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TEXAS TECH™

Operating Policy and Procedure

OP 40.11: Health Care Compliance and Hybrid Entity Designation

DATE: January 22, 2025

PURPOSE: The purpose of this Operating Policy/Procedure (OP) is to provide a framework for Texas Tech University (TTU) colleges with departments that provide health care-related services to be in compliance with federal and state laws and regulations related to privacy and security of health and personal information.

REVIEW: This TTU OP will be reviewed every two years after publication by the Texas Tech University Health Sciences Center (TTUHSC) Chief Compliance Officer and the TTU Office of Institutional Compliance with substantive revisions forwarded to the TTU President.

POLICY/PROCEDURE

1. Introduction

Texas Tech University (TTU) is a public institution of higher learning providing general academic programs and degrees through the doctoral level. By Texas statute, TTU is a legal entity governed by the Texas Tech University System (TTUS) Board of Regents. Certain TTU colleges and departments are involved in health care-related activities subject to compliance with health care regulations including the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and, as amended, by the Health Information Technology for Economic and Clinical Health (HITECH) Act and Privacy and Security Regulations at 45 CFR §§ 160, 162, and 164, all collectively referred to as "HIPAA."

HIPAA applies to individuals and entities that are health care providers, health care clearinghouses, and health plans ("covered entities"). Under HIPAA regulations, a single legal entity whose business activities include both functions that are and are not covered by HIPAA may designate itself as a hybrid entity, even if it is not primarily engaged in covered entity activities (45 CFR 164.103 and 164.105). A hybrid entity must designate its components that perform covered functions, and those components must comply with HIPAA.

2. Hybrid Entity Designation

This policy serves as TTU's formal designation of itself as a *hybrid entity,* which is a covered entity (defined below) whose business activities include some components that provide health care. The attachment hereto lists TTU's designated health care components. TTU shall segregate its health care components from its non-health care components and require the identified health care components to comply with HIPAA. Protected health information shall **not** be shared between the health care components and the non-health care components.

3. Definitions

a. *HIPAA* – Health Insurance Portability and Accountability Act of 1996 or HIPAA is the federal law that establishes national standards for the privacy and security of health information and electronic health care transactions, which are found in 45 CFR Parts 160, 162, and 164.

b. *HITECH* – Health Information Technology for Economic and Clinical Health Act, which is part of the American Recovery and Reinvestment Act of 2009, is a federal law that expands the application of HIPAA, Sections 13400-13423 Subtitle D-Privacy.

c. *Health and Safety Code, Chapter 181, Medical Records Privacy* is the state law that requires a covered entity to comply with both federal and state requirements governing the privacy and security of protected health information (PHI).

See also Texas Executive Order RP 36, relating to preventing, detecting, and eliminating fraud, waste, and abuse in state health care systems.

d. *Covered Entity* is a health care provider who transmits protected health information in electronic form in connection with a HIPAA-covered transaction (45 CFR 160.103).

Covered entity under the Texas Health and Safety Code, Medical Records Privacy, § 181.001(b)(2), is expanded to mean any person who:

(1) For commercial, financial, or professional gain, monetary fees, or dues, or on a cooperative, nonprofit, or pro bono basis, engages, in whole or in part, and with real or constructive knowledge, in the practice of assembling, collecting, analyzing, using, evaluating, storing, or transmitting protected health information. The term includes a business associate, health care payor, governmental unit, information or computer management entity, school, health researcher, health care facility, clinic, health care provider, or person who maintains an Internet site;

(2) Comes into possession of PHI;

(3) Obtains or stores PHI; or

(4) Is an employee, agent, or contractor of a person described by sections (1), (2), or (3) insofar as the employee, agent, or contractor creates, receives, obtains, maintains, uses, or transmits PHI.

e. *Business Associate* means a person (other than a workforce member) who performs functions or activities on behalf of, or provides certain services to, a covered entity that involves access by the business associate to PHI.

f. *Electronic PHI* is individually identifiable health information that is transmitted by or maintained in electronic media. Examples include, but are not limited to, Internet, extranet, leased lines, dial-up lines, private networks, hard drives, flash drives, magnetic tape/disk, CD, digital memory card, etc.

