Davis Wright Tremaine LLP

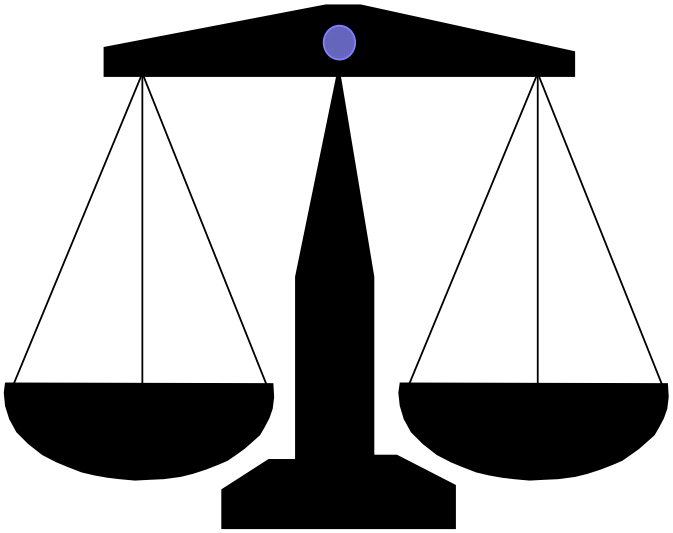
The Seventh National HIPAA Summit

HIPAA Privacy: Privacy Rule Compliance on Public Health Activities and Research

Thomas E. Jeffry, Jr.
Davis Wright Tremaine LLP
Los Angeles, California
tomjeffry@dwt.com

Davis Wright Tremaine LLP

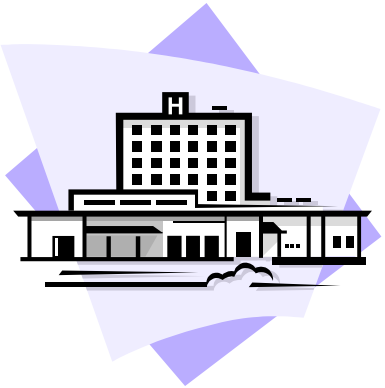
Balancing Individual Privacy and Communal Interests



A central premise of DHHS' Privacy Rule, like most health information privacy protections, is how to balance individual privacy interests with communal needs for data, like public health and health research.

Davis Wright Tremaine LLP

The Covered Entity is responsible for the protected health information it collects and maintains and is liable under HIPAA for unauthorized uses and disclosures.



Davis Wright Tremaine LLP

Covered Entity Must:

- Identify what disclosures and uses are for treatment, payment and health care operations
- Identify what disclosures and uses are subject to exceptions set forth in 45 CFR 164.512
  - To the extent required by law
  - For specified public health activities to a public health authority or other appropriate government authority
  - For specified health oversight activities
  - For research purposes with a waiver from IRB or Privacy Board
  - To avert a serious threat to health and safety
- Exercise professional judgment in the case of an emergency or disaster relief
- Account for most disclosures not authorized

Davis Wright Tremaine LLP

What is the Impact of the Privacy Rule on Public Health?

Internally **– what are the ways that the rule affects the practice of public health or public health research done by public health agencies or its partners?**

Externally **– how does the Rule impact the flow of indentifiable health data into or out of public health agencies?**

Davis Wright Tremaine LLP

Public Health Practice - Internally

To the extent that public health authorities use or disclose identifiable health data for public health purposes, they are not "covered entities," and are thus not required to adhere to the provisions of the Privacy Rule.

Davis Wright Tremaine LLP

Public Health Practice - Externally

How will the Privacy Rule affect the flow of health data to public health authorities?

Davis Wright Tremaine LLP

The Public Health Exception

The "public health" exception states that a covered entity may disclose protected health information without specific, individual authorization to a "*public health authority* that is authorized by law to collect and receive such information for the purpose of preventing and controlling disease, injury, or disability, including . . . reporting of disease . . . and the conduct of public health surveillance . . . ."

Davis Wright Tremaine LLP

Similar Public Health Exceptions

- Disclosures to maintain the quality, safety, or effectiveness of FDA products
- Disclosures to notify persons exposed to communicable diseases
- Disclosures about victims of abuse, neglect, or domestic violence
- Disclosures for health oversight activities
- Disclosures to prevent serious threats to persons or the public

Davis Wright Tremaine LLP

What is a 'Public Health Authority'?

A *public health authority* is an:

agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency . . . that is responsible for public health matters as part of its official mandate.

Davis Wright Tremaine LLP

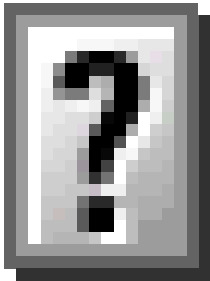
Dealing with State Reporting Laws

The privacy regulations expressly do not pre-empt (or override) state law that "provides for the reporting of disease or injury . . . or for the conduct of public health surveillance [or] investigation . . . ."

Davis Wright Tremaine LLP

Different Perspectives in Approaching the "Grey Areas"

- Required by law vs. permitted or authorized by law
- Distinguishing clinical care from research
- Distinguishing surveillance from research
- Downstream uses and disclosures of previously disclosed PHI to a public entity
- How to deal with Community Health Record to identify and service patient needs
- When to rely on disaster relief, threat to public safety to disclose information
- Can a government authority or research organization be a business associate



Davis Wright Tremaine LLP

Special Research Concerns

- Researchers need training on HIPAA requirements, waivers, and authorizations
- Authorization in Informed Consents vs. separately signed authorizations
- Identifying all the uses of and groups who may receive research PHI
- Creating a limited data set for research purposes; researchers as business associates subject to date use agreements
- Collection and use of specimens

Davis Wright Tremaine LLP

What to do about PH & Research?

When in doubt, obtain an authorization

CE and public health officials discuss and agree upon 'grey areas' in advance

Demonstrate parallel commitment toward privacy and security