

HIPAA and Hybrid Entity Status: Why most Universities Get it Wrong

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Agenda



A review of the regulations



Defining other relationships



Case studies



Questions



What is the healthcare component?

HIPAA

A Review of the Regulations

HIPAA Regulations on Hybrid Entities

Hybrid Entity

- Single legal entity that is
 - A covered entity (Healthcare Provider, Health plan, Healthcare Clearinghouse)
 - With both covered and non-covered functions and
 - Designate its health care component(s)

Covered Functions

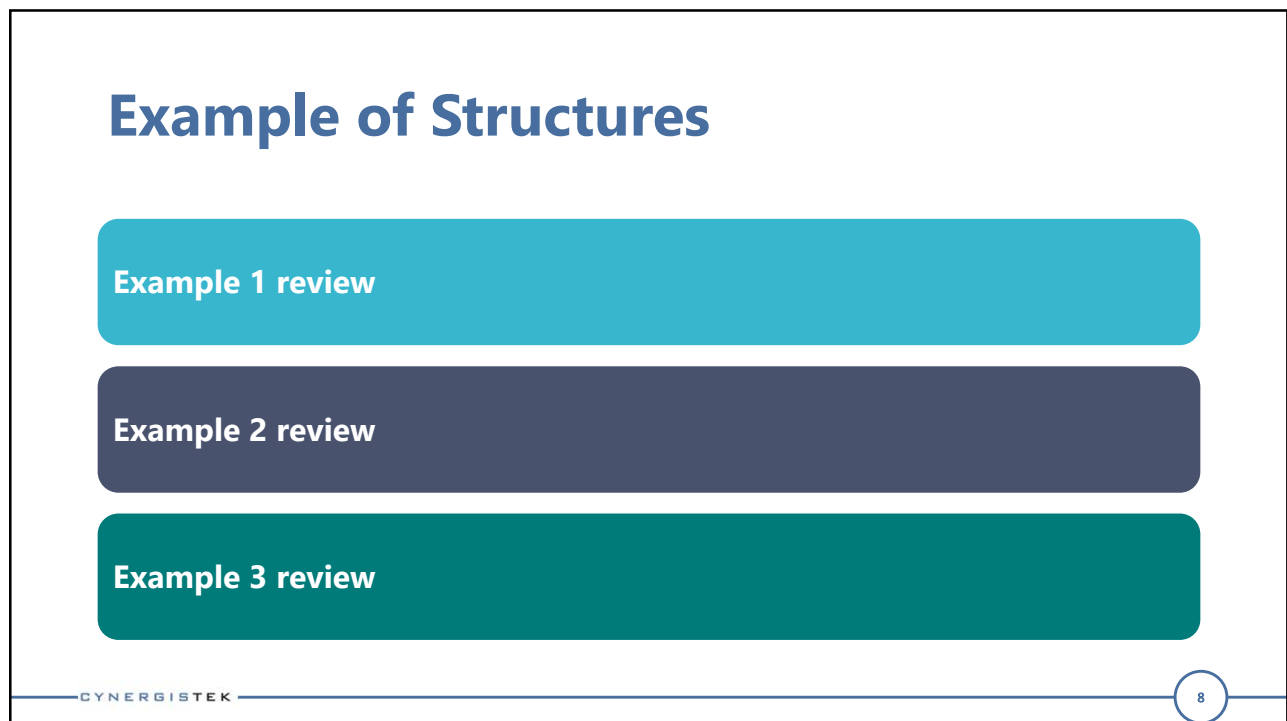
- Those functions of a covered entity the performance of which makes the entity a health plan, health care provider or health care clearinghouse.

Regulations on Hybrid Entities

- Business units of the organization engaging in activities that would make them a business associate if they were a separate legal entity must be include in the health care component of the hybrid entity to the extent they engage in those BA activities
- The health care component may only include a component to the extent it performs covered functions



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Entity for Example 1

- **XYZ University**
 - Following Colleges and Schools
 - Law
 - Business
 - Public Health
 - Education
 - Nursing
 - Dentistry
 - Medicine
 - Fine Arts
 - **Other activities and functions**
 - Owns two hospitals
 - Conducts clinical research
 - Operates a student health center that sees students, student dependents and employees
 - Has an employee health plan



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Entity for Example 2

- **ABC University**
 - Following Colleges and Schools
 - Law
 - Business
 - Public Health
 - Education
 - Nursing
 - Dentistry
 - Medicine
 - Fine Arts
 - **Other activities and functions**
 - Operates clinics in which multi-specialty faculty practice group practices
 - Conducts clinical research
 - Operates a student health center that sees students, student dependents and employees
 - Has an employee health plan



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Entity for Example 3

- **MNO University**
 - Following Colleges and Schools
 - Law
 - Business
 - Public Health
 - Education
 - Fine Arts
 - **Other activities and functions**
 - Operates a student health center that sees students, student dependents and employees
 - Has an employee health plan



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What Is in the Health Care Component?

