







Washington, DC & Boston & London, UK Alan S. Goldberg, JD, LLM



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- On behalf of such covered entity or of an organized health care arrangement...in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:
 - (A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or
 - (B) Any other function or activity regulated by this subchapter
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• Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation...management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

- A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.
- A covered entity may be a business associate of another covered entity.

- Financial, actuarial, accounting, consulting, claims, data aggregation, management, administrative, legal, accreditation, financial services
- Must have individually identifiable health information

• The current rule requires covered entities - health plans, health care providers and clearinghouses -- to have contracts with their business associates to ensure the business associates protect the privacy of the information. The proposal includes model business associate contract provisions, to make it easier and less costly for covered entities to implement the requirements. The changes also would give covered entities (except for small health plans) up to an additional year to change existing contracts, easing the burden of renegotiating contracts all at once.

A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information...
A covered entity must document the satisfactory assurances required by paragraph (e) (1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e)...

•A contract between the covered entity and a business associate must:

• (i) Establish the permitted and required uses and disclosures of such information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity...

•The Privacy Rule does not "pass through" its requirements to business associates or otherwise cause business associates to comply with the terms of the rule. The assurances that covered entities must obtain prior to disclosing PHI to business associates create a set of contractual obligations far narrower than the provisions of the rule, to protect information generally and help the covered entity comply with its obligations under the rule.

•For example, covered entities do not need to ask their business associates to agree to appoint a privacy officer, or develop policies and procedures for use and disclosure of PHI...

• HHS provides these model business associate contract provisions in response to numerous requests for guidance. This is only model language. These provisions are designed to help covered entities more easily comply with the business associate contract requirements of the Privacy Rule. However, use of these model provisions is not required for compliance with the Privacy Rule. The language may be amended to more accurately reflect business arrangements between the covered entity and the business associate. These or similar provisions may be incorporated into an agreement for the provision of services between the entities or they may be incorporated into a separate business associate agreement.

- These provisions only address concepts and requirements set forth in the Privacy Rule and alone are not sufficient to result in a binding contract under State law and do not include many formalities and substantive provisions that are required or typically included in a valid contract.
- Reliance on this model is not sufficient for compliance with state law and does not replace consultation with a lawyer or negotiations between the parties to the contract. Furthermore, a covered entity may want to include other provisions that are related to the Privacy Rule but that are not required by the Privacy Rule. For example, a covered entity may want to add provisions in a business associate contract in order for the covered entity to be able to rely on the business associate to help the covered entity meet its obligations under the Privacy Rule.

• In addition, there may be permissible uses or disclosures by a business associate that are not specifically addressed in these model provisions. For example, the Privacy Rule does not preclude a business associate from disclosing protected health information to report unlawful conduct in accordance with Sec. 164.502(j). However, there is not a specific model provision related to this permissive disclosure. These and other types of issues will need to be worked out between the parties.

Ten Commandments For Business Associates HIPAA Business Associates Do s & Don't s

Thy business associate shall:

- 1. Not use/disclose protected health information other than as permitted by contract or required by law
- 2. Use appropriate safeguards to prevent use or disclosure
- **3. Report unauthorized use or disclosure of which Business Associate becomes aware**

Thy business associate shall:

- 4. Ensure that agents agree to same covenants & restrictions
- 5. Make available PHI for individual access
- 6. Make available PHI for amendment & incorporate amendments
- 7. Make available PHI for accounting

Thy business associate shall:

- 8. Make compliance books & records available to HHS for purposes of determining Covered Entity's compliance
- 9. At end of arrangement return or destroy all PHI & return any copies or keep & protect if infeasible

- 10. **Contract must** authorize termination if Covered Entity determines that Business Associate violated material term of contract
- <u>Unless</u> inconsistent with statutory obligations of the Covered Entity or Business Associate