




# CONTRACT AMENDMENT #1

## SIGNATURE AND COVER PAGE

<b>State Agency</b> Department of Health Care Policy and Financing	<b>Original Contract Number</b> C23-174869
<b>Contractor</b> Premier Pharmaceuticals, LLC	<b>Amendment Contract Number</b> C23-174869A1
<b>Current Contract Maximum Amount</b> Initial Term State Fiscal Year 2023                      \$262,000.00 Extension Terms State Fiscal Year 2024                      \$125,000.00 State Fiscal Year 2025                      \$115,000.00 State Fiscal Year 2026                      \$115,000.00 State Fiscal Year 2027                      \$115,000.00 Total for All State Fiscal Years              \$722,000.00	<b>Contract Performance Beginning Date</b> July 1st, 2022  <b>Current Contract Expiration Date</b> June 30, 2023

### THE PARTIES HERETO HAVE EXECUTED THIS AMENDMENT

Each person signing this Amendment represents and warrants that he or she is duly authorized to execute this Amendment and to bind the Party authorizing his or her signature.

<p style="text-align: center;"><b>CONTRACTOR</b> Premier Pharmaceuticals, LLC</p> <p>DocuSigned by:  </p> <p>By: <u>88DC06F7A340465</u>                  Date: <u>9/15/2022</u></p>	<p style="text-align: center;"><b>STATE OF COLORADO</b> <b>Jared S. Polis, Governor</b> Department of Health Care Policy and Financing</p> <p>DocuSigned by:  </p> <p>By: <u>0B6A84797EA8493</u>                  Date: <u>9/15/2022</u></p>
<p>In accordance with §24-30-202 C.R.S., this Amendment is not valid until signed and dated below by the State Controller or an authorized delegate.</p> <p style="text-align: center;"><b>STATE CONTROLLER</b> <b>Robert Jaros, CPA, MBA, JD</b></p> <p>DocuSigned by:  </p> <p>By: <u>76F69541272B43A</u>                  Date: <u>9/15/2022</u>                  Amendment Effective Date: _____</p>	

**1. PARTIES**

This Amendment (the “Amendment”) to the Original Contract shown on the Signature and Cover Page for this Amendment (the “Contract”) is entered into by and between the STATE OF

COLORADO acting by and through the State agency named on the Cover Page for this Amendment (the “State,” the “Department,” or “HCPF).

## **2. TERMINOLOGY**

Except as specifically modified by this Amendment, all terms used in this Amendment that are defined in the Contract shall be construed and interpreted in accordance with the Contract.

## **3. AMENDMENT EFFECTIVE DATE AND TERM**

### **A. Amendment Effective Date**

This Amendment shall not be valid or enforceable until the Amendment Effective Date shown on the Signature and Cover Page for this Amendment. The State shall not be bound by any provision of this Amendment before that Amendment Effective Date and shall have no obligation to pay Contractor for any Work performed, or expense incurred, under this Amendment either before or after the Amendment term shown in **§3.B** of this Amendment.

### **B. Amendment Term**

The Parties’ respective performances under this Amendment and the changes to the Contract contained herein shall commence on the Amendment Effective Date shown on the Signature and Cover Page for this Amendment and shall terminate on the termination of the Contract.

## **4. PURPOSE**

The purpose of this Amendment is to update the Statement of Work to include a Deliverable from FY22 that was not completed, and to add additional Deliverables for manufacturer negotiations.

## **5. MODIFICATIONS**

The Contract and all prior amendments thereto, if any, are modified as follows:

- A. The Contract Maximum Amount table on the Contract’s Signature and Cover Page is hereby deleted and replaced with the Current Contract Maximum Amount table shown on the Signature and Cover Page for this Amendment.
- B. The Contract Definitions are hereby deleted and replaced with the Definitions for this Amendment.
- C. Quarterly Reports are added to the Reporting – Notification section of the Contract for this Amendment.
- D. Exhibit A, Statement of Work, is hereby deleted in its entirety and replaced with Exhibit A-1, Statement of Work, attached hereto and incorporated by reference into the Contract. All references within this Contract to Exhibit A shall now be deemed to reference Exhibit A-1.
- E. Exhibit B, Rates, is hereby deleted in its entirety and replaced with Exhibit B-1, Rates, attached hereto and incorporated by reference into the Contract. All references within this Contract to Exhibit B shall now be deemed to reference Exhibit B-1.
- F. Exhibit C, Terminology, is hereby deleted in its entirety and replaced with Exhibit C-1, Terminology, Applicable Laws and Regulations, attached hereto and incorporated by reference into the Contract. All references within this Contract to Exhibit C shall now be deemed to reference exhibit C-1.
- G. Exhibit D, Contractor’s Administrative Requirements, is hereby deleted in its entirety and replaced with Exhibit D-1, Contractor’s Administrative Requirements, attached hereto and

incorporated by reference into the Contract. All references within this Contract to Exhibit D shall now be deemed to reference Exhibit D-1.

## 6. LIMITS OF EFFECT AND ORDER OF PRECEDENCE

This Amendment is incorporated by reference into the Contract, and the Contract and all prior amendments or other modifications to the Contract, if any, remain in full force and effect except as specifically modified in this Amendment. Except for the Special Provisions contained in the Contract, in the event of any conflict, inconsistency, variance, or contradiction between the provisions of this Amendment and any of the provisions of the Contract or any prior modification to the Contract, the provisions of this Amendment shall in all respects supersede, govern, and control. The provisions of this Amendment shall only supersede, govern, and control over the Special Provisions contained in the Contract to the extent that this Amendment specifically modifies those Special Provisions.

## 7. DEFINITIONS

The following terms shall be construed and interpreted as follows:

- A. “**Breach of Contract**” means the failure of a Party to perform any of its obligations in accordance with this Contract, in whole or in part or in a timely or satisfactory manner. The institution of proceedings under any bankruptcy, insolvency, reorganization or similar law, by or against Contractor, or the appointment of a receiver or similar officer for Contractor or any of its property, which is not vacated or fully stayed within 30 days after the institution of such proceeding, shall also constitute a breach. If Contractor is debarred or suspended under §24-109-105, C.R.S. at any time during the term of this Contract, then such debarment or suspension shall constitute a breach.
- B. “**Business Day**” means any day other than Saturday, Sunday, or a Legal Holiday as listed in C.R.S. §24-11-101(1).
- C. “**Chief Procurement Officer**” means the individual to whom the Executive Director has delegated his or her authority, pursuant to C.R.S. §24-102-202(6), to procure or supervise the procurement of all supplies and Services needed by the state.
- D. “**Contract**” means this agreement, including all attached Exhibits, all documents incorporated by reference, all referenced statutes, rules and cited authorities, and any future modifications thereto.
- E. “**Contract Funds**” means the funds that have been appropriated, designated, encumbered, or otherwise made available for payment by the State under this Contract.
- F. “**Contractor Pre-Existing Material**” means material, code, methodology, concepts, process, systems, technique, trade or service marks, copyrights, or other intellectual property developed, licensed or otherwise acquired by Contractor prior to the Effective Date of this Contract and independent of any Services rendered under any other contract with the State.
- G. “**Colorado Open Records Act (CORA)**” means C.R.S. §24-72-200.1, *et. seq.*
- H. “**Criminal Justice Information (CJI)**” means criminal justice information collected by criminal justice agencies needed for the performance of their authorized functions, including, without limitation, all information defined as criminal justice information by the U.S. Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Security Policy, as amended and all Criminal Justice Records as defined under C.R.S. §24-72-302.

- I. **“Effective Date”** means the date on which this Contract is approved and signed by the Colorado State Controller or designee, as shown on the Cover Page for this Contract. If this Contract is for a Major Information Technology Project, as defined in §24-37.5-102(2.6), C.R.S., then the Effective Date of this Contract shall be the later of the date on which this Contract is approved and signed by the State’s Chief Information Officer or authorized delegate or the date on which this Contract is approved and signed by the State Controller or authorized delegate, as shown on the Cover Page for this Contract.
- J. **“End of Term Extension”** means the time period defined in §[Error! Reference source not found.](#)
- K. **“Exhibits”** means the exhibits and attachments included with this Contract as shown on the Cover Page for this Contract.
- L. **“Extension Term”** means the time period defined in §[Error! Reference source not found.](#)
- M. **“FDA”** means the United States Food and Drug Administration.
- N. **“FDCA”** means the Federal Food Drug and Cosmetic Act.
- O. **“Foreign Seller”** means an establishment within Canada engaged in the distribution of an Eligible Prescription Drug that is imported or offered for importation into the United States.
- P. **“Goods”** means any movable material acquired, produced, or delivered by Contractor as set forth in this Contract and shall include any movable material acquired, produced, or delivered by Contractor in connection with the Services.
- Q. **“HPFB”** means the Health Products and Food Branch of Health Canada.
- R. **“Incident”** means any accidental or deliberate event that results in or constitutes an imminent threat of the unauthorized access, loss, disclosure, modification, disruption, or destruction of any communications or information resources of the State, which are included as part of the Work, as described in C.R.S. §24-37.5-401, *et. seq.* Incidents include, without limitation, (i) successful attempts to gain unauthorized access to a State system or State Information regardless of where such information is located; (ii) unwanted disruption or denial of service; (iii) the unauthorized use of a State system for the processing or storage of DataData; or (iv) changes to State system hardware, firmware, or software characteristics without the State’s knowledge, instruction, or consent.
- S. **“Initial Term”** means the time period defined in §[Error! Reference source not found.](#)
- T. **“NDC”** means the National Drug Code.
- U. **“Party”** means the State or Contractor, and **“Parties”** means both the State and Contractor.
- V. **“Services”** means the services to be performed by Contractor as set forth in this Contract and shall include any services to be rendered by Contractor in connection with the Goods.
- W. **“SOP”** means Standard Operating Procedure
- X. **“State Confidential Information”** means any and all State Records not subject to disclosure under CORA. State Confidential Information shall include, but is not limited to, PII, PHI, PCI, Tax Information, CJI, and State personnel records not subject to disclosure under CORA. State Confidential Information shall not include information or Data concerning individuals that is not deemed confidential but nevertheless belongs to the State, which has been communicated, furnished, or disclosed by the State to Contractor which (i) is subject to

disclosure pursuant to CORA; (ii) is already known to Contractor without restrictions at the time of its disclosure to Contractor; (iii) is or subsequently becomes publicly available without breach of any obligation owed by Contractor to the State; (iv) is disclosed to Contractor, without confidentiality obligations, by a third party who has the right to disclose such information; or (v) was independently developed without reliance on any State Confidential Information.

