

STATE OF COLORADO INTERGOVERNMENTAL AGREEMENT

COVER PAGE

State Agency Department of Health Care Policy and Financing	Contract C23-177846		
Contractor Denver Health and Hospital Authority, a body corporate and political subdivision of the State of Colorado, on behalf of its division, Rocky Mountain Poison and Drug Safety	Contract Performance Beginning Date Date of Execution		
Contract Maximum Amount Initial Term State Fiscal Year 2023 \$181,250.00 Extension Terms State Fiscal Year 2024 \$160,000.00 State Fiscal Year 2025 \$155,000.00 State Fiscal Year 2026 \$155,000.00 State Fiscal Year 2027 \$155,000.00 Total for All State Fiscal Years \$806,250.00	Initial Contract Expiration Date June 30, 2023 Contract Authority Authority to enter into this Contract exists in C.R.S. §25.5-1-101, <i>et. seq.</i> 21 CFR Parts 1 and 251 - Drug Importation Final Rule 21 U.S. Code 384 - Importation of Prescription Drugs Colorado Revised Statutes §25.5-1-201 through 207 21 CFR Part 205.50		
Contract Purpose The purpose of this project is to develop and implement a program to import Canadian prescription drugs for the state of Colorado. The Contractor will be the Department's Drug Importation Reporting Vendor. They will be responsible for all required adverse event and FDA reporting as required by the Final Rule, respond to consumer inquiries, and consult on importation topics.			
Exhibits and Order of Precedence The following Exhibits and attachments are included with this Contract: <ol style="list-style-type: none"> 1. Exhibit A – HIPAA Business Associates Addendum 2. Exhibit B – Statement of Work 3. Exhibit C – Rates 4. Exhibit D – Terminology 5. Exhibit E – Contractor’s Administrative Requirements 6. Exhibit F – Sample Option Letter 7. In the event of a conflict or inconsistency between this Contract and any Exhibit or attachment, such conflict or inconsistency shall be resolved by reference to the documents in the following order of priority: <ol style="list-style-type: none"> 1. Exhibit A, HIPAA Business Associates Addendum. 2. Colorado Special Provisions in §18 of the main body of this Contract. 3. The provisions of the other sections of the main body of this Contract. 4. Exhibit B, Statement of Work. 5. Exhibit C, Terminology 6. Exhibit D, Contractor’s Administrative Requirements 7. Exhibit E, Rates. 8. Exhibit F, Sample Option Letter. 			
Principal Representatives <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> For the State: Lauren Reveley Department of Health Care Policy & Financing 1570 Grant Street Denver, CO 80203 lauren.reveley@state.co.us Lauren Reveley </td> <td style="width: 50%; border: none;"> For Contractor: Brandon Ensign Rocky Mountain Poison & Drug Safety 777 Bannock Street Denver, CO, 80204 brandon.ensign@dhha.org Brandon Ensign </td> </tr> </table>		For the State: Lauren Reveley Department of Health Care Policy & Financing 1570 Grant Street Denver, CO 80203 lauren.reveley@state.co.us Lauren Reveley	For Contractor: Brandon Ensign Rocky Mountain Poison & Drug Safety 777 Bannock Street Denver, CO, 80204 brandon.ensign@dhha.org Brandon Ensign
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SIGNATURE PAGE

THE PARTIES HERETO HAVE EXECUTED THIS CONTRACT

Each person signing this Contract represents and warrants that the signer is duly authorized to execute this Contract and to bind the Party authorizing such signature.

<p style="text-align: center;">CONTRACTOR</p> <p>Denver Health and Hospital Authority, a body corporate and political subdivision of the State of Colorado, on behalf of its division, Rocky Mountain Poison and Drug Safety Nancy Botiller, COO</p> <p style="text-align: center;">DocuSigned by: <i>Nancy Botiller</i> <small>505036FFD031456</small></p> <p>By: _____</p> <p style="text-align: right;">Date: <u>7/29/2022</u></p>	<p style="text-align: center;">STATE OF COLORADO</p> <p style="text-align: center;">Jared S. Polis, Governor</p> <p style="text-align: center;">Department of Health Care Policy and Financing Kim Bimestefer, Executive Director</p> <p style="text-align: center;">DocuSigned by: <i>Kim Bimestefer</i> <small>0B6A84797EA8493...</small></p> <p>By: _____</p> <p style="text-align: right;">Date: <u>7/29/2022</u></p>
	<p style="text-align: center;">LEGAL REVIEW</p> <p style="text-align: center;">Phil Weiser, Attorney General</p> <p>By: _____ <u>N/A</u> _____</p> <p style="text-align: right;">Date: _____</p>
<p style="text-align: center;">In accordance with §24-30-202, C.R.S., this Contract is not valid until signed and dated below by the State Controller or an authorized delegate.</p> <p style="text-align: center;">STATE CONTROLLER</p> <p style="text-align: center;">Robert Jaros, CPA, MBA, JD</p> <p style="text-align: center;">DocuSigned by: <i>Jerrold Cotosman</i> <small>76F69541272B43A...</small></p> <p>By: _____</p> <p style="text-align: right;">Effective Date: <u>8/1/2022</u></p>	

TABLE OF CONTENTS

1.	PARTIES	2
2.	TERM AND EFFECTIVE DATE.....	2
3.	DEFINITIONS	3
4.	STATEMENT OF WORK	6
5.	PAYMENTS TO CONTRACTOR	6
6.	REPORTING - NOTIFICATION	7
7.	CONTRACTOR RECORDS.....	7
8.	CONFIDENTIAL INFORMATION-STATE RECORDS.....	8
9.	CONFLICTS OF INTEREST.....	10
10.	INSURANCE	10
11.	BREACH OF CONTRACT	12
12.	REMEDIES	12
13.	DISPUTE RESOLUTION.....	14
14.	NOTICES AND REPRESENTATIVES	15
15.	RIGHTS IN WORK PRODUCT AND OTHER INFORMATION.....	15
16.	GENERAL PROVISIONS	16
17.	COLORADO SPECIAL PROVISIONS (COLORADO FISCAL RULE 3-3).....	19
	EXHIBIT A, HIPAA BUSINESS ASSOCIATES ADDENDUM.....	1
	EXHIBIT B, STATEMENT OF WORK.....	1
	EXHIBIT C, RATES	ERROR! BOOKMARK NOT DEFINED.
	EXHIBIT D, TERMINOLOGY	1
	EXHIBIT E, CONTRACTOR’S ADMINISTRATIVE REQUIREMENTS	1
	EXHIBIT F, SAMPLE OPTION LETTER.....	1

1. PARTIES

This Contract is entered into by and between the STATE OF COLORADO acting by and through the State agency named on the Cover Page for this Contract (the “State,” the “Department,” or “HCPF”) and Contractor named on the Cover Page for this Contract (the “Contractor”). Contractor and the State agree to the terms and conditions in this Contract.

2. 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 - State’s Option

The State, at its discretion, shall have the option to extend the performance under this Contract beyond the Initial Term for a period, or for successive periods, of one year or less at the same rates and under the same terms specified in the Contract (each such period an “Extension Term”). 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. Except as stated in §2.D, the total duration of this Contract, including the exercise of any options to extend, shall not exceed five years from its Effective Date absent prior approval from the Chief Procurement Officer in accordance with the Colorado Procurement Code.

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. Payments

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.

3. DEFINITIONS

The following terms shall be construed and interpreted as follows:

- A. "**Breach of Contract**" means the failure of a Party to perform any of its obligations in accordance with this Contract, in whole or in part or in a timely or satisfactory manner. The institution of proceedings under any bankruptcy, insolvency, reorganization or similar law, by or against Contractor, or the appointment of a receiver or similar officer for Contractor or any of its property, which is not vacated or fully stayed within 30 days after the institution of such proceeding, shall also constitute a breach. If Contractor is debarred or suspended under §24-109-105, C.R.S. at any time during the term of this Contract, then such debarment or suspension shall constitute a breach.
- B. "**Business Day**" means any day other than Saturday, Sunday, or a Legal Holiday as listed in C.R.S. §24-11-101(1).
- C. "**Chief Procurement Officer**" means the individual to whom the Executive Director has delegated his or her authority, pursuant to C.R.S. §24-102-202(6), to procure or supervise the procurement of all supplies and services needed by the state.
- D. "**Contract**" means this agreement, including all attached Exhibits, all documents incorporated by reference, all referenced statutes, rules and cited authorities, and any future modifications thereto.
- E. "**Contract Funds**" means the funds that have been appropriated, designated, encumbered, or otherwise made available for payment by the State under this Contract.
- F. "**Contractor Pre-Existing Material**" means material, code, methodology, concepts, process, systems, technique, trade or service marks, copyrights, or other intellectual property

developed, licensed or otherwise acquired by Contractor prior to the Effective Date of this Contract and independent of any services rendered under any other contract with the State.

- G. “**Colorado Open Records Act (CORA)**” means C.R.S. §24-72-200.1, *et. seq.*
- H. “**Criminal Justice Information (CJI)**” means criminal justice information collected by criminal justice agencies needed for the performance of their authorized functions, including, without limitation, all information defined as criminal justice information by the U.S. Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Security Policy, as amended and all Criminal Justice Records as defined under C.R.S. §24-72-302.
- I. “**Effective Date**” means the date on which this Contract is approved and signed by the Colorado State Controller or designee, as shown on the Cover Page for this Contract. If this Contract is for a Major Information Technology Project, as defined in §24-37.5-102(2.6), C.R.S., then the Effective Date of this Contract shall be the later of the date on which this Contract is approved and signed by the State’s Chief Information Officer or authorized delegate or the date on which this Contract is approved and signed by the State Controller or authorized delegate, as shown on the Cover Page for this Contract.
- J. “**End of Term Extension**” means the time period defined in §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 information resources of the State, which are included as part of the Work, as described in C.R.S. §24-37.5-401, *et. seq.* Incidents include, without limitation, (i) successful attempts to gain unauthorized access to a State system or State Information regardless of where such information is located; (ii) unwanted disruption or denial of service; (iii) the unauthorized use of a State system for the processing or storage of 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. “**Payment Card Information (PCI)**” means payment card information including any data related to credit card holders’ names, credit card numbers, or the other credit card information as may be protected by state or federal law.
- R. “**Personal Health Information (PHI)**” means any protected health information, including, without limitation any information whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the

individual. PHI includes, but is not limited to, any information defined as Individually Identifiable Health Information by the federal Health Insurance Portability and Accountability Act.

- S. **“Personally Identifiable Information (PII)”** means personally identifiable information including, without limitation, any information maintained by the State about an individual that can be used to distinguish or trace an individual’s identity, such as name, social security number, date and place of birth, mother’s maiden name, or biometric records; and any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information. PII includes, but is not limited to, all information defined as personally identifiable information in C.R.S. §24-72-501.
- T. **“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.
- U. **“State Confidential Information”** means any and all State Records not subject to disclosure under CORA. State Confidential Information shall include, but is not limited to, PII, PHI, PCI, Tax Information, CJI, and State personnel records not subject to disclosure under CORA. State Confidential Information shall not include information or data concerning individuals that is not deemed confidential but nevertheless belongs to the State, which has been communicated, furnished, or disclosed by the State to Contractor which (i) is subject to disclosure pursuant to CORA; (ii) is already known to Contractor without restrictions at the time of its disclosure to Contractor; (iii) is or subsequently becomes publicly available without breach of any obligation owed by Contractor to the State; (iv) is disclosed to Contractor, without confidentiality obligations, by a third party who has the right to disclose such information; or (v) was independently developed without reliance on any State Confidential Information.
- V. **“State Fiscal Rules”** means the fiscal rules promulgated by the Colorado State Controller pursuant to C.R.S. §24-30-202(13)(a).
- W. **“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.
- X. **“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.
- Y. **“Subcontractor”** means third-parties, if any, engaged by Contractor to aid in performance of the Work.
- Z. **“Tax Information”** means federal and State of Colorado tax information including, without limitation, federal and State tax returns, return information, and such other tax-related information as may be protected by federal and State law and regulation. Tax Information includes, but is not limited to, all information defined as federal tax information in Internal Revenue Service Publication 1075.
- AA. **“Work”** means the Goods delivered and Services performed pursuant to this Contract.
- BB. **“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 D.

