



Fifth National HIPAA SUMMIT

Advanced HIPAA Issue: HIPAA Hybrid Entity Strategies

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Agenda

- ◆ Part 1, Hybrid Entities
 - Basic Definitions and Requirements
 - Considerations, Pros and Cons
- ◆ Part 2, Case Study: Hybrid Entity at the University of Texas Southwestern
- ◆ Part 3, Case Study: County as a Hybrid Entity

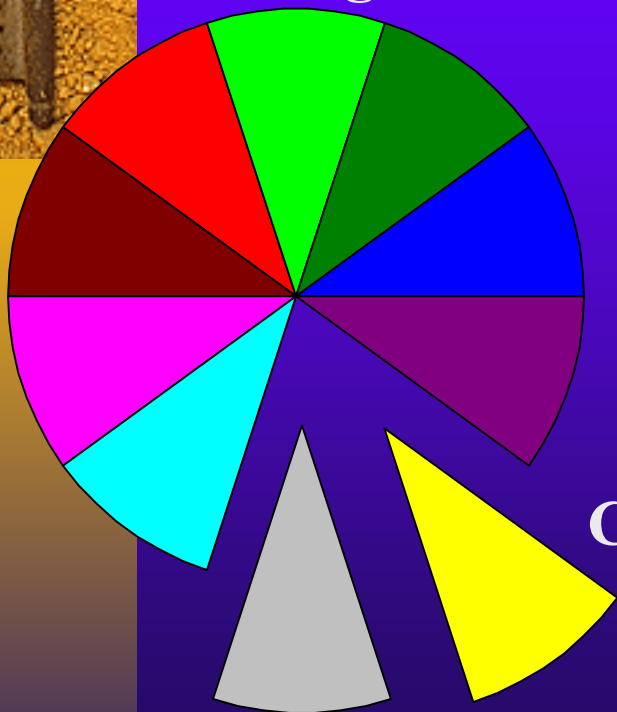


Hybrid Entities Part 1

Basic Definitions and Requirements
General Considerations, Pros and Cons

Hybrid entity

College



Clinic

Hybrid entity means a single legal entity:

- (1) That is a covered entity;
- (2) Whose business activities include both covered and non-covered functions; and
- (3) That designates health care components.

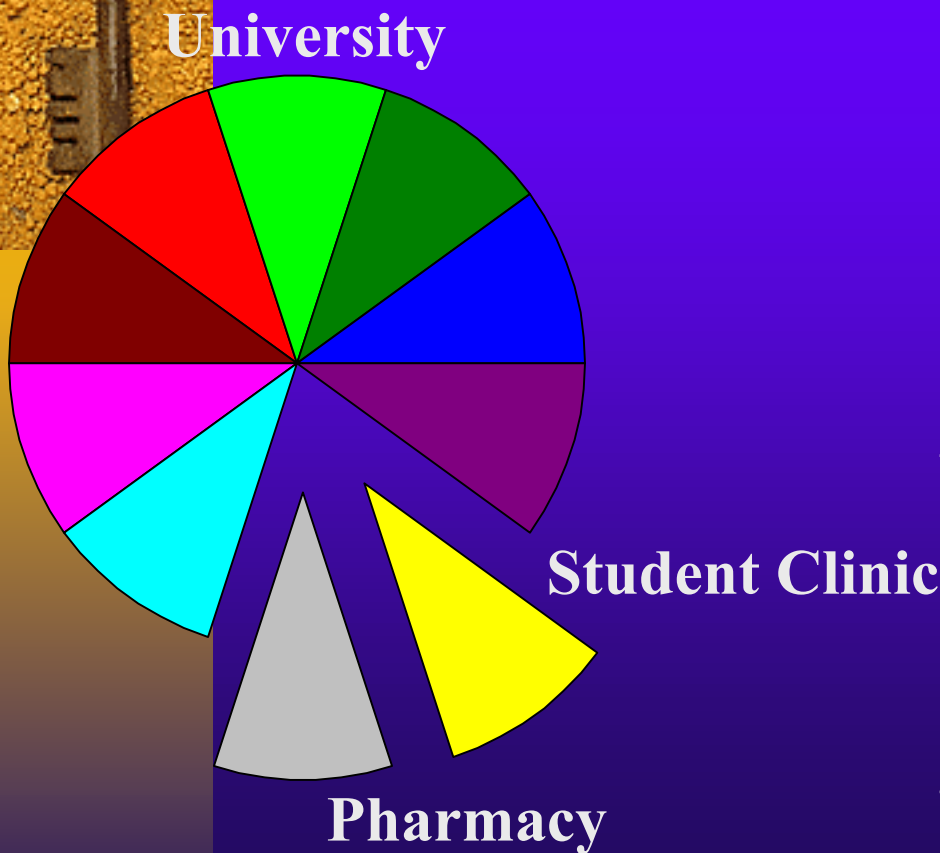
67 Fed. Reg. 53181, 53267 (Aug 14, 2002) to be codified at 45 C.F.R. §164.504 (a).