- Y. **“State Fiscal Rules”** means the fiscal rules promulgated by the Colorado State Controller pursuant to C.R.S. §24-30-202(13)(a).
- Z. **“State Fiscal Year”** means a 12-month period beginning on July 1 of each calendar year and ending on June 30 of the following calendar year. If a single calendar year follows the term, then it means the State Fiscal Year ending in that calendar year.
- AA. **“State Records”** means any and all State Data, information, and records, regardless of physical form, including, but not limited to, information subject to disclosure under CORA.
- BB. **“Subcontractor”** means third parties, if any, engaged by Contractor to aid in performance of the Work.
- CC. **“Tax Information”** means federal and State of Colorado Tax Information including, without limitation, federal and State tax returns, return information, and such other tax related information as may be protected by federal and State law and regulation. Tax Information includes, but is not limited to, all information defined as federal Tax Information in Internal Revenue Service Publication 1075.
- DD. **“W.H.I.”** means Colorado In-State Wholesaler License
- EE. **“W.H.O.”** means Colorado Out of State Wholesaler License.
- FF. **“Work”** means the Goods delivered and Services performed pursuant to this Contract.
- GG. **“Work Product”** means the tangible and intangible results of the Work, whether finished or unfinished, including drafts. Work Product includes, but is not limited to, documents, text, software (including source code), research, reports, proposals, specifications, plans, notes, studies, Data, images, photographs, negatives, pictures, drawings, designs, models, surveys, maps, materials, ideas, concepts, knowhow, and any other results of the Work. “Work Product” does not include any material that was developed prior to the Effective Date that is used, without modification, in the performance of the Work.

Any other term used in this Contract that is defined in an Exhibit shall be construed and interpreted as defined in that Exhibit, including the terminology in Exhibit C.

## 8. REPORTING – NOTIFICATION

### A. Quarterly Reports.

In addition to any reports required pursuant to this Contract or pursuant to any other Exhibit, for any contract having a term longer than 3 months, Contractor shall submit, on a quarterly basis, a written report specifying progress made for each specified performance measure and standard in this Contract for long term Deliverables, greater than 90 days, if requested by the Department. Such progress report shall be in accordance with the procedures developed and prescribed by the State. Progress reports shall be submitted to the State not later than 5 Business Days following the end of each calendar quarter or at such time as otherwise specified by the State.

## EXHIBIT A-1, STATEMENT OF WORK

### 1. PROJECT SPECIFIC STATEMENT OF WORK

#### 1.1. General Statement of Work

- 1.1.1. The purpose of this contract is to develop and implement a Program to import Canadian prescription drugs for the State. All drugs imported through this Program must be fully compliant with the Final rule set forth by the FDA. This Statement of Work outlines the role played by the Importer, a US wholesaler that is responsible for the purchase and distribution of imported products. All Deliverables described below shall be delivered in a Department approved format.
- 1.1.2. All due dates are eligible for an extension upon request by Contractor and approved by the Department.
- 1.1.3. The Contract shall support the Importation Program at all levels as previously described and may also include the following services:
  - 1.1.3.1. Importation Drug Distribution Research
  - 1.1.3.2. Drug Distribution Duties as required for the Program
  - 1.1.3.3. Incentivization of wholesalers, pharmacies, health insurance companies, and PBMs
  - 1.1.3.4. Federal application writing and support
  - 1.1.3.5. Program Development and Strategy
  - 1.1.3.6. Manufacturer Negotiation and Support
  - 1.1.3.7. Relabeling
  - 1.1.3.8. Program Communications Strategy and Stakeholder Engagement
  - 1.1.3.9. Program Reporting Functions
  - 1.1.3.10. Active importation supply chain program support as requested by the Department
  - 1.1.3.11. Other Projects as mutually agreed by Contractor and the Department

#### 1.2. Contract Requirements

- 1.2.1. The following items are requirements to adequately maintain the terms of this contract.
- 1.2.2. **Compliance with all applicable State of Colorado and federal laws**
  - 1.2.2.1. Compliance with all applicable State of Colorado and federal laws, rules and regulations, and international laws and standards regarding the development and operation of an Importation Program. The Department may terminate this Contract for noncompliance with any stated requirement and reserves the right to audit the Contractor on a scheduled or unscheduled basis.
- 1.2.3. **Maintenance of the licenses and registrations.**
  - 1.2.3.1. Contractor shall provide copies of all active licenses and inspection reports that are required to be included in the State of Colorado's SIP.
  - 1.2.3.2. Contractor shall maintain all current and future required licenses, permits, and/or registrations in good standing for the duration of this Contract. The Department reserves

the right to sanction or terminate this Contract if Contractor is found to be in violation of federal or state laws or if Contractor receives disciplinary action relating to any of these licensures.

- 1.2.3.2.1. Active Colorado Wholesaler License (W.H.O. or W.H.I.)
- 1.2.3.2.2. The subcontracted Relabeler shall have an Active FDA Registration under 21 CFR Part 207.25.
- 1.2.3.2.3. The subcontracted qualified laboratory must have an active ISO 17025 accreditation, provide an FDA inspection history that includes how the laboratory satisfactorily addressed any objectionable conditions or practices identified during its most recent FDA inspection, if applicable, and comply with applicable current Good Manufacturing Practice (GMP) requirements including laboratory controls in 21 CFR Part 211.160 and records in 21 CFR Part 211.194.
- 1.2.3.3. Contractor shall pass all applicable inspections, announced or unannounced, from federal and state agencies and additional inspections as required by the Department for the duration of this contract. Contractor shall ensure that any Subcontractors working on the Importation Program also pass all applicable inspections related to their work.
- 1.2.4. **Inspection of Records and Work Performed**
- 1.2.4.1. The Department and its authorized representatives reserve the right to enter Contractor'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.
- 1.2.5. **Facility Requirements**
- 1.2.5.1. Contractor shall comply with security and capacity requirements to ensure the safe and efficient distribution of imported products.
- 1.2.5.2. List of Facility Requirements
- 1.2.5.2.1. Contractor shall implement and adhere to the mutually agreed upon plan provided by the Department.
- 1.2.5.2.2. Contractor shall ensure Program prescription drugs have adequate space, security, and environmental conditions necessary for proper storage of imported prescription drugs.
- 1.2.5.2.3. Contractor shall ensure that the space designated for the Program is for the sole purpose of quarantining, storing and staging imported products for the Program.
- 1.2.5.2.4. Contractor's facility shall maintain the following elements while under the Contract with the Department:
  - 1.2.5.2.4.1. Standard Operating Procedures (SOPs) for all processes and procedures relating to the operation of the Importation Program, including but not limited to: security, product handling, logbooks, adverse events, environmental conditions, employee access to products, facility management, distribution processes, and employee training programs.
  - 1.2.5.2.4.2. External and internal physical security including, but not limited to, an alarm system, an internal and external security camera system, outdoor lighting, and a keycard or locking system.

- 1.2.5.2.4.3. Storage system designed specifically for the Importation Program that allows for imported products to be kept separate from the rest of Contractor's inventory. Imported products awaiting test results must be further separated and secured from imported products allowed for distribution.
- 1.2.5.2.4.4. Temperature control for all storage areas through an Environmental Monitoring System.
- 1.2.5.2.5. The Department shall inspect the facility that houses imported products for the Program every six months, or as necessary, at the Department's discretion.

**1.2.6. Development and Maintenance of Contracts**

- 1.2.6.1. Maintenance of contracts with a qualified laboratory, Relabeler/Repackager, if applicable, the State of Colorado's chosen Foreign Seller, reporting contractor, if applicable, and participating Colorado pharmacies.
  - 1.2.6.1.1. As part of its ongoing evaluation, the Department, or a designee of the Department, will evaluate the Subcontractor candidates and certify their ability to carry out the work of the Importation Program.
    - 1.2.6.1.1.1. The Department will complete site visits to the contracted Relabeler and qualified laboratory candidates on a regular basis as determined by the Department with input from Contractor.
    - 1.2.6.1.2. Each contract with participating Colorado pharmacies shall include a provision that requires pharmacies to submit annually a report that includes the number of imported drugs, by NDC, dispensed for the previous State Fiscal Year.
    - 1.2.6.1.3. The Department reserves the right to review all contracts and subcontracts relevant to the Importation Program.

**1.2.7. State Law Requirements**

- 1.2.7.1. Surety Bond of comparable Security Agreement
  - 1.2.7.1.1. Contractor shall submit evidence and maintain a surety bond or comparable Security Agreement in the minimum amount of \$25,000.00 throughout the duration of this Contract and include the State as a beneficiary.
- 1.2.7.2. Contractor shall maintain information and documentation submitted for this Contract for at least 7 years.
- 1.2.7.3. Contractor shall collect and maintain other documentation, if requested by the Department, to maintain protection of the public health.
- 1.2.7.4. Each contract with participating Colorado pharmacies shall include a provision that requires pharmacies to submit annual reports to Contractor with all required information for the annual report completed by the Department.

**1.2.8. Profit Margin and Markup Methodology**

- 1.2.8.1. To satisfy Colorado statutory obligations to set a maximum profit margin to ensure consumer cost savings, the Department has developed the following methodology to assess what the Department and Contractor feel is an appropriate and fair margin on imported products, based on the associated costs of doing business that include, but are



not limited to: general importation costs, storage, analytical testing, relabeling, company overhead, the collection of a state fee, and other costs as identified.

- 1.2.8.2. Margin: To cover the costs of conducting business Contractor shall markup imported products in a mutually agreeable fashion, and at a mutually agreeable rate, after the completion of the Profit Margin Methodology described at Section 1.3.2. of this contract.
- 1.2.8.3. Contractor and the Department shall meet at least quarterly during the first year of active importation, and at least annually in following years, to assess the needs of the Program, review volume of the past year, and projected volume for the next year. During this meeting, the Department and Contractor will come to a mutually agreeable margin for the next year, or a timeframe sooner than one year if mutually agreed upon in writing by the Department and Contractor, using industry benchmarks, fiscal analyses, and Program projections.
- 1.2.8.3.1. **DELIVERABLE:** Needs Assessment meetings
- 1.2.8.3.2. **DUE DATE:** Quarterly once active importation begins and at least annually in onward years of the Program on mutually agreeable dates as determined by the Department and Contractor
- 1.2.8.3.3. An audit and analysis shall be conducted by an outside entity, of the Department's choosing, at the close of each year of active importation to assess the appropriateness of the Markup.
- 1.2.8.3.4. **Quarterly Financial Report**
- 1.2.8.3.4.1. Contractor shall submit to the Department a Quarterly Financial Report listing the following Data, or other Data as mutually agreed upon by the Department and Contractor, for each imported product:
- 1.2.8.3.4.1.1. The final purchase price for each imported product
- 1.2.8.3.4.1.2. The number of imported products purchased, by Unit
- 1.2.8.3.4.1.3. The selling price for each imported product
- 1.2.8.3.4.1.4. The number of imported products sold to participating pharmacies
- 1.2.8.3.4.1.5. The monthly cost of testing for each imported product
- 1.2.8.3.4.1.6. The monthly cost of relabeling for each imported product
- 1.2.8.3.4.1.7. The overhead and other costs related to the operation of the Importation Program incurred by Contractor
- 1.2.8.3.4.1.8. The calculated profit retained by Contractor
- 1.2.8.3.4.2. The report shall include Data showing the financial health and performance of Contractor for the reporting period.
- 1.2.8.3.5. The report shall also include Data relating to the performance of all Subcontractors engaged in the operation of the Importation Program.
- 1.2.8.4. Collection of a state fee: The Department shall collect a state fee from the Markup, once importation has commenced on a regular basis, at a timeline agreed upon by the Department and Contractor. This fee shall be calculated and collected at the end of each month and delivered in a format and method laid out by the Department. The Department

and Contractor mutually agree to revisit the start date, amount, and timing as volume increases in following years of the Program. The Department reserves the right to delay or change the state fee with input from the Contractor based on Program factors.

