

January 2013

A Detailed Analysis of Changes to HIPAA and the Implications for Healthcare Providers and Others in the Healthcare Industry

On Friday, January 25, 2013, the Office for Civil Rights (“OCR”) of the U.S. Department of Health and Human Services (“HHS”) published a final rule modifying the HIPAA Privacy, Security, and Enforcement Rules (the “Final Rule”) as mandated by the Health Information Technology for Economic and Clinical Health (“HITECH”) Act. Many of these modifications were set forth in a Notice of Proposed Rulemaking (“NPRM”) dated July 14, 2010, although the Final Rule does not adopt all the proposals as described in the NPRM.

The Final Rule also modifies the Breach Notification Rule, which has been effective as an interim final rule since September 23, 2009. Finally, the Final Rule strengthens privacy protections for certain genetic information under the Genetic Information Nondiscrimination Act (“GINA”).

The Final Rule makes significant changes to HIPAA and the potential penalties for violating HIPAA. The Final Rule also expands the scope of HIPAA, meaning that some businesses that were not subject to HIPAA before the Final Rule now have HIPAA compliance obligations and can be subject to enforcement action for noncompliance. Healthcare providers and others in the healthcare industry should be aware of these changes and how they will apply to their particular business.

The Final Rule is effective on March 26, 2013, and Covered Entities and Business Associates must comply with the Final Rule by September 23, 2013.

Changes to the HIPAA Enforcement Rule

Background: On October 30, 2009, HHS issued an interim final rule revising the Enforcement Rule to incorporate provisions of the HITECH Act. The NPRM then proposed a number of additional modifications to the Enforcement Rule, and the Final Rule adopts several of these modifications to implement HITECH Act requirements that the interim final rule did not address or adopt.

Modifications: The Final Rule implements provisions regarding enforcement of noncompliance due to willful neglect. The Final Rule requires the Secretary to formally investigate complaints indicating violations due to willful neglect and requires that the Secretary conduct a compliance review to determine whether a Business Associate is in compliance when a preliminary review of facts indicates a possible violation. The Final Rule provides the Secretary with discretion (and removes the former mandate) to resolve investigations or compliance reviews indicating noncompliance by informal means. In addition, the Final Rule requires the imposition of civil money penalties upon finding violations due to willful neglect.

The Final Rule also adds the term “Business Associate” to certain provisions to implement the HITECH Act’s imposition of direct civil money penalty liability on Business Associates for their violations of certain provisions of the HIPAA Privacy and Security Rules.

With regards to the imposition of civil money penalties under the Enforcement Rule, the Final Rule modifies the definition of “reasonable cause” to clarify the state of mind required for violations. In addition, the Final Rule adopts changes to make a Covered Entity liable for a violation based on the act or omission of any of the Covered Entity’s agents, including workforce members or Business Associates, acting within the scope of the agency, and to make a Business Associate similarly liable for violations by its agents, including workforce

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members or subcontractors, acting within the scope of the agency. The Final Rule retains the changes to the increased and tiered civil money penalty structure as adopted in the interim final rule. The Final Rule makes changes to require the Secretary to determine civil money penalty amounts on a case-by-case basis, depending upon the nature and extent of the violation and the resulting harm. Furthermore, the Final Rule prohibits the Secretary from imposing a civil money penalty only to the extent a criminal penalty has been imposed with respect to an act under 42 U.S.C. 1320d-6, rather than in cases in which the act constitutes an offense that is criminally punishable under § 1320d-6. Finally, the Final Rule provides the Secretary with authority to waive the civil money penalty, in whole or in part, for violations of Enforcement Rule provisions that are not corrected within the applicable time period, to the extent the payment of the penalty would be excessive relative to the violation.

If you have any questions about the Final Rule or HIPAA please contact [Jill M. Girardeau](#), the principal drafter of this alert, [Sarah B. Crotts](#), [Deonys de Cárdenas](#), [Tracy Field](#), or any member of Womble Carlyle's [Healthcare Industry Team](#).

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