



COVID-19 TESTING - EMERGENCY FIXED PRICE BID
#SCDHEC-EFPB-8.21.20
SC Department of Health & Environmental Control
August 18, 2020 - REVISED 8/20/2020

The South Carolina Department of Health and Environmental Control (DHEC) is seeking qualified vendors to provide public health testing for COVID-19 as coordinated with and directed by the designated DHEC Contract Manager. Services will include lab processing of samples and reporting of results.

Services provided, at a Fixed Price under the following specifications:

1. Contractor shall have current CLIA and/or CAP certification.
2. Contractor shall not be the subject of active FDA/CMS or other quality complaints.
3. Contractor shall use PCR diagnostic testing analysis.
4. Contractor shall perform analysis in Contractor's laboratory. No third-party vendors or subcontractors.
5. Contractor shall have current capacity to process a minimum of 200 tests daily to ensure proficiency.
6. Contractor shall process 24-48 hour turn-around-time from time specimen is received at Contractor's lab.
7. Contractor shall have ability to transmit results to DHEC and the ordering facility in HL7 v2.5.1 messages. These messages should be built in accordance with the requirements found in the SC ELR Implementation Guide, HL7 ELR Implementation Guide, and the HHS letter titled "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115. Links to all of these documents are on the SC ELR web page found at:

<https://scdhec.gov/health-professionals/electronic-health-records-meaningful-use/electronic-reportable-lab-results-elr>.

Once it is determined that all requirements can be met, laboratories complete the SC ELR registration form found on the SC ELR web page and reach out to the Meaningful Use Help Desk (muhelpdesk@dhec.sc.gov) for next steps.

8. Contractor shall have ability to work directly with testing site partners subject to guidance and direction from the DHEC Contract Manager.
9. Contractor shall provide collection swab [kits, to include swabs and required transport media if applicable](#), and sample shippers to locations in South Carolina, at no additional cost to DHEC.
10. If necessary, contractor shall include arrangements for sending samples to facilities outside of South Carolina, at no additional cost to DHEC.
11. All ground shipping materials, packaging, and labeling shall be in accordance with DOT and IATA regulations.
12. Any Air shipping shall be in a non-returnable UN certified container.
13. No billable work to be performed without coordination with the DHEC Contract Managers.

FIXED PRICING

Vendors may offer pricing less than, but cannot exceed the following fixed pricing:

14. SARS-CoV2 Virus (RT-PCR) - \$70.00 each.
15. SARS-CoV2 Virus (RT-PCR) *DHEC swabs provided - \$65.00 each.
[*DHEC provided swabs include transport media.](#)

INVOICING

16. Services are to be invoiced monthly and submitted to the Invoicing Contact listed on the Purchase Order.

17. Invoice must include the following information:

- a.) Name, Address, Telephone and Fax Numbers of Contractor.
 - 1.) Contractor must be a registered vendor with the State of South Carolina.
Vendor Registration Link: <https://procurement.sc.gov/vendor/registration>
- b.) Purchase Order Number.
- c.) Period of Time services were performed.
- d.) Recap of the number of tests performed by type.
- e.) Cost per test type.
- f.) Patient Name.
- g.) Patient Date of Birth, Age, Race, Gender.
- h.) County of Patient's Residence.
- i.) Date Sample Collected.

j.) Description of Test Performed.

k.) Physical Location where Sample Collected (i.e. ABC Church, Columbia, SC; XYZ Company, Columbia, SC)

PROTESTS: If you are aggrieved in connection with the intended award or award of the contract, you may be entitled to protest, but only as provided in Section 11-35-4210. To protest an award, you must (i) submit notice of your intent to protest within five (5) business days of the date this notice is posted, and (ii) submit your actual protest within fifteen days of the date this notice is posted. Days are calculated as provided in Section 11-35-310(13). Both protests and notices of intent to protest must be in writing and must be received by the appropriate Chief Procurement Officer within the time provided. The grounds of the protest and the relief requested must be set forth with enough particularity to give notice of the issues to be decided. Any protest or notice of intent to protest must be addressed to the Chief Procurement Officer, Materials Management Office, and submitted in writing (a) by email to: protest-mmo@mmo.state.sc.us or (b) by post or delivery to: 1201 Main Street, Suite 600, Columbia, SC 29201.

The total value of the Purchase Orders cannot be pre-determined, but will be based on laboratory capacity and number of tests analyzed.

Vendor Questions may be submitted in writing to Rebecca Nichols via email at NICHOLRJ@dhec.sc.gov by 5PM ET, August 19, 2020, with **SCDHEC-EFPB-8.21.20** in the subject line. An Amendment with vendor questions and the State's responses will be published on South Carolina Business Opportunities (SCBO) website no later than Noon, August 20, 2020.

Submitting Offers

Qualified vendors should submit to Rebecca Nichols via email at NICHOLRJ@dhec.sc.gov by Midnight, August 21, 2020, the following:

1. Proof of CLIA and/or CAP Certification.
2. Acknowledgement of acceptance of the Terms and Conditions listed herein.
3. S.C. Vendor number.
4. Services vendor wishes to provide.
5. Offered rates, not to exceed the stated fixed prices. Note that lower pricing may result in increased usage.
6. Daily capacity for processing tests.
7. Turn-around-time for reporting results.
8. Completed signature page of Attachment A, DHEC's Business Associate Agreement within this document, of which a fully executed copy will be returned with a Purchase Order to awarded Offerors.

There will be no formal bid opening.

Standard Purchase Order Clauses

Any award made and purchase order resulting from this solicitation will be governed by South Carolina Law and the S.C. Standard Purchase Order Clause Set, a copy of which is attached.