1.2.8.5. Sale of imported products to Colorado pharmacies: Contractor shall sell the imported product to participating Program pharmacies (and other eligible purchasers) for the same price, regardless of geographic location, size of the pharmacy, or ownership status.

1.2.9. **Reporting Requirements**

1.2.9.1. Contractor shall submit the following reports to the correct entity (see 1.2.9.3.) on time and in a complete and accurate manner. A copy shall be submitted to the Department for any reports submitted to an entity other than the Department. Contractor shall maintain records of all reports pertaining to the Importation Program for seven years.

1.2.9.2. The reports shall be submitted in a mutually agreeable format and include all content requested by the Department.

1.2.9.3. Required Reports:

Report	Provenance	Submitted To	Cadence	Content
Annual Report	CO State Statute	The Department	Annually. Content for previous State Fiscal Year due to Department on October 1.	Data points as described at CRS 25.5-2.5-206.
Annual Financial Audit	CO State Statute	The Department	Annually. Content for previous State Fiscal Year due to Department on October 1.	Data points as described at CRS 25.5-2.5-203(2)(6).
Quarterly Financial Report	CO State Statute	The Department	Quarterly	Profit margin reporting as described in 1.2.8
Quarterly Importation Report	Final Rule	FDA, copy the Department	Quarterly	All details as laid out in §251.19 in the Final Rule.
Notification of Conviction or Violation	Final Rule	The Department	Within 5 calendar days of conviction or violation. The Department must submit to the FDA within 10 calendar days.	Notify the FDA of any applicable criminal conviction, violation of law, or disciplinary action as described in §251.3(e)(2) and (3).

1.2.9.4. The above table is not an exhaustive list of reports that may be submitted to the FDA. Contractor shall copy the Department on all reports submitted to the FDA, including, but not limited to, reports on recalls, returns, and adverse events.

1.2.10. **Program Growth**

1.2.10.1. Contractor shall notify the Department of any other states, tribes, local governments, or other entities allowed to act as a SIP Sponsor pursuing Importation Programs that approach Contractor about expanding importation work.

1.2.10.1.1. Contractor shall contact another state, tribe, local government, or other entity allowed to act as a SIP Sponsor, or subcontract with any entity that is a SIP Sponsor or who performs any Work on behalf of a SIP Sponsor. Contractor shall offer the Department the lowest rate or price offered to any other entity for work substantially similar to that in this contract.

1.2.10.2. Contractor shall brief the Department every 90 days during the first year of active importation, at the Department's request, on Contractor's business plan and financial condition to include a description of plans for expansion into new lines of business, intention of expanding or relocating the facility, and a plan for how these changes will affect the operation of the Program and, if needed, suggested remedies. In following years, Contractor shall brief the Department every six months or sooner, as requested by the Department.

1.2.11. **Acquisitions**

1.2.11.1. Contractor shall notify the Department within three Business Days if Contractor is contacted by another entity that is interested in purchasing Contractor, business lines or assets affecting the Work.

1.2.11.2. The Department reserves the right to terminate the Contract should Contractor be purchased by another entity.

1.2.12. If Contractor is contacted by another entity that is interested in acquiring Contractor, business lines or assets affecting the Work, the Department shall have the first right of refusal to purchase and operate Contractor at the rate and terms offered by the entity intending to acquire Contractor, business lines or assets affecting the Work.

1.2.13. **Department Inquiries and Contact**

1.2.13.1. Contractor shall acknowledge all Department inquiries within twenty-four (24) hours and respond to them on the next Business Day. Responses due on a weekend or State holiday shall be submitted to Contractor no later than the next Business Day.

1.2.13.2. Contractor shall meet with the Department staff both face-to-face and via video conference throughout the term of this Contract period, concerning any issues, when requested and required to fulfill the responsibilities of this Contract.

1.2.14. **Post SIP Approval**

1.2.14.1. Contractor shall implement all processes and procedures laid out in the Final Rule and laid out in the Importation Work Plan previously approved by the Department, maintaining compliance with all applicable federal and state laws, rules and regulations.

1.2.15. **Complainants Protections**

1.2.15.1. Contractor shall have a process to protect the anonymity of any complainants or whistleblowers regarding any Program concerns by Contractor employees. Contractor shall also ensure employees know and follow the adoption of processes and procedures for uncovering and addressing noncompliance, misconduct, or conflicts of interest.

1.3. **Contract Deliverables**

**1.3.1. Importation Work Plan**

**1.3.1.1. Section 2: Pre-Import Process**

1.3.1.1.1. Contractor shall develop a process for the handling of pre-import requests once the Program is approved. The process shall define how pre-import requests will be made in a timely fashion to the FDA, in an electronic format via the ESG or to an alternative transmission point identified by the FDA. The draft process must include all elements as requested in §251.5. Additionally, the process shall include a method for notifying the Department upon submission of every pre-import request.

1.3.1.1.2. Contractor shall create a draft pre-import request to the Department for prior written approval.

**1.3.1.2. Section 3: Importation Operations and Compliance Plan**

1.3.1.2.1. Identification of responsible individual(s) and a description of the respective area(s) of compliance that will be monitored by each responsible individual.

1.3.1.2.2. Development of education, training, and certification to ensure that employees of Contractor and Subcontractors engaged with the Program understand their compliance-related obligations that must be followed for all Program drugs.

1.3.1.2.3. Development of processes and procedures for uncovering and addressing noncompliance, or misconduct, by Contractor employees and shall include information outlined in 1.2.15.1 of this Contract.

1.3.1.2.4. Certification that all Contractor employees involved in the Program comply with the requirements of section 804 of the FDCA and the Final Rule.

**1.3.1.2.5. Importation of Canadian Drugs**

1.3.1.2.5.1. Development of a process, in conjunction with the Program's chosen Foreign Seller, for the imported drug to enter the US in accordance with §251.17 of the Final Rule.

1.3.1.2.5.2. Verification that Contractor is purchasing Eligible Prescription Drugs directly from the Program Foreign Seller.

1.3.1.2.5.3. Development of a process, and Data depository, for maintaining records for not less than six years, as defined in the Final Rule, that associates the product identifier placed by the Importer and serial number assigned by the Foreign Seller and the Canadian DIN.

1.3.1.2.5.4. Development of a process and Data repository for all information received from the Program Foreign Seller as described in §251.14 (c) of the Final Rule.

**1.3.1.2.6. Supply Chain Security Requirements**

1.3.1.2.6.1. Development of a screening procedure for imported drugs for finding any evidence that they are adulterated, counterfeit, diverted, stolen, damaged, tampered with, expired, or are a Suspect Foreign Product, an illegitimate foreign product, or a product that is unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

1.3.1.2.6.2. Demonstration of compliance with the applicable requirements of section §582(c) of the FDCA which includes Serialization of all imported products.

- 1.3.1.2.6.3. Demonstration of compliance with those requirements of section 251.14(d)(2) of the Final Rule, which requires Importers who subcontract repackaging operations to ensure each Subcontractor complies with section 582(e) of the FDCA.
- 1.3.1.2.7. Robust Facility Policies and Procedures for the Importation Program
  - 1.3.1.2.7.1. Development and verification of a process for maintaining the facility, including satisfactory inspections by federal and state regulatory agencies.
  - 1.3.1.2.7.2. Development of robust written compliance policies, procedures, and protocols, as defined in the mutually agreed upon plan provided by the Department.
- 1.3.1.2.8. Recall Plan
  - 1.3.1.2.8.1. Contractor shall describe how they will obtain additional recall or market withdrawal information, such as by obtaining recall information from the Department, and how Contractor will ensure that recall or market withdrawal information is shared among the Foreign Seller, Subcontractors, the Department, and FDA, and provided to the manufacturer.
  - 1.3.1.2.8.2. Contractor shall describe their written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing the procedures. The recall plan must cover recalls mandated or requested by FDA, recalls initiated by the Department, as well as recalls in Canada or the United States initiated by a drug's manufacturer that implicate a drug imported under a SIP, with which the Importer must cooperate.
  - 1.3.1.2.8.3. This plan must also cover all requirements as outlined in §251.18 (e) of the Final Rule.
- 1.3.1.2.9. Return Plan
  - 1.3.1.2.9.1. Contractor shall describe their return plan including:
    - 1.3.1.2.9.1.1. An explanation of how Contractor will ensure that product that is returned after distribution in Colorado is properly dispositioned in Colorado, if it is a nonsalable return, in order to protect patients from expired or unsafe drugs.
    - 1.3.1.2.9.1.2. An explanation of how Contractor will prevent the nonsalable returned Eligible Prescription Drugs from being exported from Colorado.
    - 1.3.1.2.9.1.3. If a returned Eligible Prescription Drug may be considered saleable, an explanation for how the returned product will be determined saleable and under what circumstances such Eligible Prescription Drugs may be redistributed in Colorado.
- 1.3.1.2.10. Post Importation Process Plan
  - 1.3.1.2.10.1. Contractor shall develop a written process for all Post Importation Requirements as listed in §251.18 of the Final Rule.
  - 1.3.1.2.10.2. Contractor shall document the process for immediately stopping importation of all drugs under SIP, notify the Department, and demonstrate to the Department that importation has in fact been stopped, if it has been determined an element of the supply chain stopped meeting the requirements of the Program.