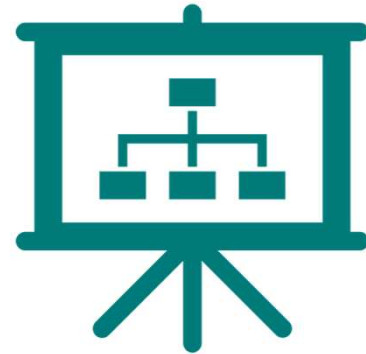
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How Are the Health Care Components Identified?

- Look at the organization chart
 - Assure it is up-to-date
 - Assure everyone understands the functions within the different components
 - Don't assume there are not covered functions solely based on the name or traditional activity of the business unit, college or school
 - Don't assume the business unit engages in covered functions simply because health care services are provided



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How Are the Health Care Components Identified?

- Start with a survey
 - Assure it gives adequate descriptor and definitions for the person answering the question to provide meaningful information.
 - Make sure the survey gets to the right person or persons of the school, college, or business unit.
 - Remind everyone that simply providing healthcare services does not make one a covered entity healthcare provider under HIPAA
 - Talk to legal counsel regarding relationships with third parties and the legal relationships of the AMC.



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How Are the Health Care Components Identified?

- Key areas of contention
 - Research
 - Student Health
 - Self-pay health care functions
 - Self-funded group health plan
 - Shared services



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Lessons From the Trenches



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Logistics



Don't believe everything you read on your own website.



Membership in the covered entity may be viewed as a status symbol.



Documentation is key!



Remember to keep your materials updated as you make changes to your organization.

Fall Out

- What do you do with entities removed from the covered entity? Time for some new policies!
- Re-training is essential!
- Just when you think it's safe to get back in the water . . .
 - HIPAA covered entity status as requirement for research funding !!!!!

Defining Research Activities

- Research
 - Clinical research
 - Prospective i.e. interactions with human subjects
 - Retrospective i.e. review of records only
 - Research on healthy subject with services performed within the health care component
 - Is IRB/Privacy Board inside or outside the health care component?
 - Committees with dual purposes
 - Radiation Safety
 - Biosafety

Assessing the Student Health Center

- Who are its patients?
 - Students only
 - If students only then data is not PHI but covered by FERPA
 - Consider what happens with students to take break for a semester or matriculate but still have student insurance
 - Staff
 - Would need to be inside the covered component if billed using standard transactions
 - Occasional care of staff as a courtesy does not count if not billed to third party
 - Student dependents
 - Would need to be inside the covered component if billed using standard transactions

Assessing the Student Health Center

- What notice is required?
 - FERPA for students
 - HIPAA NPP for non-students
 - Both?

Assessing Self-Pay Health Care Functions

- Are there components that engage in the deliver of health care services that are only self-pay?
 - Psychology clinic
 - Autism assessment center
 - Audiology and Speech Therapy
- Will these business units be required to comply with the organization's HIPAA policies?

Shared Services

- Are there components that engage in the deliver of health care services what are delivered by other parties?
 - Clinic within the School of Public Health but services are contracted through the faculty practice group and billed by them



Defining Other Relationships

What Type of Agreements/ Relationships Might Exist?

Affiliated Covered Entity (ACE)

Organized Health Care Arrangement (OCHA)

Business Associate

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Affiliated Covered Entity

- Legal separate covered entities that are affiliated designate themselves as an ACE i.e. become a single covered entity for purposes of HIPAA
- May designate the separate covered entities or any health care component of the CE)
- Required common ownership or control
- Designation must be documented

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Affiliated Covered Entity

- What constitutes evidence of common ownership or control?
 - Same "parent"
 - Overseen by a common Board
- Be prepared to demonstrate common ownership or control
- Consider liability implications of becoming an ACE

Organized Health Care Arrangement

- 45 CFR §160.103 -A clinically integrated care setting in which individuals typically receive health care from more than one health care provider
- An organized system of health care in which more than one covered entity participates and all participating CEs
 - Hold themselves out as a joint arrangement
 - Participate in joint activities that include at least one of the following:
 - Utilization review
 - Quality assessments
 - Payment activities

Business Associates

- Any component of a covered entity that is a hybrid entity must include those business functions performing BA type activities in the health care component of its hybrid entity.
 - Thus not business associate agreement is required.
- Entities that are part of an OHCA may be a business associate of another covered entity participating in the OCHA

Business Associates

- Business units, colleges or schools may have business associate relationships with external third parties
- The activities that make the unit, college or school a BA may or may not be considered covered functions
- Consideration must be given to whether separate P & Ps are required, or they would follow the health care component HIPAA P & Ps as applicable.

Business Associates

- Need for process to identify external BA relationships before the engagement is entered and to monitor during the engagement to assure
 - The risk profile is considered
 - The compliance obligations are understood
 - Breach notification is properly addressed.

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? Questions?

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Thank You

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