DHEC'S SPECIAL CLAUSES

DHEC's CONFIDENTIALITY POLICY (DHEC – MAR 2014)

Confidential information includes information known or maintained in any form, whether recorded or not, consisting of protected health information, other health information, personal information, personal identifying information, confidential business information, and any other information required by law to be treated as confidential, designated as confidential by DHEC, or known or believed by contractor or contractor's employee or agent to be claimed as confidential or entitled to confidential treatment.

- (a) Contractor will not:
- (i) access, view, use, or disclose confidential information without written authorization from DHEC, unless required to perform its responsibilities under this contract or required by law (as determined by a court or other governmental body with authority);
 - (ii) discuss confidential information obtained in the course of its relationship with DHEC with any other person or in any location outside of its area of responsibility in DHEC; or
 - (iii) make any unauthorized copy of confidential information, or remove or transfer this information to any unauthorized location or media.
- (b) If contractor discloses confidential information pursuant to a properly completed authorization or legal process, order, or requirement, contractor must document the disclosure and make the documentation and authorization available for DHEC

inspection and audit. Contractor will direct any request it receives for confidential information obtained through performance of services under this contract, including a subpoena, litigation discovery request, court order, or Freedom of Information Act request, to the DHEC Contracts Manager and DHEC Office of General Counsel as soon as possible, and in every case within one business day of receipt.

- (c) Contractor must ensure that its employees, agents, and subcontractors who may have access to DHEC confidential information are aware of and comply with these confidentiality requirements. Contractor must ensure that any release of confidential information is limited to the minimum necessary to meet its obligations under this agreement and applicable law. If contractor will or may have access to any Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-92, as amended, and regulations (45 CFR Parts 160 and 164), DHEC may require the contractor to sign and comply with DHEC's Business Associate Agreement (DHEC Form 0854, attached) and protect PHI in compliance with the referenced HIPAA laws.
- (d) Unauthorized use or disclosure of confidential information may result in termination of this agreement and may be grounds for fines, penalties, imprisonment, injunctive action, damages, civil suit, or debarment from doing business with the State. The contractor must immediately notify the DHEC Compliance Officer and the DHEC Contracts Manager of any unauthorized use or disclosure of confidential information received under this contract.
- (e) The obligations of this provision shall survive termination, cancellation, or expiration of the contract.

PREVENTING AND REPORTING FRAUD, WASTE AND ABUSE (DHEC MAR-2014)

DHEC has procedures and policies concerning the prevention and reporting of Fraud, Waste and Abuse (FWA) in agency-funded programs, including but not limited to those funded by federal grants such as Medicaid. No agency employee, agent, or contractor shall direct, participate in, approve, or tolerate any violation of Federal or State laws regarding FWA in government programs. Federal law prohibits any person or company from knowingly submitting false or fraudulent claims or statements to a federally funded program, including false claims for payment or conspiracy to get such a claim approved or paid. The False Claims Act, 31 U.S.C. §3729-3733, and other "whistleblower" statutes include remedies for employees who are retaliated against in their employment for reporting violations of the Act or for reporting fraud, waste, abuse, or violations of law in connection with federal contracts or grants, or danger to public health or safety. Under State law, persons may be criminally prosecuted for false claims made for health care benefits, for Medicaid fraud, for insurance fraud, or for using a computer in a fraud scheme or to obtain money or services by false representations. Additional information regarding the federal and State laws prohibiting false claims and DHEC's policies and procedures regarding false claims may be obtained from the agency's Contracts Manager or Bureau of Business Management.

Any employee, agent, or contractor of DHEC who submits a false claim in violation of Federal or State laws will be reported to appropriate authorities.

If Contractor, Contractor's agents or employees have reason to suspect FWA in agency programs, this information should be reported in confidence to the agency. A report may be made by writing to the Office of Internal Audits, DHEC, 2600 Bull Street, Columbia, SC 29201; or by calling the Agency Fraud, Waste and Abuse Hotline at 803-896-0650 or toll-free at 1-866-206-5202. Contractor is required to inform Contractor's employees of the existence of DHEC's policy prohibiting FWA and the procedures for reporting FWA to the agency. Contractor must also inform Contractor's employees, in writing, of their rights and remedies under 41 U.S.C. §4712 concerning reporting FWA or violations of law in connection with federal contracts or grants, or danger to public health or safety, in the predominant native language of the workforce.

[Reference: False Claims Act, 31 U.S.C. §3729-3733; 41 U.S.C. §4712]

RECORDS RETENTION (DHEC – MAR 2014)

Records with respect to all matters covered by this contract shall be retained by the contractor for six (6) years after the end of the contract period, and shall be available for audit at any time such audit is deemed necessary by DHEC. If audit has begun but is not completed at the end of the six-year period, or if audit findings have not been resolved at the end of the six-year period, the records shall be retained until resolution of the audit findings.

TOBACCO-FREE CAMPUS POLICY (DHEC - Feb 2016)

Use of all tobacco products, including smokeless tobacco and electronic cigarettes, is prohibited in any facility or on any property owned or controlled by DHEC (including parking lots, parking garages, sidewalks, and breezeways).

BUSINESS ASSOCIATE AGREEMENT CLAUSE (DHEC – JAN 2011)

Prior to any work being done on any contract resulting from this solicitation, the contractor will be required to sign DHEC's Business Associate Agreement (Form 0854) to safeguard the privacy and security of Protected Health Information (PHI) and Electronic Protected Health Information (ePHI) pursuant to requirements of the Health Insurance Portability and Accountability Act of 1995

(HIPAA). A copy of the Business Associate Agreement is included in the Appendix of this solicitation. By submission of an offer, you are agreeing to sign DHEC's Business Associate Agreement, if awarded.

