

HIPAA INTERIM FINAL RULE

- HHS published interim final rule on October 30, 2009.
- Incorporates changes to HIPAA included in the HITECH Act.
- Amends HIPAA's enforcement regulations to include:
 - New categories of violations
 - Tiered ranges of civil money penalty amounts
 - Revisions to limitations on the authority of HHS to impose civil money penalties for violations

- Penalties for violations - \$100 for each violation
- Maximum penalty amount of \$25,000 for all violations of an identical requirement or prohibition occurring during a calendar year

1. **No knowledge of violation**

- Penalty Range for each violation: \$100 - \$50,000
- Maximum Penalty*: \$1,500,000

2. **Violation due to reasonable cause**

- Penalty Range for each violation : \$1,000 - \$50,000
- Maximum Penalty*: \$1,500,000

3. **Will neglect, but violation corrected during requisite time period**

- Penalty Range for each violation : \$10,000 - \$50,000
- Maximum Penalty*: \$1,500,000

4. **Will neglect, but violation NOT corrected**

- Penalty Range for each violation : \$50,000
- Maximum Penalty*: \$1,500,000

* Represents the maximum penalty for all violations of an identical requirement or prohibition in a calendar year.

New rule keeps the same culpability definitions

REASONABLE CAUSE: Circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated.

REASONABLE DILIGENCE: The business care and prudence expected from a person seeking to satisfy a legal requirement under similar circumstances.

WILLFUL NEGLIGENCE: Conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated.

3 Affirmative Defenses

1. The violation is a criminal violation
2. No knowledge of violation and by exercise of reasonable diligence, would not have known that violation occurred
3. Violation is
 - a. Due to reasonable cause and not willful neglect
 - b. Corrected during either (i) a 30 day period or (ii) a period established by HHS.

2 Affirmative Defenses

1. The violation is criminal violation
2. Violation is:
 - a. Not due to willful neglect
 - b. Corrected during either during (i) a 30 day period or (ii) a period established by HHS.

- HHS may still continue to provide a waiver for violations due to reasonable cause that are not timely corrected.
- HHS may waive the civil money penalty, in whole or in part, to the extent the payment of the penalty would be excessive relative to the violation.

- New rule becomes effective November 30, 2009
- New penalty amounts and affirmative defense regime apply to violations occurring on or after February 18, 2009