



FOLEY & LARDNER LLP

# Responding to Joint FTC/OCR Investigations

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# AGENDA

- Statutory basis for investigations
- Review of recent enforcement
- Administrative procedures
- Negotiating with the agencies
- Internal compliance
- The independent assessor
- Practical tips

# FTC ACT & HIPAA/HITECH

- Section 5 of FTC Act
  - Unfair or deceptive practices
  
- HIPAA/HITECH
  - OCR enforces Privacy & Security Rules
  - State AGs have authority to enforce

# RECENT ENFORCEMENT

- CVS Caremark (Jan. 2009 – FTC/OCR)
- Rite Aid (July 2010 – FTC/OCR)
- Management Services Organization  
Washington, Inc. (Dec. 2010 - OCR)
- Health Net, Inc. (2010 & 2011 CT & VT)

# CIVIL INVESTIGATIVE DEMAND

- Similar to a subpoena but broader
- Documents, interviews
- The (obvious) importance of understanding your own facts
- Litigation holds
- Confidentiality/FOIA

# NEGOTIATING WITH THE AGENCIES

- **FTC**
  - 20 year terms
  - Broader requirements
  - Approving the assessor
- **OCR**
  - Specific regarding identified entities
  - 3-5 year terms
  - Interviewing the assessor
  - Negotiating the work plan

# INTERNAL COMPLIANCE

- Begin remediation immediately
- Administrative Safeguards
- Technical Safeguards
- Physical Safeguards
- The importance of project management
- Culture

# THE INDEPENDENT ASSESSOR

- Choosing the assessor
  - “certifying” compliance
- Independent third party
- Project management & scope
- Input and review
- Documentation relied upon
- Changing the assessor



# PRACTICAL TIPS

- Begin remediation immediately
- Current, quality policy program
- Effective internal enforcement
- Project management resources
- Methodology & consistency
- Confidentiality, FOIA & privilege
- Legal, consulting & forensic advice

# WHAT WE HAVE REVIEWED

- Statutory basis for investigations
- Review of recent enforcement
- Administrative procedures
- Negotiating with the agencies
- Internal compliance
- The independent assessor
- Practical tips

# QUESTIONS?

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