4. STATEMENT OF WORK

Contractor shall complete the Work as described in this Contract and in accordance with the provisions of Exhibit B, and Exhibit E. 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.

5. 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 B, Statement of Work and Exhibit C, 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.

6. REPORTING - NOTIFICATION

A. Quarterly Reports.

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

B. 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.

7. 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

Contractor shall permit the State to audit, inspect, examine, excerpt, copy and transcribe Contractor Records during the Record Retention Period. 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 as determined by the State. 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.

8. 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. If Contractor or any of its Subcontractors will or may receive the following types of data, Contractor or its Subcontractors shall provide for the security of such data according to the following: (i) the most recently promulgated IRS Publication 1075 for all Tax Information and in accordance with the Safeguarding Requirements for Federal Tax Information attached to this Contract as an Exhibit, if applicable, (ii) the most recently updated PCI Data Security Standard from the PCI Security Standards Council for all PCI, (iii) the most recently issued version of the U.S. Department of Justice, Federal Bureau of

Investigation, Criminal Justice Information Services Security Policy for all CJ, and (iv) the federal Health Insurance Portability and Accountability Act for all PHI and the HIPAA Business Associate Agreement attached to this Contract, if applicable. Contractor shall immediately forward any request or demand for State Records to the State's principal representative.

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 ensure all such agents, employees, assigns, and Subcontractors sign agreements containing nondisclosure provisions at least as protective as those in this Contract, and that the nondisclosure provisions are in force at all times the agent, employee, assign or Subcontractor has access to any State Confidential Information. Contractor shall provide copies of those signed nondisclosure provisions to the State upon execution of the nondisclosure provisions.

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, and cease to use, such State Confidential Information.

D. Incident Notice and Remediation

If Contractor becomes aware of any Incident, it 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 none of Contractor or any of its agents, employees, assigns or Subcontractors are 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, 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 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.

F. Safeguarding PII

If Contractor or any of its Subcontractors will or may receive PII under this Contract, Contractor shall provide for the security of such PII, in a manner and form acceptable to the State, including, without limitation, State non-disclosure requirements, use of appropriate technology, security practices, computer access security, data access security, data storage encryption, data transmission encryption, security inspections, and audits. Contractor shall be a "Third-Party Service Provider" as defined in §24-73-103(1)(i), C.R.S. and shall maintain security procedures and practices consistent with §§24-73-101 *et seq.*, C.R.S.

9. 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.

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.

10. 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 that are not provided through self-insurance shall be issued by insurance companies as approved by the state.

A. Contractor Insurance

The Contractor is a "public entity" within the meaning of the Colorado Governmental Immunity Act, §24-10-101, *et seq.*, C.R.S. (the "GIA") and shall maintain at all times during the term of this Contract such liability insurance, by commercial policy or self-insurance, as is necessary to meet its liabilities under the GIA.

B. Subcontractor Requirements

Contractor shall ensure that each Subcontractor that is a public entity within the meaning of the GIA, maintains at all times during the terms of this Contract, such liability insurance, by commercial policy or self-insurance, as is necessary to meet the Subcontractor's obligations under the GIA. Contractor shall ensure that each Subcontractor that is not a public entity

within the meaning of the GIA, maintains at all times during the terms of this Contract all of the following insurance policies:

i. 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.

ii. 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:

- a. \$1,000,000 each occurrence;
- b. \$1,000,000 general aggregate;
- c. \$1,000,000 products and completed operations aggregate; and
- d. \$50,000 any 1 fire.

iii. Automobile Liability

Automobile liability insurance covering any auto (including owned, hired and non-owned autos) with a minimum limit of \$1,000,000 each accident combined single limit.

iv. Protected Information

Liability insurance covering all loss of State Confidential Information, such as PII, PHI, PCI, Tax Information, and CJI, and claims based on alleged violations of privacy rights through improper use or disclosure of protected information with minimum limits as follows:

- a. \$1,000,000 each occurrence; and
- b. \$2,000,000 general aggregate.

v. Professional Liability Insurance

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

- a. \$1,000,000 each occurrence; and
- b. \$1,000,000 general aggregate.

vi. Crime Insurance

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

- a. \$1,000,000 each occurrence; and
- b. \$1,000,000 general aggregate.

C. 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.

D. 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.

E. Cancellation

All commercial 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 7 days of Contractor's receipt of such notice.

F. Subrogation Waiver

All commercial 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.

G. Certificates

For each commercial insurance plan provided by Contractor under this Contract, Contractor shall provide to the State certificates evidencing Contractor's insurance coverage required in this Contract within 7 Business Days following the Effective Date. Contractor shall provide to the State certificates evidencing Subcontractor insurance coverage required under this Contract within 7 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 7 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 7 Business Days following the request by the State, supply to the State evidence satisfactory to the State of compliance with the provisions of this §10.

11. 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.

12. REMEDIES

A. State's Remedies

If Contractor is in breach under any provision of this Contract and fails to cure such breach, the State, following the notice and cure period set forth in §11, shall have all of the remedies listed in this section, in addition to all other remedies set forth in this Contract or at law. 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 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.

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 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's terms. 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 immediate 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.

e. Intellectual Property

If any Work infringes, or if the State in its sole discretion determines that any Work is likely to infringe, a patent, copyright, trademark, trade secret or other intellectual property right, Contractor shall, as approved by the State (i) secure that right to use such Work for the State and Contractor; (ii) replace the Work with noninfringing Work or modify the Work so that it becomes noninfringing; or, (iii) remove any infringing Work and refund the amount paid for such Work to the State.

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.

13. 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.

14. 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 of 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 Sheet of 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 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.

15. RIGHTS IN WORK PRODUCT AND OTHER INFORMATION

A. Work Product

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. 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.

i. Copyrights

To the extent that the Work Product (or any portion of the Work Product) would not be considered a work 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.

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.

16. 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. 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

B. Subcontracts

Contractor shall not enter into any subcontract in connection with its obligations under this Contract without the prior, written approval of the State. Contractor shall submit to the State a copy of each such subcontract upon request by the State. 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.

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. **Additional Provisions**

Contractor shall comply with all requirements shown Exhibit A and Exhibit G.

17. COLORADO SPECIAL PROVISIONS (COLORADO FISCAL RULE 3-3)

These Special Provisions apply to all contracts except where noted in italics.

A. **STATUTORY APPROVAL. C.R.S. §24-30-202(1)**

This Contract shall not be valid until it has been approved by the Colorado State Controller or designee. If this Contract is for a Major Information Technology Project, as defined in §24-37.5-102(2.6), then this Contract shall not be valid until it has been approved by the State's Chief Information Officer or designee.

B. **FUND AVAILABILITY. C.R.S. §24-30-202(5.5)**

Financial obligations of the State payable after the current State Fiscal Year are contingent upon funds for that purpose being appropriated, budgeted, and otherwise made available.

C. **GOVERNMENTAL IMMUNITY.**

Liability for claims for injuries to persons or property arising from the negligence of the State, its departments, boards, commissions committees, bureaus, offices, employees and officials shall be controlled and limited by the provisions of the Colorado Governmental Immunity Act, §24-10-101, et seq., C.R.S.; the Federal Tort Claims Act, 28 U.S.C. Pt. VI, Ch. 171 and 28 U.S.C. 1346(b), and the State's risk management statutes, §§24-30-1501, et seq. C.R.S. No term or condition of this Contract shall be construed or interpreted as a waiver, express or implied, of any of the immunities, rights, benefits, protections, or other provisions, contained in these statutes.

D. **INDEPENDENT CONTRACTOR.**

Contractor shall perform its duties hereunder as an independent contractor and not as an employee. Neither Contractor nor any agent or employee of Contractor shall be deemed to be an agent or employee of the State. Contractor shall not have authorization, express or implied, to bind the State to any agreement, liability or understanding, except as expressly set forth herein. **Contractor and its employees and agents are not entitled to unemployment insurance or workers compensation benefits through the State and the State shall not pay for or otherwise provide such coverage for Contractor or any of its agents or employees. Contractor shall pay when due all applicable employment taxes and income taxes and local head taxes incurred pursuant to this Contract. Contractor shall (i) provide and keep in force workers' compensation and unemployment compensation insurance in the amounts required by law, (ii) provide proof thereof when requested by the State, and (iii) be solely responsible for its acts and those of its employees and agents.**

E. **COMPLIANCE WITH LAW.**

Contractor shall strictly comply with all applicable federal and State laws, rules, and regulations in effect or hereafter established, including, without limitation, laws applicable

to discrimination and unfair employment practices.

F. CHOICE OF LAW, JURISDICTION, AND VENUE.

Colorado law, and rules and regulations issued pursuant thereto, shall be applied in the interpretation, execution, and enforcement of this Contract. Any provision included or incorporated herein by reference which conflicts with said laws, rules, and regulations shall be null and void. All suits or actions related to this Contract shall be filed and proceedings held in the State of Colorado and exclusive venue shall be in the City and County of Denver.

G. PROHIBITED TERMS.

Any term included in this Contract that requires the State to indemnify or hold Contractor harmless; requires the State to agree to binding arbitration; limits Contractor's liability for damages resulting from death, bodily injury, or damage to tangible property; or that conflicts with this provision in any way shall be void ab initio. Nothing in this Contract shall be construed as a waiver of any provision of §24-106-109 C.R.S.

H. SOFTWARE PIRACY PROHIBITION.

State or other public funds payable under this Contract shall not be used for the acquisition, operation, or maintenance of computer software in violation of federal copyright laws or applicable licensing restrictions. Contractor hereby certifies and warrants that, during the term of this Contract and any extensions, Contractor has and shall maintain in place appropriate systems and controls to prevent such improper use of public funds. If the State determines that Contractor is in violation of this provision, the State may exercise any remedy available at law or in equity or under this Contract, including, without limitation, immediate termination of this Contract and any remedy consistent with federal copyright laws or applicable licensing restrictions.

I. EMPLOYEE FINANCIAL INTEREST/CONFLICT OF INTEREST. C.R.S. §§24-18-201 and 24-50-507

The signatories aver that to their knowledge, no employee of the State has any personal or beneficial interest whatsoever in the service or property described in this Contract. Contractor has no interest and shall not acquire any interest, direct or indirect, that would conflict in any manner or degree with the performance of Contractor's services and Contractor shall not employ any person having such known interests.

EXHIBIT A, HIPAA BUSINESS ASSOCIATES ADDENDUM

This HIPAA Business Associate Agreement (“Agreement”) between the State and Contractor is agreed to in connection with, and as an exhibit to, the Contract. For purposes of this Agreement, the State is referred to as “Covered Entity” and the Contractor is referred to as “Business Associate”. Unless the context clearly requires a distinction between the Contract and this Agreement, all references to “Contract” shall include this Agreement.

1. PURPOSE

Covered Entity wishes to disclose information to Business Associate, which may include Protected Health Information (“PHI”). The Parties intend to protect the privacy and security of the disclosed PHI in compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), Pub. L. No. 104-191 (1996) as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”) enacted under the American Recovery and Reinvestment Act of 2009 (“ARRA”) Pub. L. No. 111-5 (2009), implementing regulations promulgated by the U.S. Department of Health and Human Services at 45 C.F.R. Parts 160, 162 and 164 (the “HIPAA Rules”) and other applicable laws, as amended. Prior to the disclosure of PHI, Covered Entity is required to enter into an agreement with Business Associate containing specific requirements as set forth in, but not limited to, Title 45, Sections 160.103, 164.502(e) and 164.504(e) of the Code of Federal Regulations (“C.F.R.”) and all other applicable laws and regulations, all as may be amended.

2. DEFINITIONS

The following terms used in this Agreement shall have the same meanings as in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required by Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

The following terms used in this Agreement shall have the meanings set forth below:

- a. Business Associate. “Business Associate” shall have the same meaning as the term “business associate” at 45 C.F.R. 160.103, and shall refer to Contractor.
- b. Covered Entity. “Covered Entity” shall have the same meaning as the term “covered entity” at 45 C.F.R. 160.103, and shall refer to the State.
- c. Information Technology and Information Security. “Information Technology” and “Information Security” shall have the same meanings as the terms “information technology” and “information security”, respectively, in §24-37.5-102, C.R.S.

