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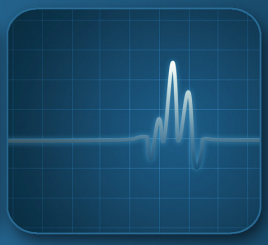
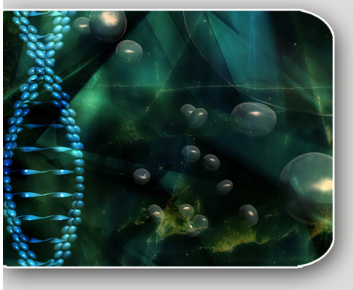



HEALTH CARE LAW IN THE NEWS

February 2013

Modifications to the Breach Notification Rule

Breaking Down the HIPAA Changes: Part 3 of our 5-Part Series



The final HIPAA omnibus rule published in the *Federal Register* on January 25, 2013 (the Final Rule) made a few changes to the Breach Notification Rule, which was implemented by an interim final rule shortly after the passage of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and became effective September 23, 2009 (the Interim Final Rule). Most significantly, the Final Rule altered the definition of "breach" – which will reshape how Covered Entities and Business Associates determine their breach notification obligations in the future.

The purpose of this e-alert is to (i) discuss the Final Rule's modifications to the Breach Notification Rule; and (ii) suggest some action items to comply with the Breach Notification Rule (as modified by the Final Rule) by September 23, 2013 -- the required compliance date.

I. Modifications to the Breach Notification Rule

A. Definition of "Breach"

One of the most notable changes made by the Final Rule to the Breach Notification Rule (as implemented by the Interim Final Rule), is a change to the definition of "breach." Under the Final Rule, there is now a presumption that an impermissible use or

disclosure of protected health information (PHI) constitutes a breach, and the "risk of harm standard" previously implemented in the Interim Final Rule is replaced with a more objective test of whether PHI has been "compromised."

Under the Final Rule, the term "breach" is defined as the acquisition, access, use or disclosure of PHI in a manner not permitted by the Privacy Rule which compromises the security or privacy of such information. There are three exceptions to this definition (all of which remain unchanged by the Final Rule):

i. *Any unintentional acquisition, access or use of PHI by a workforce member or individual acting under the authority of a Covered Entity or a Business Associate if such access or use was made in good faith and within the scope of authority and does not result in a further unauthorized use or disclosure;*

ii. *Any inadvertent disclosure by a person who is authorized to access PHI at a Covered Entity or Business Associate to another person authorized to access PHI at the same Covered Entity or Business Associate, and the information is not further used or disclosed in an impermissible manner; and*

iii. *A disclosure of PHI where a Covered Entity or Business Associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.*

Whereas, under the Interim Final Rule, the phrase "compromises the security or privacy of [PHI]" means "poses a significant risk of financial, reputational, or other harm to the individual" (e.g., the risk of harm standard) and Covered Entities and Business Associates are required to perform a risk assessment to determine if there is such a risk of harm to the individual, under the Final Rule, the United States Department of Health and Human Services (HHS) removed the risk of harm standard and added language to the definition of "breach" to clarify that an unauthorized use or disclosure of PHI that does not meet one of the three exceptions is "presumed to be a breach," unless the Covered Entity or Business Associate, as applicable, can demonstrate that there is a "low probability that the PHI has been compromised." The reason for this change stems from HHS' concerns that the risk of harm standard was too subjective, leading to inconsistent interpretations and "setting a much higher threshold for breach notification" than it intended to set.

In order to ensure a more uniform interpretation and application of the regulations, in the Final Rule, HHS also (i) modified the risk assessment process to focus more objectively on the risk that the PHI has been compromised (as opposed to the risk of harm to the individual); and (ii) identified four factors that a Covered Entity or Business Associate must consider when performing a risk assessment to determine if the PHI has been "compromised":

1. The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification. For example, could the information be used by an unauthorized recipient in a manner adverse to the individual or otherwise used to further the unauthorized recipient's own interests?

2. The unauthorized person who used the PHI or to whom the disclosure was made. For example, was the PHI impermissibly disclosed to another entity obligated to abide by HIPAA? If so, there may be a lower probability that the PHI has been compromised because the recipient of the PHI is obligated to protect the privacy and security of the PHI in a similar manner as the disclosing entity.

3. Whether the PHI was actually acquired or viewed. For example, if a laptop computer was stolen and later recovered and a forensic analysis shows that the PHI on the computer was never accessed or otherwise compromised, the entity could determine that the information was not actually acquired by the unauthorized individual even though the opportunity existed.

4. The extent to which the risk to the PHI has been mitigated. For example, did the disclosing entity obtain the recipient's satisfactory assurances that the information will not be further used or disclosed [through a confidentiality agreement or similar means] or will be returned or destroyed?

HHS emphasizes that a Covered Entity or Business Associate must evaluate all of these factors before making a determination about the probability of the risk that the PHI has been compromised, and clarified that other factors may also be considered in the risk assessment when necessary. HHS expects the risk assessment to be documented, thorough and completed in good faith, and the conclusions reached must be reasonable.

It is worth noting, however, that a Covered Entity or Business Associate, as applicable, has the discretion to provide the required notifications following an impermissible use or disclosure of PHI without performing a risk assessment. Because the Final Rule creates the presumption that a breach has occurred following every impermissible use or disclosure of PHI, entities may decide to make required breach notifications without evaluating the probability that the PHI has been compromised.

