

HIPAA ALERT

NEWLY ISSUED HHS REGULATIONS AND AUDIT PROTOCOL SIGNAL THE IMPORTANCE OF UPDATING HIPAA COMPLIANCE PROGRAMS

On January 17, 2013, the U.S. Department of Health and Human Services Office for Civil Rights issued a 563 page final regulatory rule under the Health Insurance Portability and Accountability Act (“HIPAA”). The regulations, which implement provisions of the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), create sweeping changes to HIPAA. They impose new obligations on health plans, including self-insured employer sponsored plans, health care providers, and related HIPAA-covered entities. The rule implements a number of changes including stricter breach reporting requirements. All affected parties must act quickly as the regulations impose a September 23, 2013 compliance deadline, although there is a special grandfather rule available to certain business associate agreements that are already in place.

Among other things, the final rule:

- Requires changes to the notices of privacy practices;
- Changes the standard for determining when a data breach must be reported;
- Changes the individual rights protected by HIPAA;
- Modifies the HIPAA privacy rule under the Genetic Information Nondiscrimination Act;
- Expands the definition of “business associates” to cover subcontractors of business associates;
- Applies privacy and security liability directly upon business associates (including subcontractors);
- Adopts increased civil monetary penalties;
- Amends the requirements for research related authorizations; and
- Clarifies rules precluding certain remuneration in exchange for the disclosure of PHI.

Additionally, the HHS Office for Civil Rights recently released a protocol that it is using to perform privacy and security audits mandated by the HITECH Act. HHS is using this protocol in conjunction with its recent program auditing 115 covered entities (including medical care providers and group health plans) and their business associates, for privacy and security compliance, an effort that will continue through 2013 and 2014. The protocol covers 165 areas of inquiry –78 relating to privacy, 77 covering security and 10 relating to breach notification–, and includes such areas as notices of privacy practices for protected health information and requests for privacy protections for PHI. This protocol can serve as a useful template for covered entities to ensure HIPAA compliance and to avoid issues in the case of an audit.

In light of these new regulations and the audit program, covered entities and business associates should review and update their HIPAA compliance programs, using both the regulations and the audit protocols as guides.

*The HIPAA Alert is intended to keep readers current on HIPAA matters and is not intended to be legal advice. If you have any questions about this alert or any other issues relating to HIPAA, please contact **Sandra Mihok** at 412.566.1903, **Michael Ecker** at 215.851.8507, **Elizabeth Goldberg** at 412.566.6016 or **Sarah L. Carlins** at 412.566.1918.*