



**CO L O R A D O**

**Department of Health Care  
Policy & Financing**

HCPF Invitation to Negotiate

Solicitation #:

RFP UHAA 2021000117

Colorado's Drug Importation Program

This ITN is current as of 1/25/2021. To ensure you are viewing the most current version of the ITN, please click [here](#), click public access, and search for RFP number “2021000117” for Colorado’s Drug Importation Program. If there are questions about the bidding process or this ITN, please contact Kate Rusk at [kate.rusk@state.co.us](mailto:kate.rusk@state.co.us).

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## **SECTION 1.0 INTRODUCTION AND BACKGROUND**

### **1.1. GENERAL INFORMATION**

- 1.1.1. Under 25.5-2.5-203(1), this solicitation is exempt from the Colorado Procurement Code and its implementing regulations. In order to maximize competition and obtain the most advantageous result for the State of Colorado, and its Medicaid Members and the rest of its citizens, though, the Colorado Department of Health Care Policy and Financing (Department) intends to use a competitive process that mirrors many of the processes and procedures found in those statutes and regulations. Please read through this solicitation document and its appendices carefully and note any differences from the standard solicitation processes and requirements of the Colorado Procurement Code.
- 1.1.2. The Department is soliciting competitive, responsive proposals from experienced and financially sound organizations to perform as the Colorado Drug Importation Program Contractor(s) for the Department.
  - 1.1.2.1. This ITN takes into account the recent Canadian Interim Order that aims to prevent or exacerbate drug shortages in Canada. This order in no way halts the U.S. importation program from moving forward. That said, Colorado has always intended to take any Canadian drug shortages into account when identifying drugs for importation and have expressed this sentiment to the Canadian government through their Colorado-based consulate. We will ensure that all supply chain partners abide by this Order, including through requiring timely analysis of existing or potential shortages, and reporting of any relevant information requested by the Canadian government.
- 1.1.3. General solicitation information, timelines and proposal submission requirements are available in Appendix A, Administrative Information.
- 1.1.4. While this solicitation is not subject to the Procurement Code, the Department intends to use a process similar to the Invitation to Negotiate (ITN) and will use that terminology to refer to this solicitation. To gain a better understanding of the normal ITN process that this solicitation is based off of, Offerors interested in responding to this ITN should review the presentation on this process provided by the State Purchasing and Contracts Office and available at <https://www.colorado.gov/pacific/osc/procurement-training-0>, and click “Resources” under “Vendor Training”.

### **1.2. TERMINOLOGY**

- 1.2.1. Acronyms and abbreviations are defined at their first occurrence in this ITN. Appendix D, Terminology is provided to assist the reader in understanding acronyms, abbreviations, and terminology used throughout this solicitation.

### **1.3. BACKGROUND INFORMATION**

- 1.3.1. The Department of Health Care Policy and Financing Background
  - 1.3.1.1. The Department serves as the Medicaid Single State Agency as defined by Code of Federal Regulations (C.F.R.) Title 45 Section 205.100 (45 C.F.R. §205.100). The Department develops and implements policy and financing for Medicaid and the Children's Health Insurance Program, called Child Health Plan Plus (CHP+) in Colorado, as well as a variety of other publicly funded health care programs for

Coloradans who qualify. For more information about the Department, visit [www.Colorado.gov/HCPF](http://www.Colorado.gov/HCPF).

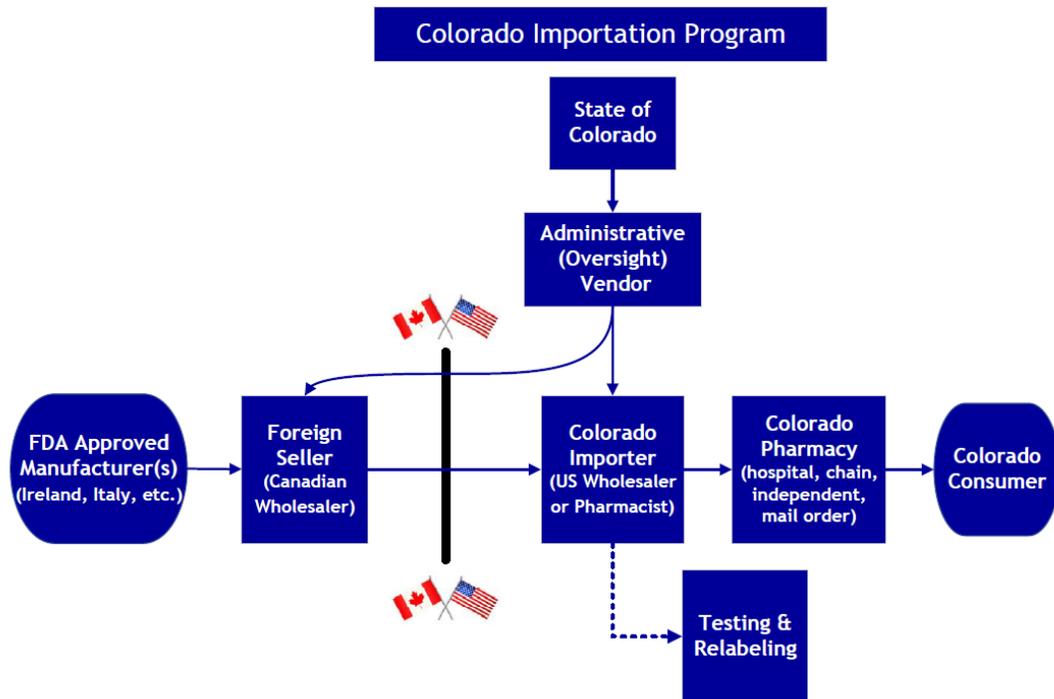
- 1.3.1.2. The Department is a Covered Entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. §1320d – 1320d-8) and its implementing regulations.
- 1.3.1.3. The Department operates the Colorado Medicaid Program, known as Health First Colorado, in accordance with the Colorado Medical Assistance Act (Section 25.5-4-104, *et seq.*, C.R.S.) and Title XIX of the Social Security Act. Colorado Medicaid is annually funded from appropriations authorized by the Colorado General Assembly and matched by federal funds.
- 1.3.1.4. In May 2019, Governor Polis of Colorado signed Senate Bill 19-005 into law. This law tasks the Department to implement a program to import prescription drugs from Canada to bring cost savings to Colorado consumers, employers and other payers. The federal government, through the Department of Health and Human Services, has issued a final rule (referred to herein as “the final rule”) which provides a regulatory framework for states to apply to FDA for approval to operate wholesale prescription drug importation programs.