Ultimately, Covered Entities and Business Associates have the burden to prove that all notifications were provided or that an impermissible use or disclosure did not constitute a breach (by demonstrating through a risk assessment that there was a "low probability that the PHI had been compromised"). Covered Entities and Business Associates must maintain documentation sufficient to meet that burden of proof.

In the Final Rule, HHS also removed the exception for limited data sets that do not contain any dates of birth and zip codes from the definition of "breach." This exception was abandoned in favor of the more comprehensive risk assessment described above. According to HHS, the factors set forth above (particularly the type of PHI involved and the identity of the recipient of the PHI) are "suited to address the probability that a data set without direct identifiers has been compromised following an impermissible use or disclosure." Although HHS anticipates that entities may reasonably determine that there is a low probability of risk that a limited data set that does not contain any dates of birth and zip codes has been compromised, it is still a fact-specific determination to be made based on the circumstances of the impermissible use or disclosure.

B. Definition of "Unsecured Protected Health Information"

The Final Rule only made a few technical changes to the definition of "unsecured protected health

information" (e.g., replacing the term "unauthorized individuals" with "unauthorized persons"). However, in the preamble to the Final Rule, HHS pointed to its *Guidance Specifying the Technologies and Methodologies That Render Protected Health Information Unusable, Unreadable or Indecipherable to Unauthorized Individuals* (HHS Guidance) and emphasized that encryption and destruction are the only two methods for rendering PHI unusable, unreadable, or indecipherable to unauthorized individuals – or "secured" – and thus, exempt from the breach notification requirements. HHS strongly encourages Covered Entities and Business Associates to take advantage of this safe harbor provision of the Breach Notification Rule by encrypting PHI pursuant to the HHS Guidance.

C. Notice Requirements

The Final Rule made very few substantive changes to the notice requirements (*i.e.*, timing, content and method). One such change was the clarification that a Covered Entity is required to notify HHS of all breaches of unsecured PHI affecting fewer than 500 individuals not later than 60 days after the end of the calendar year in which the breaches were "discovered" – not in which the breaches "occurred." HHS recognized that there may be situations where, despite having reasonable and appropriate breach detection systems in place, a breach may go undetected for some time.

In the preamble, HHS also made a few noteworthy comments on the notice requirements in connection with Business Associates, including:

Covered Entities ultimately maintain the obligation to notify affected individuals of a breach, although a Covered Entity is free to delegate the responsibility to a Business Associate responsible for the breach or to another of its Business Associates. If there is such a delegation, the Business Associate Agreement should bind the Business Associate to the same breach notification obligations that the Covered Entity has under the Breach Notification Rule.

Covered Entities and Business Associates should consider which entity is in the best position to provide notice to the individual, which may depend on various circumstances such as the functions the Business Associate performs on behalf of the Covered Entity and which entity has the relationship with the individual.

Covered Entities are encouraged to discuss and define in their Business Associate Agreements the requirements regarding how and when a Business Associate should notify the Covered Entity (and who specifically should be notified) of a potential breach.

II. Action Items to Comply with the Breach Notification Rule

In the 180 day period between the effective date of the Final Rule (March 23, 2103) and the compliance date of the Final Rule (September 23, 2013), Covered Entities and Business Associates should comply with the breach notification requirements under the Interim Final Rule. Compliance with the Breach Notification Rule, as modified by the Final Rule, is required by September 23, 2013. The following is a list of suggested action items for Covered Entities and Business Associates to take to ensure compliance with the Final Rule beginning on September 23, 2013:

⇒ Evaluate whether or not encryption is feasible for all PHI possessed by the entity – including PHI at

rest and in transit. Again, if all PHI is encrypted, then there are no breach notification requirements following an impermissible use or disclosure.

⇒ Review and, if necessary, revise Business Associate Agreements to reflect the requirements of the Breach Notification Rule, as modified by the Final Rule, and to specify (among other items) which entity is responsible for notifying affected individuals and how and when the Business Associate should notify the Covered Entity (and who specifically should be notified) of a potential breach.

⇒ Implement or revise policies and procedures to reflect the requirements of the Breach Notification Rule, as modified by the Final Rule. Covered Entities and Business Associates must ensure that when they are evaluating the risk of an impermissible use or disclosure, they consider all of the factors set forth above and other factors if necessary. However, Covered Entities and Business Associates should continue to have a process in place to mitigate the harmful effects of potential breaches despite the elimination of the "risk of harm standard."

⇒ Train and educate workforce members and other agents on the Breach Notification Rule, as modified by the Final Rule, particularly on the importance of prompt reporting of potential impermissible uses or disclosures of PHI. Note: HHS declined to adopt the notion that Covered Entities are deemed to have "discovered" a breach only when management is notified of the breach, so it is important that workforce members at all levels understand the breach notification requirements and their related obligations.

There are real consequences if a Covered Entity or Business Associate does not comply with the Breach Notification Rule. Failure to comply with the Breach Notification Rule is in and of itself a HIPAA violation which is subject to HHS enforcement actions and civil money penalties. For this reason, it is crucial that Covered Entities and Business Associate clearly understand their obligations under the Breach Notification Rule and have appropriate polices and procedures in place to promote their compliance with the Breach Notification Rule.

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