State Law Ambiguities Confronting Health Database Holders

A Few Practical Pointers

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- FDA Contract 50 State Privacy Law Survey
 - "Critical Action Matrix" Preemption Analysis Tab
 - Report Appendix Contains 50 State Overview

Problem for Database Holders

- State law "tort," "statutory" and "breach" dual liability
 - **Tort**: 4 common law torts (case law)
 - Appropriating the plaintiff's identity for the defendant's benefit
 - Placing the plaintiff in a false light in the public eye
 - Publicly disclosing private facts about the plaintiff
 - Unreasonably intruding upon the seclusion or solitude of the plaintiff
 - Statutory: Many state statutes prohibit release of "confidential health information" (mental health, HIV, genetic info) with requirements greater than HIPAA
 - Breach: Notification requirements (2005 Choicepoint)
 - 45 states have breach notification laws since 2005
 - Choicepoint cost for inadvertent disclosure of 163,000 records
 - Over \$50 mil in 2005 (FTC \$15 mil fine + other costs)

HIPAA Preemption Analysis

- HIPAA Privacy Rule *preempts* state law **unless**:
 - 1. Specific "determination" made by HHS Secretary;
 - 2. State law "relates to privacy of individually; identifiable health information" *and* "more stringent;"
 - 3. State law authorizes public health reporting; or
 - 4. State law requires health plans to report or provide access to certain information
- 4. 45 CFR 160.201 160.205

The Privacy Dilemma

- Which databases subject to state law?
 - Health Insurance/Claims Data (Private)
 - Government Agency Databases
 - Hospital/Health Institution/Medical Professionals
- Difficult to determine whether state privacy laws are "more stringent"
- Health Insurance Association of America provides non-members with a \$51,200 "HIPAA Preemption Analysis" (Study Cost approx. \$1 million)
- Numerous other studies have been undertaken

Some Inconsistent Sources of State Law

- Statutes on Criminal Procedure/Law Enforcement
- State Department of Aging
- State Board of Behavioral Sciences
- State Board of Healing Arts
- State Board of Nursing
- State Board of Optometry
- State Board of Pharmacy
- State Dental Board
- State Department of Health & Environment (hospitals, ambulatory surgery centers,
 - home health, hospices, adult care homes and labs)
- State Emergency Services Board
- State Insurance Commission
- State Social Rehabilitation Services (Medicaid regs/manuals)
- Workers Compensation

"Critical Action" Matrix Tool

- E.g., Excel Spreadsheet (e-mail me!)
- Over 200 state law privacy fields analyzed in HIPAA preemption tab
- Identified approximately 20 grey areas with HIPAA
 - Genetic information, donor databases, medical records resulting from arrest, data stored without court orders, data stored without State permission

Some Grey Areas "More Stringent" State Regulation

- Alabama "Controlled substances" Code of Ala. § 20-2-215 (2009)
- Hawaii "Birth defect studies" HRS § 324-43 (2009)
- Idaho "Individual pharmaceutical records" Idaho Code § 54-1727 (2009)
 - Need permission from Dept. of Health & Human Welfare (many states have similar statutes)
- Wyoming Medical records 'directly or indirectly' identifying patients. Wyo. Stat. § 25-10-122 (2009)

Practical Pointers

- Know where data is <u>held</u> versus where it is <u>disclosed</u>
- Secure proactive consents from government agencies
- Complete federal-state preemption analysis/audit for every databa *E.g.*, "Critical Action Matrix (Kansas)"
- Know breach notification obligations under applicable state <u>and</u> federal (they are sometimes different)
- Data breach insurance

Thank you

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