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The views expressed in this presentation belong to the speaker and do not necessarily represent the views of her organization or other organizations.

Nothing in this presentation constitutes legal advice.
**Agenda**

- HIPAA: A review of the regulations
- Case studies
- What is the healthcare component?
- Defining other relationships
- Questions

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**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
Example of Structures

Example 1 review

Example 2 review

Example 3 review
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

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
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?
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

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.
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

Lessons From the Trenches
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 delivery 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

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
**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.
Thank You