

CONTRACT AMENDMENT #1

Signature and Cover Page

State Agency Department of Health Care Policy and Financing	Original Contract Number C23-177864
Contractor AdiraMedica, LLC	Amendment Contract Number C23-177864A1
Current Contract Maximum Amount Initial Term State Fiscal Year 2023 \$448,000.00 Extension Terms State Fiscal Year 2024 \$455,000.00 State Fiscal Year 2025 \$461,000.00 State Fiscal Year 2026 \$455,000.00 State Fiscal Year 2027 \$455,000.00 Total for All State Fiscal Years \$2,274,000.00	Contract Performance Beginning Date August 2, 2022 Current Contract Expiration Date 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;">CONTRACTOR AdiraMedica, LLC</p> <p style="text-align: center;">DocuSigned by:  B33CADE480AE46F...</p> <p>By: _____ Date: <u>2/28/2023 20:50 GMT</u></p>	<p style="text-align: center;">STATE OF COLORADO Jared S. Polis, Governor Department of Health Care Policy and Financing</p> <p style="text-align: center;">DocuSigned by:  0B6A84797EA8493...</p> <p>By: _____ Date: <u>2/28/2023 13:29 PST</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;">STATE CONTROLLER Robert Jaros, CPA, MBA, JD</p> <p style="text-align: center;">DocuSigned by:  76F69541272B43A...</p> <p>By: _____ Date: <u>2/28/2023 13:59 PST</u></p> <p>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 Contractor and the State.

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 of 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 boilerplate contract language and clarify the Statement of Work.

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. 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. All references to Exhibit A shall now be deemed to reference Exhibit A-1.
- C. Exhibit B, Rates, is hereby deleted in its entirety and replaced with Exhibit B-1, Rates, attached hereto and incorporated by reference. All references to Exhibit B shall now be deemed to reference Exhibit B-1.

- D. Exhibit C, Terminology, is hereby deleted in its entirety and replaced with Exhibit C-1, Terminology, attached hereto and incorporated by reference. All references to Exhibit C shall now be deemed to reference Exhibit C-1.
- E. Exhibit D, Administrative Requirements, is hereby deleted in its entirety and replaced with Exhibit D-1, Administrative Requirements, attached hereto and incorporated by reference. All references to Exhibit D shall now be deemed to reference Exhibit D-1
- F. Section 2 through Section 16 of the Contract are hereby deleted in their entirety and replaced with the following:

6. TERM AND EFFECTIVE DATE

A. Effective Date

This Contract shall not be valid or enforceable until the Effective Date. The State shall not be bound by any provision of this Contract before the Effective Date and shall have no obligation to pay Contractor for any Work performed or expense incurred before the Effective Date or after the expiration or sooner termination of this Contract.

B. Initial Term

The Parties' respective performances under this Contract shall commence on the Contract Performance Beginning Date shown on the Cover Page for this Contract and shall terminate on the Initial Contract Expiration Date shown on the Cover Page for this Contract (the "Initial Term") unless sooner terminated or further extended in accordance with the terms of this Contract.

C. Extension Terms

This agreement may be extended up to a maximum of five years via a Contract Amendment.

D. End of Term Extension

If this Contract approaches the end of its Initial Term, or any Extension Term then in place, the State, at its discretion, upon written notice to Contractor as provided in §14, may unilaterally extend such Initial Term or Extension Term for a period not to exceed two months (an "End of Term Extension"), regardless of whether additional Extension Terms are available or not. The provisions of this Contract in effect when such notice is given shall remain in effect during the End of Term Extension. The End of Term Extension shall automatically terminate upon execution of a replacement contract or modification extending the total term of this Contract.

E. Early Termination in the Public Interest

The State is entering into this Contract to serve the public interest of the State of Colorado as determined by its Governor, General Assembly, or Courts. If this Contract ceases to further the public interest of the State, the State, in its discretion, may terminate this Contract in whole or in part. A determination that this Contract should be terminated in the public interest shall not be equivalent to a State right to terminate for convenience. This subsection shall not apply to a termination of this Contract by the State for breach by Contractor, which shall be governed by §12.

i. Method and Content

The State shall notify Contractor of such termination in accordance with §14. The notice shall specify the effective date of the termination and whether it affects all or a portion of this Contract, and shall include, to the extent practicable, the public interest justification for the termination.

ii. Obligations and Rights

Upon receipt of a termination notice for termination in the public interest, Contractor shall be subject to the rights and obligations set forth in §12.

iii. If the State terminates this Contract in the public interest, the State shall pay Contractor an amount equal to the percentage of the total reimbursement payable under this Contract that corresponds to the percentage of Work satisfactorily completed and accepted, as determined by the State, less payments previously made. Additionally, if this Contract is less than 60% completed, as determined by the State, the State may reimburse Contractor for a portion of actual out-of-pocket expenses, not otherwise reimbursed under this Contract, incurred by Contractor that are directly attributable to the uncompleted portion of Contractor's obligations, provided that the sum of any and all reimbursement shall not exceed the maximum amount payable to Contractor hereunder.

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 material obligations in accordance with this Contract after written notice and a Ten (10) day period to cure, in whole or in part or in a timely or reasonably satisfactory manner. The institution of proceedings under any bankruptcy, insolvency, reorganization or similar law, by or against Contractor (in the case of the commencement of proceedings against Contractor, if such proceedings are not dismissed after 60 days), or the appointment of a receiver or similar officer for Contractor or any of its property, which is not vacated or fully stayed within 60 days after such appointment, 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) or a legal or general holiday in Canada.
- 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. “**Contractor Confidential Information**” shall mean all information that Contractor does redact as allowed by CORA from any documents or information provided or made available by Contractor to the State and that Contractor identifies as confidential.
- E. “**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.
- F. “**Contract Funds**” means the funds that have been appropriated, designated, encumbered, or otherwise made available for payment by the State under this Contract.

- G. “**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.
- H. “**Colorado Open Records Act (CORA)**” means C.R.S. §24-72-200.1, et. seq.
- 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.
- J. “**End of Term Extension**” means the time period defined in §2.D.
- 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 §2.C
- M. “**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.
- N. “**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 State Confidential Information, 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 in Controller’s possession, custody or control; (ii) unwanted disruption or denial of service; (iii) the unauthorized use of a State system for the processing or storage of data; or (iv) changes to State system hardware, firmware, or software characteristics without the State’s knowledge, instruction, or consent.
- O. “**Initial Term**” means the time period defined in §2.B.
- P. “**Party**” means the State or Contractor, and “**Parties**” means both the State and Contractor.
- Q. “**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.
- R. “**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, 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.
- S. “**State Fiscal Rules**” means the fiscal rules promulgated by the Colorado State Controller pursuant to C.R.S. §24-30-202(13)(a).

- T. **“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.
- U. **“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.
- V. **“Subcontractor”** means third parties, if any, engaged by Contractor to aid in performance of the Work.
- W. **“Work”** means the Goods delivered and Services performed pursuant to this Contract.
- X. **“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, know-how, 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. STATEMENT OF WORK

Contractor shall complete the Work as described in this Contract and in accordance with the provisions of Exhibit A, and Exhibit D. The State shall have no liability to compensate Contractor for the delivery of any goods or the performance of any services that are not specifically set forth in this Contract.

The State, at its discretion, shall have the option to increase or decrease the statewide quantity of Goods and Services based upon rates established in this Contract, and increase the maximum amount payable accordingly. In order to exercise this option, the State shall provide written notice to Contractor in a form substantially equivalent to the Sample Option Letter attached to this contract. Delivery of Goods and performance of Services shall continue at the same rates and terms as described in this Contract.

9. PAYMENTS TO CONTRACTOR

A. Maximum Amount

Payments to Contractor are limited to the unpaid, obligated balance of the Contract Funds. The State shall not pay Contractor any amount under this Contract that exceeds the Contract Maximum for that State Fiscal Year shown on the Cover Page for this Contract.

B. Payment Procedures

i. Invoices and Payment

- a. The State shall pay Contractor in the amounts and in accordance with the schedule and other conditions set forth in Exhibit A1, Statement of Work and Exhibit B1, Rates.
- b. Contractor shall initiate payment requests by invoice to the State, in a form and manner approved by the State.

- c. The State shall pay each invoice within 45 days following the State's receipt of that invoice, so long as the amount invoiced correctly represents Work completed by Contractor and previously accepted by the State during the term that the invoice covers. If the State determines that the amount of any invoice is not correct, then Contractor shall make all changes necessary to correct that invoice.
- d. The acceptance of an invoice shall not constitute acceptance of any Work performed or deliverables provided under this Contract

ii. Interest

Amounts not paid by the State within 45 days of the State's acceptance of the invoice shall bear interest on the unpaid balance beginning on the 45th day at the rate of one percent per month, as required by C.R.S. §24-30-202(24)(a), until paid in full; provided, however, that interest shall not accrue on unpaid amounts that the State disputes in writing. Contractor shall invoice the State separately for accrued interest on delinquent amounts, and the invoice shall reference the delinquent payment, the number of day's interest to be paid and the interest rate.

iii. Payment Disputes

If Contractor disputes any calculation, determination or amount of any payment, Contractor shall notify the State in writing of its dispute within 30 days following the earlier to occur of Contractor's receipt of the payment or notification of the determination or calculation of the payment by the State. The State will review the information presented by Contractor and may make changes to its determination based on this review. The calculation, determination or payment amount that results from the State's review shall not be subject to additional dispute under this subsection. No payment subject to a dispute under this subsection shall be due until after the State has concluded its review, and the State shall not pay any interest on any amount during the period it is subject to dispute under this subsection.

iv. Available Funds-Contingency-Termination

The State is prohibited by law from making commitments beyond the term of the current State Fiscal Year. Payment to Contractor beyond the current State Fiscal Year is contingent on the appropriation and continuing availability of Contract Funds in any subsequent year (as provided in the Colorado Special Provisions). If federal funds or funds from any other non-State funds constitute all or some of the Contract Funds, the State's obligation to pay Contractor shall be contingent upon such non-State funding continuing to be made available for payment. Payments to be made pursuant to this Contract shall be made only from Contract Funds, and the State's liability for such payments shall be limited to the amount remaining of such Contract Funds. If State, federal or other funds are not appropriated, or otherwise become unavailable to fund this Contract, the State may, upon written notice, terminate this Contract, in whole or in part, without incurring further liability. The State shall, however, remain obligated to pay for Services and Goods that are delivered and accepted prior to the effective date of notice of termination, and this termination shall otherwise be treated as if this Contract were terminated in the public interest as described in §2.E.

10. REPORTING-NOTIFICATION

A. Litigation Reporting

If Contractor is served with a pleading or other document in connection with an action before a court or other administrative decision-making body, and such pleading or document relates to this Contract or may affect Contractor's ability to perform its obligations under this Contract, Contractor shall, within 10 days after being served, notify the State of such action and deliver copies of such pleading or document to the State's Principal Representative identified on the Cover Page of this Contract.

- B. To the extent not previously disclosed in accordance with §24-102-206, C.R.S., Contractor shall provide written notice to the State, in accordance with §14 and in a form designated by the State, within 20 days following the earlier to occur of Contractor's decision to perform Services outside of the State of Colorado or the United States, or its execution of an agreement with a Subcontractor to perform, Services outside the State of Colorado or the United States. Such notice shall specify the type of Services to be performed outside the State of Colorado or the United States and the reason why it is necessary or advantageous to perform such Services at such location or locations, and such notice shall be a public record. Knowing failure by Contractor to provide notice to the State under this section shall constitute a breach of this Contract. This section shall not apply if the Contract Funds include any federal funds.