Capitalized terms used herein and not otherwise defined herein or in the HIPAA Rules shall have the meanings ascribed to them in the Contract.

3. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

a. Permitted Uses and Disclosures.

- i. Business Associate shall use and disclose PHI only to accomplish Business Associate's obligations under the Contract.
- i. To the extent Business Associate carries out one or more of Covered Entity's obligations under Subpart E of 45 C.F.R. Part 164, Business Associate shall comply with any and all requirements of Subpart E that apply to Covered Entity in the performance of such obligation.
- ii. Business Associate may disclose PHI to carry out the legal responsibilities of Business Associate, provided, that the disclosure is Required by Law or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that:
 - A. the information will remain confidential and will be used or disclosed only as Required by Law or for the purpose for which Business Associate originally disclosed the information to that person, and;
 - B. the person notifies Business Associate of any Breach involving PHI of which it is aware.
- iii. Business Associate may provide Data Aggregation services relating to the Health Care Operations of Covered Entity. Business Associate may de-identify any or all PHI created or received by Business Associate under this Agreement, provided the de-identification conforms to the requirements of the HIPAA Rules.

b. Minimum Necessary. Business Associate, its Subcontractors and agents, shall access, use, and disclose only the minimum amount of PHI necessary to accomplish the objectives of the Contract, in accordance with the Minimum Necessary Requirements of the HIPAA Rules including, but not limited to, 45 C.F.R. 164.502(b) and 164.514(d).

c. Impermissible Uses and Disclosures.

- i. Business Associate shall not disclose the PHI of Covered Entity to another covered entity without the written authorization of Covered Entity.
- ii. Business Associate shall not share, use, disclose or make available any Covered Entity PHI in any form via any medium with or to any person or entity beyond the boundaries or jurisdiction of the United States without express written authorization from Covered Entity.

d. Business Associate's Subcontractors.

- i. Business Associate shall, in accordance with 45 C.F.R. 164.502(e)(1)(ii) and 164.308(b)(2), ensure that any Subcontractors who create, receive, maintain, or transmit PHI on behalf of Business Associate agree in writing to the same restrictions,

conditions, and requirements that apply to Business Associate with respect to safeguarding PHI.

- ii. Business Associate shall provide to Covered Entity, on Covered Entity's request, a list of Subcontractors who have entered into any such agreement with Business Associate.
 - iii. Business Associate shall provide to Covered Entity, on Covered Entity's request, copies of any such agreements Business Associate has entered into with Subcontractors.
- e. Access to System. If Business Associate needs access to a Covered Entity Information Technology system to comply with its obligations under the Contract or this Agreement, Business Associate shall request, review, and comply with any and all policies applicable to Covered Entity regarding such system including, but not limited to, any policies promulgated by the Office of Information Technology and available at <http://oit.state.co.us/about/policies>.
- f. Access to PHI. Business Associate shall, within ten days of receiving a written request from Covered Entity, make available PHI in a Designated Record Set to Covered Entity as necessary to satisfy Covered Entity's obligations under 45 C.F.R. 164.524.
- g. Amendment of PHI.
- i. Business Associate shall within ten days of receiving a written request from Covered Entity make any amendment to PHI in a Designated Record Set as directed by or agreed to by Covered Entity pursuant to 45 C.F.R. 164.526, or take other measures as necessary to satisfy Covered Entity's obligations under 45 C.F.R. 164.526.
 - ii. Business Associate shall promptly forward to Covered Entity any request for amendment of PHI that Business Associate receives directly from an Individual.
- h. Accounting Rights. Business Associate shall, within ten days of receiving a written request from Covered Entity, maintain and make available to Covered Entity the information necessary for Covered Entity to satisfy its obligations to provide an accounting of Disclosure under 45 C.F.R. 164.528.
- i. Restrictions and Confidential Communications.
- i. Business Associate shall restrict the Use or Disclosure of an Individual's PHI within ten days of notice from Covered Entity of:
 - A. a restriction on Use or Disclosure of PHI pursuant to 45 C.F.R. 164.522; or
 - B. a request for confidential communication of PHI pursuant to 45 C.F.R. 164.522.
 - ii. Business Associate shall not respond directly to an Individual's requests to restrict the Use or Disclosure of PHI or to send all communication of PHI to an alternate address.

- iii. Business Associate shall refer such requests to Covered Entity so that Covered Entity can coordinate and prepare a timely response to the requesting Individual and provide direction to Business Associate.

- j. Governmental Access to Records. Business Associate shall make its facilities, internal practices, books, records, and other sources of information, including PHI, available to the Secretary for purposes of determining compliance with the HIPAA Rules in accordance with 45 C.F.R. 160.310.

- k. Audit, Inspection and Enforcement.
 - i. Business Associate shall obtain and update at least annually a written assessment performed by an independent third party reasonably acceptable to Covered Entity, which evaluates the Information Security of the applications, infrastructure, and processes that interact with the Covered Entity data Business Associate receives, manipulates, stores and distributes. Upon request by Covered Entity, Business Associate shall provide to Covered Entity the executive summary of the assessment.

 - ii. Business Associate, upon the request of Covered Entity, shall fully cooperate with Covered Entity's efforts to audit Business Associate's compliance with applicable HIPAA Rules. If, through audit or inspection, Covered Entity determines that Business Associate's conduct would result in violation of the HIPAA Rules or is in violation of the Contract or this Agreement, Business Associate shall promptly remedy any such violation and shall certify completion of its remedy in writing to Covered Entity.

- l. Appropriate Safeguards.
 - i. Business Associate shall use appropriate safeguards and comply with Subpart C of 45 C.F.R. Part 164 with respect to electronic PHI to prevent use or disclosure of PHI other than as provided in this Agreement.

 - ii. Business Associate shall safeguard the PHI from tampering and unauthorized disclosures.

 - iii. Business Associate shall maintain the confidentiality of passwords and other data required for accessing this information.

 - iv. Business Associate shall extend protection beyond the initial information obtained from Covered Entity to any databases or collections of PHI containing information derived from the PHI. The provisions of this section shall be in force unless PHI is de-identified in conformance to the requirements of the HIPAA Rules.

- m. Safeguard During Transmission.
 - i. Business Associate shall use reasonable and appropriate safeguards including, without limitation, Information Security measures to ensure that all transmissions of PHI are authorized and to prevent use or disclosure of PHI other than as provided for by this Agreement.

- ii. Business Associate shall not transmit PHI over the internet or any other insecure or open communication channel unless the PHI is encrypted or otherwise safeguarded with a FIPS-compliant encryption algorithm.
- n. Reporting of Improper Use or Disclosure and Notification of Breach.
- i. Business Associate shall, as soon as reasonably possible, but immediately after discovery of a Breach, notify Covered Entity of any use or disclosure of PHI not provided for by this Agreement, including a Breach of Unsecured Protected Health Information as such notice is required by 45 C.F.R. 164.410 or a breach for which notice is required under §24-73-103, C.R.S.
 - ii. Such notice shall include the identification of each Individual whose Unsecured Protected Health Information has been, or is reasonably believed by Business Associate to have been, accessed, acquired, or disclosed during such Breach.
 - iii. Business Associate shall, as soon as reasonably possible, but immediately after discovery of any Security Incident that does not constitute a Breach, notify Covered Entity of such incident.
 - iv. Business Associate shall have the burden of demonstrating that all notifications were made as required, including evidence demonstrating the necessity of any delay.
- o. Business Associate's Insurance and Notification Costs.
- i. Business Associate shall bear all costs of a Breach response including, without limitation, notifications, and shall maintain insurance to cover:
 - A. loss of PHI data;
 - B. Breach notification requirements specified in HIPAA Rules and in §24-73-103, C.R.S.; and
 - C. claims based upon alleged violations of privacy rights through improper use or disclosure of PHI.
 - ii. All such policies shall meet or exceed the minimum insurance requirements of the Contract or otherwise as may be approved by Covered Entity (e.g., occurrence basis, combined single dollar limits, annual aggregate dollar limits, additional insured status, and notice of cancellation).
 - iii. Business Associate shall provide Covered Entity a point of contact who possesses relevant Information Security knowledge and is accessible 24 hours per day, 7 days per week to assist with incident handling.
 - iv. Business Associate, to the extent practicable, shall mitigate any harmful effect known to Business Associate of a Use or Disclosure of PHI by Business Associate in violation of this Agreement.

p. Subcontractors and Breaches.

- i. Business Associate shall enter into a written agreement with each of its Subcontractors and agents, who create, receive, maintain, or transmit PHI on behalf of Business Associate. The agreements shall require such Subcontractors and agents to report to Business Associate any use or disclosure of PHI not provided for by this Agreement, including Security Incidents and Breaches of Unsecured Protected Health Information, on the first day such Subcontractor or agent knows or should have known of the Breach as required by 45 C.F.R. 164.410.
- ii. Business Associate shall notify Covered Entity of any such report and shall provide copies of any such agreements to Covered Entity on request.

q. Data Ownership.

- i. Business Associate acknowledges that Business Associate has no ownership rights with respect to the PHI.
 - ii. Upon request by Covered Entity, Business Associate immediately shall provide Covered Entity with any keys to decrypt information that the Business Association has encrypted and maintains in encrypted form, or shall provide such information in unencrypted usable form.
- r. Retention of PHI. Except upon termination of this Agreement as provided in Section 5 below, Business Associate and its Subcontractors or agents shall retain all PHI throughout the term of this Agreement, and shall continue to maintain the accounting of disclosures required under Section 3.h above, for a period of six years.

4. OBLIGATIONS OF COVERED ENTITY

- a. Safeguards During Transmission. Covered Entity shall be responsible for using appropriate safeguards including encryption of PHI, to maintain and ensure the confidentiality, integrity, and security of PHI transmitted pursuant to this Agreement, in accordance with the standards and requirements of the HIPAA Rules.
- b. Notice of Changes.
 - i. Covered Entity maintains a copy of its Notice of Privacy Practices on its website. Covered Entity shall provide Business Associate with any changes in, or revocation of, permission to use or disclose PHI, to the extent that it may affect Business Associate's permitted or required uses or disclosures.
 - ii. Covered Entity shall notify Business Associate of any restriction on the use or disclosure of PHI to which Covered Entity has agreed in accordance with 45 C.F.R. 164.522, to the extent that it may affect Business Associate's permitted use or disclosure of PHI.

5. TERMINATION

a. Breach.

- i. In addition to any Contract provision regarding remedies for breach, Covered Entity shall have the right, in the event of a breach by Business Associate of any provision of this Agreement, to terminate immediately the Contract, or this Agreement, or both.
- ii. Subject to any directions from Covered Entity, upon termination of the Contract, this Agreement, or both, Business Associate shall take timely, reasonable, and necessary action to protect and preserve property in the possession of Business Associate in which Covered Entity has an interest.

b. Effect of Termination.

- i. Upon termination of this Agreement for any reason, Business Associate, at the option of Covered Entity, shall return or destroy all PHI that Business Associate, its agents, or its Subcontractors maintain in any form, and shall not retain any copies of such PHI.
- ii. If Covered Entity directs Business Associate to destroy the PHI, Business Associate shall certify in writing to Covered Entity that such PHI has been destroyed.
- iii. If Business Associate believes that returning or destroying the PHI is not feasible, Business Associate shall promptly provide Covered Entity with notice of the conditions making return or destruction infeasible. Business Associate shall continue to extend the protections of Section 3 of this Agreement to such PHI, and shall limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible.

6. INJUNCTIVE RELIEF

Covered Entity and Business Associate agree that irreparable damage would occur in the event Business Associate or any of its Subcontractors or agents use or disclosure of PHI in violation of this Agreement, the HIPAA Rules or any applicable law. Covered Entity and Business Associate further agree that money damages would not provide an adequate remedy for such Breach. Accordingly, Covered Entity and Business Associate agree that Covered Entity shall be entitled to injunctive relief, specific performance, and other equitable relief to prevent or restrain any Breach or threatened Breach of and to enforce specifically the terms and provisions of this Agreement.

7. LIMITATION OF LIABILITY

Any provision in the Contract limiting Contractor's liability shall not apply to Business Associate's liability under this Agreement, which shall not be limited.

