

E-ALERT | Health Care

July 26, 2010

HHS ISSUES PROPOSED RULE TO IMPLEMENT HITECH CHANGES TO HIPAA

On July 14, 2010, the U.S. Department of Health and Human Services (HHS) published in the Federal Register a [notice of proposed rulemaking](#) (NPRM) to implement several provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act, Pub. L. 111-5, enacted as part of the American Recovery and Reinvestment Act of 2009. As described in our [previous alert](#), the HITECH Act significantly expands the reach of the privacy, security, and enforcement rules promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The NPRM proposes detailed changes to the HIPAA regulations in many different areas, including:

- **Changes Affecting Business Associates and the Relationship Between Covered Entities and Business Associates**
 - *Subcontractors.* HHS proposes to include in the definition of “business associate” subcontractors who work on behalf of business associates and handle protected health information (PHI).
 - *Business Associates.* HHS also proposes several changes to implement HITECH Act provisions relating to business associates, such as the obligation to comply with the Security Rule and certain provisions of the Privacy Rule, breach notification requirements, and the application of penalties to violations by business associates.
 - *Business Associate Agreements.* The NPRM amends the business associate agreement requirements to, among other things, remove the requirement that covered entities report breaches to HHS when termination of the agreement is not feasible.
 - *Transition Provisions.* HHS proposes to allow covered entities and business associates (and business associates and their subcontractors) to continue to operate under existing contracts for up to one year beyond the compliance date of the revisions to the rules, or until either party has renewed or modified the contract following the compliance date, whichever is sooner. This transition provision applies only to the requirement to amend contracts and does not affect any other compliance obligations.
- **Changes Affecting Clinical Research and Medical Messaging Programs**
 - *Research.* The NPRM relaxes the restrictions on compound authorizations for research purposes. HHS also seeks comments on potential modifications to the rules regarding authorization for future research. These provisions are likely to be of much interest to clinical trial sponsors.
 - *Marketing.* HHS proposes several changes to the marketing restrictions. For example, the NPRM excludes from the definition of “marketing” written treatment communications for which financial remuneration is received, provided certain notice and opt-out conditions are

met; incorporates the statutory exception for communications regarding refill reminders or other drugs or biologics currently prescribed for the individual, to the extent any payment for the communication is reasonable in amount; and requires prior written authorization for remunerated health care operations communications.

■ **Changes Affecting the Relationship Between Individuals and Covered Entities**

- *Notice of Privacy Practices.* The NPRM requires covered entities to provide additional information in their notices of privacy practices, including that most uses and disclosures of PHI for marketing purposes require an authorization.
- *Individual Access to PHI.* The NPRM provides that if PHI is maintained electronically in a designated record set, the covered entity must provide an individual with the right to access that information in the electronic form and format requested by the individual.
- *Requested Restrictions.* Under the NPRM, a covered entity must, upon an individual's request, agree to a restriction on the disclosure of PHI to a health plan if: (1) the disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and (2) the PHI pertains solely to an item or service for which the individual has paid the covered entity in full.
- *Fundraising.* The NPRM requires covered entities to provide individuals with a clear and conspicuous opportunity to opt-out of fundraising communications.

■ **Effective and Compliance Dates.**

- Covered entities and business associates will have 180 days beyond the effective date of the final rule to come into compliance with new and modified standards and implementation specifications in the regulations

Comments on the NPRM are due on **September 13, 2010**. If you have questions about the proposed requirements or would like our assistance in submitting comments on the NPRM, please contact one of the lawyers listed below.

If you have any questions concerning the material discussed in this client alert, please contact the attorneys listed below:

Anna Kraus	202.662.5320	akraus@cov.com
Demetrios Kouzoukas	202.662.5057	dkouzoukas@cov.com
Rachel Grunberger	202.662.5033	rgrunberger@cov.com

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.

© 2010 Covington & Burling LLP, 1201 Pennsylvania Avenue, NW, Washington, DC 20004-2401. All rights reserved.