STATE OF FLORIDA
AGENCY FOR HEALTH CARE ADMINISTRATION
REQUEST FOR INFORMATION

CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

TABLE OF CONTENTS

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I. GENERAL INFORMATION

A. Purpose

This is a Request for Information (RFI) as defined in Section 287.012(22), Florida Statutes (F.S.), for planning purposes. This RFI is issued by the State of Florida (State), Agency for Health Care Administration (Agency), to solicit information regarding available providers for the services described herein.

An RFI is not a method of procurement. Responses to an RFI are not offers and shall not be accepted by the Agency to form a binding Contract. This RFI and Responses to it shall not result in the execution of a contract with the Agency. By submitting a Response to this RFI, a Vendor is not prohibited from responding to any related subsequent solicitation. This RFI may be used for purposes of determining whether or not to competitively procure a commodity or contractual service, determining what solicitation process to use, or researching general, special, and/or technical specifications for a solicitation. The Agency reserves the right to utilize the information gathered through the RFI process to develop a scope of services, which may be incorporated into a contract using a statutorily approved method of procurement.

B. Background

In 2019, the Florida Legislature passed House Bill 19 (HB 19) directing the Agency for Health Care Administration to establish a Canadian Prescription Drug Importation Program ("Program") and to contract with a vendor to provide services under the Program.

The Agency will initiate a competitive solicitation in Fall 2019 to procure a contract with a vendor to manage the importation of safe and effective prescription drugs from Canada. The minimum responsibilities of the vendor are as follows:

- On an annual basis, develop 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.
- 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.
- Contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and Canadian suppliers, to import drugs under the program.
- Maintain a list of all importers that participate in the program.

- Ensure all participants in the program comply with Title II of the Federal Drug Quality and Security Act, Pub. L. No. 113-54.

- Ensure that eligible importers have documentation that sample testing of the prescription drugs occurred at a qualified laboratory, as required by 21 U.S.C. 384.

- Ensure that there is 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.

- Maintain additional information and documentation from importers and Canadian suppliers as specified in HB 19.

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

The Agency is issuing this Request for Information (RFI) to ascertain an estimation of the total vendor costs for providing services under the Program. The Agency is interested in information relating to:

- Experience that the respondent may have that relates to the duties and responsibilities that the vendor will have under the resulting contract.

- Administrative and operational costs associated with implementing the Canadian Prescription Drug Importation Program.

- Ongoing administrative and operational costs associated with sustaining the Canadian Prescription Drug Importation Program.

- An estimated timeline for implementation of all state and federal requirements.

- Innovative ideas and strategies that the respondent may have in implementing the requirements of HB 19 that ensure the safe and cost-effective importation of prescription drugs under the Program.

The Agency will consider information gathered from responses to this RFI in preparing the competitive solicitation.

II. RFI RESPONSE INSTRUCTIONS

Respondents to this RFI are asked to be thorough, but concise. The RFI Response should include the following:

A. The respondent's name; place of business address(s); and contact information, including representative name and alternate, with telephone number(s) and e-mail address(s);

B. A statement of interest in the services outlined in this RFI, including an outline of a specific product, concept, technology, or approach that would meet the goals and requirements described in this RFI;

C. A description of the respondent's business and its experience as it relates to the services outlined in this RFI. This description should include a narrative explaining past experiences related to pharmaceutical importation or exportation. The respondent shall indicate any international or wholesale distribution experience it has for services similar in nature to those described in this RFI.

D. An estimate of administrative and operational costs associated with implementing the Program.

E. An estimate of ongoing administrative and operational costs associated with sustaining the Program.

F. An estimated timeline for Program implementation.

G. A description of innovative ideas and strategies in providing the services described in this RFI. As a part of the response, include any potential implementation challenges that the respondent believes the Agency should consider during the Program design phase and potential solutions.

III. PUBLIC RECORDS EXEMPTIONS, TRADE SECRET OR PROPRIETARY INFORMATION

Any portion of the submitted Response which is asserted to be exempt from disclosure under Chapter 119, Florida Statutes, shall be clearly marked "exempt", "confidential", or "trade secret" (as applicable) and shall also contain the statutory basis for such claim on every page. Pages containing trade secret shall be marked "trade secret as defined in Section 812.081, Florida Statutes". Failure to segregate and identify such portions shall constitute a waiver of any claimed exemption and the Agency will provide such records in response to public records requests without notifying the respondent. Designating material simply as "proprietary" will not necessarily protect it from disclosure under Chapter 119, F.S. An entire Response should not be considered trade secret. 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 for Health Care Administration, its employees and its representatives, for the release or disclosure of trade secret information not so identified.

IV. RESPONSE SUBMISSION

Respondents to this RFI shall submit one (1) electronic copy of its Response. The Response shall not exceed twenty (20), single sided, pages in length. The electronic

format shall be submitted via e-mail. The software used to produce the electronic files must be Microsoft Word 2013 and/or Excel 2013 or newer. The electronic files must be logically named.

The respondent shall **also** submit via e-mail one (1) electronic redacted copy of the Response suitable for release to the public. Any confidential or trade secret information covered under Section 812.081, Florida Statutes, should be either redacted or completely removed. The redacted Response shall be marked as the "redacted" copy and contain a transmittal letter authorizing release of the redacted version of the Response in the event the Agency receives a public records request.

Responses to this RFI shall be provided no later than **2:00 PM, Eastern Standard Time (EST), JUNE 25, 2019**. Responses shall be e-mailed to **solicitation.questions@ahca.myflorida.com.**

Responses shall be addressed to:

Crystal Demott
Procurement Director
Solicitation.questions@ahca.myflorida.com

After the Agency has received all Responses to this RFI, the Agency, in its sole discretion, shall determine if a meeting with respondents is necessary to clarify the information received. In the event that the Agency decides to hold a meeting, the respondent (s) will be notified via email.

V. COSTS

Respondents are responsible for all costs associated with preparing a Response to this RFI. The State of Florida, Agency for Health Care Administration, will not be responsible for any respondent costs associated with preparing a Response to this RFI.

VI. QUESTIONS

Questions concerning this RFI shall be submitted in writing via email to **solicitation.questions@ahca.myflorida.com** no later than **2:00 PM, EST, JUNE 4, 2019.**

All Responses to questions received will be made, in writing, directly to the sender.

VII. AGENCY FOR HEALTH CARE ADMINISTRATION WEBSITE

Additional information about the Florida Agency for Health Care Administration can be found on the Agency's website at: http://ahca.myflorida.com/

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