8. DISCLAIMER

Covered Entity makes no warranty or representation that compliance by Business Associate with this Agreement or the HIPAA Rules will be adequate or satisfactory for Business Associate's own purposes. Business Associate is solely responsible for all decisions made and actions taken by Business Associate regarding the safeguarding of PHI.

9. CERTIFICATION

Covered Entity has a legal obligation under HIPAA Rules to certify as to Business Associate's Information Security practices. Covered Entity or its authorized agent or contractor shall have the right to examine Business Associate's facilities, systems, procedures, and records, at Covered Entity's expense, if Covered Entity determines that examination is necessary to certify that Business Associate's Information Security safeguards comply with the HIPAA Rules or this Agreement.

10. AMENDMENT

- a. Amendment to Comply with Law. The Parties acknowledge that state and federal laws and regulations relating to data security and privacy are rapidly evolving and that amendment of this Agreement may be required to provide procedures to ensure compliance with such developments.
 - i. In the event of any change to state or federal laws and regulations relating to data security and privacy affecting this Agreement, the Parties shall take such action as is necessary to implement the changes to the standards and requirements of HIPAA, the HIPAA Rules and other applicable rules relating to the confidentiality, integrity, availability and security of PHI with respect to this Agreement.
 - ii. Business Associate shall provide to Covered Entity written assurance satisfactory to Covered Entity that Business Associate shall adequately safeguard all PHI, and obtain written assurance satisfactory to Covered Entity from Business Associate's Subcontractors and agents that they shall adequately safeguard all PHI.
 - iii. Upon the request of either Party, the other Party promptly shall negotiate in good faith the terms of an amendment to the Contract embodying written assurances consistent with the standards and requirements of HIPAA, the HIPAA Rules, or other applicable rules.
 - iv. Covered Entity may terminate this Agreement upon 30 days' prior written notice in the event that:
 - A. Business Associate does not promptly enter into negotiations to amend the Contract and this Agreement when requested by Covered Entity pursuant to this Section; or
 - B. Business Associate does not enter into an amendment to the Contract and this Agreement, which provides assurances regarding the safeguarding of PHI

sufficient, in Covered Entity's sole discretion, to satisfy the standards and requirements of the HIPAA, the HIPAA Rules and applicable law.

- b. Amendment of Appendix. The Appendix to this Agreement may be modified or amended by the mutual written agreement of the Parties, without amendment of this Agreement. Any modified or amended Appendix agreed to in writing by the Parties shall supersede and replace any prior version of the Appendix.

11. ASSISTANCE IN LITIGATION OR ADMINISTRATIVE PROCEEDINGS

Covered Entity shall provide written notice to Business Associate if litigation or administrative proceeding is commenced against Covered Entity, its directors, officers, or employees, based on a claimed violation by Business Associate of HIPAA, the HIPAA Rules or other laws relating to security and privacy or PHI. Upon receipt of such notice and to the extent requested by Covered Entity, Business Associate shall, and shall cause its employees, Subcontractors, or agents assisting Business Associate in the performance of its obligations under the Contract to, assist Covered Entity in the defense of such litigation or proceedings. Business Associate shall, and shall cause its employees, Subcontractor's and agents to, provide assistance, to Covered Entity, which may include testifying as a witness at such proceedings. Business Associate or any of its employees, Subcontractors or agents shall not be required to provide such assistance if Business Associate is a named adverse party.

12. INTERPRETATION AND ORDER OF PRECEDENCE

Any ambiguity in this Agreement shall be resolved in favor of a meaning that complies and is consistent with the HIPAA Rules. In the event of an inconsistency between the Contract and this Agreement, this Agreement shall control. This Agreement supersedes and replaces any previous, separately executed HIPAA business associate agreement between the Parties.

13. SURVIVAL

Provisions of this Agreement requiring continued performance, compliance, or effect after termination shall survive termination of this contract or this agreement and shall be enforceable by Covered Entity.

APPENDIX TO HIPAA BUSINESS ASSOCIATE AGREEMENT

This Appendix (“Appendix”) to the HIPAA Business Associate Agreement (“Agreement”) is an appendix to the Contract and the Agreement. For the purposes of this Appendix, defined terms shall have the meanings ascribed to them in the Agreement and the Contract.

Unless the context clearly requires a distinction between the Contract, the Agreement, and this Appendix, all references to “Contract” or “Agreement” shall include this Appendix.

1. PURPOSE

This Appendix sets forth additional terms to the Agreement. Any sub-section of this Appendix marked as “Reserved” shall be construed as setting forth no additional terms.

2. ADDITIONAL TERMS

- b. Additional Permitted Uses. In addition to those purposes set forth in the Agreement, Business Associate may use PHI for the following additional purposes:
 - i. Reserved.

- c. Additional Permitted Disclosures. In addition to those purposes set forth in the Agreement, Business Associate may disclose PHI for the following additional purposes:
 - i. Reserved.

- c. Approved Subcontractors. Covered Entity agrees that the following Subcontractors or agents of Business Associate may receive PHI under the Agreement:
 - i. Reserved.

- d. Definition of Receipt of PHI. Business Associate’s receipt of PHI under this Contract shall be deemed to occur, and Business Associate’s obligations under the Agreement shall commence, as follows:
 - i. Reserved.

- e. Additional Restrictions on Business Associate. Business Associate agrees to comply with the following additional restrictions on Business Associate’s use and disclosure of PHI under the Contract:
 - i. Reserved.

- f. Additional Terms. Business Associate agrees to comply with the following additional terms under the Agreement:
 - i. Reserved.

EXHIBIT B, STATEMENT OF WORK

1. PROJECT SPECIFIC STATEMENT OF WORK

1.1. General Requirements

1.2. 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. 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 the Contractor. Delivery of Goods and performance of Services shall continue at the same rates and terms as described in this Contract.

1.3. Summary of Work and Description

1.3.1. The purpose of this project is to provide contracted services to support and implement a program to import Canadian prescription drugs for the state of Colorado. All drugs imported through this program must be fully compliant with the Final Rule set forth by the United States Food and Drug Administration (FDA).

1.3.2. Phase 1 Summary

1.3.2.1. Phase 1 of the Contract shall support the Importation Program and include the following services:

1.3.2.1.1. SIP Application Writing and Support

1.3.2.1.2. Written deliverables as requested

1.3.2.1.3. Program stakeholder support

1.3.2.1.4. Hourly Consulting

1.3.2.1.5. Other Importation Project Support as mutually agreed by the Contractor and Department

1.3.2.1.6. Subcontractor Support as mutually agreed by the Contractor and Department

1.3.2.1.7. Ad Hoc Projects

1.3.3. Phase 2 Summary

1.3.3.1. Phase 2 of this contract will begin once the FDA has approved the Program to operate. An amended scope may include the following responsibilities:

1.3.3.1.1. Program Inquiries

1.3.3.1.2. Program Reporting

1.3.3.1.3. Product Quality Complaint intake, retrieval, and follow-up

1.3.3.1.4. Adverse Event reporting and all associated requirements as described in the Final Rule.

1.3.3.1.5. Medical Case Management

1.3.3.1.6. Program Services as described

- 1.3.3.1.7. Drug Recall Management
- 1.3.3.1.8. Program Education and Communication
- 1.3.3.1.9. Program Communication Support at all levels
- 1.3.3.1.10. Other Importation Project Support as mutually agreed by the Contractor and Department
- 1.3.3.1.11. Subcontractor Support as mutually agreed by the Contractor and Department

1.4. Requirements

- 1.4.1. All deliverables described below shall be delivered in a format approved by the Department.
- 1.4.2. All deliverables can be billed to the Department once the work has been completed, delivered to the Department in an acceptable format, and approved by the Department.
- 1.4.3. All due dates are eligible for an extension upon request by the Contractor and approved by the Department in writing.
- 1.4.4. All due dates are calendar days unless otherwise noted.
- 1.4.5. Compliance with all applicable state of Colorado and United States federal laws, rules and regulations regarding the development and operation of an Importation Program.
- 1.4.6. The Department may terminate this contract for noncompliance with any stated requirement and reserves the right to audit the Contractor on a scheduled basis with a two week notice to Contractor.

1.5. Phase 1 Paid Deliverables

1.5.1. Adverse Event Reporting SIP Deliverable

- 1.5.1.1. The Contractor shall develop a written product for inclusion in the Department's Section 804 Importation Program (SIP) application for how the Contractor will support the reporting requirements. This written document should contain:
 - 1.5.1.1.1. An explanation of the systems that will be used to support the reporting requirements.
 - 1.5.1.1.2. An explanation of the staff that will be dedicated to conducting the reporting processes
 - 1.5.1.1.3. How the Contractor will support the requirements as listed in §251.18 (d) Adverse Event Reports of the Final Rule.
 - 1.5.1.1.4. Due Date: Date mutually agreed by the Contractor and Department in writing.
 - 1.5.1.1.5. Cost: \$9,000.00

1.5.2. Patient Level Recall Plan SIP Deliverable

- 1.5.2.1. Description: The Contractor shall develop a written product for inclusion in the Department's Section 804 Importation Program (SIP) application. This written document should contain:
 - 1.5.2.1.1. Narrative description of how the Contractor will process patient level recalls if requested by the Importer or Department
 - 1.5.2.1.2. How the Contractor will support the requirements as listed in §251.18 (e) of the Final Rule regarding a patient level recall of a Program Medication

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

1.5.2.1.4. Cost: \$2,250.00

1.5.3. Education and Communication Plan SIP Deliverable

1.5.3.1. Description: The Contractor shall develop a written product for inclusion in the Department's Section 804 Importation Program (SIP) application regarding how the Contractor could support education and communication to the Colorado public about the Program that satisfies the Final Rule requirements.

1.5.3.1.1. Narrative description of how the Contractor could support patient education and communication that would encourage Coloradans to participate in the program and support patients in connecting with pharmacies that offer imported products.

1.5.3.1.2. How the Contractor will support the requirements as listed in the Final Rule for Program Education and Communication.

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

1.5.3.1.4. Cost: \$225.00/hour Not to Exceed \$5,000.00.

1.5.4. Hourly consultation as Requested by the Department

1.5.4.1. Description: The Contractor shall consult on topics as requested by the Department.

1.5.4.2. Deliverable: Hourly consulting when requested by the Department.

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

1.5.4.4. Cost: The Contractor shall be paid at the following hourly rate rounded up by the quarter hour based on the following scale, at the following rates:

1.5.4.4.1. State Fiscal Year 2022/2023: \$225/hour

1.5.4.4.2. State Fiscal Year 2023/2024: \$235/hour

1.5.4.4.3. State Fiscal Year 2024/2025: \$245/hour

1.5.4.4.4. State Fiscal Year 2025/2026: \$255/hour

1.5.4.4.5. State Fiscal Year 2026/2027: \$265/hour

1.5.4.4.6. The total annual cost for the hourly work shall not exceed the following amounts for each state fiscal year:

1.5.4.4.6.1. State Fiscal Year 2022/2023: \$20,000.00

1.5.4.4.6.2. State Fiscal Year 2023/2024: \$20,000.00

1.5.4.4.6.3. State Fiscal Year 2024/2025: \$15,000.00

1.5.4.4.6.4. State Fiscal Year 2025/2026: \$15,000.00

1.5.4.4.6.5. State Fiscal Year 2026/2027: \$15,000.00

1.5.5. Hourly Consulting for Pharmacy Market Intelligence, SIP Review, Manufacturer Negotiation Support, and additional Miscellaneous Consulting

1.5.5.1. Deliverable: Pharmacy Market Intelligence Consulting as requested by the Department that includes the following topics:

