

Business Associate Agreements and Similar Arrangements

As a “covered entity” under the HIPAA Privacy Rule, the Indian Health Service (IHS) is required to have a written contract with each of its “business associates” in order to disclose “protected health information” (which includes most individually identifiable health information) to the business associate. Under business associate clauses in its contracts, the IHS will obtain satisfactory assurance that the business associate will appropriately safeguard protected health information and use such information only for authorized purposes.

I. What is a business associate?

A business associate is a person or entity who provides certain functions, activities, or services for or to a covered entity under the HIPAA privacy rule, such as the IHS. The IHS’s business associates include any person or entity who does not work under the direct control of the IHS and who:

(A) acting on behalf of the IHS, performs or assists in the performance of an activity involving the use or disclosure of individually identifiable health information, including payment and health care operation activities such as claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing, or any other activity regulated by HIPAA; or

(2) provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for the IHS, where the provision of the service involves the disclosure of individually identifiable health information from the IHS or from another business associate of the IHS.

II. What factors should be considered in determining whether a person is a business associate of the IHS?

A. Does the person perform or assist in the performance of activities that are included under Section I above, on behalf of the IHS?

If **no**, the person is **not** a business associate of the IHS.

Examples:

1. An IHS facility provides protected health information about a potential organ donor to an organ transplant organization. No business associate clause is needed in the agreement between the IHS and the organization because the organ transplant organization is not performing any function or activity on behalf of the IHS; rather, the organization is providing services to the potential organ recipient on its own behalf.
2. The IHS' fiscal intermediary (FI) assists the IHS in processing claims under the IHS contract health service program, an activity involving the use or disclosure of protected health information. The FI is acting on behalf of the IHS, and a business associate clause in the contract is necessary for the IHS to disclose protected health information to the FI.
3. JCAHO performs accreditation services for many IHS facilities. Unless the IHS only discloses a "limited data set" with no direct patient identifiers, the provision of accreditation services by JCAHO would involve the disclosure of protected health information, and the IHS must include the business associate clause in its agreements with JCAHO.

B. Does the person perform or assist in the performance of activities included under paragraph 1 as part of the IHS workforce?

If **yes**, the person is **not** a business associate of the IHS.

Examples:

1. The IHS "workforce," for purposes of the HIPAA privacy rule, means employees, volunteers, trainees, and other persons who perform work for the IHS under its direct control. Thus, no business associate clause in a contract is necessary for the IHS to disclose protected health information to an IHS employee or volunteer who, for example, performs billing activities or provides accounting services for the IHS.
2. A business associate clause **would** be required, for example, where an outside consultant is under contract to perform utilization review or quality assurance services for an IHS hospital.

C. Does the function/activity that the person performs or assists with involve the use or disclosure of individually identifiable health information?

If **no**, assuming the person would have minimal or no access to protected health information, no business associate clause in the contract is needed.

Examples:

1. An IHS facility contracts with a company providing janitorial services. A business associate clause would not be needed in the contract because the cleaning services provided would not involve the use or disclosure of protected health information. Similarly, no business associate clause would be required where an IHS facility obtains photocopier repair services from a private vendor. In both instances, any disclosure of protected health information would be unintentional. Note: the IHS must have reasonable safeguards to limit inadvertent disclosures (such as may occur when a vendor overhears a discussion about a patient between two physicians or a janitor is cleaning an office).
2. An IHS facility contracts with a medical transcription service to transcribe physicians' notes. A business associate clause in the contract would be required, because the provision of transcription services necessarily involves the use or disclosure of protected health information.
3. No business associate clause or contract is required for entities such as the U.S. Postal Service and Federal Express which act merely as conduits for protected health information, since the services provided to the IHS by such entities do not involve the use or disclosure of protected health information and the likelihood of exposure of such information to a conduit is very small.

D. Is the person a health care provider to whom IHS provides protected health information only for treatment purposes?

If **yes**, a business associate clause or contract is **not** required.

Examples:

1. An IHS facility refers a patient to a cardiologist in private practice, and sends the cardiologist a copy of the patient's medical records relating to his cardiac condition. The IHS is disclosing information about the patient to the cardiologist for treatment purposes; therefore, no business associate clause or contract is needed.

2. If the IHS provides protected health information to the cardiologist in order for the cardiologist to assist the IHS in performing IHS quality assurance or IHS training activities, a business associate clause in the contract **would** be required.

E. Will the IHS only disclose a “limited data set” of protected health information, without direct identifiers, to the person for accreditation and other health care operation purpose?

If **yes**, a business associate clause in a contract is **not** required; however, a “data use agreement” must be in place. The requirements for a data use agreement are set forth at 45 C.F.R. 164.514(e)(3).

F. Is the person conducting research using protected health information from the IHS?

If **yes**, a business associate contract is **not** required as long as the protected health information is provided to the researcher for research purposes only and the disclosure is permitted under the HIPAA privacy rule (i.e., with patient authorization, pursuant to a waiver, or as a limited data set).

III. When would the HIPAA privacy rule allow the IHS to use other arrangements besides business associate contracts?

A. Is the Business Associate a governmental entity?

If the business associate is a government entity, the IHS may enter into a memorandum of understanding (MOU) with the other government entity. The MOU must contain terms that accomplish the same objectives as a business associate contract. Moreover, if another law imposes requirements on the business associate that accomplishes those same objectives, no business associate contract or MOU is required.