Attachment A: Form 0854 **DHEC'S BUSINESS ASSOCIATE AGREEMENT (DHEC – MAR 2013)**

BUSINESS ASSOCIATE AGREEMENT

BETWEEN

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

AND

PURPOSE

The South Carolina Department of Health and Environmental Control (hereafter referred to as "Covered Entity") and [REDACTED] (hereafter referred to as "Business Associate") desire to enter into this Business Associate Agreement (hereafter, "BA Agreement" or "the Agreement") for the purpose of protecting the privacy and security of clients' health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), including all pertinent regulations (45 CFR Part 160 and Part 164), as amended by Subtitle D of the Health Information Technology for Economic and Clinical Health Act (HITECH), Title XIII of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5).

II. DEFINITIONS Terms used, but not otherwise defined, in this Agreement shall have the same meanings as set forth in HIPAA and HITECH. A change to HIPAA or HITECH which modifies any defined term, or which alters the regulatory citation for the definition, shall be deemed incorporated into this Agreement.

- a. **Breach**. "Breach" shall have the meaning given under HITECH Section 13400, 42 U.S.C § 17921, and 45 CFR §164.402.
- b. **Data Aggregation**. "Data Aggregation" shall have the meaning given under the Privacy Rule, including, but not limited to, 45 CFR §164.501.
- c. **Designated Record Set**. "Designated Record Set" shall have the same meaning as the term "designated record set" in 45 CFR §164.501.
- d. **Disclose** and **Disclosure** shall have the meaning given in 45 CFR §160.103.
- e. **Electronic Protected Health Information**. "Electronic Protected Health Information" (referred to below as EPHI) shall have the same meaning as the term "electronic protected health information" in 45 CFR § 160.103.
- f. **HIPAA**. "HIPAA" shall mean the Health Insurance Portability and Accountability Act of 1996, Public Law 104-91, as amended, and related HIPAA regulations (45 CFR Parts 160-164.)
- g. **HITECH**. "HITECH" shall mean the Health Information Technology for Economic and Clinical Health Act, found in Title XIII of the American Recovery and Reinvestment Act of 2009, Public Law 111-005.
- h. **Individual**. "Individual" shall have the same meaning as the term "individual" in 45 CFR § 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).
- i. **Privacy Rule**. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information codified at 45 CFR Part 160 and Part 164, Subparts A and E and any other applicable provisions of HIPAA, or amendments thereto, including HITECH.
- j. **Protected Health Information**. "Protected Health Information" (referred to below as PHI) shall have the same definition contained in 45 CFR §160.103. For purposes of this Agreement, PHI is limited to the information created or received by Business Associate from or on behalf of Covered Entity. "Protected Health Information" includes, without limitation, "Electronic Protected Health Information," as defined below.
- k. **Required By Law**. "Required By Law" shall have the meaning given to the term under the Privacy Rule, including but not limited to, 45 CFR §164.103, and any additional requirements created under HITECH.
- l. **Secretary**. "Secretary" shall mean the Secretary of the U. S. Department of Health and Human Services or his/her designee.
- m. **Security Incident**. "Security Incident" shall have the meaning given in 45 CFR §164.304.
- n. **Security Standards**. "Security Standards" shall mean the Standards for the Protection of Electronic Protected Health Information that are codified at 45 CFR Part 160 and Part 164, Subparts A and C, and any other applicable provision of HIPAA, or amendments thereto, including HITECH.
- o. **Unsecured PHI**. "Unsecured PHI" shall mean PHI that is not secured through the use of a technology or methodology specified by the Secretary in guidance or as otherwise defined in Section 13402 of HITECH.
- p. **Use** or **Uses** shall have the meaning given in 45 CFR §160.103.

I. USE OR DISCLOSURE OF PHI BY BUSINESS ASSOCIATE

- a. Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in Contract # [REDACTED], or as otherwise provided by law, if such use or disclosure would not violate the Privacy Rule or the Security Standards if done by Covered Entity.
- b. Except as otherwise limited in this Agreement, Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, and may disclose PHI for those purposes provided that as to any such disclosure: 1) the disclosure is required by law; or 2) Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which the person is aware in which the confidentiality of the information has been breached.
- c. Business Associate will notify the Covered Entity of any breach of confidentiality or security by a person to whom the Business Associate has disclosed PHI pursuant to this Section, and will mitigate and/or assist the person and the Covered Entity in mitigating any harmful effects resulting from the breach of information.
- d. Except as otherwise limited in this Agreement, Business Associate may use PHI to provide Data Aggregation services to Covered Entity as permitted by 42 CFR § 164.504(e)(2)(i)(B).
- e. Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with § 164.502(j)(1).
- f. Business Associate may disclose PHI to any of its subcontractors for use in filling the obligations of this Agreement as long as the subcontractor agrees in writing to the restrictions and conditions in this Agreement with respect to PHI.
- g. Business Associate may disclose PHI to another entity as authorized by the Covered Entity in a separate written agreement or amendment to this agreement, if such disclosure of PHI would not violate the Privacy Rule or HITECH if done by Covered Entity itself.
- h. Business Associate, upon entering into an agreement using PHI for any of its functions and activities on behalf of the Covered Entity or in its general operations, will make available that agreement to the Covered Entity upon request..