Single Legal Entity

- ◆ In the Academic Medical Environment there may be entities that perform services, but they are not part of the same single legal entity
 - Affiliated Teaching Hospitals
 - Outsourced legal department
 - Political separateness

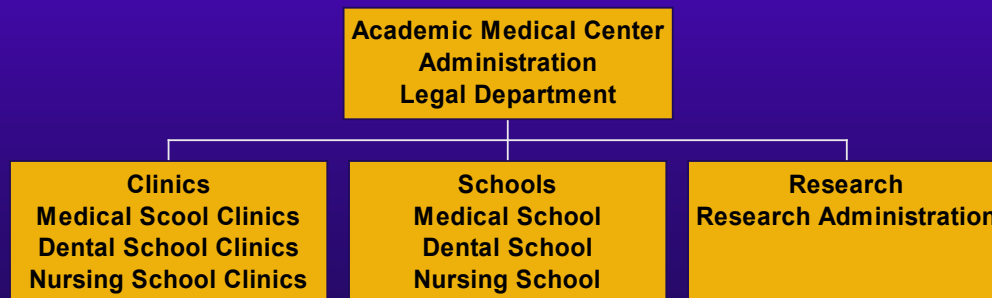
Covered Functions



- ◆ Covered functions means those functions of a covered entity the performance of which makes the entity a health plan, *health care provider*, or health care clearinghouse₆

Designation of Health Care Components

- ◆ **In order to be a hybrid entity under the proposal, a covered entity would have to designate its health care component(s).**
 - **Document the designation and retain documentation for at least 6 years**





Health Care Components

- ◆ Health care components may include:
 - (part/area/department/etc.) of the covered entity that engage in *covered functions*, and
 - any component that engages in activities that would make such component a *business associate* of a component that performs covered functions, if the two components were separate legal entities.

