the applicable Florida Statute of Limitations (see Section 95.03, F.S.).

#### d. Financial Information

In order to demonstrate financial stability, the respondent shall submit its two (2) most recent audited financial statements or its most recent Dun & Bradstreet (D&B) Report.

#### 1) Audited Financial Statements

If the respondent is a subsidiary of a parent organization, the respondent may submit the two (2) most recent audited financial statements of its parent entity. Audited financial statements of the parent organization in lieu of the respondent must include an organizational chart representing the relationship between the respondent and

the parent entity. Respondents submitting audited financial statements shall submit the following:

- a) A copy of the respondent's two (2) most recent audited financial statements (or parent organization's audited financial statements with organizational chart). If the most recent audit contains columns for the current and previous year on the balance sheet, income statement, and statement of cash flows, then only the most recent year's audit is required.
- b) Audited financial statements must be current. The period covered by the most recent audit cannot be more than one (1) fiscal year and one hundred twenty (120) calendar days old from the solicitation advertisement date.
- c) The audit must contain a signed audit statement (Audit Opinion) from a Certified Public Accountant (CPA) and the statement cannot contain an Adverse Opinion or a Disclaimer of Opinion from the CPA.

## 2) Dun & Bradstreet (D&B) Report

Respondents shall submit a complete D&B report which at a minimum shall include the Business and Executive Summaries, Credit Class Score, Financial Stress Score, and Paydex Score portions of the report. The D&B report cannot be more than twelve (12) months old at the time of response to this solicitation.

# e. Exhibit A-4, Submission Requirements and Evaluation Criteria (Technical Response)

- 1) Respondents shall complete and submit **Exhibit A-4**, Submission Requirements and Evaluation Criteria Components (Technical Response), and applicable attachments/exhibits as part of its response.
- 2) Respondents shall comply with the instructions for completing Exhibit A-4, Submission Requirements and Evaluation Criteria Components (Technical Response), which are contained therein.

# f. Exhibit A-5, Cost Proposal

The respondent shall complete and submit **Exhibit A-5**, Cost Proposal, as part of its response in accordance with the instructions contained therein.

### g. Exhibit A-5-a, Detailed Budget

The respondent shall complete and submit **Exhibit A-5-a**, Detailed Budget, as part of its response in accordance with the instructions contained therein.

### h. Exhibit A-6, Summary of Respondent Commitments

The respondent shall complete and submit **Exhibit A-6**, Summary of Respondent Commitments, as part of its response in accordance with the instructions contained therein.

### 3. Additional Response Content

### a. Exhibit A-7, Certification of Drug-Free Workplace Program

The State supports and encourages initiatives to keep the workplace of Florida's suppliers and contractors' drug free. Section 287.087, F.S. provides that, where identical tie Proposals are received, preference shall be given to a Proposal received from a respondent that certifies it has implemented a drug-free workplace program. If applicable, the respondent shall sign and submit **Exhibit A-7**, Certification of Drug-Free Workplace Program, to certify that the respondent has a drug-free workplace program.

### C. Response Submission Requirements

### 1. Hardcopy and Electronic Submission Requirements

#### a. General Provision

Electronic submissions via MyFloridaMarketPlace will not be accepted for this solicitation.

## b. Hardcopies of the Response

### 1) Original Response

The respondent shall submit **one** (1) **Original Response**. The Original Response shall be marked as the "Original" and contain the Transmittal Letter (**Exhibit A-2**) that bears the original signature of the binding authority. The box that contains the Original Response shall be marked "**Contains Original**". All forms requiring signature shall bear an original signature with the original response.

### 2) Duplicate Copy of the Original Response

The respondent shall submit **one (1) duplicate copy** of the Original Response.

## 3) Packaging and Delivery

- a) Hard copy responses shall be bound individually and submitted in no more than one (1), three-inch, three-ring binder or secured in a similar fashion to contain pages that turn easily for review.
- b) Each component of the hard copy response shall be clearly labeled and tabbed in the order specified below:
  - (1) **Exhibit A-2**, Transmittal Letter;
  - (2) Exhibit A-3, Required Certifications and Statements:
  - (3) Original Proposal Guarantee
    Note: The Original Proposal Guarantee
    must be provided in the Original Response;
  - (4) Financial Information;
  - (5) Exhibit A-4, Submission Requirements and Evaluation Criteria Components (Technical Response);
  - (6) Exhibit A-5, Cost Proposal;
  - (7) Exhibit A-5-a, Detailed Budget;
  - (8) **Exhibit A-6**, Summary of Respondent Commitments;
  - **(9) Exhibit A-7**, Certification of Drug-Free Workplace Program (if applicable); and
- **c)** Hard copy responses shall be double sided.
- d) Hard copy responses must be submitted in a sealed package (i.e., outer boxes must be sealed, individual binders within the box do not require individual sealing), to the Procurement Officer identified in Section A.1., Instructions, Sub-Section A., Overview, Item 5., Procurement Officer, no later than the time indicated in Section A.1., Instructions, Sub-Section A., Overview, Item 6., Solicitation Timeline, Table 1, Solicitation Timeline.
- e) Hard copy responses shall be submitted via United States (U.S.) mail, courier, or hand delivery. Responses sent by fax or email will not be accepted.

f) The Agency will not consider responses received after the date and time specified in **Section A.1.**, Instructions, **Sub-Section A.**, Overview, **Item 6.**, Solicitation Timeline, **Table 1**, Solicitation Timeline, and any such responses will be returned to the respondent unopened.

### c. Electronic Copy of the Response

- 1) The respondent shall submit one (1) electronic copy of the entire response on a USB flash drive.
- 2) The electronic copy of the response, including all attachments, shall be submitted as Portable Document Format (PDF) documents. The PDF documents must be searchable, allow printing and must not be password protected (unlocked).
- The electronic copy of the PDF documents shall be saved on the USB flash drive, with each component listed below saved separately in individual file folders:
  - (a) Exhibit A-2, Transmittal Letter;
  - **(b) Exhibit A-3,** Required Certifications and Statements:
  - (c) Financial Information;
  - (d) Exhibit A-4, Submission Requirements and Evaluation Criteria Components (Technical Response) and applicable attachments/exhibits;
  - (e) Exhibit A-5, Cost Proposal;
  - (f) Exhibit A-5-a, Detailed Budget;
  - (g) Exhibit A-6, Summary of Respondent Commitments: and
  - **(h) Exhibit A-7,** Certification of Drug-Free Workplace Program (if applicable).
- 4) In addition to the PDF submission, the following exhibits shall also be submitted in Microsoft Excel or Word 2016, utilizing the Agency provided templates and shall be saved on the USB flash drive:
  - (a) Exhibit A-5, Cost Proposal;
  - (b) Exhibit A-5-a, Detailed Budget; and
  - (c) Exhibit A-6, Summary of Respondent Commitments.

### 5) Electronic Redacted Copies

(a) The respondent shall submit an electronic redacted copy of the response suitable for release to the

public in one (1) PDF document on the USB flash drive. The electronic copy shall be saved in a separate file folder on the USB flash drive from the rest of the response. The file folder shall be identified as "Redacted Version Suitable for Public Release".

- (b) The PDF document must be searchable, allow printing, and must not be password protected (unlocked).
- (c) Any confidential or trade secret information covered under Section 812.081, F.S., should be redacted as described below. The redacted response shall be marked as the "redacted" copy.

### 2. Confidential or Exempt Information

- a. All submittals received by the date and time specified in Section A.1., Instructions, Sub-Section A., Overview, Item 6., Solicitation Timeline, Table 1, Solicitation Timeline, become the property of the State of Florida and are public records subject to the provisions of Chapter 119, F.S. The State of Florida shall have the right to use all ideas, or adaptations of the ideas, contained in any response received in relation to this solicitation. Selection or rejection of the response shall not affect this right.
- **b.** A respondent that asserts that any portion of the response is confidential or exempt from disclosure under Chapter 119, F.S., shall clearly mark each page of such portion as follows:
  - Pages containing trade secret shall be marked "Trade secret as defined in Section 812.081, Florida Statutes". Respondents who fail to identify trade secret as directed herein acknowledge and agree that they waive any right or cause of action, civil or criminal, against the Agency, its employees, and its representatives, for the release or disclosure of trade secret information not so identified. Respondents shall not mark their entire response as trade secret. The Agency may reject a response that is so marked.
  - Pages that do not contain trade secret but are otherwise exempt or confidential shall be marked "exempt" or "confidential," followed by the statutory basis for such claim. For example: "The information on this page is exempt from disclosure pursuant to Section 119.071(3)(b), Florida Statutes."

- Sailure to identify and mark such portions as directed above shall constitute a waiver of any claimed exemption and the Agency will provide any unmarked records in response to public records requests for those records without notifying the respondent. Designating material simply as "proprietary" will not necessarily protect it from disclosure under Chapter 119, F.S.
- c. All information included in the response (including, without limitation, technical and cost information) and any resulting Contract that incorporates the successful response (fully, in part, or by reference) shall be a matter of public record regardless of copyright status. Submission of a response to this solicitation that contains material for which the respondent holds a copyright shall constitute permission for the Agency to reproduce and disclose such material for the Agency's internal use, and to make such material available for inspection pursuant to a public records request.
- d. If a public records request is submitted to the Agency for responses submitted to this solicitation, the respondent agrees that the Agency may release the redacted response without conducting any prerelease review of the redacted response.
- Unless otherwise prohibited by law, the Agency will notify the e. respondent if a requestor contests the respondent's determination that information is confidential or exempt and asserts a right to the information under Chapter 119, F.S. or other law. The respondent bears sole responsibility for supporting and defending its determination. If an action is brought against the Agency in any appropriate iudicial forum contestina the respondent's determination of confidentiality or the redactions made by the respondent to its response, the respondent agrees that the Agency has no duty to defend against such claims and may elect not to do so, and may elect to release an un-redacted version of the response. By submitting a response, the respondent agrees to protect, defend, hold harmless and indemnify the Agency for any and all claims arising from or relating to the respondent's determinations of confidentiality or redaction, including the payment of any attorneys' fees or costs assessed against the Agency.

### D. Response Evaluation, Negotiations and Contract Award

### 1. Response Clarification

The Agency reserves the right to seek written clarification from a respondent of any information contained in the response or to request missing items from a response. However, it is a respondent's obligation to submit an adequately written reply for the Agency to evaluate. The Agency shall have no duty to conduct discussions or attempt to clarify ambiguities

in the respondent's reply if the respondent is not in the competitive range of respondents selected for negotiations.

## 2. Responsive Reply Determination

A "responsive reply" means a reply submitted by a **responsive and responsible vendor**, which conforms in all material aspects to the solicitation [Section 287.012(26), F.S.]. A "responsible vendor" means a vendor who has the capacity in all respects to fully perform the Contract requirements and the integrity and reliability that will assure good faith performance [287.012(25), F.S.]. The Procurement Officer may rely on any facts available to make a determination at any time prior to award as to whether a vendor is a responsible vendor. The Agency reserves the right to contact sources outside the reply to obtain information regarding past performance or other matters relevant to responsibility.

# 3. Non-Scored Requirements

### a. Transmittal (Cover) Letter

The Agency will review responses to this solicitation to determine if the respondent included in its response, **Exhibit A-2**, Transmittal Letter, from each required party.

### b. Required Certifications and Statements

The Agency will review responses to this solicitation to determine if the respondent included in its response, **Exhibit A-3**, Required Certifications and Statements.

#### c. Original Proposal Guarantee

The Agency will review responses to this solicitation to determine if the respondent included in its response, an original proposal guarantee in the appropriate amount, as specified in **Section B.**, Response Preparation and Content, **Sub-Section 2.**, Mandatory Response Content, **Item c**.

### d. Cost Proposal

The Agency will review responses to this solicitation to determine if the respondent included in its response, **Exhibit A-5**, Cost Proposal **and Exhibit A-5-a**, Detailed Budget.

# e. Summary of Respondent Commitments

The Agency will review responses to this solicitation to determine if the respondent included in its response, **Exhibit A-6**, Summary of Respondent Commitments.

#### 4. Financial Evaluation - Pass/Fail

#### a. Financial Statements

The respondent will be deemed to have met the mandatory requirement of financial stability if it meets all three (3) of the minimum financial ratio thresholds listed below in the most recent year or if it meets two (2) of the three (3) minimum financial ratio thresholds for the two (2) most recent years.

- 1) A positive current ratio of at least one (1.0). The current ratio is determined by dividing current liabilities into current assets.
  - a) Current assets are those held for conversion within a year or less, such as cash, temporary investments, receivables, inventory, and prepaid expenses. Board designated assets of cash or near cash instruments, where the board of directors has the option to change the authorized use of the assets and the assets are otherwise unencumbered as disclosed by the auditor, can be considered current assets for this calculation.
  - b) Current liabilities are short-term debts and unearned revenues to be paid out of current assets within a year or less.
- A positive tangible net worth as determined by the balance sheet. This shall be determined as equity (total assets less total liabilities) net of intangible assets. An intangible asset is a capital asset having no physical existence, its value being dependent on the rights that possession confers upon the owner. Examples include goodwill and trademarks.
- A positive operating cash flow. This shall be determined by whether or not the cash flow from operations reported on the statement of cash flows is positive.

### b. Dun & Bradstreet (D&B) Report

Agency staff will evaluate the respondent on its Paydex, Financial Stress, and Credit Scores from the D&B report. Scores will be based on **Table 2**, Responsibility Stability Score, below, for each category. A score of 5 in any of the three (3) categories will result in a determination that financial stability is not met. In order to be deemed financially stable, the respondent's average score of the three (3) categories must be 3.0 or lower.

|              | TABLE 2                    |  |  |  |  |  |  |  |  |  |  |  |
|--------------|----------------------------|--|--|--|--|--|--|--|--|--|--|--|
|              | RESPONDENT STABILITY SCORE |  |  |  |  |  |  |  |  |  |  |  |
| Paydex Score | Financial Stress Score     | Delinquency Predictor/Commercial<br>Credit Score | Respondent Stability Score                           |  |  |  |  |  |  |  |  |  |
| 90 or higher | 1570-1875                  | 580-670  | = 1  |  |  |  |  |  |  |  |  |  |
| 80-89        | 1510-1569                  | 530-579  | = 2  |  |  |  |  |  |  |  |  |  |
| 70-79        | 1450-1509                  | 481-529  | = 3  |  |  |  |  |  |  |  |  |  |
| 50-69        | 1340-1449                  | 453-480  | = 4  |  |  |  |  |  |  |  |  |  |
| 49 or lower  | 1339 or lower              | 452 or lower                                     | = 5 (Automatically Fails Financial Stability Review) |  |  |  |  |  |  |  |  |  |

### 5. Scored Requirements – Evaluation Criteria

# a. Technical Response Evaluation

- 1) Each evaluator will evaluate responses independently of the other evaluators and award points based on the criteria and points scale indicated in **Exhibit A-4**, Submission Requirements and Evaluation Criteria Components (Technical Response), for the detailed evaluation criteria components.
- 2) Each response will be individually scored by at least three (3) evaluators, who collectively have experience and knowledge in the program areas and service requirements for which contractual services are sought by this solicitation. The Agency reserves the right to have specific Sections of the responses evaluated by less than three (3) individuals.
- The scores of independent evaluators will be computed to determine a total score based on the detailed evaluation criteria components indicated in **Exhibit A-4**, Submission Requirements and Evaluation Criteria Components (Technical Response), and the weight factor specified in **Table 3**, Summary Score Sheet, below.

|    | TABLE 3  |                                     |     |                  |     |                               |  |  |  |  |
|----|--|-------------------------------------|-----|------------------|-----|-------------------------------|--|--|--|--|
|    | SUMMARY SCORE SH                                     | IEET                                |     |                  |     |                               |  |  |  |  |
|    |  | Maximum<br>Raw<br>Score<br>Possible |     | Weight<br>Factor |     | Maximum<br>Points<br>Possible |  |  |  |  |
| A. | Technical Response                                   |                                     |     |                  |     |                               |  |  |  |  |
|    | SRC# 1: Table of Contents                            |                                     | Х   |                  | =   |                               |  |  |  |  |
|    | SRC# 2: Executive Summary                            |                                     | Х   |                  | =   |                               |  |  |  |  |
|    | SRC# 3: Organizational Structure and History         | 10                                  | Х   | 1                | =   | 10                            |  |  |  |  |
|    | SRC# 4: Florida Presence*                            | 35                                  | Х   | 1.5              | =   | 52.5                          |  |  |  |  |
|    | SRC# 5: Contract Performance                         | 20                                  | Х   | 2                | =   | 40                            |  |  |  |  |
|    | SRC# 6: Drug Importation / Distribution Experience   | 30                                  | Х   | 1                | =   | 30                            |  |  |  |  |
|    | SRC# 7: Eligible Foreign Seller                      | 10                                  | Χ   | 1                | =   | 10                            |  |  |  |  |
|    | SRC# 8: Contracts and Agreements                     | 25                                  | Χ   | 1                |     | 25                            |  |  |  |  |
|    | SRC# 9: Track and Trace Requirements                 | 25                                  | Χ   | 2                | =   | 50                            |  |  |  |  |
|    | SRC# 10: Prescription Drugs Eligible for Importation | 25                                  | Χ   | 2                | =   | 50                            |  |  |  |  |
|    | SRC# 11: Supply Chain Quality Assurance              | 20                                  | Χ   | 2                | Ш   | 40                            |  |  |  |  |
|    | SRC# 12: Laboratory Testing                          | 20                                  | Χ   | 2                | II  | 40                            |  |  |  |  |
|    | SRC# 13: Repackaging, Labeling, and Relabeling       | 15                                  | Χ   | 2                | =   | 30                            |  |  |  |  |
|    | SRC# 14: Prescription Drug Storage                   | 40                                  | Χ   | 2                | =   | 80                            |  |  |  |  |
|    | SRC# 15: Immediate Suspension and Recalled Products  | 50                                  | Х   | 2                | =   | 100                           |  |  |  |  |
|    | SRC# 16: Drug Shortages                              | 15                                  | Х   | 2                | =   | 30                            |  |  |  |  |
|    | SRC# 17: Implementation Plan                         | 45                                  | Х   | 3                | =   | 135                           |  |  |  |  |
|    | SRC# 18: Outreach and Communications                 | 15                                  | Х   | 3                | =   | 45                            |  |  |  |  |
|    | SRC# 19: Staffing Requirements                       | 70                                  | Χ   | 1                | =   | 70                            |  |  |  |  |
|    | SRC# 20: Customer Service                            | 15                                  | Χ   | 1                | =   | 15                            |  |  |  |  |
|    | SRC# 21 Complaints                                   | 30                                  | Χ   | 1                | Ш   | 30                            |  |  |  |  |
|    | SRC# 22: Internal Quality Control Plan               | 55                                  | Χ   | 2                | Ш   | 110                           |  |  |  |  |
|    | SRC# 23: Reporting                                   | 15                                  | Χ   | 1                | =   | 15                            |  |  |  |  |
|    | SRC# 24: Cost Analysis                               |                                     | Х   |                  | =   |                               |  |  |  |  |
|    | SRC# 25: System Functionality Requirements           | 15                                  | Χ   | 1                | =   | 15                            |  |  |  |  |
|    | SRC# 26: Information Technology Requirements         | 5                                   | Х   | 1                | =   | 5                             |  |  |  |  |
|    | SRC# 27: Security Rating Score Requirements          | 5                                   | Χ   | 1                |     | 5                             |  |  |  |  |
|    | SRC# 28: Disaster Recovery Requirements              | 45                                  | Χ   | 1                |     | 45                            |  |  |  |  |
|    |  | TO1                                 | ΓAL |                  | 107 | 7.5                           |  |  |  |  |

### 6. Ranking of Responses

- **a.** A total score will be calculated for each response based on the total maximum points available as included in **Table 3**, Summary Score Sheet, above.
- **b.** The total point scores will be used to rank the responses.

