


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

Office for Civil Rights: Update on Privacy Regulations

ONC Grantee Meeting
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Adam Greene, JD, MPH
Senior Health IT and Privacy Specialist



Current OCR Rulemaking

- Breach Notification Rule
- Enforcement Rule
- HIPAA Genetic Information
Nondiscrimination Act (GINA) Rule
- HIPAA HITECH Rule
- Accounting of Disclosures Rule

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Breach Notification Rule

- Applies to HIPAA covered entities and business associates
- Interim final rule currently in effect (published August 2009)
- Requires notification to individuals, HHS, and media (large breaches only)
- Will be finalized in 2011

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Enforcement Rule

- Increased penalties in accordance with the HITECH Act
- Interim final rule currently in effect (published October 2009)
- Will be finalized in 2011

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GINA Rule

- Genetic Information Nondiscrimination Act of 2008
- Notice of proposed rulemaking (NPRM) in October 2009
- Will be finalized in 2011

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HITECH Rule

- Implements most HITECH changes to HIPAA
- Notice of proposed rulemaking (NPRM) in July 2010
- Will be finalized in 2011
 - Breach notification, GINA, Enforcement, and HITECH Rule will be finalized together

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HITECH Rule

- Business associates
 - Direct liability
 - Subcontractors
 - Clarification of HIOs, E-Prescribing Gateways, PHRs
- Enforcement
 - Willful neglect
 - Definition of reasonable cause

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HITECH Rule

- Marketing
- Fundraising
- Sale of PHI
- Right to request restrictions
- Minimum necessary (request for comments)
- Electronic access

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HITECH Rule

- Notice of privacy practices
- Research authorizations
- Student immunization records
- Decedent information
 - Limit protections to 50 years
 - Clarify communications with friends and family

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Accounting of Disclosures Rule

- Expands HIPAA accounting of disclosures
 - Adds treatment, payment, health care operations disclosures through EHR
 - Balance interest of individuals with burden on covered entities
- HITECH requires rule after initial standards for EHRs
- Proposed rule will be published in 2011
- Will be finalized separately from other HITECH rules

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Upcoming OCR Activities

- Report to Congress on Breach Notification
 - CY 2009
 - Information on large and small breaches
- Report to Congress on Enforcement
 - Aggregate and CY 2009 enforcement data

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Upcoming OCR Activities

- National Outreach Campaign with ONC
 - Digital Toolkit of Consumer Materials
 - Backgrounders with general information
 - Fact Sheets on specific topics
 - Videos on privacy and security topics
 - Train-the-Trainer PowerPoint slides

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Upcoming OCR Activities

- National Outreach Campaign with ONC
 - Community Discussions
 - Engage with consumers and consumer organizations on EHRs, privacy, and security
 - Atlanta, Chicago, San Antonio, San Francisco, Spokane, Philadelphia

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Upcoming OCR Activities

- HIPAA Audit Program
 - Addition to complaint and compliance review process
 - Reviewing effectiveness of various audit models
- State Attorneys General Training
 - Education on HIPAA
 - Coordination

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Upcoming OCR Activities

- Minimum Necessary Guidance
 - Requested comments in NPRM
 - Sunsets limited data set language of HITECH Act
- De-identification Guidance
 - Convened workshop
 - Clarify how to assure that PHI is de-identified

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Want more information?

The OCR website:

<http://www.hhs.gov/ocr/privacy/>

My contact:

adam.greene@hhs.gov

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