

December 22, 2009

Department of Labor, Employee Benefits Security Administration  
29 CFR Part 2590  
RIN 1210-AB27

Department of Health and Human Services, Centers for Medicare & Medicaid Services  
45 CRF Parts 144, 146, 148  
RIN 0938-AP37

Department of the Treasury, Internal Revenue Service  
26 CFR Part 54  
[TD9464]  
RIN 1545-BI03

Families USA, a not-for-profit consumer advocacy organization dedicated to the achievement of high-quality, affordable health care for all Americans, appreciates the opportunity to comment on the interim final rules for implementing the Genetic Information and Nondiscrimination Act (GINA).

Families USA strongly supports the interim final rules published by the Department of Labor, Department of Health and Human Services, and Department of Treasury. Timely implementation of the rules will help make health insurance coverage more accessible and affordable for Americans.

The interim final rules for GINA ensure that consumers will no longer face health coverage discrimination based on their genetic information. Families USA supports the robust protection against underwriting based on genetic information provided by the rules. The practices included in the definition of underwriting purposes, including the modification of deductibles or other cost-sharing mechanisms or the provision of “discounts, rebates, payments in kind, or other premium differential mechanisms” as incentives for completing a health risk assessment (HRA) or participating in a wellness program, are critical for preventing loopholes that undermine the strong protections Congress intended to provide with the passage of GINA. Families USA strongly supports the explicit prohibition on plans or issuers collecting genetic information, including family history, in HRAs. Any requests to exempt HRAs or wellness programs from the protections granted by GINA should be denied.

Families USA also supports the definition of family members in the rules. The rules define family members broadly to include first, second, third, and fourth degree relatives and relatives by affinity. This broad definition is critical for providing equal protection under GINA of the privacy and rights of all types of families, including adopted families. In addition, Families USA

1201 New York Avenue NW, Suite 1100 ■ Washington, DC 20005 ■ 202-628-3030 ■ Fax 202-347-2417  
E-Mail: [info@familiesusa.org](mailto:info@familiesusa.org) ■ Web site: [www.familiesusa.org](http://www.familiesusa.org)

supports the inclusion of a fetus or embryo as a protected entity under GINA.

The GINA interim final rules provide critical protections against insurance rate increases based on genetic information. Families USA strongly supports the explicit prohibition of using genetic information that was lawfully obtained before the effective date of GINA in setting insurance rates. We also support the explicit prohibitions on using the manifestation of a disease or disorder in one group member to set rates for other group members, along with the prohibition of individual market insurers using the manifestation of a disease or disorder in one individual as genetic information about other individuals covered under the policy or to increase the rates of other individuals under the policy. These and other provisions to eliminate underwriting based on genetic information will protect consumers while also potentially reducing administrative costs to insurers, as they will simplify and shorten the underwriting process.

The passage of GINA and the GINA rules as drafted will provide health care consumers with critical new protections from discrimination. The following comments suggest ways in which the rules can be strengthened to ensure that the intended protections are fully afforded to all consumers:

#### Exceptions to GINA

Along with the exception for health care providers, exceptions to GINA are provided in the interim final rules for health plans or issuers making a determination regarding payment or conducting research. Families USA suggests that for both of these exceptions, plans or issuers must provide explicit notice to the enrollee that the collection of genetic information is occurring as an exception to GINA. Such notices should include contact information for the state and federal departments responsible for responding if a consumer believes his or her GINA rights have been violated.

For the research exception, although the rules do not require plans or issuers to notify participants that there is an exception to GINA, participants do receive notice that the genetic information collected has no effect on eligibility for benefits or premium or contribution amounts. We support this notification and in addition we suggest that the “Notice of Research Exception under the Genetic Information and Nondiscrimination Act” that plans or issuers seeking the exception must submit to federal agencies also be provided to research participants. It would also be helpful if the final rules included specific examples to illustrate the types of research a health plan or issuer might conduct for which they would require genetic information.

Regarding the GINA exception for payment determination, Families USA strongly supports the provision stating that plans or issuers may request only the “minimum amount of genetic information necessary” for this purpose. However, since plans or issuers may refuse payment for a service if patients do not provide the information they request under a payment determination exception, we suggest that an appeals process be made available for consumers who do not believe that payment for a given benefit should reasonably depend on a genetic test.

