THE HIPAA PRIVACY RULE: Minimally Necessary Disclosure of Protected Health Information

The Second National HIPAA Summit
Washington, D.C.
March 1, 2001

W. Andrew H. Gantt, III

Latham & Watkins
WWW.LW.COM

Overview

Statutory Authority: HIPAA Administrative Simplification Requirements

- **Health**
- **Insurance**
- **Portability and**
- **Accountability**
- **Act of 1996**

Latham & Watkins
WWW.LW.COM

Overview

The Final Rule:

- **Delimits circumstances in which covered entities may use and disclose protected health information;**
- **Creates certain individual rights regarding protected health information; and**
- **Requires covered entities to adopt administrative safeguards to protect protected health information.**

Latham & Watkins WWW.LW.COM

The General Privacy Standard:

- **A covered entity may not use or disclose protected health information (i.e., individually identifiable health information), except as otherwise permitted.**

Latham & Watkins
WWW.LW.COM

Minimum Necessary Standard:

- **When using or disclosing PHI or where requesting PHI from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended use, disclosure or request.**

Latham & Watkins
WWW.LW.COM

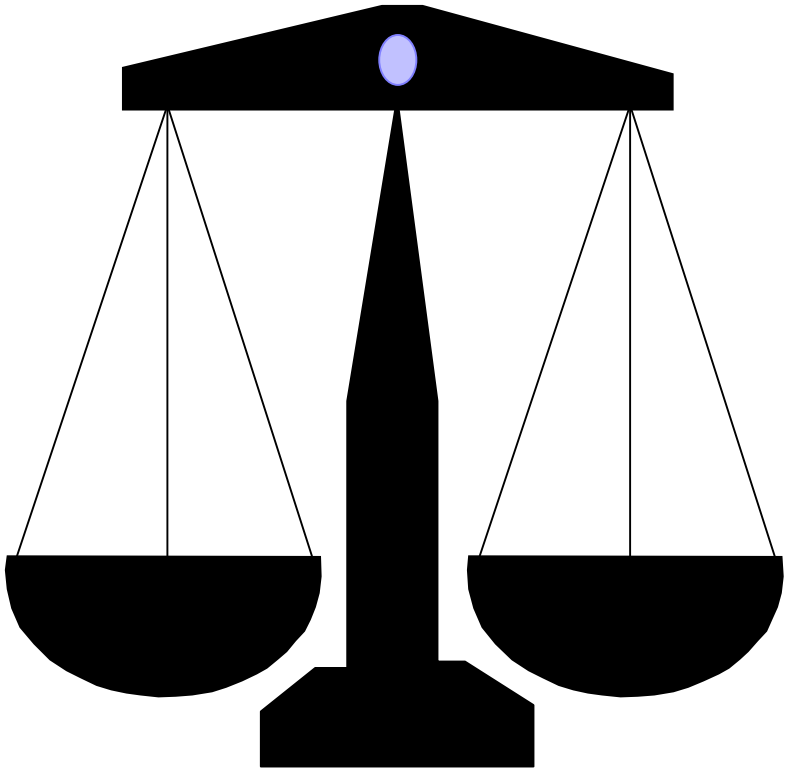
Possible Pitfalls:

- **Careful! --Different standard with different exceptions.**
- **With some exceptions, Minimum Necessary Standard applies to all uses and disclosures.**
- **Final Rule added exception for disclosure to or requests by a health care provider for treatment.**

Latham & Watkins WWW.LW.COM

Minimum Necessary Determination Must Balance:

- **Respect for privacy rights of an individual with**
- **Reasonable limits of covered entity's ability to delimit the amount of identifiable information disclosed.**



Latham & Watkins
WWW.LW.COM

What Effort is Required?

- **Proposed rule preamble suggests covered entity must make reasonable efforts and to incur reasonable expense to limit use and disclosure.**

Latham & Watkins
WWW.LW.COM

No Limits - No Disclosure

- **"Covered entities should not make uses or disclosures of protected health information where they are unable to make any efforts to reasonably limit the amount of protected health information used or disclosed for a permissive purpose."**

Latham & Watkins
WWW.LW.COM

Implementation Requirements: Three Categories to Consider

- **Routine Disclosures:**
  - **Establish policies and procedures for routine uses/disclosures, which may be standardized protocols;**
- **Non-Routine**
  - **Establish criteria to limit disclosed PHI to that reasonably necessary to accomplish purpose;**
  - **Review requests on individual basis based on criteria.**
- **Exceptions**

Latham & Watkins WWW.LW.COM

Exceptions

- **Disclosure to or requests by a health care provider for treatment;**
- **Permitted or required (right to access and accounting) disclosures to individual;**
- **Authorized use or disclosure <u>except</u> for authorizations requested by covered entity for own use/disclosure, disclosure by others or for research;**
- **Uses/disclosures mandated by law, as described under Final Rule; or**
- **Disclosures to HHS Secretary.**

Other Implementation Guidance

- **Minimum necessary determination requires an assessment as to whether purpose could be accomplished reasonably with information that is not identifiable.**

Reasonable Reliance Permitted When Making Disclosures:

- **To public officials that are permitted under HIPAA (with representation);**
- **To another covered entity;**
- **To an employee or business associate for professional services (with representation); or**
- **For research purposes (with required documentation).**

Latham & Watkins WWW.LW.COM

Preemption of State Law

- **HIPAA standards preempt contrary provisions of state law unless:**
  - **HHS Secretary decides otherwise;**
  - **State privacy provision is more stringent;**
  - **State law addresses disease reporting requirements; or**
  - **State law requires health plan to disclose for auditing, licensure and other requirements.**

Latham & Watkins WWW.LW.COM

Administrative Requirements:

- **Must Address Minimum Necessary Standard**
  - **Designation of Privacy Officer;**
  - **Training Programs for Employees;**
  - **Implementation of Safeguards to Prevent Intentional and Accidental Disclosures of Protected Information;**
  - **Complaint System; and**
  - **Sanctions for Violators.**

Latham & Watkins WWW.LW.COM

Compliance and Enforcement

- **HHS reserves the right to investigate complaints and conduct compliance reviews.**
- **No private cause of action.**
- **No longer any third-party beneficiary rights.**

Latham & Watkins WWW.LW.COM

Penalties for Non-Compliance:

- **Civil fines up to $25,000 per calendar year for each violation;**
- **Graduated criminal penalties (with maximum fine of $250,000, or 10 year prison term, or both); false pretenses, intent to sell information or reap personal gain yields higher penalties.**

Latham & Watkins WWW.LW.COM

Implementation Concerns

- **Will application of standard to most uses and disclosures impede the free flow of information?**
  - **Requirement to make determinations on individual basis may be unworkable.**
  - **Application of standard to most uses within an organization may be too burdensome for covered entities to implement.**

Implementation Concerns

- **"Reasonable Efforts" standard is vague.**
  - **What may be reasonable to a covered entity may not be considered reasonable by the Secretary of HHS.**
  - **How should a covered entity determine what is the "minimum amount of protected health information necessary" to use or disclose?**

Latham & Watkins
WWW.LW.COM

Practical Considerations:

- **What compliance efforts should you make and when should you begin?**
- **Technology changes?**
- **Contractual changes?**
- **Policy and procedure changes?**

Latham & Watkins
WWW.LW.COM