



HIPAA Enforcement Rule

Aimee Wall

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Refresher Course

- Congress passed HIPAA in 1996
- Various HIPAA rules adopted establishing national standards
 - Transactions and code sets (October 2002)
 - Privacy (April 2003)
 - Security (April 2005)
 - Identifiers
 - Employer (July 2004)
 - Provider (May 2007)
 - Claims attachments (Proposed 9/05)

* With the exception of the claims attachments rule, dates in parentheses are the compliance dates



Enforcement Rule

- Timeline

- Interim final rule published April 2003; sunset March 2006
- Final rule published February 2006; effective March 16, 2006

- Addresses US DHHS standards and procedures related to civil enforcement of all HIPAA rules

- US DOJ will handle criminal enforcement



Good News and Bad News

- Bad news: US DHHS now has a strong framework in place to enforce the rules
- Good news: US DHHS is sending a clear message to covered entities
 - “...encouraging voluntary compliance is the most effective and quickest way of obtaining compliance in most cases.”



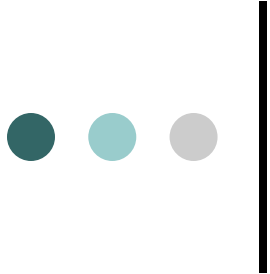
Two possible routes

- Complaint

- Anyone may file a complaint
- Must be filed within 180 days of when the complainant knew or should have known of the violation unless DHHS waives time limit for good cause

- Compliance review

- US DHHS may conduct compliance reviews at any time; not complaint driven



If your local health department is investigated...

- US DHHS will contact local health department (LHD) in writing describing the reason for the investigation
- LHD must cooperate with US DHHS requests for records and reports
- US DHHS may subpoena records or witnesses
- Interviews will be sworn; recorded and transcribed



What will happen?

- LHD must permit access to facilities and records (including PHI) during normal business hours
 - If exigent circumstances exist, LHD must permit access at any time and without notice
- If an investigation reveals noncompliance, US DHHS will try to resolve through informal means, which may include
 - Demonstrated compliance or
 - Corrective action plan



What will happen?

- If resolved informally, US DHHS will inform the LHD and the complainant (if any) in writing
- If not resolved informally, US DHHS will provide the LHD with an opportunity to submit evidence of
 - Mitigating factors
 - Affirmative defenses
 - Punishable as a criminal offense;
 - Did not know of the violation and, by exercising reasonable diligence, would not have known; or
 - Due to reasonable cause and not willful neglect and corrected within a time period approved by US DHHS



What will happen?

- If US DHHS decides to impose a fine, it will send dept a notice of proposed determination
 - NPD will outline the amount of the fine and explain the basis for the fine
 - NPD will explain that LHD has a right to a hearing if requested within 90 days
- US DHHS may settle the case and compromise the penalty at any time



What will happen?

- If no hearing requested, penalty imposed
 - NO RIGHT TO APPEAL
 - Public notification
 - Can withhold federal funds
- If hearing requested, a federal ALJ will review
 - Prehearing conference(s) with ALJ and parties
 - Document discovery but no witness depositions

