Healthcare contractual relationships between covered entities (CE) and business associates (BA) changed February 17, 2009 when the American Recovery and Reinvestment Act of 2009 (ARRA) regulated HIPAA’s privacy and security rules applicable to business associates just as for covered entities. The Act enacts the extension of certain sections of the Privacy and Security Rules to business associates as of February 17, 2010. With breach notification requirements added simultaneously, the changes urge BAs and CEs to revisit, reposition and coordinate communication and work process understanding to meet the new regulations. The changes affect BAs and CEs engaged in outsourced activities involving protected health information (PHI) addressed in business associate agreements (BAA). These breach notification provisions are found in section 13402 of the Act and apply to HIPAA covered entities and their business associates that access, maintain, retain, modify, record, store, destroy, or otherwise hold, use, or disclose unsecured protected health information.

AHIMA recognizes the urgency and challenges posed to both stakeholders particularly for breach notification compliance and has prepared this article and template contractual breach management addendum language for use as a starting point in BAA negotiations. It addresses considerations for a collaborative approach to expedite and smooth operational wrinkles as federal regulatory compliance is accomplished under the guidance of a healthcare organization’s legal counsel. The guidance provided herein is not intended to address the specialized business relationship of ‘agent’. Legal guidance is likewise encouraged in such circumstances.

At any given time, covered entities may support a large number of business associate agreements, each with customized activities, processes and expectations. Likewise, business associates may be partners with a large number of covered entities and operating under different business associate agreements, each of these agreements will different. At least two viewpoints have emerged from analysis of the ARRA law as to the necessity of updating BAAs. At a minimum AHIMA recommends the agreements be reviewed by the covered entity as the party originating the protected health information involved in the activities associated with the agreement. The decision to update an existing agreement or not is one advised be made under oversight of the CE’s legal counsel based on a particular agreement’s conditions. A CE may

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BA exercises reasonable diligence; The BA must have in place reasonable systems for discovery of breaches. (Page 42749 the Federal Register / Vol. 74, No. 162 / Monday, August 24, 2009 / Rules and Regulations)

Workforce training and education; The BA shall ensure their workforce members and other agents are adequately trained and aware of the importance of timely reporting of privacy and security incidents and of the consequences of failing to do so. The BAA shall also commit the CE to providing CE workforce members and other agents are adequately trained and aware of the importance of timely reporting of privacy and security incidents and of the consequences of failing to do so. Furthermore, the CE shall assist the BA in training their workforce members and other agents on specific or unique CE processes,

Timing of breach discovery and reporting: Business Associates shall treat all breaches as discovered and report the breach to the CE the first day known or should have been known by a BA exercising due diligence. There is an expectation of breach discovery if the BA is exercises due diligence, in such circumstances the expectation is that the BA should have known. The BA shall be required to report potential breaches to the CE on the first day known or should have been known by a BA exercising due diligence. The BAA should allow the CE to set a time limit on the number of days between discovery of a potential breach and the reporting of the breach to the CE.

Breaches Treated as Discovered – As delineated in the breach notification provisions of Section 164.404(a)(2) of the HIPAA Privacy Rule a breach shall be treated as discovered by a BA as of the first day the breach is known to the BA, or by exercising reasonable diligence would have been known to the BA. Thus, a BA is not liable for failing to provide notification in cases in which it is not aware of a breach unless the covered entity would have been aware of the breach had it exercised reasonable diligence.

Section 164.404(a)(2) further provides that a covered entity is deemed to have knowledge of a breach if such breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is a workforce member or agent of the covered entity

Because a covered entity or business associate is liable for failing to provide notice of a breach when the covered entity or business associate did not know—but by exercising reasonable diligence should have known—of a breach, it is important for the business associate agreement to required implementation of reasonable systems for discovery of breaches.

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BAA obligation begins at the discovery of a breach and continues as long as related activity continues, until all effects of the information breach are mitigated. Because the potential for private right of action exists the business associate agreement should address the obligations of all parties. The BAA must address all points of collaboration supportive of efficient resolution. The BAA should establish agreed upon mitigation timelines as well as clearly stated responsibilities with regard to breach notification and mitigation.