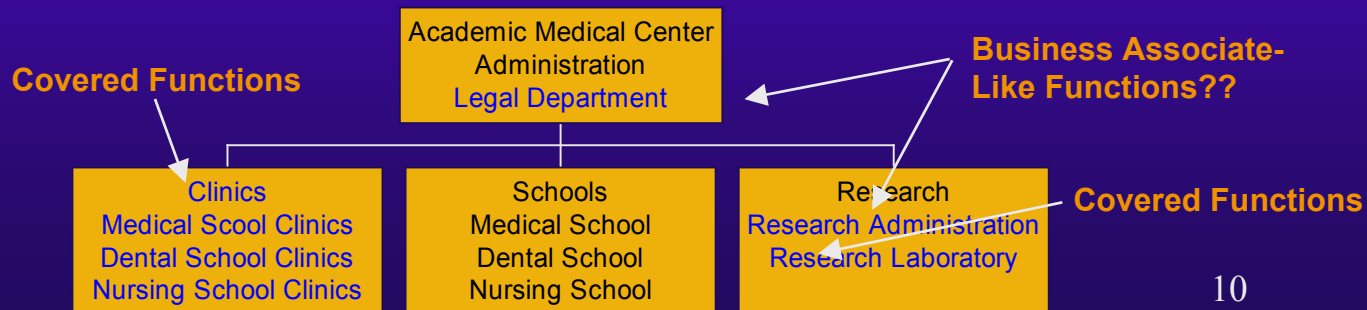


Discretionary Health Care Component Designations

- ◆ There is some discretion as to what a hybrid entity may include in its health care component:
 - a non-covered health care provider component may, but need not, be included.
 - *i.e., does not conduct a standard transaction*
- ◆ If non-covered provider is not included,
 - the health care component MIGHT be restricted from disclosing PHI to that provider for any of the non-covered provider's health care operations, absent an individual's authorization
 - examine the reason for the disclosure, and look for other types of permission to disclose, such the “treatment-related disclosures” exception

Business Associate-Like Functions

- ◆ A disclosure of PHI from the health care component to another division of the organization that is not part of the health care component must be treated as though it is a disclosure to another legal entity -- however, an entity cannot have a business associate contract with itself, so must either:
 - include the Business Associate-Like division within the health care component (but only to the extent the division performs activities on behalf of, or provides services to, the health care component); or
 - get the individual's authorization for the disclosure (unless another type of permission can be found under the Privacy Rule).





Health Care Component Designations

- ◆ The Final Rule does not require that the covered entity designate entire Business Associate-Like divisions as in or out of the health care component.
 - Only those parts or functions of the Business Associate-Like division may and must be part of the covered function component.





Compliance With HIPAA

- ✦ **Designated health care components must comply with all HIPAA privacy requirements**
 - The hybrid entity is the covered entity ultimately responsible for compliance
- ✦ **If the hybrid entity does not designate any health care component(s), the entire entity would be a covered entity and, therefore, subject to the Privacy Rule**

Safeguard Requirements: Firewall

- ◆ The Regulations require that the covered entity erect firewalls to protect against the improper use or disclosure within or by the organization
 - Health care component must treat other components within the organization as though they were separate and distinct entities
 - When other components perform covered functions they are limited to permissible use of the PHI
 - Employees that work with PHI in the health care component shall not disclose information when performing other duties in other components
 - Transfer of PHI held by the health care component to other components of the hybrid entity is a disclosure under the Privacy Rule and allowed only to the same extent such a disclosure is permitted to a separate entity

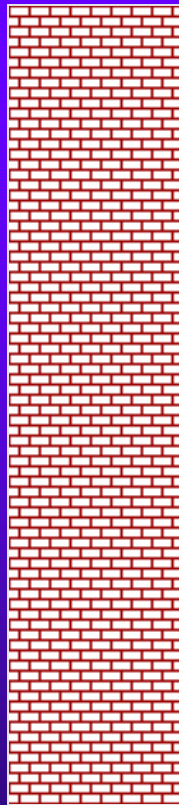
Firewall Example

Clinic Records

Health Care Component

Covered Functions

Subject to HIPAA



Personnel Records

**Not Health Care
Component**

Not Covered Functions

Not Subject to HIPAA

Individual Authorization



No Designation-No Firewalls

- ◆ If the covered entity does not designate any health care component(s), the entire covered entity would be subject to the Privacy Rule.
 - The firewall requirement between covered and non-covered portions of hybrid entities would not apply.
 - Even in this case the covered entity will be required to limit uses and disclosures of PHI to only those that are permitted by the Privacy Rule.
 - Minimum Necessary rule will apply
 - Compliance will be complicated



Part 2 Case Study: University of Texas Southwestern Medical Center

Designation of Health Care Components
Implementation Challenges - Research
Texas Privacy Law – S.B. 11



University of Texas Southwestern Medical Center

◆ Missions

- Academic
- Clinical
- Research

◆ Internal Organization

- School of Medicine
 - School of Allied Health Sciences
 - School of Biomedical Sciences
- ◆ No separate entity for faculty practice plan
- ◆ No owned hospitals



Designation of Health Components

- ◆ Required
 - Outpatient clinics with standard transactions
- ◆ Discretionary
 - “Business Associates” to Covered Functions (Legal, Research Administration, Compliance/Internal Audit, etc.)
 - Clinical functions with no standard transactions (e.g. psychology)

Designation of Health Components (cont.)