11. CONTRACTOR RECORDS

A. Maintenance

Contractor shall maintain a file of all documents, records, communications, notes and other materials relating to the Work, (the "Contractor Records"). Contractor Records shall include all documents, records, communications, notes and other materials maintained by Contractor that relate to any Work performed by Subcontractors, and Contractor shall maintain all records related to the Work performed by Subcontractors required to ensure proper performance of that Work. Contractor shall maintain Contractor Records until the last to occur of: (i) the date three years after the date this Contract expires or is terminated, (ii) final payment under this Contract is made, (iii) the resolution of any pending Contract matters, or (iv) if an audit is occurring, or Contractor has received notice that an audit is pending, the date such audit is completed and its findings have been resolved (the "Record Retention Period").

B. Inspection

Upon reasonable written request, Contractor shall permit the State to audit, inspect, examine, excerpt, copy and transcribe Contractor Records during the Record Retention Period at the State's sole cost and expense, subject to any State and State designated personnel's compliance with any Contractor policies or reasonable security requirements regarding access. Contractor may, in its sole discretion, redact any portion of the Contractor Records necessary to comply with any other contractual, legal or regulatory obligations. Contractor shall make Contractor Records available during normal business hours at Contractor's office or place of business, or at other mutually agreed upon times or locations, upon no fewer than two Business Days' notice from the State, unless the State determines that a shorter period of notice, or no notice, is necessary to protect the interests of the State.

C. Monitoring

The State, in its discretion, may monitor Contractor's performance of its obligations under this Contract using procedures provided in writing in advance to Contractor by the State, subject to Contractor's policies and reasonable security requirements regarding access. The State shall monitor Contractor's performance in a manner that does not unduly interfere with Contractor's performance of the Work.

D. Final Audit Report

Contractor shall promptly submit to the State a copy of any final audit report of an audit performed on Contractor's records that relates to or affects this Contract or the Work, whether the audit is conducted by Contractor or a third party.

12. CONFIDENTIAL INFORMATION- STATE RECORDS

A. Confidentiality

Contractor shall keep confidential, and cause all Subcontractors to keep confidential, all State Records, unless those State Records are publicly available Contractor shall not, without prior written approval of the State, use, publish, copy, disclose to any third party, or permit the use by any third party of any State Records, except as otherwise stated in this Contract, permitted by law or approved in Writing by the State. Contractor shall provide for the security of all State Confidential Information in accordance with all policies promulgated by the Colorado Office of Information Security and all applicable laws, rules, policies, publications, and guidelines. Contractor shall promptly forward any request or demand for State Records to the State's principal representative.

State shall keep confidential, and cause all Subcontractors to keep confidential, all Contractor Confidential Information. State shall not, without prior written approval of the Contractor, use, publish, copy, disclose to any third party, or permit the use by any third party of any Contractor Confidential Information, except as otherwise stated in this Contract, permitted by law or approved in Writing by the Contractor. The State will notify the Contractor if the State receives a CORA request for Contractor's Confidential Information.

B. Other Entity Access and Nondisclosure Agreements

Contractor may provide State Records to its agents, employees, assigns and Subcontractors as necessary to perform the Work, but shall restrict access to State Confidential Information to those agents, employees, assigns and Subcontractors who require access to perform their obligations under this Contract. Contractor shall attest and ensure that its employees and agents are subject to an obligation of confidentiality with regards to State Confidential Information. Contractor shall ensure all Subcontractors are subject to written obligations to maintain the confidentiality of State Confidential Information on terms at least as protective as those in this Contract, and that the obligations are in force at all times the agent, employee, assign or Subcontractor has access to any State Confidential Information.

C. Use, Security, and Retention

Contractor shall use, hold and maintain State Confidential Information in compliance with any and all applicable laws and regulations in facilities located within the United States, and shall maintain a secure environment that ensures confidentiality of all State Confidential Information wherever located. Contractor shall provide the State with access, subject to Contractor's reasonable security requirements, for purposes of inspecting and monitoring access and use of State Confidential Information and evaluating security control effectiveness. Upon the expiration or termination of this Contract, Contractor shall return State Records provided to Contractor or destroy such State Records and certify to the State that it has done so, as directed by the State. If Contractor is prevented by law or regulation from returning or destroying State Confidential Information, Contractor warrants it will guarantee the confidentiality of (unless a court order or subpoena disallows such undertaking), and cease to use, such State Confidential Information.

D. Incident Notice and Remediation

If Contractor becomes aware of any Incident, Contractor shall notify the State immediately and cooperate with the State regarding recovery, remediation, and the necessity to involve law enforcement, as determined by the State. Unless Contractor can establish that Contractor and its Subcontractors are not the cause or source of the Incident, Contractor shall be responsible for the cost of notifying each person who may have been impacted by the Incident. After an Incident, Contractor shall take steps to reduce the risk of incurring a similar type of Incident in the future as directed by the State, which may include, but is not limited to, developing and implementing a remediation plan that is approved by the State at no additional cost to the State. The State may adjust or direct modifications to this plan in its sole discretion, and Contractor shall make all modifications as directed by the State. If Contractor cannot produce its analysis and plan within the allotted time, the State, in its sole discretion, may perform such analysis and produce a remediation plan, and Contractor shall reimburse the State for the actual costs thereof. The State may, in its sole discretion and at Contractor's sole expense, require Contractor to engage the services of an independent, qualified, State-approved third party to conduct a security audit. Contractor shall provide the State with the results of such audit and evidence of Contractor's planned remediation in response to any negative findings.

E. Data Protection and Handling

Contractor shall ensure that all State Records and Work Product in the possession of Contractor or any Subcontractors are protected and handled in accordance with the requirements of this Contract, including the requirements of any Exhibits hereto, at all times.

13. CONFLICTS OF INTEREST

A. Actual Conflicts of Interest

Contractor shall not engage in any business or activities or maintain any relationships that conflict in any way with the full performance of the obligations of Contractor under this Contract. Such a conflict of interest would arise when a Contractor's or Subcontractor's employee, officer or agent were to offer or provide any tangible personal benefit to an employee of the State, or any member of his or her immediate family or his or her partner, related to the award of, entry into or management or oversight of this Contract.

B. Apparent Conflicts of Interest

Contractor acknowledges that, with respect to this Contract, even the appearance of a conflict of interest shall be harmful to the State's interests. Absent the State's prior written approval, Contractor shall refrain from any practices, activities or relationships that reasonably appear to be in conflict with the full performance of Contractor's obligations under this Contract; provided, however, nothing herein shall restrict or prevent Contractor from performing services and/or implementing a program for any other state or governmental entity in the USA to import Canadian prescription drugs for such state.

C. Disclosure to the State

If a conflict or the appearance of a conflict arises, or if Contractor is uncertain whether a conflict or the appearance of a conflict has arisen, Contractor shall submit to the State a disclosure statement setting forth the relevant details for the State's consideration. Failure to promptly submit a disclosure statement or to follow the State's direction in regard to the actual or apparent conflict constitutes a breach of this Contract.

14. INSURANCE

Contractor shall obtain and maintain, and ensure that each Subcontractor shall obtain and maintain, insurance as specified in this section at all times during the term of this Contract. All insurance policies required by this Contract shall be issued by insurance companies as approved by the State.

A. Workers' Compensation

Workers' compensation insurance as required by state statute, and employers' liability insurance covering all Contractor or Subcontractor employees acting within the course and scope of their employment.

B. General Liability

Commercial general liability insurance covering premises operations, fire damage, independent contractors, products and completed operations, blanket contractual liability, personal injury, and advertising liability with minimum limits as follows:

- i. \$1,000,000 each occurrence;
- ii. \$1,000,000 general aggregate;
- iii. \$1,000,000 products and completed operations aggregate; and
- iv. \$50,000 any one fire

C. Professional Liability Insurance

Professional liability insurance covering any damages caused by an error, omission or any negligent act with minimum limits as follows:

- i. \$1,000,000 each occurrence; and
- ii. \$1,000,000 general aggregate

D. Crime Insurance

Crime insurance including employee dishonesty coverage with minimum limits as follows:

- i. \$1,000,000 each occurrence; and
- ii. \$1,000,000 general aggregate.

E. Additional Insured

The State shall be named as additional insured on all commercial general liability policies (leases and construction contracts require additional insured coverage for completed operations) required of Contractor and Subcontractors.

F. Primacy of Coverage

Coverage required of Contractor and each Subcontractor shall be primary over any insurance or self-insurance program carried by Contractor or the State.

G. Cancellation

The above insurance policies shall include provisions preventing cancellation or non-renewal, except for cancellation based on non-payment of premiums, without at least 30 days' prior notice to Contractor and Contractor shall forward such notice to the State in accordance with §14 within seven days of Contractor's receipt of such notice.

H. Subrogation Waiver

All insurance policies secured or maintained by Contractor or its Subcontractors in relation to this Contract shall include clauses stating that each carrier shall waive all rights of recovery under subrogation or otherwise against Contractor or the State, its agencies, institutions, organizations, officers, agents, employees, and volunteers.

I. Certificates

Contractor shall provide to the State certificates evidencing Contractor's insurance coverage required in this Contract within seven Business Days following the Effective Date. Contractor shall provide to the State certificates evidencing Subcontractor insurance coverage required under this Contract within seven Business Days following the Effective Date, except that, if Contractor's subcontract is not in effect as of the Effective Date, Contractor shall provide to the State certificates showing Subcontractor insurance coverage required under this Contract within

seven Business Days following Contractor's execution of the subcontract. No later than 15 days before the expiration date of Contractor's or any Subcontractor's coverage, Contractor shall deliver to the State certificates of insurance evidencing renewals of coverage. At any other time during the term of this Contract, upon request by the State, Contractor shall, within seven Business Days following the request by the State, supply to the State evidence satisfactory to the State of compliance with the provisions of this section. Contractor shall provide all certificates electronically to the Department's designated insurance certificate submission site, unless the Department has specifically directed otherwise.

15. BREACH OF CONTRACT

In the event of a Breach of Contract, the aggrieved Party shall give written notice of breach to the other Party. If the notified Party does not cure the Breach of Contract, at its sole expense, within 30 days after the delivery of written notice, the Party may exercise any of the remedies as described in §12 for that Party. Notwithstanding any provision of this Contract to the contrary, the State, in its discretion, need not provide notice or a cure period and may immediately terminate this Contract in whole or in part or institute any other remedy in this Contract in order to protect the public interest of the State; or if Contractor is debarred or suspended under §24-109-105, C.R.S., the State, in its discretion, need not provide notice or cure period and may terminate this Contract in whole or in part or institute any other remedy in this Contract as of the date that the debarment or suspension takes effect.

