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

Comment On: IRS-2008-0103-0018
Genetic Information Nondiscrimination Act

Document: IRS-2008-0103-0052
Comment on FR Doc # E9-22512

Submitter Information

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Organization: America's Health Insurance Plans (AHIP)

General Comment

America's Health Insurance Plans (AHIP) comment submitted

Attachments

IRS-2008-0103-0052.1: Comment on FR Doc # E9-22512
IRS-2008-0103-0052.2: Comment on FR Doc # E9-22512

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December 22, 2009

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

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

Re: Proposed GINA Regulations: REG–123829–08

Dear Sir or Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments in response to the Notice of Proposed Rulemaking by Cross-Reference to Temporary Regulations (hereinafter "Notice") that was issued in the *Federal Register* on October 7, 2009 (74 Fed. Reg. 51710). The Notice was issued under 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 ensure the privacy and security of individually identifiable health information, including genetic information.

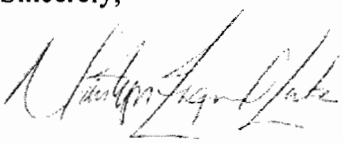
AHIP has consistently supported GINA, working with Congressional staff and key stakeholders throughout the legislative process to promote informed health care decision-making by patients and practitioners. At the same time, we were pleased that the legislation let us maintain the ability of health insurance 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.

After reviewing the Notice, we have two comments. First, the Notice indicates that the text of temporary regulations issued as part of an Interagency Rulemaking[1] "serves as the text of these proposed regulations." (74 Fed. Reg. 51710). However, the Notice does not clearly explain the legal basis or the rationale for why the IRS issued a Notice of Proposed Rulemaking separately from the Interagency GINA regulations if the same regulatory provisions are contained in both *Federal Register* notices.

Second, we believe an explicit provision should be included in 26 C.F.R. §54.9831-1(c)(1) to ensure that all appropriate "excepted benefits" are exempt from the amendments made to conform to the GINA statutory requirements. As indicated in our comments in response to the U.S. Department of Health and Human Services proposed changes to the HIPAA Privacy Rule,[2] we believe the federal regulatory requirements should be limited to those plans and products specifically enumerated in the GINA statute.

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

Sincerely,



Marilyn Zigmund Luke
Senior Regulatory Counsel

Attachment:

ahiphhsgina12.07.09.pdf

[1] The Interagency regulations are available at 74 Fed. Reg. 51664.
[2] *See,* 74 Fed. Reg. 51698. The comments submitted to HHS are attached.

America's Health Insurance Plans

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December 7, 2009

Submitted Via the Federal e-Rulemaking Portal: http://www.regulations.gov

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: GINA NPRM (RIN 0991-AB54)
Hubert H. Humphrey Building
Room 509F
200 Independence Ave., SW
Washington, D.C. 20201

Re: Proposed GINA Regulations

Dear Sir or Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments in response to the proposed regulations that were issued in the *Federal Register* on October 7, 2009 (74 Fed. Reg. 51698). The proposed regulations were promulgated pursuant to section 105 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 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 enhanced privacy and confidentiality regulations should closely mirror the important statutory protections that GINA provides. After reviewing the regulations, we are concerned that the Department 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. As an overview, our comments are focused on the following issues: (1) the proposed regulations' expansion of the GINA prohibitions on using and disclosing genetic information to entities not addressed in GINA; (2) the proposed 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; and (3) structuring requirements for providing Notices of Privacy Practices so that consumers receive necessary information in an easy-to-understand format.

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 agency in crafting final 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 proposed regulations have a broad scope that covers plans and insurers that were never intended to be covered by the GINA legislation and thus conflicts with Congressional intent. The HHS final regulations should limit the application and scope of the regulatory requirements being implemented under GINA specifically to the plans and issuers directly covered by the statute.

Discussion 1: The proposed regulations have expanded the GINA requirements to products that Congress never intended GINA to reach. The legislative language enumerates those products that the legislation is intended to cover: group health plans, group and individual health insurance issuers, and Medicare supplemental policies.[1] The legislative history also supports the intent to exclude other products.[2] While HHS relies on the administrative simplification provisions of HIPAA[3] to expand the reach of GINA to long-term care, limited-scope dental or vision benefits, state high-risk pools, and the Medicare program, such an expansion is not warranted or authorized by GINA and conflicts with GINA's explicit language which limits the plans and issuers covered by the statutory requirements.[4]

Issue and Recommendation 2: Redefining "health care operations" by removing "underwriting" in proposed §164.501 is a substantive change. We believe that the definition of "health care operations" should retain the term "underwriting" in subparagraph (3).

Discussion 2: The preamble to the regulations indicates that the current regulatory definition of "health care operations" is being modified to remove the term "underwriting" from the definition, and that this is intended as a non-substantive change. We believe, however, that this revision will constitute a substantive change to the definition of "health care operations" by removing underwriting as a permissible health care operation. In practice, this change will result in unintended consequences for individual consumers.