II. DUTIES OF BUSINESS ASSOCIATE RELATIVE TO PHI

- a. Business Associate shall comply with the Confidentiality provision contained in Contract # [REDACTED] and any Confidentiality Agreement signed by the Business Associate pursuant to that Contract for so long as this BA Agreement remains in effect.
- b. Business Associate shall not use or disclose PHI other than as permitted or required by this Agreement or as required by law. Business Associate will not use PHI in any manner that would constitute a violation of the Privacy Rule, Security Standards, HIPAA, or HITECH if so used by Covered Entity.
- c. Business Associate shall develop, implement, maintain, and use appropriate safeguards to prevent any use or disclosure of PHI or EPHI other than as provided by this Agreement, and shall implement administrative, physical, and technical safeguards to comply with the Security Standards as required by 45 CFR Sections 164.308, 164.310, 164.312 and 164.316 in order to protect the confidentiality, integrity, and availability of EPHI or PHI that Business Associate creates, receives, maintains, or transmits, to the same extent as if Business Associate were a Covered Entity, pursuant to HITECH Section 13401, 42 U.S.C. § 17931. These safeguards are required regardless of the mechanism used to transmit the information.
- d. Business Associate shall adopt the effective and appropriate technical safeguards and technology and methodology standards provided in any guidance issued by the Secretary pursuant to HITECH Sections 13401-13402, 42 U.S.C. §§ 17931-17932.
- e. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement or of a Breach of Unsecured PHI, pursuant to 45 CFR § 164.530(f) and HITECH § 13402.
- f. Business Associate shall notify Covered Entity by the most expedient manner within one business day of any use or disclosure of PHI or EPHI not authorized by this Agreement or in violation of any applicable federal or state laws or

regulations of which Business Associate becomes aware, or of any suspected or actual Security Incident or Breach, unless delayed in accordance with 45 CFR §164.412. Business Associate shall notify Covered Entity immediately upon the law enforcement delay being lifted.

- g. In addition to the notification required by IV.f, Business Associate will provide written notification of a Breach of Unsecured PHI to Covered Entity without unreasonable delay and in no event later than 5 calendar days after discovery of the Breach. A Breach of Unsecured PHI shall be treated as discovered by the Business Associate as of the first day on which such breach is known to Business Associate or, by exercising reasonable diligence, would have been known to the Business Associate. Notification of a Breach of Unsecured PHI required by this paragraph shall comply with HITECH Section 13402, 42 U.S.C. § 17932, and 45 CFR § 164.410. The Breach notice shall include, to the extent possible, the identification of each individual whose Unsecured PHI has been, or is reasonably believed by the Business Associate to have been, accessed, acquired, or disclosed during the Breach. Business Associate shall provide Covered Entity with the following information at the time of the Breach notification or promptly thereafter as soon as information becomes available:
1. A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known, and the nature of the non-permitted use or disclosure;
 2. A description of the unsecured PHI that was involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
 3. Who made the non-permitted use or disclosure;
 4. Who received the non-permitted use or disclosure;
 5. Any steps individuals should take to protect themselves from potential harm resulting from the Breach; and
 6. What Business Associate is doing to investigate the Breach, to mitigate harm to individuals, and to protect against any further breaches.
- h. Business Associate shall ensure that any agent or subcontractor to whom it provides PHI received from Covered Entity, or that creates, receives, maintains, or transmits PHI on behalf of Business Associate, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information, including this paragraph, and agrees to implement reasonable and appropriate safeguards to protect such PHI, including the safeguards required by paragraph IV.c and IV.d above with respect to PHI. Business Associate shall implement and maintain sanctions against agents and subcontractors that violate such restrictions and conditions and shall mitigate the effects of such violation.
- i. Business Associate shall provide access, at the request of Covered Entity, and in the time and manner designated by Covered Entity, to PHI in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to fulfill the requirements of 45 CFR § 164.524 if the Business Associate has PHI in a designated record set. If Business Associate receives a request directly from an Individual, Business Associate will direct the Individual to the Covered Entity.
- j. Business Associate shall make any amendment(s) to PHI in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR § 164.526 at the request of Covered Entity or an Individual, and in the time and manner designated by Covered Entity, if Business Associate has PHI in a Designated Record Set. Business Associate shall not amend PHI received from the Covered Entity or created and/or provided to the Business Associate on behalf of the Covered Entity unless the amendment is directed by or consented to by the Covered Entity. If an Individual requests an amendment of PHI directly from Business Associate or any of its agents or subcontractors, Business Associate will direct Individual to Covered Entity. The Business Associate shall provide a copy of the amended PHI to the Covered Entity.
- k. Business Associate agrees to document such disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. Business Associate agrees to collect and maintain disclosure information as it relates to PHI including: (i) the date of disclosure; (ii) the name of the entity or person who received the PHI and, if known, the address of the entity or person; (iii) a brief description of the PHI disclosed; and (iv) a brief statement of purpose of the disclosure that reasonably informs the Individual of the basis for the disclosure, or a copy of the written request for disclosure under 45 CFR § 164.502(a)(2)(ii) or 164.512, if any. Business Associate will maintain records related to disclosures of PHI for at least six (6) years after the date of the disclosure. The provisions of this subparagraph shall survive termination of this Agreement.

