

November 10, 2009

HIPAA ENFORCEMENT UPDATED UNDER HITECH: THE INTERIM FINAL RULE

AT A GLANCE

The Issue:

The Department of Health and Human Services (HHS) recently released an interim final rule updating the enforcement rule for the *Health Insurance Portability and Accountability Act of 1996* (HIPAA). These updates were necessitated by the passage of the *Health Information Technology for Economic and Clinical Health Act (HITECH)*. Specifically, the rule incorporates HITECH's categories of violations, tiered ranges of civil money penalty amounts, and limits on the HHS Secretary's authority to impose civil money penalties for established HIPAA violations. This interim final rule takes effect November 30 and its enhanced penalties will be applicable for violations occurring on or after February 18, 2009.

This *Advisory* examines the key changes to the enforcement rule adopted in this interim final rule. Comments are due by December 29.

Our Take:

The interim final rule generally appears consistent with HITECH's statutory modifications of the enforcement process. It increases the range of civil money penalties applicable for statutorily identified categories of violations by covered entities, including hospitals. Additional rulemaking related to HIPAA enforcement will be necessary as the statutory effective dates for other HITECH provisions approach. Hospitals will need to stay up to date with the evolving enforcement landscape.

What You Can Do:

- ✓ Share this advisory with your legal counsel, privacy and security officers, and other members of the HIPAA implementation team.
- ✓ Ensure that everyone in your organization understands the impact that enhanced HIPAA enforcement and increased penalties for violations will have on your organization's compliance efforts.
- ✓ Use this opportunity to re-evaluate and enhance your organization's HIPAA compliance activities.
- ✓ Look to the AHA for information about additional changes in the HIPAA enforcement landscape.

Further Questions:

Please contact Lawrence Hughes, assistant general counsel, at (202) 626-2346 or lhughes@aha.org.

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HIPAA ENFORCEMENT UPDATED UNDER HITECH: THE INTERIM FINAL RULE

BACKGROUND

The Department of Health and Human Services (HHS) recently released an interim final rule implementing certain updates to the enforcement rule for the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) necessitated by the passage of the *Information Technology for Economic and Clinical Health Act (HITECH)*. Specifically, the rule incorporates HITECH's categories of violations, tiered ranges of civil money penalty amounts, and limits on the HHS Secretary's authority to impose civil money penalties for established HIPAA violations.

This interim final rule takes effect November 30 and its enhanced penalties will be applicable for violations occurring on or after February 18, 2009. However, forthcoming rulemaking on enforcement will make additional changes to the rule to ensure that it accounts for other HITECH provisions with future statutory effective dates, including, for example, provisions that alter the affirmative defense for violations subject to criminal penalties, require formal investigations of any complaints if a preliminary investigation of the facts of the complaint indicate a violation due to willful neglect, and permit the distribution of a portion of a civil money penalty collected to the individual who is harmed as a result of a violation.

However, no amendments are necessary to make the enforcement rule consistent with the statutory provision in HITECH permitting states attorneys general to bring civil actions for violations of HIPAA in certain circumstances. The authority for this provision comes directly from the statute and does not require HHS rulemaking.

This *Advisory* examines the key changes to the enforcement rule adopted in this interim final rule. Comments are due by December 29.

AT ISSUE

Categories of violations and applicable range of civil money penalties

HITECH established categories of violations that reflect increasing culpability and corresponding tiers of civil money penalties. The interim final rule implements this penalty structure for violations occurring on or after February 18, 2009. The penalty structure (i.e., maximum of \$100 for each violation and of \$25,000 for all violations of an identical requirement or prohibition) under the current enforcement rule is retained for those violations that occurred before February 18. For violations that began prior to February 18 and continue after that date, HHS plans to use a combination of the existing and revised penalty structures, with the new penalty structure applying as of February 18.

The specific revised penalties adopted in the interim final rule are spelled out in the chart below.

CATEGORIES OF VIOLATIONS AND AVAILABLE PENALTIES		
Category of Violation	Range of Civil Money Penalty for Each Violation	Maximum for All Violations of an Identical Provision in a Calendar Year
Covered entity did not know and, by exercising reasonable diligence, would not have known of violation	\$100 - \$50,000	\$1,500,000
Violation due to reasonable cause, not to willful neglect	\$1,000 - \$50,000	\$1,500,000
Violation due to willful neglect, but corrected during the 30-day period beginning on the 1 st day the covered entity knew or, by exercising reasonable diligence, would have known of the violation	\$10,000 - \$50,000	\$1,500,000
Violation due to willful neglect, but <i>not</i> corrected during the 30-day period beginning on the 1 st day the covered entity knew or, by exercising reasonable diligence, would have known of the violation	\$50,000	\$1,500,000

HHS argues that this penalty structure is “consistent with the most logical reading” of the relevant HITECH provisions, which include conflicting language referencing two tiers of penalties for certain categories of violation, each of which provides a maximum penalty amount “for all such violations of an identical requirement or prohibition in a calendar year.” In addition, HHS argues that this structure also is consistent with “congress[ional] intent to strengthen enforcement, in part, by increasing the [available] minimum penalty amounts [by] categories of violation,” and with the “clear discretion . . . provided to impose a penalty amount” up to an outside limit.

