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Attorneys at Law

**THE HIPAA “OMNIBUS”
IS LEAVING SOON!**
Practical Steps for a Smooth
Departure for Your Hospice

August 22, 2013
11:00am - 12:00pm CT (Central Time Zone)
(9am PT, 10am MT, 12pm ET)

AGENDA

10:45 a.m. CT Attendees Sign On

11:00 a.m. CT Webinar

11:50 a.m. CT Questions and Answers

Asking Questions

Throughout the webinar, type your questions using the "send note" button at the top of the screen. Using the dropdown box, send your note to **REINHART BOERNER VAN DEUREN**. We will answer as many questions as possible during our Q & A session at the end of the webinar.

PRESENTERS

Meg S.L. Pekarske

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Meg S.L. Pekarske has devoted her legal practice to serving the ever-changing legal needs of the hospice industry. As co-chair of Reinhart's Hospice and Palliative Care Practice Group, she manages the firm's hospice practice. In working day in and day out with hospice clients across the country, Ms. Pekarske is intimately familiar with the operational challenges of hospices and has the experience to address the full spectrum of legal issues facing the industry, from routine regulatory compliance issues to multi-million dollar Zone Program Integrity Contractor (ZPIC), Medicaid and other government audits. Additionally, Ms. Pekarske routinely advises hospices on palliative care program development, innovative inpatient unit structures, fraud investigations and a wide range of contracting issues. With an extensive background in long-term care, she brings a unique perspective and skill set to helping hospices create successful partnerships with nursing homes and assisted living facilities and providing quality end-of-life care to patients.



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, but has extensive experience in compliance matters, including designing and implementing corporate compliance programs and assessing compliance program effectiveness. She also 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) and is a Certified Compliance and Ethics Professional (CCEP).

WEBINAR HOUSEKEEPING

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Handouts

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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.

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OVERVIEW: SIGNIFICANT HITECH HIPAA CHANGES

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

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KEY DATES

Published:

January 25, 2013

Effective Date:

March 26, 2013

Compliance Date:

September 23, 2013
(w/exception)



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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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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: FUNDRAISING

- Must identify that individual has right to opt out of receiving fundraising communications
 - Opt-out mechanism may not cause the individual to incur an undue burden or more than nominal cost
 - HHS encourages use of a toll-free phone number and/or an e-mail address
 - Cannot require individuals to write a letter to opt out

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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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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 ASSOCIATES: OTHER KEY CHANGES

- Business associates must have business associate agreement (BAA) with each of their subcontractors obligating them to the **same** BAA provisions to which they are subject
- 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

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IMPORTANT TO PROPERLY IDENTIFY BUSINESS ASSOCIATE RELATIONSHIP

- Liability exposure means critical to properly identify:
 - Who is and who is not your business associate
 - When you are and are not a business associate of another party (e.g., nursing home relationships do not create business associate relationship)
- Agreeing to be a business associate creates contractual obligations and regulatory risk
- Not entering into a BAA when required may give rise to liability

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HOSPICE BUSINESS ASSOCIATES: SELECT WHO'S IN/WHO'S OUT EXAMPLES

BUSINESS ASSOCIATES	NOT BUSINESS ASSOCIATES
Billing or Clinical Consultant, Accountant, Auditor, Lawyer	Nursing Home, Independent Attending Physician, Consulting Physician
Pharmacy Benefits Management Company	Pharmacy
Electronic Health Records Vendor	Internet Service Provider or Telecom Companies
Medical Director – Independent Contractor	Medical Director – Employed or Part of Workforce
Document Storage/Destruction Company	FedEx, UPS, USPS

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HIPAA OPTIONS FOR MEDICAL DIRECTORS

- Treat as member of hospice workforce
 - Usually preferable option given role and duties
 - Physician must complete hospice training and follow hospice HIPAA policies and procedures
- Treat as business associate and enter into BAA
 - May provide some contractual protection for noncompliance
 - Consider modifying template BAA to reflect special relationship (e.g., follow hospice HIPAA policies and procedures)

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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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TIMING OF NEW BAAs

- Exception to September 23, 2103 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

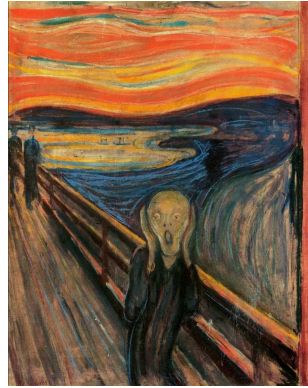


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THE NEW BREACH STANDARD



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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 BAs 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:** No breach unless significant risk of financial, reputational or other harm
- **Omnibus Rule:** *Presumed* to be breach unless covered entity demonstrates low probability that PHI was compromised

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OTHER CHANGES TO BREACH NOTIFICATION RULE

- 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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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 actually acquired or viewed
 - Extent to which risks mitigated



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HIGH RISK ACTIVITIES

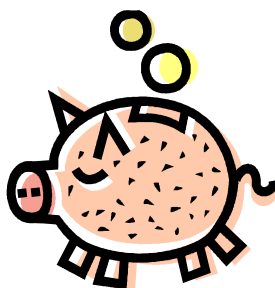
- Using **unsecure** portable media devices to access, transmit, create, maintain or store PHI (e.g., smart phones, iPads, laptops, flash drives)
- Texting and e-mailing PHI
- Failing to encrypt laptops and other electronic media storage devices where PHI resides
- Failing to properly destroy/remove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



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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, unless inconsistent with prior expressed preferences of the individual

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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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