December 9, 2008

VIA ELECTRONIC MAIL: http://www.regulations

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 20210

ATTENTION: GINA Comments

Re: Comments by the Society for Human Resource Management and the College and University Professional Association for Human Resources in Response to Request for Information Regarding Sections 101 Through 104 of the Genetic Information Nondiscrimination Act of 2008

Dear Sir or Madam:

This letter responds to the Department of Labor, Employee Benefits Security Administration ("EBSA"), on its Request for Information regarding Sections 101 through 104 of the Genetic Information Nondiscrimination Act of 2008 (GINA), which was published on October 10, 2008 in the *Federal Registe*r at 73 Fed. Reg. 60208. These comments are submitted by the Society for Human Resource Management (SHRM) and the College and University Professional Association for Human Resources (CUPA-HR).

STATEMENT OF INTEREST

The Society for Human Resource Management (SHRM) is the world's largest association devoted to human resource management. Representing more than 250,000 members in over 140 countries, the Society serves the needs of HR professionals and advances the interests of the HR profession. Founded in 1948, SHRM has more than 575 affiliated chapters within the United States and subsidiary offices in China and India.

The College and University Professional Association for Human Resources (CUPA-HR) serves as the voice of human resources in higher education, representing more than 10,000 HR professionals at over 1,600 colleges and universities across the country, including 85 percent of all U.S. doctoral institutions, 70 percent of all master's institutions, more than half of all bachelor's institutions and 465 community colleges. Higher education employs 3.3 million workers nationwide, with colleges and universities in all 50 states.

SHRM and CUPA-HR support efforts to prohibit discrimination based on the use of genetic information. In fact, both organizations worked with the drafters of GINA and other interested stakeholders to craft legislation that safeguards protections for employees while meeting the needs of employers. SHRM and CUPA-HR's members perform strategic, operational, and administrative roles within their organizations. Additionally, many HR professionals play an extensive role in the administration of employee benefit plans, including group health care plans that are the subject of GINA. SHRM, CUPA-HR, and their members, therefore, have a vested interest in regulations the EBSA will promulgate to implement the GINA requirements. These comments reflect the substantial expertise and experience of the organizations' members. Our response to the EBSA's Request for Information seeks to balance any overlaps and potential conflicts between these sets of responsibilities.

In addition, as a preliminary note, our comments only reflect the potential impact of GINA on employers' administration of group health plans, both fully insured and self-funded. SHRM and CUPA-HR members generally are not involved in the underwriting activities or decisions of group health insurance issuers that insure group health plans.

COMMENTS REGARDING REGULATORY GUIDANCE

The following comments provide responses to the specific questions posed by the agencies in the Request for Information. We have focused our comments on those questions that affect workplace health programs and information systems.

1. To what extent do group health plans currently use genetic information, such as family medical history, and for what purposes? For example, is genetic information currently used for group rating purposes, or for purposes of a wellness program that otherwise complies with HIPAA's nondiscrimination requirements?

Group health plans are presently prohibited by HIPAA from discriminating on an individual basis against participants and beneficiaries with respect to eligibility and cost based on genetic information. Because of these prohibitions, group health plans generally do not request or collect genetic information for plan purposes.

By not requesting or collecting genetic information, group health plans generally do not have any genetic information that can be used for group rating purposes. Group

health plans generally use historical claims data when performing actuarial analyses and developing participant contribution amounts and COBRA premiums. The historical data includes information on genetic conditions that have already manifested themselves and for which health care services have been, and are being, provided. However actuarial analyses do not generally reflect any genetic information on conditions that have not yet been diagnosed or manifested, again because group health plans do not request or collect genetic information.

