

Privacy and Security
Enforcement: An In-Depth
Exploration of Federal Civil
Enforcement

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Enforcement Authority

- Secretary of HHS Delegated to the Administrator, CMS Authority to Investigate Noncompliance and Enforcement of Certain Regulations:
 - Transaction and Code Set Rule
 - National Employer Identifier Number (“EIN”) Rule
 - Security Rule
 - National Provider Identifier Rule
 - National Plan Identifier Rule
- Delegation Does Not Include Authority with Respect to the Privacy Rule
 - Delegated to the Office for Civil Rights

Privacy Complaints

- Approximately 19,420 Privacy Complaints Filed With OCR
- Most Common Allegations Have Been:
 - Personal Medical Details Wrongly Disclosed
 - Information Was Poorly Protected
 - More Details Were Disclosed Than Necessary
 - Proper Authorization Was Not Obtained
 - Patients Frustrated in Attempting to Get Their Own Records
- Washington Post June 5, 2006

Security Complaints

- CMS Has Received Approximately 106 Security Complaints
 - Also Inappropriately Received 28 Privacy-Related Complaints – To be Directed to OCR
- CMS Has Received Approximately 450 Transaction & Code Set Complaints
 - 129 Remain Open
 - Majority Involve Private Sector Organizations
- Health Information Privacy/Security Alert, Melamedia LLC May 22, 2006

First Stage - Investigation

- Upon Receipt of Complaint [§ 160.306(c)]
 - Contact Complainant to Determine Whether Investigation Necessary
 - May Resolve Without Even Contacting Covered Entity
 - First Written Communication With Covered Entity Must Describe Basis of Complaint
- May Conduct Compliance Reviews [§ 160.308]
 - No Complaint Necessary
 - May Initiate on Own Discretion

Investigation

- May Issue Subpoenas [§ 160.314(a)]
 - Attendance of Witnesses
 - Production of Evidence
 - May Issue When Conducting a Compliance Review
- Investigational Inquiries [§ 160.314(b)]
 - Non-public
 - Testimony Under Oath
 - Legal Representation and Objections Allowed
 - Proceedings are Recorded & Transcribed

Investigational Powers

- Covered Entity Must Permit HHS to Have Access During Normal Business Hours to
 - Facilities
 - Books, Records, and Other Information
- But, if the Secretary Determines “Exigent Circumstances” Exist, Covered Entity Must Permit Access at Any Time Without Notice [§ 160.310]
 - Example: When Documents May be Hidden or Destroyed

Investigation

- Testimony or Other Evidence Obtained During an Investigational Inquiry, May be Used in Any HHS Activities and May be Offered Into Evidence in Any Proceeding [§ 160.314(c)]
 - Could be Used in Later, Separate Proceedings
 - Transcribed and Under Oath - Permanency
 - Important When Negotiating Informal Resolution

Informal Resolution

- If Evidence Indicates Noncompliance [§ 160.312(a)]
 - Will Attempt to Resolve via Informal Means
 - Review of Demonstrated Compliance by Covered Entity
 - Corrective Action Plan in Place
 - If Then Resolved, Notification to Covered Entity and Any Complainant

Mitigating Factors & Affirmative Defenses

- If Matter Not Resolved Informally, Notification to Covered Entity That May Submit Evidence of Mitigating Factors and Affirmative Defenses [§ 160.312(a)(3)]
 - Party Must Submit Within 30 Days
 - If No Violation Found, Notification to Covered Entity and Any Complainant

Basis For Civil Money Penalty

- Impose CMP Upon Covered Entity if Determines That Covered Entity Has Violated an Administrative Simplification Provision [§ 160.402(a)]
- Violation Attributed to a Covered Entity [§ 160.402(c)]
 - Follows Federal Common Law of Agency
 - Act or Omission of Agent
 - Unless Agent is a Business Associate
 - Importance of Business Associate Agreements!

