

January 22, 2013

## What You Will and Won't Find in the Final Omnibus HIPAA Rule

On January 17, 2013, the U.S. Department of Health and Human Services (HHS) issued the final omnibus HIPAA rule. Covered entities and business associates must comply with applicable requirements by September 23, 2013.

This bulletin lists the topics covered (and not covered) by the 563-page advance copy rule in summary fashion. The final rule is long and complicated, and covers many topics. It adopts many of the provisions in the proposed rule, but modifies some and also includes new requirements. Many of the provisions in the final rule will require changes to your policies and procedures, and other supporting documents.

This list is intended as a simple summary to inform you what is and what is not covered in the final rule. In order to make it easier to digest the substance of the rule, we will be issuing a series of bulletins over the next few weeks, each of which addresses in depth one or more of the significant changes included in the final rule.

The [section-by-section compilation of the privacy and security rules on the Bricker & Eckler website](#) has been updated to include the changes in the final omnibus HIPAA rule. The section-by-section compilation is also in the process of being updated to include the HHS Description and Commentary from the final rule as well, and that process should be completed in the next few days.

### The topics addressed in the final rule include the following:

- **Definitions** – Modifies a number of definitions, including the definition of “health care operations,” “marketing” and “business associate.”
- **Business Associate Agreements** – Adopts the changes to the provisions governing BA agreements included in the proposed rule, with some modifications.
- **Sale of PHI** – Adopts the changes included in the proposed rule and further clarifies what constitutes a sale of PHI and remuneration.
- **Research** – Modifies the authorization requirements for research.
- **Deceased Individuals** – Adopts the provisions of the proposed rule regarding PHI of deceased individuals, including the requirement that it be protected for 50 years.
- **Immunization Records** – Adopts the provisions of the proposed rule that permit the disclosure of immunization records to a school when required by state law.
- **Fundraising** – Adopts the provisions of the proposed rule regarding use of PHI for fundraising, with some additional modifications.

- **Notice of Privacy Practices** – Adopts a number of material changes to the NPP requirements, *which will require distribution of a new NPP.*
- **Requests for Restrictions** – Adopts the modifications to the requirements for requests for restrictions included in the proposed rule.
- **Requests for Access** – Adopts a number of changes in the proposed rule regarding requests for access, with modifications to the same time periods for response and the fee provisions.
- **Hybrid Entities** – Requires business associate functions to be included in a hybrid entity.
- **Enforcement** – Adopts a number of the provisions included in the proposed rule regarding enforcement actions and penalties.
- **Breach** – Materially amends the definition of breach; *this is one of the most significant changes in the final rules.*
- **Notification of Breach** – Adopts nearly all of the provisions in the proposed rule related to notification of breach, with additional clarifications.
- **Genetic Information** – Adopts almost all of the changes in the proposed rule related to genetic information, and adds additional requirements related to underwriting, as required under the Genetic Information Nondiscrimination Act of 2008 (GINA).

**The following issues were *not* addressed in the final rule:**

- **Accounting of Disclosures** – The HITECH Act requires HHS to adopt rules governing the new accounting disclosure requirements. On May 31, 2011, HHS published a proposed rule regarding accounting for disclosures. The final omnibus rule does not include this proposed rule.
- **Penalty Distribution Methodology** – The final rule specifically states that the penalty distribution methodology requirement in Section 13410(c) of the HITECH Act will be the subject of future rulemaking.

**Please watch for our series of future bulletins on the topics covered under the final rule, and for an announcement of our new tool to help you make the changes to your HIPAA compliance program required by the final rule.**

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