

# The Road Map to HIPAA Compliance: What Your Nonprofit Needs to Know

Thursday, August 8, 2013, 12:30 p.m. – 2:00 p.m. ET  
Venable LLP, Washington, DC

Moderator:

Jeffrey S. Tenenbaum, Esq., Venable LLP

Panelists:

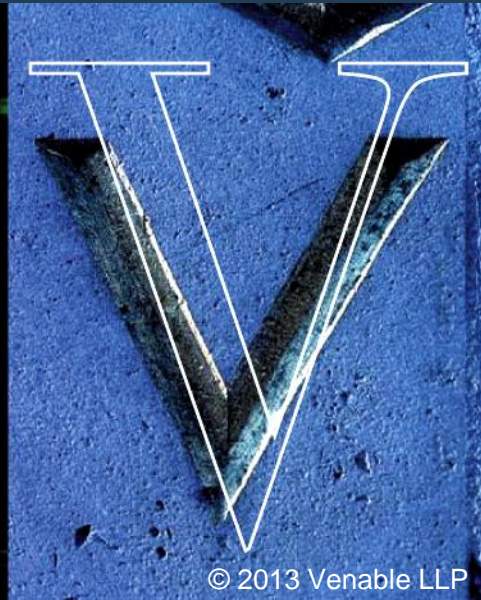
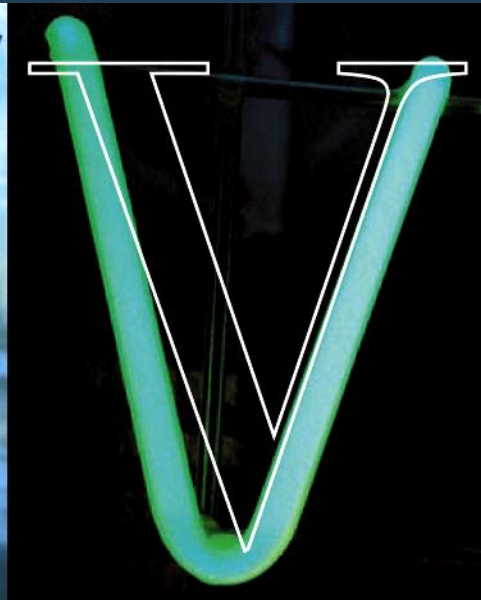
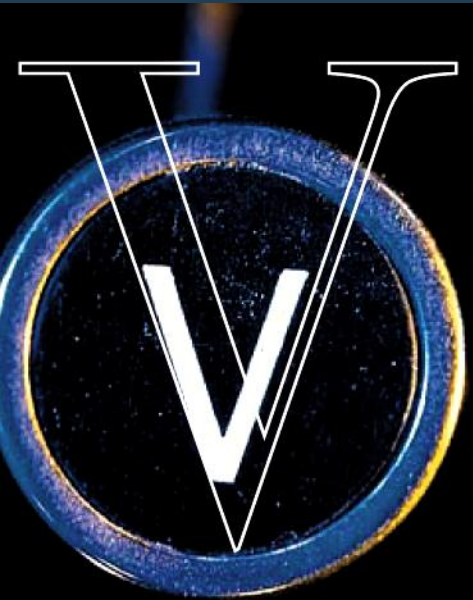
Thora A. Johnson, Esq., Venable LLP

Elizabeth C. Keenan, Esq., Venable LLP

Kelly A. DeMarchis, Esq., Venable LLP

Jennifer Spiegel Berman, Esq., Venable LLP

Molly E. G. Ferraioli, Esq., Venable LLP



# Upcoming Venable Nonprofit Legal Events

August 21, 2013 – [The IRS Final Report on Nonprofit Colleges and Universities: Lessons for All Tax-Exempt Organizations](#)

September 18, 2013 – [Keeping Up with Technology and the Law: What Your Nonprofit Should Know about Apps, the Cloud, Information Security, and Electronic Contracting](#)



# Agenda

- Overview of HIPAA
- Privacy Rule
- Notice of Breach
- Security Rule
- Business Associates & Business Associate Agreements
- Notice of Privacy Practices
- Training
- Next Steps
- Q&A



# Overview of HIPAA

## Evolution

- Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)
  - Privacy Rule (April 2003)
  - Standard Electronic Transactions – to achieve a more efficient health care system (October 2003)
  - Security Rule (April 2005)
- Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”)
  - Notification of Breach (February 2010)
  - Final Omnibus Rule



# Overview of HIPAA

## Final Omnibus Rule

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



# Overview of HIPAA

## Final Omnibus Rule

- Privacy & Security
  - Marketing
  - Sale of protected health information (PHI)
  - Fundraising
  - Right to request restrictions
  - Electronic access
  - Business Associates
- Notice of Breach
- Enforcement
- GINA
- Other
  - Notice of privacy practices (NPP)
  - Research
  - Decedents
  - Student immunizations



