Decanda Faulk, Esq.

It is common knowledge that a covered entity and business associate as defined by HIPAA must comply with HIPAA and HITECH Act requirements. Since the HITECH Act, requests are made of pharmaceutical drug makers ("Pharma Company") to enter BAAs, particularly in connection with the company's technology and technology-enabled initiatives. We caution against any Pharma Company jumping into a BAA with a technology vendor, if the Pharma Company or technology vendor each are not already a BAA or sub-BAA, without giving careful thought to whether this makes sense for either or both.

Some considerations for a Pharma Company when presented with a request to enter a BAA or sub-BAA with a technology vendor:

- Is the Pharma Company directly implicated under HIPAA? If so, how?
- How might a Pharma Company become subject to HIPAA?
- Has the Pharma Company with an HCP (or other CE) conceded such authority? If yes, then it must enter a BAA and/or sub-BAAs.

What if the Pharma Company has not contracted with an HCP (or other CE or BA) in which it has conceded such authority and it is not performing services for an HCP, CE or BA that requires it to receive, generate, use, disclose, maintain or transmit PHI – then our position remains that a Pharma Company is still not a CE and, therefore subject to HIPAA either as a CE or BA and, thus required to enter a BAA. If, however, the company is stepping into the HCPs' shoes by provisioning services that would typically be provided by the HCP (e.g. purported unbranded websites created for or on behalf of the HCP as a mechanism to further promote and sell the Pharma Company's Regulated Products) then perhaps maybe. For example, if the website or platform will be maintained by the Pharma Company on behalf of such HCP in which the company's and HCP's mutual objectives is to use the technology or technology-enabled goods or services sponsored by the Pharma Company to facilitate the promotion, marketing and sale of the Pharma Company's Regulated Products and/or reimbursement of same (e.g. prior authorization assistance) on these sponsored websites and platforms (in which case either the HCP is purchasing Regulated Products for its own practice or making them available to the consumer (patient)) under the guise that the website or platform is either wholly independent of each party (i.e. the HCP's individual website

or platform), when it is actually the Pharma Company's website or platform linked perhaps inconspicuously to together), this would perhaps require the parties enter a BAA or sub-BAA.

First point of order would be, however, that if a website or platform is sponsored by the Pharma Company for the benefit of the HCP (e.g. HCP promotes, orders and/or sells the Regulated Products, obtains reimbursement related services, including prior authorizations or other insurance information) then a proper legal, regulatory and compliance analysis of the appropriateness of such an arrangement (which this blog post intentionally omits) should be undertaken. Secondly, it must be known whether PHI is involved or is it personally identifiable information ("PII") unrelated to any health or medical condition. As the former is subject to HIPAA and the HITECH Act while the latter is not, albeit other privacy laws and regulations may be implicated necessitating compliance therewith.

Some take the position to err on the side of caution and expedite the contracting process, just have the Pharma Company enter a BAA or sub-BAA with the technology vendor engaged to structure such websites or platforms, linkages, etc., particularly if a cloud service provider ("CSP") will then hosts any PHI sponsored in connection with a Pharma Company's technology initiatives done on behalf of an HCP in which PHI will be involved. However, there is way too much information that remains to be known to reach any conclusion on this issue.

Again, the bigger and more important question is the legal, regulatory and compliance analysis that went into supporting the structure of such concepts for the activities being carried out between the HCP and Pharma Company permitting such endeavor through the use of technology and technology-enabled goods and services (i.e. unbranded websites to promote and sell the Pharma Company's Regulated Products).

In any event, if the technology vendor or CSP will perform services contracted for and through the Pharma Company and such IT vendor or CSP will manage software, including host it or provide any data storage involving PHI, then the IT vendor or CSP would likely each be a sub-BAA. Some sub-BAAs are so far down the contractual chain that it is difficult to recognize that a transaction has any HIPAA implications. However, that does not absolve the HCP, Pharma Company or any BAA or sub-BAA from HIPAA obligations. Therefore, it is up to both parties' legal counsel to discern whether the transaction or relationship implicates HIPAA and the HITECH Act and flesh this out well before conceding that the Pharma Company is deemed a BAA or sub-BAA and thus will incur the obligations related thereto. This, however, should occur after any issues have been resolved favorably that the proposed endeavors do not implicate the anti-kickback statute or false claims act. The key is transparency in discussing these matters with legal counsel who is asked to review related technology and technology-enabled contracts for these initiatives.