



Eleventh National HIPAA Summit

The New HIPAA Enforcement Rule

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Process and Procedure

- The Investigation Process
- Informal Resolution
- Notice of Proposed Determination
- Administrative Hearing
- Appeal
- Judicial Review



Investigation

- Secretary of HHS Commences Upon Receipt of Complaint [§ 160.306(c)]
 - Contact Complainant to Determine Whether Investigation Necessary
 - Secretary May Resolve Without Even Contacting Covered Entity
- Secretary May Conduct Compliance Reviews [§ 160.308]
 - No Complaint Necessary



Investigation

- Secretary May Issue Subpoenas [§ 160.314(a)]
 - Attendance of Witnesses
 - Production of Evidence
- Investigational Inquiries [§ 160.314(b)]
 - Non-public
 - Testimony Under Oath
 - Legal Representation and Objections Allowed



Investigation

- Note: Any Information Obtained by Secretary 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
 - Important When Negotiating Informal Resolution
 - Is Not Expressly Limited to HIPAA Enforcement



Investigation

- If Evidence Indicates Noncompliance [§ 160.312(a)]
 - Secretary Will Attempt to Resolve via Informal Means
 - Review of Demonstrated Compliance by Covered Entity
 - Corrective Action Plan in Place
 - Secretary Has Authority to Settle at Any Time [§ 160.514]
 - Secretary Has Authority to Compromise CMP at Any Time [§ 160.416]



Mitigating Factors & Affirmative Defenses

- If Matter Not Resolved Informally, CE May Submit Written Evidence of Mitigating Factors and Affirmative Defenses [§ 160.312(a)(3)]
 - Party Must Submit Within 30 Days
 - If Following Review, Secretary Finds CMP Should be Imposed, Then Issues Notice of Proposed Determination



Mitigating Factors

- Factors Which are 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 Offenses (Similar, Corrections)
 - Financial Condition of Covered Entity (Size)
 - Other Matters as Justice Requires



Affirmative Defenses

- **Affirmative Defenses** [§ 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 Secretary Determines



Notice of Proposed Determination

- If Secretary Finds Basis for Action, Issues Notice of Proposed Determination to Covered Entity [§ 160.420]
 - Statutory Basis for Penalty
 - Findings of Fact
 - Reasons Why Violation Subjected Covered Entity to Penalty
 - Factors in Determining Amount of Penalty
 - Instructions for Responding



Covered Entity Response

- Upon Receipt of Notice of Proposed Determination, Covered Entity Must Request Hearing [§ 160.504(a)]
 - Request Mailed Within 60 Days of NPD
 - Hearing Before Administrative Law Judge (“ALJ”)
 - Must Admit, Deny, or Explain Findings of Fact
 - Must Set Forth Defenses [§ 160.504(c)]
 - Failure to Request Results in CMP and Loss of Appeal Rights [§ 160.422]



Discovery Process

- Limited Discovery Allowed [§ 160.516]
 - Request for Production of Documents
 - No Other Discovery Specifically Allowed
- Work Product of Attorney is Protected
- Discovery Motions are Permitted
- Pre-Hearing (Not More Than 60 and Not Less Than 15 Days Before Hearing) [§ 160.518]:
 - Exchange Witness Lists, Prior Statements, and Proposed Exhibits



ALJ Hearing

- ALJ Must Dismiss a Request for Hearing [§ 160.504(d)] :
 - If Not Properly Filed
 - Upon Withdrawal
 - Upon Abandonment
 - Covered Entity's Failure to Raise an Issue that ALJ May Properly Address
 - Secretary May Settle Without ALJ Involvement or Consent [§ 160.514]



Hearing

- ALJ Conducts Hearing [§ 160.508]
 - Fair and Impartial
 - Schedules Date, Time, and Place
 - May Conduct:
 - Conferences
 - Motion Hearings
 - Examination of Witnesses
 - Issuance of Subpoenas
 - Hearing Must be Public, Unless Good Cause Shown [§ 160.534]



Limitations on ALJ

- ALJ May Not [§ 160.508(c)] :
 - Ignore or Invalidate Federal Law or Secretarial Delegations of Authority
 - Issue a Directed Verdict
 - Compel Settlement
 - Enjoin the Secretary
 - Review an Exercise of Secretary Discretion



Rights of Parties

- Parties Have Right to [§ 160.506]:
 - Legal Representation
 - With No Limitation on Attorneys' Fees
 - Conduct Discovery (Limited)
 - Stipulate as to Fact or Law
 - Examine and Cross-Examine Witnesses
 - Present Oral Arguments
 - Submit Written Briefs (Within 60 Days)
- No Right to Retaliate Against Complainants or Witnesses [§ 160.316]



Burden of Proof

- Respondent has Burden of Going Forward and of Persuasion as to [§ 160.534(b)(1)]:
 - Affirmative Defenses
 - Challenges to Amount of CMP
 - Claims for Reduction or Waiver of CMP
- Secretary has Burden as to All Other Issues [§ 160.534(b)(2)]



Witnesses

- Oral Testimony Allowed [§ 160.538(a)]
- In Discretion of ALJ Testimony, Other Than Expert Testimony, May be Submitted in Written Form [§ 160.538(b)]
- Prior Sworn Testimony, Subject to Cross, May be Admitted by ALJ
- Exclusion of Witnesses [§ 160.538(e)]
 - Not Natural Persons Who are Parties
 - Not Officer/Employee of Entity Which is Party
 - Not Other Essential Natural Person



ALJ Decision

- ALJ Issues Decision Within 60 Days After Hearing or 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
 - 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 [§ 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)]
- 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 questions now, after the session, or contact me directly

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