HIPAA's Impact on Research and Clinical Trials

Tom Merchant, Esq., GlaxoSmithKline

Leigh-Ann Patterson, Esq., Nixon Peabody LLP

The PharmaCongress • Philadelphia, PA • November 13, 2002

Overview of Presentation

I. Privacy: Past, Present, and Future

II. How HIPAA Affects Research

A. "HIPAA 101" – in context of research

B. General Rule Governing Research – PHI may be used for research under three specific circumstances

Overview of Presentation (cont.)

C. The Three Circumstances
   1. Individual Authorization
   2. Waiver of HIPAA Authorization
   3. De-identified Data

D. Other Rules
   1. Accounting of Disclosures
   2. Use of Pre-Existing PHI

Overview of Presentation (cont.)

III. How to Incorporate HIPAA Into Your Day-to-Day Research Activities

A. What should sponsors do?

B. What should researchers do?

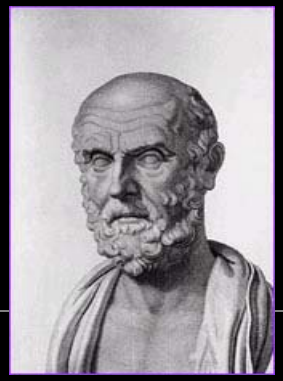
I. Privacy: Past, Present, and Future

Privacy: Past

Hippocratic Oath:

What I may see or hear in the course of the treatment …
in regard to the life of men, which on no account
one must spread abroad, I will keep to myself,
holding such things shameful to be spoken about.

Hippocrates
400 B.C.



Privacy: Present

Privacy Today

- The Common Rule
- FDA Human Subject Protection Regulations
- State Medical Confidentiality Laws

Privacy: Future

Privacy in the Future

(April 2003)

- The Common Rule
- FDA Regulations
- State Laws
- HIPAA

HHS Comment to HIPAA Privacy Rule:

"The intent of the Privacy Rule, among other things, is to supplement these protections by requiring covered entities to implement specific measures to safeguard the privacy of individually identifiable health information."

Common Rule

- IRB must determine that, when appropriate, there are adequate provisions to protect the privacy of subject and maintain the confidentiality of data.
- Informed Consent must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

FDA Human Subject Regulations

- The confidentiality of records that could identify subjects should be protected, respecting privacy and confidentiality in accordance with regulatory requirements.
- IRB must determine that, where appropriate, there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data.

HIPAA Builds Upon Existing Regulations

- Express authorization for use of PHI for research purposes
- Specific requirements for valid HIPAA Authorization
- Different standards of what data is sufficiently de-identified

II. How HIPAA Affects Research

"HIPAA 101"

- General Rule:

  Personal health information may not be used or disclosed without patient authorization.

"HIPAA 101" (cont.)

