The HIPAA HITECH headache

By Elliott C. Bankendorf and Melaina D. Jobs

On January 25, 2013, the Department of Health and Human Services (HHS) issued a Final Rule modifying the Privacy, Security, and Enforcement Rules of the Health Insurance Portability and Accountability Act’s (HIPAA). The Final Rule implements amendments made under the Health Information Technology for Economic and Clinical Health (HITECH) Act, which was enacted as part of The American Recovery and Reinvestment Act of 2009.

The amendments mandated by the HITECH Act included the extension of certain provisions of HIPAA to business associates of covered entities to strengthen such provisions and improve their workability and effectiveness. For example, business associates are now directly liable for compliance with certain HIPAA Privacy and Security Rules and are subject to civil monetary penalties for violations of such provisions.¹ The Final Rule further expanded the reach of the security and privacy provisions of HIPAA to subcontractors of business associates. Therefore, not only will business associates have to ensure that they have proper safeguards in place in regard to their relationship with covered entities, but also in relation to their dealings with their own subcontractors. Accordingly, attorneys will have an even greater burden to carry when dealing with HIPAA issues during intellectual property prosecution and litigation.

Final Rule: Subcontractors of Business Associates

The Final Rule adopted amendments to HIPAA included in the Notice of Proposed Rulemaking (Proposed Rule) issued on July 14, 2011.² Many of the changes in the Proposed Rule clarified those provisions of the HIPAA Security, Enforcement, and Privacy Rules that are applicable to business associates. As defined under HIPAA, a “business associate” includes a person who provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation or financial services to a covered entity (e.g., a health plan, a health care clearinghouse, or a health care provider), where the terms of service involve the disclosure of individually identifiable health information.³ The Final Rule modified this definition to include subcontractors, thereby making those provisions newly applicable to business associates also applicable to subcontractors of business associates.⁴

The Final Rule clarifies that a subcontractor is “a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.”⁵ In the context of trademark litigation, subcontractors would likely include survey experts, electronic document collection firms, and firms that are hired to assist with document review.
The Final Rule provides that a business associate may disclose protected health information (PHI), which is a subset of individually protected health information,\(^6\) to a subcontractor and allow the subcontractor to create or receive PHI on behalf of the business associate (e.g., patient forms that show use of a trademark), if the business associate obtains satisfactory assurances that the subcontractor will protect the information.\(^7\) Therefore, the business associate is required to enter into a contract or other arrangement with a subcontractor that is in compliance with the Security and Privacy Rules of HIPAA in the same manner that covered entities are required to enter into contracts or other arrangements with their business associates.\(^8\)

In other words, the contract or other arrangement between the business associate and the subcontractor must ensure that the subcontractor agrees to the same restrictions and conditions that apply to the business associate under its agreement with the covered entity.\(^9\) Further, a business associate that is aware of noncompliance by one of its subcontractors must react in the same manner as a covered entity in regard to a noncompliant business associate.\(^10\)

Even though the term “subcontractor” implies that a contract is in place between the parties, the Proposed Rule noted that “the definition would apply to an agent or other person who acts on behalf of the business associate, even if the business associate has failed to enter into a business associate contract with the person.”\(^11\) Further, the inclusion of subcontractors within the definition of business associates was provided to avoid security and privacy breaches of PHI because “a function is performed by an entity that is a subcontractor rather than an entity with a direct relationship with a covered entity.”\(^12\) Enabling such a lapse in privacy and security protections would allow business associates to avoid liability imposed on them simply by outsourcing duties to a subcontractor.

The Final Rule, however, does not require a covered entity to have a contract with a subcontractor of a business associate; rather, the obligation is on each business associate.\(^13\) The rationale for placing the burden on business associates to secure a contract or other arrangement with a subcontractor is that business associates are in the best position to ensure that subcontractors comply with the applicable Security and Privacy requirements of HIPAA. For example, if an attorney representing a covered entity hires a company to perform document and electronic discovery of documents such as patient forms containing PHI, the company handling the discovery would be required to comply with the applicable requirements of the HIPAA Security Rule with respect to the proper protection of electronic media and the Privacy Rule with respect to limiting the uses and disclosures of the PHI in accordance with its contract with the business associate.