16. REMEDIES

A. State's Remedies

If Contractor is in material breach under any provision of this Contract and fails to cure such material breach, the State, following the notice and cure period set forth in §11, shall have all of the remedies listed in this section A, in addition to all other remedies set forth in this Contract or at law. For the avoidance of doubt, where breach or failure to cure is due to regulatory or legal reasons related to the performance of the Services, such as a government agency not allowing the purchase or importation of drug product, such breach or failure to cure shall not be considered a material breach subject to this Section 12. The State may exercise any or all of the remedies available to it, in its discretion, concurrently or consecutively.

i. Termination for Breach

In the event of Contractor's uncured material breach, the State may terminate this entire Contract or any part of this Contract. Contractor shall continue performance of this Contract to the extent not terminated, if any, provided that payments continue with respect to the portion of the Contract not terminated.

a. Obligations and Rights

To the extent specified in any termination notice, Contractor shall not incur further obligations or render further performance past the effective date of such notice and cure period and shall terminate outstanding orders and subcontracts with third parties. However, Contractor shall complete and deliver to the State all Work not cancelled by

the termination notice and may incur obligations as necessary to do so within this Contract. At the request of the State, Contractor shall assign to the State all of Contractor's rights, title, and interest in and to such terminated orders or subcontracts. Upon termination, Contractor shall take timely, reasonable and necessary action to protect and preserve property in the possession of Contractor but in which the State has an interest. At the State's request, Contractor shall return materials owned by the State in Contractor's possession at the time of any termination. Contractor shall deliver all completed Work Product and all Work Product that was in the process of completion to the State at the State's request.

b. Payments

Notwithstanding anything to the contrary, the State shall only pay Contractor for accepted Work received as of the date of termination. If, after termination by the State, the State agrees that Contractor was not in breach or that Contractor's action or inaction was excusable, such termination shall be treated as a termination in the public interest, and the rights and obligations of the Parties shall be as if this Contract had been terminated in the public interest under §2.E.

c. Damages and Withholding

Notwithstanding any other remedial action by the State, Contractor shall remain liable to the State for any damages sustained by the State in connection with any breach by Contractor, and the State may withhold payment to Contractor for the purpose of mitigating the State's damages until such time as the exact amount of damages due to the State from Contractor is determined. The State may withhold any amount that may be due Contractor as the State deems necessary to protect the State against loss including, without limitation, loss as a result of outstanding liens and excess costs incurred by the State in procuring from third parties replacement Work as cover.

ii. Remedies Not Involving Termination

The State, in its discretion, may exercise one or more of the following additional remedies:

a. Suspend Performance

Suspend Contractor's performance with respect to all or any portion of the Work pending corrective action as specified by the State without entitling Contractor to an adjustment in price or cost or an adjustment in the performance schedule. Contractor shall promptly cease performing Work and incurring costs in accordance with the State's directive, and the State shall not be liable for costs incurred by Contractor after the suspension of performance.

b. Withhold Payment

Withhold Payment to Contractor until Contractor corrects its Work.

c. Deny Payment

Deny payment for Work not performed, or that due to Contractor's actions or inactions, cannot be performed or if they were performed are reasonably of no value to the State;

provided, that any denial of payment shall be equal to the value of the obligations not performed.

d. Removal

Demand prompt removal of any of Contractor's employees, agents, or Subcontractors from the Work whom the State deems incompetent, careless, insubordinate, unsuitable, or otherwise unacceptable or whose continued relation to this Contract is deemed by the State to be contrary to the public interest or the State's best interest.

B. Contractor's Remedies

If the State is in breach of any provision of this Contract and does not cure such breach, Contractor, following the notice and cure period in §11 and the dispute resolution process in §13 shall have all remedies available at law and equity.

17. DISPUTE RESOLUTION

A. Initial Resolution

Except as herein specifically provided otherwise, disputes concerning the performance of this Contract which cannot be resolved by the designated Contract representatives shall be referred in writing to a senior departmental management staff member designated by the State and a senior manager designated by Contractor for resolution.

B. Resolution of Controversies

If the initial resolution described in §13.A fails to resolve the dispute within 10 Business Days, Contractor shall submit any alleged breach of this Contract by the State to the Department's Procurement Official as described in C.R.S. §24-101-301(30), for resolution in accordance with the provisions of C.R.S. §§24-106-109, 24-109-101.1, 24-109-101.5, 24-109-106, 24-109-107, 24-109-201 through 24-109-206, and 24-109-501 through 24-109-505 (the "Resolution Statutes"), except that if Contractor wishes to challenge any decision rendered by the Procurement Official, Contractor's challenge shall be an appeal to the executive director of the Department of Personnel and Administration, or their delegate, under the Resolution Statutes before Contractor pursues any further action as permitted by such statutes. Except as otherwise stated in this Section, all requirements of the Resolution Statutes shall apply including, without limitation, time limitations.

18. NOTICES AND REPRESENTATIVES

Each individual identified as a Principal Representative on the Cover Page for this Contract shall be the principal representative of the designating Party. All notices required or permitted to be given under this Contract shall be in writing, and shall be delivered (A) by hand with receipt required, (B) by certified or registered mail to such Party's principal representative at the address set forth on the Cover Page for this Contract or (C) as an email with read receipt requested to the principal representative at the email address, if any, set forth on the Cover Page for this Contract. If a Party delivers a notice to another through email and the email is undeliverable, then, unless the Party has been provided with an alternate email contact, the Party delivering the notice shall

deliver the notice by hand with receipt required or by certified or registered mail to such Party's principal representative at the address set forth on the Cover Page for this Contract. Either Party may change its principal representative or principal representative contact information or may designate specific other individuals to receive certain types of notices in addition to or in lieu of a principal representative, by notice submitted in accordance with this section without a formal amendment to this Contract. Unless otherwise provided in this Contract, notices shall be effective upon delivery of the written notice.

19. RIGHTS IN WORK PRODUCT AND OTHER INFORMATION

A. Work Product

i. Copyrights

To the extent that the Work Product (or any portion of the Work Product) would not be considered works made for hire under applicable law, Contractor hereby assigns to the State, the entire right, title, and interest in and to copyrights in all Work Product and all works based upon, derived from, or incorporating the Work Product; all copyright applications, registrations, extensions, or renewals relating to all Work Product and all works based upon, derived from, or incorporating the Work Product; and all moral rights or similar rights with respect to the Work Product throughout the world. To the extent that Contractor cannot make any of the assignments required by this section, Contractor hereby grants to the State a perpetual, irrevocable, royalty-free license to use, modify, copy, publish, display, perform, transfer, distribute, sell, and create derivative works of the Work Product and all works based upon, derived from, or incorporating the Work Product by all means and methods and in any format now known or invented in the future. The State may assign and license its rights under this license.

ii. Patents

In addition, Contractor grants to the State (and to recipients of Work Product distributed by or on behalf of the State) a perpetual, worldwide, no-charge, royalty-free, irrevocable patent license to make, have made, use, distribute, sell, offer for sale, import, transfer, and otherwise utilize, operate, modify and propagate the contents of the Work Product. Such license applies only to those patent claims licensable by Contractor that are necessarily infringed by the Work Product alone, or by the combination of the Work Product with anything else used by the State.

iii. Assignments and Assistance

Whether or not Contractor is under contract with the State at the time, Contractor shall execute applications, assignments, and other documents, and shall render all other reasonable assistance requested by the State, to enable the State to secure patents, copyrights, licenses and other intellectual property rights related to the Work Product. To the extent that Work Product would fall under the definition of "works made for hire" under 17 U.S.C.S. §101, the Parties intend the Work Product to be a work made for hire. Contractor assigns to the State and its successors and assigns, the entire right, title, and interest in and to all causes of action, either in law or in equity, for past, present, or future infringement of intellectual property rights related to the Work Product and all works based on, derived from, or incorporating the Work Product.

B. Exclusive Property of the State

Except to the extent specifically provided elsewhere in this Contract, any pre-existing State Records, State software, research, reports, studies, photographs, negatives or other documents, drawings, models, materials, data and information shall be the exclusive property of the State (collectively, "State Materials"). Contractor shall not use, willingly allow, cause or permit Work Product or State Materials to be used for any purpose other than the performance of Contractor's obligations in this Contract without the prior written consent of the State. Upon termination of this Contract for any reason, Contractor shall provide all Work Product and State Materials to the State in a form and manner as directed by the State.

C. Exclusive Property of Contractor

Contractor retains the exclusive rights, title, and ownership to any and all pre-existing materials owned or licensed to Contractor including, but not limited to, all pre-existing software, licensed products, associated source code, machine code, text images, audio and/or video, and third-party materials, delivered by Contractor under the Contract, whether incorporated in a Deliverable or necessary to use a Deliverable (collectively, "Contractor Property"). Contractor Property shall be licensed to the State as set forth in this Contract or a State approved license agreement: (i) entered into as exhibits to this Contract; (ii) obtained by the State from the applicable third-party vendor; or (iii) in the case of open source software, the license terms set forth in the applicable open source license agreement.

20. GENERAL PROVISIONS

A. Assignment

Contractor's rights and obligations under this Contract are personal and may not be transferred or assigned without the prior, written consent of the State, which shall not be unreasonably withheld, except that a Contractor may assign this Contract to a person or entity that acquires all of its business or assets. Any attempt at assignment or transfer without such consent shall be void. Any assignment or transfer of Contractor's rights and obligations approved by the State shall be subject to the provisions of this Contract. If Contractor assigns this Contract to a person or entity that acquires all of its business or assets to which the Agreement primarily relates, the State shall have the right to terminate the Contract pursuant to 2.E.

B. Subcontracts

Contractor shall not enter into any subcontract in connection with its obligations under this Contract without providing notice to the State. The State may reject any such subcontract and the Parties will work together in good faith to address any concerns raised by State related to such rejection. If after such negotiations the Parties cannot resolve State's objections, Contractor shall terminate any such subcontract. Contractor shall submit to the State a copy of each such subcontract upon request by the State, which Contractor may redact to remove any terms unrelated to Contractor's delivery or performance of Goods or Services under this Contract. All subcontracts entered into by Contractor in connection with this Contract shall comply with all

applicable federal and state laws and regulations, shall provide that they are governed by the laws of the State of Colorado, and shall be subject to all provisions of this Contract.

C. Binding Effect

Except as otherwise provided in §16.A., all provisions of this Contract, including the benefits and burdens, shall extend to and be binding upon the Parties' respective successors and assigns.

D. Authority

Each Party represents and warrants to the other that the execution and delivery of this Contract and the performance of such Party's obligations have been duly authorized.

E. Captions and References

The captions and headings in this Contract are for convenience of reference only, and shall not be used to interpret, define, or limit its provisions. All references in this Contract to sections (whether spelled out or using the § symbol), subsections, exhibits or other attachments, are references to sections, subsections, exhibits or other attachments contained herein or incorporated as a part hereof, unless otherwise noted.

F. Counterparts

This Contract may be executed in multiple, identical, original counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement.

G. Entire Understanding

This Contract represents the complete integration of all understandings between the Parties related to the Work, and all prior representations and understandings related to the Work, oral or written, are merged into this Contract. Prior or contemporaneous additions, deletions, or other changes to this Contract shall not have any force or effect whatsoever, unless embodied herein.

H. Digital Signatures

If any signatory signs this agreement using a digital signature in accordance with the Colorado State Controller Contract, Grant and Purchase Order Policies regarding the use of digital signatures issued under the State Fiscal Rules, then any agreement or consent to use digital signatures within the electronic system through which that signatory signed shall be incorporated into this Contract by reference.