#### 1.4. **PROBLEM STATEMENT**

- 1.4.1. Senate Bill 19-005 established the “Canadian Prescription Drug Importation Program” (Program) for the State of Colorado (State) that will allow for the importation of eligible prescription drugs from Canada into the state of Colorado as permitted by federal and state statutes and regulations (the “State Statute”).
- 1.4.2. Colorado consumers, like all Americans, face significant challenges as a result of continually rising pharmaceutical costs, which total more than \$6 billion per year in Colorado alone. One in five Coloradans struggle to afford their prescription drugs, while nearly one in three Coloradans do not take their prescription drugs as directed because they simply cannot afford to. Lowering the cost of prescription drugs through importation will directly and meaningfully improve access to prescription drug therapy for Coloradans, thereby improving the health and well-being of our population. The state of Colorado and the Department are dedicated to the implementation of the Program as one strong lever in addressing this urgent need in our state.
- 1.4.3. The Program will likely consist of two or more vendors to manage the oversight of the program and the distribution of imported drugs from Canada to the state of Colorado. Based on its current planning, the Department foresees that it will act as the Sponsor and oversight entity of the Program. The Program will likely include an Administrative Vendor that will work closely with the Department and other vendor(s) to manage programmatic, compliance and communications aspects of the Program. A Foreign Seller, which is likely a Canadian wholesaler licensed by Canada and registered with and approved by the United States for participation in the program, will purchase the drug for the Colorado market. On the U.S. side, an Importer will likely contract with the Foreign Seller to facilitate the importation of the drug into the United States. An Importer will likely manage the drug distribution system in the U.S., including ensuring that imported products are tested to meet authenticity, degradation, and other applicable established specifications and standards through the use of a qualified laboratory, ensuring all imported products are appropriately labeled and packaged for the Colorado

market, and contracting with Colorado pharmacies to ensure Colorado consumer access to imported products. The selected Importer, through the appropriate markup applied to each drug, will be responsible for payment to the State of an administrative fee to the Department to cover the costs of program oversight and associated staff. The organization(s) filling both the Importer and Foreign Seller roles must comply with the State Statute and any corresponding regulation establishing a maximum profit margin for imported drugs. The State Statute dictates the profit margin be no greater than the profit margin would have been absent the Program. All vendors will work together to achieve the various requirements of the Program and the Department will play the primary oversight role.

1.4.4. Image 1: Colorado’s Anticipated Drug Importation Program Structure



1.4.5. Program Implementation Framework

1.4.5.1. This ITN establishes the framework for vendor participation in implementing and operationalizing the Program. The Department is seeking two or more interested vendors to fulfill the duties as outlined in this ITN. The Department is seeking vendors to fulfill the following roles:

1.4.5.1.1. Role #1 - An Administrative Vendor responsible for administrative and programmatic functions including compliance monitoring, communications and outreach, and data collection and management, and reporting.

1.4.5.1.2. Role #2 - A Foreign Seller that is an entity with a presence in Canada that is registered with Health Canada and holds a valid drug wholesaler establishment license from Health Canada, will register with the Food and Drug Administration (FDA), will purchase drugs from FDA registered manufacturers, applies a section

804 serial identifier (SSI) and is responsible for all applicable recordkeeping. The Foreign Seller must comply with all applicable requirements under the final rule.

- 1.4.5.1.3. Role #3 - An Importer that purchases drugs from a Foreign Seller and coordinates most major distribution aspects of the program, which include testing, relabeling, and distributing imported drugs to Colorado pharmacies. The Importer may contract out the testing and relabeling functions. Additionally, the Importer is responsible for all applicable recordkeeping. The Importer must comply with all applicable requirements under the final rule.
- 1.4.5.2. These three roles will work closely together and with the Department in the implementation of the Program. The Department is open to the same vendor performing two or more functions within the Program. For example, a Foreign Seller and an Importer could belong to the same parent company. Or, an Importer could bid to also administer elements of the Program in the role of the Administrative Vendor. In each of these cases, the Department expects the Offeror to include in their proposal details about how they would address potential conflicts of interest. Additionally, the Department wishes to understand if the vendor foresees a need for the Department to absorb any responsibilities due to this relationship. The Department asks that vendors only submit responses for the portions of the ITN for which they intend to bid.
- 1.4.5.3. The Department expects Offerors to include in their responses cost estimates for the work to be performed. While the Department anticipates funding portions of work throughout the duration of the project, particularly for the Administrative Vendor, we also believe that the development of a supply chain and the distribution of prescription drugs within that framework will pay for itself through additional profit once the program is successfully importing drugs. To that end, as part of a responsive proposal, the Department requests that Foreign Seller and Importer vendors include an estimate of a reasonable markup on imported products to cover their costs for Phase 2. The Department will also entertain suggestions of startup funding for Phase 1, should the responsive vendor determine its need.
- 1.4.5.4. This work is divided into two phases based on application requirements to the federal government, for which funding will be provided as work moves forward. Generally, the Department will not fund Phase 2 until Phase 1 is complete and the Department has received approval from the federal government to begin importation. The two phases are as outlined:
- 1.4.5.5. Table 1: Phase 1 - Program Development in Anticipation of Application Submission (projected 8-12 month period beginning July 2021 and ending February-July 2022):

<b>Overview of Activities</b>	<b>Vendors Involved</b>
The development of a prescription drug importation list (drug list)	Administrative Vendor, Foreign Seller and Importer
The development of a communications and outreach plan	Administrative Vendor

The development of a compliance plan and associated reporting processes	Administrative Vendor, Foreign Seller and Importer
Support the State in the application process to the FDA	Administrative Vendor, Foreign Seller and Importer
Contract development and execution	Foreign Seller and Importer
Establishing a process to transfer a state administrative fee	Importer

1.4.5.5.1. Phase 1 culminates in the submission of an application to the FDA for the Department to begin operating an importation program. The items listed above are in direct support of the development of this application.

1.4.5.6. Table 2: Phase 2 - Post Application Approval/Importation Begins (start date TBD based on approval, earliest anticipated July 2022 for a period of two years):

<b>Overview of Activities</b>	<b>Vendors Involved</b>
Purchasing of identified prescription drugs from contracted Canadian suppliers	Foreign Seller and Importer
Batch testing of imported prescription drugs to ensure safety and quality,	Importer
Repackaging, relabeling and storage of imported prescription drugs,	Importer
Wholesale distribution to participating pharmacies and other dispensers in the state of Colorado,	Importer
Post importation requirements that include compliance and programmatic monitoring, analysis,	Administrative Vendor, Foreign Seller, and Importer
The execution of a communications and outreach plan,	Administrative Vendor
The execution of a compliance plan,	Administrative Vendor
Record-keeping and reporting to the State and FDA as required.	Administrative Vendor, Foreign Seller, and Importer