1.5.5.1.1. Drug classification and identification

- 1.5.5.1.2. Retail pharmacy distribution
- 1.5.5.1.3. Pharmacy benefit management intelligence and support
- 1.5.5.1.4. Employer plan design considerations
- 1.5.5.1.5. Claim adjudication and reimbursement
- 1.5.5.1.6. Pharmacy benefit reporting and outcomes analysis
- 1.5.5.1.7. Cost: \$225/hour not to exceed \$6,750
- 1.5.5.2. SIP Review Hourly Consulting
 - 1.5.5.2.1. Deliverable: Reviewing sections of the SIP as requested by the Department
 - 1.5.5.2.2. Cost: \$225/hour up to 5 hours, not to exceed \$1,125
- 1.5.5.3. Pharmaceutical manufacturer negotiation and support Hourly Consulting
 - 1.5.5.3.1. Deliverable: Provide Manufacturer negotiation support when requested by the Department
 - 1.5.5.3.2. Cost: \$225/hour up to 5 hours, not to exceed \$1,125
- 1.5.5.4. Miscellaneous Hourly Consulting
 - 1.5.5.4.1. Deliverable: Miscellaneous Hourly consulting for importation related topics when requested by the Department.
 - 1.5.5.4.2. Cost: Cost: \$225/hour not to exceed \$6,000
- 1.5.6. Stakeholder Support
 - 1.5.6.1. Description: If requested by the Department, the Contractor shall participate in requested stakeholder engagement programs within Colorado.
 - 1.5.6.1.1. 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.
 - 1.5.6.1.2. Materials created in support of each meeting shall be submitted to the Department for review no later than 5 business days prior to the scheduled event. Contractor will require 2 weeks' notice in advance of the 5 day prior requirement. For complex requests, additional lead time may be required and can be agreed to in writing by the Contractor and Department.
 - 1.5.6.1.3. Cost: The Contractor shall be paid at the following hourly rate rounded up by the quarter hour based on the following scale, at the following rates, not to exceed \$10,000.00 per state fiscal year.
 - 1.5.6.1.3.1. State Fiscal Year 2022/2023: \$225/hour
 - 1.5.6.1.3.2. State Fiscal Year 2023/2024: \$235/hour
 - 1.5.6.1.3.3. State Fiscal Year 2024/2025: \$245/hour
 - 1.5.6.1.3.4. State Fiscal Year 2025/2026: \$255/hour
 - 1.5.6.1.3.5. State Fiscal Year 2026/2027: \$265/hour
- 1.5.7. Contractor Audit Preparation and Process Deliverable

- 1.5.7.1. Description: Upon a request from FDA or other applicable regulatory agency to complete an audit on the Program-specific systems/processes, the Contractor shall complete audit preparation and the audit.
- 1.5.7.2. Deliverable: Preparation, completion and passage of the audit.
- 1.5.7.3. The Contractor shall invoice for prep time and the audit time at the conclusion of the audit and successful passage.
- 1.5.7.4. Due Date: Date mutually agreed by the Contractor and Department in writing.
- 1.5.7.5. Cost: The Contractor shall be paid at the hourly of \$225.00 per person, not to exceed \$10,000.00 per state fiscal year.
 - 1.5.7.5.1. The total annual cost for the deliverable shall not exceed these amounts:
 - 1.5.7.5.1.1. State Fiscal Year 2022/2023: zero
 - 1.5.7.5.1.2. State Fiscal Year 2023/2024: \$10,000.00
 - 1.5.7.5.1.3. State Fiscal Year 2024/2025: \$10,000.00
 - 1.5.7.5.1.4. State Fiscal Year 2025/2026: \$10,000.00
 - 1.5.7.5.1.5. State Fiscal Year 2026/2027: \$10,000.00
- 1.5.8. Additional Section 804 Importation Program (SIP) Support, As Needed
 - 1.5.8.1. The Contractor shall provide SIP application (or amendment) content and evaluation as requested by the Department
 - 1.5.8.2. DELIVERABLE: Section 804 Importation Program Support as requested by the Department.
 - 1.5.8.3. DUE DATE: As agreed upon by the Contractor and the Department.
 - 1.5.8.4. Cost: The Contractor shall be paid at the following hourly rate rounded up by the quarter hour based on the following scale, at the following rates, not to exceed \$20,000.00 per state fiscal year.
 - 1.5.8.4.1. State Fiscal Year 2022/2023: \$225/hour
 - 1.5.8.4.2. State Fiscal Year 2023/2024: \$235/hour
 - 1.5.8.4.3. State Fiscal Year 2024/2025: \$245/hour
 - 1.5.8.4.4. State Fiscal Year 2025/2026: \$255/hour
 - 1.5.8.4.5. State Fiscal Year 2026/2027: \$265/hour
- 1.5.9. Ad Hoc Projects
 - 1.5.9.1. Description: Ad Hoc projects will be related to the overall scope of the work as described in the Purpose Statement. The description and scope of each project will be mutually agreed to in writing by the Department and Contractor.
 - 1.5.9.2. The project(s) due date shall be mutually agreed in writing by the department and Contractor.
 - 1.5.9.3. Cost: Ad Hoc Project(s) shall be paid at the same hourly rate as quoted above Not to Exceed \$100,000.00

1.6. Phase 2 – Post Program Approval Contractor Support

1.6.1. Description: Upon Program Approval, the Department and Contractor shall modify the scope of work in Phase 2 to include detailed services and costs associated with Program required services. Phase 2 of this contract will begin once the FDA has approved the Program to operate.

1.6.2. Timeline: The anticipated launch date for the start of Phase 2 work is approximately 90-180 days after program approval. The timeline and milestones may be further developed and refined throughout the onboarding/setup period. Initial work related to the onboarding, setup of systems, and training will commence upon execution of the amended contract to initiate Phase 2 work.

1.6.3. An amended scope may include the following responsibilities:

1.6.3.1. Program System Setup

1.6.3.2. Program Inquiries

1.6.3.3. Program Reporting

1.6.3.4. Product Quality Complaint Intake

1.6.3.5. Adverse Event reporting and all associated requirements as described in the Final Rule.

1.6.3.6. Medical Case Management

1.6.3.7. Program Services as described

1.6.3.8. Drug Recall Management

1.6.3.9. Program Education and Communication

1.6.3.10. Program Communication Support at all levels

1.6.3.11. Other responsibilities not listed that are essential for maintaining program compliance

1.6.3.12. The following items will be expanded upon approval:

1.6.3.12.1. CRM Technology Use

1.6.3.12.2. MIQ Platform

1.6.3.12.3. Call Center

1.6.3.13. Contact Center Services that can be expanded for future program needs:

1.6.3.13.1. Intake

1.6.3.13.2. Geographic Areas

1.6.3.13.3. Initial recognition and documentation of adverse event (AE) reports

1.6.3.13.4. Initial recognition and documentation of product complaint (PC) reports

1.6.3.13.5. Initial recognition and documentation of medical inquiries:

1.6.3.13.6. Pharmacovigilance

1.6.3.13.7. Product Retrieval

1.6.3.13.8. DSCSA Requirements

1.6.3.13.9. Information Technology and Telecom Services that include the following:

- 1.6.3.13.9.1. RMPDS Private Line
- 1.6.3.13.9.2. RMPDS IVR
- 1.6.3.13.9.3. International Services
- 1.6.3.13.9.4. Publicizing
- 1.6.3.13.9.5. Telephone Service Termination
- 1.6.3.13.9.6. Contact Center Model
- 1.6.3.13.9.7. Case Handling
- 1.6.3.13.9.8. Training
- 1.6.3.13.9.9. Quality Assurance Standard Operating Procedures
- 1.6.3.13.9.10. Data Collection Repository

1.7. Contract Requirements

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

1.7.2. Compliance with all applicable state of Colorado and federal laws

1.7.2.1. Compliance with all applicable state of Colorado and federal laws, rules and regulations, and international laws and standards regarding the development and operation of an Importation Program. The Department may terminate this contract for noncompliance with any stated requirement and reserves the right to audit the Contractor on a scheduled or unscheduled basis.

1.7.3. Inspection of Records and Work Performed

1.7.3.1. The Department and its authorized representatives reserve 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.

1.7.4. State Law Requirements

1.7.4.1. Surety Bond or comparable Security Agreement

1.7.4.1.1. 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.

1.7.4.2. The Contractor shall maintain information and documentation submitted for this Contract for at least 7 years.

1.7.4.3. The Contractor shall collect and maintain other documentation, if requested by the Department, to maintain protection of the public health.

1.7.5. Department Inquiries and Contact

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

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

1.7.6. Complainants Protections

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

1.7.7. Department Requirements

1.7.7.1. The Department shall provide the Contractor with the Following:

1.7.7.1.1. Product List

1.7.7.1.1.1. The Department shall provide an updated product list Product Information

1.7.7.1.1.1.1. Applicable reference materials, such as product labels (or inserts), extended temperature excursion data, References on determination of expected and unexpected AEs per product, References on determining severity of AEs per product, telephone number and email address of original manufacturer to send case reports to, Medical Response Documents, Frequently Asked Questions, approved website addresses and any other reference materials. Company will ensure the Contractor has accurate, up-to-date and reliable reference materials and data in order to provide the Services.

1.7.7.1.1.1.2. The Contractor shall provide information in an organized and identifiable manner and format acceptable to the Department

1.7.7.1.1.1.3. If additional materials need to be developed or custom organization of information needs to be completed at the request of the Department, such requested information will be discussed with the Contractor and additional fees may apply. These fees shall be agreed to in writing and the contract amended.

1.7.7.1.2. Escalation Procedure

1.7.7.1.2.1. The Department shall provide an escalation procedure including the Department contact list and process.

1.7.7.1.3. Holiday Schedule

1.7.7.1.3.1. The Department shall ensure the Contractor is provided with the Department's current holiday schedule.

1.7.7.1.4. Changes in Services

1.7.7.1.4.1. All changes will be mutually agreed upon in writing by the Contractor and Department prior to implementation and pursuant to the standard State contract Amendment process.

1.7.7.1.5. Advance Notice of Events

1.7.7.1.5.1. The Department shall provide the Contractor with as much advance notification as possible of any events (media, recall, program changes, meetings or

Department holiday schedules, etc.) that may result in a change in case volumes. Based on the anticipated impact, the Contractor has the right to charge reasonable fees for additional staffing during the designated impact period as agreed to in writing prior to the staffing change. The Provider will make all reasonable efforts to bring in additional staff for such coverage as needed and agreed to in writing.

- 1.7.7.1.5.2. The Department shall notify the Contractor as soon as information can be publicly released, in the event of changes to the program or program dissolution. The Department and Contractor will define continuation of Service provisions and contract assignment details.

2. DELIVERABLES, COMPENSATION, AND INVOICING

2.1. Compensation

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

2.2. Detailed Invoicing and Payment Procedures

- 2.2.1. Contractor shall invoice the Department on a monthly basis, by the 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 Contractor shall be paid by the Department based on the deliverables and compensation within this agreement. All invoices must be submitted to the Department no later than June 30th of the current fiscal year.

- 2.2.3. The invoice shall contain all of the following for the month for which the invoice covers:

- 2.2.3.1. Deliverable Name

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

- 2.2.3.2. 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 C, RATES**STATE FISCAL YEAR 2022-2023**

DELIVERABLE	DATE DUE TO THE DEPARTMENT	FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE
Adverse Event Reporting SIP Deliverable	Date mutually agreed upon	\$9,000.00
Patient Level Recall Plan SIP Deliverable	Date mutually agreed upon	\$2,250.00
Education and Communication Plan SIP Deliverable	Date mutually agreed upon	\$225.00/hour NTE \$5,000.00
Hourly consulting for Pharmacy Market Intelligence, SIP Review, Manufacturer Negotiation, and additional consulting	Date mutually agreed upon	\$225/hour, NTE \$20,000.00
Hourly Consulting for Pharmacy	Date mutually agreed upon	\$225/hour, NTE \$15,000.00
Stakeholder Support	Date mutually agreed upon	\$225/hour, NTE 10,000.00
Contractor Audit Preparation & Process Deliverable	Date mutually agreed upon	TBD - may bump to future years only
Additional Section 804 Importation Program (SIP) Support	Date mutually agreed upon	\$225/hour, NTE \$20,000.00
Ad Hoc Projects	Date mutually agreed upon	Amount agreed upon by contractor and department NTE \$100,000.00
Phase 2		TBD
TOTAL – STATE FISCAL YEAR 2022-2023		\$181,250.00

STATE FISCAL YEAR 2023-2024

DELIVERABLE	DATE DUE TO THE DEPARTMENT	FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE
Hourly consulting	Date mutually agreed upon	\$235/hour, NTE \$20,000.00
Stakeholder Support	Date mutually agreed upon	\$235/hour, NTE 10,000.00
Contractor Audit Preparation & Process Deliverable	Date mutually agreed upon	\$235/hour, NTE, 10,000.00
Additional Section 804 Importation Program (SIP) Support	Date mutually agreed upon	\$235/hour, NTE \$20,000.00
Ad Hoc Projects	Date mutually agreed upon	Amount agreed upon by contractor and department NTE \$100,000.00
Phase 2	TBD	TBD
TOTAL – STATE FISCAL YEAR 2023-2024		\$160,000.00