I. Modification

Except as otherwise provided in this Contract, any modification to this Contract shall only be effective if agreed to in a formal amendment to this Contract, properly executed and approved in accordance with applicable Colorado State law and State Fiscal Rules. Modifications permitted

under this Contract, other than contract amendments, shall conform to the policies issued by the Colorado State Controller.

J. Statutes, Regulations, Fiscal Rules, and Other Authority

Any reference in this Contract to a statute, regulation, State Fiscal Rule, fiscal policy or other authority shall be interpreted to refer to such authority then current, as may have been changed or amended since the Effective Date of this Contract.

K. External Terms and Conditions

Notwithstanding anything to the contrary herein, the State shall not be subject to any provision included in any terms, conditions, or agreements appearing on Contractor's or a Subcontractor's website or any provision incorporated into any click-through or online agreements related to the Work unless that provision is specifically referenced in this Contract.

L. Severability

The invalidity or unenforceability of any provision of this Contract shall not affect the validity or enforceability of any other provision of this Contract, which shall remain in full force and effect, provided that the Parties can continue to perform their obligations under this Contract in accordance with the intent of this Contract.

M. Survival of Certain Contract Terms

Any provision of this Contract that imposes an obligation on a Party after termination or expiration of this Contract shall survive the termination or expiration of this Contract and shall be enforceable by the other Party until the obligation is complete or assigned or transferred to another entity.

N. Taxes

The State is exempt from federal excise taxes under I.R.C. Chapter 32 (26 U.S.C., Subtitle D, Ch. 32) (Federal Excise Tax Exemption Certificate of Registry No. 84-730123K) and from State and local government sales and use taxes under §§39-26-704(1), et seq., C.R.S. (Colorado Sales Tax Exemption Identification Number 98-02565). The State shall not be liable for the payment of any excise, sales, or use taxes, regardless of whether any political subdivision of the state imposes such taxes on Contractor. Contractor shall be solely responsible for any exemptions from the collection of excise, sales or use taxes that Contractor may wish to have in place in connection with this Contract.

O. Third Party Beneficiaries

Except for the Parties' respective successors and assigns described in §16.A., this Contract does not and is not intended to confer any rights or remedies upon any person or entity other than the Parties. Enforcement of this Contract and all rights and obligations hereunder are reserved solely

to the Parties. Any services or benefits which third parties receive as a result of this Contract are incidental to this Contract, and do not create any rights for such third parties.

P. Waiver

A Party's failure or delay in exercising any right, power, or privilege under this Contract, whether explicit or by lack of enforcement, shall not operate as a waiver, nor shall any single or partial exercise of any right, power, or privilege preclude any other or further exercise of such right, power, or privilege.

Q. CORA Disclosure

To the extent not prohibited by federal law, this Contract and the performance measures and standards required under C.R.S. §24-106-107, if any, are subject to public release through the CORA.

R. Standard and Manner of Performance

Contractor shall perform its obligations under this Contract in accordance with the highest standards of care, skill and diligence in Contractor's industry, trade, or profession.

S. Licenses, Permits, and Other Authorizations

Contractor shall secure, prior to the Effective Date, and maintain at all times during the term of this Contract, at its sole expense, all licenses, certifications, permits, and other authorizations required to perform its obligations under this Contract, and shall ensure that all employees, agents and Subcontractors secure and maintain at all times during the term of their employment, agency or subcontract, all license, certifications, permits and other authorizations required to perform their obligations in relation to this Contract.

T. Indemnification

i. Force Majeure

Neither Party will incur any liability to the other Party on account of any loss or damage resulting from any delay or failure to perform all or any part of this Contract if such delay or failure is caused, in whole or in part, by events, occurrences, or causes beyond the reasonable control and without negligence of the Party whose performance has been delayed. Such events, occurrences, or causes will include, without limitation, acts of God, strikes, lockouts, riots, acts of war, failures of the Internet or technology systems over which a Party has no control, and explosions.

ii. Certain Excused Failures

Contractor will not incur any liability to the State on account of any loss or damage resulting from any delay or failure to perform all or any part of this Contract on the part of Contractor if such delay or failure is caused, in whole or in part, by events, occurrences, or causes arising out of any failure of any manufacturer to perform its manufacturing services relating

to the Services (including due to any raw material or active pharmaceutical ingredient (“API”) shortages or any raw material or API price increases), any applicable United States or Canadian Federal State or local law, regulation, standard or policy, applicable international law, regulation, standard or policy, any change in any existing applicable United States or Canadian Federal, State, local or international law, regulation, standard or policy, any change in any existing applicable law, regulation, standard or policy, any change in availability of API or raw materials necessary to perform the Services, or any actions or decisions of a regulatory body or authority related to the export of prescription drugs from Canada or importation of prescription drugs into the United States, or any other similar types of events outside the control of Contractor that relate to or impact the Importation Program or Contractor’s ability to perform its obligations under this Agreement.

iii. General Indemnification

Contractor shall indemnify, save, and hold harmless the State, its employees, agents and assignees (the “Indemnified Parties”), against any and all costs, expenses, claims, damages, liabilities, court awards and other amounts (including reasonable attorneys’ fees and related costs) incurred by any of the Indemnified Parties in relation to any act or omission by Contractor, or its employees, agents, Subcontractors, or assignees in connection with this Contract.

iv. Confidential Information Indemnification

Disclosure or use of State Confidential Information by Contractor in violation of §8 may be cause for legal action by third parties against Contractor, the State, or their respective agents. Contractor shall indemnify, save, and hold harmless the Indemnified Parties, against any and all claims, damages, liabilities, losses, costs, expenses (including reasonable attorneys’ fees and costs) incurred by the State in relation to any act or omission by Contractor, or its employees, agents, assigns, or Subcontractors in violation of §8.

v. Intellectual Property Indemnification

Contractor shall indemnify, save, and hold harmless the Indemnified Parties, against any and all costs, expenses, claims, damages, liabilities, and other amounts (including attorneys’ fees and costs) incurred by the Indemnified Parties in relation to any claim that any Work knowingly infringes a pharmaceutical patent, copyright, trademark, trade secret, or any other intellectual property right.

21. 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.

EXHIBIT A-1, STATEMENT OF WORK

1. PROJECT SPECIFIC STATEMENT OF WORK

1.1. General Requirements

1.1.1. Contractor shall complete the Work as described in this Contract and in accordance with the provisions of Exhibit D, Contractor's Administrative Requirements. The State shall have no liability to compensate the Contractor for the delivery of any goods or the performance of any services that are not specifically set forth in this Contract.

1.2. Summary of Work and Description

1.2.1. The purpose of this project is to provide contracted services to develop and implement a program to import Canadian prescription drugs for the residents of the state of Colorado. Contractor may subcontract some or all of the Foreign Seller obligations under the Final Rule and this Contract to its Canadian based subsidiary. The Contractor shall ensure, or require its Subcontractors to ensure, that all prescription drugs that Contractor is responsible for exporting for the Program are fully compliant in all material respects with the Final Rule set forth by the United States Food and Drug Administration (FDA). This scope outlines the role played by the Foreign Seller under the Final Rules, which is responsible for the purchase and distribution of Eligible Prescription Drugs directly from a manufacturer.

1.2.1.1. All Deliverables described below shall be delivered in a format provided to the Contractor and agreed to in writing and approved by the Department.

1.2.1.2. All Deliverables can be billed to the Department once the portion of the services has been completed and delivered to the Department in an acceptable format as defined in Exhibit D, 1.6.

1.2.1.3. All due dates are eligible for an extension upon request by the Contractor and approved by the Department, such approval not to be unreasonably withheld or delayed.

1.2.1.4. All due dates are calendar dates unless otherwise noted.

1.2.2. In accordance with the requirements of §24-102-206, C.R.S., Contractor or its Subcontractors when acting in the capacity as a Foreign Seller will perform its services outside the State of Colorado, including to the extent it is procuring Canadian prescription drugs from Canadian manufacturers. The Contractor or its Subcontractors will also coordinate with the Importer in order to then import those Canadian prescription drugs into the United States. To the extent that these activities with the Importer are required to be approved per the Colorado statute above and to the extent the Importer is not located in Colorado, Contractor or its Subcontractors will be providing Services outside Colorado where the Importer is located. Colorado's execution of the Agreement will constitute approval of these activities occurring outside the State of Colorado.

1.3. Contract Requirements

1.3.1. The Department may terminate this contract for material noncompliance after written notice and a reasonable opportunity to cure with any stated requirement and reserves the right to audit the Contractor on a scheduled or unscheduled basis, at a mutually agreeable time, and in accordance with Contractor's policies, procedures and reasonable restrictions, solely related to the scope of the Work or Program.

1.3.2. The following items are requirements to adequately maintain the terms of this contract.

1.3.3. Compliance with all applicable State of Colorado and federal laws

1.3.3.1. Compliance with all applicable State of Colorado and federal laws, rules and regulations, and international laws and standards applicable to the Contractor regarding the development and implementation of an Importation Program. The Department may terminate this contract after a written notice and cure period for material noncompliance with any stated requirement and reserves the right to audit the Contractor on a scheduled or, if emergency circumstances warrant, unscheduled basis, in each case at a mutually agreeable time and in accordance with Contractor's policies, procedures and reasonable restrictions.

1.3.4. Maintenance of the licenses and registrations

1.3.4.1. The Contractor shall maintain all 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 the Contractor is found to be in material violation of federal, Colorado state, or Canadian laws or if the Contractor receives disciplinary action relating to any of required licenses, except that Contractor shall have a reasonable opportunity to cure any such violations prior to the Department implementing any sanctions or terminating this Contract.

1.3.5. Successful Passage of all Applicable Inspections

1.3.5.1. The Contractor shall successfully pass all inspections conducted by Health Canada or other applicable federal or provincial agencies. Should results show unsatisfactory findings, the Contractor shall implement the necessary policies and procedures to rectify the unsatisfactory findings. The Contractor shall supply the Department with proof of successful passage or satisfactory resolution of any findings. The Contractor shall ensure, when applicable, that any Subcontractors working on the Importation Program are held to materially the same standard and are contractually obligated to either successfully pass all applicable inspections or to implement policies and procedures required for rectifying unsatisfactory results from such inspections.

1.3.5.1.1. DELIVERABLE:

1.3.5.1.1.1. Upon the completion of the inspection from the applicable agency, the Contractor shall share the results/findings with the Department within 5 business days of receiving the completed report from the applicable agency.

1.3.5.1.1.2. Upon receipt of a notice of a Health Canada Critical Observation, the Contractor shall notify the Department within 24 hours.

1.3.6. Inspection of Records, Work Performed, and the Facility

1.3.6.1. The Department and/or its authorized representatives shall, at mutually agreeable times, and in accordance with Contractor's or such other places, policies, procedures and reasonable restrictions, have the right to enter the 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. The Department shall inspect the facility that houses prescription drugs intended for importation under the Program at least annually, or as necessary under the public interest, at the Department's discretion, at mutually agreeable times and in accordance with such facility's policies, procedures and reasonable restrictions.

1.3.7. Required Contractor Information

1.3.7.1. The Contractor shall provide the following to the Department:

1.3.7.1.1. Name and Address

1.3.7.1.2. Attestation and Information statement containing a complete disclosure of any past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against or by the Contractor, or an attestation that the Contractor has not been involved in or convicted of any such violations. Such attestation and information statement must include principals, any shareholder who owns 10 percent or more of outstanding stock in non-publicly held corporations, director, officers, and any facility manager or designated representative of such manager.