### 7. **Negotiation Process**

- a. The scores from the evaluation process shall be used to determine the respondents with whom the negotiation team will negotiate. The negotiation team shall not utilize the evaluation scores in determining best value.
- b. The Agency will negotiate with the three (3) highest ranked respondents (competitive range). However, the Agency may choose not to negotiate with a respondent whose score is lower than seventy-five percent (75%) of the highest score earned by any respondent to this solicitation.
- c. The Agency may review any and all data available to the Agency including but not limited to Agency held data and respondents' performance-based information for use in negotiations.
- d. The Agency's negotiation team will conduct negotiation strategy sessions pursuant to Section 286.0113, F.S. Negotiation strategy includes determining best value criteria and developing award recommendation(s). During its strategy sessions, the Agency's negotiation team will develop a recommendation as to the award that will provide the best value (as defined in Section 287.012(4), F.S.) to the State.
- e. Negotiation sessions will include discussions of the scope of services to be provided by the respondent until acceptable terms and conditions are agreed upon, or it is determined that an acceptable agreement cannot be reached. The Agency will negotiate the terms and conditions determined to be the best value to the State according to Section 287.012(4) F.S., including, but not limited to price/cost, quality, design, and service delivery. Any terms to be negotiated must be addressed during negotiation sessions, prior to award.
- f. At least one authorized official who has the authority to bind the respondent to a contract must be present at each negotiation session. The authorized official(s) must be the Official Contact Person or Alternate Contact Person named in Exhibit A-2, Transmittal Letter.

- **g.** The Agency reserves the right at any time during the negotiation process to:
  - 1) Negotiate concurrently or sequentially with competing respondents.
  - 2) Schedule additional negotiation sessions with any or all responsive respondents.
  - 3) Require any or all responsive respondents to provide additional, revised, or final written replies addressing specific topics, including modifications to the solicitation specifications, terms or conditions, or business references.
  - 4) Require any or all responsive respondents to provide a written best and final offer or offers.
  - 5) Require any or all responsive respondents to address services, prices, or conditions offered by any other respondents.
  - **6)** Decline to conduct further negotiations with any respondent.
  - **7)** Re-open negotiations with any responsive respondent.
  - 8) Take any additional, administrative steps deemed necessary in determining the final award, including additional fact-finding, evaluation or negotiations where necessary and consistent with the terms of this solicitation.
  - **9)** Review and rely on relevant information contained in the responses.
  - 10) Request pricing options or models different from the initial Cost Proposal submission. This information may be used in negotiations to determine the best pricing solution to be used in the Contract.
- h. The Agency has sole discretion in deciding whether and when to take any of the foregoing actions, the scope and manner of such actions, the responsive respondent or respondents affected and whether to provide concurrent public notice of such decision.
- i. In the event the Agency cannot reach agreement with a respondent who has been invited to negotiation and/or a respondent withdraws its response during the negotiation phase, the Agency reserves the right to invite the next top ranking respondent to negotiations to ensure that the Agency can enter into a contract.

j. The Agency is practicing current social distancing standards and will continue to follow the guidance of the Centers for Disease Contract (CDC) and Governor DeSantis as it relates to social distancing and COVID-19. In the event that these guidelines are in place when the time comes for negotiations sessions, the Agency will use alternative means of communication and recording in order to continue negotiations while observing social distancing guidelines.

### 8. Number of Awards

The Agency anticipates the issuance of one (1) contract as a result of this solicitation for all services included within the Scope of Services. The Agency, at its sole discretion, shall make this determination.

### 9. Posting of Notice of Intent to Award

Tabulation of Results, with the recommended Contract award, will be posted to the Vendor Bid System and will be available for review by interested parties at the time and location specified in **Section A.1.**, Instructions, **Sub-Section A.** Overview, **Item 6.**, Solicitation Timeline, **Table 1**, Solicitation Timeline, and will remain posted for a period of seventy-two (72) hours, not including weekends or State observed holidays.

Any respondent desiring to protest the recommended Contract award must file a notice of intent to protest to the Procurement Officer identified in **Section A.1.,** Instructions, **Sub-Section A.** Overview, **Item 5.,** Procurement Officer, within the time prescribed in Section 120.57(3) F.S. and Rule 28-110, F.A.C.

Any notice of intent to protest must be filed electronically *or* via United States (U.S.) mail, courier, or hand delivery at the following address:

#### **Crystal Demott**

Agency for Health Care Administration 2727 Mahan Drive, Mail Stop #15 Tallahassee, Florida 32308-5403

Email: solicitation.questions@ahca.myflorida.com

Any formal protest must be filed within the time prescribed in Section 120.57(3) F.S. and Rule 28-110, F.A.C. Failure to file a protest within the time prescribed in Section 120.57(3), F.S., or failure to post the bond or other security required by law, shall constitute a waiver of proceedings under Chapter 120, F.S.

Any formal protest must be filed with the Agency Clerk, at the address below, or electronically at <a href="http://apps.ahca.myflorida.com/Efile/">http://apps.ahca.myflorida.com/Efile/</a>, a link to which can be found on the Agency's public website.

Agency for Health Care Administration C/O Agency Clerk

2727 Mahan Drive, Mail Stop #3 Building 3, Room 3407C Tallahassee, Florida 32308-5403

After submittal of the Notice of Intent to Protest, all communication regarding the solicitation must be submitted to the Agency's General Counsel's Office.

#### 10. Performance Bond

- a. A performance bond in the amount of ten percent (10%) of the total annual amount of the resulting Contract shall be furnished to the Agency by the successful respondent within thirty (30) calendar days after execution of the resulting Contract and prior to commencement of any work under the resulting Contract.
- **b.** The bond shall be furnished to the Agency's Procurement Office at:

#### **Procurement Office**

Agency for Health Care Administration 2727 Mahan Drive, Mail Stop #15 Tallahassee, Florida 32308-5403

- c. Thereafter, the 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.
- **d.** A copy of all performance bonds shall be submitted to the Agency's Contract Manager.
- e. The performance bond must not contain any provisions that shorten the time for bringing an action to a time less than that provided by the applicable Florida Statute of Limitations. (See Section 95.03, F.S.)
- f. No payments will be made to the successful respondent until an acceptable performance bond is furnished to the Agency. The performance bond shall remain in effect for the full term of the resulting Contract, including any renewal period. The Agency shall be named as the beneficiary of the successful respondent's bond. The bond shall provide that the insurer or bonding company(s) pay losses suffered by the Agency directly to the Agency.
- **g.** The cost of the performance bond will be borne by the successful respondent.

h. Should the successful respondent terminate the resulting Contract prior to the end of the resulting Contract period, an assessment against the bond will be made by the Agency to cover the costs of issuing a new solicitation and selecting a new Vendor. The successful respondent agrees that the Agency's damages in the event of termination by the successful respondent 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.

#### 11. Contract Execution

- a. This solicitation, including all its addenda, the Agency's written response to written questions, and the successful respondent's response, including information provided through negotiations, shall be incorporated by reference in the final Contract document.
- b. The successful respondent shall perform its contracted duties in accordance with the resulting Contract, this solicitation, including all addenda, the successful respondent's response to this solicitation, and information provided through negotiations. In the event of conflict among resulting contract documents, any identified inconsistency in the resulting Contract shall be resolved by giving precedence in the following order:
  - 1) The resulting Contract, including all attachments, exhibits and any subsequent amendments;
  - 2) This solicitation, including all addenda; and
  - The successful respondent's response to this solicitation, including information provided through negotiations.
- c. The successful respondent shall be registered with the Florida Department of State as an entity authorized to transact business in the State of Florida by the effective date of the resulting Contract.
- **d.** The Agency reserves the right to amend the resulting Contract within the scope set forth in this solicitation (to include the original Contract and all attachments) in order to clarify requirements.

### A.2 Special Terms and Conditions

#### A. Venue

1. By responding to this solicitation, in the event of any legal challenges to this procurement, respondents agree and will consent that hearings and depositions for any administrative or other litigation related to this procurement shall be held in Leon County, Florida. The Agency, in its sole discretion, may waive this venue for depositions.

- 2. Respondents (and their successors, including but not limited to their parent(s), affiliates, subsidiaries, subcontractors, assigns, heirs, administrators, representatives and trustees) acknowledge that this solicitation (including but not limited to the resulting Contract, exhibits, attachments, or amendments) is not a rule nor subject to rulemaking under Chapter 120 (or its successor) of the Florida Statutes and is not subject to challenge as a rule or non-rule policy under any provision of Chapter 120, F.S.
- 3. The exclusive venue and jurisdiction for any action in law or in equity to adjudicate rights or obligations arising pursuant to or out of this procurement for which there is no administrative remedy shall be the Second Judicial Circuit Court in and for Leon County, Florida, or, on appeal, the First District Court of Appeal (and, if applicable, the Florida Supreme Court). Any administrative hearings hereon or in connection herewith shall be held in Leon County, Florida.

### 4. Attorney's Fees

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

#### B. General Definitions

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

**BUSINESS DAY –** Also called Work Day. A day scheduled for regular State of Florida employees to work; Monday through Friday except holidays observed by regular State of Florida employees. Timeframes in this solicitation requiring completion within a number of business days shall mean by 5:00 P.M. Eastern Standard Time on the last work day.

**CALENDAR DAY** – 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.

**CAN** – Used to express non-mandatory provisions; words denote the permissive.

**CONTRACT** – The written, signed agreement resulting from, and inclusion of, this solicitation, any subsequent amendments thereto and the respondent's Proposal.

**CONTRACT MANAGER** – The Agency individual responsible for safeguarding State and Federal funds, deriving maximum return from those funds, and monitoring Vendor compliance with applicable laws and contract terms.

**DAY –** Calendar day, unless specified as a business day.

EST - Eastern Standard Time

**DISASTER RECOVERY PLAN** – A plan to ensure continued business processing through adequate alternative facilities, equipment, backup files, documentation and procedures in the event that the primary processing site is lost to the successful respondent.

**FISCAL YEAR (FY)** – The period used to calculate an annual budget or financial statements for a year. The State of Florida fiscal year is the twelve (12) month period beginning July 1 and ending June 30.

HIPAA (THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996) – A Federal law that includes requirements to protect patient privacy, to protect security of electronic medical records, to prescribe methods and formats for exchange of electronic medical information, and to uniformly identify providers.

**RECIPIENT** - A person who has been determined to be eligible for Medicaid assistance in accordance with the State plan(s) under Title XIV and Title XIX of the Social Security Act, Title V of the Refugee Education Assistance Act, and/or Title IV of the immigration and Nationality Act.

**SOC 2 TYPE II AUDIT** – Service Organization Control (SOC) 2 Type II is an audit of the internal controls of a service organization according to specifications defined by the American Institute of Certified Public Accountants.

STATE - State of Florida.

**SUBCONTRACT** – An agreement entered into for provision of services on behalf of the successful respondent as related to this solicitation.

**SUBCONTRACTOR** – Any entity contracting with the successful respondent to perform the services or to fulfill any of the requirements requested in this solicitation or any entity that is a subsidiary of the successful respondent that performs the services or fulfills the requirements requested in this solicitation.

WORK DAY - See Business Day.

**VENDOR** – The respondent awarded a contract resulting from this solicitation.

|             | ATTACHMENT | SECTION    | SUB-SECTION | ITEM      | ATTACHMENT | PAGE   |          |
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| VENDOR NAME | IDENTIFIER | IDENTIFIER | REFERENCE   | REFERENCE | EXHIBIT    | NUMBER | QUESTION |
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# EXHIBIT A-2 TRANSMITTAL LETTER

All respondents to this solicitation shall utilize **Exhibit A-2**, Transmittal Letter, for submission of its response. **Exhibit A-2** is available for respondents to download at: <a href="http://ahca.myflorida.com/procurements/index.shtml">http://ahca.myflorida.com/procurements/index.shtml</a>.

**DATE:**Click or tap to enter a date.

| RESPONDENT NAME:  |  |  |  |  |
|---|--|--|--|--|
| RESPONDENT ADDRESS:   |  |  |  |  |
| RESPONDENT FEDERAL EMPLOYER IDENTIFICATION NUMBER (FEID):   |  |  |  |  |
| The respondent shall provide an official contact and an alternate contact. Both the official contact person and the alternate contact person must have the authority to bind the respondent to a contract. Both person's signatures must be included. |  |  |  |  |
| OFFICIAL CONTACT PERSON:  |  |  |  |  |
| NAME:   |  |  |  |  |
| TITLE:  |  |  |  |  |
| ADDRESS:  |  |  |  |  |
| EMAIL ADDRESS:  |  |  |  |  |
| TELEPHONE NUMBER:   |  |  |  |  |
| SIGNATURE:  |  |  |  |  |
| ALTERNATE CONTACT PERSON:   |  |  |  |  |
| NAME:   |  |  |  |  |
| TITLE:  |  |  |  |  |
| ADDRESS:  |  |  |  |  |
| EMAIL ADDRESS:  |  |  |  |  |
| TELEPHONE NUMBER:   |  |  |  |  |
|   |  |  |  |  |

Failure to submit, Exhibit A-2, Transmittal Letter, signed by authorized officials who each have the authority to bind the respondent to a contract, may result in the rejection of response. If the respondent is invited to negotiations, at least one authorized official listed above must be present at each negotiation session.

SIGNATURE:

# EXHIBIT A-3 REQUIRED CERTIFICATIONS AND STATEMENTS

| <b>RESP</b> | ONDENT | NAME: |  |
|-------------|--------|-------|--|
|             |        |       |  |

### 1. ACCEPTANCE OF SOLICITATION REQUIREMENTS

I hereby certify that I understand and agree that my organization has read all requirements and Agency specifications provided in this solicitation, accepts said requirements, and that this response is made in accordance with the provisions of such requirements and specifications. By my written signature below, I guarantee and certify that all items included in this response shall meet or exceed any and all such requirements and Agency specifications. I further agree, if awarded a contract resulting from this solicitation, to deliver services that meet or exceed the requirements and specifications provided in this solicitation.

# <u>AND</u>

### 2. ACCEPTANCE OF CONTRACT TERMS AND CONDITIONS

I hereby certify that in responding to this solicitation, should my organization be awarded a contract resulting from this solicitation, it agrees to accept and comply with all terms and conditions as specified in this solicitation and in the Agency Standard Contract (**Exhibit A-8, including its Attachments**).

#### **AND**

#### 3. RELEASE OF REDACTED RESPONSE

I hereby authorize release of the redacted version of the response required by **Attachment A**, Instructions and Special Conditions, **Section A.1**, Instructions, **Sub-Section C.**, Response Submission Requirements, **Item 1.**, Hardcopy and Electronic Submission Requirements, **Sub-Item c.**, Electronic Copy of the Response, **Sub-Item 5**), Electronic Redacted Copies, in the event the Agency receives a public records request.

### **AND**

### 4. STATEMENT OF NO INVOLVEMENT

I hereby certify that neither my organization nor any person with an interest in the organization had any prior involvement in performing a feasibility study of the implementation of the subject Contract, in drafting of this solicitation or in developing the subject program.

### AND

#### 5. PROHIBITION OF GRATUITIES

I hereby certify that no elected official or employee of the State of Florida has or shall benefit financially or materially from such response or subsequent contract in violation of the provisions of Chapter 112, Florida Statutes (F.S.). I understand that any contract issued as a result of this solicitation may be terminated if it is determined that gratuities of any kind were either offered or received by any of the aforementioned parties.

#### **AND**

#### 6. NON-COLLUSION CERTIFICATION

I hereby certify that all persons, companies, or parties interested in the response as principals are named therein, that the response is made without collusion with any other person, persons, organization, or parties submitting a response; that it is in all respects made in good faith; and as the signer of the response, I have full authority to legally bind the respondent to the provisions of this solicitation.

#### **AND**

#### 7. PERFORMANCE OF SERVICES

I hereby certify my organization shall make a documented good faith effort to ensure all services, provided directly or indirectly under the Contract resulting from this solicitation, will be performed within the State of Florida.

#### **AND**

#### 8. PERFORMANCE OF SERVICES

I hereby certify my organization shall ensure all services, provided under the Contract resulting from this solicitation, will be performed within the borders of the United States and its territories and protectorates.

#### **AND**

#### 9. ORGANIZATIONAL CONFLICT OF INTEREST CERTIFICATION

The standards on organizational conflicts of interest in Chapter 48, Code of Federal Regulations (CFR) and Section 287.057(17), F.S. apply to this solicitation. A respondent with an actual or potential organizational conflict of interest shall disclose the conflict. If the respondent believes the conflict of interest can be mitigated, neutralized or avoided, the respondent shall include with its response a Conflict of Interest Mitigation Plan. The plan shall, at a minimum:

- a) Identify any relationship, financial interest or other activity which may create an actual or potential organizational conflict of interest.
- **b)** Describe the actions the respondent intends to take to mitigate, neutralize, or avoid the identified organizational conflicts of interest.
- c) Identify the official within the respondent's organization responsible for making conflict of interest determinations.

The Conflict of Interest Mitigation Plan will be evaluated as acceptable or not acceptable and will be used to determine respondent responsibility, as defined in Section 287.012(25), F.S. The Agency reserves the right to request additional information from the respondent or other sources, as deemed necessary, to determine whether or not the plan adequately neutralizes, mitigates, or avoids the identified conflicts.

Pursuant to the aforementioned requirements, I hereby certify that, to the best of my knowledge, my organization (including its subcontractors, subsidiaries and partners):

Please check the applicable paragraph below:
 Has no existing relationship, financial interest or other activity which creates any actual or potential organizational conflicts of interest relating to the award of a contract resulting from this solicitation.
 Has included information in its response to this solicitation detailing the existence of actual or potential organizational conflicts of interest and has provided a "Conflict of Interest Mitigation Plan", as outlined above.

#### <u>AND</u>

#### 10. RESPONDENT ATTESTATION FOR EXHIBIT A-4

I hereby certify that no modification and/or alteration has been made to the template, narrative and/or instructions contained in **Exhibit A-4**, Submission Requirements and Evaluation Criteria Components (Technical Response).

I understand the Agency will not consider supplemental response narrative for evaluation which is not contained within the response sections contained in **Exhibit A-4**, Submission Requirements and Evaluation Criteria Components (Technical Response).

#### **AND**

#### 11. RESPONDENT ATTESTATION REGARDING SCRUTINIZED COMPANIES LIST

Pursuant to Section 287.135, F.S. I certify that:

- a. If the resulting Contract reaches or exceeds \$1,000,000.00, my organization has not been placed on the Scrutinized Companies with Activities in Sudan List or the Scrutinized Companies with Activities in the Iran Petroleum Energy Sector List and does not have business operations in Cuba or Syria; and
- **b.** For the resulting Contract in any amount, it has not been placed on the Scrutinized Companies that Boycott Israel List and is not engaged in a boycott of Israel.

The respondent agrees that the Agency may immediately terminate the resulting Contract if the respondent is found to have submitted a false certification or is placed on the lists defined in Sections 215.473 or 215.4725, F.S., or engages in a boycott of Israel, during the term of the resulting Contract.

| 2.         | JOINT VENTURE OR PARTNERSHIPS   |
|------------|---|
|            | This response if made as a joint venture or partnership. The members of the joint venture or partnership are listed below.  |
|            |   |
|            |   |
|            |   |
|            |   |
| <u>AND</u> |   |
| 3.         | NAMES OF OPERATION  |
|            | I hereby certify the following is a list of all names under which my organization has operated during the past five (5) years from the date of solicitation issuance, as specified in <b>Attachment A</b> , Instructions and Special Conditions, <b>Section A.1.</b> , Instructions, <b>Sub-Section A.</b> , Overview, <b>Item 4.</b> , Date of Issuance. |
|            |   |
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| AND        |   |

### 14. CERTIFICATION REGARDING TERMINATED CONTRACTS

I hereby certify that my organization (including its subsidiaries and affiliates) has not unilaterally or willfully terminated any previous contract prior to the end of the Contract with a State or the Federal government and has not had a contract terminated by a State or the Federal government for cause, prior to the end of the Contract, within the past five (5) years from the date of solicitation issuance, as specified in **Attachment A**, Instructions and Special Conditions, **Section A.1.**, Instructions, **Sub-Section A.**, Overview, **Item 4.**, Date of Issuance, other than those listed on **Page 5** of this Exhibit.

#### **AND**

#### 15. LIST OF TERMINATED CONTRACTS

List the terminated Contracts in chronological order and provide a brief description (half-page or less) of the reason(s) for the termination. Additional pages may be submitted; however, no more than five (5) additional pages should be submitted in total.

The Agency is not responsible for confirming the accuracy of the information provided.