## 1.5. ANTICIPATED CONTRACT TERM - ALL VENDORS

- 1.5.1. The Contract's initial term is anticipated to begin in July 2021 and end in June 2022.
- 1.5.1.1. The total Duration of the Contract from the Operational Start Date until termination, and including the Department's exercise of any options, is not anticipated to exceed five years, though may be significantly longer than that based on negotiations and with the approval of the Office of the State Controller.
- 1.5.2. We anticipate a fully operational importation program that is importing and distributing prescription drugs by mid to late 2022. After the Department awards contracts with an intended start date in July 2021, we expect 8-12 months of work associated with Phase 1. This includes time for federal review of the Department's application. At this time, the federal timeline for review and approval of applications is unknown. Once federal approval is received, the Department will initiate Phase 2. In the federal framework set forth in the Final Rule, approved importation programs are approved for a period of two years initially. Once the program successfully demonstrates safe importation and significant cost savings to consumers, the Department can apply to the FDA to extend the term of the program by an additional two years.
- 1.5.3. The Department may extend the Contract beyond the anticipated term in this section in the event that the Department determines the extension is necessary to align the Contract with other Department contracts, to address State or Federal programmatic or policy changes related to the Contract, or to provide sufficient time to transition the Work, without changes in pricing or obligation.
- 1.5.4. The final rule requires that the supply chain for each drug being imported under the program have only one importer, one foreign seller, and one drug manufacturer. The final rule also provides that the program can initially only have one importer and one foreign seller. At this time, the Department reserves the right to add one or more additional importers or foreign sellers to the program in the future after Phase 2 begins. However, the Department is willing to negotiate with the Offerors for an exclusive contract for the contract term if the Offeror can show why it is in the best interests of the Department to do so.

## 1.6. **SUBRECIPIENT STATUS**

- 1.6.1. The Contractor may be a subrecipient subject to the requirements of the Office of Management and Budget Uniform Guidance, 2 CFR Part 200.

## **SECTION 2.0 STATEMENT OF WORK**

### **2.1. SOLUTION REQUIREMENTS**

#### 2.1.1. Overview for all Vendors

- 2.1.1.1. Solution requirements are essential services to be provided by all vendors in order to fulfill the standards and requirements for Colorado's Program. The requirements listed below, and in greater detail, in the Final Rule and federal and state statute are non-negotiable items. The Department values unique and innovative approaches to meeting the needs of the Program and this ITN provides flexibility in how Offerors approach solution requirements, however any selected Offeror must review, understand, and comply with all applicable state, federal and Canadian rules and regulations. Relevant laws and regulations include:

2.1.1.2. Table 3: Relevant law and regulations:

<b>Source</b>	<b>Location</b>
Federal Rule: Importation of Prescription Drugs, Food and Drug Administration	<a href="https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs">https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs</a>
Federal Statute: 21 U.S.C. § 384	<a href="https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim)">https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim)</a>
Federal Food, Drug, and Cosmetic Act: 21 U.S.C. Chapter 9	<a href="https://www.law.cornell.edu/uscode/text/21/chapter-9">https://www.law.cornell.edu/uscode/text/21/chapter-9</a>
Title 21 of the CFR	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm</a>
Federal Statute: Title II of the Drug Quality and Security Act (DQSA) (i.e., the Drug Supply Chain Security Act or “DSCSA”)	<a href="https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act">https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act</a>
Colorado State Statute: Senate Bill 19-005,	<a href="https://leg.colorado.gov/bills/sb19-005">https://leg.colorado.gov/bills/sb19-005</a>

Concerning Wholesale Importation of Prescription Pharmaceutical Products from Canada for Resale to Colorado Residents	
Health Canada Interim Order: Respecting drug Shortages (Safeguarding the Drug Supply)	<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/interim-order-drug-shortages-protecting-supply.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/interim-order-drug-shortages-protecting-supply.html</a>

- 2.1.1.3. All applicants are expected to review the Final Rule, relevant state and federal statutes and regulations (including applicable provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations) and Canadian Interim Orders, and must provide specific details within their proposal on their approach to ensuring Colorado maintains compliance with all requirements.
- 2.1.1.4. All vendors must include in their response how they will address the following items:
  - 2.1.1.4.1. Specific details for how they would operationalize each phase of the Program in line with all requirements as laid out in applicable state and federal statute and rule.
  - 2.1.1.4.2. A description of how the vendor will interact with the other vendor(s) identified throughout this process in support of rule compliance. This includes any portions of the work that the vendor wishes to subcontract out.
  - 2.1.1.4.3. A description of how the vendor will preserve and maintain savings from imported drugs, including, where applicable, estimates on operational costs and supply chain markups.
  - 2.1.1.4.4. An explanation of how the vendor would support data sharing for the Department’s development of a cost savings estimate, and to facilitate the exchange of information to maintain compliance with all federal and state statute and regulations.

- 2.1.1.4.5. An explanation of how the vendor will provide information required to the State in support of the submission of an application to the federal government. The vendor must describe how it will provide all information required by the Final Rule.
- 2.1.1.4.6. An explanation of how the vendor will support the development of an Annual Report for the Colorado General Assembly as detailed in State Statute.
- 2.1.1.4.7. An explanation of how the vendor will meet all reporting requirements as detailed in federal and state statute and regulation, including the submission of annual financial audits and quarterly financial reports specific to the Program, as described in the State Statute.
- 2.1.1.4.8. Evidence of a surety bond, or comparable security agreement, in an amount of at least \$25,000 that includes the State of Colorado as a beneficiary, as detailed in the State Statute.
- 2.1.1.4.9. An explanation of how the vendor intends to maintain information and documentation submitted as part of any federal or state reporting for a period of at least seven years, as detailed in the State Statute.1
- 2.1.1.4.10. An attestation of the vendors agreement to comply with all applicable federal and state statutes and regulations applicable to the Program.
- 2.1.1.5. Other attestations and disclosures
  - 2.1.1.5.1. The Offeror shall provide the following:
    - 2.1.1.5.1.1. An attestation and information statement containing a complete disclosure of any past criminal convictions or violations of the State, Federal, or Canadian laws regarding drugs or devices against or by the applicant, or an affirmative attestation that the applicant has not been involved in, or convicted of, any such violations. Such attestation and information statement must include principals, any shareholder who owns 10 percent or more of outstanding stock in any non-publicly held corporation, directors, officers, and any facility manager or designated representative of such manager.
    - 2.1.1.5.1.2. A list of (if any) all disciplinary actions, to include the date of and parties to any action imposed against the applicant by State, Federal, or Canadian regulatory bodies, including any such actions against the principals, owners, directors, officers, quality unit, or any facility manager or designated representative of such manager for the previous 7 years.
    - 2.1.1.5.1.3. An attestation that neither the vendor, nor its officers, nor its officer's close family members, have any undisclosed interest in or with any entity or property that a reasonable person would determine could affect the vendor's ability to impartially carry out its responsibilities under the Program. For illustration only, an example of such an undisclosed interest would be an investment interest or ownership interest in a drug manufacturer, or current employment in any capacity by a drug manufacturer. Another illustrative example would an employee or close family member of an employee of the State of Colorado. If such an attestation is not possible, the response must disclose and describe the potential conflict of interest in detail.

