

HHS ISSUES RULE IMPLEMENTING INCREASED PENALTIES FOR HIPAA VIOLATIONS

On October 30, 2009, the U.S. Department of Health and Human Services (“HHS”) published an interim final rule with request for comments that strengthens the civil penalty scheme for violations of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).¹ The rule conforms the HIPAA enforcement regulations to the statutory revisions that are currently in effect under the Health Information Technology for Economic and Clinical Health (“HITECH”) Act, which was enacted as part of the American Recovery and Reinvestment Act of 2009.²

The interim final rule will become effective on November 30, 2009. HHS will consider public comments on the rule submitted by December 29, 2009.

I. BACKGROUND

HIPAA required HHS to adopt national standards to protect the privacy and security of certain health information.³ These standards apply to “covered entities,” which are health plans, health care clearinghouses, and health care providers who engage in electronic transactions that have been standardized under HIPAA.⁴ Covered entities may be subject to civil money penalties and criminal penalties for violations of HIPAA requirements.⁵ HHS enforces the civil money penalties, while the U.S. Department of Justice enforces the criminal penalties.

The HITECH Act contains a number of provisions intended to strengthen civil and criminal enforcement of the HIPAA rules.⁶ Specifically, the Act:

- significantly revises the scheme for civil money penalties by establishing categories of violations that reflect increasing levels of culpability;⁷
- provides that the penalty determination must be based on the nature and extent of the violation and the nature and extent of the harm resulting from the violation; and
- establishes a range of available penalty amounts for each category of violation by reference to tiers of penalty amounts.⁸

These provisions became effective on February 18, 2009.

¹ HIPAA Administrative Simplification: Enforcement, 74 Fed. Reg. 56,123 (Oct. 30, 2009) (to be codified at 45 C.F.R. pt. 160).

² Pub. L. 111-5.

³ See 42 U.S.C. § 1320d-1 (2006).

⁴ *Id.* § 1320d-1(a).

⁵ *Id.* §§ 1320d-5, 6.

⁶ HITECH Act, § 13410(d).

⁷ *Id.*

⁸ *Id.*

II. HHS INTERIM FINAL RULE

A. AMOUNT OF CIVIL MONEY PENALTIES

For violations occurring before February 18, 2009, the HHS rule retains the range of penalty amounts imposed prior to the HITECH Act: a maximum amount of \$100 for each violation and a maximum amount of \$25,000 for all violations of an identical requirement or prohibition during a calendar year.⁹

For violations occurring on or after February 18, 2009, the rule establishes four categories of violations and sets out a range of penalties for each violation.¹⁰ The first type of violation is where the covered entity did not know and, by exercising reasonable diligence,¹¹ would not have known, that it committed a violation. The second type of violation is where the violation was due to reasonable cause¹² and not to willful neglect.¹³ The third type of violation is where the violation was due to willful neglect, but was corrected during the 30-day period beginning on the first date the covered entity liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred. Finally, the fourth type of violation is where the violation was due to willful neglect and was *not* corrected during the 30-day period beginning on the first date the covered entity liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred. The ranges of penalty amounts for each type of violation are set forth in the table below.

VIOLATION CATEGORY	EACH VIOLATION	CAP FOR MULTIPLE VIOLATIONS OF IDENTICAL PROVISION PER YEAR
Did Not Know	\$100-\$50,000	\$1,500,000
Reasonable Cause	1,000-50,000	1,500,000
Willful Neglect - Corrected	10,000-50,000	1,500,000
Willful Neglect - Not Corrected	50,000	1,500,000

⁹ 74 Fed. Reg. at 56,131.

¹⁰ *Id.*

¹¹ "Reasonable diligence" is defined as "the business care and prudence expected from a person seeking to satisfy a legal requirement under similar circumstances." *Id.* at 56,130.

¹² "Reasonable cause" is defined as "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." *Id.*

¹³ "Willful neglect" is defined as "conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated." *Id.*

B. AFFIRMATIVE DEFENSES

The HHS interim final rule also amends the provisions relating to affirmative defenses to the imposition of civil money penalties. For violations occurring before February 18, 2009, the rule retains the three affirmative defenses available prior to the HITECH Act: (1) where the violation is an act punishable as a crime under HIPAA; (2) where the covered entity can establish that it did not have knowledge of the violation and by exercising reasonable diligence would not have known that the violation occurred; and (3) where the violation is due to reasonable cause (not willful neglect) *and* corrected during either (a) the 30-day period beginning on the date the covered entity knew, or by exercising reasonable diligence would have known, that the violation occurred *or* (b) such additional period as HHS deems to be appropriate based on the nature and extent of the failure to comply.¹⁴

For violations occurring on or after February 18, 2009, however, the rule removes the second affirmative defense regarding the covered entity's lack of knowledge of the violation, as required by the HITECH Act.¹⁵ The rule also extends the affirmative defense for violations that are timely corrected, which was previously limited to violations due to reasonable cause and not to willful neglect, to all violations not due to willful neglect.¹⁶

The interim final rule does not address the statutory revision regarding the first affirmative defense pertaining to criminal violations, nor does it address the new grant of enforcement authority to state attorneys general to bring civil actions under the HIPAA rules under certain circumstances. These provisions will not take effect until February 18, 2011, and therefore are subject to future rulemaking.¹⁷

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¹⁴ *Id.* at 56,131.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.* at 56,129.