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**** ALERT ****

By: S. Whitney Rahman

Government Requests Information to Assist in Developing HITECH Act Regulations

If your organization is either a covered entity or a business associate under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), you need to be aware of a recent request for information from the Department of Health and Human Services (“HHS”).

HIPAA requires that, upon request for an accounting, covered entities must provide information about certain disclosures that have been made of the individual’s protected health information (“PHI”) over the past six years. For each disclosure, the covered entity must provide: (1) the date of disclosure; (2) the name and address (if known) of the entity or person who received the PHI; (3) a brief description of the disclosed PHI; and (4) a brief statement of the purpose of the disclosure or a copy of the written request for the disclosure. If there have been multiple disclosures for the same purposes, once the above have been identified, the covered entity need only identify the frequency, or number of disclosures and the date of the last disclosure during the accounting period.

While HIPAA exempts from accounting any disclosures made to carry out treatment, payment and health care operations, Section 13405(c) of the Health Information Technology for Economic and Clinical Health Act (“HITECH ACT”) provides that these exemptions no longer apply to “electronic health records.” Instead, individuals, upon request, now will be entitled to an accounting for all such disclosures of electronic health records for the past three years from the date of the request. An electronic health care record is “an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.” HITECH Act, Section 13400.

HHS has the duty to develop regulations to facilitate this provision. Accordingly, through a request for information published on May 3, 2010, it seeks input from individuals regarding their concerns about receiving accounting information, and from covered entities (and

business associates) regarding the administrative burden of accounting for disclosures for treatment, payment, and health care operations through an electronic health record.

Specifically, HHS has proposed the following questions for covered entities:

- (1) Are individuals aware of their current right to receive an accounting of disclosures? On what do you base this assessment?
- (2) How do you make clear to individuals their right to receive an accounting of disclosures? How many requests have you received?
- (3) Should an accounting for treatment, payment and health care operations disclosures include the date, time, patient information, user identification and a description of the disclosure or other data, and why? Should reasons for the disclosure be general or specific?
- (4) For existing electronic health record systems:
 - (a) Can the system distinguish between uses and disclosures as those terms are defined under HIPAA's privacy rule?
 - (b) If the system records access only (as opposed to use and disclosure information), what information is recorded? How long is it retained? What would the burden be to retain it for three years?
 - (c) If the system does distinguish between uses and disclosures, what data elements are automatically collected (without the need for manual input) by the system for disclosures? What information is manually entered?
 - (d) If the system does distinguish between uses and disclosures, does it record a description of disclosures in a standardized way? If so, is the feature used, and what are its benefits and drawbacks?
 - (e) Is there a single, centralized electronic health record system?
 - (f) Does the system automatically generate an accounting for disclosures under the current HIPAA privacy rule? If yes, what would be the addition burden to account for disclosures to carry out treatment, payment, and health care operations? Would additional hardware be needed? Would there be effects on the performance of the system? If no, is there a different automated system for accounting for disclosures, and does it interface with the electronic health record system?
- (5) Will covered entities be able to begin accounting for disclosures through an electronic health record to carry out treatment, payment, and health care operations by January 1, 2011? If not, how much time would it take vendors of electronic health record systems to design and implement such a feature? Once available, how long would it take a covered entity to install an updated electronic health record system with such a feature?

(6) What is the feasibility of an electronic health record module that is exclusively dedicated to accounting for all disclosures (both the original accountings under HIPAA and those required by the HITECH Act)? Would it work with covered entities that maintain decentralized electronic health record systems?

(7) What other information would be helpful to HHS in developing its regulations?

This request for information provides your organization with an opportunity to provide feedback to HHS that may help guide it in creating the regulations in this area. All comments must be submitted by May 18, 2010. They may be submitted electronically at <http://www.regulations.gov>, preferably in Microsoft Word format, although WordPerfect and Excel also are acceptable. They also may be mailed or sent overnight with an original and two copies to: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HITECH Accounting of Disclosures, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, S.W., Washington, D.C. 20201.

If you have any questions about this, or about any employment or labor law issues, please call Whitney Rahman or John Roland at 610-372-5588.