- l. Business Associate will provide to Covered Entity or an Individual, in the time and manner designated by Covered Entity, information collected in accordance with Section IV.k of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. In addition, Business Associate agrees to make PHI available for purposes of accounting of disclosures as required by Section 164.528 of the Privacy Rule and Section 13405(c)(3) of HITECH, 42 U.S.C. § 17935(c)(3). If the request for an accounting is delivered directly to Business Associate or its agents or subcontractors, Business Associate shall within five (5) days of a request forward it to Covered Entity in writing.
- m. Business Associate shall comply with any requests for restrictions on certain disclosures of PHI pursuant to Section 164.522 of the Privacy Rule to which Covered Entity has agreed and of which Business Associate is notified by Covered Entity.
- n. Business Associate shall comply, pursuant to HITECH and its implementing regulations, with all additional requirements of the Privacy Rule, including those contained in 45 CFR 164.502(e) and 164.504(e)(1)(ii) at such time as the requirements are applicable to Business Associate, pursuant to HITECH Section 13404, 42 U.S.C. § 17934.
- o. If applicable, and if requested by Covered Entity, Business Associate will provide a copy of Covered Entity's Notice of Privacy Practices to the client at the time of first contact, and maintain documentation of the client's receipt of the Notice.
- p. Business Associate shall make its internal practices, books, and records, including policies and procedures and PHI, relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity available to the Secretary for purposes of the Secretary determining compliance with the Privacy Rule. Business Associate shall comply and cooperate with any request for documents or other information from the Secretary directed to Covered Entity that seeks documents or other information held by Business Associate. Business Associate shall provide to Covered Entity a copy of any PHI that Business Associate provides to the Secretary concurrently with providing such PHI to the Secretary.
- q. Business Associate and its agents and subcontractors may only request, use, or disclose the minimum amount of PHI necessary to accomplish the purpose of the request, use, or disclosure pursuant to this agreement and consistent with Covered Entity's minimum necessary policies and procedures. Except as otherwise permitted by HIPAA standards, until the effective date on which the Secretary issues guidance on what constitutes "minimum necessary," when using or disclosing PHI or responding to a request for PHI, Business Associate and its agents or subcontractors must limit such PHI, to the extent practicable, to a Limited Data Set, or if more information than a Limited Data Set is required, to the minimum necessary to accomplish the intended purpose of such use, disclosure or request. After the effective date on which the Secretary issues guidance on what constitutes "minimum necessary," Business Associate and its agents or subcontractors shall only request, use, and disclose the minimum amount of PHI necessary to accomplish the purpose of the request, use or disclosure, and shall comply with the Secretary's guidance on what constitutes "minimum necessary." See HITECH Section 13405, 42 U.S.C. § 17935.
- r. Business Associate shall provide Covered Entity reasonable access to its premises for review and demonstration of its internal practices and procedures for safeguarding PHI of Covered Entity for purposes of determining that Business Associate has complied with this Agreement and HITECH; provided that 1) the Parties mutually agree in advance upon the scope, location and timing of such access, and 2) Covered Entity shall protect confidential and proprietary information of Business Associate to which Covered Entity has access.
- s. Business Associate acknowledges that Business Associate has no ownership rights with respect to the PHI.
- t. If Business Associate knows of a pattern of activity or practice of Covered Entity that constitutes a material breach or violation of Covered Entity's obligations under the Agreement or other arrangement, Business Associate must take reasonable steps to cure the breach or end the violation. If the steps are unsuccessful, Business Associate must terminate the Agreement or other arrangement if feasible, or, if termination is not feasible, report the problem to the Secretary. Business Associate shall provide written notice to Covered Entity of any pattern of activity or practice of the Covered Entity that Business Associate believes constitutes a material breach or violation of the Covered Entity's obligations under the Agreement within five (5) days of discovery and shall meet with Covered Entity to discuss and attempt to resolve the problem as one of the reasonable steps to cure the breach or end the violation.
- u. Business Associate acknowledges that if it violates any of the requirements provided under this Business Associate Agreement, Business Associate will be subject to the same civil and criminal penalties that a Covered Entity would be subject to if such Covered Entity violated the same requirement.

- v. The additional requirements of HITECH that relate to privacy and security and that are made applicable with respect to covered entities shall also be applicable to Business Associate and shall be and by this reference are incorporated into this Agreement.
- w. Business Associate will contact the Covered Entity's Privacy Officer at (803) 898-3318 at any time clarification or guidance is needed regarding compliance with the terms of this Agreement.
- x. Business Associate shall not use or disclose PHI for fundraising or marketing purposes.
- y. Business Associate may not enter into any agreements with its agents or subcontractors pertaining to its obligations under this Agreement without the express written consent of Covered Entity.

V. DUTIES OF COVERED ENTITY

- a. If applicable, Covered Entity shall provide the Business Associate with a copy of its policies and procedures implementing the Privacy Rule, including the Notice of Privacy Practices.
- b. Covered Entity shall notify Business Associate of any limitation(s) in Covered Entity's Notice of Privacy Practices in accordance with 45 CFR § 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI.
- c. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI, within a reasonable period of time after Covered Entity becomes aware of such changes to or revocation of permission.
- d. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to or must comply with in accordance with 45 CFR § 164.522 and HITECH § 13405(a), 42 USC § 17935(a), to the extent that such restriction may affect Business Associate's use or disclosure of PHI.
- e. Covered Entity will not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

VI. TERM AND TERMINATION

- a. Term. The Term of this Agreement shall be effective as of [REDACTED], and shall terminate when all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions in this Section.
- b. Termination for Cause. Upon Covered Entity's knowledge of a material breach of this Agreement by Business Associate, Covered Entity shall do any of the following:
 - 1. Provide an opportunity for Business Associate to cure the breach or end the violation, and terminate this Agreement and Contract # [REDACTED] if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
 - 2. Immediately terminate this Agreement and Contract # [REDACTED] if Business Associate has breached a material term of this Agreement and cure is not feasible;
 - 3. If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary;
 - 4. Immediately stop all further disclosures of PHI to Business Associate pursuant to each agreement between Covered Entity and Business Associate that is the subject of such breach, until the breach is cured.
- c. Effect of Termination.
 - 1. Except as provided in paragraph (2) of this section, upon termination of this Agreement for any reason or upon written demand from Covered Entity, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies, including backups, of the PHI. If the return or destruction of PHI held by the Business Associate is not permissible pursuant to

South Carolina law, the Business Associate will extend the protections of this Agreement to the PHI and limit further uses and disclosures to those purposes that make the return or destruction of the PHI infeasible.

