

2019

PUBLIC HEALTH LAW
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Data Sharing to Improve Community Health

Oct. 3 - 4 | Plymouth, MI

HIPAA Hybrid Entity Rules & Tools

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The Network for Public Health Law

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At no cost, the Network provides public health legal support:

- Technical assistance
- Training and resources
- Opportunities to build connections
- Visit *www.networkforphl.org*
- Join the Network! (it's free)



The Fine Print



This presentation is for informational purposes only. It is not intended as a legal position or advice from the presenters or their employers.

For legal advice, attendees should consult with their own counsel.



Workshop Outline

1. HIPAA Overview
2. Hybrid Entity Definition
3. Benefits to Becoming a Hybrid Entity and Reassessing Coverage
4. HIPAA Assessment
5. Hybrid Entity Responsibilities
6. Q & A
7. Small Group Discussion



“HIPPA” stands for the “Health Information Privacy Protection Act.”

True

False

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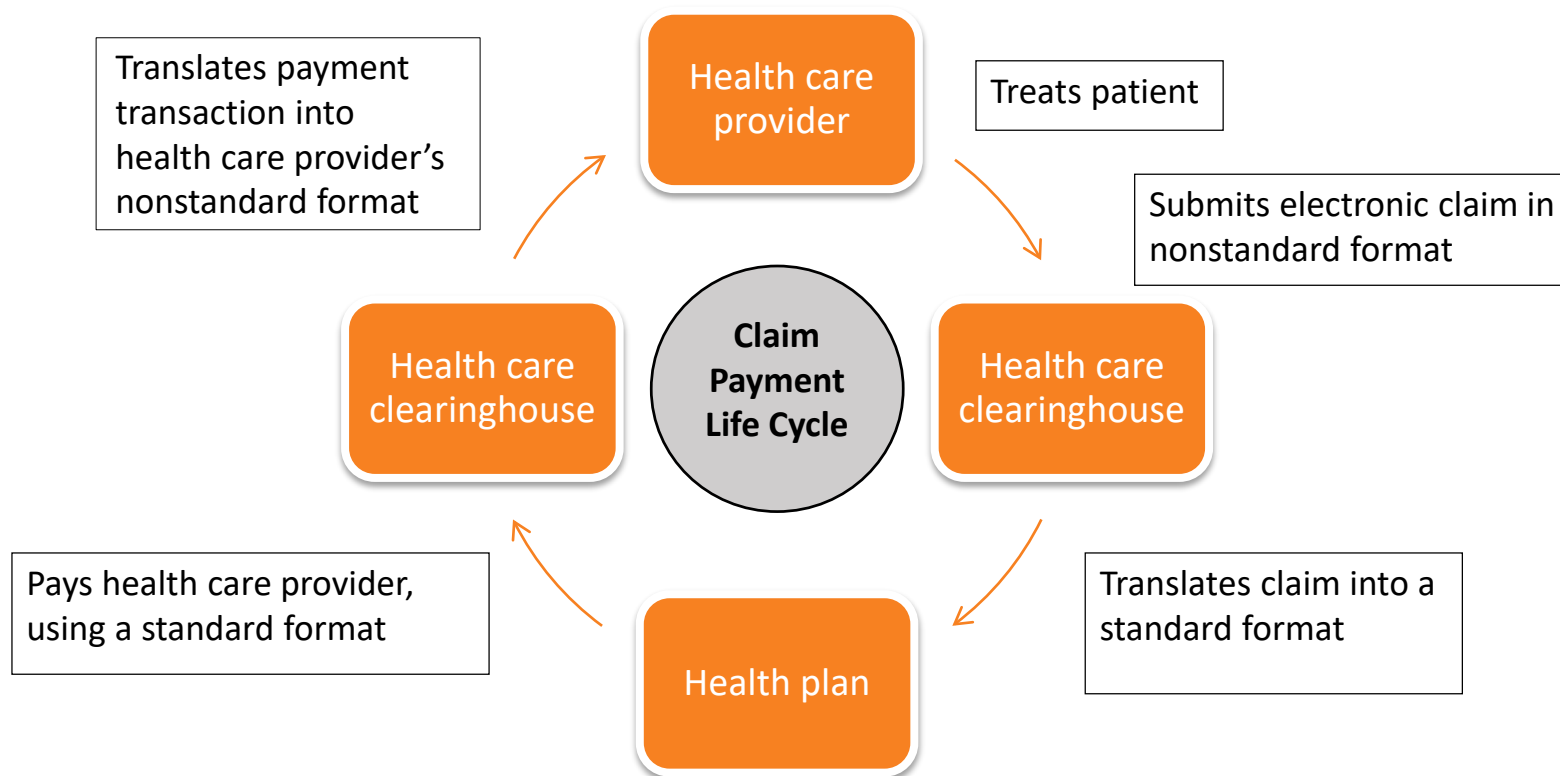
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Inn at St. John's
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“HIPPA” stands for the “Health Information Privacy Protection Act.”

⊗ False



HIPAA's Goal: Administrative Simplification



To whom does HIPAA apply?

