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Analysis of Final HIPAA Omnibus Rule: Enforcement Provisions

This is the sixth in a series of bulletins analyzing the changes in the HIPAA Omnibus Rule (Final Rule) released January 17, 2013, and published January 25, 2013 (78 Fed. Reg. 5566). As it is widely known, the HITECH Act significantly increased the enforcement of HIPAA through various mechanisms. The Final Rule makes changes to the enforcement provisions of HIPAA that continue the trend toward expanded and stronger enforcement.

Determination of Civil Monetary Penalties

The Final Rule retains the civil money penalty structure for violations based on tiered levels of culpability. The categories of culpability and penalties are:

Violation Category	Penalty for Each Violation	Maximum for All Violations of an Identical Provision in a Calendar 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

The Department of Health and Human Services (HHS) emphasized that it will not impose the maximum penalty in all cases but will determine the amount on a case-by-case basis depending on the nature and extent of the violation, the nature and extent of resulting harm, the history of non-compliance of the entity and the financial condition of the entity. Regarding the history of non-compliance, it is worth noting that the Final Rule uses the terminology “previous indications of non-compliance” in describing this factor, rather than “history of violations” as used prior to the Final Rule. HHS clarified that the change is intended to allow it to consider prior non-compliance even when there was no formal finding of a violation.

Affirmative Defenses

The affirmative defenses available to covered entities and business associates are modified under the Final Rule. The Final Rule prohibits the imposition of a civil monetary penalty for any violation, other than one due to willful neglect, if the violation is corrected within 30 days from when the entity knows of, or has constructive knowledge of the violation. Additionally, under the Final Rule, a civil monetary penalty may not be imposed if a criminal penalty has already been imposed for the violation.

Investigations

The Final Rule makes several changes that will result in more aggressive enforcement and severe penalties:

- HHS *must* initiate an investigation if preliminary review indicates a possible violation due to willful neglect; it is no longer discretionary, as it was prior to the Final Rule. HHS retains discretion to decide whether to initiate an investigation or compliance review where the preliminary review indicates a degree of culpability less than willful neglect.
- Previously, HHS was required to attempt to resolve violations by informal means. Under the Final Rule, however, HHS has discretion whether or not to do so, and is no longer obligated to try to resolve violations informally.

Liability for Business Associates

The Final Rule adopts the proposal to make covered entities liable for business associates who are their agents under federal agency law. This rule applies to business associates as well with respect to their subcontractors. Whether a business associate is an agent will be fact specific, considering the terms of the business associate agreement and the totality of the circumstances regarding the relationship. HHS noted that the factors to consider in determining whether an agency relationship exists are:

1. The time, place, and purpose of a business associate's conduct;
2. Whether a business associate engaged in a course of conduct subject to the control of the covered entity (or other business associate in a subcontractor relationship);
3. Whether a business associate's conduct is commonly done by a business associate to accomplish the service performed on behalf of a covered entity (or other business associate); and
4. Whether or not the covered entity (or other business associate) reasonably expected that a business associate would engage in the conduct in question.

HHS clarified that the labels used by the parties, such as specifying that the business associate is an independent contractor, do not control whether an agency relationship exists. One comment from HHS that is of particular concern is that a business associate may still be considered an agent even when acting in violation of the business associate agreement, if acting for the benefit of the covered entity. HHS stated: "A business associate agent would likely be acting within the scope of agency if it impermissibly disclosed more than the minimum necessary information to a health plan for purposes of payment, even if the disclosure is contrary to clear instructions of the covered entity."

Given that even acts "contrary to clear instructions of the covered entity" can lead to liability of the covered entity, avoiding an agency relationship with business associates whenever possible, and including clear indemnification provisions when agency relationship exists, will be of prime importance.

This joint e-Alert is the sixth in a series analyzing the final HIPAA Omnibus Rule. Please watch for our future e-Alerts on additional topics covered under the Final Rule, and for the announcement of our new tool to help you make changes to your HIPAA compliance program required by the Final Rule.

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