

DON'T MISS THE HIPAA "OMNIBUS"

Practical Strategies for Complying with the HIPAA-HITECH Regulations



AGENDA

11:45 am CT Attendees Sign On

12:00 pm CT Webinar

1:00 pm CT Questions and Answers

Asking Questions

Throughout the webinar, e-mail your questions to

npozgay@reinhardtlaw.com

We will answer as many questions as possible during our Q & A session at the end of the webinar

Robert J. Heath is a shareholder in the firm's Health Care Practice and serves as chair of the Long-Term Care Facilities, Assisted Living and Senior Housing Practice Group within the Health Care Department. His practice stresses general corporate, transactional and regulatory representation of health care providers, with a special emphasis on legal issues as they affect long-term care assisted living and independent living facilities. He provides legal counsel in all areas of health care law including health care acquisitions and mergers, joint ventures, managed care law and health care-related administrative law matters.



Heather L. Fields is a shareholder in the firm's Health Care Practice and the Tax-Exempt Organizations group. She addresses a wide variety of health care regulatory and transactional issues in her practice and has extensive experience in compliance matters, including designing and implementing corporate compliance programs and assessing compliance program effectiveness. She regularly advises clients regarding internal and external investigations, audits and corrective action plans, all aspects of HIPAA compliance, clinical research compliance and 340B compliance. She has assisted clients in preparing and negotiating OIG disclosures and refunding overpayments, as well as counseling clients with respect to fraud and abuse issues that arise in the context of various health care provider relationships and transactions. She is Certified in Healthcare Compliance (CHC) by the Health Care Compliance Association and is a Certified Compliance and Ethics Professional (CCEP) through the Society of Corporate Compliance and Ethics.



A. John Richter is an attorney in the firm's Health Care Practice. John provides counsel on regulatory, transactional and litigation matters.



WEBINAR HOUSEKEEPING

Viewing the Slides

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Handouts

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Asking Questions

Throughout the webinar, **e-mail your questions to npozgay@reinhardt.com**. We will answer as many questions as possible during our Q & A session at the end of the webinar.

Information

This webinar provides general information about legal issues. It should not be construed as legal advice or a legal opinion. Attendees should seek legal counsel concerning specific factual situations confronting them.

KEY DATES

Published:

January 25, 2013

Compliance Date:

September 23, 2013
(w/exception)



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OVERVIEW: SIGNIFICANT HITECH/HIPAA CHANGES

- Notice of Privacy Practices
- Business Associates
 - Expanded definition
 - Vicarious liability
- Breach Notification
- Other Changes
 - Fundraising, Marketing and Sale of PHI
 - Individual rights

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NOTICE OF PRIVACY PRACTICES



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NOTICE OF PRIVACY PRACTICES: KEY ADDITIONS

- Must expressly identify certain uses and disclosures requiring authorization (e.g., sale of PHI)
- Right to opt out of receiving fundraising communications
- Right to notification following a breach of Unsecured PHI
- Right to restrict redisclosure of PHI to a health plan with respect to treatment paid for out of pocket

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NOTICE OF PRIVACY PRACTICES: DISTRIBUTION

- Must distribute new notice **only if** prior notice requires it
- Must post new notice, or a summary, conspicuously in a clear and prominent location if you have a physical facility
- Must have new notice immediately available upon request on or after the effective date of the revision (e.g., remember to provide copies to team members conducting home visits)

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BUSINESS ASSOCIATES



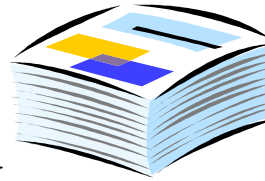
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TIMING OF NEW BAAs

- Exception to September 23, 2013 compliance date for fully compliant BAAs in place prior to January 25, 2013
- These BAAs will be deemed "compliant" until September 22, 2014 unless earlier renewed or modified



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BUSINESS ASSOCIATE CHANGES

- Definition Expanded
- Vicarious Liability Clarified
- New Considerations for Business Associate Agreements

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BUSINESS ASSOCIATE DEFINITION

- Person or entity, other than member of workforce, that, **on behalf of covered entity**, creates, receives, maintains, or transmits PHI in performing a function or activity for the covered entity
 - Includes claims processing or administration, data analysis, processing, utilization review, quality assurance, patient safety activities, billing, benefit management, repricing; or
 - Provision of legal, actuarial, accounting, consulting, data aggregation, accreditation, or financial services

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BUSINESS ASSOCIATES: KEY DEFINITION CHANGES

- Definition expanded to include **all** entities that create, receive, maintain or transmit PHI on behalf of a covered entity, such as:
 - E-prescribing gateways
 - Vendors of personal health records
 - Business associate **subcontractors**

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BUSINESS ASSOCIATE DEFINITION

- The term "business associate" does not include:
 - A health care provider who uses/discloses PHI to treat an individual (e.g., hospice, pharmacy, attending physician, etc.)
 - A member of your workforce, even if an independent contractor
 - A person or entity participating in an organized health care arrangement (e.g., a hospital medical staff member)
 - A plan sponsor

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BUSINESS ASSOCIATES: VICARIOUS LIABILITY

- Covered entity may have vicarious liability for noncompliance of its business associate if business associate is deemed an "agent" under federal common law
- Business associate may have vicarious liability for noncompliance of its subcontractor
- Agreeing to be a business associate creates contractual obligations and regulatory risk

