December 9, 2008

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4137-NC
PO Box 8017
Baltimore, MD 21244-8010

Re: Request for Information, Genetic Information Nondiscrimination Act [*73 Federal Register 60208*]

To Whom It May Concern:

The American Health Information Management Association (AHIMA) appreciates the opportunity to provide a response to the Request for Information (RFI) under sections 101 through 104 of the Genetic Information Nondiscrimination Act (GINA). AHIMA addressed those questions where we could provide specific health information management (HIM) expertise. In addition to addressing the specific questions where the departments have interest, AHIMA has provided answers to the questions under "Comments Regarding Economic Analysis, Paperwork Reduction Act, and Regulatory Flexibility Act."

AHIMA is a not-for-profit professional association representing more than 53,000 HIM professionals who work throughout the healthcare industry. AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, reporting, and utilizing data vital for patient care, while making it accessible to healthcare providers and appropriate researchers when it is needed most.

Our detailed comments and rationale on the RFI are below.

A. Comments regarding Economic Analysis, Paperwork Reduction Act and Regulatory Flexibility Act

Question 1: What policies, procedures, or practices of group health plans and health insurance issuers may be impacted by regulations under GINA? What direct or indirect costs would result? What direct or indirect benefits would result? Which stakeholders will be affected by such benefits and costs?

AHIMA contends that GINA would have the following impact on group health plans:

- Policy, Procedures, and Practices: Plans (stakeholder) would have to separate genetic data of individual(s) prior to any aggregate actuarial manipulations of a group's data
- Direct Costs to Plan (Stakeholder): Upfront costs to design and redesign systems to support business processes in policy, procedures, and practices above

- Indirect Benefits: Group members (stakeholders) are not paying for diseases that may never manifest in their group
- Indirect Benefits: Individual members (stakeholders) of group receive benefits of a group umbrella.

GINA could have the following impact on individuals:
- Policy, Procedures, and Practices: The insurer (stakeholder) would have to separate out genetic data of individual(s) prior to establishing eligibility or premium rates
- Direct Costs to Insurers (Stakeholder): Upfront costs to design/redesign systems to support business processes in Policy/Procedures/Practices above
- Direct Benefit to Individuals (Stakeholders): Protects individuals from being penalized both financially and by loss of or lack of healthcare coverage for a disease that may never exist or manifest itself
- Benefit to Individual Stakeholders: Prohibits Insurers from using genetic testing to penalize individuals financially or through the lack or loss of coverage for diseases that may never manifest

Question 2: Are there unique costs and benefits for small employers or small plans? What special consideration, if any, is needed for small employers or small plans?

The presence of a subscriber with a genetic disease manifestation may have more financial impact on a small group than when it is absorbed by a large group. A manifestation may cause a small employer to experience an increase in employer premiums and strain its ability to pay for coverage. In addition, risks could be higher in small plans because the potential impact of genetic problems or manifestations in a smaller pool is greater.

In addition, small insurers could be at a disadvantage if GINA ultimately requires them to install sophisticated electronic systems to separate out information relative to genetic testing to prevent its use for underwriting purposes. Historically, such insurers have been given more time to comply, or were permitted to comply to a lesser degree. Various remedies may have to be explored to alleviate potential problems in this area.

B. Comments Regarding Regulatory Guidance

Question 1: To what extent do group health plans and health insurance issuers currently use genetic information, such as family medical history, and for what purposes? (for example, is it used for group rating purposes, or for purposes of a wellness program that otherwise complies with HIPAA's nondiscrimination requirements?).

AHIMA has limited information regarding the extent to which group health plans or health insurance issuers use genetic information. We are aware that when information is submitted on a claim, it is maintained within the claims system. The applicable ICD-9, ICD-10, CPT, DSM, and any other codes that may identify genetic information and tests may also be entered in a data warehouse. Disease management systems also maintain this information. This is an important

question that needs to be addressed by the plans and issuers through this RFI and congressional and other hearings such as the National Committee on Vital and Health Statistics (NCVHS).

AHIMA strongly supports the public's need to know if and how their information is being used. If plans and issuers are using the information, the public needs to be confident that their information is not being used inappropriately, but only for purposes they have authorized or that are authorized by law or regulation.

Question 2: How do plans and issuers currently obtain genetic information (for example, through health risk assessments, the MIB, or other entities under common control)?

AHIMA contends that plans and issuers obtain their information primarily through the claims process. Additional means of obtaining information include the Medical Information Bureau, health risk assessments, and the medical history process. Access to information obtained on a health risk assessment likely varies among facilities. Another possible way that information is obtained is through a disease management system. For example, parent may request a genetic test for a child who is already being monitored by a disease management system.

Additionally, some plans may obtain genetic information by making a decision to pay for a genetic test for a participant. If a provider feels there is a medical need and that a genetic test could answer some medical unknowns for the patient and the provider, the information may be obtained during a preauthorization call and through the testing itself, the claims, or the applicable codes on those claims.

Question 4: Under what circumstances do plans or issuers ask for the results of a genetic test in order to make a determination regarding payment of benefits? What is the minimum amount of information necessary for a plan or issuer to make a determination under such circumstances?

Genetic test results may be needed to coordinate disease management for the plan member and communication among providers. Insurer access to this information should be role- and functionality-based, so that only the minimum amount of information necessary is made available at any time. This information may be as minimal as indicating whether or not the test was taken. Furthermore, if a test had to be preauthorized for payment, the justification of the need would be required to complete payment.

