



American Heart Association | American Stroke Association

Learn and Live

Heart Disease and Stroke. You're the Cure.

Chairman of the Board

Neil M. Meltzer, MPH

President

Clyde W. Yancy, MD, FAHA

Chairman-Elect

Debra W. Lockwood, CPA

President-Elect

Ralph L. Sacco, MD, FAHA

Immediate Past

Chairman of the Board

David A. Josserand

Immediate Past President

Timothy J. Gardner, MD, FAHA

Secretary-Treasurer

William H. Roach Jr., Esq.

Directors

Donna K. Arnett, PhD, FAHA

Kenneth D. Bloch, MD, FAHA

Mary Caldwell, RN, PhD, FAHA

Stephen R. Daniels, MD, PhD, FAHA

Pierre B. Fayad, MD, FAHA

Debra A. Geihlsler

Larry B. Goldstein, MD, FAHA

Max Gomez, PhD

Ron W. Haddock

Pamela K. Knous

Paula Lank, BSN

Mark B. McClellan, MD, PhD

Hon. Judith F. Olson

David A. Spina

Gordon F. Tomaselli, MD, FAHA

Chief Executive Officer

Nancy A. Brown

Chief Mission Officer

Meighan Girgus

Chief Administrative Officer &

Chief Financial Officer

Sunder D. Joshi

Chief Operating Officer

Field Operations & Development

Gordon L. McCullough

Chief Science Officer

Rose Marie Robertson, MD, FAHA

Executive Vice President

Communications

Matthew Bannister

Executive Vice President

ECC Programs

Michael C. Bell

Executive Vice President

Field Health Strategies

Robyn Lee Landry, APR

Executive Vice President

Corporate Secretary &

General Counsel

David Wm. Livingston, Esq.

Executive Vice President

Consumer Health

Kathy Rogers

Executive Vice President

Advocacy

Mark A. Schoeberl

Executive Vice President

Development

Suzie Upton

Executive Vice President

Technology & Customer Strategies

Michael Wilson

November 20, 2009

Employee Benefits Security Administration
U.S. Department of Labor
Attention: RIN 1210-AB27

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

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

Dear Sir/Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we are pleased to offer comments on the implementation of sections 101 through 103 of Title I of the Genetic Information Nondiscrimination Act (GINA).

AHA strongly supports GINA and we look forward to its implementation. GINA will provide Americans with broad protections against genetic discrimination by health insurance providers and employers. Under GINA, insurance providers will be prohibited from using genetic information for underwriting purposes and from requesting or requiring patients to undergo genetic testing. GINA also greatly limits employer access to genetic information and prohibits employers from discriminating against employees with respect to compensation, terms, conditions, or privileges because of genetic information.

GINA also removes barriers that discourage individuals from taking genetic tests or participating in genetic research. Upon implementation, individuals will no longer have to fear that taking a genetic test will lead to discrimination if their employer or insurer becomes aware. And potential research subjects will no longer have to fear that their participation, or the results of a genetic test, will be used against them. Increased willingness by the public to undergo recommended genetic testing and participate in clinical research is critical to the advancement of personalized healthcare where treatments can be tailored based on an individual's genetic profile and genetic tools can be used to predict and preempt disease. This is particularly important for patients with or at a risk for cardiovascular disease

since genetics plays an important role in many heart disorders and can influence risk factors for heart disease and stroke.

For these reasons, AHA strongly supported GINA during its development in Congress and we are pleased to offer our support of the agencies' efforts to implement these important genetic protections. We appreciate the agencies' strong stance on these issues and we believe the regulations implement GINA as required by the law and accurately capture Congressional intent.

We are particularly pleased by the agencies' inclusion of strong prohibitions on medical underwriting. According to the interim final rule, plans and insurers are not allowed to collect genetic information for underwriting purposes, which include changing deductibles or other cost-sharing mechanisms, or providing discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program. The rule also clarifies that genetic information includes family medical history, and that open-ended questions in HRAs need to actively discourage the submission of genetic information. Therefore, plans and insurers that offer a reward or benefit for completing a HRA or participating in a wellness program that collects an individual's genetic information or their family history is in violation of GINA and is prohibited.