Examples:

1. A tribe provides business office services to the IHS. If the tribe has an ordinance that requires it to provide the same level of protection to individually identifiable health care information as a business associate agreement, then no business associate agreement is required. If the tribe does not have such an ordinance, then the IHS must enter into a MOU that provides the same protections to the information as a business associate agreement. If instead of a tribe, the services are performed by an Urban Indian contractor, a business associate agreement is required, because the contractor is not a governmental entity.

B. Is the Business Associate required by law to provide services on behalf of the IHS?

If a business associate is required by law to perform a function or activity or provide legal, accounting or other “business associate” services on behalf of the IHS, the IHS may disclose protected health information to the business associate to the extent necessary for the business associate to meet its legal obligations. However, the IHS must make a good faith attempt to obtain the satisfactory assurances required of business associates, and if unable to do so, document the attempt and the reasons that such assurances cannot be obtained.

Example:

This provision applies to the United States Department of Justice (DOJ), which is required by law to provide legal representation to defend against malpractice claims involving care furnished by IHS providers acting within the scope of their IHS employment.

IV. When does the IHS need to modify the contract or other arrangement with the Business Associate to comply with HIPAA?

A. Was the agreement in place before October 15, 2002?

Contracts that were entered into and effective prior to October 15, 2002 are deemed compliant until April 14, 2004 unless:

1. The agreement has been renewed or modified between October 15, 2002 and April 14, 2003; or

2. The agreement will be renewed or modified after April 14, 2003 but before April 14, 2004.

If the agreement was renewed or modified between October 15, 2002 and April 14, 2003, then the agreement must be brought into compliance with HIPAA no later than **April 14, 2003**.

If the agreement will be renewed or modified between April 14, 2003 and April 14, 2004, the agreement must be made HIPAA compliant at the time it is renewed or modified.

The term “modify” includes any administrative or supplemental actions that are modified to an existing contract.

All agreements with Business Associates must be brought into compliance with HIPAA no later than April 14, 2004.

C. All agreements with Business Associates entered after October 15, 2002 must be HIPAA compliant no later than April 14, 2003.

Examples:

1. On October 1, 2002, the IHS entered a contract with a medical transcription service on for one year, with an option to renew for another year. The contract has not been modified or renewed since October 1, 2002. If IHS exercises its option to renew on October 1, 2003, the IHS must add the business associate clause to the contract at that time.
2. Same facts as example 1, but the IHS does not exercise the option to renew and the contract ends on October 1, 2003. The IHS does not need to add the business associate clause to the contract.
3. Same facts as example 1, but the IHS modifies the agreement on November 1, 2002. The IHS must add the business associate clause to the contract before April 14, 2003.
4. Same facts as example 1, but the IHS modifies the agreement on May 1, 2003. The IHS must add the business associate clause to the contract on May 1, 2003.
5. Same facts as example 1, but the term of the agreement is two years. The agreement has not been modified. The IHS must add the business associate clause before April 14, 2004.

6. The IHS enters into an agreement with an offsite record destruction service on November 1, 2002. The IHS must add the business associate clause to the contract before April 14, 2003.
7. Same facts as example 6, except that the IHS enters into the agreement on May 1, 2003. The IHS must add the business associate clause to the initial contract on May 1, 2003.

ATTACHMENT

H-1 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 within the Privacy Rule.

- a. Agreement: "Agreement" shall mean this clause and any other provisions of this contract that are incorporated by reference;
- b. Business Associate: "Business Associate" shall mean the Contractor, also known as **[Insert Business Associate's Name]**;
- c. Covered Entity: "Covered Entity" shall mean the Indian Health Service;
- d. 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 provider, (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. § 164.501)
- e. Individual: "Individual" shall have the same meaning as the term "individual" in 45 C.F.R. § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g);
- f. 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;

- g. Protected Health Information: "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 C.F.R. § 164.501, limited to the information created or received by the Contractor from or on behalf of the IHS; Required By Law: "Required By Law" shall have the same meaning as the term "required by law" in 45 C.F.R. § 164.501;
- h. Required By Law: "Required By Law" shall have the same meaning as the term "required by law" in 45 C.F.R. § 164.501;
- i. 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, terms 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 or on 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 whom the PHI pertains (45 C.F.R. §§ 164.502(a)(1)(iv) and 164.508(b)); (2) for the purpose of treatment, payment or health care operations (45 C.F.R. §§ 164.502(a)(1)(ii) and 164.506); or (3) without an authorization or consent, if in accordance with 45 C.F.R. §§ 164.506, 164.510, 164.512, 164.514(e), 164.514(t) 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 a copy of, and account for disclosures with respect to PHI pursuant to the Privacy Rule (e.g., 45 C.F.R. § 164.528 (individual request for an accounting of 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. § 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. § 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. § 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 Associate's 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. § 164.522. The IHS shall not request that the Business Associate use or disclose pm in any manner that would violate the Privacy Rule if done by the IHS.

Section 11 - Material Breach: 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 [insert contract termination for default clause]. 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 pm 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 that 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;

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

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.