The Agency reserves the right within its sole discretion, to determine the respondent to be an irresponsible bidder based on any or all of the listed Contracts and therefore may reject the response.

| Respondent Name:                                     |  |  |  |
|--|--|--|--|
| Client's Name:                                       |  |  |  |
| Term of Terminated Contract:                         |  |  |  |
| Description of Services:                             |  |  |  |
|  |  |  |  |
| Brief Summary of Reason(s) for Contract Termination: |  |  |  |
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|  |  |  |  |
| Barrier to AMaria                                    |  |  |  |
| Respondent Name:                                     |  |  |  |
| Client's Name:                                       |  |  |  |
| Term of Terminated Contract:                         |  |  |  |
| Description of Services:                             |  |  |  |
|  |  |  |  |
| Brief Summary of Reason(s) for Contract Termination: |  |  |  |
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Signature below indicates the respondent's full acknowledgement of; understanding of; and agreement with all of the certifications and statements identified above in Items 1 through 15 as written and without caveat.

| Respondent Name   |   |     |  |  |
|---|---|-----|--|--|
| Authorized Official Signature   | Date  |     |  |  |
| Authorized Official Printed Name  |   |     |  |  |
| Authorized Official Title   |   |     |  |  |
| Failure to submit, Exhibit A-3, Required Cofficial may result in the rejection of respo | Certifications and Statements, signed by an authorings. | zed |  |  |

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#### <u>Instructions to respondents for the completion of Exhibit A-4:</u>

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.

### **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:

- a. A detailed description of the respondent's organizational structure, history, legal structure, ownership, affiliations, and location(s).
- b. 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:

- a. Specifying the location of the respondent's corporate headquarters.
- b. 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.
- c. Identifying the number of full-time staff, by operational function that will be located in the State of Florida and out of state.
- d. 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).
  - (a) 5 points for corporate headquarters in Florida and no parent or joint venture organization outside Florida;
  - (b) 0 points if no relevant corporate headquarters in Florida.
- 2. 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.
  - (a) Documentation and Recordkeeping;
  - (b) Prescription drug laboratory testing;

- (c) Prescription drug storage;
- (d) Repackaging and relabeling; and
- (e) 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, Subsection A., Overview, Item 4., Date of Issuance, it has:

- a. Voluntarily terminated all or part of a drug importation or distribution contract;
- b. Had such a contract partially or fully terminated before the contract end date (with or without cause); and
- c. 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:

- (a) 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.
- (b) 0 points for any voluntary terminations, requests for reductions in responsibilities, or withdrawals from service areas.

#### For Item 2:

- (a) 5 points for no involuntary terminations.
- (b) 0 points for any involuntary termination based on performance.

#### For Item 3:

- (a) 5 points for no contract terminations due to issues with operational functions.
- (b) 0 points for any contract terminations due to issues with operational functions.

#### For Item 4:

- (a) 5 points for no contract terminations due to issues with administrative functions.
- (b) 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:

- a. The name and address of the client;
- b. The name of the contract;
- c. The specific start and end dates of the contract;
- d. A brief narrative describing the role of the respondent and the scope of work performed, including the contract's goals and objectives;
- e. The use of administrative and/or delegated subcontractor(s) and their scope of work;
- f. The annual contract amount (payment to the respondent) and annual payment amounts;
- g. The scheduled and actual completion dates for contract implementation;
- h. Barriers encountered that hindered implementation (if applicable) and the resolutions; and
- i. 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:**

- 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:

- a. 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
- Written policies and procedures demonstrating compliance with state and federal regulations for the receipt, security, storage, inventory, and distribution of prescription drugs.
- c. 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.
- 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:
  - a. Contract Manager;
  - b. Customer Service Supervisor; and
  - c. 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.
- 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:**

- 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.
- 9. 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.
- 10. The extent to which the respondent has mechanisms to ensure that quality is continually assessed and maintained. These include a consumer notification where appropriate.
- 11. 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:

- a. The respondent's approach to compiling information to include in its monthly, quarterly, and annual reports.
- b. 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.
- c. 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:

- a. The adequacy of the respondent's approach to identifying metrics reflective of information to include in its monthly status report.
- b. The adequacy of the respondent's approach to ensuring accurate and timely reporting to the Agency.
- c. 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:

- a. The utilization of each eligible drug.
- b. The net unit cost and total cost of each eligible drug.
- c. The unit cost and total cost of each eligible U.S. manufactured drug to the unit cost and total cost of its Canadian equivalent.
- d. The estimated difference between the total cost of each eligible U.S. manufactured drug and the total cost of its Canadian equivalent.
- e. The extent to which seller and wholesaler profit and the amount of markup for each drug.
- f. The costs associated with repackaging and relabeling.
- g. Costs associated with testing the drugs at an FDA-qualified laboratory.
- h. The amount of vendor costs that are offset by savings from the Program.
- i. 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:

- **a.** 5 points for a score in the top 90-100% of submitters;
- **b.** 4 points for a score in the top 80-89% of submitters;
- **c.** 3 points for a score in the top 70-79% of submitters;
- **d.** 2 points for a score in the top 60-69% of submitters;
- **e.** 1 point for a score in the top 50-59% of submitters; or
- **f.** 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.

### EXHIBIT A-5 COST PROPOSAL

- 1. Where indicated in **Table A**, Implementation Period below, the respondent shall propose a fixed, one-time cost to complete all implementation tasks and activities as specified in the final implementation plan, which will be pre-approved by the Agency.
- 2. Where indicated in **Table B**, Year One Operations below, the respondent shall propose a fixed annual cost for Year One Operations.
- **3.** Where indicated in **Table C**, Year Two Operations below, the respondent shall propose a fixed annual cost for Year Two Operations.
- **4.** Where indicated in **Table D**, Year Three Operations below, the respondent shall propose a fixed annual cost for Year Three Operations.
- 5. The respondent shall not provide a pricing range in **Exhibit A-5** or **Exhibit A-5-a**. Supplemental documentation for **Exhibit A-5** or **Exhibit A-5-a** will not be accepted. The Agency will not agree to caveats in the proposed prices within **Exhibit A-5** and **Exhibit A-5-a**.
- 6. The respondent must include the required **Exhibit A-5-a**, Detailed Budget, with this cost proposal to support and justify its proposed one-time fixed implementation cost, each of its proposed three (3) fixed annual operation year costs and each of its proposed three (3) fixed annual renewal year operation costs.

| TABLE A – Implementation Period (The anticipated implementation period is 10/19/2020.) |          |  |  |
|--|----------|--|--|
| Proposed Fixed One-Time Implementation Cost  | \$       |  |  |
| TABLE B – Year One Ope   | erations |  |  |
| (1/1/2021 – 12/31/202  |          |  |  |
| (17172021 127017202  | <br>     |  |  |
| Proposed Year One Fixed Annual Cost  | \$       |  |  |
| TABLE C – Year Two Operations  |          |  |  |
| (1/1/2022 – 12/31/2022)  |          |  |  |
| Proposed Year Two Fixed Annual Cost  | \$       |  |  |
| TABLE D – Year Three Operations  |          |  |  |
| (1/1/2023 – 12/31/2023)  |          |  |  |
| Proposed Year Three Fixed Annual Cost  | \$       |  |  |

### EXHIBIT A-5 COST PROPOSAL

- 7. Where indicated in **Table E**, Renewal Year One Operations below, the respondent shall propose a fixed annual cost for Renewal Year One Operations.
- **8.** Where indicated in **Table F**, Renewal Year Two Operations below, the respondent shall propose a fixed annual cost for Renewal Year Two Operations.
- **9.** Where indicated in **Table G**, Renewal Year Three Operations below, the respondent shall propose a fixed annual cost for Renewal Year Three Operations.

If the resulting Contract is renewed, it is the Agency's policy to reduce the overall payment amount by the Agency to the successful Vendor by at least five percent (5%) during the period of the Contract renewal, unless it would affect the level and quality of services.

| TABLE E – Renewal Year One Operations<br>(1/1/2024 – 12/31/2024) |            |  |
|--|------------|--|
| Proposed Renewal Year One Fixed Annual Cost                      | \$         |  |
| TABLE F – Renewal Year Two                                       | Operations |  |
| (1/1/2025 – 12/31/25   | 5)         |  |
| Proposed Renewal Year Two Fixed Annual Cost                      | \$         |  |
| TABLE G – Renewal Year Three Operations                          |            |  |
| (1/1/2026 – 12/31/202  | 20)        |  |
| Proposed Renewal Year Three Fixed Annual Cost                    | \$         |  |

### EXHIBIT A-5 COST PROPOSAL

| Respondent Name                  |      |  |
|----------------------------------|------|--|
| Authorized Official Signature    | Date |  |
| Authorized Official Printed Name |      |  |
| Authorized Official Title        |      |  |

The Agency will not evaluate renewal year proposals as part of the evaluation and scoring process, however proposed cost will be applied in the event the resulting contract is renewed.

Exhibit A-5, Cost Proposal, shall not include a cost that exceeds the maximum contract amount listed in Attachment A, Instructions and Special Conditions, Section A.1., Instructions, Sub-Section A., Overview, Item 13., Type and Amount of Contract Contemplated. A response which contains a cost proposal that exceeds the Agency's maximum contract amount will be rejected.

Failure to submit, Exhibit A-5, Cost Proposal, signed by an authorized official may result in the rejection of response.

The following proposed detailed budget shall include costs required for providing the services specified in this solicitation, and shall support and justify the costs as provided in Exhibit A-5, Cost Proposal.

| DESCRIPTION OF EXPENSES          | IMPLEMENTATION<br>PERIOD | YEAR ONE OPERATIONS | YEAR TWO OPERATIONS | YEAR THREE OPERATIONS |
|----------------------------------|--------------------------|---------------------|---------------------|-----------------------|
| DIRECT PERSONNEL                 |                          |                     |                     |                       |
| Salaries:                        | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Fringe Benefits:                 | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Total Salaries Expense:          | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Temporary Personnel Services:    | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Contracted Personnel:            | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Other Personnel:                 | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Other Personnel:                 | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Other Personnel:                 | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| TOTAL DIRECT PERSONNEL:          | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| OTHER DIRECT                     |                          |                     |                     |                       |
| Office Supplies:                 | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Postage, Shipping, Fulfillment:  | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Software, Hardware:              | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Equipment Rental/Purchase:       | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Office Rent (Occupancy):         | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Printing/Graphics (Materials):   | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Travel – Training:               | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Travel – Other:                  | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Telephone Charges:               | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Professional Services:           | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Advertising:                     | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Training, Licensing, Recruiting: | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Legal, Taxes, Miscellaneous:     | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Other Direct:                    | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Other Direct:                    | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| Other Direct:                    | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |
| TOTAL OTHER DIRECT*:             | \$0.00                   | \$0.00              | \$0.00              | \$0.00                |

| DESCRIPTION OF EXPENSES       | IMPLEMENTATION PERIOD | YEAR ONE OPERATIONS | YEAR TWO OPERATIONS | YEAR THREE OPERATIONS |
|-------------------------------|-----------------------|---------------------|---------------------|-----------------------|
| CAPITAL                       |                       |                     |                     |                       |
| Telecommunications Equipment: | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
| Computer Equipment:           | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
| Furniture:                    | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
| Installation/Construction:    | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
| Other Capital:                | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
| Other Capital:                | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
| Other Capital:                | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
| TOTAL CAPITAL*:               | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
|                               |                       |                     |                     |                       |
| TOTAL DIRECT PERSONNEL:       | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
| TOTAL OTHER DIRECT:           | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
| TOTAL CAPITAL:                | \$0.00                | \$0.00              | \$0.00              | \$0.00                |
| TOTAL CONTRACT EXPENSES*:     | \$0.00                | \$0.00              | \$0.00              | \$0.00                |

| DESCRIPTION OF EXPENSES          | RENEWAL<br>YEAR ONE<br>OPERATIONS | RENEWAL<br>YEAR TWO<br>OPERATIONS | RENEWAL<br>YEAR THREE<br>OPERATIONS |
|----------------------------------|-----------------------------------|-----------------------------------|-------------------------------------|
| DIRECT PERSONNEL                 |                                   |                                   |                                     |
| Salaries:                        | \$0.00                            | \$0.00                            | \$0.00                              |
| Fringe Benefits:                 | \$0.00                            | \$0.00                            | \$0.00                              |
| Total Salaries Expense:          | \$0.00                            | \$0.00                            | \$0.00                              |
| Temporary Personnel Services:    | \$0.00                            | \$0.00                            | \$0.00                              |
| Contracted Personnel:            | \$0.00                            | \$0.00                            | \$0.00                              |
| Other Personnel:                 | \$0.00                            | \$0.00                            | \$0.00                              |
| Other Personnel:                 | \$0.00                            | \$0.00                            | \$0.00                              |
| Other Personnel:                 | \$0.00                            | \$0.00                            | \$0.00                              |
| TOTAL DIRECT PERSONNEL:          | \$0.00                            | \$0.00                            | \$0.00                              |
| OTHER DIRECT                     |                                   |                                   |                                     |
| Office Supplies:                 | \$0.00                            | \$0.00                            | \$0.00                              |
| Postage, Shipping, Fulfillment:  | \$0.00                            | \$0.00                            | \$0.00                              |
| Software, Hardware:              | \$0.00                            | \$0.00                            | \$0.00                              |
| Equipment Rental/Purchase:       | \$0.00                            | \$0.00                            | \$0.00                              |
| Office Rent (Occupancy):         | \$0.00                            | \$0.00                            | \$0.00                              |
| Printing/Graphics (Materials):   | \$0.00                            | \$0.00                            | \$0.00                              |
| Travel – Training:               | \$0.00                            | \$0.00                            | \$0.00                              |
| Travel – Other:                  | \$0.00                            | \$0.00                            | \$0.00                              |
| Telephone Charges:               | \$0.00                            | \$0.00                            | \$0.00                              |
| Professional Services:           | \$0.00                            | \$0.00                            | \$0.00                              |
| Advertising:                     | \$0.00                            | \$0.00                            | \$0.00                              |
| Training, Licensing, Recruiting: | \$0.00                            | \$0.00                            | \$0.00                              |
| Legal, Taxes, Miscellaneous:     | \$0.00                            | \$0.00                            | \$0.00                              |
| Other Direct:                    | \$0.00                            | \$0.00                            | \$0.00                              |
| Other Direct:                    | \$0.00                            | \$0.00                            | \$0.00                              |
| Other Direct:                    | \$0.00                            | \$0.00                            | \$0.00                              |
| TOTAL OTHER DIRECT*:             | \$0.00                            | \$0.00                            | \$0.00                              |

| DESCRIPTION OF EXPENSES       | RENEWAL<br>YEAR ONE<br>OPERATIONS | RENEWAL<br>YEAR TWO<br>OPERATIONS | RENEWAL<br>YEAR THREE<br>OPERATIONS |
|-------------------------------|-----------------------------------|-----------------------------------|-------------------------------------|
| CAPITAL                       |                                   |                                   |                                     |
| Telecommunications Equipment: | \$0.00                            | \$0.00                            | \$0.00                              |
| Computer Equipment:           | \$0.00                            | \$0.00                            | \$0.00                              |
| Furniture:                    | \$0.00                            | \$0.00                            | \$0.00                              |
| Installation/Construction:    | \$0.00                            | \$0.00                            | \$0.00                              |
| Other Capital:                | \$0.00                            | \$0.00                            | \$0.00                              |
| Other Capital:                | \$0.00                            | \$0.00                            | \$0.00                              |
| Other Capital:                | \$0.00                            | \$0.00                            | \$0.00                              |
| TOTAL CAPITAL*:               | \$0.00                            | \$0.00                            | \$0.00                              |
|                               |                                   |                                   |                                     |
| TOTAL DIRECT PERSONNEL:       | \$0.00                            | \$0.00                            | \$0.00                              |
| TOTAL OTHER DIRECT:           | \$0.00                            | \$0.00                            | \$0.00                              |
| TOTAL CAPITAL:                | \$0.00                            | \$0.00                            | \$0.00                              |
| TOTAL CONTRACT EXPENSES*:     | \$0.00                            | \$0.00                            | \$0.00                              |

<sup>\*</sup>The Agency reserves the right to request the return of any hardware, software, equipment and furniture purchased by the successful Vendor using funds from the resulting Contract. In the event the Agency does not desire to have the hardware, software, equipment and furniture returned, the successful Vendor may retain said ownership.

| Respondent Name  |   |
|--|---|
| Authorized Official Signature  | Date  |
| Authorized Official Printed Name   |   |
| Authorized Official Title  |   |
| The Agency will not evaluate renewal year proposal be applied in the event the resulting contract is renewal | s as part of the evaluation and scoring process, however proposed cost wil wed. |

Exhibit A-5-a, Detailed Budget, shall not include a cost that exceeds the maximum contract amount listed in Attachment A, Instructions and Special Conditions, Section A.1., Instructions, Sub-Section A., Overview, Item 13., Type and Amount of Contract Contemplated. A response which contains a cost proposal that exceeds the Agency's maximum contract amount will be rejected.

Failure to submit, Exhibit A-5-a, Detailed Budget, signed by an authorized official may result in the rejection of response.

### EXHIBIT A-6 SUMMARY OF RESPONDENT COMMITMENTS

Respondents may identify and propose innovative and added value services such as additional services or standards which exceed the minimum requirements of this solicitation. Innovative and added value services beyond the submission requirements contained in **Exhibit A-4**, Submission Requirements and Evaluation Criteria Components (Technical Response). Innovative and added value services are negotiable and respondents should have the costs associated with them available at negotiations. Innovative and added value services shall not be included in the respondent's Cost Proposal (**Exhibit A-5 and Exhibit A-5-a**). The Agency will not evaluate innovative and added value services as part of the evaluation process. The Agency will review and utilize this Exhibit during the negotiation process, for respondents who are invited to negotiations.

The Agency reserves the right to include any or all innovations or added value services listed herein or as negotiated as part of the resulting Contract.

|                                 |                  |                                     | Innovation Added Value Previously in the Research | Proposed on and/or ue Service / Included sponse to A-4, for // valuation? |
|---------------------------------|------------------|-------------------------------------|---|---|
| Solicitation Section Reference  | Service/Category | Narrative Description of Innovation | Yes   | No*   |
| Example: Exhibit A-4., Category |                  |                                     |   |   |
| 5., Item a.                     | Customer Service |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |
|                                 |                  |                                     |   |   |

### EXHIBIT A-6 SUMMARY OF RESPONDENT COMMITMENTS

\*The Agency anticipates a respondent may propose innovations and added value services which exceed those captured in the respondent's submission requirement responses in **Exhibit A-4**, Submission Requirements and Evaluation Criteria Components (Technical Response). Additional innovations and added value services over and above those captured in **Exhibit A-4** will be considered during the negotiation process. If the respondent did not include the proposed innovation and/or added value services as part of its response in **Exhibit A-4**, the Respondent should answer "No".

| Respondent Name                  |      |
|----------------------------------|------|
|                                  |      |
|                                  |      |
| Authorized Official Signature    | Data |
| Authorized Official Signature    | Date |
|                                  |      |
|                                  |      |
| Authorized Official Printed Name |      |
|                                  |      |
|                                  |      |
| Authorized Official Title        |      |
| Allfnortzen Umicial Litte        |      |

### EXHIBIT A-7 CERTIFICATION OF DRUG-FREE WORKPLACE PROGRAM

In the event of Identical or Tie Bids/Proposals: Preference shall be given to businesses with drug-free workplace programs. Whenever two or more bids which are equal with respect to price, quality, and service are received by the State or by any political subdivision for the procurement of commodities or contractual services, a bid received from a business that certifies that it has implemented a drug-free work place program shall be given preference in the award process. Established procedures for processing tied awards will be followed if none of the tied vendors have a drug-free workplace program. In order to have a drug-free workplace program, a business shall:

- 1) Publish a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the workplace and specifying the actions that will be taken against employees for violations of such prohibition.
- 2) Inform employees about the dangers of drug abuse in the workplace, the business's policy of maintaining a drug-free workplace, any available drug counseling, rehabilitation, and employee assistance programs, and the penalties that may be imposed upon employees for drug abuse violations.
- Give each employee engaged in providing the commodities or contractual services that are under bid a copy of the statement specified in subsection (1).
- In the statement specified in subsection (1), notify the employees that, as a condition of working on the commodities or contractual services that are under bid, the employee will abide by the terms of the statement and will notify the employer of any conviction of, or plea of guilty or nolo contendere to, any violation of chapter 893 or of any controlled substance law of the United States or any state, for a violation occurring in the workplace no later than five (5) days after such conviction.
- 5) Impose a sanction on, or require the satisfactory participation in a drug abuse assistance or rehabilitation program if such is available in the employee's community by, any employee who is so convicted.
- 6) Make a good faith effort to continue to maintain a drug-free workplace through implementation of this section.