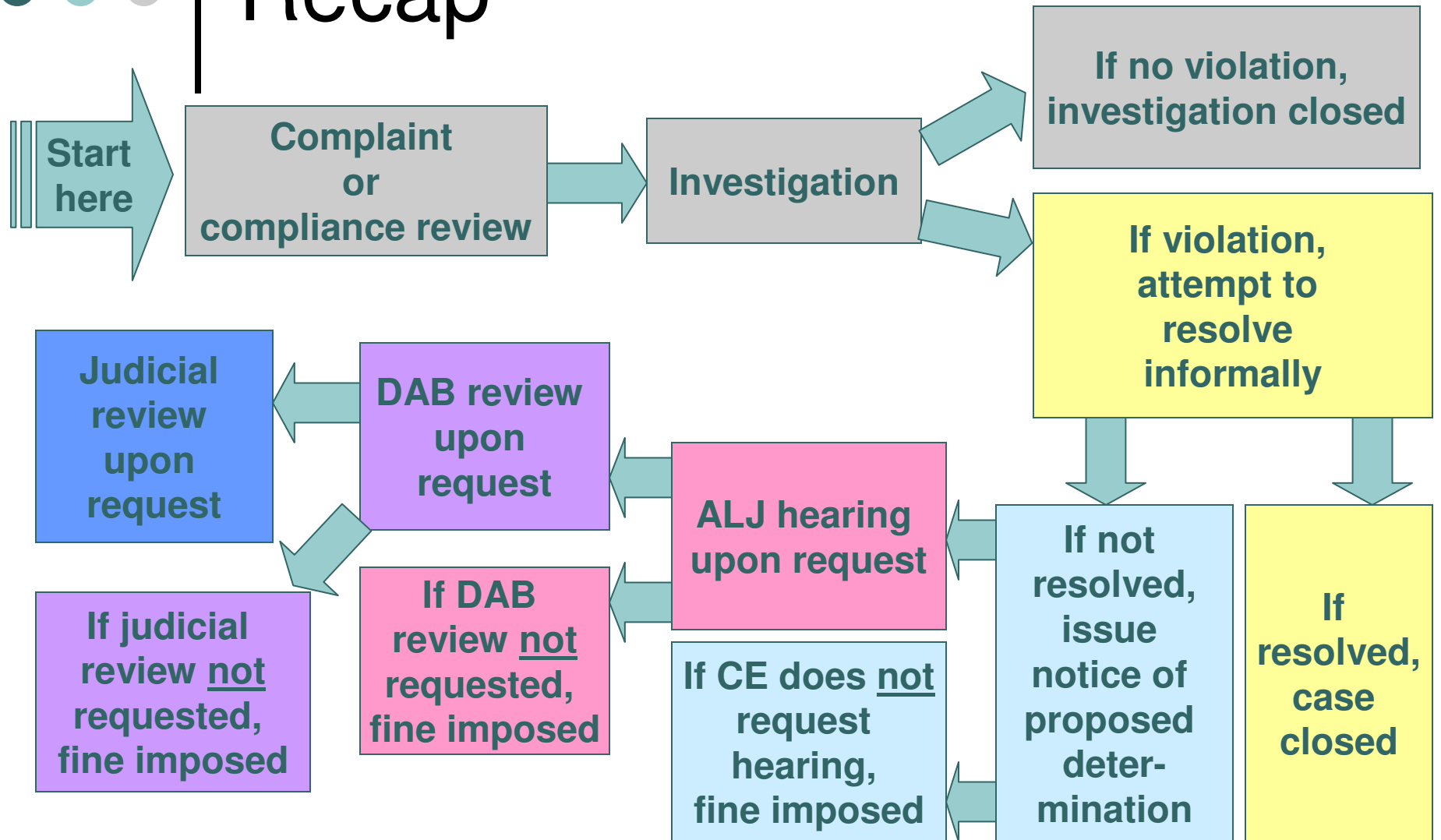


What will happen?

- ALJ may affirm, increase or reduce the penalty
- Either party may appeal to the Departmental Appeals Board
- May file for judicial review



Recap



CE = Covered entity
ALJ = Administrative Law Judge
DAB = Departmental Appeals Board



Vicarious Liability for Agents

- LHD will be liable for violations based on the act or omission of any agent acting within scope of her agency unless
 - Agent is a BA;
 - LHD complied with BA requirements; and
 - LHD did not know of a pattern of activity or practice of the BA and failed to act.



Who is an Agent?

- Workforce member: employees, volunteers, trainees, or others whose conduct in the performance of work for a covered entity is under the direct control of the entity, whether or not they are paid by the entity
- Presumption that any workforce member is an agent
- Governed by federal common law of agency (not state law)



Who is an Agent?

- Employee?
 - Yes, workforce member
- Volunteer?
 - Yes, workforce member
- Student or trainee?
 - Yes, workforce member
- Independent contractor?
 - Depends on whether “direct control”
 - If not, business associate



Calculating the fine

- Up to \$100 per violation and up to \$25,000 for violations of an identical requirement or prohibition in a calendar year
- Will not count a general requirement and a specific requirement
 - Example
 - General: Valid authorization required...
 - Specific: Expiration date or event required for an authorization to be valid



Calculating the fine

- Will not count overlapping in same subpart
 - Example
 - 164.502: Authorization required as provided in 164.508
 - 164.508: Authorization required when...Will count consequential
 - Will count if requirements in different subparts (e.g., privacy, security)



Calculating the fine

- Will count consequential violations
 - Example
 - Must conduct security risk analysis
 - Must use the analysis to implement a security risk management plan; steps in the plan follow from the analysis
 - Failure to do analysis could result in violations of both requirements



Calculating the fine

- Number of violations
 - Depends on the nature of the requirement or prohibition violated
 - Continuing violations counted in days
 - “Some provisions embody a requirement or prohibition that is of an ongoing nature or for which timeliness is an element of compliance”
 - Examples
 - Failing to adopt policies and procedures
 - Failing to provide access within the required time period



Calculating the fine

- Will consider
 - Nature of the violation
 - Circumstances, including
 - Time period of violation
 - Whether violation caused physical or financial harm
 - Whether violation hindered or facilitated individual's ability to obtain health care
 - Degree of culpability
 - History of prior (administrative simplification) violations
 - Financial condition of the covered entity
 - Other matters as justice may require



Questions?