

HIPAA Privacy for Pharma

Audioconference

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Faculty

Bill Braithwaite, MD, PhD, Director in National HIPAA Practice
PricewaterhouseCoopers LLP
Washington, DC
bill.braithwaite@us.pwcglobal.com

Julie Kaneshiro, Senior Policy Analyst
HHS Office for Human Research Protections
Rockville, MD
jakaneshiro@osophs.dhhs.gov

Kevin D. Lyles, Esq., Partner
Jones, Day, Reavis & Pogue
Columbus, OH
kdlyles@jonesday.com

Jean-Paul Hepp, PhD, Director, Global Privacy
Pharmacia Corporation
Peapack, NJ
jeanpaul.hepp@pharmacia.com

Audioconference Agenda

1:00 pm Introduction

1:05 pm Overview (Bill)

**1:10 pm Update on Privacy and the
Impact on the Pharmaceutical Sector (Bill)**

1:20 pm Impact of HIPAA on Clinical Research (Julie)

**1:40 pm Business Associates and other Legal Issues
(Kevin)**

1:55 pm The Privacy Officers Perspective (Jean Paul)

2:10 pm Questions for the Panel

2:30 pm Adjournment

Overview of Audioconference

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webmaster@HIPAASummit.com

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Update on HIPAA Privacy



HIPAA Requirements for Privacy

“Standards with respect to the privacy of individually identifiable health information ...”

- Final Rule published 12/28/2000
- Guidance issued 7/6/01.
- Compliance required 4/14/2003.
- Modifications proposed in NPRM 3/27/02.
 - Proposals decrease administrative burden on providers.
 - No change in compliance date.
 - Final rule with modifications expected by October 2002.

5 Principles of Fair Info Practices

Openness

- Existence and purpose of record-keeping systems must be publicly known.

Individual Participation

- Individual right to see records and assure quality of information.
 - accurate, complete, and timely.

Security

- Reasonable safeguards for confidentiality, integrity, and availability of information.

Accountability

- Violations result in reasonable penalties and mitigation.

Limits on Collection, Use, and Disclosure of Information:

- Collected only with knowledge and permission of subject.
- Used only in ways relevant to the purpose for which the data was collected.
- Disclosed only with permission of subject or legal authority.

Rule #1: Don't surprise the patient!!!



Key Points in Privacy Rules

Required disclosures are limited to:

- Disclosures to the individual who is the subject of information.
- Disclosures to OCR to determine compliance.

All other uses and disclosures in the Rule are permissive; i.e., information may be used only if specifically allowed in the rules.

Covered entities can provide greater protections if they want (for competitive edge).

Uses and Disclosures Allowed:

For Treatment, Payment, & Healthcare Operations (TPO) under prior written consent.

Pursuant to and in compliance with a written, revocable authorization.

For directory and involvement in care purposes

- where individual has the opportunity to agree to or prohibit or restrict the use or disclosure.

For specific listed and controlled purposes generally in the public interest

- required by law, public health, abuse, oversight, law enforcement, threats, research, ...

Individual's Rights

Individuals have the right to:

- A written notice of information practices from health plans and providers.
- Inspect and obtain a copy of their PHI.
- Obtain an accounting of disclosures.
- Amend their records.
- Request restrictions on uses and disclosures.
- Accommodation of reasonable communication requests.
- Complain to the covered entity and to HHS.

Administrative Requirements

Flexible & scalable.

Good structure for privacy program.

Covered entities are required to:

- Designate a privacy official.
- Develop policies and procedures (P&P)
 - including for receiving requests for restrictions & complaints.
- Provide privacy training on those P&P to its workforce.
- Develop a system of sanctions for employees who violate the entity's policies.
- Meet documentation requirements.

Privacy NPRM Proposed Modifications

- A. Uses and Disclosures for Treatment, Payment, and Health Care Operations
 - 1. **Consent**
 - 2. Disclosures for treatment, payment, or health care operations of another entity
- B. Notice of Privacy Practices for Protected Health Information
- C. Minimum Necessary and Oral Communications
- D. **Business Associates**
- E. Uses and Disclosures of Protected Health Information for **Marketing**
- F. Parents as Personal Representatives of Unemancipated Minors
- G. Uses and Disclosures for **Research** Purposes
 - 1. Institutional Review Board (IRB) or Privacy Board Approval of a Waiver of Authorization
 - 2. Research Authorizations
 - 3. Research Transition Provisions
- H. Uses and Disclosures For Which Authorization Is Required
- I. **De-Identification** of Protected Health Information
- J. Technical Corrections and Other Clarifications

General Impact of HIPAA Privacy

No Single Standard for Privacy

- HIPAA preempts or supercedes all “contrary” state laws.
- Exceptions:
 - HHS determination that State law accomplishes social responsibilities (fraud & abuse, industry oversight, health & safety).
 - Public health reporting.
 - State privacy law that has:
 - More restrictive use/disclosure rules.
 - Greater rights for individuals.
- HIPAA is a national floor for privacy.
- Different privacy environment in each state.
 - No ERISA preemption

May Exacerbate Liability

- HIPAA raises industry’s “standard of care” in tort claims.
- New contractual and consumer protection theories based on
 - the terms of HIPAA,
 - Gramm-Leach-Bliley and
 - internet notices, policies, procedures, and authorizations.
- HIPAA increases awareness, media coverage and enforcement of a complex patchwork of laws, rules and standards.
 - forces everyone to get control of their channels through which individual health information flows.

Impact on Pharmaceutical Sector

Availability of Information for Research

- New rules for clinical research, IRBs, de-identification
- Fear of liability may limit willingness of information providers

Pharmacy Benefit Manager (Clearinghouse or BA)

- Limits on what can be done with PHI

Limits on Information for Marketing to Patients

- Patients may have to be told when communications are remunerated.

Employer Health Benefit Plans (ERISA)

- May need to make changes as HIPAA covered entities

Resources

Administrative Simplification Web Site:

- <http://aspe.hhs.gov/admnsimp/>
 - posting of law, process, regulations, and comments.
- instructions to join Listserv to receive e-mail notification of events related to HIPAA regulations.
- submission of rule interpretation questions.

National Committee on Vital and Health Statistics

- ncvhs.hhs.gov

Centers for Medicare and Medicaid Services

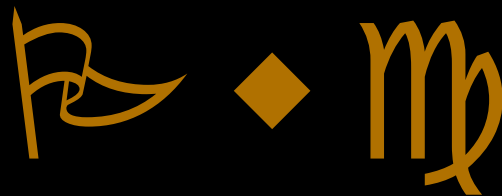
- www.cms.hhs.gov/hipaa/

Workgroup on Electronic Data Interchange

- www.wedi.org
- snip.wedi.org



William.R.Braithwaite@US.PwCglobal.com



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