- Covered entities
 - Certain (most) health care providers, **but** only if they transmit information in electronic form in connection with an electronic standard transaction that HHS has adopted a standard
 - Health plans
 - Health care clearinghouses
- Business Associates



Business Associates

- Performs functions on behalf of CE or provides services to CE
- Where access to PHI is involved
- Examples: billing services; document destruction services; outside attorneys and accountants; computer service technicians; software vendors; cloud computing vendors
- Must have written agreement (BAA)

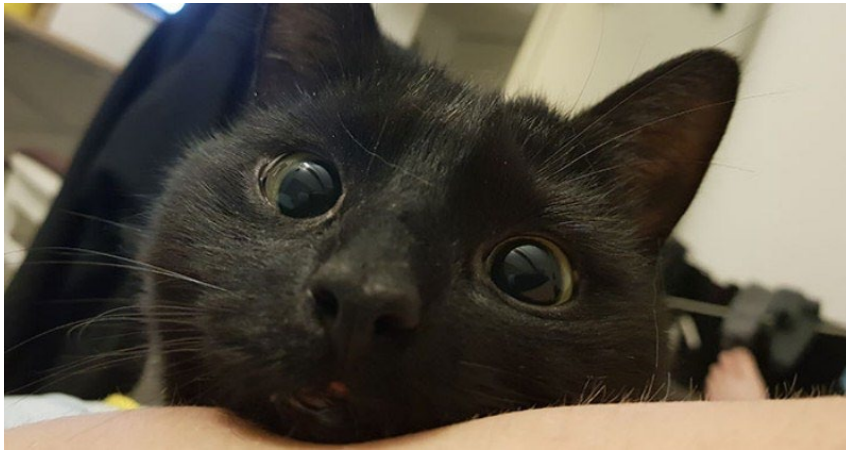


With only one HIPAA covered program...



But, HIPAA provides options

Single covered entity,
default classification

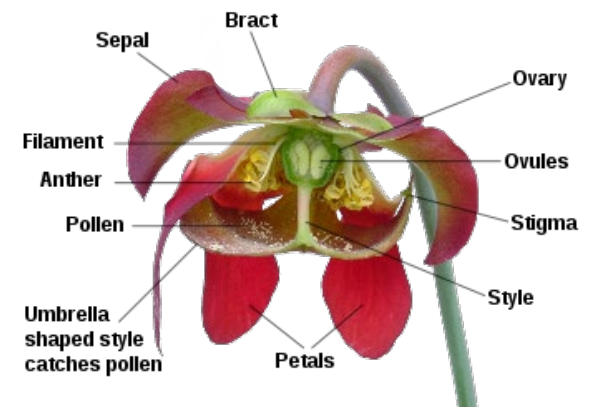


Hybrid entity



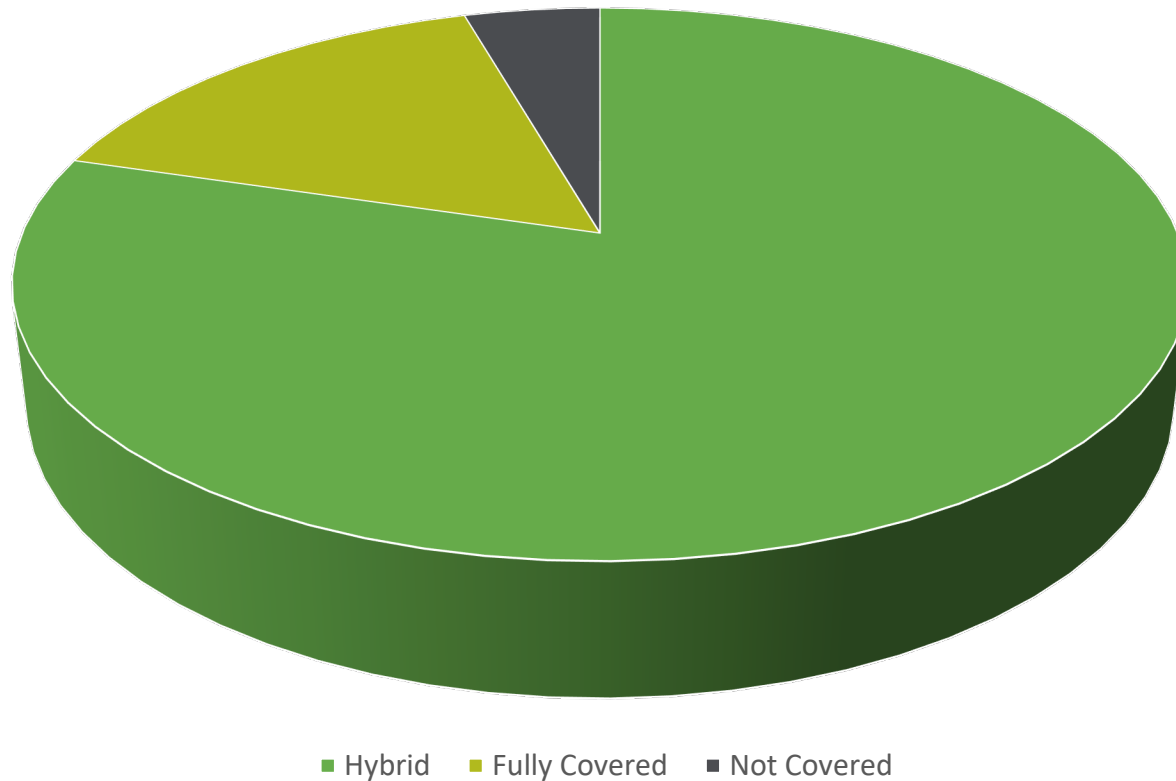
Hybrid entity means a single legal entity:

