

Get your house in order: Business Associate responsibilities under HITECH



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Our job as lawyers is to get our client's proverbial "house" in order. But as of September 23, 2013, when the Health Information Technology for Economic and Clinical Health (HITECH) Act compliance deadline regarding, in part, Business Associates, finally kicked into gear, it appears lawyers may need to do a bit of house cleaning first before continuing to advise clients.

Overall, HITECH is designed to promote and increase safeguards regarding health information technology. Business Associate Agreements (BAA) facilitate the goals of HIPAA and HITECH by creating a contractual obligation for Business Associates and covered entities (CE) to protect and safeguard the disclosure of medical patients' protected health information (PHI). Under HITECH, these BAAs now reach well beyond the parameters initially established by HIPAA, and include new liabilities for non-compliance. The scope of the new BAA requirements under HITECH require more than a cursory glance. So what implications does the new HITECH rule carry for Business Associates?

Expanded "Business Associate" definition. Pursuant to 45 C.F.R § 160.103, HITECH significantly expands the definition for Business Associates working with or for CEs. Under previous HIPAA regulations, a Business Associate was nothing more than a person or entity (other than an employee of the covered entity) providing or performing a service to or for a CE, and which involved the disclosure of PHI.

HITECH expands this same definition to any person or entity which "creates, receives, maintains, or transmits PHI" for or on behalf of a CE. Under HITECH, this now includes, but is not limited to, entities providing financial or accreditation services, data processing services, administrative services, Health Information Organizations, E-prescribing

Gateways, and anyone else "creating, receiving, maintaining, or transmitting" PHI for or on behalf of a CE. It is worth noting that Business Associate subcontractors can now also be considered Business Associates under HITECH.

Increased Liability for Non-Compliance.

Under HIPAA, the extent of a Business Associate's liability was contained in the Agreement itself. The CE's only remedy for a Business Associate's non-compliance with HIPAA was contractual in nature. More importantly, under HIPAA, the Privacy and Security rules applicable to the CE were not equally applicable to a Business Associate, and the CE bore sole responsibility for ensuring BAAs were in place, and compliant with HIPAA regulations.

HITECH changes this in several critical ways. First, certain privacy and security regulations are now directly applicable to Business Associates under 45 C.F.R § 164.104. These regulations would include, but are not limited to, 45 C.F.R § 164.308, § 164.314, and § 164.502. Second, Business Associates are directly liable under HIPAA and HITECH for non-compliance with any privacy and security provisions to the same extent as CEs. The new rule does not change a Business Associate's liability to the CE under the BAA for any violations of HIPAA, HITECH, or the BAA itself.

Third, under 45 C.F.R §164.504(e) Business Associates must now require subcontractors to enter into BAAs, and those BAAs must be as stringent

as the contract between the CE and the Business Associate. Finally, under the same rule, Business Associates are also liable for a subcontractor's non-compliance with HIPAA or HITECH, and are also liable for a CE's non-compliance. Thus, a Business Associate's knowledge of any subcontractor or CE's non-compliance now places the Business Associate at liability for such misconduct.

New Contract Terms. Under HIPAA, only CEs were burdened with ensuring any BAAs (1) required Business Associates to safeguard PHI, (2) prohibited Business Associate's from using or disclosing PHI beyond the contractual limitations of the BAA, and (3) required Business Associate's to agree to hold subcontractors to the same restrictions, among other restrictions.

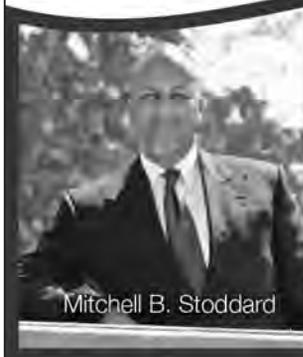
Now, under 45 C.F.R §164.504, HITECH mandates Business Associates share this burden. Not only are Business Associates equally responsible for ensuring

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a BAA is HIPAA and HITECH compliant, but Business Associates have an affirmative obligation to prevent the disclosure of PHI in violation of HIPAA or HITECH, among other requirements. As mentioned earlier, Business Associates must also enter into BAAs with subcontractors that are equally as stringent as the contract between the Business Associate and the CE.

So how does a firm get its own house in order now that the deadline has already passed? Like a champion. As always, key to complying with HIPAA and HITECH is taking the time to read the actual provisions, and ascertain exactly what is required under the regulations. The rule is much more expansive than one may believe, and it is imperative your entity has a solid understanding of what is required under the various HIPAA and HITECH subparts. Second, determine whether your firm qualifies as a Business Associate and if so whether a BAA is needed. If your firm already has a BAA, determine whether the BAA should be amended to conform to the current HIPAA and new HITECH provisions. Third, determine which subcontractors, if any, are required to sign BAAs and ensure they understand the new changes under HITECH. Finally, remind your CEs of their responsibilities under HITECH and the importance of instituting new HIPAA and HITECH compliant BAAs. ■

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