- 1.3.1.2.10.3. Contractor shall describe how the reporting requirements described in §251.18 of the Final Rule will be met. Contractor shall develop written procedures needed to fulfill the requirements in this section for the surveillance, receipt, evaluation, and reporting to the FDA, and the manufacturer, of adverse event information. The written requirements shall include procedures for employee training, and for obtaining and processing safety information from the Foreign Seller.
- 1.3.1.2.10.4. Development and verification of a process to collect and submit all required information to the FDA about imported drugs as required in FDCA 804 (d) and §251.19 of the Final Rule.
- 1.3.1.3. Section 4: Subcontractor Operations and Compliance Plans
  - 1.3.1.3.1. Program Repackager/Relabeler
    - 1.3.1.3.1.1. Name and address of Relabeler
    - 1.3.1.3.1.2. Copy of executed contract, if applicable
    - 1.3.1.3.1.3. Proof of appropriate FDA registration
    - 1.3.1.3.1.4. Evidence of any corrective actions taken in response to its most recent FDA inspection, if applicable.
    - 1.3.1.3.1.5. Processes Outlining the Following:
      - 1.3.1.3.1.5.1. Assigning an NDC per 21 CFR Part 207.33.
      - 1.3.1.3.1.5.2. Development of an approved label for imported drugs in accordance with §251.13 and §251.14 of the Final Rule.
      - 1.3.1.3.1.5.3. Demonstration of compliance with the Final Rule for relabeling by Contractor or designated Subcontractor as defined in §251.12 (b) and/or (c) and all requirements as listed in §251.13 of the Final Rule.
      - 1.3.1.3.1.5.4. Ensuring the Eligible Prescription Drug is relabeled with the required U.S. labeling, including the container and carton labeling; Prescribing Information; and patient labeling, such as Medication Guides, Instruction for Use documents, and patient package inserts, in accordance with §251.13 and §251.14(d) of the Final Rule.
      - 1.3.1.3.1.5.5. Demonstration of compliance with the Final Rule for affixing or imprinting a product identifier by Contractor or designated Subcontractor and maintaining required records for the required period in accordance with §251.14 of the Final Rule.
    - 1.3.1.3.1.6. A copy of the FDA approved drug labeling for the FDA approved counterpart of the imported drug, a copy of the proposed labeling for the imported drug, and a side-by-side comparison of the FDA approved labeling and the proposed labeling, including the prescribing information, carton and container labeling, and patient labeling (ex. medication guide, instructions for use, patient package inserts, and other labeling needs.), with all differences annotated and explained. Also include a copy of the HPFB approved labeling.
  - 1.3.1.3.2. Qualified Laboratory
    - 1.3.1.3.2.1. Name and address of qualified laboratory

- 1.3.1.3.2.2. Copy of executed contract
- 1.3.1.3.2.3. Proof of laboratory's qualification in accordance with §251.15 of the Final Rule to conduct necessary tests
- 1.3.1.3.2.4. Development and verification of a process to ensure the Program Qualified Laboratory is in compliance with §251.16 of the Final Rule for Program testing requirements.
- 1.3.1.3.2.5. Describe the testing that will be done to establish that the HPFB approved drug meets the conditions of the NDA or ANDA for the HPFB approved drug's FDA approved counterpart.
- 1.3.1.3.2.6. Explanation of Confidentiality
  - 1.3.1.3.2.6.1. Explain how the Contractor will ensure that any information that the manufacturer supplies to authenticate a prescription drug being tested and confirm that the labeling of the prescription drug complies with labeling requirements under the FDCA, and any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies for the purposes of testing or otherwise complying with the FDCA and the Final Rule are kept in strict confidence and used only for the purposes of testing or otherwise complying with the FDCA and Final Rule.
- 1.3.1.4. The contractor may submit sections for partial payment if approved and agreed upon by the Department.
- 1.3.1.5. **DELIVERABLE:** Importation Work Plan, Sections 2-4
- 1.3.1.6. **DUE DATE:** Date mutually agreed upon by the Department and Contractor
- 1.3.2. **Profit Margin Methodology**
  - 1.3.2.1. Upon the delivery of the final drug list, Contractor shall develop and propose a methodology for determining an appropriate gross profit margin. The methodology should take into account all estimated costs of the supply chain to include, but not limited to, the costs of:
    - 1.3.2.1.1. Importation
    - 1.3.2.1.2. Storage
    - 1.3.2.1.3. Analytical testing
    - 1.3.2.1.4. Repackaging and/or relabeling imported products for sale in Colorado
    - 1.3.2.1.5. Company overhead
    - 1.3.2.1.6. Collection of a state fee
    - 1.3.2.1.7. Other costs as identified
  - 1.3.2.2. Contractor shall propose different methods of payment that may include a percentage markup and/or a cost-plus methodology.
  - 1.3.2.3. The Profit Margin Methodology is due to the Department on a date mutually agreed upon by the Department and Contractor
  - 1.3.2.4. **DELIVERABLE:** Profit Margin Methodology

1.3.2.5. **DUE DATE:** Date mutually agreed upon by the Department and Contractor

1.3.3. **Section 804 (SIP) Application Support**

1.3.3.1. Contractor shall provide SIP application (or amendment) content and evaluation as requested by the Department. Contractor, in addition to supplying all necessary documentation (including state and federal inspection history), will also support the development of narrative sections pertaining to Importer processes, procedures, and compliance with all applicable federal requirements.

1.3.3.2. All written information supplied by Contractor, for inclusion into SIP, shall require approval by the Department and in a Department approved format.

1.3.3.3. The time allotted for providing all applicable licenses, paperwork, etc. and the due date shall be agreed upon in writing by the Department and Contractor.

1.3.3.4. **DELIVERABLE:** Section 804 (SIP) Application Support

1.3.3.5. **DUE DATE:** Date mutually agreed upon by the Department and Contractor

1.3.4. **Co-Marketing with the State**

1.3.4.1. Contractor shall support the Department in a regionally focused co-marketing program to solicit interest from Colorado pharmacies to participate in the Importation Program.

1.3.4.2. All presentation materials, Data, and strategy supplied by Contractor for in person co-marketing meetings shall be approved by the Department and in a Department approved format.

1.3.4.3. Contractor shall schedule Co-marketing Program Meetings according to the convenience of the Department. Materials created in support of each meeting shall be submitted to the Department for review no later than five Business Days prior to the scheduled event.

1.3.4.4. **DELIVERABLE:** Co-marketing Program Meetings

1.3.4.5. **DUE DATE:** Date mutually agreed upon by the Department and Contractor

1.3.5. **Colorado Pharmacy Contract Agreements**

1.3.5.1. Contractor shall receive a written agreement (letter of intent) from pharmacies who wish to participate in the Importation Program. The written agreement shall be drafted and approved by the Department.

1.3.5.2. This is an ongoing Deliverable to be paid upon receipt of pharmacy contract agreements for each pharmacy.

1.3.5.3. Contractor shall be paid \$250.00 per signed letter of intent in which a Colorado pharmacy agrees to participate in the Program and carry Canadian Imported drugs. Volume based incentives may be negotiated for following years. Year One and Year Two contract agreement incentive payments shall not exceed \$10,000.00.

1.3.5.4. **DELIVERABLE:** Colorado Pharmacy Contract Agreements

1.3.5.5. **DUE DATE:** Upon receipt of signed letter of intent from a Colorado pharmacy.

1.3.6. Development of a Mail Order Solution



1.3.6.1. If requested by the Department, Contractor shall develop a mail order solution plan including regulatory/legal aspects of how to use a mail order house located within Contractor’s business to dispense imported products to Coloradans.

1.3.6.2. When requested by the Department, Contractor shall develop the proposal and submit it to the Department by a mutually agreed upon date.

1.3.6.3. **DELIVERABLE:** Mail Order Solution

1.3.6.4. **DUE DATE:** Date mutually agreed upon by the Department and Contractor

1.3.7. **Stakeholder Opportunities**

1.3.7.1. If requested by the Department, Contractor shall participate in stakeholder engagement programs within Colorado.

1.3.7.2. All presentation materials, Data, and information supplied by Contractor for these meetings shall be approved by the department and in a Department approved format.

1.3.7.3. Contractor shall submit materials created in support of each meeting to the Department for review no later than five Business Days prior to the scheduled event.

1.3.7.4. **DELIVERABLE:** Stakeholder Opportunities

1.3.7.5. **DUE DATE:** No later than five Business Days prior to a scheduled event

1.3.8. **Hourly Consultation as requested by the Department**

1.3.8.1. Contractor shall consult on topics as requested by the Department.

1.3.8.1.1. **DELIVERABLE:** Hourly consulting, when requested by the Department.

1.3.8.1.2. **DUE DATE:** Date mutually agreed upon by the Department and Contractor

1.3.9. **Manufacturer Meetings and Negotiations**

1.3.9.1. Contractor shall support the negotiation process, including meetings with manufacturers and associated preparatory meetings, when requested by the Foreign Seller Contractor and/or the Department. Meetings will include Contractor selected individuals and agreed to prior to the meeting and in writing.

1.3.9.1.1. All presentation materials, Data, and information supplied by Contractor for these meetings shall be approved by the Department and in a Department approved format.

1.3.9.1.2. Materials created in support of each meeting shall be submitted to the Department for review no later than five Business Days prior to the scheduled event.

1.3.9.1.3. Goals of each meeting shall be clearly defined prior to the meeting and must be agreed upon by the Department and Contractor.

1.3.9.1.4. For each invoiced meeting, Contractor shall submit to the Department the following details:

1.3.9.1.4.1. Date

1.3.9.1.4.2. Time

1.3.9.1.4.3. Individuals present on the call, including titles

1.3.9.1.4.4. Subjects discussed

1.3.9.1.4.5. Next steps

1.3.9.2. **DELIVERABLE:** Manufacturer Meetings and Negotiations

1.3.9.3. **DUE DATE:** Date mutually agreed upon by the Department and Contractor

1.3.10. **In-Person Manufacturer Negotiation Sessions**

1.3.10.1.1. Contractor shall support manufacturer negotiations in-person, when requested by the Foreign Seller Contractor and/or the Department, to secure drug supply for the Program. The Deliverable shall include preparatory time, the manufacturer meeting(s), presentation materials, travel, and other associated costs with conducting the Deliverable.

1.3.10.1.1.1. Travel costs incurred by the contractor during a visit shall not be submitted to the Department for reimbursement as the Deliverable includes the complete cost of the meeting and all applicable costs, including travel.

1.3.10.1.1.2. Meetings will include any necessary selected representatives of the Department and Contractor. Representatives will be agreed upon prior to the meeting in writing.

1.3.10.1.1.3. Per each negotiation session, Contractor may meet with more than one manufacturer.

1.3.10.1.1.4. All presentation materials, Data, and information supplied by the Contractor for these meetings shall be in a Department approved format.

1.3.10.1.1.5. Materials created in support of each meeting shall be submitted to the Department for review no later than five Business Days prior to the scheduled event.

1.3.10.1.1.6. Goals of each meeting shall be clearly defined prior to the meeting and must be agreed upon by the Department and Contractor.

1.3.10.1.1.7. **DELIVERABLE:** In-Person Manufacturer Meetings

1.3.10.1.1.8. **DUE DATE:** Date mutually agreed upon by the Department and Contractor

1.3.10.1.2. Cost: The cost per in-person negotiation session shall be paid at the amount based on the following scale that includes an approximate 5% increase each year as shown in the following rates:

1.3.10.1.2.1. State Fiscal Year 2023 - \$5,000.00

1.3.10.1.2.2. State Fiscal Year 2024 - \$5,250.00

1.3.10.1.2.3. State Fiscal Year 2025 - \$5,500.00

1.3.10.1.2.4. State Fiscal Year 2026 - \$5,775.00

1.3.10.1.2.5. State Fiscal Year 2027 - \$6,000.00

1.3.10.1.3. Cost: Per Fiscal Year the cost for in-person negotiation sessions shall not exceed the dollar amounts in the table below:

1.3.10.1.3.1. State Fiscal Year 2023 - \$30,000.00

1.3.10.1.3.2. State Fiscal Year 2024 - \$20,000.00

1.3.10.1.3.3. State Fiscal Year 2025 - \$20,000.00

1.3.10.1.3.4. State Fiscal Year 2026 - \$20,000.00

1.3.10.1.3.5. State Fiscal Year 2027 - \$20,000.00

1.3.11. **Ad Hoc Projects**

1.3.11.1. Ad Hoc projects will be related to the overall Statement of Work as described in the 1.1.3

1.3.11.1.1. The Statement of Work will be mutually agreed upon in writing by the Department and the Contractor.

1.3.11.2. The project(s) due date(s) and cost(s) shall be mutually agreed upon in writing by the Department and Contractor.

