

**Subpart A—General Provisions****§ 164.102 Statutory basis.**

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation specifications under part C of title XI of the Act, section 264 of Public Law 104-191, and sections 13400-13424 of Public Law 111-5.

[78 FR 5692, Jan. 25, 2013]

**§ 164.103 Definitions.**

As used in this part, the following terms have the following meanings:

*Common control* exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.

*Common ownership* exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

*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 clearinghouse.

*Health care component* means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with § 164.105(a)(2)(iii)(D).

*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 in accordance with paragraph § 164.105(a)(2)(iii)(D).

*Law enforcement official* means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:

- (1) Investigate or conduct an official inquiry into a potential violation of law; or
- (2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

*Plan sponsor* is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

*Required by law* means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

[68 FR 8374, Feb. 20, 2003, as amended at 74 FR 42767, Aug. 24, 2009; 78 FR 34266, June 7, 2013]

**§ 164.104 Applicability.**

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this part apply to the following entities:

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) Where provided, the standards, requirements, and implementation specifications adopted under this part apply to a business associate.

[68 FR 8375, Feb. 20, 2003, as amended at 78 FR 5692, Jan. 25, 2013]

**§ 164.105 Organizational requirements.**

(a)(1) *Standard: Health care component.* If a covered entity is a hybrid entity, the requirements of this part, other than the requirements of this section, §§ 164.314, and 164.504, apply only to the health care component(s) of the entity, as specified in this section.

(2) *Implementation specifications:*