



*Council for
Responsible
Genetics*

COUNCIL FOR RESPONSIBLE GENETICS
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**Comments of the Council for Responsible Genetics on Interim Final Rules Prohibiting Discrimination
Based on Genetic Information in Health Insurance Coverage and Group Health Plans**

December 21, 2009

Department of Labor, Employee Benefits Security Administration
Attention: RIN 1210-AB27

Department of Health and Human Services, Centers for Medicare and Medicaid Services
Attention: CMS-4137-IFC

Department of the Treasury, Internal Revenue Service
Attention: REG-123829-08

Dear Sir/Madam:

On behalf of the Council for Responsible Genetics, we are pleased to offer comments on the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act (GINA) that were published in the Federal Register on October 7, 2009.

The Council for Responsible Genetics (CRG) was founded 26 years ago by a coalition of scientists, public and occupational health activists, and reproductive rights advocates. From its inception, CRG published articles in its magazine, *GeneWatch*, examining the societal impacts of new discoveries in applied genetics and compiled the first documentation of genetic discrimination against people who could not obtain employment, health or life insurance because they or a member of their family had a genetic condition. CRG President Jeremy Gruber has been intimately involved with the issue of genetic privacy and discrimination for many years. He served on the Commission on Genetics and Employment for the National Conference of State Legislators and worked on many of the state genetic nondiscrimination laws now in effect. Jeremy is a founder and co-chair of the Coalition for Genetic Fairness, the primary advocacy organization for the Genetic Information Nondiscrimination Act. He has had the opportunity to testify before Congress and the Equal Employment Opportunity Commission regarding GINA and has spent the last twelve years advocating for the enactment of GINA; working with all stakeholders as well as Congressional members and their staffs.

During the past several decades, our understanding of genetics has multiplied as procedures for identifying, analyzing and manipulating DNA have advanced. Among the many benefits of this growth in genetic technology are the ways such technology may influence preventive health, reproductive planning and eventually therapies to cure illnesses with a genetic component. While no one can deny that this knowledge may be a blessing in finding cures to diseases with genetic origins

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including Alzheimer's, Huntington's and many forms of cancer, the immediate consequences of such advances have led to a number of forms of individual discrimination.

The ability to identify individuals based on genetic characteristics necessarily predates the ability to use this information in the treatment of the corresponding diseases. As public concern began to rise in response to the growth of genetic discrimination, Congress was prescient enough to virtually unanimously pass GINA and place significant restrictions on the accumulation of genetic information by employers and insurers before such discrimination became permanently ingrained in the social fabric. Congress knew that without meaningful privacy safeguards and protections against discrimination, the benefits of genetic testing would ultimately be lost as individuals avoided tests in fear of adverse consequences.

GINA now provides every American not only with strong new protections against genetic discrimination but from access to and disclosure of their personal genetic information as well. Under the best of circumstances discrimination cases are difficult to prove. Employers and insurers are often the only party with access to information supporting a discrimination claim; indeed employees and consumers are often unaware, let alone able to prove that discrimination has occurred. Preventing access to information that can lead to discrimination is the best way to ensure discrimination never happens.

The Council for Responsible Genetics therefore strongly supports the agencies' efforts to implement these important protections and their strong position on these issues. We believe the regulations are consistent with the legislative history of GINA and accurately reflect the intent of Congress.

In particular, we believe the interim final rule accurately reflects GINA's broad definition of medical underwriting. According to the interim final rule, plans and insurers are not allowed to collect genetic information for underwriting purposes, period. There are no exceptions. Therefore, such entities may not change deductibles, provide discounts, rebates, in kind payments, or any other premium altering arrangements in return for such activities as completing a Health Risk Assessment (HRA) or participating in a wellness program. Regulations clarify that covered wellness programs may not include questions about family history on their HRA's if such participation affects the benefits or rewards offered to enrollees.