2. In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the parties that return or destruction of PHI is infeasible; Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.
- d. Continuing Privacy Obligation. Business Associate's obligation to protect the privacy of PHI is continuous and survives any termination, cancellation, expiration, or other conclusion of this Agreement or any other agreement between Business Associate and Covered Entity.

VII. INDEMNIFICATION (the following does not apply to other government agencies or political subdivisions)

Business Associate agrees to indemnify and hold harmless Covered Entity from any claims, demand, suit, loss, liability, or administrative penalties that the Covered Entity may sustain as a result of the Business Associate's breach of this Agreement, including any breach of confidentiality by a person to whom the Business Associate has disclosed information pursuant to this Agreement; provided, however, that the Business Associate shall not hold the Covered Entity harmless from any claims, demands or causes of action arising or resulting directly or indirectly from negligence of the Covered Entity, its officers, agents, representatives or employees, or any person or entity not subject to the Business Associate's supervision or control. This indemnification shall include reasonable expenses including attorney's fees incurred by defending such claims and damages incurred by reason of the Business Associate's failure to comply with applicable laws and regulations or for damages caused by the Business Associate, its employees and/or agents, including subcontractors. As a condition precedent to asserting a right of indemnity, the Covered Entity shall provide timely written notice to the Business Associate of the assertion of the claim to which the right of indemnification is claimed to exist.

VIII. MISCELLANEOUS

- a. Regulatory References. A reference in this Agreement to a section in the Privacy Rule or the Security Standards means the section as in effect or as amended.
- b. Amendment. The Parties agree to take such action as is necessary to amend this Agreement to comply with the requirements of the Privacy Rule, the Security Standards, HIPAA, HITECH, or any other state or federal law affecting this Agreement. If a Party believes in good faith that any provision of this Agreement fails to comply with the then-current requirements of HITECH or its regulations, such Party shall notify the other Party in writing. For a period of thirty days, the Parties shall address such concern in good faith and amend the terms of the Agreement if necessary to bring it into compliance. If, after such thirty day period, the Agreement fails to comply with HIPAA, the Privacy Rule, the Security Standards or HITECH, then either Party has the right to terminate upon written notice to the other Party.
- c. Survival. The respective rights and obligations of Business Associate under Section VI.c and VI.d of this Agreement shall survive termination of this Agreement.
- d. Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule and the Security Standards.
- e. All notices pursuant to this Agreement must be given in writing and shall be effective when received if hand-delivered or upon dispatch if sent by reputable overnight delivery service, facsimile, or U.S. Mail to the appropriate address or facsimile number. Notification of any unauthorized use or disclosure of PHI or of a Breach of Unsecured PHI under paragraphs IV.f and IV.g shall be made to the DHEC Privacy Officer at 2600 Bull Street, Columbia, SC 29201, 803-898-0707 (phone), 803-898-0476 (fax).
- f. Business Associate and Covered Entity agree that Individuals who are the subject of PHI are not third-party beneficiaries of this Agreement.
- g. The parties acknowledge that state and federal laws relating to electronic data security and privacy are evolving and that amendment of this Agreement may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA and HITECH and other applicable laws relating to the security or confidentiality of PHI. The parties understand and agree that Covered Entity must receive satisfactory written assurance from Business Associate that Business Associate will adequately safeguard all PHI that it receives or creates pursuant to this Agreement. Upon Covered Entity's request,

Business Associate agrees to promptly enter into negotiations with Covered Entity concerning the terms of any amendment to the Agreement embodying written assurances consistent with the standards and requirements of HIPAA and HITECH or other applicable laws. Covered Entity may terminate this Agreement and Contract # [REDACTED] upon thirty (30) days written notice if (i) Business Associate does not promptly enter into negotiations to amend this Agreement when requested by Covered Entity pursuant to this Section, or (ii) Business Associate does not enter into an amendment to this Agreement providing assurances regarding the safeguarding of PHI that Covered Entity, in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA and HITECH.

- h. If any provision of this Agreement violates any applicable statute, ordinance, or rule of law in any jurisdiction that governs this Agreement, such provision shall be ineffective to the extent of such violation without invalidating any other provision of this Agreement.
- i. This Agreement may not be amended, altered, or modified except by written agreement signed by Business Associate and Covered Entity.
- j. No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.
- k. The persons signing below have the right and authority to execute this Agreement for their respective entities and no further approvals are necessary to create a binding Agreement.
- l. Neither Covered Entity nor Business Associate shall use the names or trademarks of the other party or of any of the respective party's affiliated entities in any advertising, publicity, endorsement, or promotion unless prior written consent has been obtained for the particular use contemplated.
- m. All references to specific statutes, codes, or regulations shall be deemed to be references to those statutes, codes or regulations as they may be amended from time to time.
- n. Neither party is an employee, agent, partner, or joint venturer of the other. Neither party has the right or authority to control or direct the activities of the other or the right or authority to bind the other to any agreement with a third party or to incur any obligation or liability on behalf of the other party, unless expressly authorized in this or another agreement between the parties.

AS TO DHEC

BY: _____
Rebecca Nichols, Procurement Officer

DATE: _____

AS TO THE CONTRACTING PARTY

BY: _____
(NAME)

Its: _____
(TITLE)

DATE: _____

MAILING ADDRESS:

SOUTH CAROLINA PURCHASE ORDER CLAUSE SET (DEC 2015)

AGREEMENT means any transaction or agreement arising out of, relating to, or contemplated by the relationship of which this purchase order forms a part. The terms and conditions of this document (including the attached purchase order) shall apply notwithstanding any additional or different terms and conditions in any invoice or other document, including without limitation, (i) a purchase order or other instrument submitted by the State, (ii) any invoice, confirmation, or other document submitted by Contractor, or (iii) any privacy policy, terms of use, or end user agreement. Any document signed or otherwise agreed to by persons other than the Procurement Officer shall be void and of no effect.

