Aimee N. Wall
Institute of Government, UNC-CH

Forms of Covered Entities:
Hybrids Entities and Other Rare Breeds

I. Covered entities

A. What is a "covered entity": HIPAA applies to only three entities – health plans, health care clearinghouses and health care providers who transmit any health information in electronic form in connection with a HIPAA transaction. §§ 160.103; 164.500.

1. Health care providers: There are two basic parts of the test for determining whether a health care provider is a "covered entity" under HIPAA – first, do they satisfy the HIPAA definition of "health care provider" and second, do they transmit any health information in electronic form in connection with a HIPAA transaction.

   a. Part One – do they satisfy the definition of health care provider: The term "health care provider" is defined broadly to include any person who, in the normal course of business, furnishes, bills, or is paid for care, services or supplies related to the health of an individual including, but not limited to:
      i. Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body and
      ii. Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription. § 160.103.

   b. Part Two – do they transmit "health information" in electronic form in connection with a HIPAA "transaction." The definition of "health information is similar to the definition of PHI (explained above). The "transactions" that will trigger coverage of a provider under all of the HIPAA regulations are defined in the HIPAA Transactions and Code Sets regulation.[1] Once a provider transmits a single HIPAA transaction, <u>all</u> individually identifiable health information maintained by the provider is PHI protected by the regulation. Examples of HIPAA transactions include transmitting claims information to a health plan to obtain payment and transmitting an inquiry to a health plan to determine if an enrollee is covered by the health plan.

2. Health plans

   a. The term "health plan" <u>includes</u> individual or group plans that provide, or pay the cost of medical care. "Health plan" includes private insurers (such as Blue

[1] 45 C.F.R. Part 162.

Copyright © 2002. All rights reserved.
Institute of Government, School of Government, The University of North Carolina at Chapel Hill

Cross/Blue Shield) and government programs such as Medicare, Medicaid, Health Choice.

b. The term "health plan" excludes:[2]
   i. Government funded programs whose principal purpose is other than providing, or paying the cost of health care;
   ii. Government funded programs whose principal activity is the direct provision of health care to persons;
   iii. Government funded programs whose principal activity is the making of grants to fund the direct provision of health care to persons; and
   iv. "Excepted benefits" programs. The regulation specifically excludes programs that provide or pay the cost of certain "excepted benefits." These are primarily programs in which the benefits for medical care are considered secondary to other insurance benefits. Examples include workers' compensation programs, accident/disability income insurance, and liability insurance.[3]

c. Self-insured counties: Some counties are self-insured and contract with a third-party administrator to manage claims. These counties may not be considered "health plans" but they may be "plan sponsors." The term "plan sponsor" is defined in ERISA as the employer or employee organization, or both, that establishes and maintains an employee benefit plan and in the case of a plan established by two or more employers, it is the association, committee, joint board of trustees, or other similar groups representing the parties that establish and maintain the employee benefit plan.[4] Plan sponsors are not covered entities under the privacy regulation, but the regulation does require health plans to limit the information that they share with the plan sponsor and place certain conditions on the sharing of information.

d. Counties participating in the NCACC Group Benefits Pool: Based on the ERISA definition of "plan sponsor," NCACC would be the plan sponsor of the Pool because it is an association that established and maintains an employee benefit plan for county government employees. It is possible that the counties participating in the Pool as self-funded accounts (i.e., "administrative services only" or ASO accounts) may also be considered plan sponsors.

3. Health care clearinghouses. Clearinghouses are, in general, entities that assist health plans and health care providers standardize their health data. In other words, clearinghouses help other covered entities convert heath information from a nonstandard format into a standard HIPAA format (and vice versa). It is unlikely

[2] The NC Attorney General issued an advisory opinion discussing the exclusions from the definition of health plan. The opinion is located on the HIPAA Program Management Office website: http://dirm.state.nc.us/hipaa/hipaa2002/legal/legal.html
[3] The excepted benefits are listed in 42 U.S.C. 300gg-91(c)(1).
[4] "Plan sponsor" is defined in ERISA, 29 U.S.C. 1002(16)(B).