1.3.7.1.3. A list of all disciplinary actions, to include the date of and parties to any action imposed against the Contractor by Provincial or Canadian regulatory bodies, including any such actions against the principals, owners, directors, officers or any facility manager or designated representative of such manager for the previous 7 years.

1.3.7.1.4. Health Canada inspectional history for the Contractor for the previous 5 years or if the Contractor has been licensed for less than 5 years, for the duration of its period of licensure.

1.3.7.1.5. The Contractor shall register with FDA and ensure compliance with all requirements outlined in §251.9 of the Final Rule. When applicable, the Contractor shall review and update FDA registration as outlined in §251.10 of the Final Rule.

1.3.7.1.6. The Contractor shall name an official contact and U.S. agent as outlined in §251.11 of the Final Rule.

1.3.7.1.7. The Contractor shall provide copies of all active licenses and inspection reports that are required to be included in the State of Colorado's SIP.

1.3.8. Facility Requirements

1.3.8.1. The Contractor shall comply with applicable security and capacity requirements to ensure the safe and efficient distribution of prescription drugs intended for export for the Program to the Importer. These requirements apply to all Subcontractors and should a Subcontractor (e.g., third party logistics provider) change, the Department shall conduct a site visit at mutually agreeable times and in accordance

with Subcontractor(s) policies, procedures and reasonable restrictions, to verify that the Subcontractor(s) follow applicable security and capacity requirements.

- 1.3.8.1.1. Ensure prescription drugs intended for export for the Program have adequate space, security, and environmental conditions necessary for proper storage of such prescription drugs.
- 1.3.8.1.2. The Contractor shall ensure that the space designated for the Program is for the sole purpose of quarantining, storing and staging prescription drugs intended for export for the Program. As described in §251.14 (c) of the Final Rule, all products meant for export to the United States under the Program must be kept separate from those intended for sale in the Canadian market.
- 1.3.8.1.3. The Contractor or applicable Subcontractor(s) that stores prescription drugs intended for export for the Program must maintain the following elements while under contract with the Department:
 - 1.3.8.1.3.1. Standard Operating Procedures (SOPs) for all applicable processes and procedures relating to the operation of the Importation program.
 - 1.3.8.1.3.2. External and internal physical security, which may include, but not limited to, an alarm system, an internal and external security camera system, outdoor lighting, and a keycard or unique locking system.
 - 1.3.8.1.3.3. Storage system designed specifically for the Program that allows for prescription drugs intended for export to be kept separate from the rest of the Contractor's inventory.
 - 1.3.8.1.3.4. Temperature control/monitoring for all storage areas through a commercially reasonable environmental monitoring system.

1.3.9. Supply Chain Security & T3 Data Validation

- 1.3.9.1. The Contractor shall provide transactional information as described in §251.14 (6) (i - xii) of the Final Rule.

1.3.10. Development and Maintenance of Contracts

- 1.3.10.1. Maintenance of contracts with the State of Colorado's chosen Importer, the Contractor's third-party logistics warehouse(s) for the Program, and additional entities as requested by the Department.
 - 1.3.10.1.1. DELIVERABLE: The Contractor shall confirm contractual relationships with the Importer, third party logistics warehouse(s), and other Program entities on an annual basis by providing copies of those contracts or by confirming the previous contract provide is still active to the Department on or before July 15th of each calendar year.
- 1.3.10.2. The Department reserves the right to re-evaluate all contracts and subcontracts relevant to the Importation Program as state and federal guidance, regulations, or statute relating to the wholesale importation of prescription drugs are updated or changed.

1.3.11. State Law Requirements

1.3.11.1. Surety Bond or comparable Security Agreement

1.3.11.1.1. The Contractor shall submit evidence and maintain a surety bond or comparable Security Agreement in the minimum amount of \$25,000 throughout the duration of this Contract and include the State as a beneficiary.

1.3.11.1.1.1. DELIVERABLE: The Contractor shall provide the Department evidence of the surety bond on or before July 15th of each calendar year.

1.3.12. Profit Margin and Markup Methodology

1.3.12.1. In order to satisfy Colorado statutory obligations to set a maximum profit margin to ensure consumer cost savings, the Department shall assess the amount that the Contractor reasonably determines as an appropriate and fair margin on imported products, in consultation with the Contractor, based on the associated costs of doing business. Costs of doing business includes, but is not limited to: storage, affixation of a Program SSI, shipping, company overhead, and other costs as identified.

1.3.12.2. Margin: To cover the costs of conducting business the Contractor shall markup imported prescription drugs intended for export in a mutually agreeable fashion and at a mutually agreeable rate after the completion of the Profit Margin Methodology Deliverable described at Section 1.4.2 of this contract.

1.3.12.3. The Contractor and the Department shall meet at least quarterly to evaluate the current profit margin in the first contract year that includes active importation and at least annually in subsequent years, provided the Contract is extended as set forth in this Contract, to assess the needs of the Program, review volume of past fiscal year, and evaluate the projected volume for the next fiscal year.

1.3.12.4. During these meetings, the Department and the Contractor will come to a mutually agreeable margin for the next fiscal year or a timeframe shorter than one fiscal year if mutually agreed upon in writing by the Department and the Contractor, using industry benchmarks, fiscal analyses, and Program projections and the Contractor's reasonable needs.

1.3.13. Quarterly Financial Report

1.3.13.1. The Contractor shall submit a Quarterly Financial Report to the Department as required by state statute for each Eligible Prescription Drug that Contractor is actively importing once active importation has commenced. The data may include:

1.3.13.1.1. The number of Eligible Prescription Drugs, by individual saleable unit, purchased for the Program

1.3.13.1.2. The selling price to the Importer for each Eligible Prescription Drug by individual saleable unit

1.3.13.1.3. The number of Eligible Prescription Drugs, by individual saleable unit, sold to the participating Importer

1.3.13.1.4. Costs related to the operation of the importation Program incurred by the Contractor, and subcontractors, up to and including the SSI affixation costs, if applicable.

1.3.13.1.5. Contractor shall not be required to submit a Quarterly Financial Report to the Department until Contractor is actively importing Prescription Drugs for the Program.

1.3.13.1.5.1. DELIVERABLE: The Contractor shall submit a quarterly report in a format agreed upon by the Department on a quarterly basis.

1.3.14. Purchased Drug Shipment Size

1.3.14.1. To ensure savings to the Program and minimize testing costs, the Manufacturer, Department, Contractor, and Program Importer shall work together and reasonably agree in writing on the size of each lot or batch of drug prescription drug intended for export, which shall, at a minimum, take into account any Manufacturer limitations.

1.3.15. Reporting Requirements

1.3.15.1. The Contractor shall submit the following reports to the identified entity or entities on a timely basis and in a materially complete and accurate manner. A copy shall be submitted to the Department for any reports submitted to an entity other than the Department. Specifically, the Contractor shall ensure a copy is provided to the Department with respect to all reports submitted to the FDA, including, but not limited to, reports on recalls, returns, and adverse events. The Contractor shall maintain records of all reports pertaining to the Program for 7 years.

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

1.3.15.3. Required Reports:

Report	Provenance	Submitted To	Cadence	Content
Annual Report, including financial data for the Program	CO State Statute	The Department	Annually. Content for the calendar year prior due to the Department on October 1. Year will run from October 1-September 30 for reporting purposes.	Data points as described at CRS 25.5-2.5-206
Quarterly Financial Report	CO State Statute	The Department	Quarterly, when Contractor is actively importing Prescription Drugs for the Program	Profit margin reporting as described in 1.3.11.1, include information on performance of

				subcontractors, if applicable
Quarterly Importation Report	Final Rule	The Department, Importer	Quarterly, when Contractor is actively importing Prescription Drugs for the Program	All details pertaining to Foreign Seller requirements as laid out in §251.19 in the Final Rule
Notification of Conviction or Violation	Final Rule	The Department, Importer	Within 5 calendar days of conviction or violation. The Department must submit to 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).

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

1.3.16. Program Growth

1.3.16.1. The 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 indicate a desire to negotiate an agreement with the Contractor about expanding importation work.

1.3.17. Acquisitions

1.3.17.1. The Contractor shall notify the Department within 3 business days if the Contractor receives a letter of intent or a definitive term sheet from another entity that is interested in purchasing the Contractor, business lines or assets impacting the Work.

1.3.17.2. The Department reserves the right to terminate the contract should the Contractor be purchased by another entity.

1.3.18. Department Inquiries and contact

1.3.18.1. The Contractor shall acknowledge all Department inquiries within forty-eight (48) hours and respond to them within 3 Business Days, or as otherwise agreed to in writing with the State of Colorado. Responses due on a weekend, a legal or general holiday in Canada or Legal Holiday shall be submitted to the Contractor no later than the next Business Day if such requests are materially time sensitive.

1.3.18.2. The Contractor shall meet with Department staff both face-to-face and via video conference, whichever is preferable, throughout the term of this Contract period

concerning any issues when requested and required to fulfill the responsibilities of this Contract.

- 1.3.18.3. The Contractor and the Department shall determine a mutually agreeable cadence of regular meetings throughout the term of this Contract.

1.3.19. Complainants and Whistleblower Protections

- 1.3.19.1. The Contractor shall have a process to protect the anonymity of any complainants or whistleblowers regarding any Importation Program concerns by Contractor employees. The Contractor shall also ensure employees are trained on the processes and procedures for uncovering and addressing noncompliance, misconduct, or conflicts of interest with regards to the Importation Program.

1.4. Contract Paid Deliverables

1.4.1. Importation Implementation Workplan

- 1.4.1.1. The Contractor shall create an importation implementation work plan for the Program that outlines all steps and processes needed to export drugs from Canada into the United State under the Final Rule (“Work Plan”). For the avoidance of doubt, Contractor’s Work Plan requirements will be limited to Program and Final Rule requirements related to the activities of the Foreign Seller. The Work Plan should outline processes and procedures in compliance with all aspects of the Final Rule pertaining to the Foreign Seller, as well as the following.

1.4.1.2. Section 1 – Supply Chain Security Processes and Procedures

- 1.4.1.2.1. Describe the processes and procedures beginning with the acquisition of the product from the manufacturer for exportation, its transport to the selected third party logistics provider, its storage, staging, SSI affixation, and eventual exportation to the Importer.

- 1.4.1.2.2. Describe the processes and procedures in place to manage recalls and returns for products that are sold as part of the Importation Program.

- 1.4.1.2.3. Include detailed processes responsive to requirements at §251.14 (c) of the Final Rule.

- 1.4.1.2.4. Include detailed processes responsive to requirements at §251.18 and §251.19 of the Final Rule as applicable to the Foreign Seller

- 1.4.1.2.5. Include a detailed process for collecting and maintaining records to assess whether products for exportation threaten Canadian supply or contribute to shortages in the Canadian market using the Canadian regulations at C.01.014.13 - C.01.014.14 of the Food and Drug Regulations and any related guidance as a guide.