1. Who is covered?
2. What information is covered?
3. How does HIPAA define "research"?

1. Who is covered by HIPAA?

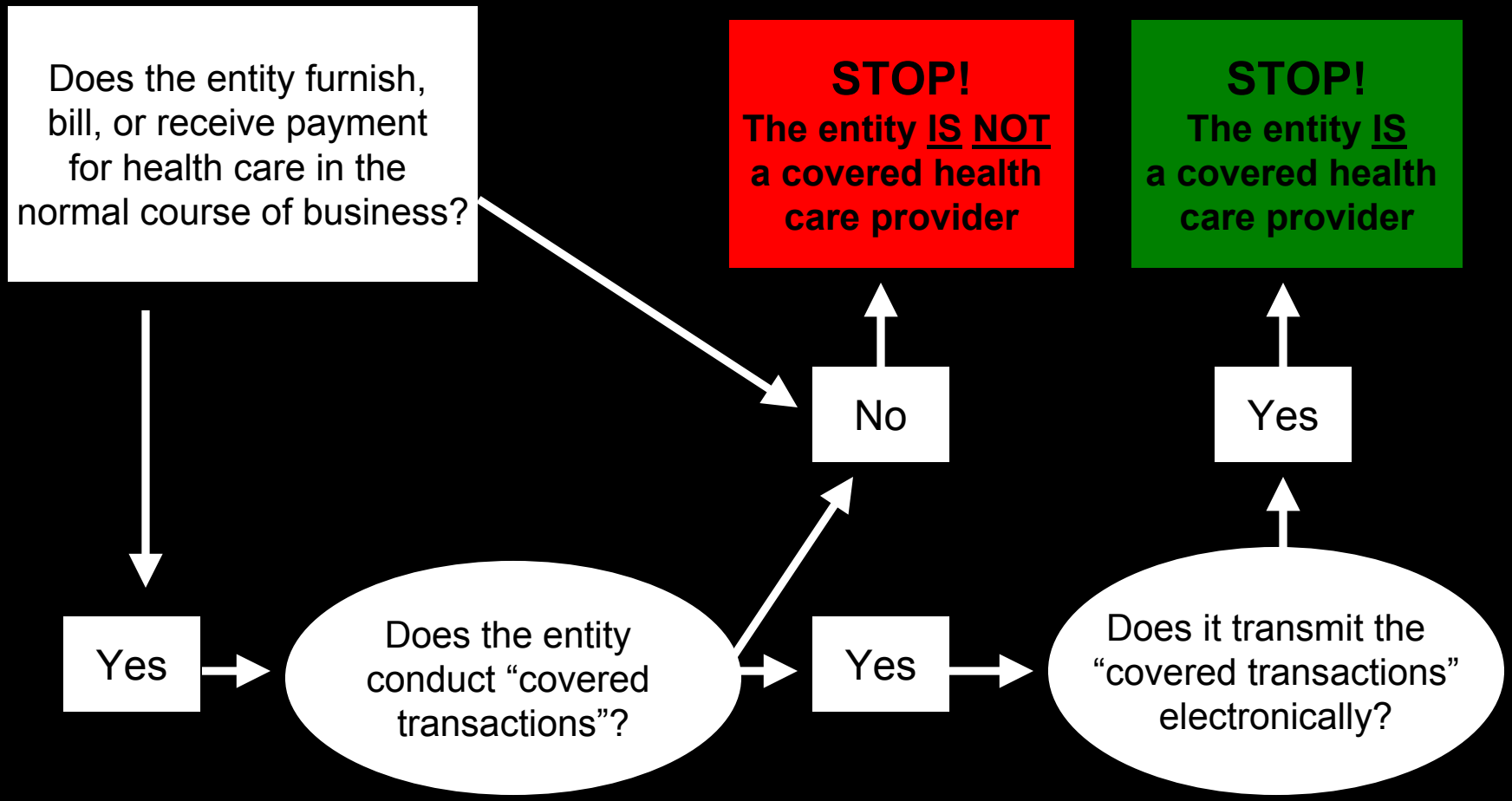
   - "Covered entities" are defined as:
     (a) Health plan
     (b) Health care clearinghouse
     (c) Health care provider

   - Who is a "covered entity" in the context of research and clinical studies?
     – Typically those in "health care provider" category

- How to determine if you fall into the “health care provider” category?
  - Use CMS’s “health care provider flow chart” on its web site
  - This site has “decision tools” and “covered entity charts”

http://www.cms.hhs.gov/hipaa/hipaa2/support/tools/decisionsupport/default.asp

CMS's "health care provider flow chart"



HOT TOPIC

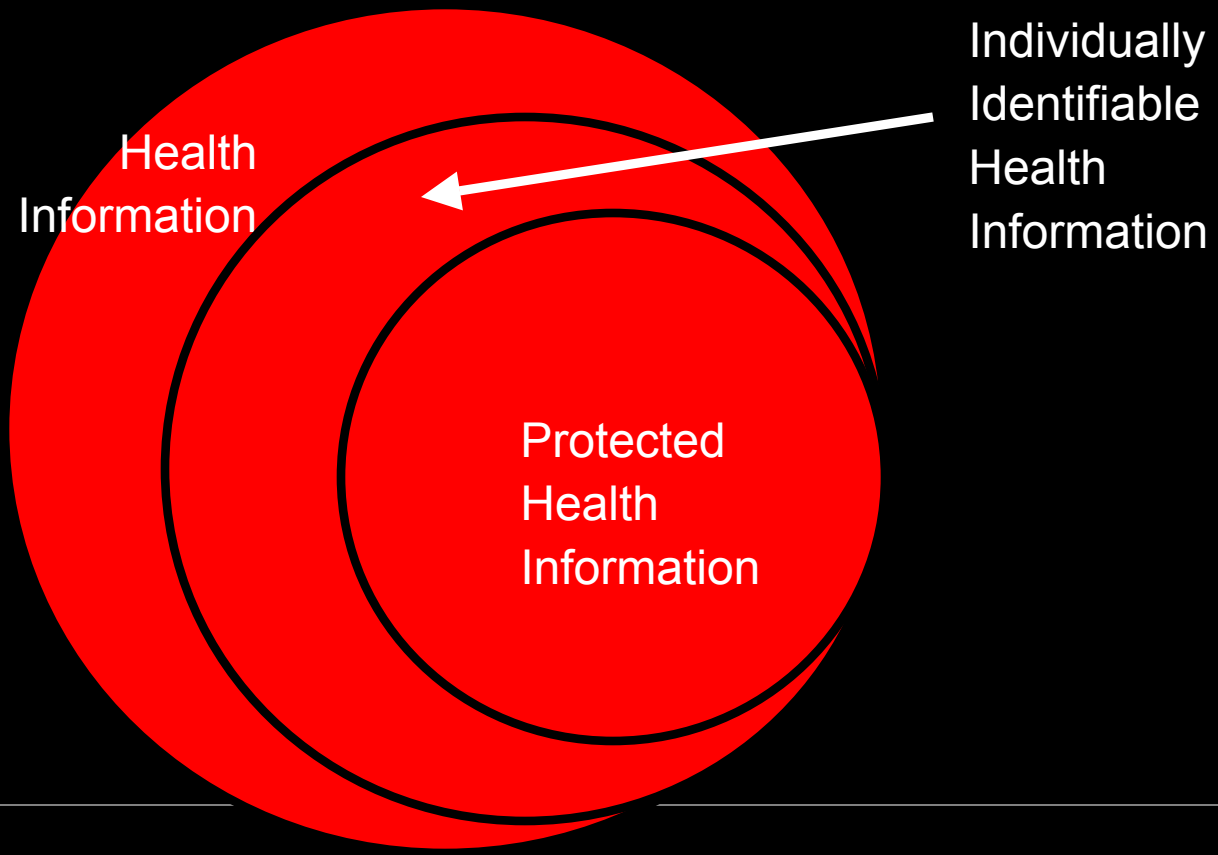
- Do pharmaceutical companies ever qualify as “health care providers”?
    - Privacy rule recognizes situations in which the answer is “yes”