Designated a point person: The BAA shall designate and provide a point of contact as well as applicable phone numbers, e-mail address, and other contact information both on and off business hours and back up point of contact for the CE and BA. The designated point person could be the staff member serving as the entities privacy official.

Meeting CE Compliance Requirements: Matters pertaining to PHI privacy and security shall be resolved to the satisfaction of the CE Compliance requirements.

Performance of Risk Assessment: The BA shall be expected to complete or participate in an investigation/risk assessment following a suspected information breach;

Immediately following a suspected security breach the CE and BA shall collaborate on the performance of a risk assessment to determine if an impermissible use or disclosure of protected health information constitutes a possible information security breach. The objective of the risk assessment shall be to determine if a significant risk of harm to the individual exists as a result of the impermissible use or disclosure. The risk assessment shall determine is a harm threshold has been crossed and there exists a significant risk of financial, reputational, or other harm to the individual.

Should the risk assessment result in a determination that individually identifiable protected health information held by the BA has been breached and a significant risk of financial, reputational, or other harm to the individual exists; the BA shall corroborate with the CE to notify the affected and individuals and mitigate the negative impact of the breach. Working with the CE the BA shall;

1. Notify CE immediately [defined in contract] upon discovery: The BA shall support the CE 60-day notification Compliance requirements by reporting suspected PHI security breaches immediately upon discovery.
2. Corroborate with the CE on breach risk assessment and investigation: The BA and CE shall commit necessary and appropriate staff and resources to the Security Incident Response
Team and Harm Threshold Assessment process to ensure compliance with mandated timelines.

3. **Commit to expeditious responses and workflow turnaround.** The BA shall commit the resources and staff necessary to ensure compliance with mandated timelines.

4. **Participate in Notification Process:** The BA shall be involved in the breach notification process; the BA may be delegated part or all of the notification process if appropriate, especially if it has been determined that responsibility for the breach rests with the BA.

5. **Deliver indemnification statement:** The BA shall indemnify the CE, against any and all liability and reasonable expenses actually and necessarily incurred by CE in connection with the defense or settlement of any action, suit or proceeding in which it is determined that financial, reputational, or other harm is inflicted upon an individual and the BA is adjudged in such action, suit or proceeding to be guilty of or liable for willful misconduct in the performance of duty and as to such matters as shall be settled by agreement predicated on the existence of such liability. The BA accepts responsibility for their actions and agrees to indemnify or compensate the CE for any claims against it that are the result of the BA’s actions or inactions.

6. **Determine if financial incurrences rest with responsible party:** If it be adjudged that the BA is at fault for financial, reputational, or other harm is inflicted upon an individual as the result of an impermissible use, identity theft, or disclosure of PHI all associated costs are the responsibility of the BA.

7. **Notify the Media involving multiple Covered Entities:** In business cases where a PHI breach occurs at a business associate involving the protected health information of multiple covered entities. The CE involved would only be required to provide notification to the media if the information breached included the protected health information of 500 or more individuals located in any one State or jurisdiction. However if the business associate discovers that breach involves PHI from multiple covered entities and the entities involved are unable to determine which entity’s protected health information was involved. The CE reserves the right to direct the business associate to take responsibility for administrating the breach notification process including the notification of the media in cases where the PHI of 500 or more individuals. The CE retains the right to oversee the process by which the media is notified. Additionally, in such cases where the entities involved are unable to determine which entity’s protected health information was involved in the PHI breach the BA shall have the obligation of notifying the Secretary under § 164.408(b) concurrently with notice to the affected individuals; however, both covered entities must include this breach in their annual submission to the Secretary pursuant to § 164.408(c).

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Business Associate Subcontractors: The BA shall ensure that provisions of the business association agreement are contained in the business associate agreement of all subcontractors that access, maintain, retain, modify, record, store, destroy, or otherwise hold, use, or disclose unsecured protected health information (PHI).

REFER TO: HOW TO REACT TO A SECURITY INCIDENT SIDEBAR: BE PREPARED TO COMMUNICATE WITH THE MEDIA, ALSO DESIGNATING A COMMUNICATIONS COORDINATOR BY NANCY DAVIS: http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_036247.hcsp?dDocName=bok1_036247#communicate

Resources:


13402(f) Notification in the Case of Breach, Content of Notification (http://thomas.loc.gov)

Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule) (http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/privrulext.txt)

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