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HIPAA Special Issues: Making Compliance Possible

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THE Secret to HIPAA:

Responsibility Belongs Where You Say It Does

- Rule applies directly to a "covered entity"
- A corporate entity, partnership or foundation can <u>narrow</u> its scope of liability through the "hybrid entity" rules.
- The "OHCA rules" can be used to streamline administrative burdens and liability
- A covered entity can voluntarily <u>expand</u> the scope of its liability by entering into a "business associate" relationship, or by using the affiliated entity rules.

The Compliance Goal:

Getting A Handle On Costly Administrative Requirements

- Acknowledgement/intake process
- Authorizations and revocations
- Access/amend/accounting
- Restricted communications
- Requests for restricted use/disclosure
- Employee training and firewalls (and developing policies/systems for same)

Just tell me what I have to do --

Why do I care about these?

"hybrid" entity "covered entity" "health care component" "business associate" "non-covered provider" "OHCA" "workforce" Perhaps the most critical implementation challenge for lawyers is establishing the relationships between these HIPAA structures and the legal entities and individuals that must implement the requirements.

HIPAA Entities Are <u>Not</u> Corporate Persons



HIPAA Entities Are <u>Designations</u> in Compliance Documentation and/or Notice



Tell me the Hybrid Entity Story...

- Hybrid entity: "A single legal entity that is a covered entity whose business activities include both covered and non-covered functions"
- That designates "health care components" (HCCs) in accord with the rule.
 - Must not leave any "covered entity" outside of a HCC
 - May include only a component that performs a "covered function" or an "internal BA"

The Hybrid Entity Lived "Happier" in HIPAA Land Because...

- A rule reference to "covered entity" refers to HCC

 (e.g., policies for workforce uses, disclosures, minimum necessary, training, security)
- A rule reference to "protected health information" refers to PHI created or received by/behalf of the health care component.
 - (e.g., access/inspect/amend/accounting; fundraising)

Compliance Teamwork:

Using OHCAs To Pool Obligations and Limit Liability

- When a HIPAA entity has a legal obligation--
 - Who -- what corporate or living person -- may perform it?
 - How do you address "apparent agency" issues?
 When does performance "count" as compliance for a particular entity?
 - Who is liable if it is not performed?

Organized Health Care Arrangements

- 1. Clinically integrated care setting in which individuals typically receive care from more than one provider.
- Organized system of care -"Hold themselves out" as joint arrangement, *and* participate in joint activities (UR, QA, PMT risk)
- 3. Group plan and HII or HMO
- 4. 2 or more group plans of same sponsor
- 5. 2 or more group plans and HMOs, HIIs

OHCA Facts

- Is a definition only; *not* a required designation.
- May have a joint notice; need not have the same P&Ps
- Need not have BAAs for "joint activities" of the OHCA
- *May* include non-covered providers
- A living human being can be in an OHCA *and* be a separate covered entity (*or* non-covered provider) no special designation required
- A covered entity can be in more than one OHCA

OHCA Issues and Utility

- A tool for managing apparent agency liability & consumer protection issues.
- Designation via Notice, which also can establish responsibility for authorizations, revocations, and exercise of certain rights (e.g., confidential communications, restrictions)
- Policies and procedures a HIPAA designation option

Special Liability Issues

- Who will sign business associate agreement for the OHCA?
- When a "use" is authorized, are there restrictions on *who* may do it?
- When a "disclosure" is authorized, are there restrictions on what the *recipient* may do with the information?
- Does the entity that is authorized to disclose have legal obligations *after* doing so?

Business Associate Agreements: Expansions of Liability

- *"On behalf of* such covered entity...performs or assists in the performance of:
 - "(A) A function or activity involving the use or disclosure of ...[PHI], or
 - "(B) Any other function or activity regulated by this subchapter, or
- "…legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services… [involving PHI]
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BA Issues? (P. 53253)

- A third party is not your BA if PHI is for:
 - A covered function (e.g., treatment, payment), unless for the third party is performing the function on your behalf (e.g., billing)
 - A non-covered function, whether or not on your behalf, that is a disclosure permitted by the regulation (e.g., research, law enforcement, public health reporting)
 - An activity where PHI access is "incidental"
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Why not do a BA -- to be sure?

- Belts and suspenders do not help you need only one compliance mechanism
- If you have a BA agreement with a third party:
 - all information transfers and all uses by the BA become "uses" by the CE -- if the BA activity is not a permissible use (i.e., TPO) the agreement is evidence of a CE violation
 - CE must cure, mitigate or report known violations
 - for each patient request of an accounting, you must have a mechanism to check BA's disclosures for purposes of providing the accounting.



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