

## **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. The Indian Health Service receives legal services from the U.S. Department of Justice (DOJ). Because DOJ is a governmental entity, and because DOJ must comply with the Privacy Act, no business associate agreement is required.

2. 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 also applies to 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. DOJ attorneys are not members of the IHS workforce. However, as discussed above, DOJ is required to protect health information under the Privacy Act. Therefore, it is not necessary for the IHS to make a good faith attempt to obtain from DOJ the satisfactory assurances required of business associates.

***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 , 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.