**OFFEROR'S RESPONSE 1. PLEASE DESCRIBE HOW THE OFFEROR WOULD FULFILL THE REQUIREMENTS OUTLINED IN SECTION 2.1.1., OVERVIEW FOR ALL VENDORS.**

**2.1.2. Role #1 - Administrative Vendor**

2.1.2.1. Description:

2.1.2.1.1. The Department seeks an administrative vendor that will work closely with the State to implement large-scale compliance and programmatic portions of the Program. While the Department will be the main Sponsor of the Program, the Administrative Vendor will assist in all aspects of compliance monitoring, reporting, communications and other program support. The Offeror is expected to provide solutions to the Department for how communication between the Department, the administrative vendor, and all other vendors will be standardized in accordance with necessary reporting deadlines as outlined in the Final Rule and Colorado State Statute. The administrative vendor will be responsible for programmatic and compliance monitoring and reporting, data collection and analysis, outreach and communication, and other oversight activities as delegated by the State.

2.1.2.2. Funding:

2.1.2.2.1. Funding will be awarded to an administrative vendor for work in all phases of the project. The offeror’s submission shall include an estimate for the cost of work being provided by the offeror.

2.1.2.3. Table 4 outlines the Objectives and Requirements of the Administrative Vendor:

Phase 1 Objectives	Phase 1 Requirements
<p>The development of a prescription drug importation list in collaboration with the Department</p>	<ul style="list-style-type: none"> <li>• Follow all requirements for drugs eligible for importation, as prescribed by the Final Rule.</li> <li>• Collaborate with the Department to identify prescription drugs most advantageous to import.</li> <li>• Collaborate with Foreign Seller and Importer to analyze and select eligible drugs for final application to FDA.</li> <li>• Employ a scorecard methodology, developed in conjunction with the Department, to evaluate suggested drugs for importation to identify those that are not only advantageous</li> </ul>

	<p>(but also do not disrupt the Canadian drug supply).</p> <ul style="list-style-type: none"> <li>• Submit proposed drug list to the Department for review and approval.</li> <li>• Review drug list for effectiveness of meeting the requirements of the Program, every three months as required by the State Statute.</li> </ul>
<p>The development of a communications and outreach plan</p>	<ul style="list-style-type: none"> <li>• Develop a communications plan with the Department taking into account all reporting requirements in the Final Rule, and applicable state and federal statutes and regulations.</li> <li>• Develop a communications strategy to educate stakeholders about the importation program. This includes, but is not limited to: <ul style="list-style-type: none"> <li>○ Education and outreach for the general public to inform them about where imported drugs are offered and the prices of those drugs.</li> <li>○ Education and outreach for health plans, pharmacy benefit managers (PBMs), employers and providers about the availability of imported drugs and how to offer them.</li> </ul> </li> <li>• Manage a Department website that will be accessible to all stakeholders with details about the program.</li> </ul>
<p>The development of compliance plans</p>	<ul style="list-style-type: none"> <li>• Develop a plan to monitor and audit the supply chain for compliance as detailed in the Final Rule, the Federal Statute, and State Statute. The plan should include: <ul style="list-style-type: none"> <li>○ How the administrative vendor will structure their oversight, and</li> <li>○ How the vendor will ensure accountability on the part of the Foreign Seller and Importer.</li> <li>○ How the vendor will communicate timely all compliance issues to the Department.</li> </ul> </li> <li>• Maintain accurate records including relevant information as required in the Final Rule.</li> </ul>

Support the Department in the application process for a final application to the FDA	<ul style="list-style-type: none"> <li>• Provide documentation as needed to inform application drafting.</li> <li>• Review and provide feedback for portions of the application.</li> </ul>
<b>Phase 2 Objectives</b>	<b>Phase 2 Requirements</b>
Implement compliance plans	<ul style="list-style-type: none"> <li>• Implement compliance oversight plan from Phase 1 for all applicable vendors and areas of the program as detailed in the Final Rule and the State Statute.</li> <li>• Ensure the Foreign Seller and Importer meet applicable federal supply chain security requirements.</li> </ul>
Implement communications and reporting plan	<ul style="list-style-type: none"> <li>• Maintain accurate and complete records of all information as detailed in the Final Rule, the FDCA, and the State Statute.</li> <li>• Engage with the Department as necessary to ensure proper communication and submission of timely reports.</li> <li>• Timely communicate all compliance issues to the Department.</li> </ul>
Implement an education and outreach plan in collaboration with the Department	<ul style="list-style-type: none"> <li>• Support development and maintenance of a Program website.</li> <li>• Develop outreach materials for a variety of audiences including, but not limited to, the general public, health plans, pharmacies, and PBMs.</li> <li>• Participate in stakeholder engagement sessions.</li> </ul>

2.1.2.4. Vendor Accountability:

2.1.2.4.1. The Department values relationships with vendors that meet standards of good management and accountability. The Department envisions commitments around correspondence and communication, management expectations, transparency and record keeping.

**OFFEROR'S RESPONSE 2. PLEASE DESCRIBE HOW THE OFFEROR WOULD FULFILL THE REQUIREMENTS OUTLINED IN SECTION 2.1.2. FOR THE ADMINISTRATIVE VENDOR. IF THE OFFEROR IS NOT PROPOSING TO FILL THE ADMINISTRATIVE VENDOR ROLE, PLEASE RESPOND TO THIS OFFEROR'S RESPONSE WITH 'NOT PROPOSING FOR THIS ROLE'.**

**OFFEROR'S RESPONSE 3. PLEASE PROVIDE A DESCRIPTION OF PERFORMANCE STANDARDS OR SERVICE LEVELS THAT THE OFFEROR COMMITS TO MEETING, INCLUDING METRICS FOR EACH AREA. THE SUBMISSION SHOULD INCLUDE HOW THE OFFEROR WOULD TIE THESE STANDARDS TO FINANCIAL INCENTIVES TO ENSURE THESE METRICS ARE MET. IF THE OFFEROR IS NOT PROPOSING TO FILL THE ADMINISTRATIVE VENDOR ROLE, PLEASE RESPOND TO THIS OFFEROR'S RESPONSE WITH 'NOT PROPOSING FOR THIS ROLE'.**

**2.1.3. Role #2 – Foreign Seller**

2.1.3.1. Description:

2.1.3.1.1. The Department seeks a Foreign Seller that will be responsible for securing prescription drugs in Canada for importation into Colorado. The Foreign Seller should be licensed by Health Canada as a drug wholesaler (at must be such by the time of the SIP application to the federal government) in Canada who has business relationships with a variety of manufacturers of FDA-approved prescription drugs to ensure the State has access to as many drugs on the approved drug list as possible. The Offeror is expected to closely coordinate with the Department on all aspects of the program and will be expected to contract directly with the approved Importer for the distribution of imported prescription drugs.

