

Advanced Issues in Privacy: Drafting and Negotiating Business Associate Contracts

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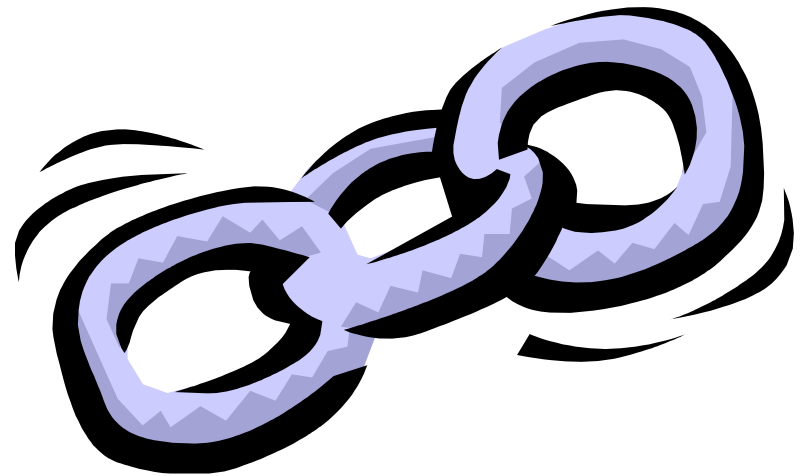
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Comparison

- ◆ Chain of Trust Agreement
 - ❖ Security Rule
- ◆ Trading Partner Agreement
 - ❖ Transaction + Code Set Rule
- ◆ Business Associate Contract
 - ❖ Privacy Rule
- ◆ Data Use Agreements
- ◆ Contracts may be combined as appropriate



Use and Disclosure — Who is a Business Associate?

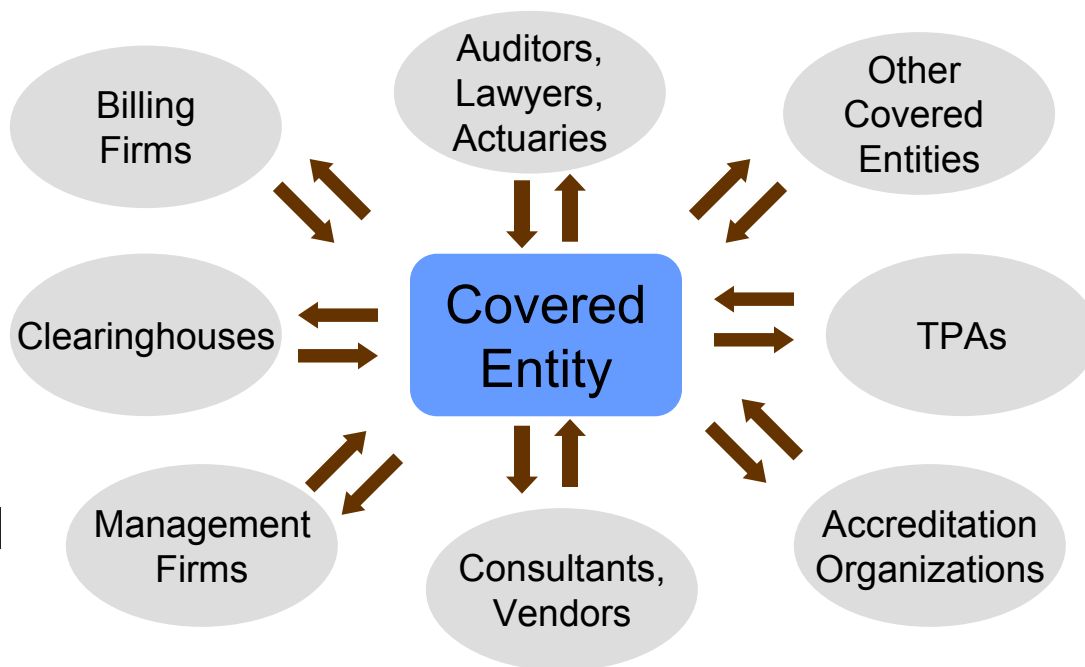
◆ A person who, on behalf of a covered entity or OHCA —

❖ Performs or assists with a function or activity involving

■ Individually identifiable information, or

■ Otherwise covered by HIPAA

❖ Performs certain identified services



Multiple Personalities

A frequent covered entity may be a business associate of another covered entity.



Business Associates — Examples

- ◆ Hospital contracts with billing company or clearinghouse
- ◆ Health plan contracts with IT vendor
- ◆ Medical group contracts with management company
- ◆ Hospital hires billing and coding consultant



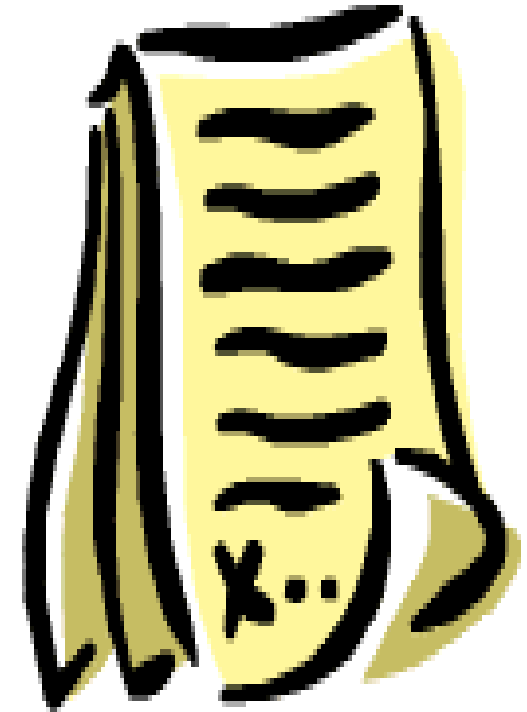
No Business Associate Relationship

- ◆ Between provider for treatment
 - ❖ But special arrangements (like QA or UM services) may create a business associate relationship
- ◆ Workforce
- ◆ Provider and plan with respect to transaction
- ◆ Hospital and medical staff member
- ◆ Group health plan and plan sponsor
- ◆ Financial institutions
- ◆ Covered entities in organized health care arrangements
- ◆ “Conduits” (mail services and electronic equivalents)