Copyright © 2002. All rights reserved.
Institute of Government, School of Government, The University of North Carolina at Chapel Hill

that a county owns or operates a health care clearinghouse (although it may contract with one).

B. Who is the covered entity? The county or the individual departments?

1. No clear answer under HIPAA: Neither the HIPAA regulations nor any guidance provided by DHHS has answered this question directly. Throughout the health care industry, the "covered entity" determination will likely vary significantly from entity to entity depending on the entity's corporate structure, ownership and organization.

2. "Single legal entity"

   a. Factors: Some of the language in the HIPAA regulations suggests that a covered entity is a "single legal entity." HIPAA does not explain what is intended by the phrase "single legal entity." One could identify several possible factors that could be used to assist in the determination of who is a legal entity. For example:
      i. Is the entity established as a legal entity by statute or regulation?
      ii. Does the entity encompass or serve more than one jurisdiction (e.g., multi-county arrangements)?
      iii. May the entity be sued and may it bring suit against others?
      iv. Would the entity be held directly accountable for paying any penalty assessed under HIPAA?
      v. Does the entity have autonomy with respect to issues such as budget, policy-making and/or personnel?

   b. Example: Applying the above factors in the context of county government, for example, one could determine that a single-county health department:
      i. Is not established as a legal entity by statute or regulation;
      ii. Serves only one county;
      iii. May not be able to sue or be sued (but rather may be required to do so through the county);[5]
      iv. Would likely rely on the county to pay any penalty assessed under HIPAA; and
      v. Has significant autonomy with respect to policy-making and personnel.

      Balancing all of these factors, one might reasonably conclude either that the county – rather than the department – is the legal entity <u>or</u> that the department is a legal entity separate from the county. For district (multi-county) health

[5] North Carolina courts have held that a single-county department of social services may not sue or be sued without the county. *See, e.g., Malloy v. Durham County Department of Social Services*, 58 N.C. App. 61, 67, 293 S.E.2d 285, 289 (1982) ("Assuming arguendo that a right of subrogation did inhere in the County of Durham in the present case, and granted that such a right is statutory and not contractual, the intervenor plaintiff [DSS], as a mere subdivision of the County, could have no more capacity to assert such right than an agent would with respect to a contractual right of his principal.")

Copyright © 2002. All rights reserved.
Institute of Government, School of Government, The University of North Carolina at Chapel Hill

departments, the analysis would more strongly suggest that the department is the covered entity rather than the participating counties.

C. What rules apply to covered entities?

1. General rule: Covered entities must comply with all requirements of the privacy rule. Some of the requirements only apply to certain types of covered entities. For example, only health care providers with direct treatment relationships are required to comply with certain requirements for disseminating the notice of privacy practices. § 164.520(c).

2. County v. Departments: Is each county a covered entity or are the individual departments the covered entities?

3. Different forms of covered entities: Different or additional rules may apply to a covered entity depending on the form that it takes. The following three forms of covered entities are discussed below:
   a. Affiliated covered entities;
   b. Hybrid entities; and
   c. Covered entities with multiple covered functions.

II. Hybrid entities

A. What is a hybrid entity?

1. Definitions: In general, the term "hybrid entity" refers to a covered entity that performs some functions not related to health care. Hybrid entities designate "health care components" and only those components are required to comply with the privacy rule. § 164.504(a) – (c).

   a. Hybrid entity: The definition of the term "hybrid entity" has three basic parts:
      i. The entity's business activities include both "covered functions" and non-covered functions (a "covered function" is a function that makes the entity a health care provider, health plan or health care clearinghouse);
      ii. The entity is a single legal entity;
      iii. The entity designates health care components.

   b. Health care component: The term "health care component" is simply defined as a component or combination of components of a hybrid entity designated as a "health care component" by the hybrid entity as provided in the rule. See Section II.B.2. below for a discussion of the rules that apply to the designation of health care components.