As the person authorized to sign the statement, I certify that this firm complies fully with the above requirements.

| Respondent Name                  |      |  |
|----------------------------------|------|--|
| Authorized Official Signature    | Date |  |
| Authorized Official Printed Name |      |  |
| Authorized Official Title        |      |  |

### EXHIBIT A-8 STANDARD CONTRACT

## STATE OF FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION STANDARD CONTRACT

All respondents should review the contract language contained below. In responding to this solicitation, a respondent has agreed to accept the terms and conditions of the Contract contained in this Exhibit. Note: If the resulting Contract is funded with Federal funds, additional terms and conditions may be included at the time of contract award based on the specific Federal requirements.

**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 **VENDOR NAME** hereinafter referred to as the "**Vendor**", whose address is **VENDOR ADDRESS**, a (type of entity), to provide service description.

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#### I. THE VENDOR HEREBY AGREES:

#### A. General Provisions

- 1. To provide services according to the terms and conditions set forth in this Contract, **Attachment I**, Scope of Services, and all other attachments named herein which are attached hereto and incorporated by reference (collectively referred to herein as this "Contract").
- **2.** To perform as an independent vendor and not as an agent, representative or employee of the Agency.
- 3. To recognize that the State of Florida, by virtue of its sovereignty, is not required to pay any taxes on the services or goods purchased under the terms of this Contract.

#### B. Florida Department of State

To be registered with the Florida Department of State as an entity authorized to transact business in the State of Florida by the effective date of this Contract.

#### C. MyFloridaMarketPlace

- 1. Each Vendor doing business with the State of Florida for the sale of commodities or contractual services as defined in Section 287.012, Florida Statutes (F.S.), shall register in MyFloridaMarketPlace, in compliance with Rule 60A-1.033, Florida Administrative Code (F.A.C.), unless exempt under Rule 60A-1.033(3), F.A.C.
- 2. This Contract has been exempted by the Florida Department of Management Services from paying the transaction fee per Rule 60A-1.031(4)(a and b), F.A.C.

#### D. Federal Laws and Regulations

- 1. This Contract contains Federal funds, therefore, the Vendor shall comply with all applicable Federal requirements pertaining to procurement, including but not limited to Chapter 2 of the Code of Federal Regulations (CFR) and any other final or interim rules.
- 2. This Contract contains Federal funding in excess of \$100,000.00, therefore, the Vendor must, upon Contract execution, complete the Certification Regarding Lobbying Form, Attachment III. If a Disclosure of Lobbying Activities Form, Standard Form LLL, is required, it may be obtained from the Agency's Contract Manager. All disclosure forms as required by the Certification Regarding Lobbying Form must be completed and returned to the Agency's Procurement Office.
- 3. Pursuant to 2 CFR 376, the Vendor must, upon Contract execution,

complete the Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion Contracts/Subcontracts Form, **Attachment IV**.

#### E. Prohibition of Gratuities

To certify that no elected official or employee of the State of Florida has or shall benefit financially or materially from this Contract in violation of the provisions of Chapter 112, F.S. This Contract may be terminated if it is determined that gratuities of any kind were either offered or received by any of the aforementioned parties.

#### F. Audits/Monitoring

- 1. 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.
- 2. Reviews may include, but shall not be limited to, reviews of procedures, computer systems, recipient records, accounting records, and internal quality control reviews. The Vendor shall work with any reviewing entity selected by the Agency.
- 3. 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 must be requested and approved by the Agency. This obligation survives termination of this Contract.
- 4. 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.
- 5. The Vendor shall maintain and file with the Agency such progress, fiscal and inventory reports as specified in **Attachment I**, Scope of Services, and other reports as the Agency may require within the period of this Contract. In addition, access to relevant computer data and applications which generated such reports should be made available upon request.
- **6.** The Vendor shall ensure that all related party transactions are disclosed to the Agency Contract Manager.
- 7. The Vendor shall include these aforementioned audit and record keeping

requirements in all approved subcontracts and assignments.

**8.** The Vendor shall submit a SSAE 16 SOC 2 report on a yearly basis to the Agency Contract Manager.

#### G. Inspection of Records and Work Performed

- 1. The Agency and its authorized representatives shall, at all reasonable times, have the right to enter the successful Vendor's premises, or other places where duties under this Contract are performed. All inspections and evaluations shall be performed in such a manner as not to unduly delay work. Persons duly authorized by the Agency and federal auditors, pursuant to 45 CFR, Part 74 and/or 45 CFR, Part 92, shall have full access to and the right to examine any of said records and documents.
- 2. The Vendor shall retain all financial records, medical records, supporting documents, statistical records, and any other documents (including electronic storage media) pertinent to performance under this Contract for a period of ten (10) years after termination of this Contract, or if an audit has been initiated and audit findings have not been resolved at the end of ten (10) years, the records shall be retained until resolution of the audit findings.
- 3. Refusal by the Vendor to allow access to all records, documents, papers, letters, other materials or on-site activities related to this Contract performance shall constitute a breach of this Contract.
- **4.** The right of the Agency and its authorized representatives to perform inspections shall continue for as long as the Vendor is required to maintain records.
- 5. The Vendor shall be responsible for all storage fees associated with all records maintained under this Contract. The Vendor is also responsible for the destruction of all records that meet the retention schedule noted above.
- 6. Failure to retain all records as required may result in cancellation of this Contract. The Agency shall give the Vendor advance notice of cancellation pursuant to this provision and shall pay the Vendor only those amounts that are earned prior to the date of cancellation in accordance with the terms and conditions of this Contract. Performance by the Agency of any of its obligations under this Contract shall be subject to the successful Vendor's compliance with this provision.
- 7. In accordance with Section 20.055, F.S., the Vendor and its subcontractors shall cooperate with the Office of the Inspector General in any investigation, audit, inspection, review or hearing; and shall grant access to any records, data or other information the Office of the Inspector General deems necessary to carry out its official duties.

**8.** The rights of access in this Section must not be limited to the required retention period but shall last as long as the records are retained.

#### H. Accounting

- 1. To maintain an accounting system and employ accounting procedures and practices that conform to generally accepted accounting principles and standards or other comprehensive basis of accounting principles as acceptable to the Agency. For costs associated with specific contracts under which the Agency must account to the federal government for actual costs incurred, the costs and charges for that contract will be determined in accordance with generally accepted accounting principles.
- 2. To submit annual financial audits (or parent organization's annual financial audits with organizational chart) to the Agency within thirty (30) calendar days of receipt.

#### I. Public Records Requests

- **1.** To comply with Section 119.0701, F.S., if applicable, and all other applicable parts of the Florida Public Records Act.
- 2. To keep and maintain public records that ordinarily and necessarily would be required in order to perform services under this Contract.
- 3. To provide the public with access to public records on the same terms and conditions that the Agency would provide the records and at a cost that does not exceed the cost provided in Section 119.07, F.S., or as otherwise provided by law.
- 4. To upon request from the appropriate Agency custodian of public records, provide the Agency with a copy of the requested records or allow the records to be inspected or copied within a reasonable time at a cost that does not exceed the cost in Section 119.07, F.S., or as otherwise provided by law.
- To ensure that public records that are exempt or confidential and exempt from public records disclosure requirements are not disclosed except as authorized by law for the duration of this Contract term and following completion of this Contract if the Vendor does not transfer the records to the Agency.
- 6. To not collect an individual's social security number unless the Vendor has stated in writing the purpose for its collection. The Vendor collecting an individual's social security number shall provide a copy of the written statement to the Agency and otherwise comply with applicable portions of Section 119.071(5), F.S.

- 7. To meet all requirements for retaining public records and transfer, at no cost, to the Agency all public records in possession of the Vendor upon termination of this Contract and destroy any duplicate public records that are exempt or confidential and exempt from public records disclosure requirements. All records stored electronically must be provided to the Agency in a format that is compatible with the information technology systems of the Agency.
- 8. If the Vendor does not comply with a public records request, the Agency shall enforce Contract provisions in accordance with this Contract.
- 9. IF THE VENDOR HAS QUESTIONS REGARDING THE APPLICATION OF CHAPTER 119, FLORIDA STATUTES, TO THE VENDOR'S DUTY TO PROVIDE PUBLIC RECORDS RELATING TO THIS CONTRACT, CONTACT THE AGENCY CUSTODIAN OF PUBLIC RECORDS FOR THIS CONTRACT. THE AGENCY CUSTODIAN OF PUBLIC RECORDS FOR THIS CONTRACT IS THE CONTRACT MANAGER.

#### J. Communications

- 1. Notwithstanding any term or condition of this Contract to the contrary, the Vendor bears sole responsibility for ensuring that its performance of this Contract fully complies with all State and Federal law governing the monitoring, interception, recording, use or disclosure of wire, oral or electronic communications, including but not limited to the Florida Security of Communications Act, Section 934.01, et seq., F.S.; and the Electronic Communications Privacy Act, 18 U.S.C. Section 2510 et seq. (hereafter, collectively, "Communication Privacy Laws").
- **2.** Prior to intercepting, recording or monitoring any communications which are subject to Communication Privacy Laws, the Vendor must:
  - a. Submit a plan which specifies in detail the manner in which the Vendor will ensure that such actions are in full compliance with Communication Privacy Laws (the "Privacy Compliance Plan"); and
  - **b.** Obtain written approval, signed and notarized by the Agency Contract Manager, approving the Privacy Compliance Plan.
- 3. No modifications to an approved Privacy Compliance Plan may be implemented by the Vendor unless an amended Privacy Compliance Plan is submitted to the Agency, and written approval of the amended Privacy Compliance Plan is signed and notarized by the Agency Contract Manager. Agency approval of the Vendor's Privacy Compliance Plan in

no way constitutes a representation by the Agency that the Privacy Compliance Plan is in full compliance with applicable Communication Privacy Laws, or otherwise shifts or diminishes the Vendor's sole burden to ensure full compliance with applicable Communication Privacy Laws in all aspects of the Vendor's performance of this Contract. Violation of this term may result in sanctions to include termination of this Contract and/or liquidated damages.

4. The Vendor agrees that it is the custodian of any and all recordings for purposes of the Public Records Act, Chapter 119, F.S., and is solely responsible for responding to any public records requests for recordings. This responsibility includes gathering, redaction, duplication and provision of the recordings as well as defense of any actions for enforcement brought pursuant to Section 119.11, F.S.

#### K. Background Screening

- 1. To ensure that all Vendor employees including managing employees that have direct access to personally identifiable information (PII), protected health information (PHI), or financial information have a County, State, and Federal criminal background screening comparable to a Level 2 background screening as described in Section 435.04, F.S., completed with results prior to employment.
- 2. Per Section 435.04(1)(a), F.S., Level 2 screening standards include, but need not be limited to, fingerprinting for statewide criminal history records checks through the Department of Law Enforcement, and national criminal history records checks through the Federal Bureau of Investigation, and may include local criminal records checks through local law enforcement agencies.
- 3. If the Vendor employee or managing employee was employed prior to the execution of this Contract, the Vendor shall ensure that the County, State, and Federal criminal background screening comparable to a Level 2 background screening is completed with results prior to the employee accessing any PII, PHI, or financial information.
- 4. Any Vendor employee or managing employee with background results that are unacceptable to the State as described in Section 435.04, F.S., or related to the criminal use of PII as described in Section 817, F.S., or has been subject to criminal penalties for the misuse of PHI under 42 U.S.C. 1320d-5, or has been subject to criminal penalties for the offenses described in Section 812.0195, F.S., Section 815, F.S., Section 815.04, F.S., or Section 815.06, F.S., shall be denied employment or be immediately dismissed from performing services under this Contract by the Vendor unless an exemption is granted.
- **5.** Direct access is defined as having, or expected to have, duties that involve access to PII, PHI, or financial information by any means including, but not

limited to, network shared drives, email, telephone, mail, computer systems, and electronic or printed reports.

- 6. To ensure that all Vendor employees including managing employees that have direct access to any PII, PHI or financial information have a County, State, and Federal criminal background screening comparable to a Level 2 background screening completed with results every five (5) years.
- 7. To develop and submit policies and procedures related to this criminal background screening requirement to the Agency for review and approval within thirty (30) calendar days of this Contract execution. The Vendor's policies and procedures shall include a procedure to grant an exemption from disqualification for disqualifying offenses revealed by the background screening, as described in Section 435.07, F.S.
- **8.** To keep a record of all background screening records to be available for Agency review upon request.
- **9.** Failure to comply with background screening requirements shall subject the Vendor to liquidated damages as described **Attachment I**, Scope of Services.

#### L. Monitoring

- 1. To provide reports as specified in **Attachment I**, Scope of Services. These reports will be used for monitoring progress or performance of the contractual services as specified in **Attachment I**, Scope of Services.
- 2. To permit persons duly authorized by the Agency to inspect any records, papers, documents, facilities, goods and services of the Vendor which are relevant to this Contract.
- 3. To ensure that each of its employees or subcontractors who performs activities related to the services associated with this Contract will report to the Agency any health care facility that is the subject of these services that may have violated the law. To report concerns pertaining to a health care facility, the Vendor employee or subcontractor may contact the Agency Complaint Hotline by calling 1-888-419-3456 or by completing the online complaint form found at https://apps.ahca.myflorida.com/hcfc.
- 4. To ensure that each of its employees or subcontractors who performs activities related to the services associated with this Contract, will report to the Agency areas of concern relative to the operation of any entity covered by this Contract. To report concerns, the Vendor employee or subcontractor may contact the Agency Complaint Hotline by calling 1-877-254-1055 or by completing the online complaint form found at <a href="https://apps.ahca.myflorida.com/smmc\_cirts/">https://apps.ahca.myflorida.com/smmc\_cirts/</a>.
- **5.** Reports which represent individuals receiving services are at risk for, or

have suffered serious harm, impairment, or death shall be reported to the Agency immediately and no later than twenty four (24) clock hours after the observation is made. Reports that reflect noncompliance that does not rise to the level of concern noted above shall be reported to the Agency within ten (10) calendar days of the observation.

#### M. Indemnification

The Vendor agrees to indemnify, defend, and hold harmless the Agency, as provided in this Clause.

- 1. Scope. The Duty to Indemnify and the Duty to Defend, as described herein (collectively known as the "Duty to Indemnify and Defend"), extend to any completed, actual, pending or threatened action, suit, claim or proceeding, whether civil, criminal, administrative or investigative (including any action by or in the right of the Vendor), and whether formal or informal, in which the Agency is, was or becomes involved and which in any way arises from, relates to or concerns the Vendor's acts or omissions related to this Contract (inclusive of all attachments, etc.) (collectively "Proceeding").
  - a. <u>Duty to Indemnify</u>. The Vendor agrees to hold harmless and indemnify the Agency to the full extent permitted by law against any and all liability, claims, actions, suits, judgments, damages and costs of whatsoever name and description, including attorneys' fees, arising from or relating to any Proceeding.
  - b. <u>Duty to Defend</u>. With respect to any Proceeding, the Vendor agrees to fully defend the Agency and shall timely reimburse all of the Agency's legal fees and costs; provided, however, that the amount of such payment for attorneys' fees and costs is reasonable pursuant to rule 4–1.5, Rules Regulating The Florida Bar. The Agency retains the exclusive right to select, retain and direct its defense through defense counsel funded by the Vendor pursuant to the Duty to Indemnify and Defend the Agency.
- **2.** Expense Advance. The presumptive right to indemnification of damages shall include the right to have the Vendor pay the Agency's expenses in any Proceeding as such expenses are incurred and in advance of the final disposition of such Proceeding.
- Enforcement Action. In the event that any claim for indemnity, whether an Expense Advance or otherwise, is made hereunder and is not paid in full within sixty (60) calendar days after written notice of such claim is delivered to the Vendor, the Agency may, but need not, at any time thereafter, bring suit against the Vendor to recover the unpaid amount of the claim (hereinafter "Enforcement Action"). In the event the Agency brings an Enforcement Action, the Vendor shall pay all of the Agency's attorneys' fees and expenses incurred in bringing and pursuing the Enforcement Action.

4. Contribution. In any Proceeding in which the Vendor is held to be jointly liable with the Agency for payment of any claim of any kind (whether for damages, attorneys' fees, costs or otherwise), if the Duty to Indemnify provision is for any reason deemed to be inapplicable, the Vendor shall contribute toward satisfaction of the claim whatever portion is or would be payable by the Agency in addition to that portion which is or would be payable by the Vendor, including payment of damages, attorneys' fees and costs, without recourse against the Agency. No provision of this part or of any other section of this Contract (inclusive of all attachments, etc.), whether read separately or in conjunction with any other provision, shall be construed to: (i) waive the State or the Agency's immunity to suit or limitations on liability; (ii) obligate the State or the Agency to indemnify the Vendor for the Vendor's own negligence or otherwise assume any liability for the Vendor's own negligence; or (iii) create any rights enforceable by third parties, as third party beneficiaries or otherwise, in law or in equity.

#### N. Insurance

- 1. To the extent required by law, the Vendor shall be self-insured against, or shall secure and maintain during the life of this Contract, Worker's Compensation Insurance for all its employees connected with the work of this Contract and, in case any work is subcontracted, the Vendor shall require the subcontractor similarly to provide Worker's Compensation Insurance for all of the latter's employees unless such employees engaged in work under this Contract are covered by the Vendor's self-insurance program. Such self-insurance or insurance coverage shall comply with the Florida Worker's Compensation law. In the event hazardous work is being performed by the Vendor under this Contract and any class of employees performing the hazardous work is not protected under Worker's Compensation statutes, the Vendor shall provide, and cause each subcontractor to provide, adequate insurance satisfactory to the Agency, for the protection of its employees not otherwise protected.
- 2. The Vendor shall secure and maintain Commercial General Liability insurance including bodily injury, property damage, personal and advertising injury and products and completed operations. This insurance will provide coverage for all claims that may arise from the services and/or operations completed under this Contract, whether such services and/or operations are by the Vendor or anyone directly, or indirectly employed by it. Such insurance shall include a Hold Harmless Agreement in favor of the State of Florida and also include the State of Florida as an Additional Named Insured for the entire length of this Contract and hold the State of Florida harmless from subrogation. The Vendor shall set the limits of liability necessary to provide reasonable financial protections to the Vendor and the State of Florida under this Contract.
- 3. All insurance policies shall be with insurers licensed or eligible to transact business in the State of Florida. The Vendor's current insurance policy(ies)

shall contain a provision that the insurance will not be canceled for any reason except after thirty (30) calendar days written notice. The Vendor shall provide thirty (30) calendar days written notice of cancellation to the Agency's Contract Manager.

**4.** The Vendor shall submit insurance certificates evidencing such insurance coverage prior to execution of this Contract.

#### O. Assignments and Subcontracts

To neither assign the responsibility of this Contract to another party nor subcontract for any of the work contemplated under this Contract without prior written approval of the Agency. No such approval by the Agency of any assignment or subcontract shall be deemed in any event or in any manner to provide for the incurrence of any obligation of the Agency in addition to the total dollar amount agreed upon in this Contract. All such assignments or subcontracts shall be subject to the conditions of this Contract and to any conditions of approval that the Agency shall deem necessary.

#### P. Subcontracting

- 1. To not subcontract, assign, or transfer any work identified under this Contract, without prior written consent of the Agency.
- 2. To not subcontract with any provider that would be in conflict of interest to the Vendor during the term of this Contract in accordance with applicable Federal and/or State laws.
- Changes to approved subcontracts and/or subcontractors require approval in writing by the Agency's Contract Manager prior to the effective date of any subcontract.
- 4. The Agency encourages Vendors to partner with subcontractors who can provide best value and the best in class solutions. However, the Vendor is responsible for all work performed under this Contract. No subcontract that the Vendor enters into with respect to performance under this Contract shall in any way relieve the Vendor of any responsibility for performance of its duties. The Vendor shall assure that all tasks related to the subcontract are performed in accordance with the terms of this Contract. If the Agency determines, at any time, that a subcontract is not in compliance with a Contract requirement, the Vendor shall promptly revise the subcontract to bring it into compliance. In addition, the Vendor may be subject to sanctions and/or liquidated damages pursuant to this Contract and Section 409.912(4), F.S. (related to sanctions).
- **5.** All payments to subcontractors will be made by the Vendor.
- **6.** To be responsible for monitoring the subcontractor's performance. The results of the monitoring shall be provided to the Agency's Contract

Manager, fourteen (14) business days after the end of each month or as specified by the Agency. If the subcontractor's performance does not meet the Agency's performance standard according to the Agency's monitoring report or the Vendor's monitoring report, an improvement plan must be submitted to the Vendor and the Agency within fourteen (14) business days of the deficient report.