1.4.1.3. Section 2 – SIP Compliance Plan

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

- 1.4.1.3.2. Development of education, training, and certification to ensure that employees of the Contractor engaged with the Program understand their compliance-related obligations that must be followed for all Program drugs.
- 1.4.1.3.3. Develop processes and procedures for uncovering and addressing noncompliance or misconduct by Contractor employees.
- 1.4.1.3.4. Develop a process to certify that all Contractor employees involved in the Program comply with the requirements of section 804 of the FD&C Act and the Final Rule.
- 1.4.1.3.5. Maintain appropriate policies and procedures for the Importation Program
- 1.4.1.4. Section 3 – Subcontractor Operations and Compliance Plan
 - 1.4.1.4.1. Third Party Logistics Provider (TPL)
 - 1.4.1.4.1.1. Name and address of the TPL
 - 1.4.1.4.1.2. Copy of the Executed Contract
 - 1.4.1.4.1.3. Verification of processes outlining the compliance with all applicable aspects of “Guidelines for environmental control of drugs during storage and transportation (GUI-0069)” to ensure Program drugs are properly stored.
 - 1.4.1.4.1.4. Demonstration of compliance with the Final Rule for affixing or imprinting a product identifier by the Contractor or designated Subcontractor in accordance with §251.14 of the Final Rule.
 - 1.4.1.4.1.5. A copy of the proposed design for an SSI
 - 1.4.1.4.1.6. TPL must develop processes and procedures for uncovering and addressing noncompliance or misconduct by subcontractor employees.
 - 1.4.1.4.1.7. TPL must develop a process to certify that all subcontractor employees involved in the Program comply with the requirements of section 804 of the FD&C Act and the Final Rule.
 - 1.4.1.4.2. Transportation Subcontractors
 - 1.4.1.4.2.1. Name and address of the transportation provider(s)
 - 1.4.1.4.2.2. Copy of executed contract
 - 1.4.1.4.2.3. Verification of processes outlining the compliance with all applicable aspects of “Guidelines for environmental control of drugs during storage and transportation (GUI-0069)” to ensure Program drugs are properly transported to and from Contractor.
- 1.4.1.5. The Work Plan shall be approved by the Department and in a format approved by the Department. The Contractor can send in single or multiple sections at a time for approval.
- 1.4.1.6. The due date for completion of the entire Work Plan shall be mutually agreed upon in writing by the Contractor and Department.

1.4.1.7. DELIVERABLE: Workplan

1.4.1.8. Cost: The total cost for the Importation Work Plan is US\$25,000.

1.4.2. Profit Margin Markup Methodology

1.4.2.1. Upon the delivery of the written request for the purchase of a particular drug product and proposed volume, the Contractor shall develop and propose a methodology by which to determine an appropriate gross profit margin. The methodology should consider all appropriate estimated costs of the supply chain to include, but not limited to costs of storage, company overhead, cost of SSI affixation, exportation costs and other costs as identified.

1.4.2.2. The Contractor should consider and propose a method of payment that may include a percentage markup and a cost-plus methodology.

1.4.2.3. The Profit Margin Methodology is due to the Department on a date mutually agreed to by the Department and Contractor, after the Department delivers the final drug list and estimated volume to the Contractor.

1.4.2.4. The deliverable shall be paid upon approval of the methodology by the Department, such approval not to be unreasonably withheld.

1.4.2.5. DELIVERABLE: Profit Margin Methodology

1.4.2.6. Cost: US \$6,000.00

1.4.3. Section 804 (SIP) Application Support

1.4.3.1. The Contractor shall support the development of the Department's SIP (or amendment) content as requested by the Department.

1.4.3.2. The Contractor shall supply all necessary documentation as it pertains to Foreign Seller requirements in the Final Rule, including Health Canada inspection history and other documentation as requested by the Department.

1.4.3.3. The Contractor shall support the development of narrative sections pertaining to Foreign Seller processes, procedures, and compliance with all applicable federal requirements.

1.4.3.4. The Contractor shall provide SIP application content and evaluation as it pertains to Foreign Seller requirements in the Final Rule as requested by the Department.

1.4.3.5. All written information supplied by the Contractor for inclusion into the SIP shall be approved by the Department, such approval not to be unreasonably withheld or delayed and in a format approved by the Department.

1.4.3.6. The time allotted for providing all applicable licenses, paperwork, etc. shall be agreed upon in writing by both parties.

1.4.3.7. The due date for edits and actual SIP writing will be agreed upon in writing by both parties.

1.4.3.8. DELIVERABLE: SIP Application support

1.4.3.9. Cost: US\$400 per hour worked, Not to Exceed US\$25,000 total. Compensation and Invoicing

1.4.4. Stakeholder Opportunities

- 1.4.4.1. If requested by the Department, the Contractor shall participate in requested stakeholder engagement programs within Colorado.
- 1.4.4.2. All presentation materials, data, and information supplied by the Contractor for these meetings shall be approved by the Department and in a format approved by the Department.
- 1.4.4.3. Materials created in support of each meeting shall be submitted to the Department for review no later than 3 business days prior to the scheduled event.
- 1.4.4.4. DELIVERABLE: Stakeholder Opportunities
- 1.4.4.5. Cost: US\$1,000 per virtual stakeholder event (includes preparatory meeting(s) slide development, etc.), US\$5,000 per in person event (to cover travel and time worked).
- 1.4.4.6. Fiscal year Cost: Per Fiscal Year the cost for stakeholder meetings shall not to exceed the dollar amounts in the table below:
 - 1.4.4.6.1. 2022/2023 - US\$5,000.00
 - 1.4.4.6.2. 2023/2024 - US\$10,000.00
 - 1.4.4.6.3. 2024/2025: US \$10,000.00
 - 1.4.4.6.4. 2025/2026: US \$10,000.00
 - 1.4.4.6.5. 2026/2027: US \$10,000.00

1.4.5. Hourly Consultation as requested by the Department

- 1.4.5.1. The Contractor shall provide hourly consulting at the request of the Department on topics relating to Canadian wholesaler processes and procedures, the role of Foreign Seller, drug pricing, manufacturer negotiations, or other issues of importation strategy.
- 1.4.5.2. DELIVERABLE: Hourly consulting when requested by the Department
- 1.4.5.3. Due Date: Date mutually agreed by the Contractor and Department in writing.
- 1.4.5.4. Cost: The Contractor shall be paid at the following hourly of US\$400, not to exceed US\$20,000 per state fiscal year.

1.4.6. Manufacturer Negotiations

- 1.4.6.1. Description: The Contractor shall engage in negotiations with Canadian prescription drug manufacturers approved by the Department. The goal of this portion of work will be to secure supply agreements with manufacturers for eligible drugs for exportation to the United States. The Department and Contractor shall work together to determine the scope of each manufacturer negotiation session. All supply agreements shall be reviewed and cleared by the Department prior to signature.
 - 1.4.6.1.1. Prescription drug manufacturers, as approved by the Department.
 - 1.4.6.1.1.1. Initial Manufacturer Meetings and Negotiations

- 1.4.6.1.1.1.1.1. Description: The Contractor shall initiate meetings with manufacturers to secure drug supply for the Program.
- 1.4.6.1.1.1.1.2. Department will provide the Contractor with a list of drugs and volume projections so that the Contractor can review and understand timing for supply acquisition.
- 1.4.6.1.1.1.1.3. Negotiate and execute a confidentiality or non-disclosure agreement with the manufacturers.
- 1.4.6.1.1.1.1.4. Meetings will include selected individuals from the Contractor agreed to prior to the meeting in writing.
- 1.4.6.1.1.1.1.5. All presentation materials, data, and information supplied by the Contractor for these meetings shall be approved by the Department and in a format approved by the Department.
- 1.4.6.1.1.1.1.6. Materials created in support of each meeting shall be submitted to the Department for review no later than 3 business days prior to the scheduled event.
- 1.4.6.1.1.1.1.7. Goals of each meeting shall be clearly defined prior to the meeting and must be agreed upon by the Contractor and Department.
- 1.4.6.1.1.1.1.8. For each invoiced meeting, the Contractor shall submit to the Department the following details:
 - 1.4.6.1.1.1.1.8.1. Date
 - 1.4.6.1.1.1.1.8.2. Time
 - 1.4.6.1.1.1.1.8.3. Individuals present on the call, including titles
 - 1.4.6.1.1.1.1.8.4. Subjects discussed
 - 1.4.6.1.1.1.1.8.5. Next Steps
- 1.4.6.1.1.1.2. DELIVERABLE: Initial Manufacturer Meeting
- 1.4.6.1.1.1.3. Cost: The Contractor shall be paid US\$500 per completed meeting. Incentive payments shall not exceed US\$40,000.00 per Fiscal year.
- 1.4.6.1.1.1.4. Due Date: TBD by the Contractor and Department
- 1.4.6.1.1.2. In-Person Manufacturer Negotiation Sessions
 - 1.4.6.1.1.2.1. The Contractor shall use commercially reasonable efforts to support the Department in manufacturer negotiations in person or virtually when there are travel restrictions in place to secure prescription drugs intended for export for the Program. The deliverable shall include preparatory time, the manufacturer meeting(s), presentation materials, and associated costs with conducting the deliverable, excluding any legal fees or costs.
 - 1.4.6.1.1.2.1.1. 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 deliverable and all applicable costs.

1.4.6.1.1.2.1.2. Meetings will include selected representatives of the Contractor, and representatives of the Department if necessary, agreed to prior to the meeting in writing.

1.4.6.1.1.2.1.3. Per negotiation session, the Contractor may meet with more than one manufacturer.

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

1.4.6.1.1.2.1.5. Materials created in support of each meeting shall be submitted to the Department for review no later than 2 business days prior to the scheduled event.

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

1.4.6.1.1.2.2. DELIVERABLE: In-Person Manufacturer Negotiation Session

1.4.6.1.1.2.3. Per Session Cost: The cost per in-person or virtual negotiation sessions shall be paid at the amount based on the following scale that includes a ~5% increase each year, or partial year, as applicable, as shown in the following rates:

1.4.6.1.1.2.3.1. 2022/2023 - US\$5,000.00 for in-person, US\$3,500.00 for virtual

1.4.6.1.1.2.3.2. 2023/2024 - US\$5,250.00 for in-person, US\$3,750.00 for virtual

1.4.6.1.1.2.3.3. 2024/2025 - US\$5,500.00 for in-person, US\$4,000.00 for virtual

1.4.6.1.1.2.3.4. 2025/2026 - US\$5,775.00 for in-person, US\$4,275.00 for virtual

1.4.6.1.1.2.3.5. 2026/2027 - US\$6,000.00 for in-person, US\$4,500.00 for virtual

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

1.4.6.1.1.2.4.1. 2022/2023 - US\$30,000.00

1.4.6.1.1.2.4.2. 2023/2024 - US\$70,000.00

1.4.6.1.1.2.4.3. 2024/2025: US \$70,000.00

1.4.6.1.1.2.4.4. 2025/2026: US \$70,000.00

1.4.6.1.1.2.4.5. 2026/2027: US \$70,000.00

1.4.6.1.1.3. Execution of a Supply Agreement with a Manufacturer

1.4.6.1.1.3.1. This is an ongoing deliverable to be paid upon signed agreement with the manufacturer.

1.4.6.1.1.3.2. Due Date: TBD by Contractor and Department

1.4.6.1.1.3.3. DELIVERABLE: Executed Supply Agreement

1.4.6.1.1.3.4. Cost: The Contractor shall be paid US\$10,000.00 per agreed upon drug in which a manufacturer agrees to participate in the Program. Incentive payments shall not exceed US \$50,000.00 for 2022/2023 Fiscal year and US\$70,000.00 per future Fiscal Years.