2.1.3.2. Funding:

2.1.3.2.1. Funding may be awarded for work in Phase 1 for potential startup costs, should the Offeror adequately outline the need for this funding. The Department assumes that funding for Phase 2 will not be provided by the State as costs associated with an active program in Phase 2 will be absorbed by the markup applied for the sale of the prescription drugs to the Importer. Offerors are given additional instructions on cost and markup estimates in Section 3 of this document.

2.1.3.3. Table 5 outlines the Objectives and Requirements of the Foreign Seller:

Phase 1 Objectives	Phase 1 Requirements
SIP application requirements and support	<ul style="list-style-type: none"> <li>Support development of the importation drug list in conjunction with the Department and other vendors, taking into account Canadian drug shortages.</li> </ul>

	<ul style="list-style-type: none"> <li>• Finalize contract with selected Importer for drug distribution, if applicable.</li> <li>• Register with the FDA as a Foreign Seller and provide related information to FDA as prescribed by the Final Rule.</li> <li>• Designate an official Program contact and U.S. agent.</li> <li>• Provide all other information to FDA and the Department, as required by the FDA for which the vendor is responsible, as detailed in the Final Rule.</li> <li>• Timely communicate all compliance issues to the Department.</li> <li>• Provide Health Canada inspection history, to the FDA and the Department, for the past five years or if the Foreign Seller has been licensed less than five years, for the duration of its period of licensure.</li> </ul>
Product and Reporting processes	<ul style="list-style-type: none"> <li>• Development of processes for assigning and affixing the SSI, and related record keeping and transaction records, as prescribed by the Final Rule.</li> <li>• Development of processes for handling suspect foreign products, illegitimate foreign products, and recalled products, as detailed in the Final Rule.</li> <li>• Development of regular reporting with the Department and Administrative Vendor as outlined in the State Statute.</li> </ul>
Management of Canadian drug shortages and reporting	<ul style="list-style-type: none"> <li>• Ensure all importation of drugs on the importation drug list will not cause or exacerbate a Canadian shortage of the drug, as outlined in Health Canada's Interim Order.</li> <li>• Develop a methodology for assessing each drug on the importation drug list, and regularly update this list to ensure compliance with applicable federal and state statutes and regulations.</li> </ul>
<b>Phase 2 Objectives</b>	<b>Phase 2 Requirements</b>

<p>Canadian drug purchasing, distribution, and related documentation and reporting</p>	<ul style="list-style-type: none"> <li>• Purchase the Canadian drugs on Colorado’s drug list from manufacturers, and ensure all such drugs meet all applicable requirements of the Final Rule, the FDCA and the State Statute.</li> <li>• Assign and affix the SSI as required by the Final Rule.</li> <li>• Engage in regular reporting with the Department and Administrative Vendor as outlined in the State Statute.</li> <li>• Comply with all post importation requirements including audits by the Administrative Vendor and the Department.</li> <li>• Timely communicate all compliance issues to the Department.</li> </ul>
<p>Drug distribution oversight verifications</p>	<p>Provide all essential documentation to the Administrative Vendor as related to:</p> <ul style="list-style-type: none"> <li>• Canadian drug approvals, labels and authorizations.</li> <li>• Record of sale by the manufacturer to the Foreign Seller and from Foreign Seller to Importer.</li> <li>• And any other documentation required by the Final Rule, the FDCA, and State Statute.</li> </ul>
<p>Post importation requirements</p>	<ul style="list-style-type: none"> <li>• Review and update FDA registration information for Foreign Seller per Final Rule.</li> <li>• Comply with all Foreign Seller supply chain security requirements as outlined in the Final Rule related to shipment protocols, assigning and affixing the SSI, and related record keeping and transaction records.</li> <li>• Provide transaction information upon request to the FDA or other appropriate State or Federal official, as related to products that are considered recalled, suspected foreign products, or illegitimate foreign products.</li> <li>• Implement a process to evaluate, identify, handle and report potential suspect products in its possession/control.</li> </ul>

2.1.3.4. Vendor Accountability:

- 2.1.3.4.1. The Department values relationships with vendors that meet standards of good management and accountability. The Department envisions commitments around correspondence and communication, management expectations, transparency and record keeping.

**OFFEROR'S RESPONSE 4. PLEASE DESCRIBE HOW THE OFFEROR WOULD COMPLETE THE REQUIREMENTS OUTLINED IN SECTION 2.1.3. FOR THE FOREIGN SELLER VENDOR, TAKING INTO ACCOUNT ALL APPLICABLE PROVISIONS IN THE FINAL RULE, THE FDCA, AND THE STATE STATUTE. IF THE OFFEROR IS NOT PROPOSING TO FILL THE FOREIGN SELLER ROLE, PLEASE RESPOND TO THIS OFFEROR'S RESPONSE WITH 'NOT PROPOSING FOR THIS ROLE'**

**OFFEROR'S RESPONSE 5. PLEASE PROVIDE A DESCRIPTION OF PERFORMANCE STANDARDS OR SERVICE LEVELS THAT THE OFFEROR COMMITS TO MEETING, INCLUDING METRICS FOR EACH AREA. THE SUBMISSION SHOULD INCLUDE HOW THE OFFEROR WOULD TIE THESE STANDARDS TO FINANCIAL INCENTIVES TO ENSURE THESE METRICS ARE MET. IF THE OFFEROR IS NOT PROPOSING TO FILL THE ADMINISTRATIVE VENDOR ROLE, PLEASE RESPOND TO THIS OFFEROR'S RESPONSE WITH 'NOT PROPOSING FOR THIS ROLE'.**

**2.1.4. Role #3 – Importer (including the Relabeler/Repackager and Qualified Laboratory responsibilities, which included activities that may be performed by the Offeror or subcontracted)**

2.1.4.1. Description:

- 2.1.4.1.1. The Department seeks a U.S. Importer that will be responsible for securing prescription drugs from a Department-approved Canadian Foreign Seller for distribution in Colorado. The Importer must be a licensed wholesaler or pharmacy in the U.S. and either have already or agree to obtain licensure from the Colorado Board of Pharmacy to operate in the State of Colorado.
- 2.1.4.1.2. Per the Federal Statute, the Final Rule, and the State Statute, an Importer can be a pharmacist or wholesaler. Pharmacies/pharmacists who submit a response to this solicitation must agree to sell and distribute, at a price that is consistent with the price in the existing wholesale market, imported drugs to any pharmacy that wishes to participate in the program.
- 2.1.4.1.3. The Importer is responsible for the testing, relabeling/repackaging and distribution of purchased medications. The Importer may contract out the testing, labeling, and

distribution of imported drugs to other vendors or complete these activities in house. Should the Importer contract out certain functions, the Offeror must describe in detail who they will partner with to fulfill these requirements and how they will oversee and remain responsible for such activities.