1.3.11.3. **DELIVERABLE:** Ad Hoc Projects

1.3.11.4. **DUE DATE:** Date mutually agreed upon by both the Department and Contractor

**2. DELIVERABLES, COMPENSATION, AND INVOICING**

2.1. **Compensation**

2.1.1. Contractor will receive payment as specified in Exhibit B, Rates.

2.2. **Detailed Invoicing and Payment Procedures**

2.2.1. Contractor shall invoice the Department on a monthly basis, by the 15<sup>th</sup> Business Day of the month following the month for which the invoice covers. Contractor shall not invoice the Department for a month prior to the last day of that month.

2.2.2. The invoice shall contain all the following for the month for which the invoice covers:

2.2.2.1. Deliverable Name

2.2.2.1.1. If the project is ad hoc, include the date the project was assigned and a project title

2.2.2.2. Dollar amount billed by Contractor

2.3. **Closeout Payments**

2.3.1. Notwithstanding anything to the contrary in this Contract, all payments for the final month of this Contract shall be paid to Contractor no sooner than 10 days after the Department has determined that Contractor has completed all of the requirements of the Closeout Period.

**EXHIBIT B-1, RATES**  
**STATE FISCAL YEAR 2023**

<b>DELIVERABLE</b>	<b>DATE DUE TO THE DEPARTMENT</b>	<b>FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE</b>
Importation Work Plan Sections 2, 3, and 4	Mutually agreed upon date	Section 2 - \$2,000.00 Section 3 - \$25,000.00 Section 4 - \$5,000.00  <b>Total: \$32,000.00</b>
Profit Margin Methodology	Mutually agreed upon date	\$5,000.00
Section 804 (SIP) Application Support	Mutually agreed upon date	\$200.00/hour NTE \$5,000.00
Co-marketing Program Meetings	Scheduled according to convenience of the Department	\$5,000.00/event NTE \$35,000.00
Colorado Pharmacy Contract Agreements	Upon Receipt	\$250.00/letter NTE \$10,000.00
Mail Order Solution	When requested & date mutually agreed upon	\$5,000.00
Stakeholder Opportunities	Mutually agreed upon date	\$1,000.00 or \$5,000.00/event NTE \$15,000.00
Hourly consulting	Mutually agreed upon date	\$200.00/hour NTE \$5,000.00
Manufacturer Negotiation Support	Mutually agreed upon date	\$200.00/hour NTE \$20,000.00
In-Person Manufacturer Meetings	Mutually agreed upon date	\$5,000.00/event NTE \$30,000.00
Ad Hoc Projects	Mutually agreed upon date	NTE \$100,000.00
<b>TOTAL – STATE FISCAL YEAR 2023</b>		<b>\$262,000.00</b>

**STATE FISCAL YEAR 2024**

<b>DELIVERABLE</b>	<b>DATE DUE TO THE DEPARTMENT</b>	<b>FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE</b>
Section 804 (SIP) Application Support	Mutually agreed upon date	\$200.00/hour NTE \$5,000.00
Colorado Pharmacy Contract Agreements	Upon Receipt	\$250.00/letter NTE \$10,000.00
Stakeholder Support As Requested by the Department	Mutually agreed upon date	\$1000.00 or \$5,000.00/event NTE \$15,000.00
Hourly consulting	Mutually agreed upon date	\$200.00/hour, NTE \$5,000.00
Manufacturer Negotiation Support	Mutually agreed upon date	\$200.00/hour NTE \$20,000.00
In Person Manufacturer Meetings	Mutually agreed upon date	\$5,000.00/event NTE \$20,000.00
Ad Hoc Projects	Mutually agreed upon date	NTE \$50,000.00
<b>TOTAL – STATE FISCAL YEAR 2024</b>		<b>\$125,000.00</b>

**STATE FISCAL YEAR 2025**

<b>DELIVERABLE</b>	<b>DATE DUE TO THE DEPARTMENT</b>	<b>FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE</b>
Section 804 (SIP) Application Support	Mutually agreed upon date	\$200.00/hour NTE \$5,000.00
Stakeholder Support As Requested by the Department	Mutually agreed upon date	\$1000.00 or \$5,000.00/event NTE \$15,000.00
Hourly consulting	Mutually agreed upon date	\$200.00/hour NTE \$5,000.00
Manufacturer Negotiation Support	Mutually agreed upon date	\$200.00/hour NTE \$20,000.00
In Person Manufacturer Meetings	Mutually agreed upon date	\$5,000.00/event NTE \$20,000.00
Ad Hoc Projects	Mutually agreed upon date	NTE \$50,000.00
<b>TOTAL – STATE FISCAL YEAR 2025</b>		<b>\$115,000.00</b>

**STATE FISCAL YEAR 2026**

<b>DELIVERABLE</b>	<b>DATE DUE TO THE DEPARTMENT</b>	<b>FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE</b>
Section 804 (SIP) Application Support	Mutually agreed upon date	\$200.00/hour NTE \$5,000.00
Stakeholder Support As Requested by the Department	Mutually agreed upon date	\$1000.00 or \$5,000.00/event NTE \$15,000.00
Hourly consulting	Mutually agreed upon date	\$200.00/hour NTE \$5,000.00
Manufacturer Negotiation Support	Mutually agreed upon date	\$200.00/hour NTE \$20,000.00
In Person Manufacturer Meetings	Mutually agreed upon date	\$5,000.00/event NTE \$20,000.00
Ad Hoc Projects	Mutually agreed upon date	NTE \$50,000.00
<b>TOTAL – STATE FISCAL YEAR 2026</b>		<b>\$115,000.00</b>

**STATE FISCAL YEAR 2027**

<b>DELIVERABLE</b>	<b>DATE DUE TO THE DEPARTMENT</b>	<b>FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE</b>
Section 804 (SIP) Application Support	Mutually agreed upon date	\$200.00/hour NTE \$5,000.00
Stakeholder Support As Requested by the Department	Mutually agreed upon date	\$1000.00 or \$5,000.00/event NTE \$15,000.00
Hourly consulting	Mutually agreed upon date	\$200.00/hour NTE \$5,000.00
Manufacturer Negotiation Support	Mutually agreed upon date	\$200.00/hour NTE \$20,000.00
In Person Manufacturer Meetings	Mutually agreed upon date	\$5,000.00/event NTE \$20,000.00
Ad Hoc Projects	Mutually agreed upon date	NTE \$50,000.00
<b>TOTAL – STATE FISCAL YEAR 2027</b>		<b>\$115,000.00</b>

**Fiscal Year Totals: SFY 2023-2027**

<b>FISCAL YEAR</b>	<b>AMOUNT</b>
Fiscal Year 2023	\$262,000.00
Fiscal Year 2024	\$115,000.00
Fiscal Year 2025	\$115,000.00
Fiscal Year 2026	\$115,000.00
Fiscal Year 2027	\$115,000.00
<b>TOTAL - All Fiscal Years</b>	<b>\$722,000.00</b>

## EXHIBIT C-1, TERMINOLOGY, APPLICABLE LAWS AND REGULATIONS

### 1. TERMINOLOGY

- 1.1. In addition to the terms defined in §7 of this Contract, the following list of terms shall be construed and interpreted as follows:
- 1.1.1. **Business Interruption** – Any event that disrupts Contractor’s ability to complete the Work for a period of time, and may include, but is not limited to a Disaster, power outage, strike, loss of necessary personnel or computer virus.
- 1.1.2. **Closeout Period** – The period beginning on the earlier of 90 days prior to the end of the last Extension Term or notice by the Department of its decision to not exercise its option for an Extension Term, and ending on the day that the Department has accepted the final Deliverable for the Closeout Period, as determined in the Department-approved and updated Closeout Plan, and has determined that the closeout is complete.
- 1.1.3. **Colorado Revised Statutes (C.R.S.)** – The legal code of Colorado; the legal codified general and permanent statutes of the Colorado General Assembly.
- 1.1.4. **Contractor Management Team** - includes the Key Personnel as defined Exhibit D, Contractor’s Administrative Requirements, section 2.3 as well as ownership of the business.
- 1.1.5. **Data** – State Confidential Information and other State information resources transferred to the Contractor for the purpose of completing a task or project assigned in the Statement of Work.
- 1.1.6. **Deliverable** – Any tangible or intangible product or service produced by Contractor as a result of the Work that is intended to be delivered to the Department, regardless of whether the object is described or called out as a “Deliverable” or not.
- 1.1.7. **Disaster** – An event that makes it impossible for Contractor to perform the Work out of its regular facility or facilities, and may include, but is not limited to, natural disasters, fire or terrorist attacks.
- 1.1.8. **Eligible Prescription Drug (Imported Drug)** - a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act that has been approved and has received a Notice of Compliance and a Drug Identification Number (DIN) from the Health Products and Food Branch of Health Canada.
- 1.1.9. **Expired Product** - a prescription drug for which the date that the manufacturer guarantees the full potency and safety of a medication has passed
- 1.1.10. **Final Rule** - The regulatory structure for State-led Importation Programs set forth by the FDA implementing 21 CFR Parts 1 and 251
- 1.1.11. **Foreign Seller** - an establishment within Canada engaged in the distribution of an Eligible Prescription Drug that is imported or offered for importation into the United States
- 1.1.12. **Fraud** – An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to that person or some other person and includes any act that constitutes Fraud under any federal or state law.
- 1.1.13. **Health Insurance Portability and Accountability Act (HIPAA)** – The Health Insurance Portability and Accountability Act of 1996, as amended.