Amount of Civil Money Penalty

- Amount of CMP to be Determined in Consideration of Mitigating Factors and Affirmative Defenses [§ 160.404]
 - Limited to \$100 for Each Violation or \$25,000 for Identical Violations During a Calendar Year
 - If Administrative Simplification Provisions Repeat Requirements, Then Only One CMP Imposed

Violations of Identical Requirement

- The Number of Violations of an Identical Requirement or Prohibition (“Identical Violations”) Will be Determined Based On:
 - Nature of Covered Entity’s Obligation to Act or Not Act With Respect to Certain Persons
 - Continuing Violations – a Separate Violation Deemed to Occur on Each Day Such Violation Continues [§ 160.406]

Failing to Address Standards (Security Rule)

- As applied to Addressable Standards, Definition of Violate Includes Failure to Document Reasons Implementation Was Not Reasonable or Appropriate and the Equivalent Alternative Measure Implemented in Its Place
- Two Violations Occur:
 - Failure to Implement Standard and
 - Failure to Document Implementation

Mitigating Factors

- Factors Which May Be Utilized in Determining Amount of CMP [§ 160.408]
 - Nature of Violation, in Light of Purpose of Rule
 - Circumstances, Such as
 - Time Period During Violation Occurred
 - Whether Violation Caused Physical Harm
 - Whether Violation Hindered Health Care
 - Whether Violation Resulted in Financial Harm
 - Degree of Culpability (Intentional, Beyond Control)
 - History of Prior Compliance With Administrative Simplification Provisions (Similar, Corrections)
 - Financial Condition of Covered Entity (Size)
 - Other Matters as Justice Requires

Affirmative Defenses

- Affirmative Defenses -- May Not Impose a CMP if Established – Includes the Following: [§ 160.410]:
 - Act is Punishable Criminally
 - Covered Entity Had No Knowledge
 - Covered Entity Would Not Have Known Using Reasonable Diligence
 - Violation Result of Reasonable Cause, Not Willful Neglect and Corrected Within 30 Days or Such Additional Time as Determined

Limitations Period

- No Action May be Entertained Unless Commenced within 6 Years From the Date of the Occurrence of the Violation [§ 160.414]

Notice of Proposed Determination

- If Finds Basis for Action, Issues Notice of Proposed Determination to Covered Entity [§ 160.420]
- Where HHS Bases Proposed Penalty on Statistical Sampling, a Copy of HHS's Expert Report Must Accompany Notice

Notice to Public and Agencies

- When Proposed Penalty Becomes Final, Will Notify, in a Manner Deemed Appropriate of The Penalty and Reason it was Imposed, the Public and the Following Entities [§ 160.426]:
 - State or Local Medical or Professional Organizations
 - State Agency Administering State Health Care Programs
 - Utilization and Quality Control Peer Review Organizations
 - State or Local Licensing Agency
- Could Include Posting to HHS Web Site and/or Federal Register Publication

FOIA and Public Notice

- Basis for Public Notice is Not HIPAA, Rather FOIA
 - FOIA Requires Final Opinions and Orders Made in Adjudication Cases to be Available for Public Inspection
 - Would Not Apply to Informal Resolutions
 - Mandatory, Not Able to Withhold Information if Released After Conclusion of Proceedings
 - Another Reason to Consider Informal Resolution!

Administrative Hearing

- Upon Receipt of Notice of Proposed Determination, Covered Entity Must Request Hearing [§ 160.504(a)]
 - Request Mailed Within 90 Days of NPD
 - Hearing Before Administrative Law Judge (“ALJ”)
 - Must Admit, Deny, or Explain Findings of Fact
 - Must Set Forth Defenses [§ 160.504(c)]
 - Affirmative Defenses May be Raised at Any Time

Discovery

- Limited Discovery Allowed [§ 160.516]
 - Request for Production of Documents
 - No Other Discovery Authorized
- Work Product of Attorney is Protected
- Party Receiving Request Has 30 Days to Respond
- Discovery Motions are Permitted
 - Within 30 Days of Receipt of Objections