2. Example: Botts County wants to determine whether it may be a hybrid entity under the privacy regulation. Applying the three parts of the definition, the county decides that it may be a hybrid entity if it so chooses.

Copyright © 2002. All rights reserved.
Institute of Government, School of Government, The University of North Carolina at Chapel Hill

Aimee N. Wall
Institute of Government, UNC-CH

a. The county has both covered and non-covered functions. An example of a covered function is the health department's activities as a health care provider (such as immunization and prenatal clinics). Examples of non-covered functions are the county's library and waste management programs.
b. The county concluded that it is a single legal entity and that it will be the "covered entity" under HIPAA rather than the individual departments.
c. The county designated health care components. After reviewing the rules that apply to designating health care components, the county evaluated all of its operations and designated several health care components including the EMS department, part of the local health department and part of the department of social services.

B. What special rules apply to hybrid entities: Below are some of the special rules that apply to hybrid entities.

1. Application of and compliance with the privacy rule: If a covered entity designates itself a hybrid entity:

   a. Only the entity's health care component(s) are required to comply with the requirements of the privacy rule. §§ 164.504(b); 164.504(c)(1).

   b. The covered entity (rather than the health care component) is ultimately responsible for activities related to compliance and enforcement (such as responding to requests from the US DHHS for compliance reports). § 164.504(b)(3)(i).

   c. The covered entity is ultimately responsible for developing policies and procedures to ensure compliance with the privacy rule. § 164.504(b)(3)(ii). (See Administrative Requirements outline for further discussion of required policies and procedures)

2. Designation of health care components: If a covered entity wishes to be a hybrid entity, it *must* designate the health care component(s) and document the designation.

   a. Mandatory components: If a covered entity is designating a health care component(s), it *must* include any component that would meet the definition of covered entity if it were a separate entity. In other words, if the component is a health plan or health care clearinghouse or if the component is a health care provider that transmits HIPAA transactions electronically, it *must* be designated a health care component (or part of a larger health care component).

   b. Optional components: In addition to those "mandatory" components, a covered entity that is a hybrid entity has the option of designating other types of components health care components (or parts of health care components).
      i. A covered entity may include other components that are "health care providers" but that do not conduct HIPAA transactions electronically. In

Copyright © 2002. All rights reserved.
Institute of Government, School of Government, The University of North Carolina at Chapel Hill

Aimee N. Wall
Institute of Government, UNC-CH

other words, the entity may have a component that is providing health care to individuals but is not billing an insurer for that care (such as a county 911 call center or a jail health program). Because that component would not be a covered entity if it were a separate entity, it is not a mandatory health care component. However, the entity may choose to designate the component as a health care component and thereby require it to comply with the privacy rule. The entity may limit the scope of the component's designation so that it is only required to comply with the privacy rule to the extent that it provides health care to individuals.

ii. A covered entity may include other components that perform activities that would make the component a business associate of the health care component if the two components were separate legal entities. In other words, if a health care component (such as the health department) relied on another component of the entity (such as the county finance office) to perform a "business associate" activity on their behalf (such as filing insurance claims or collecting on past due accounts), the entity could choose to include the business associate component (i.e., the finance office) in the health care component. The entity may limit the scope of the component's designation so that it is only required to comply with the privacy rule to the extent that it performs business associate activities – it will not be required to comply with the privacy rule for all identifiable health information that it maintains.

3. Safeguards § 164.504(c)(2).

   a. Compliance with privacy rule: The hybrid entity must ensure that the health care component(s) comply with the applicable requirements of the privacy rule.

   b. Firewalls: The hybrid entity must ensure that the health care component(s) does not disclose PHI to another component in any way that would be prohibited by the privacy rule if the two components were separate legal entities.

   c. Workforce: The hybrid entity must ensure that if a workforce member performs duties for both health care and non-health care components, the member does not use or disclose PHI from the health care components in violation of the privacy rule.

   d. Business associate components: A component of the covered entity that performs business associate activities on behalf of a health care component may not use or disclose PHI that it creates or receives from (or on behalf of) the health care component in any way that is prohibited by the privacy rule.