2.1.4.1.4. The Offeror is expected to closely coordinate with the Department on all aspects of the program and will also be expected to contract directly with the approved Foreign Seller for the acquisition and distribution of imported prescription drugs.

2.1.4.1.5. The selected Importer will be responsible for payment of a modest administrative fee per imported drug to the Department to cover the costs of HCPF program oversight and associated staff. The Department will develop a methodology for establishing this fee. This fee may be incorporated into the Importer’s drug markup price however the markup price must comply with state statute and any corresponding regulation establishing a maximum profit margin for imported drugs. Statute dictates the profit margin be no greater than such margin absent the Program.

2.1.4.2. Funding:

2.1.4.2.1. Funding may be awarded for work in Phase 1 for potential startup costs, should the Offeror adequately outline the need for this funding. The Department assumes that funding for Phase 2 will not be provided by the state as costs associated with an active program in Phase 2 will be absorbed by the markup applied for the sale of the prescription drugs throughout the rest of the distribution chain. This markup should include estimates of appropriate costs for the relabeling and testing of imported products. Offerors are given additional instructions on cost and markup estimates in Section 3 of this document.

2.1.4.3. Table 6 outlines the Objectives and Requirements of the Importer:

Phase 1 Objectives	Phase 1 Requirements
Support SIP application development	<ul style="list-style-type: none"> <li>• Support development of the importation drug list in conjunction with the Department and other vendors.</li> <li>• Acquire and ensure any contracted parties acquire all required state and federal registrations/licenses.</li> <li>• Provide information on any contracted vendors already secured (ie; labeler, qualified lab), and any other vendor to support the program and include required documentation for those vendors, as detailed in the Final Rule.</li> <li>• Develop and submit to the Department the process for submitting pre-import requests, testing, relabeling, reporting, record-keeping, and auditing as required in the Final Rule.</li> </ul>

	<ul style="list-style-type: none"> <li>• Develop and submit to the Department a process for requesting and receiving required information from the manufacturer to conduct the testing for importable drugs and how the process will ensure the protection of trade secrets and commercial and or financial information that is privileged or confidential.</li> <li>• The State and Federal inspectional history for the Importer for the previous five years or, if the Importer has been licensed for less than five years, for the duration of its period of licensure.</li> </ul>
Finalize necessary contracts and identify subcontractors as applicable for the program	<ul style="list-style-type: none"> <li>• Ensure all all contracted and/or subcontracted parties (if any - e.g., relabeler and/or qualified laboratory) meet all applicable requirements set forth in the Final Rule as part of the contracting process.</li> <li>• Finalize contract with the Foreign Seller for drug distribution.</li> <li>• Secure contracts for labeling, testing, and any other necessary vendors to support the program and ensure all requirements for the vendors as listed in the Final Rule are met.</li> <li>• Establish contracts with Colorado pharmacies to ensure consumer access to imported drugs.</li> </ul>
Establish a state fee process	<ul style="list-style-type: none"> <li>• Develop a process, in collaboration with the Department, for the transfer of a modest administrative fee to the state of Colorado, as outlined in the State Statute.</li> </ul>
<b>Phase 2 Objectives</b>	<b>Phase 2 Requirements</b>
Purchase Canadian drugs and maintain related documentation	<ul style="list-style-type: none"> <li>• Submit Pre-Import Requests to the FDA, as required by the Final Rule.</li> <li>• Purchase Canadian drugs on Colorado’s importation list from the Foreign Seller.</li> <li>• Implement the process to verify and receive required documentation from the Foreign Seller and manufacturer for purposes of testing and distribution, as detailed in the Final Rule.</li> </ul>

Testing Imported Products	<ul style="list-style-type: none"> <li>• Implement the process for requesting and receiving required information from the manufacturer to conduct the testing for importable drugs and ensure confidentiality of such information.</li> <li>• Implement the process for conducting the statutory testing on randomly selected, statistically valid, batch samples of each imported drug for authenticity and degradation, and any established specifications or standards, as required in the Final Rule.</li> </ul>
Relabeling process and ensuring compliance	<ul style="list-style-type: none"> <li>• Implement the relabeling process to affix and include all required label and labeling information, including the new NDC, the name of the Importer product identifier, and other U.S. requirements for relabeling as required by the Final Rule.</li> </ul>
Drug supply chain compliance and recordkeeping	<ul style="list-style-type: none"> <li>• Ensure compliance with the Final Rule and Title II of the DQSA as related to all distribution requirements.</li> <li>• Maintain, and submit to FDA as required by the Final Rule, records demonstrating each imported drug was purchased directly from the approved Foreign Seller in Canada.</li> <li>• Retain all records demonstrating compliance with DSCSA's and the Final Rule's traceability requirements and verify all transaction documents that are received from the manufacturer match the records the manufacturer gave to the Foreign Seller.</li> <li>• all essential documentation to the Administrative Vendor as necessary.</li> <li>• Ensure all reporting to the FDA is completed as required in the Final Rule.</li> </ul>
Post importation requirements and reporting	<ul style="list-style-type: none"> <li>• Comply with all post importation requirements as detailed in the Final Rule.</li> <li>• Submit NDA and ANDA field alert reports, as required by the FDCA and the Final rule, to the manufacturer and FDA.</li> </ul>

	<ul style="list-style-type: none"> <li>• Maintain adverse event reporting records and submit to FDA and the manufacturer.</li> <li>• Submit any additional reports required by state or federal statutes and/or regulations (including for any imported combination product).</li> <li>• <u>Timely communicate all compliance issues to the Department.</u></li> </ul>
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2.1.4.4. Vendor Accountability:

2.1.4.4.1. The Department values relationships with vendors that meet standards of good management and accountability. The Department envisions commitments around correspondence and communication, management expectations, transparency and record keeping.