AHA supports wellness programs and recognizes the benefits of HRAs. However, we believe that participation in such programs should be voluntary, especially when there are requests for sensitive information such as genetic information. However, many of the programs used by insurers today utilize a system of incentives or disincentives to compel participation. These incentives may include significant financial discounts or penalties applied to an individual's health insurance premium, deductible, or coinsurance amount. For example, one individual who declined to participate in an insurer-sponsored "voluntary" wellness program was then assessed an annual 50% premium increase for failure to participate. Financial penalties such as this coerce people to participate in these programs meaning they are no longer truly voluntary. We are pleased the regulations prohibit plans and insurers from exercising this unfair practice to coerce enrollees into revealing their private genetic information.

We are however aware that a few organizations have objected to the rule's provisions addressing HRAs and wellness programs and have requested a delay in the effective date. AHA opposes such a delay and urges the agencies to move forward with implementation of these provisions as planned. The prohibition against collecting genetic information in connection with underwriting is not only the right public policy to protect enrollees from discrimination; it is also what the law requires. The final interim rule simply implements the law's requirements, requirements that plans, insurers, and wellness program/HRA developers have been aware of since GINA was passed in May 2008. Therefore, we believe that the argument advanced by some wellness program and HRA sponsors – that the rule should be delayed because many have already printed and distributed HRAs that request genetic information and offer an incentive – is immaterial. Program sponsors have had sufficient time – 18 months – to revise their wellness programs and HRAs, by, for instance, removing questions about family history, to ensure compliance with the law.

We also understand that some are questioning the restrictions against the collection of family medical history. These groups claim that family medical history is needed to stratify and enroll individuals in the appropriate risk or disease management program. While AHA sees immense value in family medical history and strongly encourages individuals to learn their family medical history and share it with their physician and other health care providers, we are unaware of evidence demonstrating a positive health impact from sharing this information with your insurer. The Surgeon General's Office, which also recognizes the value of family medical history and launched the Family Health History Initiative several years ago to encourage people to learn and collect their family medical history, also encourages people to share it with their "family doctor" or "health care worker"; it does not recommend sharing your family medical history with your plan or insurer. Thus, AHA and the Surgeon General's Family Health History Initiative concur, it is important to share family medical history with your health care professional.

We also agree with the agencies' assessment, as described in the fourth HRA example included in the rule, that using family medical history to determine eligibility for plan benefits such as a risk or disease management program is a form of genetic discrimination. Most wellness programs focus on broad wellness themes such as smoking cessation, weight loss, proper nutrition, increased physical activity, and stress management. It would appear that these types of programs would benefit all individuals regardless of their genetics. Wellness program sponsors might be better served by opening these types of programs up to their entire membership. We also believe that the decision to enroll in a wellness program should be voluntary and not made through mandatory assignment. Individuals could make this selection based on the outcomes of a HRA and a consultation with a health care professional.

In addition, some detractors from the rule have expressed concern that the wellness program/HRA restrictions will severely limit program sponsors' ability to promote the programs and ensure their effectiveness. However, we believe that wellness programs and HRAs can continue to be effective under GINA. If plans or insurers want to utilize HRAs that include genetic information, they may do so as long as no rewards or incentives are provided and they are not conducted in connection with or prior to enrollment. Similarly, plans and insurers can offer incentives for completing a HRA or participating in a wellness program if requests for genetic information are excluded.

In closing, AHA reiterates our support for 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 and provide Americans with strong protections against genetic discrimination. By prohibiting plans and insurers from collecting and utilizing genetic information for underwriting purposes and by clarifying that this prohibition also applies to wellness programs and HRAs, you are ensuring that individuals will not be subject to financial pressure by their health plans or insurers to disclose their family's private medical information.

We strongly encourage the agencies to proceed with the rule as drafted and to deny requests to delay its enactment or exempt wellness programs and HRAs from the rule. As discussed above,

wellness programs and HRAs can continue to operate under the guidelines established by GINA and they should not be exempt from this important federal civil rights statute.

Thank you for consideration of our comments.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Regulatory Affairs Manager, at 202-785-7908 or susan.k.bishop@heart.org, or Derek Scholes, PhD, Government Relations Manager, at 202-785-7927 or derek.scholes@heart.org.

Sincerely,

A handwritten signature in black ink on a light blue background. The signature is cursive and appears to read "Clyde W. Yancy".

Clyde W. Yancy, MD, FAHA
President
American Heart Association