Business Associate Contract

- ◆ A covered entity may disclose PHI to business associates if:
 - ❖ Obtains “satisfactory assurance” that business associates will appropriately safeguard the information
- ◆ Business associate contract required
- ◆ Breach of BAC by a covered entity that also is a business associate = HIPAA violation



Business Associate Contracts — Required Terms

- ◆ Use and disclose information only as authorized in the contract
 - ❖ No further uses and disclosures
 - ❖ Such uses and disclosures may not exceed what the covered entity may do under HIPAA
 - ❖ Data aggregation services exception
- ◆ Implement appropriate privacy and security safeguards
- ◆ Report unauthorized disclosures to covered entity
- ◆ Make available protected health information under access, amendment and accounting of disclosures rights
- ◆ Incorporate any amendments



Business Associate Contracts — Required Terms

- ◆ Make available its records to HHS for determination of covered entity's compliance
- ◆ Return/destroy protected health information upon termination of arrangement, if feasible
 - ❖ If not feasible, extend BAC protections
- ◆ Ensure agents and subcontractors comply
- ◆ Authorize termination by covered entities



Business Associate Contract Forms and Templates

- ◆ Many forms circulating around including Appendix to revised Final Rule, 67 Fed. Reg. at page 53264 (8/14/2002)
- ◆ Beware of particular biases in the forms
- ◆ Description of permitted uses and disclosures by its nature should be individualized and tailored to the services being provided by the Business Associate

Covered Entity Perspective

- ◆ Manage risk and avoid liability
- ◆ Business Associate held to a higher level of accountability
- ◆ Indemnification and other assurances from Business Associate beyond what is required under the standard for business associate contracts
- ◆ Uniformity of BA contracts

Vendor Perspective

- ◆ Contract limited to terms required under 42 CFR 164.504(e)
- ◆ Least restrictions on its use and disclosure of PHI obtained from the covered entity
- ◆ Minimize liability; no indemnification
- ◆ Uniformity of BA contracts; consistency with subcontracts



Specific Language Considerations: Permissible Use & Disclosure by Business Associates

- ◆ May permit business associate to use PHI:
 - ❖ For its proper management and administration (presumably as relates to its business associate functions)
 - ❖ To carry out its legal responsibility
 - ❖ For data aggregation
- ◆ May permit business associate to disclose PHI:
 - ❖ If required by law
 - ❖ If BA obtains reasonable assurances of confidentiality and requires notification of breach
- ◆ BAs will want least restriction to use and disclosure



Specific Language Considerations: Covered Entity Obligations

- ◆ Provide notice to business associate
- ◆ Notify business associate of changes/revocation of individual permissions
- ◆ Notify business associate of restrictions to which covered entity has agreed
- ◆ No covered entity requests for business associate to act in a nonpermissible manner
- ◆ BA would want this
- ◆ CE may want to avoid



Specific Language Considerations: Duty To Mitigate

- ◆ CE has duty to mitigate under HIPAA
 - ❖ Would want assistance from BA
 - ❖ No cost to CE
- ◆ BA will want to avoid



Specific Language Considerations

- ◆ Indemnification
- ◆ Insurance
- ◆ Right to review contracts between business associates and their subcontractors/agents
- ◆ Right to inspect/investigate/audit
- ◆ Effective date and “placeholder” provisions
- ◆ Ownership



Specific Language Considerations

Other Things to Think About . . .

- ◆ Change in law
 - ❖ Agree to negotiate amendments
 - ❖ Unilateral amendments
- ◆ No third-party beneficiaries
 - ❖ Beneficial to both parties



Liability for Business Associates

- ◆ If covered entity knows of a pattern of activity constituting a breach by the business associate, then
 - ❖ Must take reasonable steps to
 - Cure the breach or end the violation
 - Require business associate to cure
 - ❖ If unsuccessful,
 - Must terminate if feasible or
 - Report to DHHS
- ◆ How much monitoring is required?
 - ❖ Affirmative representations by business associate
 - ❖ Investigate complaints
- ◆ Covered entity should train its workforce to recognize and report violations by business associates



Contract Compliance Considerations

- ◆ Decide on scope (may vary depending on relationship)
 - ❖ Addendum
 - ❖ Integration of key provisions into contract
 - ❖ Stand-alone contract
- ◆ Proactive or reactive approach
- ◆ Ultimately, subject to negotiations
- ◆ Use of checklist
 - ❖ AHA
 - ❖ Create your own
- ◆ Forms no substitute for legal advice (per AHA)



Business Associate Compliance Considerations

- ◆ Create business associate inventory
 - ❖ Start by listing everyone who receives individually identifiable health information
 - ❖ Determine who is/likely to be a business associate
- ◆ Create contract inventory
- ◆ Review existing contracts
- ◆ Allow for educational lead time
- ◆ Transition with new contracts



Transition Provisions

- ◆ Covered entities may continue existing contracts for up to one year beyond April 14, 2003
- ◆ Existing contract prior to effective date of final amendment
- ◆ Contract not renewed between effective date and April 14, 2003
- ◆ Covered entity still required to comply with Privacy Rule



Questions?

For more information, contact

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