



HHS SIGNIFICANTLY REVISES HIPAA ENFORCEMENT REGULATIONS TO COMPLY WITH HITECH ACT

On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009. Included in the Act was the Health Information Technology for Economic Health Act (the "HITECH Act"), which included significant changes to the privacy and security protections implemented pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). On October 30, 2009, the Department of Health and Human Services ("DHHS") published an interim final rule revising the HIPAA enforcement regulations. DHHS's revisions implement the HITECH Act's changes to the civil money penalties that may be imposed for breaches of the HIPAA privacy and security rules, as well as the affirmative defenses for violations of such rules.

DHHS's changes are effective November 30, 2009, but, as mandated by the HITECH Act, apply to all violations of the HIPAA privacy and security rules occurring on or after February 18, 2009. Because the penalties established in the statute were effective on the day after enactment (February 18, 2009), DHHS has waived the notice-and-comment period normally required for regulatory provisions. However, DHHS is accepting comments on the interim final regulations. Comments must be received by DHHS by December 29, 2009.

1. Revised Penalty Structure.

Prior to the HITECH Act, penalties for violation of the HIPAA rules were limited to \$100 per violation, not to exceed \$25,000 for violation of any identical requirement during a calendar year. The HITECH Act established tiered ranges of civil monetary penalty amounts based upon the nature of the violation. However, the language of the HITECH Act was open to various interpretations as to how the penalties would be applied. DHHS has adopted a stringent interpretation of the HITECH Act's civil money penalties provision to require that penalties be assessed as follows:

Violation Category	Range of Penalties per Violation	Maximum Penalty for All Violations of an Identical Provision in a Calendar Year
Unknowing violation	\$100 - \$50,000	\$1,500,000
Violation due to "reasonable cause"	\$1,000 - \$ 50,000	\$1,500,000
Violation due to "willful neglect" but corrected within 30 days	\$10,000 - \$50,000	\$1,500,000
Violation due to "willful neglect" but not corrected within 30 days	\$50,000	\$1,500,000

In the preamble to the interim final rule, DHHS states that it will not impose the maximum penalty in all cases. Rather, DHHS states that "penalty determinations will be based on the nature and extent of the violation, the nature and extent of the resulting harm, as well as other factors set forth in § 160.408 (such as the covered entity's history of prior compliance or financial condition)."

2. Affirmative Defenses.

Prior to the HITECH Act, the HIPAA statute limited DHHS's authority to impose a penalty on a covered entity that could establish that it "did not know, and by exercising reasonable diligence would not have known" of the violation. The HITECH Act eliminated this limitation, and DHHS has therefore removed a covered entity's lack of knowledge as an affirmative defense for violations occurring on or after February 18, 2009. The elimination of this affirmative defense leaves two remaining affirmative defenses recognized by DHHS:

- a. The violation is punishable under HIPAA's criminal penalties; or
- b. The violation is not due to willful neglect and is corrected either 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; or such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply."

DHHS retains the right to waive all or part of the civil money penalties for violations "due to reasonable cause and not willful neglect that are not corrected" during this period if the Secretary of DHHS determines that the penalty would be excessive relative to the violation.

3. Further Revisions Expected.

The October 30 interim final rule does not include amendments to the enforcement rule for HITECH provisions that are not yet effective. Rather, the October 30 rule is the latest in what is likely to be a series of amendments to the HIPAA privacy, security, and enforcement rules necessary to implement the HITECH Act's requirements.

4. Other Enforcement News.

In another sign that federal agencies are taking a stricter stance with regard to HIPAA violations, a physician and two hospital employees in Little Rock, Arkansas pled guilty to misdemeanor HIPAA violations and, on October 26, 2009, were sentenced to a year's probation for inappropriately accessing protected health information relating to a local news anchorwoman for "curiosity purposes." The physician was fined \$5,000 and ordered to perform 50 hours of community service educating professionals about patient privacy and HIPAA. The hospital employees were fined \$2500 and \$1500. The hospital whose records were breached fired the two employees and suspended the physician's medical staff privileges for two weeks, while also requiring him to complete online HIPAA training.

Health Law Update

Inquiries concerning topics addressed in the Health Law Update may be directed to any of our Health Care attorneys listed below. Your comments, questions, and suggestions are encouraged.

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