



AMERICAN BENEFITS  

---

COUNCIL

December 9, 2008

Office of Health Plan Standards and Compliance Assistance  
Employee Benefits Security Administration  
Room N-5653  
U.S. Department of Labor  
200 Constitution Avenue, NW  
Washington, DC 20010  
Attention: GINA Comments

**Re: Response to Request for Information on Genetic Information  
Nondiscrimination Act**

Dear Sirs/Madams:

The American Benefits Council (the "Council") appreciates the opportunity to respond to the Request for Information ("RFI") on the Genetic Information Nondiscrimination Act issued by the Department of Labor, Department of Health and Human Services, and Internal Revenue Service. We understand from the RFI that a response submitted to one agency will be shared with the other agencies, and that commenters are not to submit comments to more than one agency.

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly or provide services to retirement and health plans that cover more than 100 million Americans.

The Council supports the general intent of the legislation to protect individuals against discrimination based on genetic information. We are concerned, however, that without careful crafting, implementing regulations could interfere with legitimate plan practices or otherwise result in unintended consequences. Such plan practices include, for example, health promotion, disease management, and quality improvement reporting. We believe the request for information in anticipation of a rulemaking will be helpful in reducing the risk of unintended consequences.

GINA generally prohibits a group health plan from requesting or requiring genetic information for underwriting purposes or prior to enrollment, or from adjusting premiums or contributions on the basis of genetic information. It is our understanding that group health plans do not use genetic information for traditional underwriting purposes or to adjust premiums or contributions, as these activities are already generally prohibited under the HIPAA nondiscrimination rules. Plans do, however, request or collect genetic information incidentally to other information, as explained below.

### How Plans Currently Use Genetic Information

The RFI specifically asks how group health plans currently obtain or use genetic information, including as part of a wellness program or health risk assessment. Plan sponsors typically offer some type of wellness program through their employer health plans. These programs range from simply providing educational materials to more extensive incentive programs that reward participants for achieving a particular health status. To the extent a program relates to an individual's health information (particularly if an incentive is given), these programs must comply with the HIPAA nondiscrimination and other federal law or regulations that apply to wellness programs (including ERISA, HIPAA privacy rules, the Americans with Disabilities Act, and tax rules).

A common wellness program design involves collecting participant data through a health risk assessment ("HRA"). Participants answer a questionnaire with a range of health-related questions. These questions typically ask about family health history. Group health plans may use HRAs to identify an individual's appropriateness for a particular wellness program or provide the individual with educational material specific to his or her risk factors. For example, if an overweight individual indicates on an HRA a positive family history of heart disease, that combination of risk factors may prompt the plan to send the individual specific educational materials about healthy eating or exercise, or invite the individual to participate in a more comprehensive wellness program designed to address these risk factors. Wellness program participation and feedback is much more positive when individuals are identified based on a specific condition, rather than when individuals receive mass-marketed materials aimed at an entire population.

Plans also use HRA results more globally to design future plan benefits or wellness programs. For example, if a plan's overall HRA results indicate an unusually high genetic history of breast cancer in the plan population, the plan sponsor may design a new educational or wellness program related to mammography screening.

Some plans may request that participants complete an HRA prior to or simultaneous with enrollment, which facilitates the placement of the participant in a wellness

program for an entire plan year. This is particularly the case where a plan also must comply with the HIPAA wellness program rules. These rules limit rewards based on the cost of coverage, which most plans determine on an annual basis. In addition, some plans require participants to complete an HRA or participate in a wellness program as a part of coverage, or offer incentives that affect premiums or contributions based on participation in an HRA or wellness program. While these practices comply with the limitations of HIPAA or other applicable laws, there is uncertainty as to how GINA would impact them. We recommend that implementing guidance clarify that, consistent with Congressional intent, the collection and use of genetic information is permissible for the administration of wellness programs.

### Collection of Genetic Information Incidentally

The RFI also asks how genetic information may be collected incidentally. As discussed above, plans often encounter this information through HRAs that are offered to plan participants in the enrollment process for health benefits coverage. Health risk assessments typically ask a number of health and lifestyle questions, including information on family history for certain conditions. Information obtained through HRAs is useful for identifying individuals who might benefit from a particular wellness programs that an employer offers. Plans may also use the HRA to inform plan design in order to tailor health promotion programs to particular workforce health needs.