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule dictates that the requestor of the information determines the minimum amount of information necessary to process a claim. The provider, or the individual, submitting the claim, has the right to disagree, but the requestor, if it is an insurer, has the right to withhold payment. AHIMA believes that the "minimum amount of information" issue needs further clarification and may ultimately require a legislative or regulatory framework. This is certainly an appropriate topic for the NCVHS and other applicable congressional committees to review.

Question 5: What types of research do plans or issuers currently conduct or support using genetic tests?

AHIMA believes this question is best left for the plans and issuers to answer. There has been congressional testimony on this issue and Kaiser Permanente stated that individuals can benefit from research projects conducted by plans "to examine genetic and environmental factors that influence common diseases…By combining the genetic, health, and survey information from hundreds of thousands of members into databases, researchers hope to gain a deeper understanding of what combinations of genes and environmental factors influence the risk of complex diseases…"[1]

AHIMA believes this topic needs further scrutiny from policymakers. An important question to pose is whether or not the researchers, including the research supporters (funders), use genetic information gathered from subjects with known genetic test findings, to determine the incidence of disease manifestation over time and to match it against the predisposition. In addition, will the research findings impact coverage decisions for the patients and theirfamilies, or for the insurers entire covered aggregate population? These topics enhance the importance of the notice and the consent. Consumers need to know the potential risks when they provide information to their insurers.

Question 6: Would a model notice be helpful to facilitate disclosure to plan participants and beneficiaries in regard to a plan's or issuer's use of the research exception? In this regard, what information would be most helpful to participants and beneficiaries?

AHIMA believes a model notice would facilitate explanations to plan participants and beneficiaries about how the research exception works in regard to the use and disclosure of genetic information. A model notice crafted to be consistent, clear, concise, and simple in defining and distinguishing between a manifestation and a genetic predisposition, and how each could or could not be used, would be very helpful. If the language were standardized then the risk of confusion and misinformation would be minimized. A likely problem is that the law may not be consistently interpreted by those who must decipher it and therefore, the notice can provide a sanctioned interpretation that applies to and is available to all including plans, issuers and consumers. In addition, notice regulations should apply to any research conducted by or supported by a group health plan or issuer.

The model notice should contain clear and concise statements that explain:

- The request for a test must be made in writing by the plan
- The purpose of the research, methodology, and the protection of subjects
- The research is compliant with Federal and State regulations and the common rule for the protection of human subjects in research
- Agreeing to have a genetic test is totally voluntary, and refusing the test will have no impact on receiving coverage or increasing their plan premium

[1] Corwin, William, MD, Testimony of Americas Health Insurance Plans on Genetic Information and Testing to the Health Subcommittee of the House Energy and Commerce Committee. March 8, 2007.

- Provide reasoning for why the option to have a genetic test is being offered and the implications of either choice on the health plan, on the individual, and on research. It should include the intended use of the test findings, both immediately and whether and how it would be used in the future
- The genetic information resulting from the test cannot be used for underwriting purposes
- The plan or issuer has notified the appropriate secretary in writing that it is conducting such research activities, including a description of the activities conducted
- The plan or issuer complies with other conditions as may be required by regulations for such activities. This should be spelled out if possible
- If applicable, the clinical reason for requesting the test
- Provide a clear description of the implications regarding how the genetic information could impact their life, if the test is agreed to

This section of the legislation requires a voluntary written informed consent. AHIMA believes that the development of a standardized consent form would be beneficial for consumers and research bodies by eliminating the confusing discrepancies that exist amongst the multitude of differing consent forms in existence. This consent form should clearly define the research body, the reason for the research, the use of the data, what will happen to the data when the research is complete, and the individual's consent to the research.

Question 8: When might genetic information be collected incidentally?

Genetic information could be collected incidentally under a range of circumstances:

- When genetic information is a byproduct of another operation, such as medical history and physical, screening, research, case management, and similar circumstances
- When genetic information is included in other information disclosed for a specific purpose
- When a family member seeks treatment for a disease with strong genetic influences

Question 9: What terms or provisions (such as genetic information, genetic test, genetic services, or underwriting) would require additional clarification to facilitate compliance? What specific clarifications would be helpful?

AHIMA believes that some minor clarification is necessary for the following definitions:

- Family member—clarify that a "dependent" includes non-blood individuals such as stepchildren, adopted children, and domestic partners who are covered by their partner's insurance. In addition, it is important to clarify that the genetic information for the dependent who is not blood-related would also be protected and that the genetic make-up would not carry the same genetic signatures as other family members that are blood related. In addition, it is important to clarify the need to protect the information of family members who are entered incidentally into the records of those insured or their dependents, but who are no longer insured by their parents, spouses, or partners

- Genetic test—the term “Genetic test” should include the order for such a test to insure that the individual is protected. This is necessary because the mere fact that a test is taken can be just as revealing as the information itself

Conclusion

AHIMA appreciates the opportunity to comment on this RFI. If AHIMA can provide further information, or if there are any questions or concerns with regard to this letter and its recommendations, please contact Don Asmonga, MBA, CAE AHIMA’s director of government relations at (202) 659-9440 or don.asmonga@ahima.org, or me at (202) 659-9440 or dan.rode@ahima.org.

Sincerely,

Dan Rode, MBA, FHFMA

Vice President, Policy and Government Relations

cc: Don Asmonga, MBA, CAE