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Proposed Modifications to the HIPAA Privacy, Security, and Enforcement Rules According to the HITECH Act

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The Office of Civil Rights of the Department of Health and Human Services ("**HHS**") recently released its proposed regulations for the modification of the HIPAA Privacy, Security, and Enforcement Rules (collectively, the "**HIPAA Rules**") under the Health Information Technology for Economic and Clinical Health Act ("**HITECH**"). The stated purpose of the proposed regulations is to implement statutory amendments under HITECH, to strengthen the protection and security of health information, and to improve the workability and effectiveness of the HIPAA Rules.

Although for the most part the proposed regulations simply track the changes set forth in HITECH of which many healthcare providers are already aware, in some instances they set forth proposed modifications that were not as easily anticipated. This Client Alert focuses on some of the more significant changes, unanticipated changes, and certain questions that remain open in light of the proposed regulations.

Significant Proposed Changes

Some of the more significant changes to the HIPAA Rules set forth by the proposed regulations affect: a) business associates; b) enforcement; c) the sale and use in marketing or fundraising of Protected Health Information ("**PHI**"); and d) patients' rights with respect to their PHI.

Expansion of Scope to Business Associates

Perhaps the most significant change set forth in the proposed regulations is the expansion of the scope of applicable provisions of the HIPAA Rules so that they apply directly to business associates in the same way that they apply to covered entities. This makes business associates responsible for protecting PHI and for following applicable provisions of the HIPAA Rules just as covered entities are required to do, and subjects business associates to the same penalties and enforcement actions for noncompliance as covered entities. Despite this expansion of scope, the requirement that covered entities and business associates enter into contracts (business associate agreements) defining the appropriate uses and disclosures of PHI nonetheless remains in the proposed regulations.

Subcontractors as Business Associates

Another significant proposal is the inclusion of subcontractors who perform services for business associates and require access to PHI within the meaning of "business associate." If the proposal

becomes final, this means that subcontractors will be required to enter into business associate agreements as well. However, unlike most business associates who must enter into an agreement with the covered entity on whose behalf they gain access to PHI and perform certain functions, the subcontractor will have to enter into an agreement with the business associate, not covered entity, on whose behalf they gain access to PHI and perform certain functions.

Uncertainty arises when more parties are added to the equation and subcontractors try to further contract out work that requires access to PHI. The proposed regulations leave open the question of how far down the chain of subcontractors the requirement of complying directly with the HIPAA Rules survives. This is an area that would benefit strongly from further guidance in the final regulations.

Modifying Enforcement of the HIPAA Rules

The proposed regulations modify how the HIPAA Rules are enforced in multiple ways, including requiring the Secretary of HHS to investigate a complaint or conduct a compliance review, as applicable, to determine whether a violation of the HIPAA Rules has occurred, changing the definition of "reasonable cause" as it applies to the tiered civil monetary penalties, and removing the provision that exists under the current HIPAA Rules which provides that a covered entity will not be liable for certain acts of a business associate if the business associate is an agent of the covered entity.

The proposed regulations also provide for delaying the actual enforcement of the final regulations 180 days beyond their effective date, but it is unclear precisely to which provisions this "grace period" applies. This is another area that would benefit from clarification in the final regulations. Furthermore, the proposed regulations provide covered entities and business associates some flexibility in updating their business associate agreements as well by providing them with a one-year transition period beyond the compliance date of the final regulations.

Restricting the Sale and Use in Marketing or Fundraising of PHI

The proposed regulations, with several exceptions, prohibit a covered entity from selling an individual's PHI without prior authorization from the individual to do so. One notable exception to this rule is for exchanges related to the sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that, following such transaction, will become a covered entity, and all due diligence related to such transaction. If this exception becomes final, it should provide some additional comfort to healthcare entities as they pursue various transactions and ventures. The proposed regulations also narrow the definition of marketing, further restrict the use of PHI in connection with fundraising, and prohibit conditioning treatment upon agreement to receive fundraising materials.

Expanding Patients' Rights With Respect to Their PHI

The proposed regulations impose new requirements on covered entities which result in greater patient rights, such as requiring covered entities, if requested by an individual, to agree to a restriction on the disclosure of PHI to a health plan if it is for the purpose of carrying out payment or healthcare operations, is not otherwise required by law, and the PHI pertains solely to a healthcare item or service for which the covered entity has been paid out of pocket in full by someone other than the health plan.

Take Away

Many of the changes in the proposed regulations will come as no surprise to those healthcare providers who have already reviewed the statutory provisions of HITECH because most of them largely track the modifications in HITECH. Nevertheless, the proposed regulations do contain important changes, such as expansion of the term "business associate" to encompass subcontractors who will receive PHI in the course of their respective duties for business associates, attempted clarification of certain enforcement measures, an extended "grace period" for many changes to the HIPAA Rules, and revisions affecting patient rights.

While we advise providers to review the actual text of the proposed regulations, we note that there is no guarantee that the current content of the proposed regulations will survive the comment period which extends until 60 days after the date of publication of the proposed regulations in the federal register. For this reason, while it is important to consider the implications of these proposed regulations, it is also important that affected entities be measured and prudent in their respective responses to these proposed changes.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings Los Angeles lawyers:

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