g. *Employees* are faculty and staff who receive W-2 wages from TTU and who provide health care services or items and/or participate in health care operations, including, but not limited

to, administrative support, preparation of health care claims, billing of health care items or services, or similar activities.

h. *Fraud* has the same meaning as contained in Section 07.03, Fraud policy, *Regents' Rules*.

i. *Non-compliance* means failure or refusal to follow applicable state or federal laws or institutional policies, whether or not such conduct results in financial risk to TTU. It can include acts that constitute fraud, violations of law, or failure to comply with this operating policy or other applicable TTU policies and procedures.

j. *Providers* are employees of TTU in any college or school who engage or participate in providing health care service or items billed under a TTU Federal Tax Identification Number. This term includes, but is not limited to, psychologists, counselors, and other licensed clinicians.

k. *Protected Health Information* (PHI) is individually identifiable health information created, maintained, or transmitted by TTU or any other covered entity in any form or medium, including information transmitted orally, or in written or electronic form (45 CFR 160.103).

l. *Workforce Member* means employees, residents, students, volunteers, and other persons whose conduct, in performance of work for a covered entity, is under the direct control of the covered entity, whether or not they are paid by the covered entity. It does not include business associates or their employees and agents (45 CFR 160.103).

m. *Violation of Law* means failure or refusal to follow any applicable state or federal law, such that criminal and/or civil penalties may be imposed.

4. Designated Health Care Components

a. TTU shall appoint a health care compliance liaison to coordinate health care compliance activities for its designated components. Upon approval of the TTUHSC Chief Compliance Officer, the TTU health care liaison may be appointed to serve on TTUHSC compliance committees as an ex officio member.

b. TTU's designated health care components are listed on the attachment. This list shall be reviewed every two years and updated as needed.

c. Each TTU health care component shall identify an individual within the component who is responsible for accountability for privacy, security, and, if applicable, billing compliance within the component. These individuals will work with the TTUHSC Billing Compliance Officer, TTUHSC Institutional Privacy Officer, and TTU Institutional Security Officer as set forth below.

d. These TTU health care components are subject to compliance with federal HIPAA laws and regulations governing health information. Providers and employees within the components who also submit claims for reimbursement to government health care programs are subject to the False Claims Act and Medicare/Medicaid billing regulations.

5. Agreement for Healthcare Compliance Services

a. To assist TTU designated health care components in complying with applicable health care requirements, TTU shall enter into an Agreement for Healthcare Compliance Services with Texas Tech University Health Sciences Center (TTUHSC), a public institution of higher education and separate legal entity also governed by the TTUS Board of Regents.

b. Pursuant to TTUHSC OP 52.01, Institutional Compliance Plan, TTUHSC has appointed a Chief Compliance Officer (CCO) and has designated compliance committees to include a Billing Compliance Advisory Committee and a Privacy and Security Committee to assist in the development and oversight of the TTUHSC Institutional Compliance Plan. The CCO, working with these committees, is responsible for implementing and monitoring a continuous, collaborative, and proactive culture of compliance at TTUHSC.

c. TTUHSC, through its Chief Compliance Office, will provide compliance services to TTU as set forth below and in accordance with the Department of Health and Human Services' Office of Inspector General Compliance Program Guidance.

d. Compliance Officer and Compliance Committee

The TTUHSC CCO will serve as the designated TTU compliance and privacy officer and will be charged with the responsibility of overseeing and monitoring the compliance program. The CCO will report directly to the TTU President. TTU will also designate a health care compliance liaison to work with the covered entity departments and the TTUHSC CCO.

The TTUHSC CCO will provide annual compliance updates to the TTU President or liaison, which may include training completion rates, auditing and monitoring results, hotline calls, investigation findings, government inquiries, and other significant compliance matters.

e. Policies and Procedures

The TTUHSC Compliance Department will provide applicable policies and procedures regarding the operation of the compliance program, including TTU's compliance with federal health care program requirements (e.g., billing and reimbursement and HIPAA privacy and security policies). TTUHSC shall assess and update, as necessary, the compliance policies and procedures and distribute to applicable covered persons.

f. Training

The TTUHSC Compliance Department will provide education and training programs for all affected TTU employees and students. Compliance training may consist of live and/or online education modules to include general fraud and abuse, general or specific HIPAA privacy and security, and applicable billing training.