1.4.6.1.1.4. Manufacturer Contract Legal Support

1.4.6.1.1.4.1. Description: The department shall reimburse the contractor for legal fees associated with negotiation of an NDA and a supply agreement.

1.4.6.1.1.4.2. DELIVERABLE: Legal support for completed NDA and/or supply chain agreement.

1.4.6.1.1.4.3. Cost: The Department shall reimburse the Contractor up to the following dollar amounts billed hourly:

1.4.6.1.1.4.3.1. US\$5,000.00 for the negotiation of an NDA

1.4.6.1.1.4.3.2. US\$15,000.00 for the negotiation of a supply agreement contract

1.4.6.1.1.4.3.3. The total dollars in this deliverable shall not exceed the following fiscal year dollar amounts:

1.4.6.1.1.4.3.3.1. 2022/2023: US \$80,000.00

1.4.6.1.1.4.3.3.2. 2023/2024: US \$100,000.00

1.4.6.1.1.4.3.3.3. 2024/2025: US \$140,000.00

1.4.6.1.1.4.3.3.4. 2025/2026: US \$140,000.00

1.4.6.1.1.4.3.3.5. 2026/2027: US \$140,000.00

1.4.6.1.1.5. Consulting Support for the Importation Program

1.4.6.1.1.5.1. Hourly consulting regarding importation matters on topics relating to Canadian wholesaler processes and procedures, the role of Foreign Seller, drug pricing, manufacturer negotiations, or other issues of importation strategy.

1.4.6.1.1.5.2. DELIVERABLE: Hourly consulting support

1.4.6.1.1.5.3. Due Date: Date mutually agreed in writing by the Contractor and Department

1.4.6.1.1.5.4. Cost: The Contractor shall be paid at the hourly rate of US\$600, not to exceed US\$45,000 per state fiscal year.

1.4.6.1.1.6. Ad Hoc Projects

1.4.6.1.1.6.1. Ad Hoc Projects will be related to the overall scope of the work as described in 1.2.1. The Description and scope of each project will be mutually agreed to in writing by the Department and Contractor.

1.4.6.1.1.6.2. Due Date: Due date(s) shall be mutually agreed to in writing by the Department and Contractor

1.4.6.1.1.6.3. DELIVERABLE: Ad Hoc Projects

1.4.6.1.1.6.4.	Cost: Fiscal Year Cost: Ad Hoc Project(s) shall not exceed the dollar amounts shown in the table below:
1.4.6.1.1.6.4.1.	2022/2023: US \$122,000.00
1.4.6.1.1.6.4.2.	2023/2024: US \$90,000.00
1.4.6.1.1.6.4.3.	2024/2025: US \$50,000.00
1.4.6.1.1.6.4.4.	2025/2026: US \$50,000.00
1.4.6.1.1.6.4.5.	2026/2027: US \$50,000.00

2. COMPENSATION

2.1.1. The Contractor will receive payment as specified in Exhibit B-1, Rates.

2.2. Detailed Invoicing and Payment Procedures

2.2.1. Contractor shall invoice the Department on a monthly basis, by the 15th 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 of 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 being billed

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 2022-2023 (ALL \$ AMOUNTS IN USD)**

DELIVERABLE	DATE DUE TO THE DEPARTMENT	FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE
Importation Work Plan	TBD, Mutually Agreed	\$25,000.00
Profit Margin Methodology	TBD, Mutually Agreed	\$6,000.00
SIP Application Writing & Support	TBD, Agreed upon by Department	NTE \$25,000.00
Stakeholder Opportunities	TBD, Agreed upon by Department	NTE \$5,000.00
Hourly Consulting	TBD, Agreed upon by Department	NTE \$20,000.00
Manufacturer Negotiation Meetings	TBD, Agreed upon by Department	NTE \$40,000.00
Manufacturer In-Person Negotiation Sessions	TBD, Agreed upon by Department	NTE, \$50,000.00
Manufacturer Supply Agreement	TBD, Agreed upon by Department	NTE \$30,000.00
Manufacturer Contract Legal Support	TBD, Agreed upon by Department	NTE \$80,000.00
Consulting support for the Importation Program	TBD, Agreed Upon by the Department	NTE \$45,000.00
Ad Hoc Projects	TBD, Agreed upon by Department	\$122,000

TOTAL – STATE FISCAL YEAR 2022-2023	\$448,000.00
--	---------------------

STATE FISCAL YEAR 2023-2024 (ALL \$ AMOUNTS IN USD)

DELIVERABLE	DATE DUE TO THE DEPARTMENT	FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE
SIP Application Writing & Support	TBD, Agreed upon by Department	NTE \$15,000.00
Profit Margin Methodology	TBD, Mutually Agreed	\$6,000.00
Stakeholder Opportunities	TBD, Agreed upon by Department	NTE \$10,000.00
Hourly Consulting	TBD, Agreed upon by Department	NTE \$15,000.00
Manufacturer Negotiation Meetings	TBD, Agreed upon by Department	NTE \$40,000.00
Manufacturer In Person Negotiation Sessions	TBD, Agreed upon by Department	NTE, \$70,000.00
Manufacturer Contract Execution	TBD, Agreed upon by Department	NTE \$70,000.00
Manufacturer Contract Legal Support	TBD, Agreed upon by Department	NTE \$100,000.00
Consulting support for the Importation Program	TBD, Agreed Upon by the Department	NTE \$45,000.00
Ad Hoc Projects	TBD, Agreed upon by Department	NTE \$90,000
TOTAL – STATE FISCAL YEAR 2023-2024		\$461,000.00

STATE FISCAL YEAR 2024-2025 (ALL \$ AMOUNTS IN USD)

DELIVERABLE	DATE DUE TO THE DEPARTMENT	FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE
SIP Application Writing & Support	TBD, Agreed upon by Department	NTE \$15,000.00
Stakeholder Opportunities	TBD, Agreed upon by Department	NTE \$10,000.00
Hourly Consulting	TBD, Agreed upon by Department	NTE \$15,000.00
Manufacturer Negotiation Meetings	TBD, Agreed upon by Department	NTE \$40,000.00
Manufacturer In Person Negotiation Sessions	TBD, Agreed upon by Department	NTE, \$70,000.00
Manufacturer Contract Execution	TBD, Agreed upon by Department	NTE \$70,000.00
Manufacturer Contract Legal Support	TBD, Agreed upon by Department	NTE \$140,000.00
Consulting support for the Importation Program	TBD, Agreed Upon by the Department	NTE \$45,000.00
Ad Hoc Projects	TBD, Agreed upon by Department	NTE \$50,000
TOTAL – STATE FISCAL YEAR 2024-2025		\$455,000.00

STATE FISCAL YEAR 2025-2026 (ALL \$ AMOUNTS IN USD)

DELIVERABLE	DATE DUE TO THE DEPARTMENT	FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE
SIP Application Writing & Support	TBD, Agreed upon by Department	NTE \$15,000.00
Stakeholder Opportunities	TBD, Agreed upon by Department	NTE \$10,000.00
Hourly Consulting	TBD, Agreed upon by Department	NTE \$15,000.00
Manufacturer Negotiation Meetings	TBD, Agreed upon by Department	NTE \$40,000.00
Manufacturer In Person Negotiation Sessions	TBD, Agreed upon by Department	NTE, \$70,000.00
Manufacturer Contract Execution	TBD, Agreed upon by Department	NTE \$70,000.00
Manufacturer Contract Legal Support	TBD, Agreed upon by Department	NTE \$140,000.00
Consulting support for the Importation Program	TBD, Agreed Upon by the Department	NTE \$45,000.00
Ad Hoc Projects	TBD, Agreed upon by Department	NTE \$50,000
TOTAL – STATE FISCAL YEAR 2025-2026		\$455,000.00

STATE FISCAL YEAR 2026-2027 (ALL \$ AMOUNTS IN USD)

DELIVERABLE	DATE DUE TO THE DEPARTMENT	FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE
SIP Application Writing & Support	TBD, Agreed upon by Department	NTE \$15,000.00
Stakeholder Opportunities	TBD, Agreed upon by Department	NTE \$10,000.00
Hourly Consulting	TBD, Agreed upon by Department	NTE \$15,000.00
Manufacturer Negotiation Meetings	TBD, Agreed upon by Department	NTE \$40,000.00
Manufacturer In-Person Negotiation Sessions	TBD, Agreed upon by Department	NTE, \$70,000.00
Manufacturer Contract Execution	TBD, Agreed upon by Department	NTE \$70,000.00
Manufacturer Contract Legal Support	TBD, Agreed upon by Department	NTE \$140,000.00
Consulting support for the Importation Program	TBD, Agreed Upon by the Department	NTE \$45,000.00
Ad Hoc Projects	TBD, Agreed upon by Department	NTE \$50,000
TOTAL – STATE FISCAL YEAR 2026-2027		\$455,000.00

Total Contract Dollars, All Fiscal years (All \$ amounts in USD)	
Contract Year	Total Yearly Cost
FY 22/23	\$448,000.00
FY 23/24	\$461,000.00
FY 24/25	\$455,000.00
FY 25/26	\$455,000.00
FY 26/27	\$455,000.00
Total Contract dollars, all years	\$2,274,000.00

EXHIBIT C-1, TERMINOLOGY

1. IN ADDITION TO THE TERMS DEFINED IN §3 OF THIS CONTRACT, THE FOLLOWING LIST OF TERMS SHALL BE CONSTRUED AND INTERPRETED AS FOLLOWS:

- 1.1. Business Day – means any day other than Saturday, Sunday, or a Legal Holiday as listed in C.R.S. §24-11-101(1).
- 1.2. Business Interruption – Any event that disrupts Contractor’s ability to complete the Work for a period, and may include, but is not limited to a Disaster, power outage, strike, loss of necessary personnel or computer virus.
- 1.3. 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.
- 1.4. Colorado Revised Statutes (C.R.S.) – The legal code of Colorado; the legal codified general and permanent statutes of the Colorado General Assembly.
- 1.5. Health Canada Critical Observation – describes a situation that is likely to result in a product that may result in an immediate or latent health risk, or that involves fraud, misrepresentation or falsification of processes, products or data.
- 1.6. Deliverable – Any tangible or intangible object produced by Contractor as a result of the work conducted pursuant to Exhibit A, Statement of Work and Exhibit D, Contractor’s Administrative Requirements, as each may be amended, regardless of whether the object is specifically described or called out as a “Deliverable” or not.
- 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.
- 1.8. Eligible Prescription 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 from the Health Products and Food Branch of Health Canada.
- 1.9. Final Rule – The regulatory structure for state-led importation programs set forth by the FDA implementing 21 CFR Parts 1 and 251
- 1.10. 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
- 1.11. Individual Saleable Unit – smallest container of product sold by the Foreign Seller that is intended for individual sale to the Importer and eventually a dispenser.
- 1.12. 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.