As permitted under HIPAA, group health plans may require an employee to complete a health-risk assessment as a condition of enrollment. However, in compliance with HIPAA's wellness program requirements, eligibility to participate is not conditioned on the results of the health-risk assessment, but only on the simple completion of the assessment. Similarly, a group health plan may invite a participant to complete a health-risk assessment in order to assist the participant in identifying health-related concerns. In most cases of required or optional health-risk assessments, the genetic information is provided to a third-party service provider, not directly to the group health plan. This is so a third-party health care professional can assist the employee in identifying and addressing risks exposed by the health-risk assessment; in most cases, the employer does not have the capacity in-house to conduct these assessments. The group health plan typically directs the third-party service provider to maintain the confidentiality of the information and to not provide any of the information to the group health plan. The group health plan neither seeks nor wants any of the health-risk assessment information from the third-party service provider, either in individual or collective form. The only information the group health plan generally requests from the third-party service provider is verification that an employee completed the health-risk assessment.

It is important to distinguish between the group health plan itself and the health care service providers who provide the services that are covered by the group health plan. Health care service providers may, in the course of treating a group health plan participant, request or require that the participant provide genetic information (including, for example, medical histories of dependents and relatives up to the fourth degree) to enable the health care service provider to diagnose and treat the participant's condition. However, that genetic information is generally held in confidence by the health care service provider and not disclosed to the group health plan unless required by the group health plan for a permitted use under HIPAA (*e.g.,* for claims processing). Employers may, however, obtain genetic information through implementation of an on-site wellness program or through an in-house health care provider. These concerns are discussed more fully in the response to question eight, focused on the incidental collection of genetic information.

In summary, genetic information is generally not requested or collected by group health plans and is not used by group health plans themselves for group health plan rating purposes or for purposes of any wellness programs.

2. How do plans currently obtain genetic information (for example, through health risk assessments, the Medical Information Bureau, or other entities under common control)?

Group health plans themselves generally do not obtain any genetic information from employees or participants. Any genetic information disclosed by an employee or participant in a health-risk assessment is generally given directly to and retained by the third-party service provider engaged to conduct the health-risk assessments. Any genetic information disclosed by an employee or participant to a health care professional providing covered services under the plan is generally not provided to the group health plan unless required for a permitted use under HIPAA. In that situation, the group health plan itself generally has a third-party administrator or a group health plan insurer who is receiving that information. In most situations, the group health plan itself does not receive any genetic information directly from employees or plan participants or from any third-party service provider, including health care professionals, in either individual or collective form.

3. Under what circumstances do plans currently request or require an individual to take a genetic test?

As a rule, group health plans do not request or require an individual to take a genetic test. A participant's health care provider may request or require a plan participant to take a genetic test in connection with a course of treatment or consultation with respect to a course of treatment. However, those test results remain with the health care provider and the plan participant. The test results themselves are usually not provided to the group health care plan.

4. Under what circumstances do plans currently ask for the results of a genetic test in order to make a determination regarding payment of benefits? What is the minimum amount of information necessary for a plan to make a determination under such circumstances?

Verification of the type of genetic test administered and the fact that the test has been conducted are generally all that is required by the group health care plan in order to determine if the test is a covered service and the amount that the group health plan will pay for the test. Because payment is not conditioned on the results of the test, test results are generally neither requested nor required by the group health plan as a condition of payment. In general, a genetic test is treated the same as any other type of diagnostic test--verification that the test was administered is required for payment of benefits, but results of the test are not.

5. What types of research do plans currently conduct or support using genetic tests?

Employer-sponsored group health plans are generally not engaged in independent research that includes or requires genetic tests. An employer that is a research facility or

a group health insurer that conducts research using genetic test results or other genetic information, is usually acting in its capacity as a research facility or group health insurer and not in its capacity as a group health plan sponsor. In addition, it generally is using genetic information from a population greater than its own employee population. Group health plans may grant third-party service providers permission to use aggregate, unidentified genetic test results or other genetic information provided by plan participants in research efforts conducted by insurance companies or research organizations. However, these uses of genetic test results or genetic information are generally conditioned on the test results or information not being identifiable to specific individuals or employer groups.