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[1] Refer to GINA §105; *See also,* GINA §§101-104.

[2] See 154 Cong. Rec. H2978 (daily ed. May 1, 2008). (statement by Mr. Green: "One segment of the health care marketplace was excluded from the bill's protections - - the long-term care insurance market. This bill was never intended to regulate the long-term care insurance market, and I understand that current statute treats long-term care insurance differently.") *See also,* H.R. Rept. No. 110-28, pt 1, at 35 and 69 (2008); S. Rept. No. 110-48, at 27 (2008).

[3] 42 U.S.C.A. §1320d et seq.

[4] *See also,* Chevron U.S.A., Inc., v. Nat. Resources Def. Council, Inc., 467 U.S. 837 (1984) (discussing a standard for a court to use when Congress has directly spoken to a precise question at issue, and, if Congressional intent is clear, evaluating whether an agency's action gave effect to Congressional intent).

Since promulgation of the HIPAA Privacy Rule, the definition of "health care operations" has been essential for health plans and other HIPAA covered entities to use and disclose protected health information for legitimate business purposes. Health care operations include the ability to price products appropriately. Underwriting includes functions such as developing guidelines that help a company in a voluntary market assess risks in designing products, whereas premium rating is typically thought to be one function (i.e., a subset) of underwriting that is limited to the way prices are calculated for a plan or policy (i.e., applying the correct factors and performing an actuarial calculation).[5]

In addition, "premium rating" and "underwriting" in the context of health insurance is largely dependent on state laws and regulations that set specific parameters for these terms, what types of information can be used and disclosed for these functions, how rates and filings are approved by state Insurance Commissioners, and the prices that individual consumers pay for products. We are concerned that excluding the word "underwriting" from the definition of "health care operations" would limit the application of the definition in ways that exceed GINA's scope, and could set up conflicts with state laws and regulations that permit or require health information to be used or disclosed for these business functions.[6]

Issue and Recommendation 3: The definition of "manifestation or manifested" in proposed §160.103 is too narrow and fails to recognize that clinical diagnosis by genetic tests can precede the appearance of "signs or symptoms." The proposed 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 the key - and perhaps the only

[5] Note that premium rating is typically governed by state law and the factors that can be included can vary by jurisdiction. Some examples are an individual's age, gender, occupation, the number of people to be covered, and the type of coverage (e.g., an accident policy, a specific illness policy, etc.).

[6] E.g., Or. Rev. Stat. §746.600 that defines "health care operations" to include underwriting, 31 Pa. Code §146b.11 which describes underwriting as an "insurance function" exempt from the authorization requirements for disclosure of non-public information.

currently available - diagnostic tool. 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 definition of "underwriting purposes" in §164.501 extends beyond the scope of the legislation. The final regulations should contain a definition of "underwriting purposes" that mirrors the statutory definition.

Discussion 4: 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.[7] 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 take control of their health, understand health risks, and improve health outcomes.

The proposed 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."[8] 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 receipt of an individual's family history (i.e., the genetic

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[7] 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.")

[8] 74 Fed. Reg. 51709.

information) is not the basis for adjusting a premium or contribution amount by giving an incentive or reward; the basis for providing the incentive or reward is the individual's own choice to participate in and to complete the requirements of the program.

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 proposed 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 5: The regulatory requirements of proposed regulation §164.520 pertaining to Notices of Privacy Practices (NPPs) should be refined to clarify that NPPs should be updated if a plan makes a material change to its privacy policies and practices as a result of GINA. In addition, we propose that NPPs be made available electronically and posted on a health plan website. Any required paper notices can be sent to individuals within 60 days of the later of either: (1) the final GINA regulations taking effect; or (2) final HITECH or other privacy regulations taking effect.

Discussion 5: Proposed regulation §164.520 requires a covered entity that is a health plan to update its NPP if the entity uses protected health information for an underwriting purpose. We agree that the NPPs should be updated if a plan uses protected health information that is genetic information for an underwriting purpose, but do not believe that revised NPPs should be issued by entities that did not and do not use genetic information for such purposes. Otherwise, individual consumers could have a mistaken belief about the ways their health information was being used.

In addition, we would like to propose additional, optional elements for inclusion in the final regulation. Some HIPAA covered entities may have already made or will be making updates to their NPPs to comply with the GINA requirements. In addition, many health plans are anticipating future changes to their NPPs based on future regulations (e.g., regulations that are anticipated from HHS pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH), as included in the American Recovery and Reinvestment Act (Pub. L. No 111-5) or other privacy updates). In an effort to avoid confusion to consumers who may receive multiple updated NPPs in a short period of time, many of the changes can be communicated to consumers very quickly if affected entities were allowed to utilize electronic processes (e.g., email and webpage postings) to provide individual consumers with information. We suggest that HHS adopt new provisions for delivering NPPs to individuals in more efficient electronic processes that are expedient ways to deliver information to consumers.