The Council for Responsible Genetics strongly supports this interpretation. One of the primary purposes of GINA was to give individuals back control over their own genetic information. Whatever terms are chosen to describe such programs, whether they be called incentives, surcharges or rewards, the end result is that individuals who fail to participate in such programs are in a lesser financial position than individuals that do participate. The failure to participate in such programs can result in the loss of hundreds and even thousands of dollars and merchandise. Any program that puts an individual in a lesser financial position for failure to participate in a health risk assessment that asks for genetic information should be considered to meet the definition of underwriting. Particularly in today's economy, these programs are coercive; few people are in any financial position to turn down tangible or even intangible benefits. The only way to protect individuals from being coerced into revealing their genetic information and family history is by implementing the strict provisions set forth in the interim rule.

For similar reasons, HRA's may not collect genetic information, including family history information, prior to or in connection with enrollment. This is the case even if no specific financial incentives are offered. This is because in these situations, the enrollment itself is the incentive and few individuals are willing to do anything they perceive as risking the obtainment of such a vital resource in today's society.

Finally, an HRA must include an explicit statement that genetic information should not be provided if it asks a open-ended question that may elicit such information. Under the rules' approach to incidental collection of genetic information, genetic information obtained in the absence of such a statement will be considered in violation of GINA. This is a common sense approach to ensure that individuals have the opportunity to make informed decisions about sharing their genetic information.

The Council for Responsible Genetics supports wellness programs and HRA's generally and believes that they are an important component of preventative care. Wellness programs can be an effective tool to manage health and reduce rising health care costs. Employer based wellness programs, in particular, can be a win-win for employers and employees. Most individuals want to be healthy but often lack the proper knowledge and ability to realize this aspiration. Well designed wellness programs provide individuals these tools. Furthermore, health risk assessments can be a useful way to determine what kind of workplace wellness program intervention will hold the highest likelihood of success, measure its progress and track the changes in health of the aggregate employee population.

We commend the agencies for providing numerous specific examples of how wellness programs can continue to utilize HRA's in their programming. For example, if plans or insurers want to utilize HRA's that include genetic information, they may do so as long as no incentives or rewards are offered and that they are not conducted in connection with or prior to enrollment. Additionally, plans and insurers can offer incentives for completing an HRA or participating in a wellness program if requests for genetic information are excluded. Certainly GINA puts no limitations on virtually any of the most effective broad based approaches to wellness, including dietary options and guidance, as well as exercise, weight loss and smoking cessation programs. And most importantly, GINA puts no limitations on sharing personal health information with a treating clinician.

We strongly recommend that the agencies continue to study this issue to ensure that further recommendations and guidelines can be developed for how wellness programs can continue to grow and flourish under GINA. We believe quite strongly that they can and will. Furthermore, we recommend that the agencies coordinate efforts with the EEOC so that the full impact of final rules pertaining to both Titles of GINA and the administration of wellness programs can be clear and unambiguous.

GINA is one of the most well understood and debated laws in recent memory. For over 12 years, every stakeholder in GINA had an opportunity to be heard and participate in the discussion. Every provision in GINA was debated in Congress. The interim final rule simply reflects the intent of GINA upon final passage and therefore there should be no exemptions for wellness programs and HRA's and no delay in implementing the rule. Program sponsors have had over 18 months to revise their wellness programs and HRA's to be in compliance with GINA.

In closing, the Council for Responsible Genetics strongly supports GINA and the implementing regulations. We appreciate the efforts of the Employee Benefits Security Administration, Centers for Medicare & Medicaid Services, and the Internal Revenue Service to ensure that the regulations accurately reflect Congressional intent to provide every American with strong protections against genetic discrimination and to give them back control over their personal health information.

Thank you for consideration of these comments. Please do not hesitate to contact us if you have any questions, or require additional information or comment.

Sincerely,

A handwritten signature in black ink that reads "Jeremy Gruber". The signature is fluid and cursive, with "Jeremy" on top and "Gruber" below it, though the two words are connected.

Jeremy Gruber, JD
President
Council for Responsible Genetics