United States Department of Health & Human Services
Office of the Secretary
Office for Civil Rights (OCR)

HIPAA Omnibus Final Rule and Research

Federal Demonstration Partnership

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Omnibus Rule

- Final Rule on HITECH Privacy, Security, & Enforcement Provisions (and certain non-HITECH changes) (proposed rule published July 2010)
- Final Rule on new HITECH CMP Structure (interim final rule published Oct. 2009)
- Final Rule on HITECH Breach Notification (interim final rule published Aug. 2009)
- Final Rule on GINA Privacy Provisions (proposed rule published Oct. 2009)

Omnibus Components

- **HITECH Privacy & Security**
  - Business associates
  - Marketing & Fundraising
  - Sale of PHI
  - Right to request restrictions
  - Electronic access
- **HITECH Breach Notification**
- **HITECH Enforcement**
- **GINA Privacy**
- **Other (non-statutory) Modifications**
  - Research authorizations
  - Notice of privacy practices (NPP)
  - Decedents
  - Student immunizations

Today's Focus

- Compound authorizations for research
- Authorizations for future research
- Period of protection for decedents
- Sale of protected health information (PHI)
- Breach notification
- Business associates (BA)

Important Dates

- Published in Federal Register – January 25, 2013
- Effective Date – March 26, 2013
- Compliance Date – September 23, 2013
- Transition Period to Conform BA Contracts – Up to September 22, 2014, for Qualifying Contracts

Compound Authorizations – Old Rule

- Not permitted for use/disclosure of PHI for conditioned and unconditioned research activities (e.g., separate authorization forms required for use/disclosure of PHI in a clinical trial and storage of PHI in a biorepository)

Compound Authorizations – New Rule

- Single authorization form permitted for use/disclosure of PHI for conditioned and unconditioned research activities, with clear opt in for voluntary (unconditioned) component
- Flexibility permitted on ways to differentiate the components
- Better aligns with Common Rule informed consent requirements

Future Use Authorizations – Old Rule

- Not permitted – authorizations for research must include descriptions that are study specific

Future Use Authorizations – New Rule

- Permitted if authorization has adequate description such that it would be reasonable for the individual to expect his/her PHI could be used for the research
- Better aligns with Common Rule informed consent requirements

Decedent Information

- Old Rule
  - Health information about decedents generally protected in same manner/extent than that of living individuals
- New Rule
  - Decedent's information is no longer PHI after 50-year period

Sale of PHI – Old Rule

- Covered entities prohibited from “selling” patient information; however, no general prohibition on receiving remuneration for disclosure of PHI that is otherwise permissible

Sale of PHI – New Rule

- Even where disclosure is permitted, CE is prohibited from disclosing PHI (without individual authorization) in exchange for remuneration
- If authorization obtained, authorization must state that disclosure will result in remuneration
- Limited research exception – remuneration must be limited to cost to prepare and transmit PHI

Definition of Breach – Old Rule

- Impermissible use or disclosure of (unsecured) PHI which compromises the security or privacy of the information
  - Compromises means poses a significant risk of financial, reputational, or other harm to the individual
- To determine if must notify, preamble stated CE/BA must perform risk assessment, based on at least:
  - What type or amount of PHI was used or disclosed
  - Who received/accessed the information
  - Potential that PHI was actually accessed or acquired
  - What steps were taken to mitigate
- Exceptions for inadvertent, harmless mistakes
- Narrow exception for limited data sets without dates of birth & zip codes

Definition of Breach – New Rule

- Harm standard removed
- New standard – impermissible use/disclosure of (unsecured) PHI *presumed* to require notification, unless CE/BA can demonstrate low probability that PHI has been compromised based on risk assessment of at least:
  - Nature & extent of PHI involved
  - Who received/accessed the information
  - Potential that PHI was actually acquired or viewed
  - Extent to which risk to the data has been mitigated

Definition of Breach – New Rule

- Exceptions for inadvertent, harmless mistakes remain
- Exception for limited data sets without dates of birth & zip codes removed

Business Associates – Old Rule

- Covered entities may disclose PHI to BAs provided there is a contract in place to protect the information
- No direct liability on BAs for misuse of information or lack of safeguards
- Researchers not BAs by virtue of research activities (although they may become BAs in some other capacity)

Business Associates – New Rule

- BAs must comply with the technical, administrative, and physical safeguard requirements under the Security Rule; directly liable for violations
- BAs must comply with the use or disclosure limitations expressed in BA contract and those in the Privacy Rule; directly liable for violations
- Subcontractors of BA are now defined as BAs
  - BA liability flows to all subcontractors
- Researchers still not considered BAs by virtue of research activities
  - Preamble also clarifies that IRBs are not BAs by virtue of their research review, approval, and oversight functions

Guidance/Compliance Tools

- De-identification Guidance

  http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html

- Sample Business Associate Contract Language

  http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html

- Risk Analysis Guidance

  http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidance.html

- Security for Mobile Devices (video/web)

  http://www.healthit.gov/mobiledevices

Guidance/Compliance Tools What's in the Works

- Fact Sheets/Q&A on New Provisions
  - Includes research-specific materials
- Breach Risk Assessment Tool
- Minimum Necessary Guidance
- Expanded Consumer Materials/Videos

For More Information

www.hhs.gov/ocr/privacy/