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BUSINESS ASSOCIATE AGREEMENTS: PROVISIONS TO UPDATE OR ADD

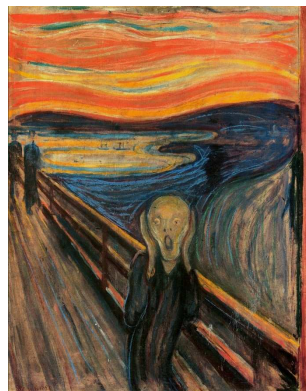
- HIPAA Security Rule compliance details
- Limitation on subcontractors
- Notice of nonpermitted use/disclosure—not just "breach" notification
- Audit rights and records retention requirements
- Indemnification

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THE NEW BREACH STANDARD



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THE BREACH NOTIFICATION RULE

- Interim Final Rule: August 24, 2009
 - Requires covered entities to give notice of breaches of unsecured PHI
 - Requires business associates to notify covered entities of breaches
- Codified by Omnibus Rule with modifications

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DEFINITION OF BREACH

The acquisition, access, use or disclosure of PHI in a manner not permitted by HIPAA that **compromises** the privacy or security of the PHI

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DEFINITION OF BREACH (cont.)



- **Interim Final Rule "compromise"**: means significant risk of financial, reputational or other harm to the individual
- **Omnibus Rule "compromise"**: Unpermitted use or disclosure of PHI presumed to be breach unless covered entity demonstrates low probability that PHI was compromised using four factor test

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BREACH NOTIFICATION: FORMAL RISK ASSESSMENT

- Four factors to document:
 - Nature and extent of PHI involved
 - Persons who used PHI or to whom disclosed
 - Whether PHI was actually acquired or viewed
 - Extent to which risks mitigated



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DEFINITION OF BREACH: THREE EXCEPTIONS

- Unintentional acquisition, access or use of PHI by a workforce member
- Inadvertent disclosure of PHI from an authorized person to another authorized person
- Good faith belief that the unauthorized individual, to whom the impermissible disclosure was made, not able to retain the information

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ADDITIONAL BREACH NOTIFICATION RULE CHANGES

- Limited Data Sets
 - Interim Final Rule: Not a breach (if it excludes DOB and ZIP code)
 - Omnibus Rule: Presumption of breach
- Minimum Necessary Rule
 - Omnibus Rule clarifies that violations must be analyzed as potential breach

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HIGH RISK ACTIVITIES

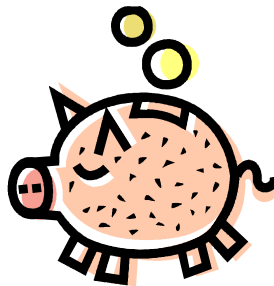
- Using **unsecure** portable media devices to access, transmit, create, maintain or store PHI (e.g., smart phones, iPads, laptops, flash drives)
- Texting and e-mailing PHI
- Failing to encrypt laptops and other electronic media storage devices where PHI resides
- Failing to properly destroy/remove electronic PHI prior to disposal of device

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OTHER CHANGES: FUNDRAISING, MARKETING AND SALE OF PHI



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FUNDRAISING CHANGES

- Types of PHI that may be used for fundraising expanded (e.g., demographic info, name of attending physician, insurance status, outcomes)
- Must provide individuals option to opt out of additional fundraising communications
 - No undue burden or more than nominal cost
- Must have data management systems and processes to ensure individuals who opt out do not receive additional communications

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MARKETING CHANGES

- Must obtain authorization for all treatment or health care communications (e.g., availability of massage therapy, acupuncture, etc.) where the covered entity receives financial remuneration from a third party for making the communication, except for:
 - Cost-based compensation to provide refill reminders or communicate about a drug or biologic that is currently being prescribed for the individual

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SALE OF PHI

- Broad definition—includes direct or indirect compensation
- Authorization required that states that disclosure will result in remuneration to the covered entity

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SELECT CHANGES TO INDIVIDUAL RIGHTS



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RIGHT TO REQUEST RESTRICTIONS

- Covered entity must agree to an Individual's request to restrict disclosure of PHI to health plan if:
 - The disclosure is for the purpose of carrying out payment or health care operations and is not otherwise Required by Law; and
 - The PHI pertains solely to a health care item of service for which the Individual, or a person other than the health plan on behalf of the Individual, has paid the covered entity in full

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RIGHTS OF DECEASED INDIVIDUALS

- Covered entities must comply with Privacy Rule with respect to PHI for deceased individuals for 50 years after death
- **If permitted under state law**, may disclose PHI after death to family members, other relatives or close family friends involved in care or payment prior to death **to the extent of such persons involvement in treatment or payment**, unless inconsistent with prior expressed preferences of the individual

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IMMEDIATE COMPLIANCE STEPS

- Revise:
 - Notice of Privacy Practices
 - Business Associate Agreements
 - Breach Notification policy/forms
 - Other policies and procedures
- Provide updated training to ensure changes implemented



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Questions?



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THANK YOU!

Thank you for attending our webinar. If you have questions, please contact your Reinhart attorney or one of our webinar presenters.

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