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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.

GINA

Background: GINA prohibits discrimination based on an individual's genetic information in both the employment and health coverage contexts. In 2009, HHS published a notice of proposed rulemaking to strengthen the privacy protection for genetic information by, among other things, explicitly stating in the Privacy Rule that genetic information is PHI and that health plans may not use or disclose genetic information for underwriting purposes.

Modifications: The Final Rule includes a specific prohibition against the use or disclosure of PHI that is genetic information by health plans (excluding issuers of long term care policies) for underwriting purposes. To help clarify for health plans the types of uses and disclosures that are prohibited by this new provision, the Final Rule makes several definitional additions and changes, including the addition of definitions for the terms "genetic information," "genetic services," "genetic test," and "underwriting purposes." Finally, as described above in the section discussing NPPs, health plans that perform underwriting (except for issuers of long term care policies) must include in their NPPs a statement that they are prohibited from using or disclosing genetic information for such purposes.

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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Client Alert

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