### Minimum Necessary Standard

The Final Rule also directly applies the minimum necessary standard to business associates. Therefore, when business associates use, disclose, or request PHI, they must limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.\(^14\) In other words, a business associate is not making a permitted use or disclosure under the Privacy Rule of HIPAA if it does not apply the minimum necessary standard.\(^15\) Further, although not expressly stated, because subcontractors are now included within the definition of business associate, it can be presumed that the minimum necessary standard also applies to them.

It is most likely that an attorney would face HIPAA privacy provisions during trial, especially during the pleading and discovery stages when documents containing PHI may be exchanged or used as exhibits. In this case, the attorney should ensure that the documents attached as exhibits or provided to opposing counsel contain only a limited data set. Additionally, attorneys can limit their exposure to HIPAA during discovery by narrowing the scope of “relevant information” during a preliminary meeting with opposing counsel such as the conference required by Rule 26(f) of the Federal Rules of Civil Procedure. This way, information that is subject to the privacy provisions of HIPAA can be excluded from discoverable information. Or, if such information needs to be provided to opposing counsel, it can be properly de-identify so that the information is not considered individual identifiable health information and therefore not subject to the privacy provisions of HIPAA.\(^16\)

The document producer may wish to prepare multiple sets of document production, starting with the unredacted raw
document, then sequentially numbering each document page, then redacting for HIPAA protected health information, then redacting for confidentiality per the appropriate protective order. Such would be a natural workflow in many cases. Parties could begin with discovery disclosure of the most redacted information, and only disclose the less redacted if there were good faith need. In many intellectual property cases the personal information is irrelevant; the date and location, often only state, are the material facts.

Compliance Date
The Final Rule goes into effect on March 26, 2013, and provides that covered entities and business associates have 180 days (or until September 23, 2013) to comply with new standards or implementation specification in the HIPAA Rules, except as otherwise provided. However, the Final Rule does provide a one year window from the compliance date for covered entities and business associates to bring their existing contracts into compliance with the Final Rule.

Conclusion
The Final Rules extend many provisions of HIPAA not only to business associates, but also to subcontractors of business associates. Thus, attorneys have yet another potential obstacle to face during intellectual property prosecution and litigation. Proper preparation will provide the tools necessary to meet and comply with HIPAA.

1. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; and Other Modifications to the HIPAA Rules, 78 Fed Reg. 5566 (January 25, 2013).

2. See Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act 75 Fed Reg. 40868 et. seq. (July 14, 2010).

3. 45 C.F.R. § 160.103. Individually identifiable health information is information “that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.” Id.

4. Under new rule 45 C.F.R. 160.103 as provided in the Final Rule, a business associate includes “a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.” 78 Fed. Reg. 5573, 5677.


6. As provided in the Final Rule, under revised rule 45 C.F.R. § 160.103, protected health information “means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:
(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information:

(i) In education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) In records described at 20 U.S.C. 1232g(a)(4)(B)(iv);

(iii) In employment records held by a covered entity in its role as employer; and

(iv) Regarding a person who has been deceased for more than 50 years."


10. The Final Rule adds a new provision C.F.R. § 164.504(e)(1)(iii), which provides that business associates that are aware of a pattern of activity or practice of its subcontractor that constitutes a material breach or violation of the subcontractor’s obligation under the contract or other arrangement to take reasonable steps to cure the breach or terminate the contract, if possible. 78 Fed. Reg. 5600, 5601.


12. Id.


14. 45 C.F.R. § 164.502(b).


16. 45 C.R.F. §164.514(a) (“Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.”)


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Concurrent with the 25Jan2013 release by US Department of Health & Human Services of its Final Rule modifying HIPAA, it also released a Sample Business Associate Agreement. The Final Rule extended certain HIPPA provisions to business associates of HIPAA covered entities.

-http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html-.  

-Editor.

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