◆ Excluded

- Academic offices/functions
- School of Biomedical Sciences
- Willed Body Program
- Human Resources

◆ Undetermined

- Police
- Research



Research and the Hybrid Rule

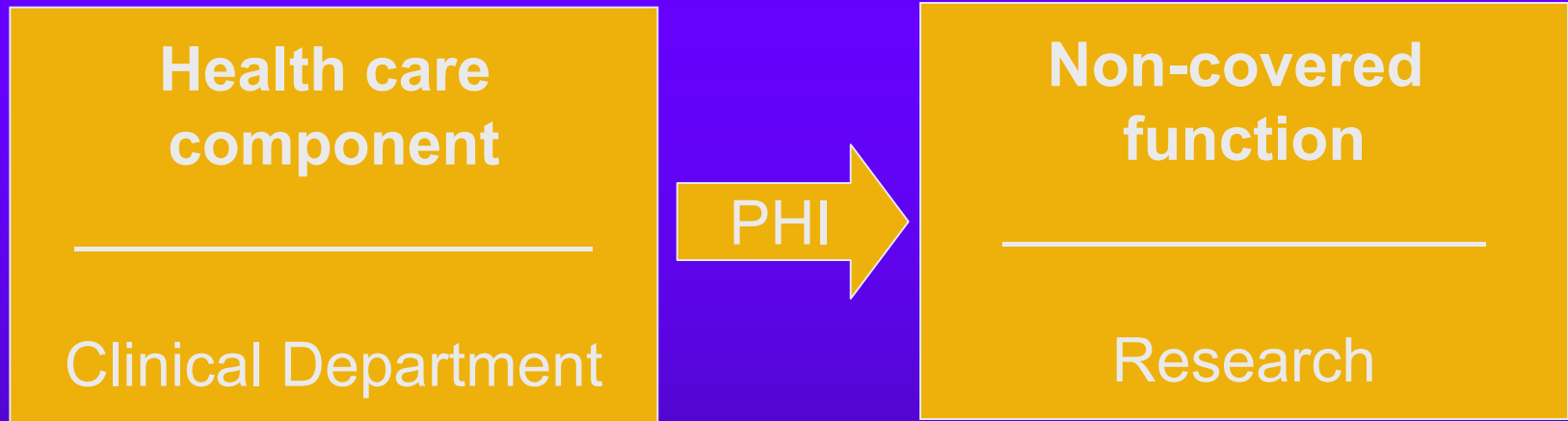
- ◆ Internal vs. External researchers
- ◆ Research per se is not a “covered function”
- ◆ What about research involving treatment?
 - Standard electronic transactions – Required
 - Health care provider activities with no standard electronic transactions – Discretionary (67 FR 14803)
- ◆ Is researcher a business associate?
 - 65 FR 82694, 67 FR 53252
- ◆ Hybrid Entity vs. Single Entity
 - Access by researcher to PHI of covered entity
 - Disclosure by researcher of research records



HYBRID ENTITY VS. SINGLE ENTITY

**ACCESS BY RESEARCHER
TO COVERED ENTITY'S PHI**

Hybrid Entity



Disclosures to researcher of covered entity's PHI:

- Authorization
- Waiver
- Data Use Agreement (limited data set)
- Reviews preparatory to research
- Research on decedents

Single Covered Entity

Clinical Department

Research



Uses by researcher of covered entity's PHI:

- Authorization
- Waiver
- Data Use Agreement (limited data set)
- Reviews preparatory to research
- Research on decedents



Hybrid Entity vs. Single Entity Access by Researcher

- ◆ Uses vs. Disclosures of the covered entity's PHI by the researcher is generally the same
- ◆ Recruitment Activities (67 FR 53230-31)
 - Use by covered entity permitted
 - Disclosure to third party requires waiver
- ◆ Implementation Issues
 - Accountings of Disclosures
 - Policies and Procedures, Training, etc.



