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December 4, 2009

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

RE: RIN 0991-AB54:
HIPAA Administrative Simplification Enforcement: Standards for Privacy of Individually Identifiable Health Information

Dear Ms. Verdugo:

The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the Office for Civil Rights' (OCR) proposed rule to modify certain provisions of the "Standards for Privacy of Individually Identifiable Health Information" as issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and new legislation coming from the Genetic Information Nondiscrimination Act of 2008 (GINA) as posted in the October 7, 2009 *Federal Register* (Vol. 74, No. 193).

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 has focused considerable attention and resources on compliance education and also the certification of HIM professionals specifically in healthcare privacy and security.

AHIMA has long been an active proponent of the need to eliminate inappropriate discrimination from the use of health information no matter where that information resides. Accordingly, AHIMA has been among the various healthcare professional associations seeking protection for

genetic information. Some of these protections have come forward in the GINA and we look forward to these protections being included in the HIPAA privacy regulations.

As noted, AHIMA believes that while GINA is a major step in the right direction, the legislation fell short of addressing goals for inappropriate non-discrimination in the use of all health information. We are also aware that consumers are concerned with the protection of their health information, including genetic information, as the healthcare industry adopts standard electronic health records (EHRs) and develops electronic health information exchange (HIE). Accordingly, we have reviewed these proposed changes from the perspective of health plans, healthcare providers, and consumers even though the Office of Civil Rights (OCR) suggests that these rule changes only impact health plans and consumers.

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.

II Description of Proposed Modifications (74FR51633)

AHIMA understands the approach that ONC has taken in modifying the HIPAA sections to accommodate GINA, however, we note that the Secretary has wide latitude to promulgate privacy standards via regulations that can be added to HIPAA and we believe it is important to consider some areas not included in the proposed rule, such as:

- Insuring that research done by or under the sponsorship of a health plan that could involve genetic information requires either an explicit statement to ensure that consumers (and health plans) understand that such information may not and will not be used for underwriting purposes; and, would not be shared for any purpose beyond the stated purpose of the research. Genetic research should be encouraged by the passage of GINA and the neglect of addressing the research requirements under HIPAA should not be a barrier to that potential.

- The proposed changes do not prohibit the use of genetic information by health plans for uses outside of underwriting purposes. This raises a potential problem for health care providers who may be asked by a health plan for an individual's protected health information (PHI), now potentially including genetic information. How should a provider ensure that releasing an individual's information will not result in an inappropriate disclosure to a health plan for underwriting purposes?

  Presumably, healthcare providers can differentiate between what is genetic information and what is not, as defined in these regulations. However, while we understand this proposal's approach is to put the compliance burden on health plans, we are not sure consumers will accept the fact that providers will potentially make genetic information available without some indication on the part of the health plan that it will be used appropriately. We realize that presently health plans

routinely ask for health information under the treatment, payment and operations option with the presumption that the plan only asks for information absolutely needed. However, pending regulations from the American Recovery and Reinvestment Act of 2009 (ARRA) Title XIII Health Information Technology for Economic and Clinical Health Act (HTECH) suggest that more scrutiny will be required of providers both though a pending option by individuals to pay for services directly so as not to have information flow to a health plan; or through more emphasis on a provider only supplying the "minimum necessary" when an information request is received.

- The proposed changes raise the concept of "extended family members." We understand the concept that ONC has addressed; however, this also raises new concerns related to the access to health information by family members. The question that arises is: What are the rules for access to PHI by an individual's extended family members seeking to determine if they are affected by a genetic trait? What process should providers use to determine what to release, and what authorization process might be necessary depending on the condition of the individual to give such authorization? This is one of those situations not addressed in GINA, but is raised in your discussion of the proposed changes and potentially will impact some healthcare providers in the future.

- A few members have also raised questions about the use of potential genetic information, specifically the family medical history, which might be requested for programs sponsored or run by the individual's employer. The proposed rule does not address this; however, we are aware that GINA does address employers, and the questions relate to potential authorizations to release such information to employers. We hope ONC will address these questions in some manner quickly.

- With regard to the definition of "underwriting purposes," several of our members suggested the need for clearer wording or explanation in the first part of the definition since the definition uses terms such as "determination of eligibility" or "determination of benefits," which is understood to be a subject of inquiry often conducted between a provider of healthcare and a health plan when an individual presents themselves for treatment or diagnosis. The parenthetical clarification did not suffice when displayed on page 74FR51709.

- With regard to ONC's request for means of updating a health plan's Notice of Privacy practices (NPP) AHIMA suggests that health plans update their NPP just as any other such notice should be updated, and especially since, as you note, this is not a requirement that will fall on all health plans. It is difficult to provide the advice that you seek, since we do not know the pending schedule of other notices associated with HITECH or potentially through healthcare reform. We believe there is an obligation to the consumer, in spite of the cost of mailing or other forms of notification, however, for an extension of say another 30 days would not be unreasonable, if ONC recognizes that a new NPP could also accommodate other changes ONC is requiring in the same time period.

Again, AHIMA welcomes this opportunity to comment on this Proposed Rule and to continue to work with HHS, OCR, ONC, and the healthcare industry to ensure our national goals for genetic information nondiscrimination can be accomplished within the framework of the HIPAA rules. 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 to Allison Viola, AHIMA's director for federal affairs at (202) 659-9440 or allison.viola@ahima.org.

Our thanks 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

2009/CPS/ARRA