- That is a covered entity
- Whose business activities include both covered and non-covered functions; and
- That designates health care components by separating them from its other components and documenting the designation



2018 HIPAA Coverage Classification

State Health Departments



Many Benefits to Becoming a Hybrid Entity and Reassessing Coverage

1. Improved data sharing
2. Reduced compliance burden and risk of breach
3. Reassessment helps ensure compliance



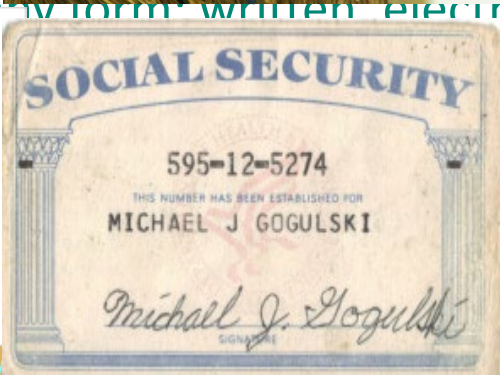
Improved Data Sharing:

What does HIPAA Privacy Rule cover?

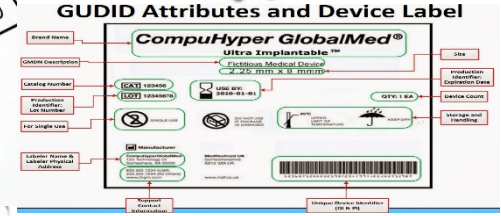
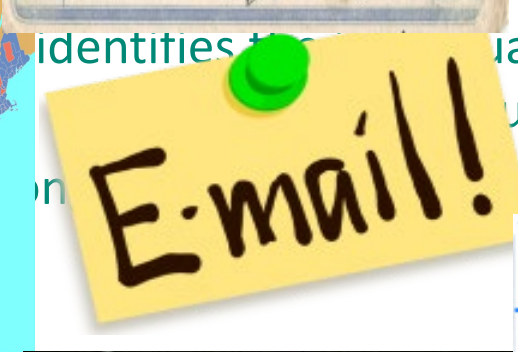
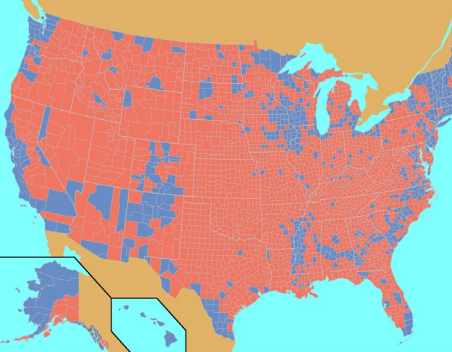
Use and disclosure of *protected health information (PHI)*

- Use – The sharing, employment, application, utilization, examination, or analysis of PHI within the entity that maintains the PHI
- Disclose – The release, transfer, provision of access to, or divulging in any manner of PHI outside the entity holding the PHI





information:

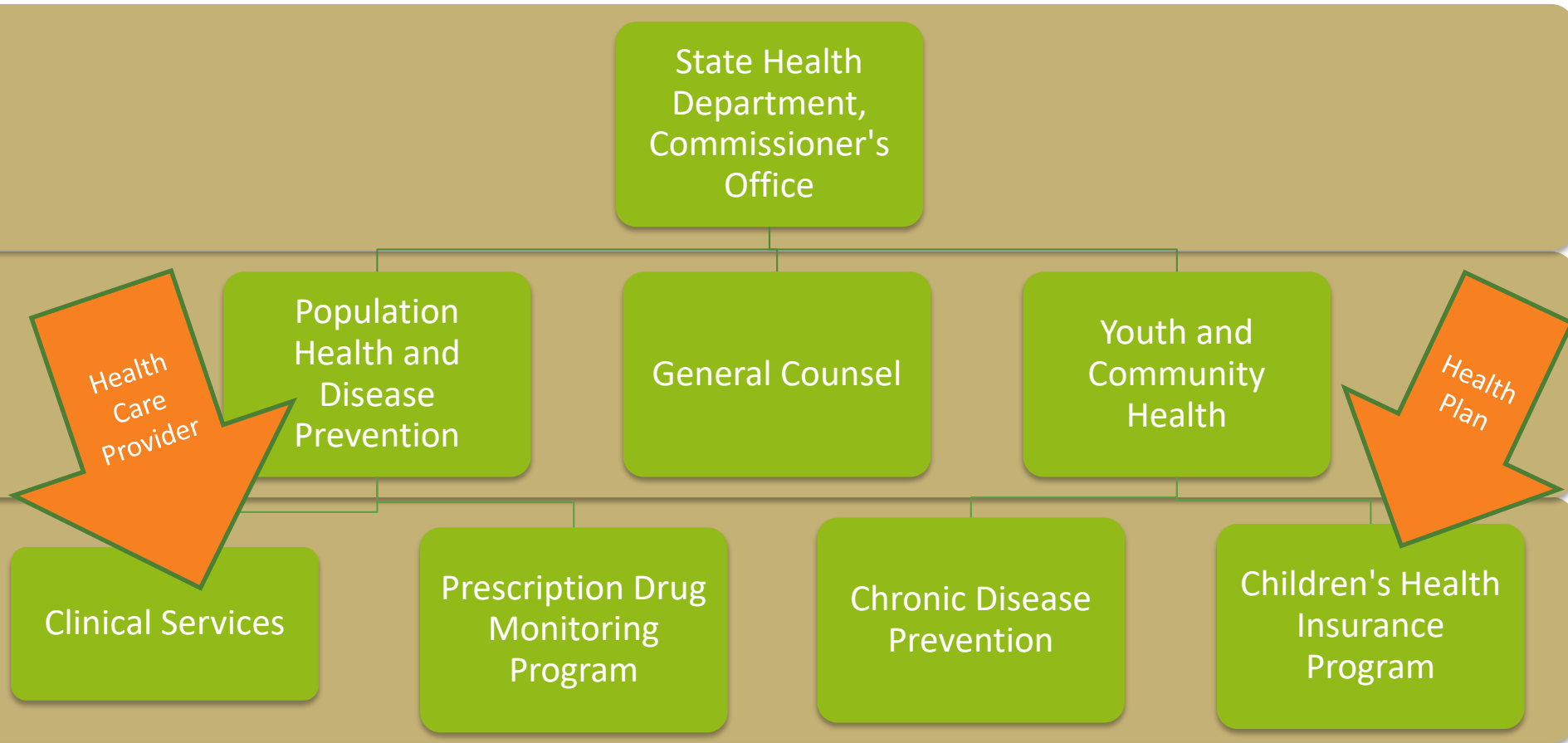


HELLO
MY NAME IS

What's in a
Name?



State Health Department – HIPAA Covered



**Aggregate data does not identify individuals.
This means that I can release the data below
with no HIPAA concerns.**

2018 pediatric H1N1 cases by county

	< 1year	1-5years	6-10yrs	11-17yrs
Auburn	2	0	1	3
Beacon	10	18	7	6
Calhoun	0	4	1	2
Davis	4	1	2	1

True

False



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⊗ False



Is your health department able to share electronic data?

Improve the health of
communities?

Data Lock-
Down

Promote w

Address social
determinants of health
and increase health
equity?

2019

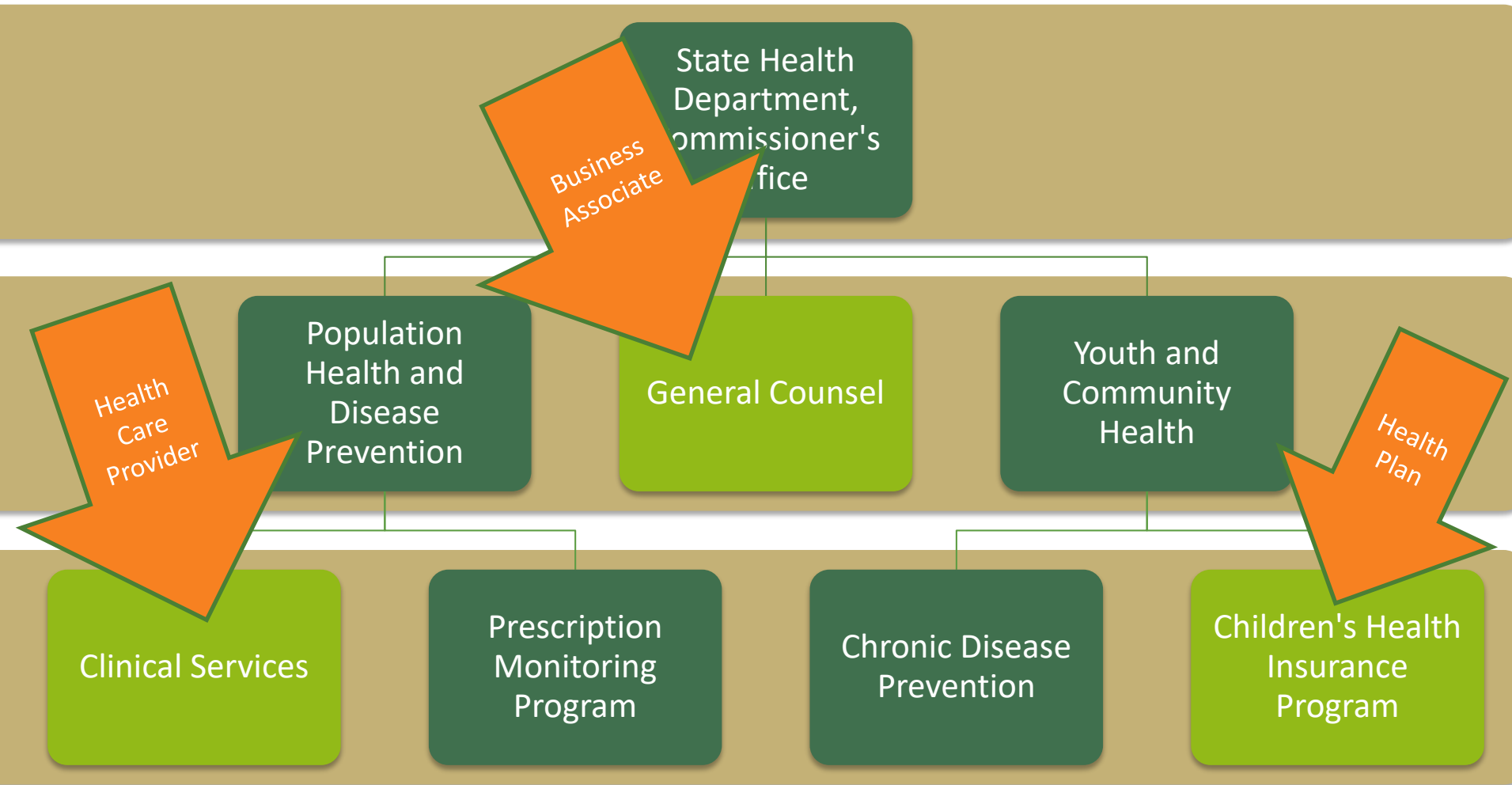
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State Health Department – HIPAA Hybrid Entity