ASSIGNMENT, NOVATION, AND CHANGE OF NAME, IDENTITY, OR STRUCTURE (FEB 2015): (a) Contractor shall not assign this contract, or its rights, obligations, or any other interest arising from this contract, or delegate any of its performance obligations, without the express written consent of the responsible Procurement Officer. The foregoing restriction does not apply to a transfer that occurs by operation of law (e.g., bankruptcy; corporate reorganizations and consolidations, but not including partial asset sales). Notwithstanding the foregoing, contractor may assign monies receivable under the contract provided that the State shall have no obligation to make payment to an assignee until thirty days after contractor (not the assignee) has provided the responsible Procurement Officer with (i) proof of the assignment, (ii) the identity (by contract number) of the specific State contract to which the assignment applies, and (iii) the name of the assignee and the exact address or account information to which assigned payments should be made. (b) If contractor amends, modifies, or otherwise changes its name, its identity (including its trade name), or its corporate, partnership or other structure, or its FEIN, contractor shall provide the Procurement Officer prompt written notice of such change. (c) Any name change, transfer, assignment, or novation is subject to the conditions and approval required by Regulation 19-445.2180, which does not restricts transfers by operation of law.

CHOICE-OF-LAW: The Agreement, any dispute, claim, or controversy relating to the Agreement, and all the rights and obligations of the parties shall, in all respects, be interpreted, construed, enforced and governed by and under the laws of the State of South Carolina, except its choice of law rules. The UN Convention on the International Sale of Goods shall not apply to this agreement.

CONTRACTOR: means the business entering the contract of which this purchase order forms a part.

CONTRACTOR PERSONNEL: You shall enforce strict discipline and good order among your employees and other persons carrying out the Work. You shall not permit employment of unfit persons or persons not skilled in tasks assigned to them.

CONTRACTOR'S USE OF STATE PROPERTY: Upon termination of the contract for any reason, the State shall have the right, upon demand, to obtain access to, and possession of, all State properties, including, but not limited to, current copies of all State application programs and necessary documentation, all data, files, intermediate materials and supplies held by you. You shall not use, reproduce, distribute, display, or sell any data, material, or documentation owned exclusively by the State without the State's written consent, except to the extent necessary to carry out the Work. **CONTRACTOR'S OBLIGATION - GENERAL:** You shall provide and pay for all materials, tools, equipment, labor and professional and non-professional services, and shall perform all other acts and supply all other things necessary, to fully and properly perform and complete the Work. You must act as the prime contractor and assume full responsibility for any subcontractor's performance. You will be considered the sole point of contact with regard to all situations, including payment of all charges and the meeting of all other requirements.

DELIVERY / PERFORMANCE LOCATION: F.O.B. Destination. Destination is the shipping dock of the State's designated receiving site, or other location, as specified herein. All services shall be provided at the location specified herein.

DISPUTES: (1) Choice-of-Forum. All disputes, claims, or controversies relating to the Agreement shall be resolved exclusively by the appropriate Chief Procurement Officer in accordance with Title 11, Chapter 35, Article 17 of the South Carolina Code of Laws, or in the absence of jurisdiction, only in the Court of Common Pleas for, or a federal court located in, Richland County, State of South Carolina. Contractor agrees that any act by the Government regarding the Agreement is not a waiver of either the Government's sovereign immunity or the Government's immunity under the Eleventh Amendment of the United States Constitution. (2) Service of Process. Contractor consents that any papers, notices, or process necessary or proper for the initiation or continuation of any disputes, claims, or controversies relating to the Agreement; for any court action in connection therewith; or for the entry of judgment on any award made, may be served on Contractor by certified mail addressed to Contractor at the address provided on the last invoice received by State from Contractor or by personal service or by any other manner that is permitted by law, in or outside South Carolina. Notice by certified mail is deemed duly given upon deposit in the United States mail.

DRUG FREE WORK PLACE CERTIFICATION: You certify that you will comply with all applicable provisions of The Drug-free Workplace Act, Title 44, Chapter 107 of the South Carolina Code of Laws, as amended.

ILLEGAL IMMIGRATION: (An overview is available at www.procurement.sc.gov) By accepting this purchase order, you certify that you will comply with the applicable requirements of Title 8, Chapter 14 of the South Carolina Code of Laws and agree to provide to the State upon request any documentation required to establish either: (a) that Title 8, Chapter 14 is inapplicable to you and your subcontractors or sub-subcontractors; or (b) that you and your subcontractors or sub-subcontractors are in compliance with Title 8, Chapter 14. You agree to include in any contracts with your subcontractors language requiring your subcontractors to (a) comply with the applicable requirements of Title 8, Chapter 14, and (b) include in their contracts with the sub-subcontractors language requiring the sub-subcontractors to comply with the applicable requirements of Title 8, Chapter 14.

IRAN DIVESTMENT ACT - CERTIFICATION: ~~(a) The Iran Divestment Act List is a list published pursuant to Section 11-57-310 that identifies persons engaged in investment activities in Iran. Currently, the list is available at procurement.sc.gov(.) Section 11-57-310 requires the government to provide a person ninety days written notice before he is included on the list. The following representation, which is required by Section 11-57-330(A), is a material inducement for the State to award a contract to you. (b) By accepting this purchase order, you certify that, as of the date you accept, you are not on the then-current version of the Iran Divestment Act List.~~

ETHICS CERTIFICATE: By accepting this purchase order, you certify that you have and will comply with, and have not, and will not, induce a person to violate Title 8, Chapter 13 of the South Carolina Code of Laws, as amended (ethics act). The State may rescind any contract and recover all amounts expended as a result of any action taken in violation of this provision. If contractor participates, directly or indirectly, in the evaluation or award of public contracts, including without limitation, change orders or task orders regarding a public contract, contractor shall, if required by law to file such a statement, provide the statement required by Section 8-13-1150 to the Procurement Officer at the same time the law requires the statement to be filed.

