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December 29, 2009

Georgia Verdugo
Office for Civil Rights
US Department of Health and Human Services
Attention: HITECH Breach Notification
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

RE: RIN 0991-AB55: HIPAA Administrative Simplification Enforcement – October 30, 2009 Interim Final Rule

Dear Ms. Verdugo:

The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the Office for Civil Rights (OCR) interim final rulemaking (IFR) on conformance related to regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and legislation coming from the Health Information Technology for Economic and Clinical Health Act (HTECH) – title XIII under the American Recovery and Reinvestment Act of 2009 (ARRA) as posted in the October 30, 2009 Federal Register (Vol. 74, No.209).

AHIMA is a not-for-profit professional association representing more than 54,000 health information management (HIM) professionals who work throughout the healthcare industry in both HIPAA and non-HIPAA related entities. HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, protecting, reporting, releasing, and utilizing data vital for patient care, while making it accessible to patients, healthcare providers and appropriate researchers when it is needed most.

Insuring patient information confidentiality and security has been a significant function of the HIM profession for decades. Since the introduction of the HIPAA privacy and security requirements, AHIMA focused considerable attention and education on compliance education and also the certification of HIM professionals specifically in healthcare privacy and security.

The increases in incidents of information breach and identity theft have raised public concern with healthcare entities' attention to confidentiality and security. AHIMA members have been active in seeking to prevent such incidents and insuring compliance with the HIPAA requirements. We welcome the attention the Congress, the Department of Health and Human

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Services (HHS), and the Office for Civil Rights (OCR) have given to the issue by taking actions such as the HITECH privacy legislation and OCR and HHS' increasing attention to the problems at hand. The HIM profession believes that addressing confidentiality and security is crucial to maintaining consumers' trust in our healthcare systems.

AHIMA has been an advocate for the conversion of the healthcare industry to electronic health records (EHRs) and electronic health information exchange (HIE). We believe that the development and use of these HIT tools can only occur when there is consumer trust, and we welcome and support OCR's efforts. AHIMA also believes that there is no failsafe or perfect security system and privacy adherence. To insure compliance we believe that all individuals or organizations that engage in inappropriate discrimination based on health information or misuse of health information should be prosecuted and appropriately punished; it is clear that the proposed changes are leading the healthcare and information industries in that direction.

In consultation with our members and expert staff, we have the following comments related to your proposed rulemaking. Our comments follow your section-by-section analysis and statement of the proposed rule. Where we have not commented, please assume that we are in agreement.

III Approach to the Interim Final Rule (74FR56126)

AHIMA understands the approach that OCR is taking with this interim final rule and we appreciate the complexity that HITECH has added to your enforcement duties. Never-theless, we look forward to OCR finalizing all of the regulations necessary for the healthcare and information industries' understanding to enable compliance as soon as possible.

IV Provisions in the Interim Final Rule (74FR561-26)

Subpart D – Imposition of Civil Money Penalties

Section 160.401 – Definitions

AHIMA concurs with the definitions that have been used previously under HIPAA Section 160.410 and understands the need to move these definitions within the regulation. Our members have expressed a desire -for OCR to post examples of how these terms -would apply to situations where OCR has found it necessary to investigate or take action on a potential violation. Such education would be helpful beyond the preamble explanations provided at 70FR20224.

Section 160.404 – Amount of Civil Money Penalties

AHIMA agrees with the OCR that the HITECH language (Section 13410 – Improved Enforcement) applying the four tiers is very confusing. We support the recommended application that OCR proposes for this section across the four designated categories (did not know, reasonable cause, willful neglect–corrected, and willful neglect-not corrected).

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In reviewing the IFR, several of our members suggested that OCR further provide a definition or guidance on what timeline exists for correction under the language contained for "willful neglect." Is this the 30-day period covered under HIPAA Section 160.410? If so do we assume that the 30-day period begins with steps taken by OCR with the offender, or is it at an earlier time, such as perhaps when a complaint is filed with the entity's privacy officer? While we would hope it is the latter, we think the application should be clarified for all situations.

Some members have also asked for similar clarification or guidance as to how the numbers of "occurrences" are determined. This question is raised due to current uncertainty. For instance, under breach notification requirements there are different requirements for numbers of breach incidents above and below 500, suggesting that if penalties are applied against possible breaches – actual harm, the penalties could be very significant. Again, how the OCR determines the number of violations is not clear as one reads the IFR or section 160.410.

Other Comments

Beyond these two sections, we have no further comments on integrating the HITECH changes into these applicable HIPAA sections. In the concerns noted above there appears to be two questions. First, given OCR's experience with violations of the privacy and security rule, is 30 days to correct a violation sufficient? Further, some of our members are interested in the metrics that OCR uses as it investigates a potential violation. These members believe that such information may assist covered entities and business associates in their compliance planning and education activities.

Again, AHIMA welcomes this opportunity to comment on this Interim Final Rule and to continue to work with HHS, OCR, ONC, and the healthcare industry to ensure our national goals for EHRs and HIE are accomplished with maximum protections for confidentiality, privacy, and security. We hope these comments are useful, and stand ready to respond to any further questions or concerns you may have. Please direct your questions to me at either (202) 659-9440 or dan.rode@ahima.org, or in my absence either to Allison Viola, AHIMA's director for federal affairs at (202) 659-9440 or allison.viola@ahima.org, or Harry Rhodes, AHIMA's director, practice leadership at (312) 233-1119 or harry.rhodes@ahima.org.

Thank you for your time and consideration of these comments.

Sincerely,

Dan Rode, MBA, CHPS, FHFMA

Vice President, Policy and Government Relations

cc. Allison Viola, MBA, RHIA – director, federal affairs Harry Rhodes, MBA, RHIA, CHPS, CPHIMS, FAHIMA – director, practice leadership