Becoming a Hybrid Entity is Key to Reducing Risk and Compliance Burden

- Smaller footprint
 - Fewer employees to train on HIPAA privacy and security
 - Shorter assessments and analyses
 - Reduced reach of HIPAA breach rule
 - Fewer staff who can make costly HIPAA mistakes



Accurate + Current Hybrid Entity Assessment is Important

- 2016 UMass Settlement = \$650,000 + corrective action plan
- UMass reported a breach to OCR
- UMass is a hybrid entity
- Breach occurred in a division that was not identified as covered, but should have been
- Consequently, no firewall in place, which allowed the malware to gain access to UMass system



HIPAA Reassessment < 2013 ???!

- Before 2013 Omnibus Rule Changes, legal entity had discretion as to whether to include components that function as business associates. Now, hybrid entity policy must include both covered entity and business associate components.
- In 2013, many new types of business associates, such as health information organizations, data/records storage + subcontractors and their subcontractors
- Reassess against new rules!



So, your health department decides it wants to become a hybrid entity or reassess its HIPAA coverage. What next?


Confirm Legal Identity

Perform HIPAA Assessment

Address Responsibilities

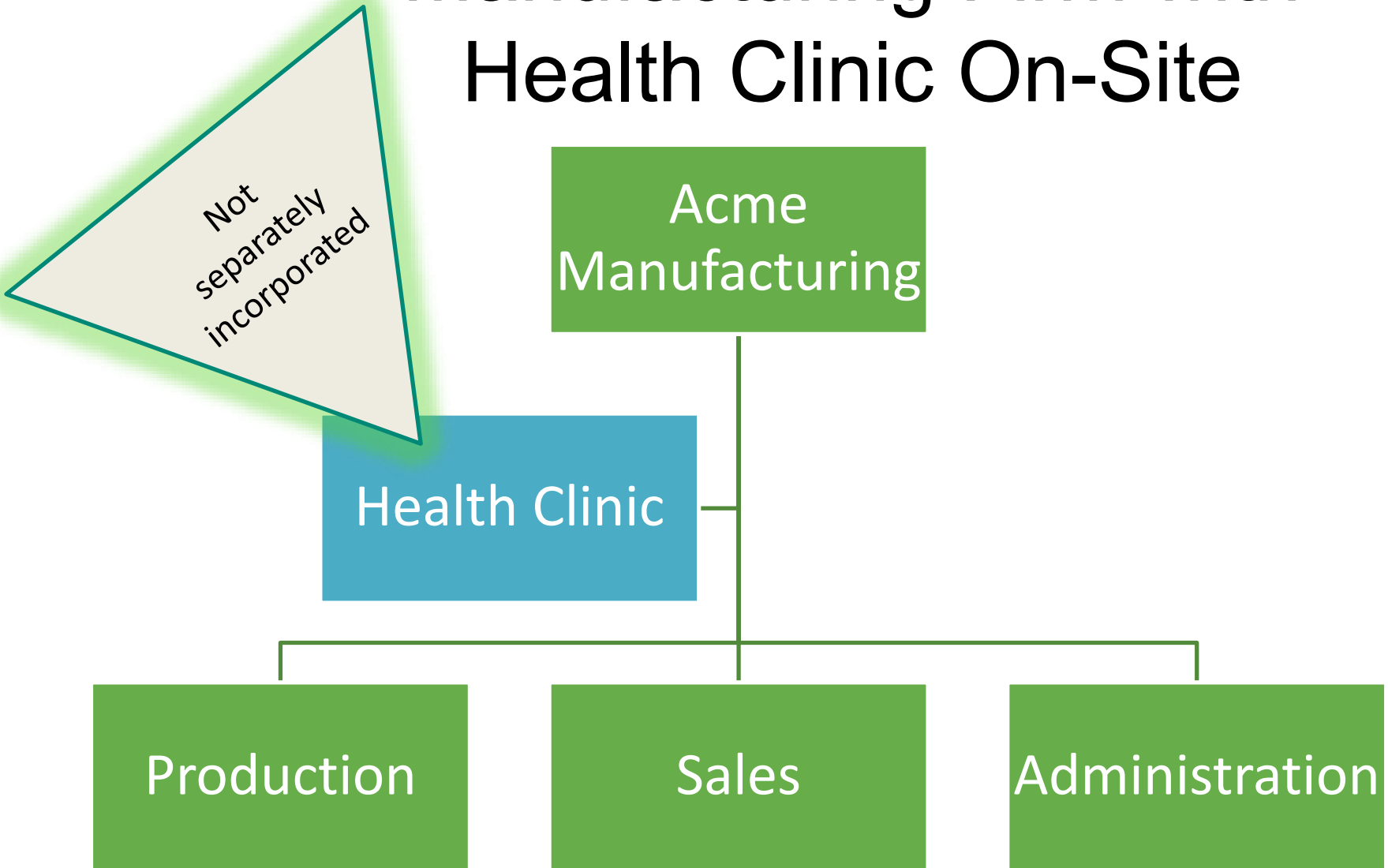


Confirm Legal Identity

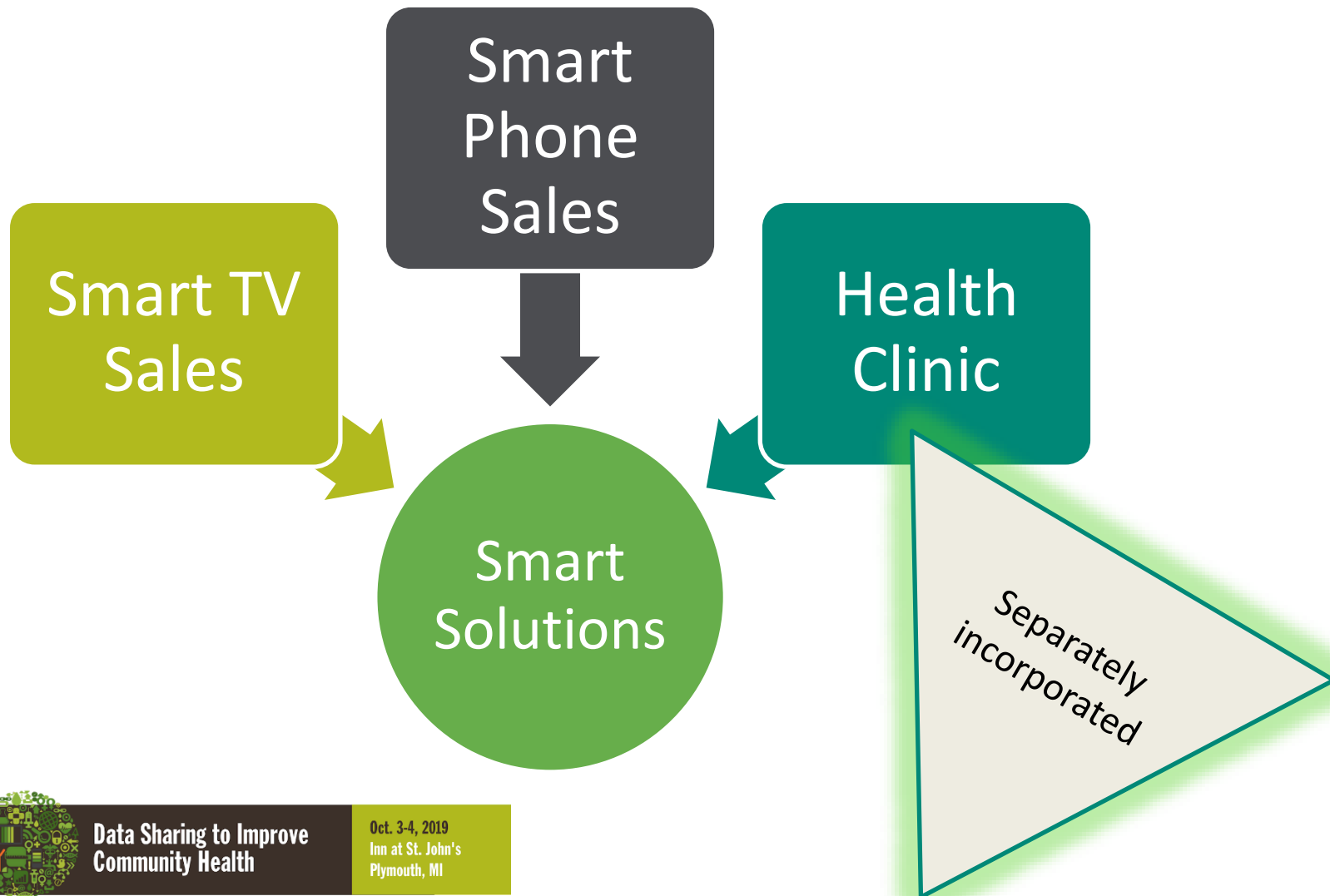
- 
- Is the organization a separate legal entity?
 - Is it part of a larger umbrella organization?
 - Can it be further legally subdivided?