ANOTHER HOT TOPIC

- Are pharmaceutical companies who sponsor clinical trials the “business associates” of the site/investigators?
  - Depends on what the company does in a particular study
  - Depends on who you ask

2. What information is covered by HIPAA?

PHI, which is a subset of IIHI, which is a subset of HI



3. How does HIPAA define “research”?

- Same as Common Rule
- A “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”

HIPAA's General Rule Covering Research

Covered entities may only use or disclose PHI for research purposes in three circumstances.

Three circumstances:

1. Individual Authorization
2. Waiver of Authorization
3. De-identified data and "limited data sets"

1. Individual Authorization

The Rule: PHI may be used for research if individual authorization is obtained from the subject.

Requirements for valid HIPAA Authorization:

- 6 “core elements” PLUS
- 3 additional “statements” PLUS
- Authorization is written in plain language PLUS
- Give subject signed copy of Authorization

The Six "Core Elements"

1. Describe type of PHI to be used in the study
2. Describe the person or class of people who can use the PHI (consider identifying pharma here)
3. Describe the person or class of people to whom the PHI may be disclosed (consider identifying pharma)
4. Describe the purpose of the use or disclosure
5. State whether or not there is an expiration date
6. Have the subject sign and date Authorization

The Three Additional Mandatory "Statements"

Must tell the subject:

1. About the right to revoke the authorization
2. Whether treatment, payment, enrollment or eligibility for benefits is conditioned on giving the authorization
    a. Sometimes permissible
    b. Sometimes not
3. About the potential for re-disclosure by authorized recipient; then no protection

- Plain language requirement – Write the Authorization in plain English using easy-to -understand words.

- Copy to individual – Covered entity must provide the individual with a copy of the signed authorization.

Notable changes from prior version of Rule

- New Rule eliminates distinction between research-related treatment and other forms of research.
- New Rule eliminates separate authorization requirement.
- New Rule eliminates expiration requirement.

2. Waiver of Authorization

The Rule: PHI may be used for research without Individual Authorization from the subject if you obtain waiver of HIPAA Authorization from IRB or HIPAA Privacy Board.

Waiver Criteria in Final Rule

1. Use or disclosure of PHI in research involves only “minimal risk” to individual’s privacy.
2. Research couldn’t “practicably” be conducted without waiver.
3. Research couldn’t “practicably” be conducted without access to this particular PHI.

- “Minimum necessary” requirement applies to use of PHI in study.
- Note: “Minimum necessary” requirement does not apply when acting pursuant to an authorization.

3. De-Identified Data and Limited Data Sets

- The Rule: PHI may be used for research without obtaining HIPAA authorization from subject if the PHI is properly de-identified.

When does HIPAA consider data properly “de-identified”?

1. When it doesn’t identify an individual (no key to re-identify)
2. When there is no reason to believe recipient could identify individual alone or in combination with other information

Two ways to make the de-identification determination:

1. Have statistician do it, or
2. Remove all 18 specific identifiers (this creates a presumption of de-identification)

Does a covered entity need authorization in order to remove the specific identifiers and create de-identified data?