- 1.1.14. **Importer** - a pharmacist or wholesaler. An Importer must be a State-licensed pharmacist, or a State- or FDA-licensed wholesale distributor, who is the U.S. owner of an Eligible Prescription Drug at the time of entry into the United States.
- 1.1.15. **Key Personnel** – The position or positions that are specifically designated as such in this Contract.
- 1.1.16. **Margin** - the difference between the purchase price and selling price of an imported product.
- 1.1.17. **Markup** - an amount added to an imported product to cover the costs of conducting the business of the Importation Program
- 1.1.18. **Member** – Any individual enrolled in the Colorado Medicaid program, Colorado’s CHP+ program or the Colorado Indigent Care Program, as determined by the Department.
- 1.1.19. **Operational Start Date** – When the Department authorizes Contractor to begin fulfilling its obligations under the Contract.
- 1.1.20. **Other Personnel** – Individuals and Subcontractors, in addition to Key Personnel, assigned to positions to complete tasks associated with the Work.
- 1.1.21. **Program** - Colorado Drug Importation Program
- 1.1.22. **Program Foreign Seller** - the Foreign Seller selected by the Department
- 1.1.23. **Program Qualified Laboratory** - the qualified laboratory selected to participate in the Importation Program
- 1.1.24. **Program Pharmacy** – any pharmacy that purchases Program imported medications for the purpose of dispensing to Colorado residents.
- 1.1.25. **Program Repackager** - the qualified repackager selected to participate in the Importation Program
- 1.1.26. **Qualifying Laboratory** - a laboratory in the United States that has been approved by FDA for the purposes of section 804 of the Federal Food, Drug, and Cosmetic Act.
- 1.1.27. **Recalled product** - a prescription medicine removed from the market because it is found to be either defective or potentially harmful
- 1.1.28. **Relabeler** - an establishment that relabels a drug and is registered with FDA.
- 1.1.29. **Serialization (Pharmaceutical)** - a comprehensive system to track and trace the passage of prescription drugs through the entire supply chain
- 1.1.30. **State** - State of Colorado
- 1.1.31. **State Statute** - SB19-005 passed in May 2019, allowing the Colorado Drug Importation Program to be developed. Can be found in the Colorado Revised Statutes at §25.5-1-201 through §25.5-1-207.
- 1.1.32. **Start-Up Period** – The period starting on the Effective Date and ending on the Operational Start Date.
- 1.1.33. **Suspect Foreign Product/Illegitimate Foreign Product** - a drug purchased by a Foreign Seller from a manufacturer, and intended for sale to an Importer in the United States, for which the Foreign Seller has reason to believe that such product: (1) Is potentially counterfeit, diverted, or stolen; (2) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (3) Is potentially the subject

of a fraudulent transaction; or (4) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

- 1.1.34. **Unit** - the smallest saleable package of a drug (ex: individual box, bottle, and other forms of saleable packaging.)
- 1.1.35. **Warehouse Management system (WMS)** - software application designed to support and optimize warehouse functionality and distribution center management.
- 1.1.36. **Wholesale Drug Distributor (WDD)** - any individual or organization engaged in wholesale distribution of prescription drugs.

## 2. ACRONYMS AND ABBREVIATIONS

- 2.1. To assist the reader in understanding certain acronyms and abbreviations used in this Contract, the following list is provided:
  - 2.1.1. **CFR** – Code of Federal Regulations
  - 2.1.2. **CORA** –Colorado Open Records Act, C.R.S. §24–72–200.1, et. seq.
  - 2.1.3. **C.R.S.** – Colorado Revised Statutes
  - 2.1.4. **FDA** - United State Food and Drug Administration
  - 2.1.5. **FDCA** - Federal Food Drug & Cosmetic Act
  - 2.1.6. **HIPAA** – Health Insurance Portability and Accountability Act of 1996, as amended.
  - 2.1.7. **HPFB** - the Health Products & Food Branch of Health Canada
  - 2.1.8. **NDC** - National Drug Code
  - 2.1.9. **SFY** – State Fiscal Year
  - 2.1.10. **SIP** - Section 804 Importation Proposal - the name of the application to the FDA for an Importation program
  - 2.1.11. **SOP** - Standard Operating Procedure
  - 2.1.12. **U.S.C.** – United States Code
  - 2.1.13. **W.H.I.** - Colorado In-State Wholesaler License
  - 2.1.14. **W.H.O.** - Colorado Out of State Wholesaler License

## 3. APPLICABLE LAWS & REGULATIONS

- 3.1. [21 CFR Parts 1 and 251 - Drug Importation Final Rule](#)
- 3.2. [21 U.S. Code 384 - Importation of Prescription Drugs](#)
- 3.3. [Title II of the Drug Quality and Security Act - Drug Supply Chain Security Act \(DSCSA\)](#)
- 3.4. [Colorado Revised Statutes §25.5-1-201 through 207 \(beginning at page 43\)](#)
- 3.5. [DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry](#)
- 3.6. [Identifying Trading Partners Under the Drug Supply Chain Security Act Guidance for Industry](#)
- 3.7. Facility standards:
  - 3.7.1. [21 CFR Part 205.50](#)

## EXHIBIT D-1, CONTRACTOR ADMINISTRATIVE REQUIREMENTS

### 4. CONTRACTOR'S GENERAL REQUIREMENTS

- 4.1. The Department will contract with only one organization, the Contractor, and will work solely with that organization with respect to all tasks and Deliverables to be completed, Services to be rendered, and performance standards to be met under this Contract.
- 4.2. Contractor may be privy to internal policy discussions, contractual issues, price negotiations, confidential medical information, Department financial information, advance knowledge of legislation, and other Confidential Information. In addition to all other confidentiality requirements of the Contract, the Contractor shall also consider and treat any such information as Confidential Information and shall only disclose it in accordance with the terms of the Contract.
- 4.3. The Contractor shall work cooperatively with Department staff and, if applicable, the staff of other State contractors to ensure the completion of the Work. The Department may, in its sole discretion, use other contractors to perform activities related to the Work that are not contained in the Contract or to perform any of the Department's responsibilities. In the event of a conflict between Contractor and any other State contractor, the State will resolve the conflict and Contractor shall abide by the resolution provided by the State.
- 4.4. The Contractor shall inform the Department on current trends and issues in the healthcare marketplace and provide information on new technologies in use that may affect the Contractor's responsibilities under this Contract.
- 4.5. The Contractor shall maintain complete and detailed records of all meetings, system development life cycle documents, presentations, project artifacts, and any other interactions or Deliverables related to the Work described in the Contract. The Contractor shall make such records available to the Department upon request throughout the term of the Contract.
- 4.6. **Deliverables**
  - 4.6.1. All Deliverables shall meet Department-approved format and content requirements. The Department will specify the number of copies and media for each Deliverable.
    - 4.6.1.1. Contractor shall submit each Deliverable to the Department for review and approval and shall adhere to the following Deliverable process for any documentation, review, and acceptable cycle, the Contractor shall:
      - 4.6.1.1.1. Gather and document requirements for the Deliverable.
      - 4.6.1.1.2. Create a draft in the Department-approved format for the individual Deliverable.
      - 4.6.1.1.3. Perform internal quality control review(s) of the Deliverable, including, but not limited to:
        - 4.6.1.1.3.1. Readability.
        - 4.6.1.1.3.2. Spelling.
        - 4.6.1.1.3.3. Grammar.
        - 4.6.1.1.3.4. Completion.
      - 4.6.1.1.4. Adhere to all required templates or development of templates.

- 4.6.1.1.5. Perform modifications that include version control and tracked changes.
- 4.6.1.2. The Department will review the Deliverable and may direct Contractor to make changes to the Deliverable. Contractor shall make all changes within five Business Days following the Department's direction to make the change unless the Department provides a longer period in writing.
  - 4.6.1.2.1. Changes the Department directs may include but are not limited to: modifying portions of the Deliverable, requiring new pages or portions of the Deliverable, requiring resubmission of the Deliverable, requiring inclusion of information, or components that were left out of the Deliverable.
  - 4.6.1.2.2. The Department may also direct Contractor to provide clarification or provide a walkthrough of any Deliverable to assist the Department in its review. Contractor shall provide the clarification or walkthrough as directed by the Department.
- 4.6.1.3. Once the Department has received an acceptable version of the Deliverable, including all changes directed by the Department, the Department will notify Contractor of its acceptance of the Deliverable in writing. A Deliverable shall not be deemed accepted prior to the Department's notice to Contractor of acceptance of that Deliverable.
- 4.6.2. Contractor shall employ an internal quality control process to ensure that all Deliverables are complete, accurate, easy to understand and of high quality, as described herein. Contractor shall provide Deliverables that, at a minimum, are responsive to the specific requirements for that Deliverable, organized into a logical order, containing accurate spelling and grammar, uniformly formatted, containing accurate information, and correct calculations. Contractor shall retain all draft and marked-up documents and checklists utilized in reviewing Deliverables for reference as directed by the Department.
- 4.6.3. In the event any due date for a Deliverable falls on a day that is not a Business Day, the due date shall be automatically extended to the next Business Day, unless otherwise directed by the Department.
- 4.6.4. All due dates or timelines that reference a period of days, months or quarters shall be measured in calendar days, months and quarters unless specifically stated as being measured in Business Days or otherwise. All times stated in the Contract shall in Mountain Time, adjusted for Daylight Saving Time as appropriate, unless specifically stated otherwise.
- 4.6.5. No Deliverable, report, Data, procedure, or system created by Contractor for the Department that is necessary to fulfil Contractor's responsibilities under the Contract, as determined by the Department, shall be considered proprietary.
- 4.6.6. If any Deliverable contains ongoing responsibilities or requirements for the Contractor, such as Deliverables that are plans, policies, or procedures, then Contractor shall comply with all requirements of the most recently approved version of that Deliverable. Contractor shall not implement any version of any such Deliverable prior to receipt of the Department's written approval of that version. Once a version of any Deliverable described in this subsection is approved by the Department, all requirements, milestones, and other Deliverables contained within that Deliverable shall be requirements, milestones, and Deliverables of this Contract.
  - 4.6.6.1. Any Deliverable described as an update of another Deliverable shall be a version of the original Deliverable for the purposes of this subsection.

#### **4.7. Stated Deliverables and Performance Standards**

4.7.1. Any section within this Statement of Work headed with or including the term "DELIVERABLE" or "PERFORMANCE STANDARD" is intended to highlight a Deliverable or Performance Standard contained in this Statement of Work and provide a clear due date for the Deliverables. The sections with these headings are for ease of reference not intended to expand or limit the requirements or responsibilities related to any Deliverable or Performance Standard, except to provide the due date for the Deliverables.

**4.8. Communication with the Department**

4.8.1. The Contractor shall enable all Contractor staff to exchange documents and electronic files with the Department staff in formats compatible with the Department's systems. The Department currently uses Microsoft Office 2016 and/or Microsoft Office 365 for PC. If the Contractor uses a compatible program, then the Contractor shall ensure that all documents or files delivered to the Department are completely transferrable and reviewable, without error, on the Department's systems.

4.8.2. The Department will use electronic mail to provide the Contractor with official direction within the scope of the Contract. The Contractor shall comply with all direction contained within these Program emails. For a transmittal to be considered complete, it must include, at a minimum, all of the following:

4.8.2.1. The date the request will be effective.

4.8.2.2. Direction to the Contractor regarding performance under the Contract.

4.8.2.3. A due date or timeline by which the Contractor shall comply with the direction contained in the request.

4.8.2.4. The signature of the Department employee who has been designated to sign transmittals.

4.8.2.4.1. The Department will provide the Contractor with the name of the person it has designated to sign documents on behalf of the Department, who will be the Department's primary designee. The Department will also provide the Contractor with a list of backups who may sign a transmittal on behalf of the Department if the primary designee is unavailable. The Department may change any of its designees by providing notice to the Contractor through an email request.

4.8.3. The Department may deliver a completed request to the Contractor in hard copy, as a scanned attachment to an email or through a dedicated communication system, if such a system is available.