# Overview of HIPAA

## Glossary

- Covered Entity
  - Health care provider who bills, etc. using electronic medium
  - Health Plan (public or private, self-insured or insured)
  - Clearinghouse (billing service, repricing company, etc.)
  - Medicare Prescription Drug Plan Sponsors
- Business Associate
  - Entity that creates, receives, maintains, or transmits PHI on behalf of a covered entity
  - Enumerated service providers (e.g., lawyers, actuaries & consultants)
  - Subcontractors



# Overview of HIPAA

## Glossary

- Protected Health Information (“PHI”)
  - Individually Identifiable Health Information
    - Health information, including demographic information
    - Relates to past, present, or future physical or mental health condition, provision of healthcare, or payment for provision of healthcare, and
    - Does or may identify the individual
    - In any form (oral, written or electronic)
  - In the possession of a covered entity or business associate





# Overview of HIPAA

## Compliance Package

- Privacy and security policies and procedures
- Designation of privacy and security officers
- Business associate agreements
- Training
- Notice of privacy practices
  - Only applies to covered entities



# Overview of HIPAA

## Statutory Penalties

<b>Violation Due to:</b>	<b>Penalty Range (per violation):</b>
Unknown cause	\$100-\$50,000
Reasonable cause and not willful neglect	\$1,000-\$50,000
Willful neglect (violation corrected within 30 days)	\$10,000-\$50,000
Willful neglect (violation not corrected within 30 days)	At least \$50,000

A \$1.5 million annual cap applies for violations of an identical privacy or security requirement.



# Overview of HIPAA

## Resolution of Agreements

- Five Resolution Agreements and Corrective Action Plans Negotiated in 2012 (\$4.85 million)
- Two Resolution Agreements and Corrective Action Plans Negotiated in 2013 (\$450,000)
- Expect continued growth and emphasis on significant cases – remain small proportion of all the cases OCR reviews
- Enforcement of compliance with new provisions after September 2013 – continue to enforce with respect to existing provisions not subject to change

From the U.S. Department of Health and Human Services, Office for Civil Rights



# Overview of HIPAA

## Audit Program

- Completed audits of 115 entities
  - 61 Providers, 47 Health Plans, 7 Clearinghouses
- Total 979 audit findings and observations
  - 293 Privacy
  - 592 Security
  - 94 Breach Notification
- Small entities struggle with all three areas
- Help identify compliance areas of greatest weaknesses
- Evaluation underway to guide OCR in making audit a permanent part of enforcement efforts

From the U.S. Department of Health and Human Services, Office for Civil Rights



# The Privacy Rule

## The Use and Disclosure of PHI

- PHI can be used/disclosed for treatment, payment and health care operations
- PHI can be used/disclosed for any purpose pursuant to a valid authorization
- PHI can also be used/disclosed for certain other purposes consistent with policy objectives
  - *e.g.*, public health activities, law enforcement, otherwise required by law
- Generally subject to minimum necessary standard



# The Privacy Rule

## Restrictions on Marketing

- Marketing = a communication about a product or service that encourages recipients to purchase or use the product or service
- Authorization required
- Exceptions
  - A promotional gift of nominal value provided by a covered entity
  - A face-to-face communication made by a covered entity to an individual
  - Refill reminders (and similar communications) if remuneration does not exceed cost to the individual
  - No remuneration



# The Privacy Rule

## Restrictions on the Sale of PHI

- Sale of PHI
  - Includes remuneration received directly or indirectly from entity to whom PHI is disclosed
  - Not limited to financial remuneration
- Requires an authorization that states that the entity is being paid to sell PHI
- Excludes
  - Research, or other permitted disclosure, if remuneration is limited to a reasonable cost-based fee to cover the cost to prepare and transmit PHI; or
  - Fee is otherwise expressly permitted by law



# The Privacy Rule

## Fundraising

- Fundraising for the covered entity is part of “health care operations”
- Covered entities and any institutionally-related foundation can use the following to raise funds:
  - Demographic patient information
  - Dates of service
  - Treating physician information
  - Department of service information\*
  - Outcome information\*

\* Use is limited to permit filtering





# The Privacy Rule

## Fundraising

- Must disclose opportunity to opt-out of fundraising in notice of privacy practices
- Notice of privacy practices **MUST** be provided prior to receiving a fundraising solicitation of any type
- Each solicitation (oral or written) must contain opt-out information
  - Must be “clear and conspicuous”
- Opt-out mechanism cannot impose a burden on the recipient
- *Simple, quick and inexpensive*
  - Requiring mailing a letter to opt-out **IS** not permitted