Penalty amounts to be based on nature, extent of violation and resulting harm

HHS notes that it will not impose the maximum penalty in all cases. As required, the penalty amount will be determined on the basis of the nature and extent of the violation and the nature and extent of the harm that results, as well as the factors (e.g., prior compliance history and financial condition of the violating covered entity) already outlined in the current enforcement rule’s section 160.408.

The interim final rule continues the authority of the Secretary to waive civil money penalties, partially or entirely, for violations that are due to reasonable cause and not willful neglect that are not corrected within the 30-day period after the covered entity knows, or should know, of the violation “to the extent that the payment of the penalty would be excessive relative to the violation.”

The interim final rule also leaves intact the methodology described in the current enforcement rule’s preamble for counting the number of violations. HHS will continue to use it for determining the number of violations from February 18 forward.

Rule alters affirmative defenses

As required by HITECH, the interim final rule also modifies the available affirmative defenses that a covered entity may establish and, thereby, avoid the imposition of a civil money penalty for a violation. These revisions apply to violations occurring on or after February 18, 2009. The affirmative defenses available under the existing enforcement rule will continue to apply for violations that occur prior to February 18.

First, the interim final rule strikes the affirmative defense that a covered entity “did not know, and by exercising reasonable diligence would not have known” of the violation. Instead, covered entities in this category may now be subject to the lowest level of penalty under the revised penalty structure previously outlined, unless, as discussed below, they also correct the violation within the 30-day period after they know, or should have known, of the violation.

Second, the interim final rule extends the affirmative defense for violations that are corrected in a timely manner to all violations that are not due to willful neglect. Previously, the defense was limited to violations due to reasonable cause and not to willful neglect. HHS nevertheless clarifies that the Secretary may continue to use discretion in providing technical assistance, obtaining corrective action and resolving possible noncompliance by informal means where the possible noncompliance is due to reasonable cause or in the event a covered entity did not reasonably know of a violation.

The interim final rule retains the affirmative defense for violations that are criminal acts, and for now HHS cannot impose civil penalties for such violations. However, forthcoming rulemaking will make specific changes in this provision consistent with a provision of HITECH which becomes effective on February 18, 2011.

In the preamble to the interim final rule, HHS reminds covered entities that “knowledge” of a violation means that the covered entity “must have knowledge that a violation has occurred, not just knowledge of the facts underlying the violation.” However, HHS cautions that because of the reasonable diligence requirement, the affirmative defense for violations that are not due to willful neglect will be unavailable when the covered entity’s lack of knowledge results from its failure to inform itself of compliance obligations or to investigate complaints received or other information suggesting likely noncompliance.

HHS has not altered any provisions related to the 30-day period for curing violations. Determinations of when a covered entity first had knowledge of a violation and whether that violation was cured timely will be based on evidence gathered during HHS’ investigation of the violation and necessarily made on a case-by-case basis.

Additional information included in the Notice of Proposed Determination

Under the existing enforcement rule, HHS must provide a written notice of the intent to impose a penalty for violations of HIPAA’s requirements. The interim final rule adds additional information to the notice. Specifically, HHS will identify in the notice the applicable category of violation (see above) that is the basis for the proposed penalty amount. HHS points out that while such additional information is not specifically required by statute, it has been added to the notice in order to provide “additional notice and information to benefit [covered entity’s] understanding of the violation findings” in the notice.

NEXT STEPS

Hospitals will need to stay up to date with the evolving enforcement landscape. In the interim final rule, HHS explicitly recognizes that additional amendments to the enforcement rule will be necessary as other statutory provisions of HITECH take effect.

However, the rule, as published, is effective November 30. HHS nevertheless invites comments on any aspect, particularly whether:

- The penalty structure established by HHS is “consistent with the most logical reading” of the conflicting language in the relevant HITECH provisions that references two tiers of penalties for certain categories of violation.
- There are alternative approaches for determining the beginning of the 30-day period for curing violations and, thereby, incurring a lesser penalty amount.

For questions about the interim final rule’s requirements, contact Lawrence Hughes, AHA assistant general counsel, at lhughes@aha.org or (202) 626-2346.