- 7. The State supports and encourages supplier diversity and the participation of small and minority business enterprises in State contracting, both as Vendors and subcontractors. The Agency supports diversity in its Procurement Program and requests that all subcontracting opportunities afforded by this Contract enthusiastically embrace diversity. The award of subcontracts should reflect the full diversity of the citizens of the State of Florida. Vendors can contact the Office of Supplier Diversity at (850) 487-0915 or online at <a href="http://osd.dms.state.fl.us/">http://osd.dms.state.fl.us/</a> for information on minority Vendors who may be considered for subcontracting opportunities.
- 8. A minority owned business is defined as any business enterprise owned and operated by the following ethnic groups: African American (Certified Minority Code H or Non-Certified Minority Code N); Hispanic American (Certified Minority Code I or Non-Certified Minority O); Asian American (Certified Minority Code J or Non-Certified Minority Code P); Native American (Certified Minority Code K or Non-Certified Minority Code Q); or American Woman (Certified Minority Code M or Non-Certified Minority Code R).

#### Q. Return of Funds

To return to the Agency any overpayments due to unearned funds or funds disallowed pursuant to the terms of this Contract that were disbursed to the Vendor by the Agency. The Vendor shall return any overpayment to the Agency within forty (40) calendar days after either discovery by the Vendor, its independent auditor, or notification by the Agency, of the overpayment.

#### R. Purchasing

#### P.R.I.D.E.

It is expressly understood and agreed that any articles which are the subject of, or required to carry out, this Contract shall be purchased from the corporation identified under Chapter 946, F.S., if available, in the same manner and under the same procedures set forth in Section 946.515(2) and (4), F.S.; and for purposes of this Contract the person, firm, or other business entity carrying out the provisions of this Contract shall be deemed to be substituted for this Agency insofar as dealings with such corporation are concerned.

The "Corporation identified" is PRISON REHABILITATIVE INDUSTRIES AND DIVERSIFIED ENTERPRISES, INC. (P.R.I.D.E.) which may be

contacted at:

P.R.I.D.E. 12425 28th Street North, Suite 300 St. Petersburg, FL 33716 info@pride-enterprises.org (727) 556-3300

Toll Free: 1-800-643-8459 Fax: (727) 570-3366

#### 2. RESPECT of Florida

It is expressly understood and agreed that any articles that are the subject of, or required to carry out, this Contract shall be purchased from a nonprofit agency for the blind or for the severely handicapped that is qualified pursuant to Chapter 413, F.S., in the same manner and under the same procedures set forth in Section 413.036(1) and (2), F.S.; and, for purposes of this Contract the person, firm, or other business entity carrying out the provisions of this Contract shall be deemed to be substituted for this Agency insofar as dealings with such qualified nonprofit agency are concerned.

The "nonprofit agency" identified is RESPECT of Florida which may be contacted at:

RESPECT of Florida 2475 Apalachee Parkway, Suite 205 Tallahassee, Florida 32301-4946 (850) 487-1471 www.respectofflorida.org

#### S. Procurement of Products or Materials with Recycled Content

It is expressly understood and agreed that any products which are required to carry out this Contract shall be procured in accordance with the provisions of Section 403.7065, F.S.

#### T. Civil Rights Requirements/Vendor Assurance

The Vendor assures that it will comply with:

- 1. Title VI of the Civil Rights Act of 1964, as amended, 42 United States Code (U.S.C.) 2000d et seq., which prohibits discrimination on the basis of race, color, or national origin.
- **2.** Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794, which prohibits discrimination on the basis of handicap.

- **3.** Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. 1681 et seq., which prohibits discrimination on the basis of sex.
- **4.** The Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101 et seq., which prohibits discrimination on the basis of age.
- 5. Section 654 of the Omnibus Budget Reconciliation Act of 1981, as amended, 42 U.S.C. 9849, which prohibits discrimination on the basis of race, creed, color, national origin, sex, handicap, political affiliation or beliefs.
- 6. The Americans with Disabilities Act of 1990, Public Law (P.L.) 101-336, which prohibits discrimination on the basis of disability and requires reasonable accommodation for persons with disabilities.
- **7.** Chapter 409, F.S.
- **8.** Rule 62-730.160, F.A.C. pertaining to standards applicable to generators of hazardous waste.
- **9.** All applicable standards, orders or regulations issued pursuant to the Clean Air Act, 42 United States Code (U.S.C.) 7401 et seq.
- **10.** The Medicare-Medicaid Fraud and Abuse Act of 1978.
- **11.** Other Federal omnibus budget reconciliation acts.
- **12.** The Balanced Budget Act of 1997.
- **13.** All regulations, guidelines, and standards as are now or may be lawfully adopted under the above statutes.

The Vendor agrees that compliance with this assurance constitutes a condition of continued receipt of or benefit from funds provided through this Contract, and that it is binding upon the Vendor, its successors, transferees, and assignees for the period during which services are provided. The Vendor further assures that all contractors, subcontractors, subgrantees, or others with whom it arranges to provide services or benefits to participants or employees in connection with any of its programs and activities are not discriminating against those participants or employees in violation of the above statutes, regulations, guidelines, and standards.

#### U. Equal Employment Opportunity (EEO) Compliance

To not discriminate in its employment practices with respect to race, color, religion, age, sex, marital status, political affiliation, national origin, or handicap.

#### V. Discrimination

Pursuant to Section 287.134(2)(a), F.S., an entity or affiliate who has been placed on the Discriminatory Vendor List may not submit a Bid, Proposal, or Reply on a contract to provide any goods or services to a public entity; may not submit a Bid, Proposal, or Reply on a contract with a public entity for the construction or repair of a public building or public work; may not submit Bids, Proposals, or Replies on leases of real property to a public entity; may not be awarded or perform work as a contractor, supplier, subcontractor, or consultant under a contract with any public entity; and may not transact business with any public entity. The Florida Department of Management Services is responsible for maintaining the Discriminatory Vendor List. Questions regarding the Discriminatory Vendor List may be directed to the Florida Department of Management Services, Office of Supplier Diversity at (850) 487-0915.

#### W. Requirements of Section 287.058, Florida Statutes

- 1. To submit bills for fees or other compensation for services or expenses in detail sufficient for a proper pre-audit and post-audit thereof.
- 2. Where applicable, to submit bills for any travel expenses in accordance with Section 112.061, F.S. The Agency may establish rates lower than the maximum provided in Section 112.061, F.S.
- 3. To provide units of deliverables, including reports, findings, and drafts, in writing and/or in an electronic format agreeable to both Parties, as specified in **Attachment I**, Scope of Services, to be received and accepted by the Contract Manager prior to payment.
- **4.** To comply with the criteria and final date, as specified herein, by which such criteria must be met for completion of this Contract.
- 5. This Contract shall begin upon execution by both Parties or **BEGIN DATE**, (whichever is later) and end on **END DATE**, inclusive.
- 6. In accordance with Section 287.057(13), F.S., this Contract may be renewed for a period that may not exceed three (3) years or the term of the original Contract, whichever period is longer. Renewal of this Contract shall be in writing and subject to the same terms and conditions set forth in the initial Contract. A renewal Contract may not include any compensation for costs associated with the renewal. Renewals are contingent upon satisfactory performance evaluations by the Agency, are subject to the availability of funds, and optional to the Agency.
- 7. If this Contract is renewed, it is the Agency's policy to reduce the overall payment amount by the Agency to the Vendor by at least five percent (5%) during the period of this Contract renewal, unless it would affect the level and quality of services.
- **8.** The Vendor agrees that the Agency may unilaterally cancel this Contract for refusal by the Vendor to allow public access to all documents, papers,

letters, or other material made or received by the Vendor in conjunction with this Contract, unless the records are exempt from Section 24(a) of Article I of the State Constitution and the Florida Public Records Act, Chapter 119, F.S.

- **9.** To comply with Patents, Royalties, Copyrights, Right to Data, and Works for Hire/Software requirements as follows:
  - a. The Vendor, without exception, shall indemnify and hold harmless the Agency and its employees from liability of any nature or kind, including cost and expenses for or on account of any copyrighted, patented, or unattended invention, process, or article manufactured or supplied by the Vendor. The Vendor has no liability when such claim is solely and exclusively due to the combination, operation or use of any article supplied hereunder with equipment or data not supplied by the Vendor or is based solely and exclusively upon the Agency's alteration of the article.
  - b. The Agency will provide prompt written notification of a claim of copyright or patent infringement and shall afford the Vendor full opportunity to defend the action and control the defense. Further, if such a claim is made or is pending, the Vendor may, at its option and expense procure for the Agency the right to continue the use of, replace or modify the article to render it non-infringing (if none of the alternatives is reasonably available, the Agency agrees to return the article on request to the Vendor and receive reimbursement, if any, as may be determined by a court of competent jurisdiction).
  - c. If the Vendor brings to the performance of this Contract a preexisting patent, patent-pending and/or copyright, at the time of Contract execution, the Vendor shall retain all rights and entitlements to that pre-existing patent, patent-pending and/or copyright, unless this Contract provides otherwise.
  - d. If the Vendor uses any design, device, or materials covered by letter, patent, or copyright, it is mutually agreed and understood without exception that the proposed prices shall include all royalties or cost arising from the use of such design, device, or materials in any way involved in the work. Prior to the initiation of services under this Contract, the Vendor shall disclose, in writing, all intellectual properties relevant to the performance of this Contract which the Vendor knows, or should know, could give rise to a patent or copyright. The Vendor shall retain all rights and entitlements to any pre-existing intellectual property which is so disclosed. Failure to disclose will indicate that no such property exists. The Agency will then have the right to all patents and copyrights which arise as a result of performance under this Contract as provided in this Sub-Section.

- e. If any discovery or invention arises or is developed in the course of, or as a result of, work or services performed under this Contract, or in any way connected herewith, the Vendor shall refer the discovery or invention to the Agency for a determination whether patent protection will be sought in the name of the State of Florida. Any and all patent rights accruing under or in connection with the performance of this Contract are hereby reserved to the State of Florida. All materials to which the Agency is to have patent rights or copyrights shall be marked and dated by the Vendor in such a manner as to preserve and protect the legal rights of the Agency.
- f. Where activities supported by this Contract produce original writing, sound recordings, pictorial reproductions, drawings or other graphic representation and works of any similar nature, the Agency has the right to use, duplicate and disclose such materials in whole or in part, in any manner, for any purpose whatsoever and to have others acting on behalf of the Agency to do so. If the materials so developed are subject to copyright, trademark, or patent, legal title and every right, interest, claim, or demand of any kind in and to any patent, trademark or copyright, or application for the same, shall vest in the State of Florida, Department of State for the exclusive use and benefit of the State. Pursuant to Section 286.021, F.S., no person, firm, corporation, including parties to this Contract shall be entitled to use the copyright, patent, or trademark without the prior written consent of the Florida Department of State.
- **g.** The Agency will have unlimited rights to use, disclose, or duplicate, for any purpose whatsoever, all information and data developed, derived, documented, or furnished by the Vendor under this Contract.
- h. All rights and title to works for hire under this Contract, whether patentable or copyrightable or not, shall belong to the Agency and shall be subject to the terms and conditions of this Contract.
- i. The computer programs, data, materials and other information furnished by the Agency to the Vendor hereunder shall be and remain the sole and exclusive property of the Agency, free from any claim or right of retention by or on behalf of the Vendor. The services and products listed in this Contract shall become the property of the Agency upon the Vendor's performance and delivery thereof. The Vendor hereby acknowledges that said computer programs, materials and other information provided by the Agency to the Vendor hereunder, together with the products delivered and services performed by the Vendor hereunder, shall be and remain confidential and proprietary in nature to the extent provided by Chapter 119, F.S., and that the Vendor shall not disclose, publish or use same for any purpose other than the purposes provided in

this Contract; however, upon the Vendor first demonstrating to the Agency's satisfaction that such information, in part or in whole, (1) was already known to the Vendor prior to its receipt from the Agency; (2) became known to the Vendor from a source other than the Agency; or (3) has been disclosed by the Agency to third parties without restriction, the Vendor shall be free to use and disclose same without restriction. Upon completion of the Vendor's performance or otherwise cancellation or termination of this Contract, the Vendor shall surrender and deliver to the Agency, freely and voluntarily, all of the above-described information remaining in the Vendor's possession.

- j. The Vendor warrants that all materials produced hereunder shall be of original development by the Vendor and shall be specifically developed for the fulfillment of this Contract and shall not knowingly infringe upon or violate any patent, copyright, trade secret or other property right of any third party, and the Vendor shall indemnify and hold the Agency harmless from and against any loss, cost, liability or expense arising out of any breach or claimed breach of this warranty.
- **k.** The terms and conditions specified in this Sub-Section shall also apply to any subcontract made under this Contract. The Vendor shall be responsible for informing the subcontractor of the provisions of this Sub-Section and obtaining disclosures.
- 10. The financial consequences that the Agency must apply if the Vendor fails to perform in accordance with this Contract are outlined in **Attachment I**, Scope of Services.

### X. Sponsorship

Pursuant to Section 286.25, F.S., all non-governmental Vendors must assure that all notices, information pamphlets, press releases, advertisements, descriptions of the sponsorship of the program, research reports, and similar public notices prepared and released by the Vendor shall include the Statement: "Sponsored by (name of Vendor) and the State of Florida, Agency for Health Care Administration." If the sponsorship reference is in written material, the words, "State of Florida, Agency for Health Care Administration" shall appear in the same size letters or type as the name of the organization.

#### Y. Final Invoice

The Vendor must submit the final invoice for payment to the Agency no more than NUMBER calendar days after this Contract ends or is terminated. If the Vendor fails to do so, all right to payment is forfeited and the Agency will not honor any requests submitted after the aforesaid time period. Any payment due under the terms of this Contract may be withheld until all reports due from the Vendor and necessary adjustments thereto have been approved by the

Agency.

### Z. Use of Funds for Lobbying Prohibited

To comply with the provisions of Section 216.347, F.S., which prohibits the expenditure of Contract funds for the purpose of lobbying the Legislature, the judicial branch or a State agency.

## AA. Public Entity Crime

A person or affiliate who has been placed on the Convicted Vendor List following a conviction for a public entity crime may not be awarded or perform work as a contractor, supplier, subcontractor, or consultant under a contract with any public entity, and may not transact business with any public entity in excess of the threshold amount provided in Section 287.017, F.S., for category two, for a period of thirty six (36) months from the date of being placed on the Convicted Vendor List.

### BB. Health Insurance Portability and Accountability Act

- 1. To comply with the Department of Health and Human Services Privacy Regulations in the CFR, Title 45, Sections 160 and 164, regarding disclosure of protected health information as specified in **Attachment II**, Business Associate Agreement.
- 2. The Vendor must ensure it meets all Federal regulations regarding required standard electronic transactions and standards for privacy and individually identifiable health information as identified in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009 and associated regulations.
- 3. 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 Federal Information Processing Standards (FIPS), and/or the National Institute of Standards and Technology (NIST) publications regarding cryptographic standards.

### CC. Confidentiality of Information

1. The Vendor shall not use or disclose any confidential information, including social security numbers that may be supplied under this Contract pursuant to law, and also including the identity or identifying information concerning a Medicaid recipient or services under this Contract for any purpose not in conformity with State and Federal laws, except upon written consent of the recipient, or his/her guardian.

- 2. All personally identifiable information, including Medicaid information, obtained by the Vendor shall be treated as privileged and confidential information and shall be used only as authorized for purposes directly related to the administration of this Contract. The Vendor must have a process that specifies that patient-specific information remains confidential, is used solely for the purposes of data analysis or other Vendor responsibilities under this Contract, and is exchanged only for the purpose of conducting a review or other duties outlined in this Contract.
- 3. Any patient-specific information received by the Vendor can be shared only with those agencies that have legal authority to receive such information and cannot be otherwise transmitted for any purpose other than those for which the Vendor is retained by the Agency. The Vendor must have in place written confidentiality policies and procedures to ensure confidentiality and to comply with all Federal and State laws (including the HIPAA and HITECH Acts) governing confidentiality, including electronic treatment records, facsimile mail, and electronic mail).
- 4. The Vendor's subcontracts must explicitly state expectations about the confidentiality of information, and the subcontractor is held to the same confidentiality requirements as the Vendor. If provider-specific data are released to the public, the Vendor shall have policies and procedures for exercising due care in compiling and releasing such data that address statutory protections of quality assurance and confidentiality while assuring that open records requirements of Chapter 119, F.S., are met.
- 5. The Vendor and its subcontractors shall comply with the requirements of Section 501.171, F.S. and shall, in addition to the reporting requirements therein, report to the Agency any breach of personal information.
- **6.** Any releases of information to the media, the public, or other entities require prior approval from the Agency.

#### DD. Employment

The Vendor shall comply with Section 274A of the Immigration and Nationality Act. The Agency will consider the employment by any contractor of unauthorized aliens a violation of this Act. If the Vendor knowingly employs unauthorized aliens, such violation shall be cause for unilateral cancellation of this Contract. The Vendor shall be responsible for including this provision in all subcontracts with private organizations issued as a result of this Contract.

### **EE.** Work Authorization Program

The Immigration Reform and Control Act of 1986 prohibits employers from knowingly hiring illegal workers. The Vendor shall only employ individuals who may legally work in the United States (U.S.) – either U.S. citizens or foreign citizens who are authorized to work in the U.S. The Vendor shall use the U.S.

Department of Homeland Security's E-Verify Employment Eligibility Verification system, <a href="https://e-verify.uscis.gov/emp">https://e-verify.uscis.gov/emp</a>, to verify the employment eligibility of all new employees hired by the Vendor during the term of this Contract and shall also include a requirement in its subcontracts that the subcontractor utilize the E-Verify system to verify the employment eligibility of all new employees hired by the subcontractor performing work or providing services pursuant to this Contract.

### FF. Scrutinized Companies Lists

Pursuant to Section 287.135, F.S. the Vendor certifies that:

- 1. If this Contract reaches or exceeds **\$1,000,000.00**, it has not been placed on the Scrutinized Companies with Activities in Sudan List or the Scrutinized Companies with Activities in the Iran Petroleum Energy Sector List and does not have business operations in Cuba or Syria; and
- 2. For contracts of any amount, it has not been placed on the Scrutinized Companies that Boycott Israel List and is not engaged in a boycott of Israel.

The Vendor agrees that the Agency may immediately terminate this Contract if the Vendor is found to have submitted a false certification or is placed on the lists defined in Sections 215.473 or 215.4725, F.S., or engages in a boycott of Israel, during the term of this Contract.

#### GG. Performance of Services

The Vendor shall ensure all services provided under this Contract will be performed within the borders of the United States and its territories and protectorates. State-owned Data (data collected or created for or provided by the Agency) will be processed and stored in data centers that are located only in the forty eight (48) contiguous United States.

#### HH. Venue

- 1. In the event of any legal challenges to this Contract, the Vendor agrees and will consent that hearings and depositions for any administrative or other litigation related to this Contract shall be held in Leon County, Florida. The Agency, in its sole discretion, may waive this venue for depositions.
- 2. Respondents (and their successors, including but not limited to their parent(s), affiliates, subsidiaries, subcontractors, assigns, heirs, administrators, representatives and trustees) acknowledge that this Contract (including but not limited to exhibits, attachments, or amendments) is not a rule nor subject to rulemaking under Chapter 120 (or its successor) of the Florida Statutes and is not subject to challenge as a rule or non-rule policy under any provision of Chapter 120, F.S.

- This Contract shall be delivered in the State of Florida and shall be construed in accordance with the laws of Florida. Wherever possible, each provision of this Contract shall be interpreted in such a manner as to be effective and valid under applicable law, but if any provision shall be found ineffective, then to the extent of such prohibition or invalidity, that provision shall be severed without invalidating the remainder of such provision or the remaining provisions of this Contract.
- 4. The exclusive venue and jurisdiction for any action in law or in equity to adjudicate rights or obligations arising pursuant to or out of this Contract for which there is no administrative remedy shall be the Second Judicial Circuit Court in and for Leon County, Florida, or, on appeal, the First District Court of Appeal (and, if applicable, the Florida Supreme Court). Any administrative hearings hereon or in connection herewith shall be held in Leon County, Florida.