Hybrid Entity vs. Single Entity Access by Researcher (Cont.)

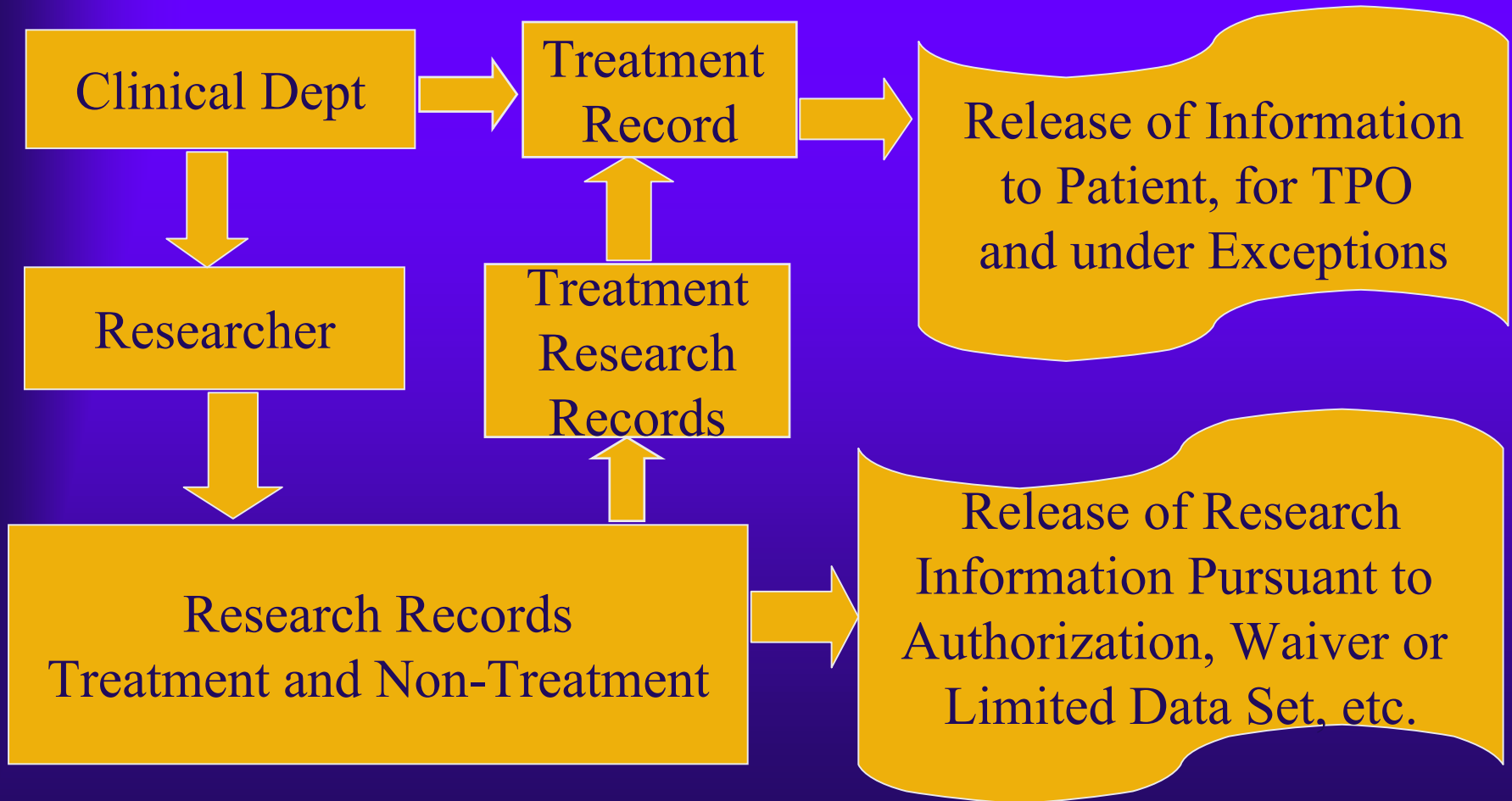
- ♦ Minimum Necessary Rule - 164.514(d)
 - Applies to Waivers, Reviews Preparatory to Research and Research on Decedents
 - Doesn't apply to Authorizations
 - Uses by researcher within a covered entity require workforce and information designations
 - Disclosures to researcher require documentation or representations from researcher



