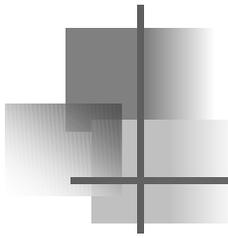


# HIPAA Entity Status

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*Impacts on Information sharing*  
*(Internal and External to the Entity)*

Leah Hole-Curry, JD Fox Systems  
[Leah.hole-curry@foxsys.com](mailto:Leah.hole-curry@foxsys.com)



# Overview

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## **PART I**

- Covered Entities
- Hybrid (and other) Status
- Public Function Designations

## **Part II**

- Sharing Information

# Legal Entity/ Health Plans

What is the legal entity that will be responsible for compliance with HIPAA? (Medicaid may be part of an “umbrella entity”)

- Named health plan under HIPAA?
  - Medicaid agency
- Other named programs include
  - Employee welfare benefits plans, Group health plans, Medicare, SCHIP, Indian Health Service, etc.

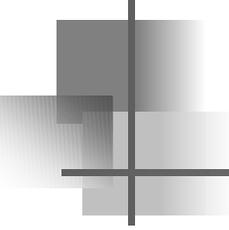
Note: Named health plans cannot utilize exceptions

# Health Plan (Catch-all)

- HIPAA Health Plan: Any other program or plan that pays or provides the cost of medical care
  - What other programs function as a health plan within the HIPAA Covered Entity?
- Health Plan Exceptions: Government funded programs where (1) the primary purpose is not health care, (2) health care is provided directly, or (3) direct provision of care is through grants
  - Do you have exceptions?

# Providers and Clearinghouse

- Health Care Provider
  - Many programs provide “health care” including care, services, or assessment with respect to the physical or mental condition of an individual.
  - Examples: case management, assessment, counseling, vaccines, clinics, etc.
- Only providers who transmit health information electronically are covered entities.
  - Do you have covered provider programs?
- Clearinghouse also covered entity



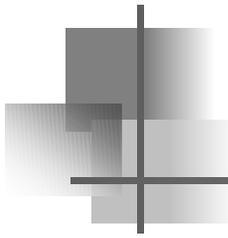
# Define the CE' s

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- You need to define the organizational unit that makes up your covered entities (e.g. the health plans and providers). The component is not regulatorily defined. Examples:
  - Is the Medicaid health plan a state program, division, department, or agency?
  - An Agency contains a division with three major programs. Two programs provide health care to children (and bill electronically). Is each program a health care provider? Is the division a health care provider?

# Hybrid Entity Status

- Agency that is a single legal entity whose business activities include both covered and non-covered functions can designate itself as a Hybrid
  - Only Health Care Component Covered
  - Hybrid entity must:
    - Designate health care component(s) and ensure HC component complies with requirements
    - Create adequate separation (firewalls) between components
    - no disclosures between health care component and other parts except as allowed under privacy
    - Workforce members with duties to multiple components must abide by applicable requirements and not disclose information of covered component except as allowed by privacy rule



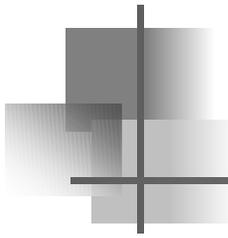
# Hybrid Entity Pro/Con

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- Pros
  - Limited Application
  - Targeted Training
- Cons
  - Internal system firewalls and/or safeguards between programs
  - Information shared outside health care component may be more limited and disclosure must be tracked
  - Only certain staff have access to information
  - Clients, business partners may view inconsistent treatment and more forms as problematic
  - Staff confusion may be higher, enforcement may be harder
- Consider significant client or program overlap, shared work areas, shared systems, etc.

# Health Care Components

- Must designate “health care component(s)”
  - Must include any component(s) that, if a separate legal entity would meet the definition of a covered entity
    - Health Plan
    - Health Care Provider
    - Health Care Clearinghouse
  - May include component(s) only to the extent it
    - Performs covered functions
    - Performs activities on behalf of a covered component that would be equivalent to a business associate if the components were separate legal entities



# Multi-Function Entity

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- Entity that performs multiple covered functions that make it a combination of plan, provider, or clearinghouse
  - Must comply with the standards applicable to the function
  - May use/disclose PHI of individuals who receive plan or provider services, but not both, only for purposes related to that function

# Additional Role(s)

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- Public Health Authority is: a Government agency or entity acting on behalf of public agency that is responsible for public health matters as part of its official mandate.
- Health Oversight Agency is: a Government agency or entity acting on behalf of a public agency that is authorized to oversee the health care system (public or private) or government programs in which health information is necessary to determine eligibility or compliance or to enforce civil rights laws.