Manufacturing Firm with Health Clinic On-Site



Multi-National Corporation with Separate Subsidiary Corporations



Legal Identity: State health department with the primary statutory authority to promote and protect public's health and prevent disease

Review:

State Constitution

Statutes

Regulations

Executive Orders

Attorney General Opinion

State Health Departments



■ Freestanding or independent

■ Part of umbrella organization



Legal Identity: Centralized state health department is a state public health structure operating all or most of the LHDs

Review:

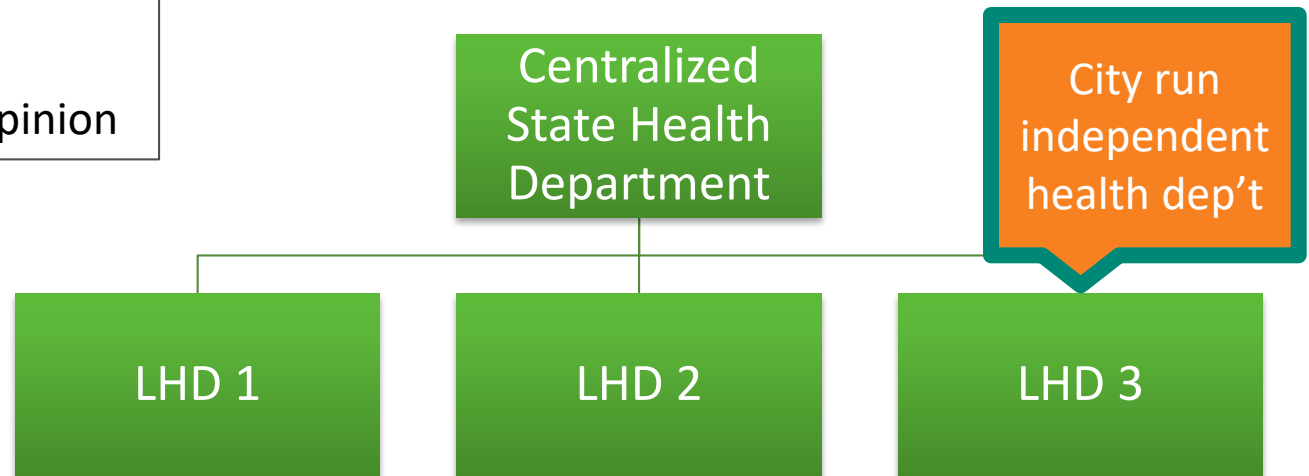
State Constitution

Statutes

Regulations

Executive Orders

Attorney General Opinion



Legal Identity: LHDs serve a jurisdiction(s) geographically smaller than a state and have the primary statutory authority to promote and protect public's health and prevent disease

Review:

State resources

City or county charter

City and county codes

Municipal summaries of
key laws and codes

Locally
governed

Local
entity of a
centralized
state
health
dep't

City;
county;
city-
county;
county;
district; or,
regional



Legal Identity: Tribal health departments

- Federal government recognizes 573 Tribes within the US
- Federal government has a “government to government” relationship with Tribes
- Tribes are sovereign nations and have authority to make their own laws
- Tribes also have cultural sovereignty and each is unique



What if the law is not clear? Answering the following questions might be helpful...

1. Does your health department have authority to sue or be sued in its own name?
2. Is control and supervision of the health department vested within the health department? Or is it vested within a broader organization, such as a city or an umbrella organization?
3. What is the degree of financial autonomy and the source of operating expenses for the health department?
4. What do relevant organizational charts and websites reflect?



Perform HIPAA Assessment Across the Legal Entity

- **Covered health care provider** – hospitals, physicians, dentists, other practitioners and any other person or organization that furnishes, bills or is paid for health care + electronically transmits standard transactions
 - Health care – care, services or supplies related to health care of an individual
- **Covered health plan** – plans that provide or pay the cost of medical care
- **Health care clearinghouse** – translation and standardization of transactions
- **Business associate components**



Covered Government Funded Health Plans

- Listed health plans, such as Medicare, Medicaid, Indian Health Service program, CHIP
- Government programs whose principal purpose and activity is paying for the cost of health care, *not* through grants or direct provision of health care
- *Excepted* benefits include workers' compensation, coverage for on-site medical clinics, coverage for medical care which is secondary or incidental to other insurance benefits



Public Health Exception to HIPAA

- Covered entities may share PHI with a public health authority to prevent or control disease, injury or disability
- Includes: disease, injury and vital events reporting, public health surveillance, investigations and interventions
- “Traditional public health functions”

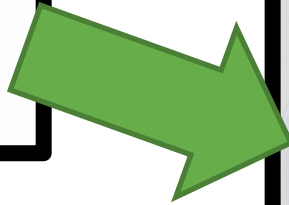


Practice Questions


- Does HIPAA apply to:
 - Clinic?
 - Medicaid?
 - Vision screening program?
 - CHIP?
 - Title X family planning grant services?
 - WIC program?
 - Laboratory testing?