#### II. THE AGENCY HEREBY AGREES:

#### A. Contract Amount

To pay for contracted services according to the conditions of **Attachment I**, Scope of Services, in an amount not to exceed **\$AMOUNT**, subject to the availability of funds. The State of Florida's performance and obligation to pay under this Contract is contingent upon an annual appropriation by the Legislature.

## B. Contract Payment

Section 215.422, F.S., provides that agencies have five (5) business days to inspect and approve goods and services, unless bid specifications, Contract or Purchase Order specifies otherwise. With the exception of payments to health care providers for hospital, medical, or other health care services, if payment is not available within forty (40) calendar days, measured from the latter of the date the invoice is received or the goods or services are received, inspected and approved, a separate interest penalty set by the Comptroller pursuant to Section 55.03, F.S., will be due and payable in addition to the invoice amount. To obtain the applicable interest rate, please contact the Agency's Fiscal Section at (850) 412-3858, or utilize the Department of Financial Services website at www.myfloridacfo.com/aadir/interest.htm. Payments to health care providers for hospital, medical or other health care services, shall be made not more than thirty five (35) calendar days from the date eligibility for payment is determined, and the daily interest rate is .0003333%. Invoices returned to a vendor due to preparation errors will result in a payment delay. Invoice payment requirements do not start until a properly completed invoice is provided to the Agency. A Vendor Ombudsman, whose duties include acting as an advocate for vendors who may be experiencing problems in obtaining timely payment(s) from a State agency, may be contacted at (850) 413-5516 or by calling the State Office of Financial Regulation Consumer Helpline, 1-877-693-5236.

#### III. THE VENDOR AND AGENCY HEREBY MUTUALLY AGREE:

#### A. Termination

#### 1. Termination at Will

This Contract may be terminated by the Agency upon no less than thirty (30) calendar day's written notice, without cause, unless a lesser time is mutually agreed upon by both Parties. Said notice shall be delivered by certified mail, return receipt requested, or in person with proof of delivery.

#### 2. Termination Due to Lack of Funds

In the event funds to finance this Contract become unavailable, the Agency may terminate this Contract upon no less than twenty four (24) clock hours' written notice to the Vendor. Said notice shall be delivered by certified mail, return receipt requested, or in person with proof of delivery. The Agency will be the final authority as to the availability of funds. The Vendor shall be compensated for all acceptable work performed up to the time notice of termination is received.

#### 3. Termination for Breach

- a. Unless the Vendor's breach is waived by the Agency in writing, the Agency may, by written notice to the Vendor, terminate this Contract upon no less than twenty four (24) clock hours' written notice. Said notice shall be delivered by certified mail, return receipt requested, or in person with proof of delivery. If applicable, the Agency may employ the default provisions in Rule 60A-1.006(3), F.A.C.
- **b.** Waiver of breach of any provisions of this Contract shall not be deemed to be a waiver of any other breach and shall not be construed to be a modification of the terms of this Contract. The provisions herein do not limit the Agency's right to remedies at law or to damages.

#### B. Contract Managers

**1.** The Agency's Contract Manager's contact information is as follows:

Name
Agency for Health Care Administration
Address
City, State Zip Code
Phone Number

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

Name
Vendor Name
Address
City, State Zip Code
Phone Number

3. All matters shall be directed to the Contract Managers for appropriate action or disposition. A change in Contract Manager by either Party shall be reduced to writing through an amendment to this Contract by the Agency.

## C. Renegotiation or Modification

- 1. Modifications of provisions of this Contract shall only be valid when they have been reduced to writing and duly signed during the term of this Contract. The Parties agree to renegotiate this Contract if Federal and/or State revisions of any applicable laws, or regulations make changes in this Contract necessary.
- 2. The rate of payment and the total dollar amount may be adjusted retroactively to reflect price level increases and changes in the rate of payment when these have been established through the appropriations process and subsequently identified in the Agency's operating budget.

#### 3. Preferred Pricing

The Vendor represents and warrants that the prices and terms for its services under this Contract are no less favorable to the Agency than those for similar services under any existing contract with any other party. The Vendor further agrees that, within ninety (90) calendar days of the Vendor entering into a contract or contract amendment or offering to any other party services similar to those under this Contract under prices or terms more favorable than those provided in this Contract, the Vendor will report such prices and terms to the Agency, which prices or terms shall be effective as an amendment to this Contract upon the Agency's written acceptance thereof. Should the Agency discover such other prices or terms, the same shall be effective as an amendment to this Contract retroactively to the earlier of the effective date of this Contract (for other contracts in effect as of that date) or the date they were first contracted or offered to the other party (for subsequent contracts, amendments or offers) and any payment in excess of such pricing shall be deemed overpayments. The Vendor shall submit an affidavit no later than July 31st of each year during the term of this Contract attesting that the Vendor is in compliance with this provision, as required by Section 216.0113, F.S.

#### D. All Terms and Conditions

This Contract and its attachments as referenced herein contain all the terms and

conditions agreed upon by the Parties.

This Contract is and shall be deemed jointly drafted and written by all Parties to it and shall not be construed or interpreted against the Party originating or preparing it. Each Party has the right to consult with counsel and has either consulted with counsel or knowingly and freely entered into this Contract without exercising its right to counsel.

**IN WITNESS THEREOF,** the Parties hereto have caused this number page Contract, which includes any referenced attachments, to be executed by their undersigned officials as duly authorized. This Contract is not valid until signed and dated by both Parties.

| VENDOR NAME      | STATE OF FLORIDA, AGENCY FOR HEALTH CARE ADMINISTRATION |  |
|------------------|---|--|
| SIGNED BY: NAME: | SIGNED BY: NAME:  |  |
| TITLE:           | TITLE:  |  |
| DATE:            | DATE:   |  |

FEDERAL ID NUMBER (or SS Number for an individual): NUMBER

VENDOR FISCAL YEAR ENDING DATE: DATE

List of Attachments included as part of this Contract:

| Specify    | Letter/ |  |
|------------|---------|--|
| Туре       | Number  | Description  |
| Attachment | I       | Scope of Services (NUMBER Pages)                             |
| Attachment | II      | Business Associate Agreement (4 Pages)                       |
| Attachment | Ш       | Certification Regarding Lobbying (1 Page)                    |
| Attachment | IV      | Certification Regarding Debarment, Suspension, Ineligibility |
|            |         | and Voluntary Exclusion Contracts/Subcontracts (1 Page)      |

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# ATTACHMENT II BUSINESS ASSOCIATE AGREEMENT

The parties to this Attachment agree that the following provisions constitute a business associate agreement for purposes of complying with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This Attachment is applicable if the Vendor is a business associate within the meaning of the Privacy and Security Regulations, 45 C.F.R. 160 and 164.

The Vendor certifies and agrees as to abide by the following:

- 1. <u>Definitions</u>. Unless specifically stated in this Attachment, the definition of the terms contained herein shall have the same meaning and effect as defined in 45 C.F.R. 160 and 164.
  - a. <u>Protected Health Information</u>. For purposes of this Attachment, protected health information shall have the same meaning and effect as defined in 45 C.F.R. 160 and 164, limited to the information created, received, maintained or transmitted by the Vendor from, or on behalf of, the Agency.
  - b. <u>Security Incident</u>. For purposes of this Attachment, security incident means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system and includes any event resulting in computer systems, networks, or data being viewed, manipulated, damaged, destroyed or made inaccessible by an unauthorized activity.
- Applicability of HITECH and HIPAA Privacy Rule and Security Rule Provisions. As provided by federal law, Title XIII of the American Recovery and Reinvestment Act of 2009 (ARRA), also known as the Health Information Technology Economic and Clinical Health (HITECH) Act, requires a Business Associate (Vendor) that contracts with the Agency, a HIPAA covered entity, to comply with the provisions of the HIPAA Privacy and Security Rules (45 C.F.R. 160 and 164) and comply with 45 C.F.R. 162 as applicable.
- 3. <u>Use and Disclosure of Protected Health Information</u>. The Vendor shall comply with the provisions of 45 CFR 164.504(e)(2)(ii). The Vendor shall not use or disclose protected health information other than as permitted by this Contract or by federal and state law. The sale of protected health information or any components thereof is prohibited except as provided in 45 CFR 164.502(a)(5). The Vendor will use appropriate safeguards to prevent the use or disclosure of protected health information for any purpose not in conformity with this Contract and federal and state law. The Vendor will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of electronic protected health information the Vendor creates, receives, maintains, or transmits on behalf of the Agency.
- 4. <u>Use and Disclosure of Information for Management, Administration, and Legal</u> Responsibilities. The Vendor is permitted to use and disclose protected health

information received from the Agency for the proper management and administration of the Vendor or to carry out the legal responsibilities of the Vendor, in accordance with 45 C.F.R. 164.504(e)(4). Such disclosure is only permissible where required by law, or where the Vendor obtains reasonable assurances from the person to whom the protected health information is disclosed that: (1) the protected health information will be held confidentially, (2) the protected health information will be used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and (3) the person notifies the Vendor of any instance of which it is aware in which the confidentiality of the protected health information has been breached.

- 5. <u>Disclosure to Third Parties</u>. The Vendor will not divulge, disclose, or communicate protected health information to any third party for any purpose not in conformity with this Contract without prior written approval from the Agency. The Vendor shall ensure that any agent, including a subcontractor, to whom it provides protected health information received from, or created or received by the Vendor on behalf of the Agency, agrees to the same terms, conditions, and restrictions that apply to the Vendor with respect to protected health information. The Vendor's subcontracts shall fully comply with the requirements of 45 CFR 164.314(a)(2)(iii).
- 6. <u>Access to Information</u>. The Vendor shall make protected health information available in accordance with federal and state law, including providing a right of access to persons who are the subjects of the protected health information in accordance with 45 C.F.R. 164.524.
- 7. <u>Amendment and Incorporation of Amendments</u>. The Vendor shall make protected health information available for amendment and to incorporate any amendments to the protected health information in accordance with 45 C.F.R. 164.526.
- 8. Accounting for Disclosures. The Vendor shall make protected health information available as required to provide an accounting of disclosures in accordance with 45 C.F.R. 164.528. The Vendor shall document all disclosures of protected health information as needed for the Agency to respond to a request for an accounting of disclosures in accordance with 45 C.F.R. 164.528.
- 9. <u>Privacy Protection</u>. The Vendor shall permit an individual to request a restriction on the use and disclosure of protected health information about the individual to carry out treatment, payment, or health care operations; and disclosures permitted under 164.510(b) in accordance with 45 C.F.R. 164.522. The Vendor shall permit an individual to request to receive communications of protected health information from the Vendor by alternative means or at alternative locations in accordance with 45 C.F.R. 164.522.
- 10. Access to Books and Records. The Vendor shall make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the Vendor on behalf of the Agency, available to the Secretary of the Department of Health and Human Services ("HHS") or the Secretary's designee for purposes of determining compliance with the HHS Privacy Regulations.
- 11. Reporting. The Vendor shall make a good faith effort to identify any use or disclosure of protected health information not provided for in this Contract.

- a. <u>To Agency</u>. The Vendor will report to the Agency in the manner and format obtained from the Contract Manager or Agency contact, within ten (10) business days of discovery, any use or disclosure of protected health information not provided for in this Contract of which the Vendor is aware. The Vendor will report to the Agency in the manner and format obtained from the Contract Manager or Agency contact, within twenty-four (24) hours of discovery, any security incident of which the Vendor is aware. A violation of this paragraph shall be a material violation of this Contract. Such notice shall include the identification of each individual whose unsecured protected health information has been or is reasonably believed by the Vendor to have been, accessed, acquired, used, or disclosed during such breach.
- To Individuals. In the case of a breach of protected health information discovered b. by the Vendor, the Vendor shall first notify the Agency of the pertinent details of the breach and upon prior review by the Agency shall notify each individual whose unsecured protected health information has been, or is reasonably believed by the Vendor to have been, accessed, acquired, used or disclosed as a result of such breach. Such notification shall be in writing by first-class mail to the individual (or the next of kin if the individual is deceased) at the last known address of the individual or next of kin, respectively, or, if specified as a preference by the individual, by electronic mail. Where there is insufficient, or outof-date contact information (including a phone number, email address, or any other form of appropriate communication) that precludes written (or, if specifically requested, electronic) notification to the individual, a substitute form of notice shall be provided, including, in the case that there are 10 or more individuals for which there is insufficient or out-of-date contact information, a conspicuous posting for a period of at least 90 days on the Web site of the covered entity involved or notice in major print or broadcast media, including major media in the geographic areas where the individuals affected by the breach likely reside. In any case deemed by the Vendor to require urgency because of possible imminent misuse of unsecured protected health information, the Vendor may also provide information to individuals by telephone or other means, as appropriate.
- c. <u>To Media</u>. In the case of a breach of protected health information discovered by the Vendor where the unsecured protected health information of more than 500 persons is reasonably believed to have been, accessed, acquired, used, or disclosed, after prior review by the Agency, the Vendor shall provide notice to prominent media outlets serving the State, relevant portion of the State, or jurisdiction involved.
- d. <u>To Secretary of Health and Human Services (HHS)</u>. The Vendor shall cooperate with the Agency to provide notice to the Secretary of HHS of unsecured protected health information that has been acquired or disclosed in a breach.
  - i. <u>Vendors Who Are Covered Entities.</u> In the event of a breach by the Vendor, or a contractor or subcontractor of the Vendor, and the Vendor is

a HIPAA covered entity, the Vendor, not the Agency, shall be considered the covered entity for purposes of notification to the Secretary of HHS pursuant to 45 CFR 164.408. The Vendor shall be responsible for filing the notification to the Secretary of HHS and will identify itself as the covered entity in the notice. If the breach was with respect to 500 or more individuals, at least 5 business days prior to filing notice with the Secretary of HHS the Vendor shall provide a copy of the notice and breach risk assessment to the Agency for review. Upon prior review by the Agency of the notice and breach risk assessment, the Vendor shall file the notice with the Secretary of HHS within the notification timeframe imposed by 45 C.F.R. 164.408(b) and contemporaneously submit a copy of said notification to the Agency. If the breach was with respect to less than 500 individuals, the Vendor shall notify the Secretary of HHS within the notification timeframe imposed by 45 C.F.R. 164.408(c) and shall contemporaneously submit a copy of said notification to the Agency.

- e. <u>Content of Notices</u>. All notices required under this Attachment shall include the content set forth in 42 U.S.C. 17932(f) and 45 C.F.R. 164 Subpart D, except that references therein to a "covered entity" shall be read as references to the Vendor.
- f. <u>Financial Responsibility</u>. The Vendor shall be responsible for all costs related to the notices required under this Attachment.
- g. Other Reporting. The Vendor shall comply with any other applicable reporting requirements in conformity with federal and state laws. If notifications are made under any such laws, copies of said notifications shall be provided contemporaneously to the Agency.
- Mitigation. Vendor shall mitigate, to the extent practicable, any harmful effect that is known to the Vendor of a use or disclosure of protected health information in violation of this Attachment.
- 13. <u>Termination</u>. Upon the Agency's discovery of a material breach of this Attachment, the Agency shall have the right to assess liquidated damages as specified elsewhere in the contract to which this Attachment is included, and/or to terminate this Contract.
- 14. Effect of Termination. At the termination of this Contract, the Vendor shall return all protected health information that the Vendor still maintains in any form, including any copies or hybrid or merged databases made by the Vendor; or with prior written approval of the Agency, the protected health information may be destroyed by the Vendor after its use. If the protected health information is destroyed pursuant to the Agency's prior written approval, the Vendor must provide a written confirmation of such destruction to the Agency. If return or destruction of the protected health information is determined not feasible by the Agency, the Vendor agrees to protect the protected health information and treat it as strictly confidential.

The Vendor has caused this Attachment to be signed and delivered by its duly authorized

representative, as of the date set forth below.

| <b>VENDOR NAME</b> |        |  |
|--------------------|--------|--|
| SIGNED<br>BY:      |        |  |
|                    |        |  |
| NAME:              | TITLE: |  |

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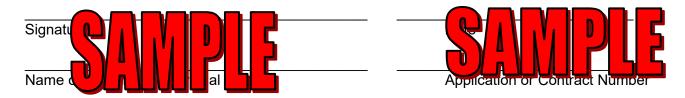
### ATTACHMENT III

# CERTIFICATION REGARDING LOBBYING CERTIFICATION FOR CONTRACTS, GRANTS, LOANS AND COOPERATIVE AGREEMENTS

The undersigned certifies, to the best of his or her knowledge and belief, that:

- (1) No federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a member of congress, an officer or employee of congress, or an employee of a member of congress in connection with the awarding of any federal contract, the making of any federal grant, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.
- (2) If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a member of congress, an officer or employee of congress, or an employee of a member of congress in connection with this federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- (3) The undersigned shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, Title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.



Name and Address of Organization

#### **ATTACHMENT IV**

# CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY AND VOLUNTARY EXCLUSION CONTRACTS/SUBCONTRACTS

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, signed February 18, 1986. The guidelines were published in the May 29, 1987, Federal Register (52 Fed. Reg., pages 20360-20369).

#### **INSTRUCTIONS**

- 1. Each Vendor whose contract/subcontract equals or exceeds \$25,000 in federal monies must sign this certification prior to execution of each contract/subcontract. Additionally, Vendors who audit federal programs must also sign, regardless of the contract amount. The Agency for Health Care Administration cannot contract with these types of Vendors if they are debarred or suspended by the federal government.
- 2. This certification is a material representation of fact upon which reliance is placed when this contract/subcontract is entered into. If it is later determined that the signer knowingly rendered an erroneous certification, the Federal Government may pursue available remedies, including suspension and/or debarment.
- The Vendor shall provide immediate written notice to the contract manager at any time the Vendor learns
  that its certification was erroneous when submitted or has become erroneous by reason of changed
  circumstances.
- 4. The terms "debarred," "suspended," "ineligible," "person," "principal," and "voluntarily excluded," as used in this certification, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the contract manager for assistance in obtaining a copy of those regulations.
- 5. The Vendor agrees by submitting this certification that, it shall not knowingly enter into any subcontract with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this contract/subcontract unless authorized by the Federal Government.
- 6. The Vendor further agrees by submitting this certification that it will require each subcontractor of this contract/subcontract, whose payment will equal or exceed \$25,000 in federal monies, to submit a signed copy of this certification.
- 7. The Agency for Health Care Administration may rely upon a certification of a Vendor that it is not debarred, suspended, ineligible, or voluntarily excluded from contracting/subcontracting unless it knows that the certification is erroneous.
- 8. This signed certification must be kept in the contract manager's contract file. Subcontractor's certifications must be kept at the contractor's business location.

#### **CERTIFICATION**

- (1) The prospective Vendor certifies, by signing this certification, that neither he nor his principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this contract/subcontract by any federal department or agency.
- (2) Where the prospective Vendor is unable to certify to any of the statements in this certification, such prospective Vendor shall attach an explanation to this certification.



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For purposes of this solicitation the successful vendor shall be referred to as Vendor. The contract or purchase order resulting from this solicitation shall be referred to as Contract.

### 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 (s.) 381.02035, Florida Statutes (F.S.) establishing the Canadian Prescription Drug Importation Program (Program) within the Agency for Health Care Administration (Agency). legislation limits the eligible importers to pharmacists or wholesalers providing services to individuals on behalf of State programs such as 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 (i.e., controlled substances, biologic drugs, etc.). The Agency's implementation of this Program is contingent on finalization of the Food and Drug Administration's Final Rule on the Importation of Prescription Drugs (currently proposed rule at FDA-2019-N-5711) and Federal approval of a Section 804 Importation Program proposal for Florida.

## B. Overview/Purpose

The purpose of this ITN is to compare alternative approaches to implementation and management of the Canadian Prescription Drug Importation Program (Program), and to determine the best value to the State of Florida (State).