Training will be provided on an annual basis or as required by law. Each TTU covered entity department will be responsible for ensuring employees and students complete the training requirements. Each individual who is required to complete training shall certify, in writing or in electronic form, that he or she has received the required training. Completion rates will be monitored and reported to the TTU compliance liaison.

g. Auditing and Monitoring

TTUHSC will provide auditing/monitoring templates for billing and privacy compliance activities. On an annual basis, the Compliance Department staff will conduct oversight or risk-based audits to determine compliance with applicable federal and state requirements. If TTU has contracted with a third-party company for billing or coding services, the compliance staff will conduct a yearly sample review of claims to verify accuracy.

h. Ineligible Persons

TTU will provide federal and state exclusion screening reviews to verify that all applicable individuals are eligible to participate in the federal health care programs. All applicable individuals will be screened prior to employment and on a routine basis thereafter.

i. Disclosure Program

TTU has established a hotline, via a privacy contractor (EthicsPoint), to provide a confidential avenue for reporting concerns. Reports submitted through EthicsPoint that relate to the relevant covered health care components will be forwarded to the TTUHSC Compliance Office for prompt and appropriate action. The Texas Whistleblower Act protects anyone who, in good faith, reports unlawful activity from retaliation for making such a report.

6. Health Care Operating Policies

a. TTU and TTUHSC are also an *affiliated covered entity,* being legally separate but under common control of the TTUS Board of Regents. Both TTU and TTUHSC will comply with applicable health care laws and regulations and are separately subject to liability for non-compliance.

b. TTU will comply with TTUHSC billing and privacy policies until specific policies may be implemented for TTU. Applicable TTUHSC policies include, but are not limited to, the following:

- Billing compliance policies;
- HIPAA policies; and
- General compliance policies.

c. HIPAA forms – TTU will use forms approved by the TTUHSC HIPAA Privacy Officer until specific forms are implemented for TTU.

d. Both HIPAA, which covers health care records, and the Family Education Rights and Privacy Act (FERPA), which covers educational records, require prior written authorization before records are disclosed.

7. TTU Workforce Members in Designated TTU Health Care Components

a. As part of the TTU workforce, faculty, staff, students, volunteers, and others are expected to follow federal and state laws as well as TTUHSC policies discussed above.

b. TTU faculty, staff, students, volunteers, and others are subject to HSC OP 70.20, Employment Background Screening Policy, and HSC OP 52.11, Sanction Check Process.

TTU may prohibit the employment of any person listed by a federal or state agency as debarred, excluded, or otherwise ineligible for participation in federal or state funded programs to maintain compliance with federal and/or state laws.

8. Vendors in Designated TTU Health Care Components

a. Vendors shall follow applicable federal and state laws as well as the TTUHSC policies discussed above.

b. Vendors shall also be subject to HSC OP 52.16, Health Care Vendor Interactions.

9. Violations

Reporting suspected fraud, violations of law, or non-compliance is essential to the effectiveness of TTU health care compliance. Individuals shall report suspected violations of or non-compliance with federal or state laws and/or TTU policies. There are various methods and resources available to report suspected fraud, violations of law, or non-compliance. Any member of the TTU community who has a reasonable basis for believing fraud, violation of law, or other non-compliance has occurred has a responsibility to promptly notify his/her supervisor, TTUS Office of Audit Services, Texas Tech Police Department, Human Resources, as applicable, the TTUHSC Institutional Compliance Office, or use the external confidential hotline (see TTU OP 10.14, Reporting Suspected Wrongdoing).

Once notified of the reported breach, the TTU compliance liaison will contact the TTUHSC Institutional Compliance Office for guidance on any reported violation. An investigation will be conducted by the TTUHSC Institutional Compliance Office, according to TTUHSC Operating Policies and Procedures. If a violation is found, all costs associated with providing the required notices (if applicable) and fines will be the responsibility of the TTU department that committed the violation.

10. Right to Change Policy

TTU reserves the right to interpret, change, modify, amend, or rescind any policy, in whole or in part, at any time without the consent of workforce.

Attachment: *Designated Health Care Components*