STATE FISCAL YEAR 2024 - 2025

DELIVERABLE	DATE DUE TO THE DEPARTMENT	FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE
Hourly consulting	Date mutually agreed upon	\$245/hour, NTE \$15,000.00
Stakeholder Support	Date mutually agreed upon	\$245/hour, NTE 10,000.00
Contractor Audit Preparation & Process Deliverable	Date mutually agreed upon	\$245//hour, NTE, 10,000.00
Additional Section 804 Importation Program (SIP) Support	Date mutually agreed upon	\$245/hour, NTE \$20,000.00
Ad Hoc Projects	Date mutually agreed upon	Amount agreed upon by contractor and department NTE \$100,000.00
Phase 2	TBD	TBD
TOTAL – STATE FISCAL YEAR 2024-2025		\$155,000.00

STATE FISCAL YEAR 2025 - 2026

DELIVERABLE	DATE DUE TO THE DEPARTMENT	FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE
Hourly consulting	Date mutually agreed upon	\$255/hour, NTE \$15,000.00
Stakeholder Support	Date mutually agreed upon	\$255/hour, NTE 10,000.00
Contractor Audit Preparation & Process Deliverable	Date mutually agreed upon	\$255/hour, NTE 10,000.00
Additional Section 804 Importation Program (SIP) Support	Date mutually agreed upon	\$255/hour, NTE \$20,000.00
Ad Hoc Projects	Date mutually agreed upon	Amount agreed upon by contractor and department NTE \$100,000.00
Phase 2	TBD	TBD
TOTAL – STATE FISCAL YEAR 2025-2026		\$155,000.00

STATE FISCAL YEAR 2026 - 2027

DELIVERABLE	DATE DUE TO THE DEPARTMENT	FIXED PRICE PAID UPON ACCEPTANCE OF DELIVERABLE
Hourly consulting	Date mutually agreed upon	\$265/hour, NTE \$15,000.00
Stakeholder Support	Date mutually agreed upon	\$265/hour, NTE 10,000.00
Contractor Audit Preparation & Process Deliverable	Date mutually agreed upon	\$265/hour, NTE 10,000.00
Additional Section 804 Importation Program (SIP) Support	Date mutually agreed upon	\$265/hour, NTE \$20,000.00
Ad Hoc Projects	Date mutually agreed upon	Amount agreed upon by contractor and department NTE \$100,000.00
Phase 2	TBD	TBD
TOTAL – STATE FISCAL YEAR 2026-2027		\$155,000.00

All Fiscal years

FISCAL YEAR	PAYMENT
2022/2023	\$181,250.00
2023/2024	\$160,000.00
2024/2025	\$155,000.00
2025/2026	\$155,000.00
2026/2027	\$155,000.00
TOTAL ALL YEARS	\$806,250.00

EXHIBIT D, TERMINOLOGY

1. TERMINOLOGY

- 1.1. In addition to the terms defined in §3 of this Contract, the following list of terms shall be construed and interpreted as follows:
- 1.1.1. Adverse Event (AE) - Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in a professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action. Provider will only capture adverse events related to Company's product(s), unless otherwise requested by Company.
 - 1.1.2. Adverse Event (AE) Follow Up - shall mean, upon request of the Company, Provider will conduct outbound follow-ups, in an agreed upon manner and timeframe, to collect additional information for a previously captured AE report. The Company will determine what specific information is required to fulfill the follow-up request. All information collected will be based on the information provided by the contact
 - 1.1.3. Business Interruption – Any event that disrupts Contractor's ability to complete the Work for a period of time, and may include, but is not limited to a Disaster, power outage, strike, loss of necessary personnel or computer virus.
 - 1.1.4. Case - A documented Provider interaction on behalf of the Company. Interaction will be at the direction of the Company and may be via telephone, email, fax, or mail. Cases shall be documented on a form or in an agreed upon application and reported as agreed upon by both parties. A single case may result in multiple case components.
 - 1.1.5. Case Component - Each constituent of an interaction and/or case. Medical inquiries, non-medical inquiries, adverse events, product complaints, correspondence (including company directives), response package fulfillments, and outbound communication (email/phone) are all examples of individual case components. Intake and follow-up activity associated with the case are also considered case components.
 - 1.1.6. Closeout Period – The period beginning on the earlier of 90 days prior to the end of the last Extension Term or notice by the Department of its decision to not exercise its option for an Extension Term, and ending on the day that the Department has accepted the final deliverable for the Closeout Period, as determined in the Department-approved and updated Closeout Plan, and has determined that the closeout is complete.
 - 1.1.7. Colorado Revised Statutes (C.R.S.) – The legal code of Colorado; the legal codified general and permanent statutes of the Colorado General Assembly.
 - 1.1.8. Contractor - Rocky Mountain Poison & Drug Safety ("RMPDS")
 - 1.1.9. Contractor Management Team - includes the Key Personnel as defined Exhibit D, Contractor's Administrative Requirements, section 2.3 as well as ownership of the business.
 - 1.1.10. Controlled Documents - Standard Operating Procedures ("SOP"), Work Instructions ("WI"), Ancillary Document ("ANC"), Quality Agreement ("QAG").

- 1.1.11. Correspondence - A repository of the emails generated around a particular case. May include, case correspondence generated for dissemination (i.e. email responses, transmissions, case detail reports and other reports), record of other Contact/reporter communications, or case attachments
- 1.1.12. Data – State Confidential Information and other State information resources transferred to the Contractor for the purpose of completing a task or project assigned in the Statement of Work.
- 1.1.13. Database - collectively databases, systems and related documentation
- 1.1.14. Deliverable – Any tangible or intangible object produced by Contractor as a result of the work that is intended to be delivered to the Department, regardless of whether the object is specifically described or called out as a “Deliverable” or not.
- 1.1.15. Department - Department of Healthcare Policy & Financing
- 1.1.16. Disaster – An event that makes it impossible for Contractor to perform the Work out of its regular facility or facilities, and may include, but is not limited to, natural disasters, fire or terrorist attacks.
- 1.1.17. Drug Supply Chain Security Act (DSCSA) Support - Service Provider will fill out required documentation and handle at the direction of the Company.
- 1.1.18. Eligible Prescription Drug (Imported Drug) - a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act that has been approved and has received a Notice of Compliance and a Drug Identification Number (DIN) from the Health Products and Food Branch of Health Canada.
- 1.1.19. Expired product - a prescription drug for which the date that the manufacturer guarantees the full potency and safety of a medication has passed
- 1.1.20. FDCA - Federal Food Drug & Cosmetic Act
- 1.1.21. Final Rule - The regulatory structure for state-led importation programs set forth by the FDA implementing 21 CFR Parts 1 and 251
- 1.1.22. Foreign Seller - an establishment within Canada engaged in the distribution of an eligible prescription drug that is imported or offered for importation into the United States
- 1.1.23. Fraud – An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to that person or some other person and includes any act that constitutes fraud under any federal or state law.
- 1.1.24. Health Insurance Portability and Accountability Act (HIPAA) – The Health Insurance Portability and Accountability Act of 1996, as amended.
- 1.1.25. Importer - a pharmacist or wholesaler. An Importer must be a State-licensed pharmacist, or a State- or FDA-licensed wholesale distributor, who is the U.S. owner of an eligible prescription drug at the time of entry into the United States.
- 1.1.26. ICSR - Individual Case Safety Report that captures information needed to support reporting of adverse events, product problems, and consumer complaints associated with the use of FDA regulated products
- 1.1.27. Key Personnel – The position or positions that are specifically designated as such in this Contract.

- 1.1.28. Literature Review - literature includes: Writing and running AE searches on an agreed upon frequency, reviewing abstracts and ordering articles, Writing and running of searches required for AE annual reports (assuming Medline search only).
- 1.1.29. Medication Guide – paper handouts that come with many prescription medicines. The guides address issues that are specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events.
- 1.1.30. Medical Inquiry also known as Medical Information (MI) - An inquiry in which the contact’s intent is to gain information related to the Company’s product(s) and its application in the diagnosis, treatment, or mitigation of a health or safety related condition, also known as, Medical Information Request (“MIR”), Electronic Medical Information Request (“eMIR”), and Electronic Medical Information Request Form (“eMIRF”).
- 1.1.31. Non-Medical Related Inquiries - Any question of non-medical nature, or all other inquiries.
- 1.1.32. Operational Start Date – When the Department authorizes Contractor to begin fulfilling its obligations under the Contract.
- 1.1.33. Other Personnel – Individuals and Subcontractors, in addition to Key Personnel, assigned to positions to complete tasks associated with the Work.
- 1.1.34. Package insert - includes details and directions that health care providers need to prescribe a drug properly, including approved uses for the drug, contraindications, potential adverse reactions, available formulations and dosage, and how to administer the drug.
- 1.1.35. Prescribing Information - also known as United States Prescribing Information (USPI), reflects FDA's finding regarding the safety and effectiveness of the human prescription drug under the labeled conditions of use.
- 1.1.36. Product Complaint (PC) - Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a Company's drug or device after it is released for distribution. Any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article.
- 1.1.37. Product Complaint (PC) Follow-up - Upon request of the Company, Provider will conduct outbound follow-ups, in an agreed upon manner and timeframe, to collect additional information for a previously captured PC report. The Company will determine what specific information is required to fulfill the follow-up request. All information collected will be based on the information provided by the contact.
- 1.1.38. Program - Colorado Drug Importation Program
- 1.1.39. Program Foreign Seller - the foreign seller selected by the Department
- 1.1.40. Program Pharmacy – any pharmacy that purchases program imported medications for the purpose of dispensing to Colorado residents.
- 1.1.41. Qualifying Laboratory - a laboratory in the United States that has been approved by FDA for the purposes of section 804 of the Federal Food, Drug, and Cosmetic Act.
- 1.1.42. Serialization (Pharmaceutical) - a comprehensive system to track and trace the passage of prescription drugs through the entire supply chain
- 1.1.43. Recalled product - a prescription medicine removed from the market because it is found to be either defective or potentially harmful

- 1.1.44. Response Package - Documentation provided as a result of an unsolicited request for documentation of information. Response Package may be sent via facsimile, email, or USPS mail.
- 1.1.45. Serious Adverse Event - Triage, Data Entry, Coding, Narrative, Assessment, Verification. Initial and 2 follow-ups.
- 1.1.46. Signal Detection Analysis and Annual Report - The activities include; Preparation and analysis of line listings, preparation and analysis of case type line listings, Signal evaluation, Signal Prioritization, Analysis with total exposure data, Report of Signal Evaluation trending and analysis; Assistance with generation of an annual report.
- 1.1.47. SIP Proposal/Application - Section 804 Importation Proposal - the name of the application to FDA for an Importation program
- 1.1.48. State - State of Colorado
- 1.1.49. State Statute - SB19-005 passed in May 2019, allowing the Colorado drug importation program to be developed. Can be found in the Colorado Revised Statutes at §25.5-1-201 through §25.5-1-207.
- 1.1.50. Start-Up Period – The period starting on the Effective Date and ending on the Operational Start Date.
- 1.1.51. Suspect Foreign Product/Illegitimate Foreign Product - a drug purchased by a Foreign Seller from a manufacturer, and intended for sale to an Importer in the United States, for which the Foreign Seller has reason to believe that such product: (1) Is potentially counterfeit, diverted, or stolen; (2) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (3) Is potentially the subject of a fraudulent transaction; or (4) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.
- 1.1.52. Unit - the smallest saleable package of a drug (ex: individual box, bottle, etc.)

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. CFR – Code of Federal Regulations
 - 2.1.2. CORA –Colorado Open Records Act, C.R.S. §24–72–200.1, et. seq.
 - 2.1.3. CRM – Customer Relationship Management
 - 2.1.4. C.R.S. – Colorado Revised Statutes
 - 2.1.5. CPI – Consumer Price Index
 - 2.1.6. DID – Direct Inward Dialing
 - 2.1.7. DIN - Canadian Drug Identification Number (Canadian version of an NDC)
 - 2.1.8. FDA - United State Food and Drug Administration
 - 2.1.9. FDCA - Federal Food Drug & Cosmetic Act
 - 2.1.10. HCP – Healthcare professional
 - 2.1.11. HIPAA – Health Insurance Portability and Accountability Act of 1996, as amended.

