

HEALTH LAW ALERT

November 2, 2009

HHS Adopts Stringent HITECH Act Penalties for HIPAA Violations Maximum Penalty \$1.5 Million

The Department of Health and Human Services (HHS) amended the HIPAA enforcement rule on Friday to incorporate revisions required by the Health Information Technology for Economic and Clinical Health Act (the HITECH Act). The amendments apply to the HIPAA Administrative Simplification requirements established in the HIPAA Privacy, Security, Transactions, and Breach Notification Rules (the HIPAA Rules).

Under the amendments, HHS may impose substantially higher Civil Money Penalties on covered entities that violate the HIPAA Rules—the amendments increase the maximum penalty for a single violation from \$100 to \$50,000 or more; the limit on Civil Money Penalties for multiple identical violations in a single year increases from \$25,000 to \$1,500,000. The amendments also limit the affirmative defenses a covered entity may employ in enforcement proceedings. For example, the amendments now allow HHS to assess Civil Money Penalties against a covered entity for violations of which the covered entity was not aware despite exercising reasonable diligence.

HHS adopted the amendments in an interim final rule, which goes into effect on November 30, 2009. Notwithstanding this effective date, the provisions will apply to all violations that take place on or after February 18, 2009. The public may comment on the amendments through December 29, 2009. HHS acknowledges that additional amendments to the HIPAA Enforcement Rule will be required as other HITECH Act enforcement provisions go into effect.

Tiered Penalties

The HITECH Act established and the amendments adopt three “categories of violations that reflect increasing levels of culpability” and three penalty “tiers” that correspond to those culpability levels. Thus, HHS may impose a penalty of:

- Between \$100 and \$50,000 for each violation of which the covered entity did not know and, by exercising reasonable diligence, would not have known.
- Between \$1,000 and \$50,000 for each violation due to reasonable cause and not willful neglect.

- Between \$10,000 and \$50,000 for each violation due to willful neglect, but that the covered entity corrected within 30 days.
- A minimum of \$50,000 for each violation due to willful neglect that the covered entity fails to correct within 30 days.

For each category of culpability, the maximum Civil Money Penalty for multiple identical violations in a single calendar year is \$1,500,000. In contrast, with respect to violations that took place prior to enactment of the HITECH Act, HHS may impose a maximum Civil Money Penalty of \$100 for each violation, irrespective of the covered entity's culpability, and no more than \$25,000 for identical violations in a calendar year.

Affirmative Defenses

Under the amendments, a covered entity will no longer be able to rely on the affirmative defense that it did not know of, and could not have known of the violation by exercising reasonable diligence. Rather, such violations will subject the covered entity to Civil Money Penalties of between \$100 and \$50,000. Covered entities that correct violations within 30 days (or such longer time HHS determines to be appropriate) will not be assessed Civil Monetary Penalties, however, unless the violation is due to willful neglect.

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