**OFFEROR'S RESPONSE 6. PLEASE DESCRIBE HOW THE OFFEROR WOULD COMPLETE THE REQUIREMENTS OUTLINED IN SECTION 2.1.4. FOR THE IMPORTER VENDOR. IF THE OFFEROR IS NOT PROPOSING TO FILL THE IMPORTER ROLE, PLEASE RESPOND TO THIS OFFEROR'S RESPONSE WITH 'NOT PROPOSING FOR THIS ROLE'**

**OFFEROR'S RESPONSE 7. PLEASE PROVIDE A DESCRIPTION OF PERFORMANCE STANDARDS OR SERVICE LEVELS THAT THE OFFEROR COMMITS TO MEETING, INCLUDING METRICS FOR EACH AREA. THE SUBMISSION SHOULD INCLUDE HOW THE OFFEROR WOULD TIE THESE STANDARDS TO FINANCIAL INCENTIVES TO ENSURE THESE METRICS ARE MET. IF THE OFFEROR IS NOT PROPOSING TO FILL THE ADMINISTRATIVE VENDOR ROLE, PLEASE RESPOND TO THIS OFFEROR'S RESPONSE WITH 'NOT PROPOSING FOR THIS ROLE'.**

**OFFEROR'S RESPONSE 8. PLEASE PROVIDE A DESCRIPTION OF HOW THE OFFEROR WILL ENSURE THAT ALL PHARMACIES PARTICIPATING IN THE PROGRAM WILL BE TREATED EQUALLY WITH REGARD TO IMPORTED DRUGS, REGARDLESS OF PHARMACY SIZE, GEOGRAPHIC LOCATION WITHIN COLORADO, OR EXISTING CONTRACTUAL RELATIONSHIPS WITH THE OFFEROR. THIS SHOULD INCLUDE PURCHASE VOLUMES, DELIVERY TIMES, PRICE, AND OTHER PERTINENT ASPECTS**

## **SECTION 3.0 COST ESTIMATE**

### **3.1. REQUEST FOR COST ESTIMATE**

#### **3.1.1. Administrative Vendor Cost Estimate**

3.1.1.1. The Department requests that responsive proposals for the Work of the Administrative Vendor include a cost estimate of the work to be performed for both phases of the Program.

#### **3.1.2. Foreign Seller and Importer Cost Estimate**

3.1.2.1. The Department requests that responsive bids for both the Foreign Seller and the Importer include a cost estimate of the work to be performed for both phases of the Program, taking into account the market forces at play in the development and operations of a profitable distribution supply chain. The Department does not expect to fund any portion of work to be performed in Phase 2, but is open to cost estimates for startup funding in Phase 1. Estimates for appropriate markups of imported products and a fee structure to cover the costs of operations are expected in all responsive bids,

including the methodology used to reach the proposed markup.

- 3.1.2.1.1. The Department highlights the following goals in the creation of an appropriate fee structure for the Program:
  - 3.1.2.1.1.1. The fee structure incentivizes the purchase of the lowest cost importable products.
  - 3.1.2.1.1.2. The fee structure does not limit savings to Colorado consumers.
  - 3.1.2.1.1.3. For example, the proposed fee structure could be volume based, include a fixed fee per unit, or include pricing tiers for a fee per transaction, etc.

The Department seeks recommendations on the setting of a maximum profit margin on imported products, as outlined in the State Statute.

**OFFEROR'S RESPONSE 9. PLEASE DESCRIBE THE OFFEROR'S PRICING STRUCTURE AND MARKUP ESTIMATE, AS APPLICABLE, FOR THE PORTION OF THE WORK INCLUDED IN A RESPONSIVE offer.**

**SECTION 4.0 EXPERIENCE AND PERSONNEL**

**4.1. ORGANIZATIONAL EXPERIENCE**

- 4.1.1. The Department recognizes that importation programs are innovative and new, yet, entities working within and alongside the drug distribution system have in depth experience in navigating the complexities of the drug supply chain and FDA rules that are fundamental to operationalizing the Program.
- 4.1.2. The Department will evaluate the Offeror's experience pertaining to the following:
  - 4.1.2.1. Role #1 (Administrative Vendor): Drug policy, financing, compliance and communications experience required. Insurer, employer and PBM partnership experience preferred. Importation subject matter expertise preferred.
  - 4.1.2.2. Role #2 (Foreign Seller): Manufacturer and wholesaler partnership experience, ability to negotiate significant price discounts, strong Canadian safety regulatory record required. Access to a broad network of manufacturer offerings for a robust drug list preferred. A successful response will include verification of Health Canada registration and, five years of Health Canada safety inspectional history (if licensed for less than five years, include this information for the duration of licensure). Withdrawn from a contracted state or other service area; or has requested any reductions in its responsibilities under the terms of the contract.
  - 4.1.2.3. Role #3 (Importer) Strong U.S. drug distribution safety and regulatory compliance record. Internal testing and repackaging and relabeling experience or subcontractor experience preferred. Experience importing drugs from Canada and Colorado drug distribution experience preferred. A successful response will include verification of all relevant federal licenses and inspectional histories. Provide details on experience and contracts pertaining to drug importation and distribution

- 4.1.3. For all vendors, provide details on relevant prior or existing contracts pertaining to prescription drug importation activities, prescription drug distribution, and/or drug policy.
- 4.1.3.1. The Offeror is expected to provide details regarding such contracts including a summary of the work performed, subcontractor roles and responsibilities, if relevant, and information regarding any contract terminations or withdrawals.

**OFFEROR'S RESPONSE 10. PROVIDE A DETAILED DESCRIPTION OF OFFEROR'S ORGANIZATIONAL EXPERIENCE RELATED TO THE WORK AS DESCRIBED IN §4.1.**

**4.2. PERSONNEL**

- 4.2.1. The Offeror is expected to designate people to hold the following Key Personnel (or similar) positions per vendor:
  - 4.2.1.1. All Vendors: Project Lead
    - 4.2.1.1.1. The Department will evaluate the Project Lead based on the following qualifications:
      - 4.2.1.1.1.1. Serving as Contractor's primary point of contact for the Department.
      - 4.2.1.1.1.2. Ensuring the completion of all Work in accordance with the Contract's requirements. This includes, but is not limited to, ensuring the accuracy, timeliness and completeness of all work and maintaining compliance with all FDA, federal, and state documentation requirements.
      - 4.2.1.1.1.3. Overseeing all other Key Personnel and Other Personnel and ensuring proper staffing levels throughout the term of the Contract.
  - 4.2.2. In addition to a Project Lead, the Department expects that Offerors will need the following key personnel or individuals to fill the role, though exact personnel structures are negotiable:
    - 4.2.2.1. Administrative Vendor
      - 4.2.2.1.1. Compliance Officer
      - 4.2.2.1.2. Communications Officer
      - 4.2.2.1.3. Data and Reporting Officer
    - 4.2.2.2. Foreign Seller
      - 4.2.2.2.1. Distribution Lead
      - 4.2.2.2.2. Inspection Lead
      - 4.2.2.2.3. Compliance Lead
      - 4.2.2.2.4. Reporting Lead

- 4.2.2.3. Importer
  - 4.2.2.3.1. Distribution Lead
  - 4.2.2.3.2. Inspection Lead
  - 4.2.2.3.3. Compliance Lead
  - 4.2.2.3.4. Reporting Lead
  - 4.2.2.3.5. Testing Lead
  - 4.2.2.3.6. Relabeling/Repackaging Lead
- 4.2.3. Other than the specific personnel outlined above, the Offeror(s) may propose any other personnel or structure such as the combining of the roles listed above, if the Offeror believes it is most efficient and effective at completing the work.
  - 4.2.3.1. The Offeror is expected to provide documentation, such as resumes or curriculum vitae (CV), for identified personnel. The Department reserves the right to request additional information or replacement of personnel.

