American Medical Informatics Association
The professional home for biomedical and health informatics

December 4, 2009

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

45 CFR PARTS 160 and 164

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

Dear Secretary Sebelius:

On behalf of the American Medical Informatics Association (AMIA), I am pleased to submit these comments in response to the above-referenced proposed rule. AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy. AMIA seeks to enhance health and healthcare delivery through the transformative use of information and communications technology.

AMIA's 4,000 members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public/population health, and translational science with the ultimate objective of improving health. Our members work throughout the health system in various clinical care, research, academic, government, and commercial organizations.

As a source of informed, unbiased opinions on policy issues relating to the national health information infrastructure, uses and protection of clinical and personal health information, and public health considerations, we appreciate the opportunity to submit comments on the proposed rule.

AMIA thanks the Department of Health and Human Services (HHS, or the Department) for issuing this proposed rule, which implements section 105 of Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA) (Pub. L. 110-233, 122 Stat. 881). In providing input to the Department, we will

4915 St. Elmo Avenue, Suite 401 ▫ Bethesda, MD 20814
Phone 301.657.1291 ▫ Fax 301.657.1296
E-mail: mail@amia.org ▫ www.amia.org

respond to the requests for comment included in the information that was published in the Federal Register and discuss as well other selected provisions of the proposed rule.

AMIA supports the inclusion in the HIPAA Privacy Rule of a definition for *genetic information* at §160.103 and the prohibition against the use of such information for *underwriting purposes* at §154.502 (a)(3). Directed by GINA, these changes to the Privacy Rule will encourage the expanded use of genetic testing and reduce the fear that information obtained from such testing could be used against an individual. Believing that increased use of genetic testing will improve the health of the patient population and the overall quality of the larger healthcare system, AMIA supports the Department's decision to apply the prohibition against using and disclosing genetic information for underwriting purposes to all health plans subject to the Privacy Rule, rather than only to the subset of health plans described in GINA.

AMIA believes that the inclusion of a definition for *manifestation* at §160.103 is helpful in increasing the clarity of the proposed rule, and wise in limiting the scope of the prohibition. Given that the rule is being promulgated to prohibit genetic information from being used for underwriting purposes, it is helpful to know that a condition that has manifested in an individual (i.e. a condition that can reasonably be identified by a physician who is not basing the diagnosis principally on genetic information) is not genetic information for purposes of the proposed rule. Similarly, the rule specifies that the manifestation of a condition in an individual's family member, or genetic tests that have been performed on a family member, are genetic information with respect to the individual, and so they cannot be used for underwriting purposes. AMIA believes that this approach to distinguishing which types of information must be prohibited from being used for underwriting purposes is proper, because GINA did not intend to remove all health information (such as non-genetic diagnoses), but rather only genetic information, which might describe (or attempt to predict) a condition that has not yet manifested in an individual, from underwriting decisions.

The Department has requested comment on whether unintended consequences might flow from the decision to remove the term "underwriting" from the definition of "health care operations." AMIA supports the changes the proposed rule makes to the definition of *health care operations* at §164.501. We do not foresee any unintended consequences due to this change, and we agree that the inclusion of the term "enrollment" in the express list of "health care operations" activities will help to clarify that the new ordering of definitions was a change in form, and not a substantive change.

In §164.501 within the definition of *underwriting purposes*, AMIA is concerned with the inclusion [at (1)(i)] of health risk assessments and wellness programs. We appreciate that if such activities produce genetic information, such genetic information should be prohibited from being used for underwriting purposes, but we think the rule is overly inclusive as written, because both items could produce positive results without gathering any genetic information. For instance, if a health plan were to offer a discount on premiums to customers who participate in a "wellness program" that simply required the customer to do 30 minutes of cardiovascular activity three times a week, there would be no genetic information involved. Similarly, a "health risk assessment" that asked questions about the individual's sex, age,

lifestyle (such as smoking, exercise, alcohol consumption, and diet), physiological data (such as height, weight, blood pressure, and cholesterol level) and personal medical history, but not family medical history, would contain no genetic information.

Our concern regarding what we see as overly broad language is twofold: from a policy perspective, we think it is a good idea to allow health plans to incentivize health risk assessments and wellness programs, to the extent that they do not require genetic information; and we do not see any language in GINA which would give HHS authority to regulate health risk assessments and wellness programs that are independent of genetic information. We therefore suggest the definition of *underwriting purposes* be modified to read "…in return for activities such as completing a health risk assessment or participating in a wellness program **to the extent to which such activities produce genetic information as defined at §160.103.**

AMIA appreciates the proposed rule's discussion of how the rule should apply in cases where a covered entity (CE) is both a health plan and a health care provider. Because a CE such as an HMO plays both roles, it is helpful that HHS has explicitly stated that the CE may use genetic information for certain purposes, including diagnosing and treating the individual, but is prohibited from using genetic information for underwriting purposes. For such dual-purpose entities, it is particularly important that the proposed rule prohibits [by adding a cross-reference at §164.506 (a) concerning the prohibition at §164.502(a)(3)] a CE from using genetic information for underwriting purposes even if an individual has signed an authorization purporting to allow such use. AMIA agrees that the non-discrimination provision should not be waivable. Moreover, we agree with the Department that CEs must properly train their staff members on which uses of genetic information are permissible and which are impermissible in order to ensure compliance with the proposed rule.

AMIA supports the language in the proposed rule at §164.520 that requires a CE's Notice of Privacy Practices (NPP) to specifically inform individuals that if the CE intends to use their protected health information (PHI) for underwriting, it cannot use genetic information for underwriting. We agree with the Department that absent such a specific statement, many individuals would be unaware of the rule change, and would therefore be ignorant of the new legal protection their genetic information will enjoy. Since without knowledge of this protection, individuals may be less willing to allow their physicians to administer genetic tests that would enhance their course of care, AMIA believes requiring CEs to include a statement about the new protection of genetic information is a good policy choice.

The Department has requested comments on ways to inform individuals of this change to privacy practices without undue burden to health plans. Of the four options mentioned in the proposed rule, AMIA prefers option (1), which replaces the 60-day requirement with a requirement for health plans to notify their members of material changes to the NPP in their annual mailings. We believe this would result in the least undue burden to health plans, while sufficiently informing members of NPP changes, and avoiding the "notice fatigue" that has a tendency to cause recipients of such messages about rule changes to ignore the messages when there are an unreasonably large number of them.

AMIA again wishes to thank the Department for issuing this proposed rule and appreciates the opportunity to submit comments. Please feel free to contact me at any time for further discussion of the issues raised here.

Sincerely,

Edward H. Shortliffe, MD, PhD
President and CEO