In some cases, plans may require or provide rewards for completion of an HRA, although the rewards are not based on specific responses, but the mere completion of the form. Genetic information that is obtained through an HRA (such as family history) is incidental to the more comprehensive information obtained through the HRA. We recommend clarification that obtaining genetic information in this manner, when not the sole purpose of the questionnaire and when rewards are not based on a particular response is incidental and would not be not considered "underwriting" under GINA's definition.

Another scenario where genetic information may be incidentally obtained or collected is through employer on-site health centers or periodic health fairs. Genetic information may be collected as a part of treatment at one of these centers or fairs. For example, an on-site mammography clinic likely would encounter (or even request) information about an individual's family history of breast cancer. GINA expressly states that it does not apply to health care providers. In addition, GINA uses HIPAA's definition of "group health plan," which contains an exception for on-site medical clinics. On-site clinics and health fairs are no different than any other provider participating in a group health plan's network. As GINA does not apply to these providers, we believe that GINA should also not apply to on-site clinics and health fairs. Clarification on this point would be useful, however, since HIPAA does not further define "on-site clinic," and ERISA arguably uses a more limiting term in its exception of on-premises medical

facilities. We believe that on-site clinics or health fairs should be treated in the same manner as providers and are therefore outside the scope of GINA.

Another way that genetic information may be collected incidentally is through the process of obtaining information for purposes of quality improvement. For example, plans frequently rely on claims data for measurement and reporting of provider performance. Collection of such data may result in the incidental collection of genetic information. A clarification that such collection is incidental would help ensure that GINA does not unnecessarily disrupt quality improvement systems that benefit plans and participants.

### Additional Clarifications

The RFI also solicits input regarding terms in GINA that might require additional clarification and other specific clarifications that would be helpful to facilitating compliance. We recommend the following clarifications:

"Incidental" – GINA provides an exception where a plan obtains genetic information "incidental to" requesting or requiring other information concerning an individual, but does not further define this term. As noted above, plans often obtain genetic information in connection with wellness programs, HRAs, on-site clinics, health fairs, or quality improvement activities. Obtaining genetic information is not the primary focus of these activities, but may be one element of many that is used as part of these programs, which benefit participants. We recommend that "incidental" be clarified to include situations where genetic information is not the primary focus, using examples of the collection of genetic information for wellness programs, HRAs, on-site clinics, or quality improvement activities.

"Premium" – GINA provides that a group health plan may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information. As we discuss above, plans often provide wellness programs or have participants complete HRAs that may address family history. Typically, family history is only one aspect of the HRA or wellness program, along with other questions or risk factors. Many times, plans will provide an incentive for participants to complete an HRA or complete a wellness program, which may be a premium holiday or additional employer contribution. In these cases, plans are simply providing rewards based on overall completion of an HRA or wellness program, not any particular genetic result. We recommend a clarification that adjusting "premiums" does not include rewards involving premium amounts that are otherwise permitted under the HIPAA nondiscrimination rules (or that any genetic information under these types of programs fall under the "incidental use" exception).

"Underwriting" - GINA provides that a group health plan cannot request or require genetic information for "underwriting" purposes, which is defined to mean rules for eligibility, including enrollment or continued eligibility. As discussed above, group health plans may request that participants complete HRAs that ask about family history. Plans may use this information for plan design purposes or to offer wellness programs to individuals. In some cases, plans require or provide rewards for completion of an HRA (or penalties for failing to complete), although the rewards are not based on specific responses, but the mere completion of the form. We recommend a clarification that obtaining genetic information in this manner, when not the sole purpose of the questionnaire and when rewards are not based on a particular response, is not considered "underwriting" under GINA's definition.

Enforcement and Remedies– Guidance should also make clear that remedies for Title I violations remain exclusive to those provided in that Title. Such guidance would be consistent with Congressional intent and ensure that employer sponsors of group health plans and issuers are not subject to frivolous or excessive litigation and damages for matters related to administration of health benefit plans.

\* \* \*

The Council appreciates the opportunity to provide information and recommendations regarding anticipated regulatory guidance for implementation of GINA. Please do not hesitate to contact me at 202-621-1975 or [kwilber@abcstaff.org](mailto:kwilber@abcstaff.org) with any questions or if the Council can be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "Kathryn Wilber". The signature is written in a cursive, flowing style.

Kathryn Wilber  
Senior Counsel, Health Policy