



Association for Healthcare Documentation Integrity
Medical Transcription Industry Association
4230 Kiernan Ave
Suite #130
Modesto, CA 95356

September 10, 2010

US Department of Health and Human Services
Office for Civil Rights
Attention: HITECH Privacy and Security Rule Modifications
Hubert H Humphrey Building
Room 509F
200 Independence Ave SW
Washington, DC 20201

Ladies and Gentlemen:

The Association for Healthcare Documentation Integrity (AHDI) and the Medical Transcription Industry Association (MTIA) appreciate the opportunity to submit our comments on the Department of Health and Human Services' (HHS) "Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act; Proposed Rule," as posted in the Federal Register of July 14, 2010.

AHDI and MTIA are professional associations that speak for over 100,000 healthcare documentation specialists, trained and credentialed professionals who are experts in medical language and the real-world practice of medicine. Our members and colleagues serve the public and the healthcare sector by assisting in the creation of an accurate and secure healthcare record for all Americans. AHDI and MTIA have long been concerned with the safety and reliability of healthcare documents, and in continued pursuit of those goals, we offer the following comments:

Comment on

III. Section-by-Section Description of the Proposed Amendments to Subparts A and B of Part 160
"We request comment on the use of the term 'subcontractor' and its proposed definition."

With regard to proposed modifications to §160.103 (3)(iii): The Association for Healthcare Documentation Integrity and MTIA offer our strong support for bringing clarity to the definition of "subcontractor" as someone who acts on behalf of a business associate, other than in the capacity of a member of the workforce.

Maintaining the confidentiality, integrity and security of protected health information (PHI) is of utmost importance to the healthcare industry, and that is nowhere more precisely reflected than in the

business associate agreements (BAAs) that are entered into between covered entities and their business associates. These agreements evidence the good faith intentions of the parties to uphold the standards instituted by HIPAA and HITECH. Extending requirements to include subcontractors in the business associate agreement process can only serve to demonstrate this commitment even further.

With respect to including subcontractors in the definition of business associate, we feel the proposed modifications reflect the correct standard that subcontractors, who share protected health information with business associates, should be held accountable under the same privacy and security rules. Furthermore, we believe it is appropriate for business associates to enter into business associate agreements with their subcontractors to memorialize such obligations. With respect to the defined term subcontractor, we think the proposed modifications set forth a definition that is generally understood in commercial contexts.

However, we do suggest that the proposed modifications should offer additional guidance with respect to the defined term subcontractor, as well as the scope of review a business associate must undertake in order to ensure that a subcontractor of such business associate continues to comply with HIPAA and the HITECH Act. We further suggest that the Secretary offer a few more examples of the subcontractor relationship within the healthcare industry to further clarify the variety of scenarios where a business associate might be required to ensure compliance with the rules by its subcontractor.

Some of the issues of concern relate to holding accountable offshore subcontractors and home-based independent contractors working for multiple business associates. Additionally, it is difficult and potentially costly to assess and validate home based offices for HIPAA compliance, thereby creating further challenges for business associates to remain in compliance with the new regulations. Clearly, as more health information management services are outsourced by covered entities (for example medical coding and billing services), these challenges will be extended to those business associates as well.

We agree that the lack of a contract should not exclude a subcontractor from the liabilities of HIPAA regulation, and we further would encourage the addition of language that requires contracts and business associate agreements be in place within 18 months of publication of the final rule. Ideally, contracts with all subcontractors should be current upon access to or use of protected health information (PHI). We agree that allowing such a lapse in privacy and security protections may appear to allow business associates to avoid liability imposed upon them by sections 13401 and 13404 which is not in keeping with the congressional intent. By requiring subcontractors that create or receive PHI to keep business associate contracts updated and in place, it stands to further strengthen the rule overall and eliminates any loophole in perceived liability.

We also believe that a covered entity may request disclosure of any third-party subcontractor business associate agreements and that they should be provided upon request within 30 days as evidence of compliance and confidence between the covered entity and the primary business associate.

Comment on

VI. Section-by-Section Description of the Proposed Amendments to the Privacy Rule

B. Section 164.501

"...[W]e request comment on the above proposal with regard to these issues..."

AHDI and MTIA encourage HHS and Office of Civil Rights to maintain the status of communications regarding healthcare operations and treatment to be considered exceptions in order for covered entities

to use electronic PHI for marketing purposes. This will allow the covered entity to provide services to patients with specified health conditions and management of those health conditions.

AHDI and MTIA do support that an individual should be made aware of, and have the ability to opt out of, subsidized treatment communications from his or her provider in the instance where a business associate is receiving direct or indirect payment for making such communications. We agree that the communication should be part of the notice of privacy practices that a covered entity provides to the patient.

Comment on

VII. Regulatory Analysis

C. Costs

9. Business Associates and Covered Entities and Their Contractual Relationships

"We welcome comments on our analysis ..."

It is the opinion of AHDI and MTIA that the majority of business associates are already HIPAA compliant as far as their policies, agreements and practices are concerned, and make a good faith effort to comply with current privacy and security standards. The actual renegotiation of BAAs will not be particularly burdensome as long as a phased-in approach is being adopted. The costs associated with these renegotiations, however, should also include administrative time as well as the legal hours that are noted in the proposed modifications. Administrative time may include database updates, revising employee training programs to reflect the new rules, and customer communications. It is unclear who a 'legal professional' is meant to be in the rules; if this is an attorney, the \$90.00 hourly rate appears low and not reflective of current fee trends.

Additionally, we suggest that it should be made clear in the final rules that covered entities or business associates are not obligated to audit or monitor other parties to ensure compliance with the rules. This would be unduly burdensome, prohibitively expensive and create another level in the compliance process when ultimately, the BAA is each party's affirmation that they will abide by the imposed regulations. Auditing, monitoring and any other oversight by a non-governmental entity should be unnecessary if the proper due diligence has been conducted and assurances of compliance received. A model business associate agreement issued by HHS as a reference guide would be very beneficial to the parties once renegotiation of expired BAAs commence.

Conclusion

The Association for Healthcare Documentation Integrity and the Medical Transcription Industry Association appreciate the opportunity to comment on the above sections of the proposed rule. We will continue to support the work of HHS and OCR in their work to safeguard the nation's healthcare information and to ensure the best possible medical care for all Americans. If we can assist the Secretary, HHS and OCR in any way to achieve these goals, please contact us.

Thank you for your consideration.

Signed: Eileen Dwyer, Chair, Board of Directors, MTIA
Barbara Marques, President, Board of Directors, AHDI
Peter Preziosi, PhD, CAE, CEO, AHDI and MTIA