HYBRID ENTITY VS. SINGLE ENTITY

DISCLOSURE OF RESEARCH RECORDS

Research PHI Flow





Hybrid Entity vs. Single Entity Disclosure of Research Records

◆ Treatment Record

- Covered Entity retains responsibility for research records that become part of the treatment record


◆ Research Record

- Single Entity -- Entire entity is subject to HIPAA
- Hybrid Entity -- Where are the HIPAA obligations?
 - Billing disclosures?
 - Treatment disclosures?
 - Business associate disclosures?
 - Accounting obligations?



IN SUMMARY

- ◆ Research implementation challenges may be driving force in hybrid analysis
- ◆ Hybrid election may impose different requirements for different types of research
- ◆ Implementation brings both positives and negatives
- ◆ Consider research areas sooner rather than later



Texas Medical Record Privacy Act

“S.B. 11”

- ◆ Incorporates or mirrors many of HIPAA’s provisions
- ◆ Expands HIPAA privacy to a wider universe of covered entities
- ◆ More stringent on Marketing, Research
- ◆ Civil claim of \$3,000 per violation / \$250,000 for repeated pattern or practice
- ◆ Compliance September 1, 2003



Texas Covered Entity

- ◆ S.B. 11 expands definition of "Covered Entity"
 - Texas Covered Entity includes almost any person or entity that comes into possession of PHI
- ◆ Some examples:
 - Health Care Providers who don't bill standard electronic transactions
 - Business Associates
 - Researchers
 - Employees, agents, and contractors of Texas covered entities



Importation of HIPAA

- ◆ Most definitions
- ◆ Some Patient Rights:
 - Access to PHI
 - Amendment of PHI
- ◆ Uses and Disclosures of PHI, including requirements relating to consent
- ◆ Notice of Privacy Practices



Hybrid Entity Rule Not Extended by S.B. 11

- ◆ HIPAA Hybrid Entity Rule
 - Health care components limited to “covered functions” and “business-associate like functions”
 - Limits ability to disclose PHI from health care components to non health care components
- ◆ Hybrid Entity Analysis Under S.B.11
 - Category of health care components are expanded to include more components
 - May allow more disclosures in more circumstances
- ◆ To extend Hybrid Entity Rule under S.B.11 may be less, not more stringent – Preemption??



Impact of S.B. 11 on Hybrid Entity Rule

- ◆ Academic and Research portions of the school will likely be subject to S.B. 11 even if a hybrid entity designation is made
 - S.B. 11 does not specifically import the administrative provisions
 - Policies and procedures
 - Privacy Officer
 - Documentation
 - However, since the Notice of Privacy Practices, Access and Amendment provisions are imported some compliance requirements will be needed




BOTTOM LINE

DON'T LET S.B. 11 COME TO A
THEATER NEAR YOU !!!!



Counties as Hybrid Entities

- ◆ Depending on size, may have multiple functions that are clearly health care:
 - Clinics, hospitals, mental health programs, preventive health, AIDS care, drug treatment programs, etc.)
- ◆ May also have functions that seem to, but may not, be health care:
 - Adult Protective Services
 - Child Abuse Prevention Program
 - Employee Assistance Programs



Helpful Effect of August 14, 2002 Modifications

- ◆ No longer need to determine **first** whether an activity is actually “health care”
 - Instead, determine whether HIPAA electronic transactions are used
 - If not, need not include in covered function component
 - If inclusion helps information sharing, will need to determine whether it’s “health care”
 - If transactions are used, must include in a component



Roadmap for Counties as Hybrid Entities

- ◆ Identify each health care, health plan and health care clearinghouse function
- ◆ As to the **health care** functions (or possible health care functions):
 - Determine whether any electronic transactions are performed
 - If no transactions are performed, determine the PHI disclosures to the function, and how/whether those would be impacted if the function is not within a covered component



Roadmap for Counties as Hybrid Entities, con't

- Based on impact on PHI-sharing, along with cost of implementation and compliance and political realities, determine whether non-covered health care function will be in covered function component.