**OFFEROR'S RESPONSE 11. INCLUDING THE KEY PERSONNEL DESCRIBED IN §4.2, PROPOSE A PERSONNEL STRUCTURE AND POSITIONS THAT ARE APPLICABLE TO THIS WORK, WHO THE OFFEROR INTENDS TO FILL THESE POSITIONS, AND HOW THE OFFEROR WILL ENSURE SUFFICIENT STAFF ARE MADE AVAILABLE. FOR THE KEY PERSONNEL AND ANY OTHER INDIVIDUALS THAT THE OFFEROR DETERMINES ARE CRITICAL TO THE SUCCESS OF THE WORK, PROVIDE RESUMES DESCRIBING THE EXPERIENCE OF THOSE INDIVIDUALS.**

## **EVALUATION METHODOLOGY**

### **4.3. EVALUATION COMMITTEE**

- 4.3.1. The Department will establish an Evaluation Committee(s) utilizing measures to ensure the integrity of the evaluation process. These measures include the following:
  - 4.3.1.1. Selecting Evaluation Committee members who do not have a conflict of interest regarding this solicitation.

- 4.3.1.2. Ensuring the fair and impartial treatment of all Offerors.
- 4.3.2. The objective of the Evaluation Committee is to conduct reviews of the initial proposals and Negotiated Proposals that were submitted, hold frank and detailed discussions among members of the Evaluation Committee, and score the proposals to determine a competitive range and make an award.

#### **4.4. EVALUATION AND NEGOTIATION PROCESS**

- 4.4.1. The Evaluation Committee(s) will evaluate the Offeror's proposal, using the factors in §4.5.1 and any other pertinent factors to determine if the proposal is within the competitive range of responses that are most advantageous to the State. Only proposals that are within that competitive range will be considered for negotiation of a Negotiated Proposal, and all others that are not within that competitive range will be removed from further consideration.
  - 4.4.1.1. It is the Offeror's responsibility to ensure that Offeror's proposal is complete in accordance with the direction provided within all solicitation documents.
  - 4.4.1.2. The Evaluation Committee may, if it deems necessary, request clarifications or have Offerors present oral presentations. However, proposals may be reviewed, and determinations made without such activities so Offerors should submit their best proposal and not rely on clarifications or negotiations. Offerors should be aware that the opportunity for further explanation may not exist; therefore, it is important that all proposal submissions are complete.
- 4.4.2. Offeror's proposals that are determined to be in the competitive range, may be invited to engage in negotiations with the Evaluation Committee(s).
  - 4.4.2.1. The Department will determine the process for these negotiations, including, without limitation, the following:
    - 4.4.2.1.1. The date, time, and location of the negotiation meetings.
    - 4.4.2.1.2. The format of the negotiations.
    - 4.4.2.1.3. Who must be present from the Offeror at the negotiation meetings, to include a person who can commit the Offeror to any changes.
    - 4.4.2.1.4. The agenda and topics to be covered during each negotiation meeting.
  - 4.4.2.2. Based on the negotiations, the Department may contract with more than one Offeror and may separate the work into multiple contracts with different Offerors.
- 4.4.3. The Evaluation Committee(s) will recommend award of this solicitation to the Offeror whose proposal is determined to be most advantageous to the State, taking into account the price, the evaluation factors contained in this ITN, and the results of the negotiations.
- 4.4.4. During any point in the negotiation, if the Department determines that an Offeror is no longer reasonably susceptible of an award, the Department may remove that Offeror from further consideration, including stopping negotiations if negotiations were in progress.

#### **4.5. EVALUATION FACTORS**

- 4.5.1. The evaluation factors for this ITN are as follows and are presented in no particular order:

<b>FACTORS</b>
Organizational Experience
Personnel
Price
Overview for All Vendors
Administrative Response
Foreign Seller Response
Importer Response

**4.6. SCOPE OF NEGOTIATIONS**

4.6.1. The portions and requirements of the Template Contract shown in Appendix B are only negotiable as follows:

4.6.1.1. The Special Provisions required by State Fiscal Rule 3-3 are not negotiable, except to the extent that a waiver that is applicable to the Contract has been granted by the Colorado Office of the State Controller.

4.6.1.2. The requirements of the HIPAA Business Associate Agreement issued by the Colorado Office of the State Controller, if one is required, are not negotiable.

4.6.1.3. The requirements of the main body of the Template Contract, other than the Special Provisions, or any exhibits to the Template Contract are negotiable in accordance with policies issued by the Colorado Office of the State Controller, and any substantive changes to those provisions may require additional approval of the Office of the State Controller, the Colorado Attorney General’s Office, The Governor’s Office of Information Technology, or the State’s Risk Manager.

4.6.1.4. Limitations of liability may only be included through negotiation if the limitation of liability:

4.6.1.4.1. Only applies in excess of the insurance coverage included in the Contract;

4.6.1.4.2. Does not apply to the Contractor’s indemnity obligations under the Contract;

4.6.1.4.3. Does not apply to disclosure of confidential information or data loss; and

4.6.1.4.4. Is not otherwise void under §24-106-109, C.R.S.

4.6.1.5. No term may be included through negotiations that would be void under §24-106-109, C.R.S. or that would violate any other state or federal statute or regulation.

4.6.2. All functional requirements shown in this ITN are negotiable except for the following:

4.6.2.1. Designating a person to be a Project Lead and the responsibilities of that role described in §4.2.1.1, except that the title of the position and the individual holding it may be negotiated.

4.6.2.2. Compliance with state and federal laws, regulations, rules, and policies as described in §1.4.3, §2.1.1.1, and §2.1.4.1.5, though how the Offeror complies with those requirements is negotiable.

- 4.6.2.3. The requirement for the Offeror filling the role of the Importer to be a licensed wholesaler or pharmacy in the U.S. and either have already have, or agree to obtain prior to commencing work under a Contract, licensure from the Colorado Board of Pharmacy to operate in the State of Colorado, as described in §2.1.4.1.1.
- 4.6.2.4. The requirement to sell and distribute, at a profit that is consistent with the existing wholesale market, imported drugs to any pharmacy that wishes to participate in the program as described in §2.1.4.1.2.