



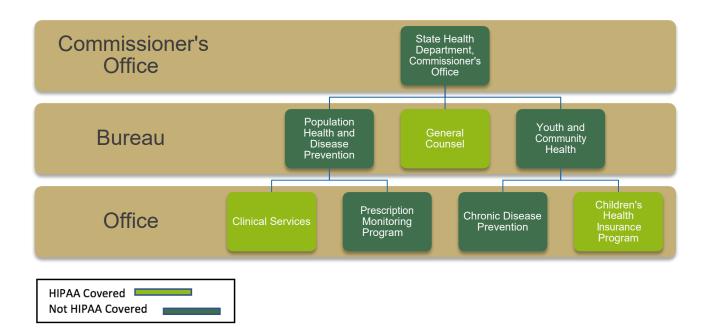
Hybrid Entity Use Cases

Use Case 1: What does hybrid entity look like?

A hybrid entity is a single legal entity that has at least one covered entity component, provides non-covered services and adopts a hybrid entity policy in compliance with the Health Insurance Portability and Accountability Act ("HIPAA"), Public Law 104-191. With a hybrid entity, HIPAA covers some, but not all, of the components.

Below is a snapshot of State Health Department's organizational structure. State Health Department is an independent or freestanding health department at the state level. In 2003, State Health Department decided not to become a hybrid entity and to remain fully covered by HIPAA.

State Health Department is made up of one Commissioner's Office, three bureaus, and four offices. Since it has been many years since State Health Department reviewed its HIPAA coverage assessment, the Health Commissioner asked her Privacy Officer to perform a HIPAA assessment. Here is what she found:



The assessment reveals that:

- The Office of Clinical Services is a health care provider that engages in standard transactions and if it were a separate legal entity, would be a covered health care provider under HIPAA. This Office is a covered entity component.
- The Offices of the Prescription Monitoring Program and Chronic Disease Prevention are public health programs and not covered by HIPAA. These Offices provide non-covered services.
- The Children's Health Insurance Program is a health plan, and if it were a separate legal entity, would be a covered health plan under HIPAA. This Office is a covered entity component.
- The Bureaus for Population Health and Disease Prevention, and Youth and Community Health, are not health care providers or health plans, and while they manage Offices that are covered entity components under their supervision, they do not receive any protected health information (PHI) from them. They provide non-covered services.
- The Bureau for General Counsel provides legal services for the entire health department and receives PHI from both the Office of Clinical Services and the Children's Health Insurance Program. This Bureau would be a business associate if it were a separate legal entity. This Bureau is a business associate component.
- The Commissioner's Office is neither a health care provider nor a health plan, and while this Office is responsible
 for covered entity and business associate components, the Commissioner's Office does not receive PHI. This
 Office provides non-covered services.
- HIPAA applies to the following components: the Bureau for General Counsel, the Office of Clinical Services and the Children's Health Insurance Program.

The assessment reveals that some of the components are covered by HIPAA and some are not.

A legal entity that is a covered entity may choose to remain a single, fully HIPAA covered entity. Or, it may choose to become a hybrid entity and restrict HIPAA coverage to those components where it is required by law to apply. To be a hybrid entity, HIPAA requires that all covered entity and business associate components be identified and listed in the hybrid entity policy; they are covered by HIPAA. The remainder of the hybrid entity is not generally covered by HIPAA.

Given that the HIPAA covered components only comprise 3/8 of the health department, the Health Commissioner decides to make State Health Department a hybrid entity. The Health Commissioner approved a hybrid entity policy, along with a directive that it be reviewed annually.

Use Case 2: We are a hybrid entity. It's only been three years since we've done a HIPAA assessment. Do we really need to do this again?

Yes. Periodic HIPAA re-assessment is critical for compliance.

County Health Department updated its hybrid entity policy three years ago when there was a mass re-organization. There have been no changes in HIPAA regulation since that time and management hopes that the three-year old review is adequate. County Health Department has undergone recent budget cuts, and resources are very limited. Staff are needed to focus on service delivery and operations.

County Health Department's Privacy Officer is aware of a relatively new program that provides hearing healthcare primarily for elementary age children. This program began one year ago and has two FTEs. Colleagues tell the Privacy Officer that other children's healthcare programs are not identified as covered entity components and that the hearing program probably isn't either.

Out of an abundance of caution, the Privacy Officer decides to assess the new hearing healthcare program to determine if it would be classified as a covered entity if it were a separate legal entity from County Health Department. The Privacy Officer utilized the Covered Entity Guidance tool and concludes that the hearing program is actually a health care provider, as it bills for its services by transmitting covered transactions electronically. The hearing program is covered by

HIPAA. The other children's healthcare programs are grant funded and do not bill for services; their status as non-covered is correct.

The Privacy Officer updated County Health Department's Hybrid Entity Policy by adding the children's hearing program as a covered entity component. Next steps include implementing policies and procedures for this program to ensure compliance with the HIPAA Privacy and Security Rules.

Failure to properly list covered entity and business associate components within a hybrid entity policy may result in fines. In an agreement with the federal Office for Civil Rights, the University of Massachusetts Amherst (UMass) settled alleged HIPAA violations for a monetary payment of \$650,000 along with a corrective action plan. Here, UMass failed to identify all of its covered entity components when becoming a hybrid entity. This resulted in serious deficiencies in safeguarding PHI, as well as in HIPAA Privacy and Security Rule compliance. This gap resulted in a breach of PHI, with disclosure of 1,670 individuals' "names, addresses, social security numbers, dates of birth, health insurance information, diagnoses and procedure codes." There were other compliance failures, including a lack of technical security and risk analysis.

Use Case 3: We are a hybrid entity. It's been ten years since we've done a HIPAA assessment, but we have had absolutely no changes in our organization. Do we really need to do this again?

Yes, even if you are not aware of changes. Periodic review of your hybrid entity policy is a critical component of HIPAA compliance. There may be functional or technological changes that occur over time that result in a change of HIPAA status. Changes in law may also occur. Periodic re-assessment of HIPAA coverage is required to expose needed changes in the hybrid entity policy.

City Health Department's Privacy Officer performed a HIPAA coverage assessment of all of its components and reported his initial findings at the weekly leadership team meeting. The team was surprised to learn that the Privacy Officer recommended that several of their offices be identified as business associate components in City Health Department's Hybrid Entity Policy.

The Office of Civil Rights changed its rules regarding hybrid entity policy on January 25, 2013. Previously, the legal entity had discretion as to whether to include business associate components in the hybrid entity policy. As of 2013, all business associate components *must* be listed in the policy.

City Health Department's components that are business associates, which receive PHI on behalf of one or more of its covered entity or other business associate components, include:

- Attorneys
- Accountants
- Health Commissioner's Office

The Privacy Officer recommends that the Health Commissioner revise the hybrid entity policy to add these three additional business associate components, to the extent that they are performing HIPAA covered functions. HIPAA provides significant flexibility to the hybrid entity. When workforce members from any of these three offices perform services in support of traditional public health activities, such as public health surveillance, investigations, and interventions, they are not covered by HIPAA.

Change in law requires review of a legal entity's hybrid entity policy.

SUPPORTERS



The Network for Public Health Law is a national initiative of the Robert Wood Johnson Foundation.

¹ U.S. Department of Health and Human Services. (2016, November 22). UMass settles potential HIPAA violations following malware infection. Retrieved from https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/umass.

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