Roadmap for Counties as Hybrid Entities, con't

- ◆ As to the **health plan** functions, determine whether they fall under the health plan exception for government-funded programs
 - “(A) Whose principal purpose is other than providing or paying the cost of health care; or (B) Whose principal activity is: (1) the direct provision of health care to persons; or (2) The making of grants to fund the direct provision of health care to persons.” 45 C.F.R. 160.103.

Roadmap for Counties as Hybrid Entities, con't

- ◆ If the County has health plan functions, note and avoid the possible “504(g)(2) problem”
 - “A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity’s health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.”



Example: Effect on Disclosures to a Noncovered HCP Function

- ◆ County-employed health care providers (who engage in transactions) give health care and mental health services to juveniles who are adjudicated delinquent and are housed in County detention facility. Pre-HIPAA, PHI is disclosed from these HCPs to County-employed LCSWs who work with County juvenile court judges on placement decisions and follow-up care.
- ◆ Can these disclosures continue post-HIPAA?



Example, con't: Analysis Method

- ◆ Disclosure would be from covered health care provider function to either
 - a health care provider function (albeit a non-covered one) (LCSWs), or
 - a non-health care provider
- ◆ Does anything in HIPAA allow these disclosures? If not, authorization must be obtained.



Example, con't: Analysis Method

- ◆ Are these are “treatment-” related disclosures?
 - “provision, coordination, or management of health care **and related services** by one or more health care providers, **including the coordination and management of health care by a health care provider with a third party**”
- ◆ If not, authorization must be obtained -- may be difficult.



Example, con't Analysis Method

- ◆ If not allowed as “treatment” and authorization cannot be obtained, would that change if the LCSWs were part of covered function component?
 - Probably not; disclosures to the courts by the LCSWs would still have to be justified under HIPAA



Example, con't

Analysis Method

- ◆ Does keeping the LCSWs outside the covered function component make the desired disclosures more difficult under HIPAA?
 - Probably not; whether the LCSWs are inside or outside the covered function component, the HCPs who are disclosing PHI to them for retransmission to the courts must justify those disclosures under HIPAA.

Roadmap for Counties as Hybrid Entities, con't

- ◆ Determine which parts of the County provide “Business Associate-Like” services to a covered function component
 - County Auditor
 - County Counsel
 - Treasurer
 - Information Technology Services
 - etc.



Roadmap for Counties as Hybrid Entities, con't

- ◆ Determine whether these parts of the County could enter into a “legally binding MOU” in lieu of being combined with the covered function component, to the extent of their services to the component. (65 Fed. Reg. p. 53206 (8/14/02))
 - What does “legally binding” mean?

Roadmap for Counties as Hybrid Entities, con't

- ◆ If MOU is not an option, determine what it means to make the “Business Associate-Like” service a “part” of the covered function component, to the extent of those services. Probably at least:
 - “firewalls” around PHI obtained while providing services
 - training of staff in component’s relevant privacy policies
 - enforcement of sanctions for noncompliance



Roadmap for Counties as Hybrid Entities, con't

- ◆ Develop a recommendation list for the County's board of directors
 - That the County be designated a hybrid covered entity
 - That the Board designate one or more specified covered function components
 - Those that must be included
 - Those that may be included
 - Those that must not be included



Roadmap for Counties as Hybrid Entities, con't

- ◆ Recommendation to the Board, con't
 - That those County departments that provide Business Associate-Like services be deemed a part of one or more covered function components, to the extent of the services provided (or that either a legally-binding MOU be entered into).
- ◆ Begin/continue compliance efforts!