INDEMNIFICATION-THIRD PARTY CLAIMS - GENERAL (NOV 2011): Without limitation, and to the fullest extent permitted by law, Contractor shall defend and hold harmless Indemnitees for and against any and all suits or claims of any character (and all related damages, settlement payments, attorneys' fees, costs, expenses, losses or liabilities) by a third party which are attributable to bodily injury, sickness, disease or death, or to injury to or destruction of tangible property arising out of or in connection with the goods or services acquired hereunder or caused in whole or in part by any act or omission of contractor, its subcontractors, their employees, workmen, servants, agents, or anyone directly or indirectly employed by them or anyone for whose acts any of them may be liable, regardless of whether or not caused in part by an Indemnitee, and whether or not such claims are made by a third party or an Indemnitee; however, if an Indemnitee's negligent

act or omission is subsequently determined to be the sole proximate cause of a suit or claim, the Indemnitee shall not be entitled to indemnification hereunder. Contractor shall be given timely written notice of any suit or claim. Contractor's obligations hereunder are in no way limited by any protection afforded under workers' compensation acts, disability benefits acts, or other employee benefit acts. This clause shall not negate, abridge, or reduce any other rights or obligations of indemnity which would otherwise exist. The obligations of this paragraph shall survive termination, cancelation, or expiration of the parties' agreement. This provision shall be construed fairly and reasonably, neither strongly for nor against either party, and without regard to any clause regarding insurance. As used in this clause, "Indemnitees" means the State of South Carolina, its instrumentalities, agencies, departments, boards, political subdivisions and all their respective officers, agents and employees.

LICENSES AND PERMITS: You are responsible for obtaining, and maintaining in good standing, all licenses (including professional licenses, if any), permits, inspections and related fees for each or any such licenses, permits and /or inspections required by the State of South Carolina, county, city or other government entity or unit to accomplish the Work.

MATERIAL AND WORKMANSHIP: Unless otherwise specifically provided in the purchase order, all equipment, material, and articles incorporated in the Work are to be new and of the most suitable grade for the purpose intended.

NO INDEMNITY OR DEFENSE (FEB 2015): Any term or condition is void to the extent it requires the State to indemnify, defend, or pay attorney's fees to anyone for any reason.

OWNERSHIP OF DATA & MATERIALS: All data, material and documentation prepared for the State pursuant to this Agreement shall belong exclusively to the State.

PAYMENT & INTEREST: (a) The State shall pay the Contractor, after the submission of proper invoices or vouchers, the prices stipulated in this contract for supplies delivered and accepted or services rendered and accepted, less any deductions provided in this contract. Unless otherwise specified herein, including the purchase order, payment shall not be made on partial deliveries accepted. (b) Unless otherwise agreed, payment will be made by check mailed to the address appearing on the purchase order form. (c) Notwithstanding any other provision, payment shall be made in accordance with S.C. Code Section 11-35-45, or Chapter 6 of Title 29 (real property improvements) when applicable, which provides the Contractor's exclusive means of recovering any type of interest from the Owner. Contractor waives imposition of an interest penalty unless the invoice submitted specifies that the late penalty is applicable. Except as set forth in this paragraph, the State shall not be liable for the payment of interest on any debt or claim arising out of or related to this contract for any reason. (d) Amounts due to the State shall bear interest at the rate of interest established by the South Carolina Comptroller General pursuant to Section 11-35-45 ("an amount not to exceed fifteen percent each year"), as amended, unless otherwise required by Section 29-6-30. (e) Any other basis for interest, including but not limited to general (pre- and post-judgment) or specific interest statutes, including S.C. Code Ann. Section 34-31-20, are expressly waived by both parties. If a court, despite this agreement and waiver, requires that interest be paid on any debt by either party other than as provided by items (c) and (d) above, the parties further agree that the applicable interest rate for any given calendar year shall be the lowest prime rate as listed in the first edition of the Wall Street Journal published for each year, applied as simple interest without compounding. (f) The State shall have all of its common law, equitable and statutory rights of set-off.

PROCUREMENT OFFICER means the person executing this purchase order or the State's procurement director.

PUBLICITY (JAN 2006): Contractor shall not publish any comments or quotes by State employees, or include the State in either news releases or a published list of customers, without the prior written approval of the Procurement Officer.

STATE means the governmental unit identified in the purchase order.

TERMINATION DUE TO UNAVAILABILITY OF FUNDS (JAN 2006): Payment and performance obligations for succeeding fiscal periods shall be subject to the availability and appropriation of funds therefore. When funds are not appropriated or otherwise made available to support continuation of performance in a subsequent fiscal period, the contract shall be canceled. In the event of a cancellation pursuant to this paragraph, contractor will be reimbursed the resulting unamortized, reasonably incurred, nonrecurring costs. Contractor will not be reimbursed any costs amortized beyond the initial contract term.

YOU and YOUR means Contractor.

WORK means all labor, materials, equipment, services, or property of any type, provided or to be provided by the Contractor to fulfill its obligations under the Contract.

[07-07C010-3]

South Carolina Purchase Order Clause Set

Page 2 of 2

Rebecca Nichols, NICHOLRJ@dhec.sc.gov, 803-898-1262
South Carolina Department of Health & Environmental Control
301 Gervais Street, Columbia, SC 29201-3073
www.scdhec.gov