III. Affiliated covered entities

A. What is an affiliated covered entity?

Copyright © 2002. All rights reserved.
Institute of Government, School of Government, The University of North Carolina at Chapel Hill

1. Definition: Two (or more) legally separate entities may choose to designate themselves as a single "affiliated covered entity" if they are under common ownership or common control. § 164.504(d)(2)(i).
   a. Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity. § 164.504(a).
   b. Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity. § 164.504(a).

2. Example: A hospital chain would likely satisfy the test for common ownership. If many of the administrative functions are centralized for all of the hospitals in the chain, it could satisfy the common control test as well, but it is only required to satisfy one of the two tests in order to qualify for a designation as an affiliated covered entity. The hospital chain would evaluate the feasibility and suitability of designating all of the hospitals (or only some of the hospitals) in the chain as a single covered entity.

B. What special rules apply to affiliated covered entities?

1. Documentation: If the entities designate themselves as a single affiliated entity, they must document the designation. § 164.504(d)(2)(ii).

2. Multiple covered functions: If the affiliated entity combines the functions of a plan, provider and/or clearinghouse, the entity must comply with the requirements of the privacy regulation applicable to the specific function. (See Section IV.) §§ 164.504(d)(2)(iii); 164.504(g).

3. Consolidated policies, procedures, etc.: The rule does not explicitly state that affiliated covered entities must have uniform policies and procedures or a single notice that applies to all of the affiliated entities. In the preamble, the US DHHS explains that "such organizations *may* promulgate a single shared notice of information practices…" 65 Fed. Reg. at 82,503 (emphasis added). This decision, therefore, is in the discretion of the entities participating in the affiliation.

4. Information-sharing: One of the benefits of being an affiliated covered entity is that the entities participating in the affiliation may be able to pool information in some situations. For example, all of the entities may be able to combine information in order to perform a joint marketplace analysis (which would be a health care operations activity) or evaluate collection activities (which would be a payment-related activity). It is important to note that the entities are still bound by the minimum necessary rule, even for uses of PHI within the affiliation.

IV. Entities with multiple covered functions

A. What is an entity with multiple covered functions:

Copyright © 2002. All rights reserved.
Institute of Government, School of Government, The University of North Carolina at Chapel Hill

1. Definition: The term "entity with multiple covered functions" is not explicitly defined in the privacy rule but intuitively the term seems to refer to a single legal entity that performs the functions of two or more different types of covered entities.

2. Example: Botts County has a health department, a department of social services that provides home health services, and a self-administered dental insurance plan for county employees. Botts County is a single legal entity that performs functions of both a health care provider (the health department and DSS) and a health plan (the dental plan) and therefore it is a covered entity with multiple covered functions.

B. What special rules apply to entities with multiple covered functions

1. Compliance: A covered entity with multiple covered functions must comply with the requirements of the privacy rule applicable to the functions that it performs. For example, the privacy rule includes a series of specific requirements that are only applicable to group health plans. Botts County's dental plan is a "health plan" under the rule and therefore it must comply with all of the general requirements as well as the specific requirements applicable to the health plan. § 164.504(g)(1).

2. Use or disclosure: If a covered entity creates or receives PHI about an individual related to only one covered function, it may not use or disclose the information for a different covered function. If the individual participates in (or receives services from) multiple covered functions of the same entity, the entity may use and disclose the individual's PHI within and among the covered functions as otherwise permitted by the rule. § 164.504(g)(2). For example, an employee of Botts County is enrolled in the dental plan but *does not* receive dental services at the Botts County health department. The dental plan may not disclose PHI about the employee to the health department's dental clinic without the employee's authorization.

Copyright © 2002. All rights reserved.
Institute of Government, School of Government, The University of North Carolina at Chapel Hill