

# BUSINESS ASSOCIATES

## Definition of a "Business Associate."

Commentators have expressed a wide array of opinions about precisely what functions or activities a person or entity must engage in to qualify as a business associate under the Privacy Rule. Some commentators have identified business associates as those entities that engage in "covered functions" for, or on behalf of, a covered entity. While others have defined business associates as persons or entities that perform any function or activity for, or on behalf of, a covered entity so long as the function or activity involves the use or disclosure of PHI.

The Guidance offers yet another slightly more definitive interpretation of the term "business associate." According to OCR, a business associate is a person or entity that performs certain specific functions, activities or services that involve the use or disclosure of PHI on behalf of a covered entity. The types of functions or activities that could make a person or entity a business associate include payment or health care operations activities, such as claims processing or administration, data analysis, utilization review, quality assurance, billing, benefit management, practice management, repricing and any other function or activity regulated by the Administrative Simplification Rules. This is in contrast to "covered functions," which the Rule defines as those functions performed by health plans, health care providers, or health care clearinghouses that make them covered entities.

## Transition Period for Existing Contracts.

The modifications to the Privacy Rule made in August 2002, included changes to the business associate requirements. Business associate contracts in existence prior to October 15, 2002 are not required to be in compliance with the Privacy Rule until one year after the April 14, 2003 compliance date, or until such contracts are renewed or modified, whichever occurs first (such contracts are referred to as "Transition Period Contracts"). The change was designed to ease some of the administrative and financial burdens on covered entities associated with re-negotiating existing agreements. However, because there could be difficulty in keeping track of different types of contracts, the safest course of action, if time and resources permit, may be to re-negotiate as many Transition Period Contracts as possible prior to the April 14, 2003 compliance date.

According to the Guidance, some, but not all, of the compliance obligations under the Privacy Rule are applicable to business associates that perform functions pursuant to the terms of Transition Period Contracts. The Guidance states that covered entities have the following obligations with respect to PHI held by any such business associate: (a) PHI must be made available to the Secretary of HHS as necessary for the Secretary to determine if the covered entity is in compliance with HIPAA; (b) PHI maintained by any such business associate in a designated records set must be made available to fulfill an individual's right to access and amend her PHI; and (c) covered entities must mitigate, to the extent practicable, any harmful effect of an impermissible use or disclosure of PHI by the business associate. In spite of these obligations, the Guidance goes on to say that there is absolutely no requirement for covered entities to obtain satisfactory assurance from the business associate that the privacy requirements are met.

## Software Vendors.

Merely selling or providing software to a covered entity is not sufficient to establish a business associate relationship. According to the Guidance, in order to qualify as a business associate, the software vendor must need access to the covered entities' PHI in order to provide its service. Executing a business associate contract helps shift the risk of noncompliance away from the covered entity and back to the third party, who may be in a better position to protect against the risk of its own failure to comply with HIPAA, in accordance with the terms of the business associate agreement. Moreover, HHS has consistently stated that covered entities are not required to monitor or oversee the extent to which its business associates abide by the privacy requirements under business associate contracts.