The Vendor shall manage and oversee all aspects of the Program and ensure the Canadian Supplier(s) and eligible importers comply with all federal and State law requirements. Eligible importers are limited to wholesalers. Prescription drugs imported under this Contract will be for use by consumers who are being served by certain State/government programs. The Program must also comply fully with Title II of the Drug Quality Security Act (DQSA) (Pub. L. No. 113-54), the Federal Drug Supply Chain Security Act (DSCSA).

The Agency will retain ultimate responsibility for ensuring that the Program operates consistently with any federal rules and regulations that are ultimately adopted by the Department of Health and Human Services (DHHS). The Agency will maintain active oversight and monitoring functions over Vendor operations and will actively collaborate with DHHS to ensure success under the Program.

#### C. Order of Precedence

The Vendor shall perform its contracted duties in accordance with this Contract, AHCA ITN 008-19/20, including all addenda and the Vendor's Response to AHCA ITN 008-19/20. In the event of conflict among Contract documents, any identified

inconsistency in this Contract shall be resolved by giving precedence in the following order:

- 1. This Contract, including all attachments, exhibits and any subsequent amendments;
- 2. AHCA ITN 008-19/20, including all addenda; and
- **3.** The Vendor's Response to AHCA ITN 008-19/20, including information provided through negotiations.

### 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 the Vendor's compliance with the requirements of this Contract.
- 2. Providing information related to federal and State requirements related to the provision of services under this Contract and expectations of the Vendor.
- 3. 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.
- **4.** 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.
- **5.** 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.
- **6.** Determining whether the Vendor has violated a contractual obligation and assessing liquidated damages or monetary sanctions, when necessary.
- 7. 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 2727 Mahan Drive, MS#8 Tallahassee, FL 32308

- **8.** 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.
- **9.** Meeting with the Vendor in person 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.
- **10.** Notifying other state agencies about the implementation of this Contract.
- **11.** 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 commercial importation of prescription drugs into Florida from the approved Canadian Supplier(s). Allowable prescription drugs that are imported under the Program must have the greatest potential for savings to the State. 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; Section 381.02035, 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) Request from the Food and Drug Administration (FDA) a list of FDA-approved manufacturing facilities outside of the United States (U.S.) for the drugs on the qualifying prescription drugs list.
  - 4) Utilize publicly available registration data connected with drug labeler codes to identify FDA-approved manufacturers for qualifying prescription drugs.

- 5) Develop a list of the prescription drugs quarterly that have the highest potential for cost savings to State of Florida programs, including prescription drugs for which there are shortages, specialty prescription drugs, and high-volume prescription drugs.
- 6) Establish a process for receiving orders and delivery information from State agencies that will receive imported prescription drugs.
- 7) Identify Canadian suppliers 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.
- 8) Contract with such eligible Canadian supplier(s), or facilitate contracts between eligible importers and Canadian supplier(s), to import drugs under the program.
- 9) Be responsible for directly reimbursing the Canadian Supplier(s) for imported prescription drugs.
- 10) Maintain documentation that sample testing of the prescription drugs occurred at a qualified laboratory, as required by 21 U.S.C. 384.
- 11) Maintain documentation that the imported prescription drug has been certified as being approved for marketing in the United States, has not been adulterated or misbranded, and meets all labeling requirements under federal law.
- 12) Maintain additional information and documentation from importers and Canadian supplier(s) as specified in Section 381.02035, F.S.
- 13) Assist the Agency in the preparation of an annual legislative report on the efficacy of the Program.
- 14) Respond to all Agency inquiries within twenty-four (24) hours.
- 15) 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.
- 16) Develop, manage, maintain, and modify an electronic system and database specific to the requirements of this Contract.

- 17) Support the exchange of data with necessary partners, as approved by the Agency, in the required formats as is necessary to support this Contract.
- 18) 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.
- 19) Create and deliver an implementation plan.
- 20) Provide outreach and communication to other state agencies as approved and directed by the Agency.
- 21) Deliver training to pharmacies, Agency staff, and other state agencies as identified in this Contract or otherwise directed by the Agency.
- 22) Provide for its office and workspace, equipment, and supplies necessary for the performance of duties specified in this Contract at a location within the State of Florida.
- 23) Provide sufficient qualified staff to meet the requirements of this Contract.
- 24) Support a Customer Service Call Center as specified in this Contract.
- 25) Maintain Agency-approved procedures for all aspects of the work performed under this Contract.
- 26) Develop and 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.
- 27) Develop and submit internal quality control (IQC) assurances that ensure appropriate administration of Vendor responsibilities specified under this Contract.
- 28) Obtain approval from the Agency prior to any delegation of responsibilities related to this Contract.
- 29) Submit all policies and procedures to the Agency in accordance with an Agency-approved implementation plan and as otherwise specified in this Contract.

## 2. Eligible Importer

- a. The Vendor shall:
  - 1) Serve as the importer of prescription drugs from Canada on behalf of the following Florida State agencies: Agency for Health Care Administration (Agency) (and its Medicaid managed care plans), Agency for Persons with Disabilities (APD), Department of Children and Families (DCF), Department of Corrections (DOC), and Department of Health (DOH).
  - 2) Execute agreements with APD, DCF, DOC, and DOH to act on their behalf as the primary importer of the prescription drugs from the approved Canadian Supplier(s).
  - 3) Serve as an intermediary between the Canadian Supplier(s) and the eligible importers (wholesalers providing services on behalf of State programs).
- b. The Vendor shall maintain all required licenses, permits, and/or registrations on active and clear status for the life of this Contract.

## 3. Eligible Canadian Supplier(s)

- a. The Vendor shall:
  - Identify an eligible Canadian Supplier(s) that is in compliance with relevant Canadian federal and provincial laws, received eligible prescription drugs from an FDAapproved 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 facilitate contracts between eligible importers and the Canadian Supplier(s) who has agreed to export 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) Ensure that the Canadian Supplier(s) provides the importer with all of the following:
    - (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(s) 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.
- 4) Be responsible for directly reimbursing the Canadian Supplier(s) for imported prescription drugs.

### 4. Track and Trace Requirements

- a. The Vendor shall ensure that the Program complies with Title II of the Drug Quality and Security Act (DQSA).
- b. The Vendor shall develop an electronic system and database for collecting and storing the following information as the prescription drug travels through the supply chain:
  - 1) Transaction information such as:
    - Proprietary or established name or names of the product;
    - Strength and dosage form of the product;
    - National Drug Code (NDC) number of the product;
    - Container size:
    - Number of containers;
    - Lot number of the product;
    - Date of the transaction;
    - Date of the shipment, if more than twenty-four (24) hours after the date of the transaction;
    - Business name and address of the person from whom ownership is being transferred; and
    - Business name and address of the person to whom ownership is being transferred.
  - 2) Transaction history, including the transaction information for each prior transaction going back to the manufacturer of the product.

- 3) Transaction Statement, a Statement in paper or electronic form, that the entity transferring ownership in a transaction:
  - Is authorized as required under the DSCSA;
  - Received the product from a person that is authorized as required under the DSCSA;
  - Received transaction information and a transaction Statement from the prior owner of the product;
  - Did not knowingly ship suspect or illegitimate product;
  - Had systems and processes in place to comply with verification requirements; and
  - Did not knowingly provide false transaction information or alter the transaction history.

## 5. Prescription Drugs Eligible for Importation

- a. The Vendor shall:
  - 1) Identify the list of prescription drugs that can be imported and update the list quarterly, or as designated by the Agency.
  - 2) Ensure that the listed prescription drugs have the highest potential for cost savings to the State programs.
  - 3) Provide transparent pricing information and a process for updating the State with information on the entry of lower priced products into the market.
  - 4) Ensure any price changes and product additions or deletions are loaded within five (5) business days of the manufacturer price change or manufacturer product addition(s) or deletion(s).
  - 5) Maintain the same formulation as FDA-approved products.
  - 6) Import prescription drugs that must not have been "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) days prior to the scheduled date of arrival of an imported prescription drug shipment.
- 12) Report to the Agency quarterly with a list of the prescription drugs that have the highest potential for cost savings to State of Florida programs, including prescription drugs for which there are shortages, specialty prescription drugs, and high-volume prescription drugs.

## 6. 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), Section 381.02035, F.S., and Chapter 61N-1, F.A.C.
  - 2) Implement supply chain standards for manufacturers, Canadian Supplier(s), and the prescription drug wholesaler to ensure that prescription drugs manufactured outside of Canada are commercially exported to Canada by the manufacturer and labeled for the Canadian market and sold directly to the Canadian Supplier(s).
  - 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.

## 7. Laboratory Testing

- a. The Vendor shall:
  - 1) Ensure testing is conducted by an FDA-approved, qualified laboratory.
  - 2) Submit an initial list of qualified laboratories no later than thirty (30) days after Contract execution, a final list of qualified laboratories no later than sixty (60) days after Contract execution, and quarterly report thereafter by the fifteenth (15<sup>th</sup>) day of the second month following the reporting quarter.
  - 3) Ensure testing 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 the Canadian Supplier(s) provides documentation that either the manufacturer or supplier has tested the drugs in a qualified laboratory. If the manufacturer/supplier has not tested the prescription drug in a qualified laboratory, the Vendor shall have the appropriate batch sample sent to a qualified laboratory for testing.
  - 5) 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.
  - 6) Comply with the frequency of testing as specified in 21 U.S.C. § 384 and shall maintain documentation of all testing that occurred.
  - 7) Have policies and procedures of the steps the Vendor shall take if any of the drugs fail laboratory testing.
  - 8) Document 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, and describe the availability of the Certificate of Analysis and testing results when requested.

### 8. Repackaging and Relabeling

- a. The Vendor shall:
  - 1) After importation, ensure prescription drugs are repackaged and/or relabeled in accordance with federal and State law 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 repackagers are 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 regarding the facility where the relabeling and any limited repackaging activities 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 only one (1) drug is brought into the repackaging area at a time and that all remaining drugs from previous repackaging are removed to prevent mix-ups.
  - 5) Have processes and procedures in place to prevent cross-allergenicity (e.g., penicillin reactions).
  - 6) Ensure the repackaging and relabeling facility has a humidity-controlled environment that will not jeopardize the stability of the drugs.
  - 7) Have control procedures that will prevent relabeling mix ups.
  - 8) Ensure that relabeling provides all FDA required information and Drug Enforcement Agency (DEA) warnings as applicable.

## 9. Prescription Drug Storage

The Vendor shall:

- a. Provide the information where the eligible prescription drug(s) will be stored pending testing, relabeling, and FDA determination of admissibility. The Vendor shall bear the risk of loss of the drugs until the drugs are received by the recipient.
- b. Ensure daily environmental conditions related to temperature, humidity, light, and air quality are tracked in the storage facility through conducting minimum twice-daily recordings and controls.

### 10. Prescription Drug Distribution

The Vendor shall:

- a. Establish a process for receiving orders and delivery information from State agencies that will receive imported prescription drugs.
- b. Maintain responsibility for ensuring the distribution of imported prescription drugs directly to State agency facilities, their network providers, or subcontractors;
- c. Provide each State agency with a monthly report by the thirtieth (30<sup>th</sup>) 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;
- d. Submit copies of these monthly reports to the Agency;
- e. Ensure the manufacturer does not distribute drugs with a shelf life expiration date of less than one (1) year;
- f. 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;
- g. 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 and appropriate; and
- h. Develop and maintain a written procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, State, or national emergency occurs

### 11. 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 must be adequate to deal with recalls and withdrawals due to:
  - 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 develop a procedure to ensure that any outdated prescription drugs are segregated from other drugs and returned to the manufacturer or repackager or destroyed. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for two (2) years after disposition of the outdated drugs.
- c. 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 wholesale distributor and the Canadian Supplier(s)) 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.
- d. If the investigation finds that the prescription drugs are illegitimate products, the Vendor shall (in coordination with the wholesale distributor and the Canadian Supplier(s)):
  - 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 reasonable assistance for disposition to parties who have received the illegitimate products, including the payment of refunds as applicable; and
- 5) Retain a sample.
- e. 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. Additionally, federal law requires a specific notification process.

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

## 13. Implementation Plan

- a. The Vendor shall develop and submit to the Agency a draft implementation plan, no-later-than seven (7) calendar 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:
  - 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 onboarding 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 not deviate from the Agency approved final implementation plan. Any deviation shall 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.
- h. If the Vendor fails to comply with the requirements of this section, 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**, Deliverables, Performance Standards and Liquidated Damages.

#### 14. 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 seven (7) 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) calendar 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.

### 15. Corporate Capability/Office Location

a. The Vendor shall establish a State of Florida 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 5:00 PM, ET.

## 16. 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 qualified staff to comply with all terms of this Contract.
- d. The Vendor shall meet all requirements for doing business in the State of Florida.
- e. The Vendor shall submit a resume for any candidates to fill any key named position for Agency approval.
- f. The Vendor shall ensure that key name positions are not vacant for more than thirty (30) calendar days.
- g. 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.
- h. The Vendor shall submit a quarterly Organizational Chart by the fifth (5<sup>th</sup>) 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.
- i. Key Staffing Positions:
  - The Vendor shall designate a Contract Manager to work 1) 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 fulltime employee of the Vendor. The Vendor Contract Manager shall have the authority to administer the day-today 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 Customer Service Call Center Supervisor to the Contract. The Vendor's Customer Service Call Center Supervisor shall possess at least two (2) years of experience managing a Call Center and Contract of similar scope. The Customer Service Call Center

- Supervisor shall have a minimum of two (2) years of supervisory experience.
- 3) 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.
- j. The Vendor shall notify the Agency in writing of any key staff resignations, dismissals, or personnel changes within one (1) business day 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.
- k. 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.

#### 17. Customer Service

- a. The Vendor shall secure a Customer Service Call Center located in the State of Florida.
- b. The Vendor shall develop and implement a complaint resolution/customer service and tracking system that identifies and tracks all provider calls, complaints and requests for assistance, and that is made available to the Agency upon request.
- c. The Vendor shall provide to its Customer Service Call Center staff initial and ongoing training on the policies and procedures for operation of the Customer Service Call Center, a desk reference with call scripts, and a system for recording customer questions and complaints.
- d. The Vendor shall provide a United States (U.S.) based toll-free telephone number connected to a help desk staffed by English and Spanish-speaking staff who are qualified to address customer service inquiries. Upon request, the Vendor shall provide, at no cost to the provider or the Agency, interpreters for providers whose primary language is not English.
- e. The customer service telephone system shall be staffed with trained customer service representatives who can respond to all inquiries during normal business hours of 8:00 AM to 5:00 PM, ET, Monday through Friday, excluding State of Florida observed holidays.

- f. The Vendor shall provide a before and after business hours' message advising callers of the hours of operation and allowing them to leave a message. The Vendor shall ensure callers do not encounter a busy signal during normal business hours.
- g. The Vendor shall respond to voice messages left before 4:00 PM, ET, within one (1) hour, and for voice messages left on or after 4:00 PM ET, the Vendor shall respond by noon the following business day.
- h. The Vendor shall measure its performance on a monthly basis and report on the following Customer Service Call Center performance standards:
  - 1) At least ninety percent (90%) of all calls received within normal business hours shall be answered within thirty (30) seconds.
  - 2) The first-call resolution rate shall be at least eighty percent (80%).
  - 3) The average hold time shall not exceed sixty (60) seconds.
  - 4) The quality assurance monitoring score shall be eighty-five percent (85%) or greater.
  - 5) The average speed of answer shall not exceed thirty (30) seconds.
  - 6) The call abandonment rate shall not exceed five percent (5%).
  - 7) The call blockage rate, as reported from the telecom provider, is no more than one-half percent (0.5%).
  - 8) At least ninety-five percent (95%) of calls received outside of normal business hours are returned within the time frames specified in this Contract.

### 18. 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.

### 19. 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.
- 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 Agencyapproved dashboard for this process.

### 20. 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.

### 21. 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:

- 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.

### 22. Prohibition of Marketing

The Vendor shall not market Vendor business interests to other state agencies or other individuals.

### 23. Emergency Management Plan

- a. The Vendor shall submit to the Agency in accordance with an Agency-approved implementation plan and by September 1<sup>st</sup> 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 Section 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,** Deliverables, Performance Standards and Liquidated Damages, 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) must 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. All reports shall be developed and produced 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.
- 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 (15<sup>th</sup>) 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;
  - 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;
  - 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(s) 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; and
- 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. 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 must 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 Section 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.

# 2. Laboratory and Relabeling and Repackaging Monitoring Requirements

- **a.** The Vendor shall monitor the quality and performance of its laboratory(s) and relabeling and repackaging facility(s). At the beginning of this Contract period, the Vendor shall notify its laboratory(s) and relabeling and repackaging facility(s) of the metrics used by the Vendor for evaluating performance.
- **b.** The Vendor shall have a review process that results in the following:
  - Review of the relabeling and repackaging facility(s)'s processes and procedures to ensure compliance with Title 21 CFR § 211 and Rule 61N-1.032, F.A.C.
  - Review of the laboratory(s)'s processes and procedures to ensure compliance with ISO 17025 accreditation standards and section 804(d)(1)(J) and (L) of the Food, Drug, and Cosmetic Act.

- Review of the laboratory(s)'s testing results, complete laboratory records, description of the selection method for the samples, testing methods used, and data derived from the tests pertaining to drugs tested to determine whether they meet FDA specifications of their counterparts sold in the U.S.
- Review of the laboratory(s)'s processes and procedures for randomly and representatively selecting samples from batches or shipments of imported prescription drugs.
- Review processes and procedures of laboratory(s) and relabeling and repackaging facility(s) to ensure prevention of contamination, purity, sterility, and stability of imported prescription drugs.

### 3. Canadian Supplier Monitoring Requirements

- a. The Vendor shall monitor the quality and performance of its Canadian Supplier(s). At the beginning of this Contract period, the Vendor shall notify its Canadian Supplier(s) of the metrics used by the Vendor for evaluating performance.
- b. The Vendor shall have a review process that results in the following:
  - Review to confirm that each imported Canadian Health Products and Food Branch (HPFB) approved prescription drug has an FDA-approved counterpart that is marketed in the U.S;
  - Review to confirm the identity of establishments where the active ingredients for each prescription drug are manufactured;
  - Review processes and procedures to ensure prevention of contamination, purity, sterility, and stability of imported prescription drugs; and
  - Review the product name, strength and dosage form, container size, number of containers, dates of shipment and transaction, business names and addresses of the Canadian Supplier(s) and importer, and Canadian drug identification number.

#### III. Method of Payment:

This is a fixed price Contract. 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**, Deliverables, Performance Standards and Liquidated Damages.

### 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

Unless written approval is obtained from the Agency, and at the discretion of the Agency, correct invoices with documentation received forty-six (46) to sixty (60) calendar days after the Agency's acceptance of the deliverable(s) will be paid at ninety percent (90%) of the amount of the invoice. Correct invoices with documentation received sixty-one (61) to ninety (90) calendar days after the Agency's acceptance of the deliverable(s) will be paid at seventy-five percent (75%) of the invoice. Invoices received ninety-one (91) calendar days or more after the Agency's acceptance of the deliverable(s) will **not** be paid.

