

## Proposed Changes to HIPAA Privacy and Security Regulations

On July 14, 2010, the Department of Health and Human Services (“DHHS”) proposed changes to HIPAA regulations in order to implement requirements of the HITECH Act<sup>1</sup>. Many of these changes merely reiterate the corresponding provisions of the HITECH Act, and therefore, may look very familiar. There were, however, some very significant “surprises” that, if included in the final regulations, will require operational and policy changes for covered entities and their business associates. For example, the proposed regulations would require covered entities to revise their existing business associate agreements. In addition, perhaps most notably, the proposed definition of “business associate” would be expanded to include all subcontractors of business associates that have access to PHI.

### WHEN WILL THE CHANGES BE EFFECTIVE?

Comments regarding the proposed rules are welcomed during the sixty (60) day comment period, which ends on September 12, 2010. Upon review of submitted comments, DHHS will publish final rules. We cannot definitively predict when this will occur, but we would anticipate that the final regulations will not be published until, at the earliest, Fall or Winter of this year.

In the commentary to the proposed rules, DHHS recognized that most of the provisions of the HITECH Act went into effect in February 2010, and that it will be difficult for business associates and covered entities to comply with such HITECH statutory provisions when the implementing regulations have not yet been finalized. Therefore, DHHS intends to provide covered entities and business associates with 180 days beyond the effective date of the final rule to come into compliance with the new regulations and the corresponding provisions of the HITECH Act. For example, the HITECH Act requires that patients be permitted to ask for and receive their records in an electronic format, if available. Covered entities will not need to be in compliance with this requirement until 180 days after the implementing regulations become final and effective.

### WHAT WILL CHANGE?

The proposed modifications address, among others, the following:

- (i) Revisions to the definition of a business associate, which would be expanded to include, among others, subcontractors of a business associate;
- (ii) Requirements for business associates to enter into business associate agreements with their subcontractors;
- (iii) Revisions to existing business associate agreements, which in most cases would need to be accomplished within one (1) year from the effective date of the final rules;
- (iv) Revisions to privacy notices;

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<sup>1</sup> The term “HITECH Act” refers to be the Health Information Technology for Economic and Clinical Health Act of 2009.

- (v) Modifications to the marketing rules, primarily with regard to payments for PHI to be used in marketing activities;
- (vi) New standards regarding opt-out language in marketing and fundraising communications;
- (vii) Prohibitions on the sale of PHI;
- (viii) Use of compound patient authorizations for research studies;
- (ix) Use of immunization records;
- (x) Requests for restrictions on disclosures to insurers; and
- (xi) Patient rights to obtain copies of electronic records containing PHI.

DHHS has requested further comments from the public on certain HIPAA issues (e.g., research, fundraising and other topics) rather than making a formal proposal for changes at this time. Further, this proposed rulemaking does not address accountings, which will be covered in a separate rulemaking.

#### **WHAT SHOULD ENTITIES BE DOING NOW?**

While we do not believe that any actions should be taken in direct response to the proposed rules at this time, we do recommend that covered entities and business associates begin to identify and locate their business associates/business associate agreements to prepare to enter into new business associate agreements when the final rules are published. In addition, covered entities should be aware that changes to their privacy notices may be required in the future once the new rules are finalized.

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GW is available to advise clients about the necessary steps to maintaining compliance with HIPAA and HITECH Act requirements. If you require any assistance or want to learn more about the proposed rules, please call any of the attorneys at GW.

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