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Request for Information Regarding Sections 101 through 104 of the Genetic Information Nondiscrimination Act of 2008

Comment On: CMS-2009-0081-0023

Interim Final Rules for Sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008

Document: CMS-2009-0081-0040

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General Comment

Attached please find comments from America's Health Insurance Plans. Thank you.

Attachments

CMS-2009-0081-0040.1: DC

CMS-2009-0081-0040.2: DC

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Submitted via the Federal e-Rulemaking Portal: <http://www.regulations.gov>

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention: CMS-4137-IFC
P.O. Box 8017
Baltimore, MD 21244-8010.

Internal Revenue Service
Attention: REG-123829-08
Room 5205
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

U.S. Department of Labor
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Attention: RIN 1210-AB27
Room N-5653
200 Constitution Avenue, NW
Washington, DC 20210

Re: Interagency GINA Regulations: CMS-4137-IFC /REG-123829-08/RIN 1210-AB27

Dear Sir or Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments in response to the interim final regulations that were issued in the *Federal Register* on October 7, 2009 (74 Fed. Reg. 51664). The regulations were promulgated pursuant to §§101 through 103 of Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA, Pub. L. No. 110-233).

America's Health Insurance Plans (AHIP) is the national association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of health insurance products in the commercial marketplace and have demonstrated a strong commitment to participation in public programs.

For many years, AHIP's members have worked diligently to protect health information from unauthorized uses and disclosures. Their policies, procedures, and practices were designed to

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ensure the privacy and security of individually identifiable health information, including genetic information.

AHIP has consistently supported GINA, working with Congressional staff and key stakeholders throughout the legislative process to promote informed health care decision-making by patients and practitioners. At the same time, we were pleased that the legislation let us maintain the ability of health insurance plans to help consumers by offering state-of-the-art disease management and wellness programs that support early prevention, coordination of care, and improved health outcomes.

AHIP members believe that the Interagency interim final regulations should closely mirror the important statutory protections that GINA provides. After reviewing the regulations, we are primarily concerned that the Departments would be implementing regulatory requirements that appear to be inconsistent with Congress' intent in passing GINA and may impact patients adversely by making it difficult for them to participate in valuable programs that have been proven to benefit consumers. We are primarily concerned with the regulations' effort to define regulatory terms in ways that will limit the ability of individual consumers to participate in disease management and wellness programs and receive related incentives.

Our specific comments and recommendations are discussed in more detail in Attachment A. We appreciate your review of our comments and recommendations and hope that they assist the Departments in crafting regulations that more closely follow GINA's requirements and Congressional intent.

Thank you for the opportunity to comment on this important topic.

Sincerely,

Marilyn Zigmund Luke
Senior Regulatory Counsel

Cc: Robert Kocher, MD, Special Assistant to the President
National Economic Council, The White House

Ezekiel Emanuel, MD, Special Advisor for Health Policy
Office of the Director, Office of Management and Budget

Attachment A

Issue and Recommendation 1: The definition of “underwriting purposes” used in the regulations¹ extends beyond the scope of the legislation. The regulations should contain a definition of “underwriting purposes” that mirrors the statutory definition.

Discussion 1: Congress did not impose restrictions on disease management or wellness programs. Instead, legislative history indicates that GINA was not intended to create new regulatory schemes or change the ways that plans or insurers use genetic information to help patients and highlight recommended tests and courses of action.² Disease management and wellness programs and health risk assessment tools can improve individuals’ health outcomes and help contain health care costs by encouraging members to understand their health risks and find out about programs and services available to them, learn techniques to change health-related lifestyle behaviors, and ultimately take control of their health.

The regulations expand the statutory definition of “underwriting purposes” broadly to include “changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program” and “discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program.” We believe that the addition of these new and very specifically-targeted categories to the regulatory definition exceeds the literal wording of the statutory provisions as well as Congressional intent.

The statute prohibits covered plans and issuers from adjusting premiums or contribution amounts under a plan or policy on the basis of genetic information. In the case of disease management and wellness programs, the basis for providing an incentive or reward is the individual’s own choice to participate in and to complete the requirements of the program.