If assessment reveals a covered component, by default = entire legal entity is HIPAA covered



Hybrid Entity Responsibilities

-  Hybrid entity policy that identifies HIPAA covered components- CEs and BAs
- Optional – may also include health care providers that do not bill electronically
- Memorialize the policy in hard copy or record it electronically
- Retain policy for six years from creation or date when last in effect, whichever is later



Legal Entity has Responsibilities

- Ensuring that covered entity and BA components do not use or disclose PHI in violation of HIPAA, particularly related to sharing between covered and non-covered components
- Verifying HIPAA privacy and security policies are adopted
- Ensuring that all related contracts – BAAs and other organizational requirements - are in place





HIPAA Privacy Rule: Hybrid

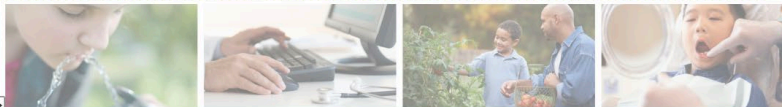
Becoming a Hybrid Entity: As Defined b

Congress passed the Health Insurance Portability and Accountability Act of 2003 ("HIPAA") to address the need for unique health identifiers. HHS issued its first

HHS recognizes that many organizations, including health plans, health care providers, and health care clearinghouses, lines of health insurance or a health care provider. Reducing compliance burden, HHS offers organizations the option to become a hybrid entity under HIPAA if they were separate legal entities. Both entities must have a HIPAA component.

The HIPAA Privacy Rule defines the hybrid entity classification. 45 CFR §§ 164.103 and 164.105. Organizations must implement certain safeguards and undertake certain responsibilities.

Since 2000, HHS has twice amended this rule to clarify the interpretation of regulatory provisions, and



Resources for Understanding, Evaluating and Becoming a Hybrid Entity

1. The U.S. Department of Health and Human Services, Office for Civil Rights (OCR), hosts a comprehensive website regarding the HIPAA Privacy Rule that includes many useful guidance documents, tools and training materials regarding HIPAA privacy and security regulations. The website is at <http://www.hhs.gov/ocr/privacy>.
 - For a "Summary of the HIPAA Privacy Rule" that provides information on who is covered, what it means to be a hybrid entity and what information is protected, go to <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>.
 - For FAQs regarding becoming a hybrid entity, go to:
 - "Are state, county or local health departments required to comply with the HIPAA Privacy Rule?" This FAQ explains how a health department can become a hybrid entity. <https://www.hhs.gov/hipaa/for-professionals/faq/358/are-state-county-or-local-health-departments-required-to-comply-with-hipaa/index.html>.
 - "When does a covered entity have discretion to determine whether a research component of the entity is part of their covered functions, and therefore, subject to the HIPAA Privacy Rule?" <https://www.hhs.gov/hipaa/for-professionals/faq/315/when-does-a-covered-entity-have-discretion-to-determine-covered-functions/index.html>.
 - "Can a postsecondary institution be a 'hybrid entity' under the HIPAA Privacy Rule?" <https://www.hhs.gov/hipaa/for-professionals/faq/522/can-a-postsecondary-institution-be-a-hybrid-entity-under-hipaa/index.html>.
2. The Electronic Code of Federal Regulations provides the current and complete HIPAA Privacy Rule text. This rule defines the hybrid entity classification and sets forth the organizational requirements, including the standards and implementation specifications. [45 CFR §§ 164.103 and 164.105](#).
3. The following are tools for evaluating whether your health department is covered by HIPAA:
 - To determine if your health department is a covered entity:

template

entity's health care components

and designate its health care component pursuant to the Health Insurance Portability and Accountability Act of 2003 (Public Law 104-191 and the Health Information Technology Act ("HITECH Act"), Public Law 111-5). 5 C.F.R. §§ 164.103 and 164.105.

entity, that has both covered entity and non-covered entity components, may elect to be a hybrid entity by designating certain functions of the entity to be a hybrid entity, a legal entity that is not a covered entity and business associate components. A health care component, any component that is a business associate, if it were a separate health clinic that conducts covered functions (submission) is a covered entity. A health clinic as part of the health care component must also include the claims submission component; the claims submission component is a health care provider as part of the health care component; the claims submission component may decide to include its laboratory in the health care component if the laboratory does not conduct any covered functions.

designation

entity as health care components:

Any Questions?



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Small Group Discussion

- Join table with topic of your choice
- Three rounds – 10 minutes each
- Table will identify a host who will record discussion
- Table will answer questions on a hand-out specific to topic
- At end of round, table host will stay to greet next group and get them up to speed on prior group's discussion
- Start rounds 2 & 3 with identifying a host...
- At end of round 3, table hosts will present wisdom for the harvest

Thank you to all who submitted use cases!



Thank you!

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[NPHL Hybrid Entity Toolkit](#) or
www.networkforphl.org < Topics &
Resources < HIPAA Hybrid Status

