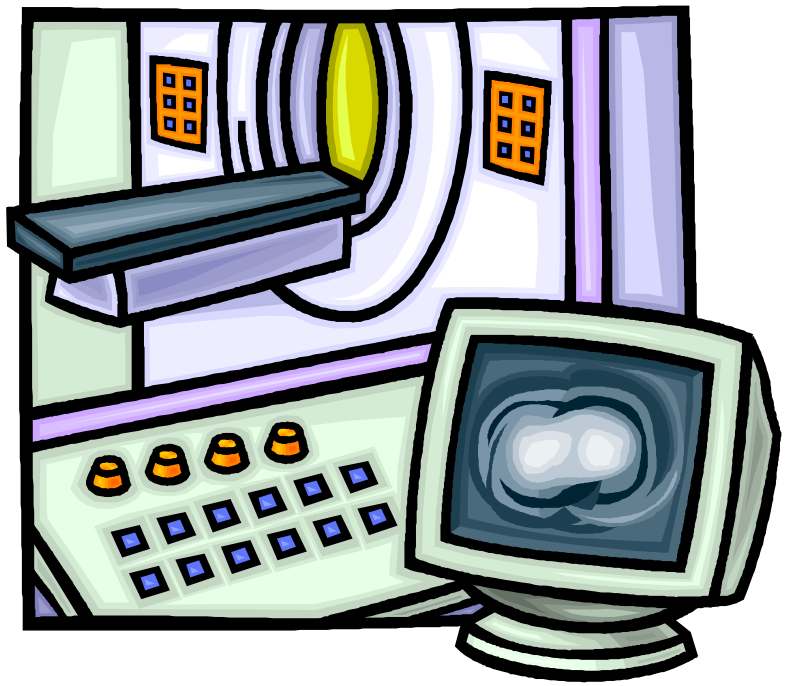
HIPAA Privacy Rule



Positive Changes Affecting Hospitals' Implementation of the Rule

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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

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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

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

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

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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"

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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

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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

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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

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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."

- Limited data set of "facially de-identified" data (admission and discharge dates, service dates, date of death, date of birth, 5-digit zip codes)
- Requires "data use agreement" with recipient of data
- Re-identification codes or other means of record identification permitted by §164.514(c) expressly excepted from the listed safe harbor identifiers
- Age now may be in months, days and hours

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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 (other than automatically) or modified between 10/14/02 and 4/14/04
- New sample language provided

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Business associate compliance delayed for up to one year for certain existing contracts (cont.)

- 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))

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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 language continues to include some optional provisions that hospitals *may not want to include* in their business associate agreements

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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

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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

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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

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