



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

**The First National HIPAA Summit
Washington, D.C.
October 16, 2000**

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Overview

Statutory Authority: HIPAA Administrative Simplification Requirements

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

Overview (cont.)

Scope of HIPAA Privacy Standards:

- **What is covered?**
- **Who is covered?**
- **Scalability**

Overview (cont.)

The Proposed Regulations:

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

The General Privacy Standard:

- **A covered entity may not use or disclose an individual's protected health information (i.e., individually identifiable health information) that is or *has* been electronically transmitted or maintained by a covered entity, except as otherwise permitted.**

Exceptions:

- **Permissive Disclosures;**
- **Mandatory Disclosures; and**
- **De-identified Information.**

Minimum Necessary Disclosure:

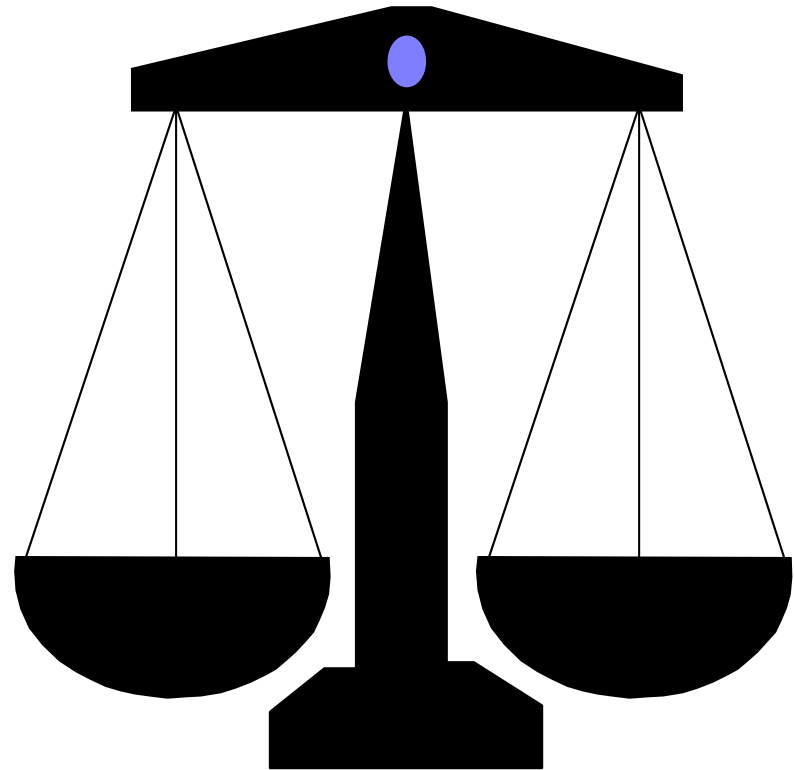
- **Covered entities must “make all reasonable efforts not to use or disclose more than the minimum amount of protected health information necessary to accomplish the intended purpose of the use or disclosure, taking into consideration practical and technological limitations.”**

Minimum Necessary Disclosure (cont.):

- **With some exceptions, Minimum Necessary Disclosure Standard applies to all uses and disclosures made, including those for payment, treatment and health care operations.**

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.**



Exceptions

Standard does not apply to uses or disclosures:

- **Made in accordance with §164.508(a)(1) (authorized disclosure), § 164.514 (access provisions), or § 164.522 (HIPAA compliance audits and enforcement);**
- **Mandated by law and permitted under §164.510;**
- **Required for compliance with applicable HIPAA requirements; or**
- **Made by covered health care provider to covered health plan for audit and related purposes.**

Requirements of Implementation

- **Covered Entity must:**

- **Establish policies and procedures to limit amount of protected health information used or disclosed;**
- **Identify appropriate persons to make determination;**
- **Ensure that such persons carry out task, when required; and**
- **Make such determinations individually, within the entity's technological capabilities.**

Reasonableness Standard

- **Standard requires entity to make all reasonable efforts and to incur reasonable expense to limit use and disclosure.**

Elements to Consider

- **Amount of information to be used/disclosed;**
- **Whether use/disclosure increases number of persons/entities who have access;**
- **Importance of use/disclosure;**
- **Likelihood that further uses/disclosures could occur;**

Elements to Consider (cont.)

- **Potential to achieve same purpose with de-identified information;**
- **Technology available to delimit amount of used/disclosed information;**
- **Cost**
- **Other relevant considerations**

Limiting Access:

- **Proposed rule contemplates that implementing procedures will limit physical access that employees, business partners and others have to protected information.**
- **Entities with advanced IT should consider limiting access to portions of information, where practical.**

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.”**

Other Implementation Guidance

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

Other Implementation Guidance (cont.)

- **Disclosure of entire medical record presumptively violates standard, absent specific request.**
- **Request for entire record requires explanation as to why less extensive disclosure would not meet intended purpose.**

Reliance Permitted

- **When making disclosures to public officials that are permitted under HIPAA, a covered entity may reasonably rely on the representations of such officials that the requested information is the minimum amount reasonably necessary for the stated purpose(s).**

Individual Rights Affected by Minimum Necessary Standard:

- **Right to Notice of Information Practices; and**
- **Right to Receive Accounting of Disclosure.**

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.**

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.**

Compliance and Enforcement

- **HHS reserves the right to investigate complaints and conduct compliance reviews.**
- **No private cause of action, but . . .**
- **Third-party beneficiary rights.**

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.**

Implementation Concerns

- **Will application of standard to all uses and disclosures impede the free flow of information?**
 - Requirement to make determinations on individual basis may be unworkable.
 - Application of standard to all uses within an organization may be too burdensome for covered entities to implement.
 - Application to disclosures made for payment, treatment and health care operations may be difficult 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?**

Implementation Concerns (cont.)

- **Secretary Should Consider Alternatives to “Reasonable Efforts” Standard, Including:**
 - **“Good Faith” standard;**
 - **Defined guidelines;**
 - **Deleting Minimum Necessary Standard;**
 - **Other**

Practical Considerations:

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