- Criticisms of de-identification standard – data is virtually useless!
  - Leads to more waiver requests, which leads to the paradoxical effect of disclosing more PHI than if researcher had used de-identified data.
  - HHS created “limited data sets” to address this paradoxical effect.

- Limited Data Set
    - Special data set that doesn’t include certain direct identifiers
    - Does include zip codes, geocodes and DOB

- Limited Data Set (cont.)
  - May only be used for research, public health, and health care operations
  - Must have Data Use Agreement
  - Subject to “minimum necessary”

How HIPAA Relates to FDA Regulations

HIPAA's Privacy Rule does not override the Common Rule or FDA's Human Subjects Regulations.

Other Aspects of Research Affected by HIPAA

Accounting for Research Disclosures

Accounting for Research Disclosures

- When required
- When not required
- New simplified accounting procedures when research involves more than 50 subjects (e.g., large database research)

Other Aspects of Research Affected by HIPAA

Grandfather Provision for Pre-Existing PHI

Use of Pre-Existing PHI

- A change from prior version of rule
  - Now there is no distinction among various types of legal permission for research use of PHI

Use of Pre-Existing PHI (cont.)

- What is the significance of this change?
- Allows researchers to rely upon any type of legal permission to continue using pre-existing PHI in their possession after April 2003 (i.e., they don't need to re-consent subjects to continue to use PHI).

Use of Pre-Existing PHI (cont.)

- But if you never obtained any legal permission before, then you must obtain authorization (or waiver of authorization) to continue using pre-existing PHI after April 2003.

Uses and Disclosures Regarding FDA Regulated Products and Activities

- Rule: No HIPAA Authorization is required to disclose PHI to a "person subject to the jurisdiction of the [FDA]" for public health purposes related to the quality, safety, or effectiveness of FDA regulated products or activities.

Who is a “person subject to the jurisdiction of the [FDA]”?

- Final rule makes this clear
- Includes manufacturers of FDA regulated drugs and devices that have reporting obligations

What are “quality, safety, or effectiveness” purposes?

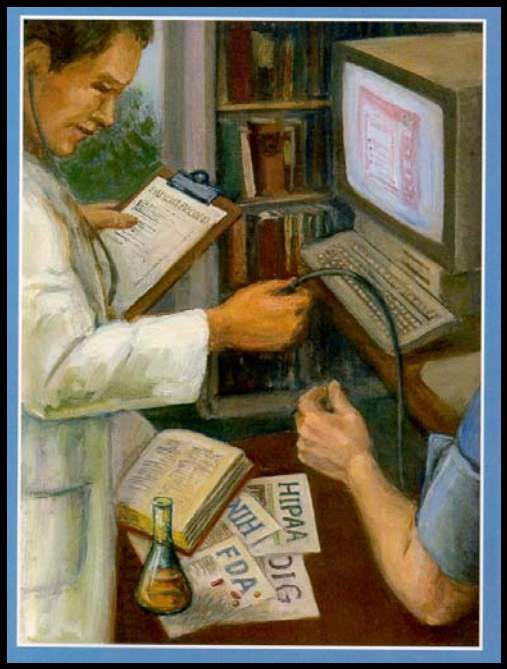
- Reporting adverse events
- Post-market surveillance of products
- Product tracking
- Recalling dangerous or defective products

An example of what is not a “quality, safety, or effectiveness” purpose

- Evaluating effectiveness of pharma’s marketing program

- All disclosures under the “FDA regulated products or activities” exception are subject to the “minimum necessary” requirement.

III. How to Incorporate HIPAA Into Your Day-To-Day Research



- What should sponsors do?
- What should other researchers do?

What Should Sponsors Do?

- Protect PHI
- Assure IRB Investigator
- Education and awareness efforts
- Amend clinical study documents

Which Documents Might Need To Be Amended?

- Clinical Study Agreement Template
- Informed Consent Template
- SOPs:
  - Informed Consent
  - Preparation of Case Report Forms
  - Corporate Privacy Policy
- Clinical Investigator Agreement Template
- CRO Agreements

What Should Researchers Do?

- Epidemiology/Outcomes Research
  - Assure records are de-identified or
  - Use limited data set with data use agreement
  - Also assure there is no other HIPAA violation

- Post-Marketing Surveillance
  - Expect refusals to supply Adverse Event information
  - The Rule not intended to hinder safety monitoring
  - Expect to be subject to "minimum necessary“ requirement

IV. Questions

How to Reach Us

Leigh-Ann Patterson, Esq.

Boston • 617-345-1258

New York City • 212-940-3000

lpatterson@nixonpeabody.com

Tom Merchant, Esq.

Philadelphia • 610-787-3620

thomas.e.merchant@gsk.com