Prehearing Exchange of Information

- Parties Must Exchange, Not More than 60 and Not Less Than 15 Days Before the Hearing:
 - Witness Lists
 - Prior Written Statements of Witnesses
 - Copies of Proposed Hearing Exhibits
- ALJ May Exclude Evidence if Not Exchanged Unless Extraordinary Circumstances and If So, Whether Substantial Prejudice if Admitted
- Unless Party Objects, Documents Deemed Authentic
- Respondent Must Provide Copy of Statistical Expert's Report Not Less Than 30 Days Before Hearing

Post-Hearing Briefs

- ALJ May Require Parties to File Post-Hearing Briefs and, in Any Event, Any Party May Do So [§ 160.544]
- Must File Within 60 Days From Date Parties Receive Transcript of Hearing or Stipulated Record
- May Include Proposed Findings of Fact and Conclusions of Law
- ALJ May Permit Reply Briefs

ALJ Decision

- ALJ Issues Decision Within 60 Days After Time For Submission of Post-Hearing Briefs [§ 160.546]
 - If Misses Deadline, Must Simply Explain and Set New Date
 - Decision Based Solely on Record
 - Sets Forth Findings of Fact & Conclusions of Law
 - May Affirm, Increase, or Reduce Penalties
 - Unless Appealed, Becomes Final 60 Days From Date of Service

Appeal

- Party Must File Notice of Appeal Within 30 Days of ALJ Decision [§ 160.548(a)]
- Appeal is to HHS Departmental Appeals Board
 - For Good Cause Shown, May Extend Additional 30 Days
 - ALJ Must Forward Copy of Record [§ 160.548(b)]
 - Must be Accompanied by Brief Specifying Objections and Reasons [§ 160.548(b)]
 - Opposition Brief May be Filed Within 30 Days of Notice and Brief [§ 160.548(c)]

Appeal

- Party Has No Right to Appear Personally Before Board [§ 160.548(d)]
- Board May Not Consider Any Issue Not Briefed, Nor Issue Not Raised Before ALJ [§ 160.548(e)]
 - Except for Affirmative Defenses
- Board May Remand to ALJ [§ 160.548(f)]
- Board's Decision:
 - Decline to Review
 - Affirm
 - Increase or Reduce Penalty
 - Reverse or Remand [§ 160.548(g)]

Appeal

- Board's Standard of Review
 - Issue of Fact:
 - ALJ Decision Supported by Substantial Evidence on Whole Record [§ 160.548(h)]
 - Issue of Law:
 - ALJ Decision Erroneous [§ 160.548(h)]
 - Harmless Error Rule Applies as Well [§ 160.552]
- Board Must Issue Decision Within 60 Days of Briefing [§ 160.548(i)]
- Decision of Board is Final 60 Days After Service, Except if Remanded or if Reconsideration Requested [§ 160.548(j)]

Reconsideration

- Party May File Motion for Reconsideration
 - Prior to Decision of Board Becoming Final [§ 160.548(j)(3)]
 - Must be Accompanied by Brief
 - Opposition Brief May be Filed Within 15 Days of Receipt
- Board to Reconsider Only if Clear Error of Fact or Error of Law [§ 160.548(j)(2)]
 - New Evidence Not Basis Unless Not Previously Available
 - Must Rule on Motion within 30 Days
 - Decision Becomes Final Unless Petition for Judicial Review [§ 160.548(j)(4)]

Judicial Review

- Respondent Must File Petition Within 60 Days of Board's Final Decision [§ 160.548(k)]
- Appeal to U.S. Court of Appeals
- Copy Must be Served on HHS General Counsel
- Decision May be Stayed Pending Review [§ 160.550(a)]
 - Respondent May Request Stay of Penalty
 - Automatically Stays Until ALJ Rules
 - ALJ Must Rule Within 10 Days

Questions?

- Please Feel Free to Ask Me Now or After the Session

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