

Final PRIVACY RULE

Presentation by
Richard Campanelli, Director OCR/HHS
at
5th National HIPAA Summit
Washington, D.C.
October 31, 2002

Some of the Key Modifications to the Privacy Rule: August 14, 2002

- Consent made voluntary & notice strengthened
- Clearer rules for marketing uses of information
- Permits incidental uses and disclosures with reasonable safeguards
- Facilitates research activities
- Simplifies and consolidates authorization requirements
- Continues reporting of adverse events related to FDA regulated products/activities
- Defers to state law on parental access to medical information of minors
- Gives covered entities up to an additional year to conform business associate contracts

OCR HIPAA Privacy Resources

- Available at: <http://www.hhs.gov/ocr/hipaa/>
- Resources include:
 - Complete Privacy Rule Text, as modified
 - Fact Sheets and Press Releases on modifications
 - Frequently Asked Questions about the Privacy Rule
 - Sample Business Associate Contract Provisions

Privacy Rule Modifications

Uses and Disclosures for Treatment, Payment and Health Care Operations (TPO)

- Consent no longer mandated, but is permitted
 - Voluntary consent permits providers to retain existing consent mechanisms
- PHI sharing allowed for treatment, payment, and quality related health care operations of others
- Strengthened notice and right to request restrictions maintain values public attributed to consent

Privacy Rule Modifications

Notice

- Notice strengthened by requiring direct treatment providers to make good faith effort to get acknowledgement of receipt of notice
 - preserves “initial moment” to discuss privacy issues
 - emergency exception to good faith effort
- Otherwise retains Notice of information practices and individual rights at first service delivery for direct treatment providers

Privacy Rule Modifications

Marketing Definition (1)

➤ MARKETING IS:

- to make a communication that encourages a person to purchase or use a product or service

➤ MARKETING IS ALSO:

- Arrangements where covered entity is paid to disclose PHI to a 3rd party for that party to market its own products or services directly to individuals

➤ Authorization is always required for marketing, unless

- Communication is face-to-face or involves promotional gifts of nominal value

Privacy Rule Modifications

Marketing Definition (2)

➤ MARKETING IS NOT a communication about :

- A covered entity's own health-related products and services
- The individual's treatment
- Care coordination, case management, or recommending treatment alternatives for an individual

➤ Eliminates remuneration as condition for these exceptions

Privacy Rule Modifications

Incidental Disclosures

- Adds express permission to use/disclose PHI that is incidental to an otherwise permitted use or disclosure, provided minimum necessary and safeguard standards are met
 - Allows for common practices if reasonably performed
 - **Examples:** Talking to patient in semi-private room;
Talking to other providers if passers-by are present;
Waiting room sign in sheets;
Patient chart at bedside, etc.

Privacy Rule

Compliance and Enforcement

Privacy Rule

Compliance and Enforcement

- Technical Assistance from OCR/HHS
 - FAQs
 - Privacy Rule Guidance
 - Sample Business Associate Contract Provisions
 - Technical assistance for targeted audiences, including patients
 - OCR website: <http://www.hhs.gov/ocr/hipaa/>
 - Public education – conferences, seminars
 - Secretary's Regional HIPAA Conferences

Privacy Rule

Standards for Civil Money Penalties

- CMPs may be imposed on a “person who violates a provision of this part.”
- CMPs may not be more than –
 - \$100/violation
 - \$25,000/calendar year/same violation
- CMPs may not be imposed if –
 - The act is punishable as criminal offense
 - HHS determines that the person “did not know, and by exercising reasonable diligence would not have known” of the violation, or
 - The failure to comply was due to reasonable cause and not willful neglect and is corrected in the 30-day cure period (or longer period as determined by Secretary)