#### Incidental Collection of Genetic Information

Families USA strongly supports the requirement that, in order to qualify for an exception to GINA for the incidental collection of information, plans and issuers must inform individuals that they should not reveal genetic information when it is reasonable to anticipate that such information may be received. We recommend that plans and issuers be provided and required to

use a specific statement to ensure that this warning for consumers is sufficiently broad and easy to understand. On page 51862, example number 7 provides a statement that could be used for this purpose. It reads, “In answering this question, you should not include any genetic information. That is, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk.” This statement clearly defines genetic information so that consumers are explicitly aware of what information they should not provide to plans or issuers, and therefore should be required on documents where it is reasonable to anticipate that genetic information may be disclosed. Such a warning should also include contact information for the state and federal departments responsible for responding if a consumer believes his or her GINA rights have been violated.

Families USA also supports the explicit prohibition on using incidentally collected genetic information for underwriting purposes. We believe that compliance with this prohibition would be more likely if the final rules required plans and issuers to excise any incidentally collected genetic information from their records or databases. Such a requirement is especially important given that plans and issuers may conduct certain medical tests such as HIV tests, complete blood counts, cholesterol tests, liver function tests, or tests for the presence of alcohol or drugs without violating GINA, as long as genetic information is not collected. Requiring plans to excise any genetic information would better control how information extracted from such tests is used.

In addition, we suggest that applications for health insurance be required to state that plans and issuers are prohibited from collecting genetic information from individuals prior to their effective date of coverage and that individuals should not include any genetic information, defined as family medical history or information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which the individual is at-risk, on health insurance applications. Such a notice statement would better protect consumers and make compliance with the GINA’s prohibitions on the collection of genetic information more likely. Health insurance application documents should also include contact information for the state and federal departments responsible for responding if a consumer believes his or her GINA rights have been violated.

#### GINA Enforcement

The Departments assume that plans will rely on issuers, or in case the of self-insured plans, wellness vendors and other service providers, for complying with the important prohibition on collecting genetic information on HRAs for which incentives are provided. However, we are concerned that there is no specific required process through which the departments will ensure compliance with this and other important provisions of GINA. In general, the interim final rules state that the Secretary of Labor has authority to impose a penalty against issuers if they fail to comply with GINA and are subject to ERISA. States have the authority to ensure that plans that are not covered by ERISA comply with GINA, and if states fail to do so, the Secretary of Health and Human services will enforce the law. However, Families USA is concerned about the lack of a formal mechanism to ensure that the Secretaries of the responsible departments are aware of any failures among ERISA-covered plans to comply or failures among states to enforce compliance of state-regulated plans. Experiences with HIPAA indicate that without any formal mechanisms, enforcement may not adequately occur.

Therefore, we suggest that the responsible departments periodically monitor state enforcement of

GINA and GINA compliance among plans subject to ERISA. Plans and issuers should be required to cooperate with the submission of data to the departments tasked with enforcing GINA to ensure compliance with the law. In addition, all relevant documents provided to consumers should include contact information for the state and federal departments responsible for responding if an individual believes his or her GINA rights have been violated. Such information should explain to consumers that if they are not satisfied with their state's response, they may contact the responsible federal department. All departments with GINA oversight and enforcement responsibilities should also prominently display individuals' rights under GINA and contact information for the department responsible for responding if a consumer believes his or her GINA rights are being violated on their Web sites. In addition, such departments should conduct outreach, such as through the media, in order to publicize individuals' rights under GINA.

The lack of specific GINA enforcement and oversight mechanisms is especially concerning given that plans and issuers may have access to genetic information through incidental collection, exceptions to GINA, or through allowable medical tests that permit the collection of biomaterial, but not for genetic purposes. We are concerned about how the responsible departments or states will ensure that when issuers or plans potentially have access to genetic information through these means, they do not use the information for underwriting purposes. Families USA suggests that the responsible state or federal departments require plans and issuers to cooperate with authorized audits or data submission requests to ensure that any incidentally or allowably collected genetic information is not used for underwriting purposes.

Families USA appreciates the opportunity to share our strong support of the interim final rules for the Genetic Information and Non-Discrimination Act (GINA). Their timely implementation, with no further exceptions, will protect Americans from genetic discrimination in health insurance and improve access to quality coverage.

Thank you for considering our comments.

If you have any questions, please contact Claire McAndrew at [cmcandrew@familiesusa.org](mailto:cmcandrew@familiesusa.org) or Cheryl Fish-Parcham at [cparcham@familiesusa.org](mailto:cparcham@familiesusa.org). Both individuals may also be reached by telephone at 202-628-3030.

Sincerely,

Claire McAndrew, MPH  
Health Policy Analyst  
Families USA