- 1.13. Key Personnel – The position or positions that are specifically designated as such in this Contract.
- 1.14. Legal Holiday – a day on which Contractor or Department are authorized or required by United States or Canadian law or other United States or Canadian national, state or provincial government action to close. The recognized legal holidays in Canada are: New Year’s Day, Good Friday (or Easter Monday), Victoria Day, Canada Day, Labour Day, Thanksgiving Day, Remembrance Day, Christmas Day, and Boxing Day.
- 1.15. Other Personnel – Individuals and Subcontractors, in addition to Key Personnel, assigned to positions to complete tasks associated with the Work.
- 1.16. Program – Colorado Drug Importation Program
- 1.17. State – State of Colorado
- 1.18. 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.

2. ACRONYMS AND ABBREVIATIONS

- 2.1. The following list is provided to assist the reader in understanding certain acronyms and abbreviations used in this Contract:
 - 2.1.1. API – Active Pharmaceutical Ingredient
 - 2.1.2. CFR – Code of Federal Regulations
 - 2.1.3. C.R.S. – Colorado Revised Statutes
 - 2.1.4. FDA – United State Food and Drug Administration
 - 2.1.5. SIP – Section 804 Importation Proposal - the name of the application to FDA for an Importation program
 - 2.1.6. U.S.C. – United States Code
 - 2.1.7. TPL – Third Party Logistics Provider

EXHIBIT D-1, CONTRACTOR'S ADMINISTRATIVE REQUIREMENTS

1. CONTRACTOR'S GENERAL REQUIREMENTS

1.1. 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.

1.2. 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.

1.3. 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.

1.4. The Contractor shall maintain complete and detailed records of all Work related to Deliverables and Importation Program. The Contractor shall make such records available to the Department upon request throughout the term of the Contract.

1.5. Certain Excused Failures to Perform. Contractor will not incur any liability to the State on account of any loss or damage resulting from any delay or failure to perform all or any part of this Contract on the part of Contractor if such delay or failure is caused, in whole or in part, by events, occurrences, or causes arising out of any failure of any manufacturer to perform its manufacturing services relating to the Services (including due to any raw material or API shortages or any raw material or API price increases), any applicable United States Federal State or local law, regulation, standard or policy, applicable international law, regulation, standard or policy, any change in any existing applicable United States, Federal, State, local or international law, regulation, standard or policy, any change in any existing applicable law, regulation, standard or policy, any change in general market conditions with respect to the raw materials necessary to perform the Services, or any actions or decisions of a regulatory body or authority related to the importation of prescription drugs into the United States, or any other similar types of events outside the control of Contractor that relate to or impact the Importation Program or Contractor's ability to perform its obligations in the Statement of Work.

1.6. Deliverables

1.6.1. All Deliverables shall meet Department-approved format and content requirements. The Department will specify the number of copies and media for each Deliverable.

1.6.1.1. Contractor shall submit each Deliverable to the Department for review and approval and shall adhere to the following Deliverable process such for any documentation creation, review, and acceptable cycle, the Contractor shall:

1.6.1.1.1. Gather and document requirements for the Deliverable.

1.6.1.1.2. Create a draft in the Department-approved format for the individual Deliverable.

1.6.1.1.3. Perform internal quality control review(s) of the Deliverable, including, but not limited to:

1.6.1.1.3.1. Readability.

1.6.1.1.3.2. Spelling.

1.6.1.1.3.3. Grammar.

1.6.1.1.3.4. Completion.

1.6.1.1.4. Adhere to all required templates or development of templates.

1.6.1.1.5. Perform modifications that include version control and tracked changes.

1.6.1.2. The Department will review the Deliverable and may direct Contractor to make changes to the Deliverable. Contractor shall use its best efforts to 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.

1.6.1.2.1. Changes the Department direct include, but are not limited to, modifying portions of the Deliverable, requiring new pages or portions of the Deliverable, requiring resubmission of the Deliverable or requiring inclusion of information or components that were left out of the Deliverable.

1.6.1.2.2. 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.

1.6.1.3. 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 its acceptance of that Deliverable.

1.6.2. 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, contain accurate spelling and grammar, are formatted uniformly, and contain 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.

1.6.3. 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.

1.6.4. 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 be considered to be in Mountain Time, adjusted for Daylight Saving Time as appropriate, unless specifically stated otherwise.

1.6.5. No Deliverable, report, data, procedure or system created by Contractor for the Department that is necessary to fulfilling Contractor's responsibilities under the Contract, as determined by the Department, shall be considered proprietary, unless the information was redacted as confidential or proprietary to the Contractor.

1.6.6. 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 of that Deliverable. 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 considered to be requirements, milestones and Deliverables of this Contract.

1.6.6.1. Any Deliverable described as an update of another Deliverable shall be considered a version of the original Deliverable for the purposes of this subsection.

1.7. Stated Deliverables and Performance Standards

1.7.1. 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.

1.8. Communication with the Department

1.8.1. 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, on the Department's systems.

1.8.2. 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:

1.8.2.1. The date the request will be effective.

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

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

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

1.8.2.4.1. 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 from time to time by providing notice to the Contractor through an email request.

1.8.3. 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.

1.8.4. 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.

1.8.5. In the event that 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.

1.8.6. Transmittals may not be used in place of an amendment, and may not, under any circumstances be used to modify the term of the Contract or any compensation under the Contract. Transmittals are not intended to be the sole means of communication between the Department and the Contractor, and the Department may provide day-to-day communication to the Contractor without using a transmittal.

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

1.8.8. Business Continuity Plan

1.8.8.1. 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.

1.8.8.1.1. DELIVERABLE: Confirmation of a Business Continuity Plan

1.8.8.1.2. DUE: 10 Business Days prior to active importation beginning and then annually on or before July 15th, upon execution of the Contract in future years.

1.9. Closeout Period

1.9.1. During the Closeout Period, the Contractor shall complete all of the following:

1.9.1.1. 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.

1.9.1.2. Take all reasonable steps necessary to transfer all responsibilities under the Contract to the Department, or to another contractor at the Department's direction.

1.9.1.3. Notify any Subcontractors of the termination of the Contract, as directed by the Department.

1.9.1.4. Notify all applicable Subcontractors, that Contractor will no longer be the Contractor 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.

1.9.1.4.1. DELIVERABLE: Subcontractor Notifications

1.9.1.4.2. DUE: 30 days prior to termination of the Contract

1.9.1.5. Continue meeting each requirement of the Contract as described in the Department-approved and updated Closeout Plan, or until the Department determines that specific requirement is being performed by the Department or another contractor, whichever is sooner. The Department will determine when any

specific requirement is being performed by the Department or another contractor, and will notify the Contractor of this determination for that requirement.

1.9.1.6. The Closeout Period may extend past the termination of the Contract. The Department will perform a closeout review to ensure that Contractor has completed all requirements of the Closeout Period. If Contractor has not completed all of the requirements of the Closeout Period by the date of the termination of the Contract, then any incomplete requirements shall survive termination of the Contract.

1.9.2. The Department may, choose to not exercise any renewal option in the Contract for any reason. If the Department chooses to not exercise an option, it may reprocur the performance of the Work in its sole discretion.

1.9.3. The Parties may amend the Contract to extend beyond five years, in accordance with the Colorado Procurement Code and its implementing rules, in the event that the Department determines the extension is necessary to align the Contract with other Department contracts, to address state or federal programmatic or policy changes related to the Contract, or to provide sufficient time to transition the Work.

1.9.4. In the event that 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.

1.9.5. 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.

2. CONTRACTOR PERSONNEL

2.1. Personnel General Requirements

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

2.1.1.1.1. The Contractor shall designate people to hold the Key Personnel positions. The Contractor shall ensure the following roles are filled and the Contractor is able to complete the requirements on an ongoing basis.

2.1.1.1.2. In the event of change(s) to the designed people holding the following Key Personnel positions, the Department shall be notified within three business days.

2.1.1.1.3. The Contractor shall notify the Department of any change to the individual(s) holding the following Key Personnel positions.

2.1.1.2. DELIVERABLE: Notify the Department of change(s) to the individual(s) holding the following Key Personnel positions.

2.1.1.3. DUE: Within three Business Days after the change(s)

2.2. DELIVERABLE: Identify mutually agreeable replacement(s) to the designated Key Personnel based on the change notification

2.3. DUE: Within 30 days after the notice of change(s) is provided to the Department.

2.3.1.1. Contractor shall provide the Department with a final list of individuals assigned to the Contract and appropriate contact information for those individuals.

2.3.1.1.1. DELIVERABLE: Final list of individuals assigned to the Contract

2.3.1.1.2. DUE: Within fifteen Business Days after the Effective Date

2.3.1.2. Contractor shall update this list upon the Department's request to account for changes in the individuals assigned to the Contract.

2.3.1.2.1. DELIVERABLE: Updated list of individuals assigned to the Contract

2.3.1.2.2. DUE: Within five Business Days after the Department's request for an update

2.3.2. 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 to be assigned as Key Personnel.

2.3.3. 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 and resume and for any proposed replacement whenever there is a change to Key Personnel.

2.3.4. 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.

2.3.4.1. DELIVERABLE: Name(s) and resume(s) for the person(s) replacing anyone in a Key Personnel position during a voluntary change

2.3.4.2. DUE: At least five Business Days prior to the change in Key Personnel

2.3.5. 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.

2.3.5.1. DELIVERABLE: Name(s) and resume(s) for the person(s) replacing anyone in a Key Personnel position who leaves employment with Contractor

2.3.5.2. DUE: Within 10 Business Days after Contractor's receipt of notice that the person is leaving employment, unless the Department allows for a longer time in writing for Contractor to recruit a replacement

2.4. Personnel Availability

2.4.1. Contractor shall ensure Key Personnel and Other Personnel assigned to the Contract will make themselves available for meetings with the Department during the Department's normal business hours, at mutually agreeable time. Contractor shall also make these personnel available outside of the Department's normal business hours and on weekends with prior written notice of 2 business days from the Department.

2.4.2. 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.

2.4.3. 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.

2.4.4. At the Department's direction and at mutually agreeable times, 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.

2.5. Key Personnel

2.5.1. 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 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:

2.5.1.1. Project Lead

2.5.1.1.1. The Project Lead shall have the following qualifications and responsibilities under this Contract:

2.5.1.1.1.1. Serves as the Contractor's primary point of contact for the Department.

2.5.1.1.1.2. Ensures 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.

2.5.1.1.1.3. Oversees all other Key Personnel and Other Personnel and ensures proper staffing levels throughout the term of the Contract.

2.5.1.1.1.4. Has Project Management experience.

2.5.1.1.1.5. The Project Lead may serve as the Project Lead while also holding another Key Personnel position, as set forth herein.

2.5.1.1.2. The Project Lead shall be responsible for all of the following:

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

2.5.1.1.2.2. 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.

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

2.5.1.2. Exportation Operations Manager

2.5.1.3. Purchasing Manager

2.5.1.4. Quality Assurance Manager

2.5.2. 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.

2.5.3. In the event of significant change in the Contractor's CEO or President, the Department shall be notified within three business days and reserves the right to terminate the Contract if mutually agreeable replacements are not identified within 30 days.

2.5.4. 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:

2.5.4.1. Contractor shall provide the organizational name of each Subcontractor and all items to be worked on by each Subcontractor to the Department.

2.5.4.1.1. DELIVERABLE: Name of each Subcontractor and items on which each Subcontractor will work

2.5.4.1.2. DUE: The later of 30 days prior to the Subcontractor beginning work or the Effective Date