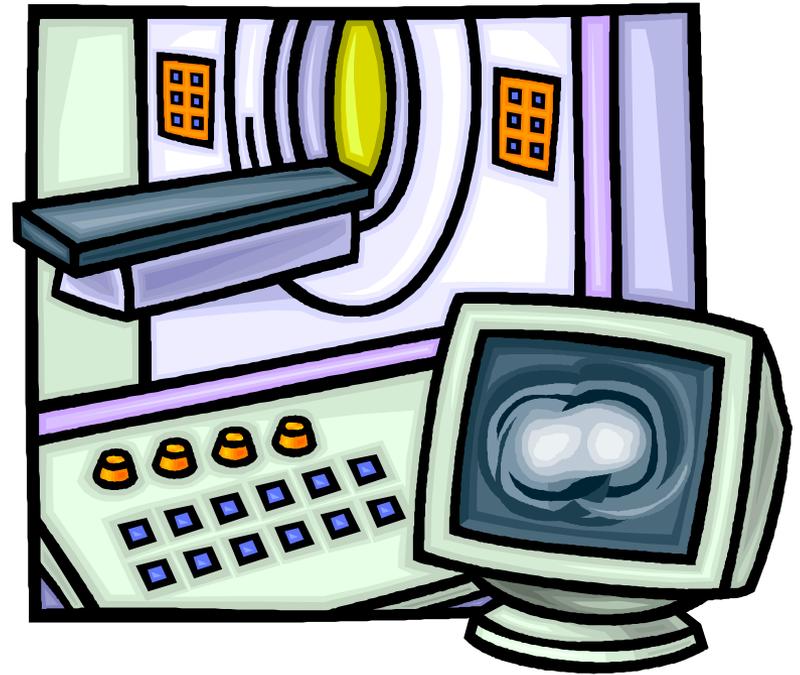


HIPAA Privacy Rule



Positive Changes Affecting Hospitals' Implementation of the Rule

Melinda Hatton -- Oct. 31, 2002

The Final Rule: Changes

The purpose . . . is to **maintain strong protections for the privacy** of individually identifiable health information while clarifying certain of the Privacy Rule's provisions, **addressing the unintended negative effects** of the Privacy Rule on health care quality or access to health care, **and relieving unintended administrative burdens** created by the Privacy Rule.



Final Rule, August 14, 2002

The Final Rule: Positive Changes for Hospitals

- **Written** acknowledgment replaces written consent
- Disclosure allowed **for other covered entities'** treatment, payment and *some* health care operations
- **Incidental disclosures** are *not* privacy rule violations
- **Authorized disclosures exempt from accounting** requirement

The Final Rule: Positive Changes for Hospitals (cont.)

- **Business associate compliance delayed** for up to one year for certain existing contracts
- Creation of **limited data set and clarification of de-identification** safe harbor

Written acknowledgment replaces written consent

“The notice acknowledgment process is intended **to alert individuals to the importance of the notice** and **provide** them the **opportunity to discuss privacy** issues with their providers.”

- Flexibility in designing the process
- Good faith effort required (HHS’s promise re “good faith”: future guidance through FAQs or other materials in response to specific scenarios raised by field)
- Not required in emergency situations
- Option to get consent remains and providers have “complete discretion in designing the consent process”

Disclosures allowed **for other covered entities'** treatment, payment and *some* health care operations

“The proposal would **broaden the uses and disclosures** that are permitted without authorization **as part of treatment, payment, and health care operations so as not to interfere inappropriately with access to quality and effective health care, while limiting this expansion** in order to continue **to protect** the **privacy** expectations of the individual.”

- PHI must pertain to the relationship
- Allowed where other covered entity's relationship is *past* relationship
- Limits scope of health care operations of other covered entity for which PHI may be so used or disclosed
- Allows disclosures to or by a business associate

Incidental disclosures are *not* privacy rule violations

“The Privacy Rule **must not impede essential health care communications** and practices. **Prohibiting all incidental uses and disclosures would have a chilling effect on** normal and **important communications** among providers, and between providers and their patients, **and**, therefore, **would negatively affect individuals’ access to quality health care.**”

- Secondary use or disclosure that cannot reasonably be prevented, is limited in nature, and that occurs as a by-product of an otherwise permitted use or disclosure
- Any permissible use or disclosure made to any person
- Must still apply appropriate safeguards (§164.530(c)), and minimum necessary requirements (§§164.502(b),164.514(d))
- No need to include in accounting of disclosures

Authorized disclosures exempt from accounting requirement

“[A]ccounting for authorized disclosures **d[oes] not serve to add to the individual’s knowledge** about disclosures of protected health information.”

- Also exempt from minimum necessary requirements

Business associate compliance delayed for up to one year for certain existing contracts

“The transition provisions are **intended to address the concerns** . . . that the **two-year period** between the effective date and compliance date . . . **is insufficient to** reopen and **renegotiate all existing contracts** . . . [to] bring[] them into compliance with the Rule. These provisions **also provide** covered entities with **added flexibility to incorporate** the business associate contract **requirements at the time they would otherwise** modify or **renew** the existing contract.”

- Must be a writing prior to effective date of modification
- Applies only to those not renewed or modified prior to the April 14, 2003
- New model language provided

Business associate compliance delayed for up to one year for certain existing contracts

- Not relieved of the responsibilities:
 - to make information held by a business associate available to the Secretary
 - respecting individual's rights (access, amend, accounting of disclosures)
- Required to mitigate, to the extent practicable, any harmful effect known of a use or disclosure of protected health information by its business associate (§164.530(f))

Creation of **limited data set** and clarification of **de-identification** safe harbor

“We have created **the limited data set** option because we believe that this mechanism **provides a way to allow important research, public health and health care operations activities** to continue in a manner **consistent with the privacy protections** of the Rule.”

- AHA has called for creation of a limited data set of “facially de-identified” data (admission and discharge dates, service dates, date of death, age, 5-digit zip codes)
- expressly excepted from the listed safe harbor identifiers re-identification code or other means of record identification permitted by §164.514(c) Now includes age

The Final Rule: Some Disappointments

- Fundraising restrictions remain unchanged
- Business associate agreement still required between two covered entities
- HHS declines to provide a business associate certification process
- Sample business associate agreement continues to include some optional provisions that hospitals *may not want to include* in their business associate agreements

The Final Rule: Some Disappointments (cont.)

- No mitigation for covered entities' liability and individual rights obligations with regard to their business associates during “deemed compliance” period
- HHS declines to exempt disclosures for public health and health oversight purposes from the accounting of disclosures requirement

Compliance = April 14, 2003

- AHA urging phase-in of enforcement
 - First 2 years after compliance date
 - HHS to focus on education and technical assistance, not fines and penalties
- Congressional interest in phase-in approach
 - Letter from Rep. Hobson (R-OH) to HHS Secretary Thompson dated July 15, 2002

A Word on the Security Rule

- Currently proposed only
- HHS's *latest* promise on publication: October 2002
- No potential conflict between of privacy and security requirements (Preamble, Final Rule, August 14, 2002)
 - Security Rule will apply only to electronic health information systems
 - HHS, in preparing final Security Rule, is working to ensure it works “hand in glove” with Privacy Rule requirements