The Impact of HIPAA on US Biomedical Research

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Overview

- HIPAA Background
  - What is HIPAA?
  - Who is covered?
  - What is permitted?
- Impact of HIPAA on Biomedical Research
- Impact Management Strategies

“Biomedical Research”

- Clinical Research
- Epidemiologic Research
- Outcomes Research

What is HIPAA?

- The Health Insurance Portability and Accountability Act of 1996; and
- Three sets of regulations issued by the Department of Health and Human Services:
  - ***Privacy Regulations*** - April 14, 2003 Compliance Deadline
  - ***Transaction Standards*** - October 16, 2002 Compliance Deadline or October 16, 2003 with an extension
  - ***Security Regulations*** - Pending

Who is covered?

- HIPAA "Covered Entities"
  - **Health Care Providers** that transmit health data electronically in connection with 1 or more of 8 "HIPAA Transactions"

    Physicians Hospitals Clinics

    Group Practices Pharmacies
  - **Health Care Plans**

    HMOs Health Insurers Medicare

    PBMs Group Health Plans Medicaid
  - **Health Care Clearinghouses**

    Entities that transmit data into a HIPAA "standard" format from a non-standard format or vice versa
- "Business Associates" of HIPAA Covered Entities

  Entities that use protected health information (PHI) for or on behalf of covered entities

What is permitted?

HIPAA Covered Entities must obtain one-time written patient acknowledgement that they have been given the Covered Entities' Notice of Privacy Practices and then may use "protected health information" (PHI) **only** for TPO:

Treatment of patients
Payment for treatment
Health Care **O**perations

How does HIPAA impact human-subject biomedical research?

- Pharmaceutical industry research sponsors generally are **not** HIPAA Covered Entities or Business Associates of such entities.
- Virtually all entities through which pharmaceutical companies conduct human-subject biomedical research **are** HIPAA Covered Entities.
- Research is **not** included in TPO.

HIPAA Requirements for Research

Uses or disclosures of PHI for research require:

- Signed, HIPAA compliant "authorizations" from each study participant, *and Common Rule informed consents which can be combined into one document*;
- IRB or "Privacy Board" waivers of some or all of the authorization requirements; or
- "De-identification" of patient data via one of two methods:
  - Removing each of 18 prescribed data elements; or
  - Statistical Analysis and opinion

NOTE: ***The Final Privacy Rule allows use of a limited identifiable data set that could be very useful for epidemiologic and outcomes research. Given proposed restrictions on use, this data set would likely not be useful in clinical research.***

HIPAA Requirements for Research - Cont.

Covered Entities Must Also:

- Provide detailed notices of their privacy policies and practices to all study participants;
- Provide physical, technical and administrative security;
- Allow data subjects to access and correct PHI about them.
- Disclose the minimum PHI necessary to achieve the authorized purposes; and
- Document and provide, on request, an accounting of all disclosures of PHI for research purposes.

NOTE: The Final Rule has eliminated the minimum necessary and accounting requirements for research conducted under HIPAA Authorizations.

Authorization Requirements

HIPAA Authorizations Must:

Be written in plain language and signed by each study participant;
Specify the data that will be collected and each use to which it will be put;
Specify the persons, or types of persons, who will have access to the data;
Specify a date or event after which the covered entity will no longer collect, use or disclose the data;
State that the individual may refuse to sign or revoke the authorization at any time and that data collected before revocation will continue to be used;
State that once the data are provided to the study sponsor, HIPAA will no longer protect them; and
Disclose any payments from the sponsor to the investigator for use or disclosure of the data.

De-identification Requirements (Two Methods)

HIPAA Safe Harbor 45 CFR 164.514(b)(2)(i)
Names
Geographic subdivisions smaller than a state
Zip codes
Dates (birth, admission, discharge, death)
Age, if over 89
Telephone numbers
Fax numbers
E-mail addresses
Social security numbers
Medical record numbers
Health plan beneficiary numbers
Account numbers
Certificate and license numbers
Vehicle identification and serial numbers
License plate numbers
Device identifiers and serial numbers
URLs
Internet Protocol address numbers
Biometric identifiers (finger and voice prints)
Full face photos and comparable images
Any other unique identifiers

Statistical 45 CRF 164.514(b)(1)
A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable;
Determines that the risk of re-identification of the data, alone or in combination with other reasonably available data, is very small; and
Documents the methods and results.

