Business Associate Agreement Clause

Pursuant to the ***Health Insurance Portability and Accountability Act (HIPAA) of 1996*** and its implementing regulation, the Standards of Privacy of Individual Identifiable Health Information at 45 C.F. R Part 160 and 164, Subpart A and E ("Privacy Rule"), the Indian Health Service is required to enter into an agreement with the Business Associate, pursuant to which the Business Associate shall comply with and appropriately safeguard Protected Health Information ("PHI") that it will use and disclose when performing functions, activities or services ("Services") for the Indian Health Service. The Business Associate by signing the contract shall comply with the following terms in addition to other applicable contract terms and conditions relating to the safekeeping, use and disclosure of PHI.

DEFINITIONS – Terms used in this Agreement, but not otherwise defined, shall have the same meaning as those terms contained with the Privacy Rule.

1. Agreement: "Agreement" shall mean this clause and any other provisions of this Contract that are incorporated by reference;
2. Business Associate: "Business Associate" shall mean Contractor, also known as _____;
3. Covered Entity: "Covered Entity" shall mean the Indian Health Service;
4. Designated Record Set: "Designated Record Set" shall mean (1) a group of records maintained by or for a covered entity that is: (i) the medical records and billing records about individuals maintained by or for a covered health care rovidpr, (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan, or, (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals. (2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity. (45 C.F.R δ 164.501)
5. Individual: "Individual" shall have the same meaning as the term "individual" in 45 C.F.R. δ 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R δ 164.501(g);
6. Privacy Rule: "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Parts 160 and 164, Subparts A and E;
7. Protected Health Information: "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 C.F.R. δ 164.501, limited to the information created or received by the Contractor from or on behalf of the IHS;
8. Required by Law: "Required by Law" shall have the same meaning as the term "required by law" in 45 C.F.R δ 164.501;
9. Secretary: "Secretary" shall mean the Secretary of the United States Department of Health and Human Services or his designee.

Section 1 – Privacy Rule Compliance

The Business Associate agrees to comply with the Business Associate Agreement requirements under the Privacy Rule and the provisions of this Agreement throughout the term of this Agreement. The Business Associate agrees that it will require all of its agents, employees, subsidiaries, affiliates and subcontractors, to whom the Business Associate provides PHI, or who create or receive PHI on behalf of the Business Associate for the IHS, to comply with the Privacy Rule and to enter into a written agreement with the Business Associate that provides the same restrictions, term and conditions as set forth in this Agreement. Any subcontracts shall be let as provided for in this contract, but, notwithstanding any exemption from any requirement for written consent contained in the subcontracting clause, the Business Associate shall nonetheless obtain the Contracting Officer's written consent before placing any subcontract pursuant to which the contractor discloses PHI to the subcontractor.

Section 2 – Permitted Uses and Disclosures

The Business Associate shall not use or disclose PHI except as provided for in this Agreement, the Privacy Rule or other applicable law, to perform functions, activities or services for on or behalf of the IHS as specified herein. The Business Associate agrees that it may use or disclose PHI on behalf of the IHS only; (1) upon obtaining the authorization of the patient to who the PHI pertains (45 C.F.R. δδ 164.501(a)(1)(iv) and 164.508(b); (2) for the purpose of treatment, payment or health care operations (45 C.F.R. δδ 164.502(a)(1)(ii) and 164.506; or (3) without an authorization or consent, if in accordance with 45 C.F.R δδ 164.506, 164.510, 164.512, 164.514(e), 164.514(f) or 164.514(g). Except as otherwise limited in this Agreement, the Business Associate may use PHI for the management and administration of the Business Associate or to carry out responsibilities of the Contractor required by law.

Section 3 – Safeguards

The Business Associate shall develop and use appropriate procedural, physical and electronic safeguards to protect against the use or disclosure of PHI or the Privacy Rule. The Business Associate will limit any use, disclosure, or request for use or disclosure of PHI to the minimum amount necessary to accomplish the intended purpose of the use, disclosure or request in accordance with the requirements of the Privacy Rule.

Section 4 – Safeguards for Electronic PHI

The Business Associate shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of any electronic PHI that it creates, receives, maintains, or transmits on Behalf of the IHS as required by 45 C.F.R., part 164, subpart C, Security Standards for the Protection of Electronic Health Information.

Section 5 – Reporting of Disclosure

The Business Associate shall promptly report to the IHS any knowledge of uses or disclosures of PHI that are not in accordance with this Agreement or applicable law. In addition, the Business Associate shall mitigate, to the extent practicable, any harmful effect

that is known to the Business Associate of a use or disclosure of PHI by the Business Associate in violation of the requirements of the Privacy Rule.

