



## BUSINESS ASSOCIATE AGREEMENTS -- A CASE EXAMINING OBLIGATIONS

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In the self-funded industry, the prevalence of business associate agreements (“BAAs”) is undisputed, as covered entities and business associates regularly execute them. The Health Insurance Portability and Accountability Act (“HIPAA”) generally requires covered entities and business associates to enter into contracts with their business associates. The BAA is integral to the relationship between a covered entity and business associate, as it defines the contractual obligations for the use and disclosure of protected health information (“PHI”).

Elements of a BAA are quite standard, although the parties do have some flexibility when drafting other contractual provisions, such as indemnification or audits language. As for the standard elements, HIPAA lists ten mandated provisions that must be included and also generally requires that the contractual language adequately establish the permitted and required uses and disclosures of PHI. These provisions are not only essential for compliance with HIPAA but are also important when considering the liability of the business associate. Deviating from the uses and disclosures permitted in the BAA or those required by law can have significant repercussions and may result in civil or criminal liability.

Through a complaint filed on April 11, 2025, in the United States District Court, Western District of Texas, Austin Division, a business associate recently experienced this situation. In *CareNexa, LLC v. Ntirety, Inc.*, CareNexa, LLC, dba Molecular Testing Labs (“MTL”), alleged that its business associate, Ntirety, Inc., failed to safeguard the PHI of its patients and satisfy the indemnification provision within their BAA. Within the complaint, MTL asserted its identity as a “covered entity,” as defined by HIPAA, by virtue of being a healthcare provider that collects, manages, and stores PHI. The complaint notes that Ntirety, a data hosting and security provider, is a business associate of MTL. As such, the parties entered into a BAA on September 28, 2018.

MTL’s complaint discusses Ntirety’s alleged failure to use appropriate safeguards to prevent the unauthorized use or disclosure of PHI, a provision that is required to be within the BAA. As noted above, of the ten mandated provisions, HIPAA requires that the BAA state that the business associate will “use appropriate safeguards and comply, where applicable, with [the HIPAA Security Rule] with respect to electronic protected health information, to prevent use or disclosure of the information other than as provided for by its contract.” Guidance from the United States Department of Health and Human Services (“HHS”) indicates that the phrase “appropriate safeguards” includes reasonable and appropriate administrative, physical, and technical safeguards for securing electronic PHI. Rather than dictating specific safeguards, HHS provides that, when establishing such safeguards, regulated entities should consider several factors, such as the entity’s size, capabilities, technical infrastructure, hardware and software security capabilities, security costs, and the probability of potential risks to electronic PHI.

MTL alleges that Ntirety failed to implement these administrative, physical, and technical safeguards, resulting in a violation of the BAA and the HIPAA Security Rule. MTL’s allegation is based on information it received notifying it of a material breach of data that was required to be secured by Ntirety per the BAA. The forensic investigation performed at the request of MTL indicated that electronic PHI under Ntirety’s management, control, and protection was obtained by unknown threat actors.

As a result of this breach, the threat actors demanded a ransom payment from MTL. Failure to pay the ransom would result in public disclosure of the electronic PHI. MTL insists that the investigation confirms that the threat actors took advantage of the deficiencies in Ntirety’s safeguards, allowing them to access PHI from both Ntirety’s and MTL’s computer systems. Consequently,



MTL argues that the investigation's findings are evidence of Ntirety's violation of the BAA and the HIPAA Security Rule.

MTL's complaint also asserts that Ntirety breached its obligations under the BAA by failing to indemnify MTL. As noted above, the indemnification provisions within a BAA are separate from HIPAA's required provisions, and the parties may draft the language in a mutually agreed-upon manner. The complaint offers a glimpse into the BAA by describing the relevant portions of the indemnification provision for purposes of Ntirety's alleged breach. MTL asserts that the relevant contractual provisions require Ntirety to indemnify and hold MTL harmless from any losses, expenses, damage, or injuries sustained as a result of Ntirety's breach of the BAA, including any unauthorized use, disclosure, or breach of PHI, as well as Ntirety's negligence or failure to perform its obligations as a business associate under the BAA and HIPAA. MTL outlined a series of damages it has or will incur and seeks indemnification from Ntirety.

This case is in its infancy, as it was only filed last month. It is important to note that with only the complaint and no response yet filed on behalf of Ntirety, the situation is only represented through the point of view of one party, and Ntirety's position remains unknown. Despite being in its early stages, the themes within this complaint function as key reminders for both covered entities and business associates.

The complaint emphasizes the importance of a BAA as a means of protecting the covered entity when PHI may be mishandled by the other party. It also creates awareness for business associates to confirm they are utilizing processes that are thorough and adequate for the safeguarding of PHI under HIPAA and their BAAs. Fundamentally, implementing appropriate safeguards is necessary for compliance with HIPAA, but this case serves as a reminder that adequate and appropriate safeguards can insulate the business associate from what could otherwise be a source of contractual liability for the business associate under the BAA. ■

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