# The Privacy Rule

## Fundraising

- Covered entity may not condition treatment or payment on individual's decision
- Must have a system to track and apply opt-outs
  - Covered entity must honor opt out (no further fundraising communications permitted)
- Flexibility provided in scope of opt out and method to opt back in is permitted



# The Privacy Rule

## Right to Request Restrictions / Alternative Communications

- Individuals can request that covered entities and business associates disclose PHI in an alternative method, and they can restrict disclosure of their PHI
- For alternative methods, covered entities and business associates are generally required to comply
- For requested restrictions, covered entities and business associates are generally NOT required to comply, except where an individual requests a restriction on:
  - Disclosure of PHI to a health plan for purposes of payment or operations (not treatment)
  - Where the PHI relates to an item/service for which the provider has been paid in full out of pocket



# The Privacy Rule

## Right to Request Restrictions / Alternative Communications

- Must have system that accommodates requests in a timely manner
- Potential problem areas
  - What if the check bounces?
  - Can provider collect full balance before providing services?
  - What does the patient have to tell the provider?
  - Does this apply to Medicare?
  - Can the patient pick and choose what is restricted?
  - Part of a bundled service?



# The Privacy Rule

## Right to Access / Amend

- Individual may inspect/obtain copies of their own PHI in a designated record set
- If patient asks for his/her PHI in a particular electronic format, covered entity **MUST** provide it if possible
- Must provide copies to designated third party upon receipt of written request
- State laws limit per page charges, but HIPAA limits charges to cost of compliance
- Individuals may also request that inaccurate PHI be amended



# The Privacy Rule

## Right to an Accounting of Disclosures

- Currently an individual has a right to an accounting of disclosures going back 6 years, but subject to multiple exceptions, including disclosures made for treatment, payment and health care operations
- New HITECH rule will require electronic disclosures for prior 3-years to be included in accounting (no exception for treatment, payment or health care operations)
  - Delayed effective date, awaiting guidance



# Notice of Breach

## Federal and State Requirements

- Most state laws have breach notification statutes for personal information, but few cover health data
- HHS Omnibus Rule finalizes (with amendments) nationwide breach notification standards for PHI
- Federal Trade Commission issued similar notification rule for:
  - Vendors of “personal health records”
  - Related entities such as advertisers on vendors’ sites
  - Third party servicers to vendors and related entities
- For “dual role” entities, either HHS or FTC rule applies depending on role in which organization suffered breach



# Notice of Breach

## Overview

- Notification to certain parties is required following discovery of a breach of “unsecured” PHI
- “Unsecured” = not rendered unusable, unreadable, or indecipherable to unauthorized persons under HHS guidance, currently:
  - Encryption
  - Destruction





# Notice of Breach

## Whom to Notify

- Business associate notifies covered entity
  - May notify individuals if arranged with covered entity
  - Must provide certain information about breach
- Covered entity notifies:
  - Individuals
  - HHS Secretary
    - Same time as individuals if 500 or more individuals (will be posted online)
    - Annual log if fewer than 500 individuals
  - Media notice, for breach involving more than 500 residents of jurisdiction



# Notice of Breach

## What Is a “Breach”?

- Acquisition, access, use or disclosure of PHI
  - Not permitted by HIPAA Privacy Rule
  - And compromises the security or privacy of the PHI
- If the HIPAA Privacy Rule is violated, a breach is presumed unless the covered entity or business associate demonstrates low probability of compromise based on risk assessment of:
  - Nature and extent of PHI
  - Unauthorized person involved
  - Whether PHI was actually acquired or viewed
  - Extent of risk mitigation



# Notice of Breach

## What Is Not a “Breach”?

- Unintentional acquisition, access or use by workforce member, if in good faith and within scope of authority, and no further use or disclosure (*i.e.*, not snooping)
- Inadvertent disclosure to a colleague who is also authorized to access PHI, and no further use or disclosure
- Disclosure where there is a good faith belief that the unauthorized person was not reasonably able to retain the information



# Notice of Breach

## Notice to Individuals

- To individuals (or their representatives) whose information is reasonably believed to have been accessed, acquired, used or disclosed without authorization
- Use plain language
- Include certain required information (e.g. description of breach, dates, types of information involved)



# Notice of Breach

## Notice to Individuals

- Provide via:
  - First-class mail
  - E-mail if individual has agreed
  - If insufficient contact information, substitute notice via telephone or media
  - Urgent telephone notice in some cases
- Translation to other languages or formats if required



# Notice of Breach

## When to Notify

- “Without unreasonable delay” and no later than 60 days after “discovery of breach” (even if investigation is ongoing)
- Clock starts for a business associate breach depending on relationship:
  - For independent contractor, 60 days from notification to covered entity
  - For agent, 60 days from business associate’s own discovery
- Law enforcement delay is possible



