

Tennessee Department of Health

HIPAA Policies

Privacy

Policy Title: HIPAA Hybrid Entity Designation

Policy Number: 101

Effective Date: January 4, 2022

PURPOSE:

To define the State of Tennessee, Department of Health (“TDH”) as a hybrid entity and designate its HIPAA covered health care components, in accordance with the privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act (“HIPAA”), Public Law 104-191 and the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”), Public Law 111-5. This HIPAA Hybrid Entity Designation Policy addresses the requirements of 45 C.F.R. §§ 164.103 and 164.105.

POLICY:

General:

1. Scope. This policy applies to all offices, divisions, programs, and workforce members of TDH health care components identified under Section 3 of this policy.
2. Background.
 - a. TDH is a public health authority as defined at 45 C.F.R. § 164.501.
 - b. County health departments in Tennessee, operating under the direct supervision of TDH, are HIPAA covered entities. Some larger urban counties, including Madison, Shelby, Knox, Davidson, Hamilton and Sullivan, have health departments that operate under local governance and are separate legal entities.
 - c. A single legal entity that is a HIPAA covered entity, whose activities and services include both HIPAA covered and non-covered functions, may elect to be a hybrid entity by designating its HIPAA covered components. Health care components are any TDH component that, if a separate legal entity, would meet the definition of a covered entity or business associate.
 - d. By choosing to be a hybrid entity, a legal entity may limit application of HIPAA to only its health care components. For example, an agency that includes a health clinic that conducts HIPAA covered transactions electronically (*e.g.*, electronic

claim submission) is a covered entity component, and the legal entity must designate the clinic as part of the hybrid entity's health care component. The single legal entity must also include the claims submission department that handles the clinic's billing as a health care component because the claims submission department serves as a business associate to the clinic.

- e. A single legal entity may choose to include a non-covered health care provider as part of the health care components. For example, an agency may decide to include its laboratory in its health care components, even though its laboratory does not conduct any covered transactions.

3. Designation of Health Care Components. TDH designates the following Divisions/Offices as health care components:

a. Covered entity components:

- i. Community Health Services, Regional and Local Health Departments
- ii. Community Health Services, Office of the Medical Director
- iii. Laboratory Services, Office of the Knoxville Regional Lab Director
- iv. Laboratory Services, Office of the Clinical Division Director
- v. Laboratory Services, Office of Laboratory Services Director

b. Business associate components:

- i. Community Health Services, Office of the Assistant Commissioner
- ii. Community Health Services, Office of the Fiscal Administrator
- iii. Community Health Services, Business Solutions
- iv. Community Health Services, EMR Solutions
- v. Community Health Services, Administrative Services
- vi. Family Health & Wellness, Reproductive & Women's Health Section
- vii. Laboratory Services, Administration
- viii. Laboratory Services, Office of the Administrative Director
- ix. Communications & Media Relations

- x. Compliance & Ethics
 - xi. Office of the General Counsel, Non-Health Licensure, Regulation Attorneys & Staff
 - xii. Office of the Chief Medical Officer
 - xiii. Core Informatics, Office of Informatics and Analytics*
 - xiv. Quality Improvement
 - xv. Office of the Deputy Commissioner for Population Health
 - xvi. Administrative Services
 - xvii. Information Technology Services
- c. This designation is based upon the “Tennessee Department of Health’s HIPAA Hybrid Assessment Findings and Recommendations, Final Report” dated June 7, 2021.
 - d. Whenever TDH policies, procedures, or guidelines refer to TDH as covered under HIPAA, they refer *only* to the health care components listed above.
4. General Procedures and Responsibilities. As a hybrid entity, TDH must ensure that:
- a. Its health care components do not use or disclose PHI to another component of the covered entity in circumstances in which the HIPAA Privacy Rule would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities.
 - b. Its health care components protect access to electronic PHI by TDH’s non-covered components within the hybrid entity, in compliance with the HIPAA Security Rule, as if the health care components and the non-covered components were separate and distinct legal entities.
 - c. If a workforce member performs duties for **both** the health care component in the capacity of a member of the workforce of such component **and** for another non-covered component of the entity in the same capacity with respect to that component, such workforce member must not use or disclose PHI created or received in the course of, or incident to, the member's work for the health care component in a way prohibited by HIPAA.

* Advanced Analytics & Visualization and Data Governance, Office of Informatics and Analytics are designated as non-covered components.

5. Health Care Component Procedures and Responsibilities. TDH has the following responsibilities with respect to its health care components:
 - a. Compliance with the HIPAA Security Rule.
 - b. Compliance with the HIPAA Privacy Rule including implementation of policies and procedures to ensure compliance, and the safeguard requirements.
 - c. Compliance with the HIPAA Privacy Rule regarding business associate arrangements and other organizational requirements.
 - d. Designation of health care components in compliance with the HIPAA Privacy Rule. TDH must maintain documentation of its designation for six years from the date of its creation or the date when it was last in effect, whichever is later.
6. Disclosures for Public Health Activities. For public health functions pursuant to TDH's activities as a public health authority:
 - a. A health care component may disclose PHI to a non-covered component without written patient authorization if the disclosure is made for a specified public health purpose, such as preventing or controlling disease, injury, or disability, or as required by state or local law.
 - b. A health care component may reasonably rely on a minimum necessary determination made by the non-covered component in requesting the PHI.
 - c. For routine and recurring public health disclosures, a health care component may develop standard protocols that address the types and amount of PHI that may be disclosed for such purposes.
7. Sanctions. Failure to comply with this policy may subject individuals to sanctions, up to and including disciplinary action, suspension, termination of employment, dismissal from TDH, and legal action. Some violations may constitute criminal offenses under local, state, and federal laws. TDH will carry out its responsibility to report such violations to the appropriate authorities.

Reference(s):

- 45 C.F.R. § 164.103
- 45 C.F.R. § 164.105
- 45 C.F.R. § 164.501
- 45 C.F.R. § 164.512(b)(1)(i)
- 45 C.F.R. § 164.514(d)(3)(i)
- 45 C.F.R. § 164.514(d)(3)(iii)(A)

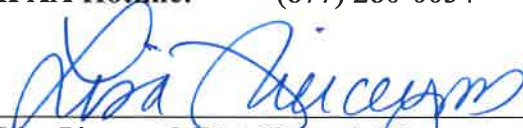
Related policies:

HIPAA Policies #102 - #113

Contact(s):

- **Privacy Program Office:** (615) 741-1969
- **Security Officer:** security.health@tn.gov
- **TDH HIPAA Hotline:** (877) 280-0054

Approved by:



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Approved on:

November 10, 2021

Review/change history:

Review cycle: Annual