4.8.4. If the Contractor receives conflicting requests, the Contractor shall contact the Department's primary designee, or backup designees if the primary designee is unavailable, to obtain direction. If the Department does not provide direction otherwise, then the request or directive with the latest Effective Date shall control.

4.8.5. If the Contractor receives direction from the Department outside of the normal process, it shall contact the Department's primary designee, or backup designees if the primary designee is unavailable, and have the Department confirm that direction through a written communication prior to complying with that direction.

4.8.6. The Contractor shall retain all written requests for reference and shall provide copies of any received transmittals upon request by the Department.

**4.8.7. Business Continuity Plan**

- 4.8.7.1. The Contractor shall maintain a Business Continuity Plan that the Contractor will follow in order to continue operations after a Disaster or a Business Interruption. The Business Continuity Plan shall include, but is not limited to, all of the following:
  - 4.8.7.1.1. Staff Replacement plan for the Colorado Program
  - 4.8.7.1.2. Information Back Up Systems Process
  - 4.8.7.1.3. In the event of a Disaster, the plan for participating Colorado Program Medications
  - 4.8.7.1.4. Maintenance of backup copies of all Data, Databases, operating programs, files, systems, and software pertaining the State Program
  - 4.8.7.1.5. Department Communication Plan
  - 4.8.7.1.6. Back Up Facility Plan for Colorado Program Medications.
  - 4.8.7.1.7. Transition Time period to the backup facility
  - 4.8.7.1.8. **DELIVERABLE:** Business Continuity Plan
  - 4.8.7.1.9. **DUE:** 10 Business Days prior to active importation beginning and then annually upon execution of the Contract in future years.

4.9. **Closeout Period**

- 4.9.1. During the Closeout Period, the Contractor shall complete all of the following:
  - 4.9.1.1. Finalize existing projects as directed by the Department.
  - 4.9.1.2. Provide to the Department, or any other contractor at the Department's direction, all reports, Data, systems, Deliverables and other information reasonably necessary for a transition as determined by the Department or included in the most recent Closeout Plan or Closeout Plan Update that has been approved by the Department.
  - 4.9.1.3. Ensure that all responsibilities under the Contract have been transferred to the Department, or to another contractor at the Department's direction, without significant interruption.
  - 4.9.1.4. Notify any Subcontractors of the termination of the Contract, as directed by the Department.
  - 4.9.1.5. Notify all applicable Subcontractors, that Contractor will no longer be the Importer as directed by the Department. Contractor shall create these notifications and deliver them to the Department for approval. Once the Department has approved the notifications, Contractor shall deliver these notifications to all applicable Subcontractors, but in no event shall Contractor deliver any such notification prior to approval of that notification by the Department.
    - 4.9.1.5.1. **DELIVERABLE:** Subcontractor Notifications
    - 4.9.1.5.2. **DUE:** 30 days prior to termination of the Contract

4.10. **Performance Reviews**

- 4.10.1. The Department may conduct performance reviews or evaluations of the Contractor in relation to the Work performed under the Contract.
- 4.10.2. The Department may work with the Contractor in the completion of any performance reviews or evaluations or the Department may complete any or all performance reviews or evaluations

independently, at the Department's sole discretion.

- 4.10.3. The Contractor shall provide all information necessary for the Department to complete all performance reviews or evaluations, as determined by the Department, upon the Department's request. The Contractor shall provide this information regardless of whether the Department decides to work with the Contractor on any aspect of the performance review or evaluation.
- 4.10.4. The Department may conduct these performance reviews or evaluations at any point during the term of the Contract, or after termination of the Contract for any reason.
- 4.10.5. The Department may make the results of any performance reviews or evaluations available to the public or may publicly post the results of any performance reviews or evaluations.

**4.11. Renewal Options and Extensions**

- 4.11.1. The Department may, within its sole discretion, choose to not exercise any renewal option in the Contract for any reason. If the Department chooses to not exercise an option, it may reprocure the performance of the Work at its sole discretion.
- 4.11.2. The Parties may amend the Contract to extend beyond five years, in accordance with the Colorado Procurement Code and its implementing rules, if the Department determines an 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.
- 4.11.3. If the Contract is extended beyond five years, the annual maximum compensation for the Contract in any of those additional years shall not exceed the Contract maximum amount for the prior State Fiscal Year (SFY) plus the annual percent increase in the Consumer Price Index for All Urban Consumers (CPI-U) for the Denver-Boulder-Greeley metropolitan area for the calendar year ending during that prior SFY. If the CPI-U for Denver-Boulder-Greeley is for some reason not available as specified in this subsection, the increase shall be equal to the percent increase in the CPI-U (U.S.) for the same period.
- 4.11.4. The limitation on the annual maximum compensation in this Contract shall not include increases made specifically as compensation for additional Work added to the Contract.

**4.12. Department System Access**

- 4.12.1. If the Contractor requires access to any Department computer system to complete the Work, the Contractor shall have and maintain all hardware, software, and interfaces necessary to access the system without requiring any modification to the Department's system. The Contractor shall follow all Department policies, processes, and procedures necessary to gain access to the Department's systems.
- 4.12.2. The Contractor shall be responsible for any costs associated with obtaining and maintaining access to systems needed to perform the Work under this solicitation, as determined by the Department. The Department will not reimburse the Contractor for any costs associated with obtaining and maintaining access to Department systems.

**5. CONTRACTOR PERSONNEL**

**5.1. Personnel General Requirements**

- 5.1.1. Contractor shall provide qualified Key Personnel and Other Personnel as necessary to perform the Work throughout the term of the Contract.

- 5.1.1.1. Contractor shall provide the Department with a final list of individuals assigned to the Contract and appropriate contact information for those individuals.
- 5.1.1.1.1. **DELIVERABLE:** Final list of individuals assigned to the Contract
- 5.1.1.1.2. **DUE:** Within five Business Days after the Effective Date
- 5.1.1.2. Contractor shall update this list upon the Department's request to account for changes in the individuals assigned to the Contract.
- 5.1.1.2.1. **DELIVERABLE:** Updated list of individuals assigned to the Contract
- 5.1.1.2.2. **DUE:** Within five Business Days after the Department's request for an update
- 5.1.2. Contractor shall not permit any individual proposed for assignment to Key Personnel positions to perform any Work prior to the Department's approval of that individual's assignment as Key Personnel.
- 5.1.3. Contractor shall not voluntarily change individuals in Key Personnel positions without the prior written approval of the Department. Contractor shall supply the Department with the name, resume, and references for any proposed replacement whenever there is a change to Key Personnel. Any individual replacing Key Personnel shall have qualifications that are equivalent to or exceed the qualifications of the individual that previously held the position, unless otherwise approved in writing by the Department.
- 5.1.3.1. **DELIVERABLE:** Name(s) and resume(s) for any person(s) replacing a Key Personnel position during a voluntary change
- 5.1.3.2. **DUE:** At least five Business Days prior to the change in Key Personnel
- 5.1.4. If any individual filling a Key Personnel position leaves employment with Contractor, Contractor shall propose a replacement person to the Department. The replacement person shall have qualifications that are equivalent to or exceed the qualifications of the individual that previously held the position, unless otherwise approved, in writing, by the Department.
- 5.1.4.1. **DELIVERABLE:** Name(s) and resume(s) for any person(s) replacing a Key Personnel position who leaves employment with Contractor
- 5.1.4.2. **DUE:** Within 10 Business Days after Contractor's receipt of notice of resignation unless the Department allows for a longer time in writing for Contractor to recruit a replacement.
- 5.1.5. Contractor's Key Personnel shall perform the majority of their work and responsibilities on this project in the Denver metropolitan area, unless the Department grants permission otherwise in writing.
- 5.1.6. If any of Contractor's Key Personnel or Other Personnel are required to have and maintain any professional licensure or certification issued by any federal, state, or local government agency, then Contractor shall submit copies of such current licenses and certifications to the Department.
- 5.1.6.1. **DELIVERABLE:** All current professional licensure and certification documentation as specified for Key Personnel or Other Personnel
- 5.1.6.2. **DUE:** Within five Business Days of receipt of updated licensure or upon request by the Department

## 5.2. Personnel Availability



- 5.2.1. Contractor shall ensure Key Personnel and Other Personnel assigned to the Contract are available for meetings with the Department during the Department's normal business hours, as determined by the Department. Contractor shall also make these personnel available outside of the Department's normal business hours, and on weekends, with prior notice from the Department.
- 5.2.2. Contractor's Key Personnel and Other Personnel shall be available for all regularly scheduled meetings between Contractor and the Department unless the Department has granted prior written approval otherwise.
- 5.2.3. Contractor shall ensure that the Key Personnel and Other Personnel attending all meetings between the Department and Contractor have the authority to represent and commit Contractor regarding work planning, problem resolution, and Program development.
- 5.2.4. At the Department's direction, the Contractor shall make its Key Personnel and Other Personnel available to attend meetings, as subject matter experts, with stakeholders both within the State government and external private stakeholders.
- 5.2.5. All of Contractor's Key Personnel and Other Personnel that attend any meeting with the Department or other Department stakeholders shall be physically present at the location of the meeting, unless the Department gives prior, written permission to attend by telephone or video conference. If Contractor has any personnel attend by telephone or video conference, Contractor shall provide all additional equipment necessary for attendance, including any virtual meeting space or telephone conference lines.
- 5.2.6. The Contractor shall respond to all telephone calls, voicemails, and emails from the Department within two Business Days of receipt by the Contractor.

**5.3. Key Personnel**

5.3.1. The Contractor shall provide the Department with a list of individuals assigned to the Contract and appropriate contact information for those individuals. The Contractor shall designate people to hold the following Key Personnel positions. The Contractor shall ensure that the following roles are filled, and the Contractor is able to complete the requirements on an ongoing basis. The Contractor shall designate people to hold the following Key Personnel positions:

5.3.1.1. Project Lead

5.3.1.1.1. The Project Lead shall have the following qualifications:

5.3.1.1.1.1. Project Management Experience

5.3.1.1.1.2. The project lead may serve as the project lead and hold a different Key Personnel position, as defined below.

5.3.1.1.2. The Project Lead shall be responsible for the following:

5.3.1.1.2.1. Serving as Contractor's primary point of contact for the Department.

5.3.1.1.2.2. 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.

5.3.1.1.2.3. Overseeing all other Key Personnel and Other Personnel and ensuring proper staffing levels throughout the term of the Contract.