- 2.1.12. HPFB - the Health Products & Food Branch of Health Canada
- 2.1.13. MFCU – the Colorado Medicaid Fraud Control Unit in the Colorado Department of Law
- 2.1.14. NDC - National Drug Code
- 2.1.15. SFY – State Fiscal Year
- 2.1.16. SIP - Section 804 Importation Proposal - the name of the application to FDA for an Importation program
- 2.1.17. U.S.C. – United States Code

3. APPLICABLE US LAWS/REGULATIONS

- 3.1. [21 CFR Parts 1 and 251 - Drug Importation Final Rule](#)
- 3.2. [21 U.S. Code 384 - Importation of Prescription Drugs](#)
- 3.3. [Title II of the Drug Quality & Security Act - Drug Supply Chain Security Act \(DSCSA\)](#)
- 3.4. [SB19-005 - Import Prescription Drugs from Canada \(State of Colorado\)](#)
- 3.5. [FDA Individual Case Safety reports](#)
- 3.6. [FDA Adverse Event Reporting System \(FAERS\) Electronic Submissions](#)
- 3.7. [Combination Product Reporting Specifics](#)
- 3.8. [21 CFR Part 11 - Electronic Records; Electronic Signatures - Scope and Application](#)

EXHIBIT E, 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 inform the Department on current trends and issues in the healthcare marketplace and provide information on new technologies in use that may impact the Contractor's responsibilities under this Contract.
- 1.5. The Contractor shall maintain complete and detailed records of all meetings, system development life cycle documents, presentations, project artifacts, and any other interactions or Deliverables related to the Work described in the Contract. The Contractor shall make such records available to the Department upon request throughout the term of the Contract.
- 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 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.
- 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, without error, 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. The Contractor shall retain all written requests for reference and shall provide copies of any received transmittals upon request by the Department.
 - 1.8.7. Business Continuity Plan

- 1.8.7.1. The Contractor shall create a Business Continuity Plan that the Contractor will follow in order to continue operations after a Disaster or a Business Interruption. The Business Continuity Plan shall include, but is not limited to, all of the following:
 - 1.8.7.1.1. How the Contractor will replace staff that are lost or unavailable during or after a Business Interruption so that the Work is performed in accordance with the Contract.
 - 1.8.7.1.2. How the Contractor will back-up all information necessary to continue performing the Work, so that no information is lost because of a Business Interruption.
 - 1.8.7.1.2.1. In the event of a Disaster, the plan shall also include how the Contractor will make all information available at its back-up facilities.
 - 1.8.7.1.3. How the Contractor will maintain complete back-up copies of all data, databases, operating programs, files, systems, and software pertaining to enrollment information at a Department-approved, off-site location.
 - 1.8.7.1.4. How the Contractor will minimize the effects on Members of any Business Interruption.
 - 1.8.7.1.5. How the Contractor will communicate with the Department during the Business Interruption and points of contact within the Contractor's organization the Department can contact in the event of a Business Interruption.
 - 1.8.7.1.6. Planned long-term back-up facilities out of which the Contractor can continue operations after a Disaster.
 - 1.8.7.1.7. The time period it will take to transition all activities from the Contractor's regular facilities to the back-up facilities after a Disaster.
- 1.8.8. Closeout Plan
 - 1.8.8.1. The Contractor shall create a Closeout Plan that describes all requirements, steps, timelines, milestones, and Deliverables necessary to fully transition the services described in the Contract from the Contractor to the Department or to another contractor selected by the Department to be the contractor after the termination of the Contract.
 - 1.8.8.1.1. The Closeout Plan shall also designate an individual to act as a closeout coordinator who will ensure that all requirements, steps, timelines, milestones, and deliverables contained in the Closeout Plan are completed and work with the Department and any other contractor to minimize the impact of the transition on Members and the Department.
 - 1.8.8.1.2. The Contractor shall deliver the Closeout Plan to the Department for review and approval.
- 1.9. Closeout Period
 - 1.9.1. During the Closeout Period, the Contractor shall complete all of the following:
 - 1.9.1.1. Implement the most recent Closeout Plan or Closeout Plan Update as approved by the Department in the Operations Guide, as described herein and complete all steps, Deliverables and milestones contained in the most recent Closeout Plan or Closeout Plan Update that has been approved by the Department.
 - 1.9.1.2. Provide to the Department, or any other contractor at the Department's direction, all reports, data, systems, Deliverables and other information reasonably necessary for a

transition as determined by the Department or included in the most recent Closeout Plan or Closeout Plan Update that has been approved by the Department.

- 1.9.1.3. Ensure that all responsibilities under the Contract have been transferred to the Department, or to another contractor at the Department's direction, without significant interruption.
- 1.9.1.4. Notify any Subcontractors of the termination of the Contract, as directed by the Department.
- 1.9.1.5. Notify all applicable subcontractors, that Contractor will no longer be the Importer as directed by the Department. Contractor shall create these notifications and deliver them to the Department for approval. Once the Department has approved the notifications, Contractor shall deliver these notifications to all applicable subcontractors, but in no event shall Contractor deliver any such notification prior to approval of that notification by the Department.
 - 1.9.1.5.1. DELIVERABLE: Subcontractor Notifications
 - 1.9.1.5.2. DUE: 30 days prior to termination of the Contract
- 1.9.1.6. 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.
- 1.9.1.7. 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.

1.10. Performance Reviews

- 1.10.1. The Department may conduct performance reviews or evaluations of the Contractor in relation to the Work performed under the Contract.
- 1.10.2. The Department may work with the Contractor in the completion of any performance reviews or evaluations or the Department may complete any or all performance reviews or evaluations independently, at the Department's sole discretion.
- 1.10.3. The Contractor shall provide all information necessary for the Department to complete all performance reviews or evaluations, as determined by the Department, upon the Department's request. The Contractor shall provide this information regardless of whether the Department decides to work with the Contractor on any aspect of the performance review or evaluation.
- 1.10.4. The Department may conduct these performance reviews or evaluations at any point during the term of the Contract, or after termination of the Contract for any reason.
- 1.10.5. The Department may make the results of any performance reviews or evaluations available to the public or may publicly post the results of any performance reviews or evaluations.

1.11. Renewal Options and Extensions

- 1.11.1. The Department may, within its sole discretion, choose to not exercise any renewal option in the Contract for any reason. If the Department chooses to not exercise an option, it may reprocur the performance of the Work in its sole discretion.
- 1.11.2. 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.
- 1.11.3. 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.
- 1.11.4. The limitation on the annual maximum compensation in this Contract shall not include increases made specifically as compensation for additional Work added to the Contract.
- 1.12. Department System Access
 - 1.12.1. In the event that the Contractor requires access to any Department computer system to complete the Work, the Contractor shall have and maintain all hardware, software, and interfaces necessary to access the system without requiring any modification to the Department's system. The Contractor shall follow all Department policies, processes, and procedures necessary to gain access to the Department's systems.
 - 1.12.2. The Contractor shall be responsible for any costs associated with obtaining and maintaining access to systems needed to perform the Work under this solicitation, as determined by the Department. The Department will not reimburse the Contractor for any costs associated with obtaining and maintaining access to Department systems.

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. Contractor shall provide the Department with a final list of individuals assigned to the Contract and appropriate contact information for those individuals.
 - 2.1.1.1.1. DELIVERABLE: Final list of individuals assigned to the Contract
 - 2.1.1.1.2. DUE: Within five Business Days after the Effective Date
 - 2.1.1.2. Contractor shall update this list upon the Department's request to account for changes in the individuals assigned to the Contract.
 - 2.1.1.2.1. DELIVERABLE: Updated list of individuals assigned to the Contract
 - 2.1.1.2.2. DUE: Within five Business Days after the Department's request for an update
- 2.1.2. Contractor shall not permit any individual proposed for assignment to Key Personnel positions to perform any Work prior to the Department's approval of that individual to be

assigned as Key Personnel.

- 2.1.3. Contractor shall not voluntarily change individuals in Key Personnel positions without the prior written approval of the Department. Contractor shall supply the Department with the name, resume and references for any proposed replacement whenever there is a change to Key Personnel. Any individual replacing Key Personnel shall have qualifications that are equivalent to or exceed the qualifications of the individual that previously held the position, unless otherwise approved in writing by the Department.
 - 2.1.3.1. DELIVERABLE: Name(s) and resume(s) for the person(s) replacing anyone in a Key Personnel position during a voluntary change
 - 2.1.3.2. DUE: At least fifteen Business Days prior to the change in Key Personnel
- 2.1.4. If any individual filling a Key Personnel position leaves employment with Contractor, Contractor shall propose a replacement person to the Department. The replacement person shall have qualifications that are equivalent to or exceed the qualifications of the individual that previously held the position, unless otherwise approved, in writing, by the Department.
 - 2.1.4.1. DELIVERABLE: Name(s) and resume(s) for the person(s) replacing anyone in a Key Personnel position who leaves employment with Contractor
 - 2.1.4.2. DUE: Within 15 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.
- 2.1.5. Contractor's Key Personnel shall perform the majority of their work and responsibilities on this project in the Denver metropolitan area, unless the Department grants permission otherwise in writing.
- 2.1.6. If any of Contractor's Key Personnel or Other Personnel are required to have and maintain any professional licensure or certification issued by any federal, state or local government agency, then Contractor shall submit copies of such current licenses and certifications to the Department.
 - 2.1.6.1. DELIVERABLE: All current professional licensure and certification documentation as specified for Key Personnel or Other Personnel
 - 2.1.6.2. DUE: Within five Business Days of receipt of updated licensure or upon request by the Department
- 2.2. Personnel Availability
 - 2.2.1. Contractor shall ensure Key Personnel and/or Other Personnel assigned to the Contract are available for meetings with the Department during the Department's normal business hours, as determined by the Department. Contractor shall also make these personnel available outside of the Department's normal business hours and on weekends with prior notice from the Department.
 - 2.2.2. Contractor's Key Personnel and Other Personnel shall be available for all regularly scheduled meetings between Contractor and the Department, unless the Department has granted prior written approval otherwise.
 - 2.2.3. Contractor shall ensure that the Key Personnel and Other Personnel attending all meetings between the Department and Contractor have the authority to represent and commit Contractor regarding work planning, problem resolution and program development.

- 2.2.4. At the Department’s direction, the Contractor shall make its Key Personnel and Other Personnel available to attend meetings as subject matter experts with stakeholders both within the State government and external private stakeholders.
- 2.2.5. All of Contractor’s Key Personnel and Other Personnel that attend any meeting with the Department or other Department stakeholders shall be physically present at the location of the meeting, unless the Department gives prior, written permission to attend by telephone or video conference. If Contractor has any personnel attend by telephone or video conference, Contractor shall provide all additional equipment necessary for attendance, including any virtual meeting space or telephone conference lines.
- 2.2.6. The Contractor shall respond to all telephone calls, voicemails, and emails from the Department within two Business Days of receipt by the Contractor.