# Notice of Breach

## When is a Breach “Discovered”?

- “Discovery” means first day on which breach is known or by exercising reasonable diligence would have been known to any employee, officer, or agent
- Organization should have in place:
  - Systems for detecting breach
  - Training and policies to ensure that breaches are reported to management by any employee



# The Security Rule

- Electronic PHI (“ePHI”): PHI transmitted by or maintained in an electronic media
  - Including hard drive, disk, CD and internet
  - Excluding paper fax
- Must ensure confidentiality of ePHI and protect against reasonably anticipated threats
- 18 Standards (*i.e.*, safeguards): administrative, physical, technical
- 36 Implementation specifications: some mandatory, others “addressable”





# The Security Rule

## Administrative Safeguards

- Policies & procedures
- Personnel designations
- Risk analysis & management plan
- Access control & management
- Training



# The Security Rule

## Physical Safeguards

- Workstation use & security
- Control access to facility
- Device & media controls



# The Security Rule

## Technical Safeguards

- Access authorization; screensavers; encryption
- Audit controls
- Integrity measures; virus scans; firewalls
- Authentication through password management
- Transmission security



# The Security Rule

## Risk Analysis

- Review data
  - Type of data
  - Storage location
  - Persons with access
  - Access procedures
  - Audit logs
  - Encryption
- Gap Analysis
- Implement appropriate security measures



# Business Associates & BAAs

## New Rules for Business Associates

- Business Associates must comply with the Security Rule's technical, administrative, and physical safeguard requirements
- Business Associates must comply with use or disclosure limitations expressed in its contract and in the Privacy Rule
- Business Associate definition includes Health Information Organizations, E-prescribing Gateways, others who perform data transmission services requiring access to PHI on a routine basis, and PHR vendors providing services to covered entities
- Subcontractors of a Business Associate are now defined as Business Associates
  - Business Associate liability flows to all subcontractors



# Business Associates & BAAs

## Timing Considerations

- Final HIPAA/HITECH rules were effective on March 26, 2013.
- By September 23, 2013, Business Associates have to meet all obligations under new rules, except:
  - If an existing BAA was in place prior to 1/25/2013 and the agreement was not renewed prior to 3/25/2013, the parties have until 9/22/2014 to modify the BAA.



# Business Associates & BAAs

## Updating Business Associate Agreements

- Identify existing agreements and any gaps
- Review existing terms
- Update for final rules



# Notice of Privacy Practices

- Must be maintained and distributed by covered entities
- Describes
  - Use and disclosure of PHI
  - Individual rights
  - Legal duties regarding PHI





# Notice of Privacy Practices

## Key Changes

- NPP must include:
  - Purposes that require authorization (sale of PHI, marketing, and psychotherapy notes)
  - Right to opt out of receiving fundraising communications
  - Requirement to agree to restrict disclosure of health information to health plan if individual pays out of pocket in full (providers only)
  - Right to receive notice of breach
  - Genetic information may not be used for underwriting purposes (health plans that underwrite only)



# Training

- Workforce members with access to PHI must be trained on HIPAA privacy & security policies and procedures
- Best practices:
  - Formal training on an annual basis
  - Updates/refreshers as needed
- Document:
  - Attendees
  - Date/time of training
  - Subject of training



# Next Steps

- Perform a risk analysis
- Review and revise policies and procedures
  - Don't forget to also update any HIPAA forms (*e.g.*, notice of breach assessment forms)
- Update/negotiate business associate agreements
- Adopt systems to detect breach and Incident Response Plan
- Train workforce
- Update notice of privacy practices
  - Only applies to covered entities



# Questions?

**Jeffrey S. Tenenbaum, Esq.**  
[jstenenbaum@Venable.com](mailto:jstenenbaum@Venable.com)  
t 202.344.8138

**Kelly A. DeMarchis, Esq.**  
[kademarchis@Venable.com](mailto:kademarchis@Venable.com)  
t 202.344.4722

**Thora A. Johnson, Esq.**  
[tajohnson@Venable.com](mailto:tajohnson@Venable.com)  
t 410.244.7747

**Jennifer Spiegel Berman, Esq.**  
[jsberman@Venable.com](mailto:jsberman@Venable.com)  
t 410.244.7756

**Elizabeth C. Keenan, Esq.**  
[eckeenan@Venable.com](mailto:eckeenan@Venable.com)  
t 410.244.7473

**Molly E. G. Ferraioli, Esq.**  
[mefarraioli@Venable.com](mailto:mefarraioli@Venable.com)  
t 410.244.7668

To view Venable's index of articles, presentations, and upcoming programs on nonprofit legal topics, see [www.Venable.com/nonprofits/publications](http://www.Venable.com/nonprofits/publications), [www.Venable.com/nonprofits/recordings](http://www.Venable.com/nonprofits/recordings), [www.Venable.com/nonprofits/events](http://www.Venable.com/nonprofits/events).