- 5.3.1.2. Importation Wholesale Manager
  - 5.3.1.2.1. Pharmaceutical Wholesale management experience
  - 5.3.1.2.2. Management of a quality assurance program including on site evaluations, internal audits, and customer surveys
  - 5.3.1.2.3. Pharmaceutical commercial experience
  - 5.3.1.2.4. Pharmaceutical pedigree tracking system experience
  - 5.3.1.2.5. Background in the practice of pharmacy management
- 5.3.1.3. Importation Operations Manager
  - 5.3.1.3.1. Supply Chain Experience
  - 5.3.1.3.2. Warehouse Management System (WMS) Experience
  - 5.3.1.3.3. Data Analysis experience
  - 5.3.1.3.4. Pharmaceutical pedigree tracking system experience
  - 5.3.1.3.5. Pharmaceutical wholesaler management experience
  - 5.3.1.3.6. Inventory management experience
- 5.3.2. Contractor shall not allow for any individual to fill more than one of the roles defined as Key Personnel unless stated above or approved in writing by the Department.
- 5.3.3. In the event of significant change in the Contractor's management team, Contractor shall notify the Department within three Business Days and the Department reserves the right to terminate the Contract if mutually agreeable replacements are not identified within 30 days.
- 5.3.4. The Contractor shall ensure the Department is aware of changes in Key Personnel working on the Importation Program. Should changes to the core team occur, the Contractor shall send resumes for newly added staff member who has an operational or oversight role in the Program.
- 5.3.5. The Department reserves the right to request changes to the Key Personnel working on the Program should the Department have concerns about the capabilities, responsiveness, or general quality of work.
- 5.4. Other Personnel Responsibilities
  - 5.4.1. Contractor shall use its discretion to determine the number of Other Personnel necessary to perform the Work in accordance with the requirements of this Contract. If the Department determines that Contractor has not provided sufficient Other Personnel to perform the Work in accordance with the requirements of this Contract, Contractor shall provide all additional Other Personnel necessary to perform the Work in accordance with the requirements of this Contract at no additional cost to the Department.
  - 5.4.2. Contractor shall ensure that all Other Personnel have sufficient training and experience to complete all portions of the Work assigned to them. Contractor shall provide all necessary training for its Other Personnel, except for State-provided training specifically described in this Contract.
  - 5.4.3. Contractor may subcontract to complete a portion of the Work required by the Contract. The conditions for using a Subcontractor or Subcontractors are as follows:

- 5.4.3.1. Contractor shall not subcontract more than 40% of the Work on behalf of, or in addition to, the Contractor.
- 5.4.3.2. Contractor shall provide the organizational name of each Subcontractor and all responsibilities of each Subcontractor to the Department.
- 5.4.3.3. The Department may request a specific expertise profile to fulfill certain aspects of importation-related work.
- 5.4.3.4. If the Contractor determines that a Subcontractor's expertise is needed, the Contractor shall submit that Subcontractor's name and qualifications to the Department for review and written approval.
- 5.4.3.5. No subcontractor may begin Work before written approval is provided by the Department.
- 5.4.3.5.1. **DELIVERABLE:** Approval Request with Subcontractor List and Responsibilities
- 5.4.3.5.2. **DUE:** The later of 30 days prior to the Subcontractor beginning work or the Effective Date

5.5. Non-Solicitation of Department Employees

- 5.5.1. Contractor shall not recruit any employee of the Department for employment with Contractor during the term of this Contract, except that Contractor may accept applications from Department employees submitted independently by the employee.
- 5.5.2. Contractor acknowledges that all State employees are subject to the ethical principles described in §24-18-105, C.R.S. Contractor further acknowledges that State employees may be subject to the requirements of §24-18-105, C.R.S. with regard to this Contract. For the avoidance of doubt, an actual or apparent conflict of interest shall exist if Contractor employs or contracts with any State employee or any former State employee, or any immediate family member of such current or former State employee, within six months following such employee's termination of employment with the State. Contractor shall provide a written disclosure to the Department no later than ten days following entry into a contractual or employment relationship as described in this section. Failure to timely submission of a disclosure statement shall constitute a Breach of Contract. Contractor may also be subject to such penalties as permitted by law.

**6. INFORMATION TECHNOLOGY RELATED REQUIREMENTS**

6.1. Protection of System Data

- 6.1.1. In addition to the requirements of the main body of this Contract, if Contractor, or any Subcontractor, is given access to State Records by the State, or its agents in connection with Contractor's performance under the Contract, Contractor shall protect all State Records in accordance with this Exhibit. All provisions of this Exhibit that refer to Contractor shall apply equally to any Subcontractor performing Work in connection with the Contract.
- 6.1.2. For the avoidance of doubt, the terms of this Exhibit shall apply to the extent that any one of the following statements is true in regard to Contractor access, use, or disclosure of State Records:
  - 6.1.2.1. Contractor provides physical or logical storage of State Records.
  - 6.1.2.2. Contractor creates, uses, processes, discloses, transmits, or disposes of State Records.

- 6.1.2.3. Contractor is otherwise given physical or logical access to State Records to perform Contractor's obligations under this Contract.
- 6.1.3. Contractor shall, and shall cause its Subcontractors, to do the following:
  - 6.1.3.1. Provide physical and logical protection for all hardware, software, applications, and Data that meets or exceeds industry standards and the requirements of this Contract.
  - 6.1.3.2. Maintain network, system, and application security, which includes, but is not limited to: network firewalls, intrusion detection (host and network), annual security testing, and improvements or enhancements consistent with evolving industry standards.
  - 6.1.3.3. Comply with State and federal rules and regulations related to overall security, privacy, confidentiality, integrity, availability, and auditing.
  - 6.1.3.4. Provide that security is uncompromised by unauthorized access to workspaces, computers, networks, software, Databases, or other physical or electronic environments.
  - 6.1.3.5. Promptly report all Incidents, including Incidents that do not result in unauthorized disclosure or loss of Data integrity, to the State.
- 6.1.4. Colorado Information Security Policy (CISP) Compliance
  - 6.1.4.1. Contractor shall assess its compliance with the CISPs, in effect at the time of the assessment, issued by the Governor's Office of Information Technology ("OIT") posted at [www.oit.state.co.us/about/policies](http://www.oit.state.co.us/about/policies) under Information Security.
  - 6.1.4.2. For the purposes of reviewing and assessing compliance with the CISPs, the Contractor shall consider itself to be both the Information Technology Service Provider (ITSP) and Business Owner.
  - 6.1.4.3. Contractor shall deliver to the State the signed CISP Attestation, on a form provided by the Department, indicating that Contractor has assessed its compliance with the CISPs and has developed a plan to correct, in a timely manner, any security vulnerabilities identified during the assessment.
    - 6.1.4.3.1. **DELIVERABLE:** CISP Attestation
    - 6.1.4.3.2. **DUE:** Within 30 Business Days after the Effective Date
  - 6.1.4.4. Contractor shall assess its compliance with the CISPs on an annual basis and deliver to the State the signed CISP Attestation, on a form provided by the Department.
    - 6.1.4.4.1. **DELIVERABLE:** Annual CISP Attestation
    - 6.1.4.4.2. **DUE:** Annually, by June 30<sup>th</sup> of each year
  - 6.1.4.5. Contractor shall cause its Subcontractors to comply with the CISPs and to assess their compliance on at least an annual basis. If any Subcontractor's assessment determines that the Subcontractor is not in compliance, then Contractor shall ensure that Subcontractor corrects, in a timely manner, any security vulnerabilities identified during the assessment.
- 6.1.5. Subject to Contractor's reasonable access security requirements and upon reasonable prior notice, Contractor shall provide the State with scheduled access for the purpose of inspecting and monitoring access and use of State Records, maintaining State systems, and evaluating physical and logical security control effectiveness.

- 6.1.6. Contractor shall perform background checks on all its respective employees and agents performing Services or having access to State Records provided under this Contract. A background check performed during the hiring process shall meet this requirement. Contractor shall perform a background check on any employee if the Contractor becomes aware of any reason to question the employability of an existing employee. Contractor shall require all Subcontractors to meet the standards of this requirement.
- 6.1.6.1. Contractor shall deliver to the State the signed Background Check Attestation, on a form provided by the Department, indicating that background checks were completed on employees participating in operations related to this Contract.
- 6.1.6.1.1. **DELIVERABLE:** Background Check Attestation
- 6.1.6.1.2. **DUE:** Within 30 Business Days of the Effective Date
- 6.1.6.2. If Contractor will have access to Federal Tax Information under the Contract, Contractor shall agree to the State's requirements regarding Safeguarding Requirements for Federal Tax Information and shall comply with the background check requirements defined in IRS Publication 1075 and §24-50-1002, C.R.S.

## 6.2. Data Handling

- 6.2.1. The State, in its sole discretion, may securely deliver State Records directly to Contractor. Contractor shall maintain these State Records only within facilities or locations that Contractor has attested are secure, including for the authorized and approved purposes of backup and Disaster recovery purposes. Contractor may not maintain State Records in any Data center or other storage location outside the United States for any purpose without the prior express written consent of the State.
- 6.2.2. Contractor shall not allow remote access to State Records from outside the United States, including access by Contractor's employees or agents, without the prior express written consent of OIS. Contractor shall communicate any request regarding non-U.S. access to State Records to the Security and Compliance Representative for the State. The State shall have sole discretion to grant or deny any such request.
- 6.2.3. Upon request by the State made any time prior to 60 days following the termination of this Contract for any reason, whether or not the Contract is expiring or terminating, Contractor shall make available to the State a complete and secure download file of all Data that is encrypted and appropriately authenticated. This download file shall be made available to the State within 10 Business Days of the State's request, and shall contain, without limitation, all State Records, Work Product, and system schema and transformation definitions, or delimited text files with documents, detailed schema definitions along with attachments in its native format. Upon the termination of Contractor's provision of Data processing services, Contractor shall, as directed by the State, return all State Records provided by the, and the copies thereof, to the State or destroy all such State Records and certify to the State that it has done so. If legislation imposed upon Contractor prevents it from returning or destroying all or part of the State Records provided by the State to Contractor, Contractor shall guarantee the confidentiality of all State Records provided by the State to Contractor and will not continue to actively process such Data.
- 6.2.4. The State retains the right to use the established operational services to access and retrieve State Records stored on Contractor's infrastructure at its sole discretion and at any time. Upon request of the State or of the supervisory authority, Contractor shall submit its Data

processing facilities for an audit of the measures referred to in this Exhibit in accordance with the terms of this Contract.

### 6.3. Contractor's General Requirements Deliverables

<b>DELIVERABLE</b>	<b>DATE DUE TO THE DEPARTMENT</b>
Business Continuity Plan	10 Business Days prior to active importation
Subcontractor Notifications	30 days prior to termination of Contract
Final List of Individuals Assigned to the Contract	Within five Business Days after the Effective Date
Updated List of Individuals Assigned to the Contract	Within five Business Days after the Department's request for an update
Name(s) and Resume(s) for new Key Personnel During a Voluntary Change	At least five Business Days prior to the change in Key Personnel
Name(s) and Resume(s), for new Key Personnel Replacing Resigning Key Personnel	Within 10 Business Days after Contractor's receipt of notice from Resigning Key Personnel
Professional Licensure and Certification Documentation	Within five Business Days of receipt of updated licensure/certification or upon request by the Department
List of Subcontractors and Responsibilities	The later of 30 days prior to the Subcontractor beginning Work or the Effective Date
CISP Attestation	Within 30 Business Days after the Effective Date
Annual CISP Attestation	Annually, by June 30 <sup>th</sup> of each year
Background Check Attestation	Within 30 Business Days of the Effective Date