# Overall Status - Decide and Document

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1. Determine Covered Entity Units
2. Determine application of privacy
  - Health care component or all of Entity
3. Determine Public Function Designations
  - Document Decision factors and Application
  - Communicate to Stakeholders
    - Staff, Clients, Trading partners
  - Retain Documentation in accordance with rule

# PART II - Impacts on Sharing

- Government entities/component(s) that are covered can use/disclose information:
  - for their own treatment, payment, health care operations
  - to a provider for its treatment or payment activities
  - to another covered entity for its payment
  - to another covered entity for certain health care operations, fraud, and abuse if each party had a relationship with individuals

# Permitted Sharing

## Government Programs (164.512(k)(6))

- Government health plan providing public benefits may disclose or share systems with eligibility or enrollment information
  - Only with other programs providing public benefits
  - If required or expressly authorized by statute or regulation
- Government agency providing public benefits may disclose PHI relating to the program
  - To another covered entity agency providing public benefits
  - If programs serve same or similar populations, and
  - If it is necessary to coordinate or improve administration of covered functions

# Additional Permitted Sharing

Required by law (164.512(a))

- Provision permits CE to disclose information where required by law
  - Does not restrict purpose or receiving entity
  - Examples may include certain disease registries, immunization, and abuse reporting
  - Must comply with and be “limited to the relevant requirements” of such law
    - Much Public health oversight and Public health information collection is not based on specific law requiring disclosure

# Additional Permitted Sharing

## Public Health Activities (164.512b)

- Permitted to release to public health authority that is authorized to collect data for purposes of:
  - Disease, injury, or disability prevention
  - Conduct of public health surveillance, interventions, and investigation
  - Reporting of Vital Statistics
  - For child and elder abuse investigation
- Don't need specific law but must be for listed purpose and to health authority

# Additional Permitted Sharing

## Health Oversight Activities (164.512d)

- Permitted to release to health oversight agency for oversight activities including:
  - Audits, Inspections, civil, administrative, criminal investigations
  - Licensure or disciplinary actions
  - Other activities necessary to oversight of health care system or government benefits programs or entities subject to regulatory programs or civil rights laws for which health information is relevant to compliance
    - Exception where individual is subject of investigation
- Don't need specific law but must be for listed purpose and to health oversight agency

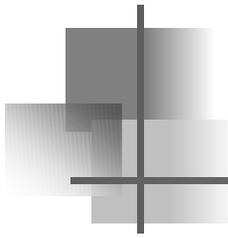
# Additional Permitted Sharing

## Limited Data Set (164.514(e))

- Permitted to use/release limited data set for research, public health, or operations
  - Must sign data use agreement with recipient
  - Cannot include 16 listed direct identifiers
    - Names; addresses; telephone, social security, license, beneficiary and other numbers, web and email addresses, biometric identifiers and full face photos
  - May include dates and geographic elements
- Recipient must use/disclose only for permitted purpose specified in agreement, not identify individuals, report violations, etc.

# Other Authorized Mechanisms

- **Research** (164.512i)
  - May disclose for research if IRB or privacy board approval
- **Avert serious threat to health or safety** (164.512j)
  - Consistent with law and standards of ethics, and necessary to prevent or lessen serious and imminent threat to health or safety of person or public
- **Individual Authorization** (164.508)
- **Exception determination from Secretary** (160.103)
  - For state law not meeting public health preemption exception, may apply for determination that intrusion of privacy is warranted for purpose of compelling public health, safety, or welfare.



# Process changes

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- Entities are required to use/disclose only minimum necessary to accomplish task
- Collection of data –
  - document justification
- For Use or disclosure of data, document:
  - Allowed under the rules or get authorization
  - What information is necessary to share
  - Are protocols in place
  - Other Requirements (accounting, limitations, etc.)

# Dual Role - Impacts

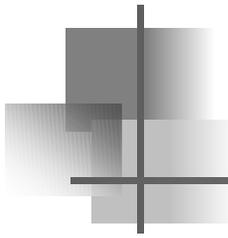
- Government entities that are covered public health or health oversight agencies:
  - Can always use for treatment, payment, health care operations
  - Can still receive, use, and disclose for public health and health oversight
  - Can use limited data sets
  - Must put appropriate safeguards in place
    - Physical, administrative, and technical
  - Limited Individual Rights Impact on Public Health or Health Oversight Activities
    - Generally do not have designated record set
    - Tracking of information disclosure

# Public Health Authority Information Disclosure/Use

- If the covered entity is also a public health authority, the covered entity is permitted to use PHI in all cases in which it is permitted to disclose such information for public health activities. 164.512(a) and (b)(2)
  - As required by law
  - Disease, injury, or disability prevention including surveillance and investigation
  - Vital Statistics
  - For child and elder abuse investigation
  - Notification of person exposed to communicable disease where authorized by law

# Health Oversight Information Use

- Covered entity may disclose PHI to a health oversight entity for oversight activities authorized by law, and is permitted to use PHI for oversight if covered entity is also a health oversight agency including: 164.512(d)
  - Audits, Inspections, civil, administrative, criminal investigations
  - Licensure or disciplinary actions
  - Other activities necessary to oversight of health care system; government benefits programs for which health information is relevant to eligibility;
    - Exception where individual is subject of investigation



# Discussion

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## Questions and Comments