"Limited Use" Data Set

Allowed

- Admission Dates
- Discharge Dates
- Service Dates
- Death Date
- Age (in hours, months or days)
- Age (for those over 90)
- Five Digit Zip Codes

Not Allowed

- Names
- Street Addresses
- Telephone and Fax Numbers
- e-Mail Addresses
- Social Security Numbers
- Certificate or License Numbers
- Vehicle ID and Serial Numbers
- URLs and IP Addresses
- Full Face Photos and Comparable Images
- MR numbers
- Health Plan Beneficiary Numbers
- Biometric Identifiers

Waiver and Alteration Requirements (HIPAA vs. CR)

HIPAA 45 CFR 164.512(2)(ii)

Use or disclosure involves no more than minimal risk to individuals based on the IRB or Privacy Board's evaluation of whether there is:

- An adequate plan to protect the identifiers from improper use or disclosure;
- An adequate plan to destroy the identifiers at the earliest opportunity, unless retention of identifiers is required by law or is justified by research or health issues; and
- Adequate written assurance that the PHI will not be disclosed or used except as required by law or permitted authorization;

Research could not practicably be conducted without the alteration or waiver;

Research could not practicably be conducted without access to and use of PHI;

Common Rule 45 CFR 46.116(d)

A. Research involves no more than minimal risk to subjects;

B. Waiver or alteration will not adversely affect the rights and welfare of subjects;

C. Research could not practicably be carried out without the waiver or alteration; and

D. Whenever appropriate, subjects will be provided with additional pertinent information after participation

Exceptions:

Covered entities may use and disclose PHI without authorizations, waivers, or de-identification where:

the disclosure is to a person who is subject to FDA jurisdiction and is required by FDA to:

- report adverse events;
- track products;
- enable product recalls, repairs or replacements; or
- conduct post-marketing surveillance.

the information is used in preparation for research (e.g., protocol development), provided that it does not leave the covered entity; or

the information relates to deceased individuals.

HIPAA Transition Provisions

Transition (Grandfather) Provisions for ***Research That Includes Treatment***:

For patients who sign informed consents before April 14, 2003:

- data collected *before* April 14, 2003 may be used and disclosed for research after April 14, 2003 without the need for authorizations; and
- data may be collected, used and disclosed for research *after* April 14, 2003 without the need for authorizations, provided that
- data are collected, used and disclosed in consistently with the Common Rule informed consents.

Research authorizations required for patients who sign Common Rule informed consents on or after April 14, 2003.

HIPAA Liability

Violations of HIPAA can result in:

- Civil sanctions on covered entities
- Criminal sanctions
- Interruption of data collection, use and disclosure by covered entities

Impact On Clinical Research

As a practical matter, each of the following will be required to conduct CLINICAL studies under HIPAA:

Common Rule Informed Consent to participate in the study

Written Acknowledgement from the patient that he/she has been given the Notice of Privacy Practices

HIPAA Authorization to allow use of existing medical records for research

HIPAA Authorization to allow the study site to collect, use and disclose PHI to the sponsor for research purposes

HIPAA Notice of Privacy Practices detailing covered entities' HIPAA compliant policies and procedures.

Impact On Public Health Research

As a practical matter, the following will be required to conduct non-clinical EPIDEMILOGIC and OUTCOMES research under HIPAA:

HIPAA Authorization to allow use of existing medical records for research; or

IRB Waiver of some or all of the Authorization requirements.

OR

Limited Data Set: Use of partially identifiable data under an agreement with the providing Covered Entity that binds the researcher to use and disclose the data only for research and public health purposes, and to not re-identify or contact any data subject.

Practical Implications

- More conservative IRB scrutiny of research protocols and waiver requests;
- Attempts by some research institutions to contractually impose HIPAA requirements on pharmaceutical company research sponsors;
- Increased paperwork, expense, time and difficulty in enrolling patients and administering studies; and
- Need for pre-contract consideration by research sponsors of research partner HIPAA compliance.
- Greater reluctance amongst US physicians to provide AE and pregnancy registry information to pharmaceutical companies;

HIPAA Impact Management Strategy

- Engage pharmaceutical industry research sponsors, leading research institutions, IRBs and trade associations in discussions regarding the practical impact of HIPAA on research and build consensus regarding key issues and appropriate solutions.

Questions?