¹ 26 C.F.R. §54.9802-3T(b), (d)(1); 29 C.F.R. §2590.702-1(a), (d)(1); 45 C.F.R. §146.122(a)(7), (d)(1); 45 C.F.R. §148.180(a), (f)(1).

² 154 Cong. Rec. H2974 (daily ed. May 1, 2008) (statement of Mr. Camp: “But genetic information can also be used to help patients. Health plans have an ability to interact with both patients and providers to highlight recommended tests and courses of action. For example, a person that has a gene for a certain type of cancer would be recommended to receive more frequent cancer screenings. Knowing this, the health insurer would know to approve coverage for these additional screenings because they would be at a higher risk of developing that type of cancer.” *Id.* (statement of Mr. Upton: “We also made numerous clarifications to make sure that the new regulatory scheme did not disrupt reasonable and needed activities by health plans to improve health care, coordinate benefits, process benefits, or educate beneficiaries. It is important for the Congress to be mindful that we are not writing on a blank slate each and every time that we launch one of these new regulatory and liability schemes.”)

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GINA also prohibits covered plans and insurers from requesting, requiring, or purchasing genetic information for underwriting purposes. The statute contains no specific prohibitions for disease management or wellness programs, and we believe the regulations, if adopted, would curtail the ability of individuals to participate in, and health plans to offer, disease management and wellness programs.

Issue and Recommendation 2: The regulations may limit the ability to use health information for public health initiatives. The agencies should issue final regulations clarifying that health information (including genetic information) can be used and disclosed for public health purposes.

Discussion 2: Federal public health efforts have been making strides to empower consumers by increasing their knowledge about genetic conditions and potential risks of developing diseases based on family history. For example, the Surgeon General’s Family Health History Tool³ provides individuals with an easy-to-use tool focused on family health. The Surgeon General recognizes that health insurance plans can be key partners in this effort through the web-based portals and personal health records they offer to individuals. Ultimately, it is hoped that the tool and the use of family health history information will improve the quality of care and potentially reduce disease and its costs.⁴ GINA regulations should make clear that neither the law nor the regulations were designed to impact such important efforts.

Issue and Recommendation 3: The regulatory definition of “manifestation or manifested” is too narrow and fails to recognize that clinical diagnosis by genetic tests can precede the appearance of “signs or symptoms.” The narrow definition could have the unanticipated effect of discouraging such diagnostic testing because of a concern that the GINA protections would not apply. We recommend that the definition of “manifestation or manifested” be revised by deleting the sentence that reads, “For purposes of this subchapter, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.”

Discussion 3: In the majority of situations, a disease, disorder, or pathological condition will be “manifested” when an individual exhibits “signs or symptoms” that prompt a health care professional to perform a genetic test as part of the clinical diagnostic process. However, there are a few diseases (e.g., cystic fibrosis) for which a genetic test is perhaps the only diagnostic

³ Available at <http://www.hhs.gov/familyhistory/>.

⁴ *Id.*

⁵ 26 C.F.R. §54.9802-3T(a) (6); 29 C.F.R. §2590.702-1(a)(6); 45 C.F.R. §146.122(a)(6); 45 C.F.R. §148.180(a).

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tool that is available to help consumers receive accurate and valuable health care services. In these situations, the genetic test serves as the primary basis to render a proper diagnosis.

As the field of genetics evolves over time, we believe that genetic tests will continue to expand the medical evidence base and will be used more frequently for diagnoses. For these reasons, we believe the proposed definition of “manifestation or manifested” is too limited and may not keep pace with evolving medical evidence and clinical diagnostic guidelines.

Issue and Recommendation 4: The effective date of the regulations does not allow adequate time for entities to implement the new regulatory interpretations. Federal regulators should implement a 1-year enforcement delay to allow entities additional time to come into compliance with the requirements.

Discussion 4: The Interagency GINA regulations offered new and different perspectives for implementing GINA’s requirements specific to disease management and wellness programs and related uses of health risk assessments and incentives. As discussed above in Issue 1, the regulations set out new interpretations for the activities that are prohibited by GINA. The timing of the regulations preceded the majority of open enrollment periods for many consumers, which has resulted in increased efforts to comply with the new requirements in good faith by the effective date of the regulations on December 7, 2009. Affected entities could benefit from more time to come into compliance with the new interpretations and regulatory requirements.