



December 9, 2008

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration, Room N-5653
United States Department of Labor
200 Constitution Avenue North West
Washington, District of Columbia 20210

Re: Genetic Information Nondiscrimination Act of 2008

The National Business Group on Health appreciates the opportunity to comment on sections 101 through 104 in response to the Request for Information on Title I of the Genetic Information Nondiscrimination Act of 2008. We applaud the law's efforts to prevent discrimination in employment and health coverage based on genetic information. Our comments seek clarification in the final regulations that the growing practice of requesting health risk assessments (HRAs) that often include family medical history questions prior to employer plan enrollment, offering financial incentives for the completion of HRAs that also happen to ask about family medical history, and genetic testing for effectiveness and, subsequently, eligibility for specific medical treatments are not prohibited by GINA. All of these practices use what GINA has defined as genetic information to identify appropriate preventive services and treatment and to improve the effectiveness and quality of care for patients and not to discriminate in employment or health coverage.

The National Business Group on Health represents about 300 large employers providing health coverage to more than 55 million U.S. employees, retirees, and their families. We are the nation's only non-profit organization devoted exclusively to finding innovative and forward-thinking solutions to large employers' most important health care and related benefits issues. Business Group members are primarily Fortune 500 and large public sector employers, with 64 members among the Fortune 100.

Question #1 – Group Health Plan use of Genetic Information in the form of Family Medical History

As you are aware, GINA defines “family medical history” as “genetic information”. Requesting family medical history now falls under the category of “genetic counseling” in the law, which prohibits collection of such information prior to actual plan enrollment. Many employer group health plans currently request family medical history on health risk assessments for new employees prior to plan enrollment and as part of open enrollment for current employees. Health risk assessments identify individuals at risk and provide an opportunity for referral for preventive treatment services, disease management, and other behavioral change initiatives focused on creating higher quality medical outcomes.

Employer group health plans often provide incentives for the completion of health risk assessments such as lower annual deductibles, premium discounts, and cash bonus payments. Some employers require that employees complete health risk assessments to be eligible for coverage, or to qualify for these financial incentives. While we understand that GINA prohibits tying financial incentives to

genetic information, the financial incentive in these cases is for the completion of HRAs and not predicated on the provision of family medical information. We urge that the final regulations clarify that this growing practice will not be prohibited.

Employer group health plans conduct risk assessments and implement such requirements to secure participants' early focus, attention, and participation and to alert vendors who evaluate health risk to provide appropriate referrals and information to plan participants and their medical providers. They do not seek information from HRAs, including family medical history, for the purpose of discrimination in employment or health benefits.

Plans use the information for the express purpose of providing more efficient treatment and services to participants to improve their health and maximize opportunities to receive benefits under the plans. Group health plans do not collect and evaluate the family medical history information disclosed in HRAs for any "Underwriting Purposes" as defined in GINA.

Question #4 - Preservation of Genetic Testing to Determine Payment of Benefits

The many different types of genetic testing include pharmacogenomic, presymptomatic, carrier screening, pre-implantation, prenatal, and newborn screening. Medical providers develop individual treatment protocols based on information from genetic testing in the growing field of "personal medicine". The practice of personal medicine offers more individualized and efficient care leading to higher quality health outcomes.

Group health plans occasionally use the results of these tests, particularly pharmacogenomic tests, to assure that plan participants receive effective treatment and determine benefits. A contemporary example is prescribing Herceptin for the treatment of breast cancer. Some group health plans may not cover Herceptin if genetic tests do not indicate that it will be an effective treatment for individual patients. In the operation and administration of group health plans, these practices are not significantly different than any other diagnostic and predictive tests to determine appropriate and efficient medical treatment and those claims eligible for payment or reimbursement. In the future, group health plans will utilize more genetic testing to identify treatment protocols that lead to the highest quality medical outcomes and to design benefit payment policies that encourage their use where treatment effectiveness depends on patients' genetic markers.

Using genetic information to determine benefit payments, and health plan approvals of benefits, is very different from GINA's prohibition of the use of genetic information to exclude employees from participation or enrollment in the plan. Using genetic testing to identify appropriate treatment, and denials of benefits where inappropriate, ineffective, or unnecessary treatments have been given, should be preserved under GINA and clarified in the regulations. Preservation of the ability of group health plans to account for the most appropriate and effective medical treatment and to condition determination of benefits on the results of genetic testing is also vital to the evolution of evidenced-

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based benefit plan design where the eligible benefit provisions and benefit determinations are made by relying on the most current medical research findings.

Personalized treatment protocols specifically designed for individuals based on genetic testing will only become more prolific in the future as medicine advances. Appropriate medical care based on genetic testing, and the subsequent determinations of benefits by group health plans, should be preserved under GINA.

We urge you to consider clarification in the final regulations that requests by group health plans to complete health risk assessments that include family medical history questions prior to enrollment, to offer financial incentives for the completion of HRAs that include questions on family medical history, and that conditioning plan payment for certain treatments known to be effective only for patients with specific genetic markers or requiring that plan enrollees take a genetic test to determine the effectiveness of a treatment are not prohibited by GINA.

Thank you, again, for the opportunity to provide comments in response to the RFI.

Please do not hesitate to contact me or Steven Wojcik, Vice President of Public Policy, at 202.585.1812 if you have questions or would like to discuss this feedback in further detail.

Sincerely,

A handwritten signature in cursive script that reads "Helen Darling". The signature is written in black ink and is positioned above the typed name.

Helen Darling
President