2.3. Key Personnel

2.3.1. The Contractor shall provide the Department with a list of individuals assigned to the Contract and appropriate contact information for those individuals. The Contractor shall designate people to hold the following Key Personnel positions. The Contractor shall ensure 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:

2.3.1.1. Project Lead

2.3.1.1.1. The Project Lead shall have the following qualifications:

2.3.1.1.1.1. Project Management Experience

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

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

2.3.1.1.2.1. Serving as Contractor’s primary point of contact for the Department.

2.3.1.1.2.2. Ensuring the completion of all Work in accordance with the Contract’s requirements.

2.3.1.1.2.3. This includes, but is not limited to, ensuring the accuracy, timeliness and completeness of all work.

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

2.3.1.1.2.5. The project lead may serve as the project lead and in a specific role as defined below.

2.3.1.2. Key Personnel 1 – Pharmacist Contact Center Supervisor

2.3.1.2.1. Serving as Contractor’s primary point of contact for the Department.

2.3.1.2.2. Oversee all functions of the program in both medical information and the pharmacovigilance capacity.

2.3.1.2.3. Ensuring the completion of all Work in accordance with the Contract’s requirements.

2.3.1.2.4. This includes, but is not limited to, ensuring the accuracy, timeliness and completeness of all work.

- 2.3.1.2.5. Overseeing all scope of other Key Personnel and Other Personnel and ensuring proper staffing levels throughout the term of the Contract.
- 2.3.1.2.6. Guide and oversee alignment of adverse events, product quality and medical inquiry practices
- 2.3.1.2.7. Responsible for content management, training adherence and ongoing coaching to others within this program.
- 2.3.1.2.8. May participate in additional medical information projects, develop documents or reports.
- 2.3.1.2.9. Ensuring the completion of all Work in accordance with the Contract’s requirements for pharmacovigilance reporting and follow-up.
- 2.3.1.2.10. This includes, but is not limited to, ensuring the accuracy, timeliness and completeness of all work pertaining to report submissions to the regulatory bodies.
- 2.3.1.2.11. Responsible for content management, training adherence and ongoing coaching to others within this program as affiliated to pharmacovigilance.
- 2.3.1.2.12. May participate in additional medical projects, develop documents or reports.
- 2.3.1.2.13. Facilitate periodic reports and submission to the FDA.
- 2.3.1.3. Key Personnel #2 – Medical Director (MD)
 - 2.3.1.3.1. Review and Approve SOP’s
 - 2.3.1.3.2. Safety Case Review and adjudication as necessary
 - 2.3.1.3.3. Serve as the point-of-contact for medical escalations
- 2.3.1.4. Key Personnel #3 – Contact Center Healthcare Professional Team
 - 2.3.1.4.1. Support the hours of operation as outlined for this program
 - 2.3.1.4.2. Comprised of Pharmacists and Registered Nurses
 - 2.3.1.4.3. Satisfy inbound inquiries specific to scope within the program requirements.
 - 2.3.1.4.4. Field unsolicited adverse reactions, capture adverse events, and participate in requirements of adverse event reporting to the FDA.
- 2.3.1.5. Additional Key Personnel
 - 2.3.1.5.1. The Following key personnel experiences may be requested based on the needs of the Importation Program.
 - 2.3.1.5.1.1. Project Consultant with pharmaceutical experience
 - 2.3.1.5.1.2. Pharmaceutical commercial experience
 - 2.3.1.5.1.3. Pharmacy PBM Market Intelligence Expertise
 - 2.3.1.5.1.4. Global Pharmacovigilance consultant
 - 2.3.1.5.1.5. Regulatory consultant
 - 2.3.1.5.1.6. Additional attributes and personnel outside of this description shall be agreed upon in writing by the Contractor and Department prior to starting work under

this contract Contractor shall not allow for any individual to fill more than one of the roles defined as Key Personnel.

- 2.3.1.5.2. 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.
- 2.3.2. The Contractor shall ensure the Department is aware of changes in Key Personnel working on the Importation Program. Should changes to the core team be made, the Contractor shall send resumes for newly added staff that has an operational or oversight role in the Program.
- 2.3.3. 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. Deliverable: All key personnel resumes required for the work shall be delivered to the Department.
- 2.3.5. Due: Within five Business Days of receipt of the execution of the Contract
- 2.4. Other Personnel Responsibilities
 - 2.4.1. Contractor shall use its discretion to determine the number of Other Personnel necessary to perform the Work in accordance with the requirements of this Contract. If the Department determines that Contractor has not provided sufficient Other Personnel to perform the Work in accordance with the requirements of this Contract, Contractor shall provide all additional Other Personnel necessary to perform the Work in accordance with the requirements of this Contract at no additional cost to the Department.
 - 2.4.2. Contractor shall ensure that all Other Personnel have sufficient training and experience to complete all portions of the Work assigned to them. Contractor shall provide all necessary training to its Other Personnel, except for State-provided training specifically described in this Contract.
 - 2.4.3. Subcontractor or Subcontractors are as follows:
 - 2.4.3.1. The Contractor shall provide the organizational name of each Subcontractor and all items to be worked on by each Subcontractor to the Department.
 - 2.4.3.2. The Department may request a specific expertise profile to fulfill certain aspects of importation-related work. If it is determined a subcontractor is needed by the Contractor, the Department shall approve of the subcontractor's expertise prior to agreeing to the subcontractor doing the work on behalf or in addition to the Contractor.
 - 2.4.3.3. Contractor may subcontract to complete a portion of the Work required by the Contract. The conditions for using a Subcontractor or Subcontractors are as follows:
 - 2.4.3.4. Contractor shall provide the organizational name of each Subcontractor and all items to be worked on by each Subcontractor to the Department.
 - 2.4.3.5. DELIVERABLE: Name of each Subcontractor and items on which each Subcontractor will work
 - 2.4.3.6. DUE: The later of 30 days prior to the Subcontractor beginning work or the Effective Date
 - 2.4.3.7. The Contractor shall obtain prior consent and written approval for any use of Subcontractor(s).

2.5. Non-Solicitation of Department Employees

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

3. INFORMATION TECHNOLOGY RELATED REQUIREMENTS

3.1. Protection of System Data

- 3.1.1. In addition to the requirements of the main body of this Contract, if Contractor or any Subcontractor is given access to State Records by the State or its agents in connection with Contractor's performance under the Contract, Contractor shall protect all State Records in accordance with this Exhibit. All provisions of this Exhibit that refer to Contractor shall apply equally to any Subcontractor performing work in connection with the Contract.
- 3.1.2. For the avoidance of doubt, the terms of this Exhibit shall apply to the extent that any of the following statements is true in regard to Contractor access, use, or disclosure of State Records:
 - 3.1.2.1. Contractor provides physical or logical storage of State Records.
 - 3.1.2.2. Contractor creates, uses, processes, discloses, transmits, or disposes of State Records.
 - 3.1.2.3. Contractor is otherwise given physical or logical access to State Records in order to perform Contractor's obligations under this Contract.
- 3.1.3. Contractor shall, and shall cause its Subcontractors, to do all of the following:
 - 3.1.3.1. Provide physical and logical protection for all hardware, software, applications, and data that meets or exceeds industry standards and the requirements of this Contract.
 - 3.1.3.2. Maintain network, system, and application security, which includes, but is not limited to, network firewalls, intrusion detection (host and network), annual security testing, and improvements or enhancements consistent with evolving industry standards.
 - 3.1.3.3. Comply with State and federal rules and regulations related to overall security, privacy, confidentiality, integrity, availability, and auditing.
 - 3.1.3.4. Provide that security is not compromised by unauthorized access to workspaces, computers, networks, software, databases, or other physical or electronic environments.
 - 3.1.3.5. Promptly report all Incidents, including Incidents that do not result in unauthorized disclosure or loss of data integrity, to the State.

3.1.4. Colorado Information Security Policy (CISP) Compliance

3.1.4.1. Contractor shall assess its compliance with the CISPs, in effect at the time of the assessment, issued by the Governor’s Office of Information Technology (“OIT”) posted at www.oit.state.co.us/about/policies under Information Security.

3.1.4.2. For the purposes of reviewing and assessing compliance with the CISPs, the Contractor shall consider itself to be both the Information Technology Service Provider (ITSP) and Business Owner.

3.1.4.3. Contractor shall deliver to the State the signed CISP Attestation, on a form provided by the Department, indicating that Contractor has assessed its compliance with the CISPs and has developed a plan to correct, in a timely manner, any security vulnerabilities identified during the assessment.

3.1.4.3.1. DELIVERABLE: CISP Attestation

3.1.4.3.2. DUE: Within 30 Business Days after the Effective Date

3.1.4.4. Contractor shall assess its compliance with the CISPs on an annual basis and deliver to the State the signed CISP Attestation, on a form provided by the Department.

3.1.4.4.1. DELIVERABLE: Annual CISP Attestation

3.1.4.4.2. DUE: Annually, by June 30th of each year

3.1.4.5. Contractor shall cause its Subcontractors to comply with the CISPs and to assess their compliance on at least an annual basis. If any Subcontractor’s assessment determines that the Subcontractor is not in compliance, then Contractor shall ensure that Subcontractor corrects, in a timely manner, any security vulnerabilities identified during the assessment.

3.1.5. Subject to Contractor’s reasonable access security requirements and upon reasonable prior notice, Contractor shall provide the State with scheduled access for the purpose of inspecting and monitoring access and use of State Records, maintaining State systems, and evaluating physical and logical security control effectiveness.

3.1.6. Contractor shall perform background checks on all of its respective employees and agents performing services or having access to State Records provided under this Contract. A background check performed during the hiring process shall meet this requirement. Contractor shall perform a background check on any employee if the Contractor becomes aware of any reason to question the employability of an existing employee. Contractor shall require all Subcontractors to meet the standards of this requirement.

3.1.6.1. Contractor shall deliver to the State the signed Background Check Attestation, on a form provided by the Department, indicating that background checks have been completed on employees participating in operations related to this Contract.

3.1.6.1.1. DELIVERABLE: Background Check Attestation

3.1.6.1.2. DUE: Within 30 Business Days of the Effective Date

3.1.6.2. If Contractor will have access to Federal Tax Information under the Contract, Contractor shall agree to the State’s requirements regarding Safeguarding Requirements for Federal Tax Information and shall comply with the background check requirements defined in IRS Publication 1075 and §24-50-1002, C.R.S.

3.2. Data Handling

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

EXHIBIT F, SAMPLE OPTION LETTER**OPTION LETTER**

State Agency Department of Health Care Policy and Financing	Option Letter Number Insert the Option Number (e.g. "1" for the first option)
Contractor Insert Contractor's Full Legal Name, including "Inc.", "LLC", etc...	Original Contract Number Insert CMS number or Other Contract Number of the Original Contract
Current Contract Maximum Amount	Option Contract Number Insert CMS number or Other Contract Number of this Option
Initial Term State Fiscal Year 20xx \$0.00	Contract Performance Beginning Date The later of the Effective Date or Month Day, Year
Extension Terms State Fiscal Year 20xx \$0.00 State Fiscal Year 20xx \$0.00 State Fiscal Year 20xx \$0.00 State Fiscal Year 20xx \$0.00	
Total for All State Fiscal Years \$0.00	Current Contract Expiration Date Month Day, Year

1. Options

- A. Option to extend for an Extension Term.
- B. Option to change the quantity of Goods under the Contract.
- C. Option to change the quantity of Services under the Contract.
- D. Option to modify the Contract rates.
- E. Option to initiate next phase of the Contract.

2. Required Provisions

- A. **For use with Option 1(A):** In accordance with Section(s) Number of the Original Contract referenced above, the State hereby exercises its option for an additional term, beginning Insert start date and ending on the current contract expiration date shown above, at the rates stated in the Original Contract, as amended.
- B. **For use with Options 1(B and C):** In accordance with Section(s) Number of the Original Contract referenced above, the State hereby exercises its option to Increase/Decrease the quantity of the Goods/Services or both at the rates stated in the Original Contract, as amended.
- C. **For use with Option 1(D):** In accordance with Section(s) Number of the Original Contract referenced above, the State hereby exercises its option to modify the Contract rates specified in Exhibit/Section Number/Letter. The Contract rates attached to this Option Letter replace the rates in the Original Contract as of the Option Effective Date of this Option Letter.
- D. **For use with Option 1(E):** In accordance with Section(s) Number of the Original Contract referenced above, the State hereby exercises its option to initiate Phase indicate which Phase: 2, 3, 4, etc, which shall begin on Insert start date and end on Insert ending date at the cost/price specified in Section Number.
- E. **For use with all Options that modify the Contract Maximum Amount:** 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 above.

3. Option Effective Date

- a. The Effective Date of this Option Letter is upon approval of the State Controller or the Effective Date of this Option Letter, whichever is later.

STATE OF COLORADO
John W. Hickenlooper, Governor
Department of Health Care Policy and Financing
Kim Bimestefer, Executive Director

By: Kim Bimestefer, Executive Director

Date: _____

In accordance with C.R.S. §24-30-202, this Option is not valid until signed and dated below by the State Controller or an authorized delegate.

STATE CONTROLLER
Robert Jaros, CPA, MBA, JD

By: _____
Greg Tanner, Controller; Department of Health Care Policy and Financing

Option Effective Date: _____