8. When might genetic information be collected incidentally?

This is the greatest area of concern for employers because incidental collection of genetic information about employees, their dependents, and their family members can occur under a number of normal employment scenarios that are unrelated to the group health plan. Neither Title I nor Title II of GINA fully appreciates the flow of genetic information for a wide range of legitimate and nondiscriminatory purposes in the workplace. GINA, however, imposes on the employer the obligation to prove that the employer has not used information for any impermissible purpose.

The following examples highlight instances in which an employer may inadvertently come across genetic information:

Example 1. An employee has a claims dispute with the group health plan's third-party administrator or insurer over payment for a medical procedure or test. The employee requests assistance from the employer's human resources department. The claims dispute involves medical tests related to a genetic disorder. By assisting the employee, the employer (through the human resources department) may now be aware that this employee has undergone a genetic test, likely knows the exact type of genetic test administered to the employee, and may also become aware of the results of the test.

Example 2. An employer institutes a "Weight Watchers at Work" program as a voluntary program unrelated to the group health plan, so that the program is not subject to the HIPAA wellness program requirements. In the course of the weight loss program, an employee-participant discloses to a fellow employee that family members have a genetic disease. The information then flows into the employee population.

Example 3. An employer has an on-site health care facility and directly employs the health care professionals that staff the facility. In an emergency situation at the worksite, the on-site health care professional comes into possession of an employee's genetic information.

Example 4. An employer requires an employee who takes bereavement leave to provide a death certificate or death notice for the deceased family member as substantiation for

the leave. The cause of death disclosed on the death certificate or the narrative in the death notice implies that the deceased had a genetic condition. Similarly, an employer announces the death of an employee's relative and the employee's request for memorial donations to an organization dedicated to fighting or curing a specific disease discloses genetic information about the employee.

In each of the above examples, genetic information has been disclosed to the employer in the course of other legitimate and legal employment or benefit plan purposes. Unlike the HIPAA privacy rules regarding protecting the confidentiality of protected health information (PHI), which permit PHI to be obtained and used for other legitimate and legal employment purposes, GINA does not provide any exclusion for the collection or use of genetic information under the situations in the above examples. GINA imposes a blanket prohibition on an employer's acquisition of genetic information, and does not provide any statutory exceptions that would possibly be applicable in these situations.

In summary, as evidenced above, GINA has the potential to expose employers to liability simply for having access to or being aware of the flow of information between employees and employers for legitimate and legal benefit plan and employment purposes. Regulations drafted by the Departments and the EEOC need to be coordinated to avoid any unintended consequences of employers reducing or eliminating activities intended to benefit employees to avoid potential GINA violations.

9. What terms or provisions (such as genetic information, genetic test, genetic services, or underwriting) would require additional clarification to facilitate compliance? What specific clarifications would be helpful?

It would be helpful to employers sponsoring group health plans if the Departments clarify how a connection between legitimately obtained genetic information and cost development for group health plans is established, so employers can develop the necessary internal safeguards to properly isolate and protect that genetic information. For example, can a self-insured group health plan prove compliance with GINA by using an independent health plan actuary for group rating purposes and obtaining certifications from the actuary as to what claims data or other demographic information was used by the actuary in developing the group ratings? To what extent can health actuaries certify that the information they use for group rating purposes does not include genetic information?

Because of the overlapping burdens imposed on employers by Title I and Title II of GINA, the Departments should coordinate regulations with the Equal Employment Opportunity Commission so that conflicting requirements are not imposed with respect to genetic information properly and permissibly collected by the employer, including providing clear standards on issues than span both titles, such as wellness programs.

CONCLUSION

SHRM and CUPA-HR appreciate the opportunity to submit comments to EBSA on the development of regulations implementing GINA. We look forward to working with the Departments to provide regulations consistent with the statute. If we can be of assistance on this matter, please do not hesitate to contact us.

Yours Truly,

Michael P. Aitken
Society for Human Resource Management

/s/
Josh Ulman
College and University Professional Association for Human Resources

Of Counsel:
Antoinette M. Pilzner, Esq.
Butzel Long