Section 6 – Records: IHS Access

The Business Associate shall maintain records of PHI received from or created or received on behalf of the IHS and shall document subsequent uses and disclosures of such information by the Business Associate. The Business Associate shall promptly make available to the IHS, such information as the IHS may require to fulfill its obligations to provide access to, provides copy of, and account for disclosures with respect to the PHI pursuant to the Privacy Rule (e.g., 45 C.F.R. δ 164.528 (individual request for an accounting PHI disclosures) and other applicable law.

Section 7 – Records; Individual Access

The Business Associate shall maintain a designated record set, as defined by the Privacy Rule (45 C.F.R δ 164.501), for each patient for which it has PHI. In accordance with a patient's right to access his PHI under the Privacy Rule, the Business Associate shall make available all PHI in the patient's designated record set to the patient to whom that information pertains, or to the patient's authorized representative, upon request by the patient or his authorized representative to meet the requirements under 45 C.F.R δ 164.524. The Business Associate shall document all disclosures under this section and shall promptly make such information available to the IHS pursuant to section 6 above.

Section 8 – Disclosure

Upon request, the Business Associate shall make available to the IHS or to the Secretary, PHI and the Business Associate's internal practices, books, and records, including its policies and procedures, including any agreements required by Section 1 with subcontractors, vendors and other agents relating to the use and disclosure of PHI received from the IHS, or created or received by the Business Associate on behalf of the IHS, for purposes of determining the IHS compliance with the Privacy Rule. The Business Associate shall not disclose PHI to any requesting party other than as provided for in this section and sections 2 and 7 above. The Business Associate shall forward all other requests to the IHS for handling.

Section 9 – Amendments of Information

The Business Associate shall make PHI available to the IHS for the IHS to fulfill its obligations pursuant to the Privacy Rule to amend PHI and shall, as directed by the IHS, incorporate any amendments into PHI held by the Business Associate and ensure incorporation of any such amendments into PHI held by its agents or subcontractors. The Business Associate shall not make any amendments to PHI and shall forward all amendment requests to the IHS Contracting Officer for approval.

Section 10 – Obligations of the IHS

The IHS Contracting Officer shall provide the Business Associate with its notice of privacy practices, produced under 45 C.F.R δ 164.520 and any changes to the notice. The IHS Contracting Officer shall also provide the Business Associate with any changes in, or

revocation of, individuals' authorizations to use or disclose PHI, if such changes affect the Business Associates' permitted or required uses or disclosures of PHI. The IHS Contracting Officer shall notify the Business Associate of any restrictions to the use or disclosure of PHI that the IHS has agreed to pursuant to an individual's request under 45 C.F.R. δ 164.522. The IHS shall not request that the Business Associate use or disclose PHI in any manner that would violate the Privacy Rule if done by the IHS.

Section 11 – Material Breech; Termination

If the Business Associate breaches a material obligation of this Agreement or fails to comply with the Privacy Rule, the IHS will give the Contractor an opportunity to cure the breach, but if the Contractor fails to cure the breach, the IHS will terminate the Agreement, as provided in 52.249-12. If, at the determination of the IHS Contracting Officer, neither cure nor termination are feasible, IHS shall report the material breach to the Secretary. Termination of this Agreement shall not affect any provision of this Agreement, which, by its wording or nature, is intended to remain in effect and to continue to operate in the event of termination. Termination of the underlying contract between the parties will result in the termination of this Agreement.

Section 12 – Return or Destruction of Information

When this Agreement/contract terminates, the Business Associate, at the IHS's option, shall return to the IHS, or destroy, all PHI in its possession, and keep no copies of PHI except as requested by the IHS or required by law. The IHS Contracting Officer shall notify the Business Associate whether the Business Associate must return or destroy any PHI in its possession. If the Business Associate or its agent or subcontractor destroys any PHI, then the Business Associate will provide the IHS with documentation evidencing such destruction. Any PHI maintained by the Business Associate shall continue to be extended the same protections set forth in this Agreement for as long as it is maintained.

Section 13 – Term

The term of this Agreement shall begin on the effective date of this modification and or contract award and end with the completion of the contract, except as provided in Section 12.

Section 14 – Amendment of Agreement

After the date of execution of this Agreement and after learning the material changes have been made to the Privacy Rule, the parties agree to amend this Agreement to ensure that it complies with the Privacy Rule and that IHS can continue to comply with the Privacy Rule.

Section 15 – Miscellaneous Provisions

(1) All notices under this Agreement shall be as provided in this contract.

(2) This Agreement shall be binding upon, inure to the benefit of and be enforceable by and against the Parties and their successors and assigns.
Any novation, assignment, or other transfer of rights, interests, or duties under this Agreement by the Contractor shall be as provided in this contract;

(3) Any ambiguity in this Agreement shall be resolved to bring the Agreement into compliance with the most current version of the Privacy Rule;

(4) If a court of competent jurisdiction deems any provision of this Agreement unenforceable, such provision shall be severed from this Agreement and every other provision of the Agreement shall remain in full force and effect.