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.
- b. 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 #1**, Performance Standards and Liquidated Damages, below and as outlined in **Exhibit A**, Deliverables, Performance Standards and Liquidated Damages.

| TABLE #1 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.  | <b>\$500.00</b> per calendar day for each calendar day after the due date until an acceptable performance bond is furnished to the Agency.                            |  |  |  |
| HIPAA  |   |  |  |  |
| The Vendor shall comply with provisions of Health Insurance Portability and Accountability Act (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.  | <b>\$500.00</b> to <b>\$5,000.00</b> , per incident, per occurrence, depending upon the severity.   |  |  |  |

| TABLE #1 PERFORMANCE STANDARDS AND LIQUIDATED DAMAGES  |   |  |  |  |
|--|---|--|--|--|
| Performance Standard Requirement   | Liquidated Damages to be Imposed  |  |  |  |
| Records  |   |  |  |  |
| The Vendor shall comply with public records laws, in accordance with Section 119.0701, F.S.  |   |  |  |  |
| Background Screening   |   |  |  |  |
| Complete initial and renewal background screenings within required timeframes.   | \$250.00 per occurrence.  |  |  |  |
| Submit policies and procedures within thirty (30) calendar days of Contract execution.   | <b>\$250.00</b> per calendar day beyond the due date.   |  |  |  |
| Security Rating Score  |   |  |  |  |
| Annually maintain a top tier security rating score from the Agency's selected information security rating service.   |   |  |  |  |
| Service Organization Controls (SOC) 2 Type II Audit  |   |  |  |  |
| Annually submit the SOC 2 Type II audit report by April 30 <sup>th</sup> of each Contract year. \$1,000.00 per calendar day for e calendar day beyond the due date.  |   |  |  |  |
| Services   |   |  |  |  |
| Implement the approved Corrective Action Plan (CAP) by the Agency specified date.  | <b>\$500.00</b> per calendar day for each calendar day that the approved CAP is not implemented to the satisfaction of the Agency.                                      |  |  |  |
| Submit the final implementation plan and timeline no later than thirty (30) days after Contract execution.   | <b>\$1,000.00</b> per day for each business day past the due date that the Agency has not received the Implementation Plan and any associated supporting documentation. |  |  |  |
| Quarterly by the fifth (5th) day of the quarter, submit an Organizational Chart identifying each person by position and attesting that each employee meets the contract requirement for said position as applicable. | \$100.00 per calendar day for each calendar day beyond the due date.  |  |  |  |
| Respond to all Agency inquiries within twenty-four (24) hours.   | <b>\$1,000.00</b> per day for each day beyond the due date until the Vendor response is provided to the Agency.   |  |  |  |
| A written or verbal reply with information responsive to the request within twenty-four  | <b>\$1,000.00</b> per day for each day beyond the due date until the Vendor response is provided to the Agency.   |  |  |  |

| TABLE #1 PERFORMANCE STANDARDS AND LIQUIDATED DAMAGES   |  |  |  |
|---|--|--|--|
| Performance Standard Requirement  | Liquidated Damages to be Imposed   |  |  |
| (24) hours of the request, unless a later response time is approved by the Agency.  |  |  |  |
| Submit supply chain documentation for inclusion of all the required information in 21 U.S.C. § 384(d)(1).   | One percent (1%) of the total monthly invoice per occurrence.  |  |  |
| Submit a final list of qualified laboratories no later than sixty (60) days after Contract execution and quarterly thereafter. The Vendor shall inform the Agency of any new laboratory source added to the policies and procedures at least ten (10) days prior to allowing testing. | \$2,500.00 per occurrence, plus \$500.00 per day for each day beyond the due date until provided to the Agency.                |  |  |
| Report actual or potential shortages or recalls to the Agency on a monthly basis by the fifth (5th) day of the following month in a manner and format specified by the Agency.  | \$2,500.00 per occurrence, plus \$500.00 per day for each day beyond the due date until provided to the Agency.                |  |  |
| Submit the Training/Outreach Report within fifteen (15) days of the end of the reporting month.   | <b>\$500.00</b> for each business day past the due date that the Agency has not received the monthly Training/Outreach Report. |  |  |
| Submit initial documentation of staffing compliance within forty-five (45) days after Contract execution and quarterly thereafter.  | \$1,000.00 per month in which minimum staffing requirements are not met.   |  |  |
| Submit a copy of its organizational structure within thirty (30) days of Contract execution and annually thereafter.  | <b>\$200.00</b> per day past the timeframe the Agency requires for resolution of staffing shortages.                           |  |  |
| Submit monthly reporting of its Customer Service Call Center performance standards by the fifteenth (15 <sup>th</sup> ) day of the following month.   | \$1,000.00 per month in which Customer Service Call Center performance standards are not met.                                  |  |  |
| Submit the emergency management plan to<br>the Agency within thirty (30) days after<br>Contract execution and by September 1st<br>of each Contract year.  | <b>\$1,000.00</b> for each day past the due date that the Agency has not received the emergency management plan.               |  |  |
| Submit the Monthly Prescribed Drug Program Report within fifteen (15) days following the end of the reporting month.  | <b>\$1,000.00</b> for each day past the due date that the Agency has not received the Monthly Prescribed Drug Program Report.  |  |  |
| Submit the Annual Program Report within forty-five (45) calendar days following the end of each Contract year.  | \$1,000.00 for each day past the due date that the Agency has not received the Annual Prescribed Drug Program Report.          |  |  |
| Submit annual financial reporting no later than ninety (90) days after the end of the calendar year, in a manner and format specified by the Agency.  | \$1,000.00 for each day past the due date that the Agency has not received the audited annual financial report.                |  |  |

| TABLE #1 PERFORMANCE STANDARDS AND LIQUIDATED DAMAGES  |  |  |  |
|--|--|--|--|
| Performance Standard Requirement   | Liquidated Damages to be Imposed   |  |  |
| Submit quarterly unaudited financial reports no later than thirty (30) calendar days following the end of the preceding quarter.   | <b>\$500.00</b> for each day past the due date that the Agency has not received the unaudited quarterly financial report.              |  |  |
| Submit ad hoc reports to the Agency within thirty (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. | <b>\$500.00</b> for each day past the due date that the Agency has not received the ad hoc report.                                     |  |  |
| Submit the Complaint Report within fifteen (15) days following the end of the reporting month.   | <b>\$500.00</b> for each day past the due date that the Agency has not received the complaint report.                                  |  |  |
| Submit a beta version of its performance dashboard to the Agency for approval seven (7) days prior to publication.   | <b>\$500.00</b> for each day past the due date that the Agency has not received the link to the completed draft performance dashboard. |  |  |

#### 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 Section 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 must 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 liquidated damages, sanctions and/or contract interpretations, the Vendor must request that the Agency's Deputy Secretary for Medicaid or designee, hear and decide the dispute.

b. The Vendor must 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 must be received by the Agency within twenty-one (21) calendar days after the issuance of 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 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

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)].

### A. 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.

### B. Financial Reporting

- 1. 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.
- 2. The Vendor shall submit all financial reports to the Agency in accordance with Section D., Reporting Requirements.
- 3. 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. 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.

### VIII. 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.

#### IX. Performance Bond

A. A performance bond in the amount specified in **Table #2**, Performance Bond Requirements, below, shall be furnished to the Agency by the Vendor for the specified Contract term.

| TABLE #2 PERFORMANCE BOND REQUIREMENTS |                                    |                                     |  |  |
|--|------------------------------------|-------------------------------------|--|--|
| Contract Term                          | "Estimated" Annual Contract Amount | Performance Bond<br>Amount<br>(10%) |  |  |
| TBD                                    | TBD                                | TBD                                 |  |  |
| TBD                                    | TBD                                | TBD                                 |  |  |
| TBD                                    | TBD                                | TBD                                 |  |  |

### 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 must not contain any provisions that shorten the time for bringing an action to a time less than that provided by the applicable Florida Statute of Limitations. (See Section 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(ies) 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.

### X. 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.** 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.
- C. 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 must 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.

### XI. 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 recipient 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.

### XII. Information Technology

- **A.** The Vendor shall have the necessary information technology (IT) resources needed to fully manage the product required in this Contract.
- B. Agency Contract Managers shall be responsible for submitting and managing Vendor staff requests or needs for access connectivity to the Agency's data communications network, and the relevant information systems attached to this network, in accordance with all applicable Agency policies, standards and guidelines. The Vendor shall notify the Agency of termination of any staff with access to the Agency's network within twenty-four (24) hours of the termination.
- C. Vendor staff that have access connectivity to the Agency's data communications network shall be required to complete Agency Security Awareness Training and Agency HIPAA Training. The Vendor shall also be required to sign an Acceptable Use Acknowledgement Form and submit the completed form to the Agency's Information Security Manager (ISM). The requirements described in this Item must be completed before access to the Agency's network is provided.

#### D. Development Requirements

This Sub-Section is applicable if the Vendor solution or service includes interoperability with the Agency's information technology enterprise.

- 1. The Vendor shall provide the Agency, providers, and others as identified in this Contract, with the necessary software to execute the requested system.
- 2. The Vendor's software when implemented, shall meet the implementation day's industry's best practices and standards NIST (National Institute for Standards and Technology), and W3C (World Wide Web Consortium) which includes development tools.
- 3. The Vendor shall develop a system that allows Agency staff to access the system from the Agency network and mobile devices.
- 4. The Vendor shall allow Agency access to the data for reporting purposes.

  Data exports shall comply with the National Information Exchange Model (NIEM) format.
- 5. The Vendor's architecture and design document will be reviewed by the Agency's Division of IT before coding starts. This will require a personal presentation by the Vendor's architect(s).
- **6.** Comments will be used in the code to help other developers to understand the coding methodology/logic that was used.
- **7.** Proper exception handling is required.
- **8.** Logging and Auditing may be required for some systems.
- **9.** Usage of Session and Cache should be limited.
- **10.** Hard coded values are not allowed for referencing the shared resource address and name. This includes: URL (Uniform Resource Locator) name, file path, email address, database connection string, etc.
- **11.** The website shall be Section 508 compliant and follow W3C industry standards and best practices.
- **12.** The website shall contain the Agency header and footer that are currently on ahca.myflorida.com.
- 13. Chrome, Firefox, Safari and Internet Explorer are the most commonly used browsers. Internet applications must be compatible with all internet browsers recognized by the World Wide Web Consortium, <a href="http://www.w3.org/">http://www.w3.org/</a>. The Vendor shall deploy the system to be browser agnostic while keeping up with the most current versions of Internet browser releases in coordination with the Agency's Division of IT standards. Compatibility is required by the Vendor with all supported versions within six (6) months of the browser's official release.
- 14. All code shall be submitted to the Agency by the Vendor for standards review prior to user testing. This code review requires a personal presentation by the Vendor's coder(s).

- **15.** The Vendor's test plan shall be prior-approved by the Agency's Division of IT. The system will be tested on and off site using different browsers and different devices.
- **16.** The documents listed below are required as part of the Vendor's application development:
  - a. Architecture design;
  - b. Security model;
  - c. Technical specifications;
  - d. Database entity relationship diagram;
  - e. Data Dictionary;
  - f. User documentation;
  - g. Test plan;
  - h. Deployment plan; and
  - i. Maintenance requirements.

### E. Below is the Agency's current environment:

- 1. HIPAA and CJIS (Criminal Justice Information System) compliance;
- **2.** Microsoft office;
- **3.** SQL (Structured Query Language) server;
- **4.** Microsoft Azure and Office 365;
- **5.** SFTP (Secure File Transfer Protocol);
- **6.** WEB Services:
- **7.** MVC (Model View Controller);
- **8.** C#;
- **9.** TFS (Team Foundation Server);
- **10.** WEB Applications;
- 11. Laserfiche;
- **12.** SharePoint;

- **13.** SSL (Secure Sockets Layer) and TLS (Transport Layer Security); Mobile devices; and
- **14.** SSRS (SQL Server Report Services) and Tableau.
- **F.** The Vendor must adhere and comply with the Agency's Division of IT standards regarding SSL Web interface(s) and TLS.
- **G.** The Vendor must adhere to the Driver Privacy Protection Act (DPPA) rules that address a memorandum of understanding and security requirements as well as other requirements contained in Rule.
- Н. The Vendor, its employees, subcontractors and agents shall provide immediate notice to the Agency Information Security Manager ("ISM") in the event it becomes aware of any security breach and any unauthorized transmission or loss of any or all of the data collected or created for or provided by the Agency ("State Data") or, to the extent the Vendor is allowed any access to the Agency's information technology ("IT") resources, provide immediate notice to the ISM, of any allegation or suspected violation of security procedures of the Agency. Except as required by law and after notice to the Agency, the Vendor shall not divulge to third parties any confidential information obtained by the Vendor or its agents, distributors, resellers, subcontractors, officers or employees in the course of performing this Contract work according to applicable rules, including, but not limited to, Rule 60GG, Florida Administrative Code (FAC) and its successor regulation, security procedures, business operations information, or commercial proprietary information in the possession of the State or the Agency. After the conclusion of this Contract unless otherwise provided herein, the Vendor shall not be required to keep confidential information that is publicly available through no fault of the Vendor, material that the Vendor developed independently without relying on the State's confidential information, or information that is otherwise obtainable under State law as a public record.
- I. In the event of loss of any State Data or record where such loss is due to the negligence of the Vendor or any of its subcontractors or agents, the Vendor shall be responsible for recreating such lost data in the manner and on the schedule set by the Agency at the Vendor's sole expense, in addition to any other damages the Agency may be entitled to by law or this Contract. In the event lost or damaged data is suspected, the Vendor will perform due diligence and report findings to the Agency and perform efforts to recover the data. If it is unrecoverable, the Vendor shall pay all the related costs associated with the remediation and correction of the problems engendered by any given specific loss. Further, failure to maintain security that results in certain data release will subject the Vendor to the administrative sanctions for failure to comply with Section 501.171, F.S., together with any costs to the Agency of such breach of security caused by the Vendor. If State Data will reside in the Vendor's system, the Agency may conduct, or request the Vendor conduct at the Vendor's expense, an annual network penetration test or security audit of the Vendor's system(s) on which State Data resides. All Vendor personnel who will have access to State-owned Data will undergo the background checks and screenings described in this Contract.

- J. The Vendor shall ensure that the Customer Service Call Center, Information Technology (IT) help desks or any other type of customer support provided directly under this Contract, shall be located only in the forty-eight (48) contiguous United States.
- K. The Vendor must 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 <a href="Cybersecurity-Framework">Cybersecurity-Framework</a> and <a href="NIST.SP.800-53r4">NIST.SP.800-53r4</a>.
- **L.** The Vendor must employ traffic and network monitoring software and tools on a continuous basis to identify obstacles to optimum performance.
- **M.** The Vendor must 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.
- **N.** The Vendor must 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.
- **O.** The Vendor must employ traffic and network monitoring software and tools on a continuous basis to prevent adware or spyware from deteriorating system performance.
- **P.** The Vendor must 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.
- **Q.** The Vendor must employ traffic and network monitoring software and tools on a continuous basis to monitor bandwidth usage and identify bottlenecks that impede performance.
- R. The Vendor must employ traffic and network monitoring software and tools on a continuous basis to provide methods to flag recipient data to exclude Protected Health Information (PHI) from data exchanges as approved by the State, and to comply with recipient rights under the HIPAA privacy law for: 1) Requests for restriction of the uses and disclosures on PHI (45 Code of Federal Regulations (CFR) § 164.522(a)); 2) Requests for confidential communications (45 CFR § 164.522(b)); and 3) Requests for amendment of PHI (45 CFR § 164.526). The Vendor must also enter into a Business Associate Agreement ("BAA") with the Agency. The provisions of the BAA apply to HIPAA requirements and in the event of a conflict between the BAA and the provisions of this **Sub-Section**, the BAA shall control. (See **Attachment III**, Business Associate Agreement).
- S. 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 Federal Information Processing Standards (FIPS), and/or

the National Institute of Standards and Technology (NIST) publications regarding cryptographic standards.

T. 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).

### XIII. 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**.

### XIV. Smartphone Applications

The Vendor shall receive written approval from the Agency Division of Information Technology before implementation of a smartphone application. If the Vendor uses smartphone applications (apps) to allow providers direct access to Agency-approved documents and/or content, the Vendor shall comply with the following:

- A. The smartphone application shall disclaim that the application being used is not private and that no PHI or Personally Identifiable Information (PII) should be published on this application by the Vendor or provider; and
- **B.** The Vendor shall ensure that software applications obtained, purchased, leased, or developed are based on secure coding guidelines; for example:
  - **1.** OWASP [Open Web Application Security Project] Secure Coding Principles <a href="http://www.owasp.org/index.php/Secure Coding Principles">http://www.owasp.org/index.php/Secure Coding Principles</a>;
  - 2. CERT Security Coding <a href="http://www.cert.org/secure-coding/">http://www.cert.org/secure-coding/</a>; and
  - Top10SecuritycodingPractices <a href="https://www.securecoding.cert.org/confluence/display/seccode/Top+10+S">https://www.securecoding.cert.org/confluence/display/seccode/Top+10+S</a> ecure+Coding+Practices

### XV. Social Networking

All social networking applications, tools or media interactions and communications must be approved in writing by the Agency, prior to use. Any vendor using social networking applications is responsible and accountable for the safeguarding of PHI and all HIPAA Privacy Rule related information must be maintained and monitored.

In addition to all other review and monitoring aspects of this Contract, the Agency, at its discretion, reserves the right to monitor or review the Vendor's monitoring of all social networking activity without notice.

The Vendor shall not conduct business relating to this Contract that involves the exchange of personally identifying, confidential or sensitive information on the Vendor's social network application. The Vendor shall not post information, photos, links/URLs or other items online that would reflect negatively on any individual(s), its enrollees, the Agency or the State.

Any violations of this provision shall subject the Vendor to administrative action by the Agency as determined by the Agency.

### XVI. Definitions and Acronyms

#### A. Definitions

**Active Ingredient** – As defined in 21 CFR § 210.3.

**<u>Ad Hoc</u>** – 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.

<u>Agency Information Technology (IT) Enterprise</u> – 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.

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

<u>Calendar Day</u> – 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.

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

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

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

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

<u>Contract Year</u> – 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.

**Day** – See calendar day.

**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.

Representative Sample - As defined in 21 CFR § 210.3.

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

#### B. Acronyms

**Apps** Applications

**BAA** Business Associate Agreement

**CAP** Corrective Action Plan

**CFR** Code of Federal Regulations

**CJIS** Criminal Justice Information System

**DPPA** Driver Privacy Protection Act

**DSCSA** Drug Supply Chain Security Act

**EEO** Equal Employment Opportunity

**FAC** Florida Administrative Code

**FDA** U.S. Food Drug and 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

IT Information Technology

**MVC** Model View Controller

NDC National Drug Code

**NIEM** National Information Exchange Model

NIST National Institute for Standards and Technology

**PHI** Protected Health Information

**PII** Personally Identifiable Information

PL Public Law

**SFTP** Secure File Transfer Protocol

**SOC** Service Organization Controls

**SQL** Structured Query Language

**SSL** Secure Sockets Layer

**SSRS** SQL Server Report Services

**TFS** Team Foundation Server

**TLS** Transport Layer Security

**URL** Uniform Resource Locator

**US** United States

**U.S.C.** United States Code

W3C World Wide Web Consortium

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# ATTACHMENT B. EXHIBIT B-1 ASSOCIATED BAYMENT AND FINANCIAL CONSEQUEN

### DELIVERABLES, ASSOCIATED PAYMENT AND FINANCIAL CONSEQUENCES

#### DELIVERABLE

Implementation of the Prescribed Drug Program

#### **SUPPORTING DOCUMENTATION**

The Initial and Final Implementation Plan shall outline, in detail, all steps necessary for the Vendor to comply with implementation, operation, and reporting of activities under this Contract and as outlined in **Attachment B**, Scope of Services, and in compliance with the Food and Drug Administration's Final Rule on the Importation of Prescription Drugs (currently proposed rule at FDA-2019-N-5711).

#### **EVALUATION CRITERIA**

The Agency will review the implementation plan in contrast with the Scope of Services requirements to confirm compliance with criteria established in **Attachment B**, Scope of Services.

**DUE DATE(S)** 

**TBD** 

<u>1.</u>

**AMOUNT** 

TBD:

#### PERFORMANCE STANDARDS

The Vendor shall submit the deliverable in accordance with the description provided in **Attachment B**, Scope of Services.

### **LIQUIDATED DAMAGES**

\$1,000.00 per day for each business day past the due date that the Program is not operational.

#### DELIVERABLE

Operation of the Prescribed Drug Program

#### SUPPORTING DOCUMENTATION

The Vendor will operate the Canadian Prescription Drug Importation Program and conduct monthly monitoring of the Program in accordance with all requirements listed in Attachment B, Scope of Services.

### **EVALUATION CRITERIA**

The Agency will review implementation plan in contrast with the Scope of Services requirements to confirm compliance with criteria established in **Attachment B**, Scope of Services, Section II., Manner of Service(s) Provision, Sub-Section D. Reporting, Item 2. Monthly Reporting.

<u>2.</u>

### **DUE DATE(S)**

The Vendor shall submit the Monthly Prescribed Drug Program Report no later than fifteen (15) days following the end of the reporting month.

#### **AMOUNT**

TBD; will be paid out in a monthly administrative payment.

### PERFORMANCE STANDARDS

The vendor shall submit the deliverable in compliance with **Attachment B.**, Scope of Services, Section II. Manner of Service(s) Provision, Sub-Section D. Reporting, Item 2. Monthly Reporting.

#### **LIQUIDATED DAMAGES**

**One Percent (1%)** of the monthly payment will be reduced for each infraction of non-compliance with the requirements of this Contract.