January 5, 2010

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: RIN 1210–AB27

Re: Comments on Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans

New York Business Group on Health (NYBGH) is pleased to submit this response to the request for comments on the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 (“GINA”). The request was published by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the “Departments”) in the Federal Register on October 7, 2009.

NYBGH is an employer-driven coalition dedicated to improving the quality and efficiency of healthcare, locally and nationally. We are a not-for-profit coalition of more than 175 employers, unions, health plans, providers, and other healthcare organizations operating in New York, New Jersey, and Connecticut. Since 1982, NYBGH has been representing healthcare purchasers in their efforts to drive healthcare reform and has aided employers in their quest for value in the healthcare system.

The Title I Interim Final Rules implement provisions of GINA that prohibit group health plans from discriminating on the basis of genetic information. GINA provides that a group health plan may not (1) increase premiums or contributions for a group based on the genetic information of individuals in the group, (2) request or require an individual or family member to undergo a genetic test, or (3) request, require, or purchase genetic information prior to or in connection with enrollment or for underwriting purposes.

Many of our employer members have indicated that the above sections of GINA, in their current form, will have adverse effects on: their ability to conduct effective wellness interventions, the health of their employee population, and health care cost containment efforts.

HEALTH RISK ASSESSMENTS & WELLNESS PROGRAMS

NYBGH members have long been committed to the use and expansion of wellness, prevention, and disease management programs. The increasing effectiveness of these programs is often times attributed to the ability of employers to collect family medical history and other genetic information through a comprehensive health risk assessment (“HRA”). Health risk assessments typically include questions requesting family medical history along with rewards that encourage employees to complete an HRA. Family medical history is requested because of its ability to assess and predict one’s future health risks and vulnerability to chronic diseases. As demonstrated by our employers, incentives are offered because they significantly increase HRA completion rates.

Information collected through an HRA allows medical professionals to design programs that encourage and guide healthy behavior while also addressing the individual health needs of employees, with special attention paid to chronic diseases or conditions for which they are potentially vulnerable (as highlighted by the family medical history). Key goals of these programs include identifying and targeting effective interventions designed to mitigate the effects of increasingly costly and prevalent chronic conditions, such as heart disease, diabetes, and obesity. Leaders and innovators in health and welfare benefit programs, our members consider HRAs a
critical component of their employee engagement strategies and have found them to be useful tools in lowering overall health care costs, improving quality of life, and improving productivity and health status.

IMPACT OF THE REGULATION

The Title I Interim Final Rules interpret GINA so as to preserve the voluntary nature of the disclosure by permitting group health plans to either request family medical history or offer an incentive to complete the HRA, but not in conjunction with each other. Risk assessment is a component key to the success of managing a population’s health and restraining rising health care costs. By prohibiting the request of family medical history using a financial incentive, HRA completion rates will suffer, participation in wellness programs will plummet, and employers will be forced to surrender the accuracy and pertinence of this assessment tool. The regulation will also hamstring employers’ ability to guide employees into disease management programs based on information provided in an HRA. In broader terms, the Rules diminish the effectiveness of HRAs in potentially reigning in skyrocketing health costs and improving individual and population health status.

Most employees need to be encouraged to complete a long, detailed HRA and to begin participating in a program of healthy living; financial incentives provide a key motivational trigger. The Interim Final Rules would diminish the effectiveness of many employers’ wellness programs by precluding their ability to provide a financial incentive to individuals who complete an HRA that requests family medical history and to provide rewards to employees for meeting certain health-related goals.

NYBGH MEMBERS’ CONCERNS

*Employer A: Major Medical Center*

One of our members, a major medical center in New York City, is concerned with the ambiguity of GINA and how it may undercut the effectiveness of its disease management programs, especially aspects of it conducted on-site or in employee health and wellness clinics. The Interim Final Rules do not limit the authority of a health care professional who is providing services to an individual to request family medical history or undergo a genetic test. 29 CFR § 2590.702(c)(2). Furthermore, the Rules cite an example stating that an HMO physician advising a patient would be considered a health care professional under this exception, even though the physician also works for the plan (i.e. the HMO). 29 CFR § 2590.702(c)(3), Example 2. While we applaud the Departments’ acknowledgment of the importance of allowing employer-sponsored medical professionals to request genetic information, we urge that the Rules go further in clarifying how the medical professional exception relates to services provided as part of disease management, coaching, and/or counseling programs offered through an employer.

Physicians, nurses, and other trained professionals who provide clinical guidance and services frequently do so as part of disease management programs that offer coaching or counseling services. An aspect of these may include on-site screenings (for example, for cholesterol, blood pressure, weight, diabetes, or osteoporosis) or other comprehensive services for a variety of chronic diseases. Health care professionals, as a routine part of their assessment and examination, often times request family medical history. This information is gathered in order to better understand test results and thus offer helpful clinical feedback and recommendations. In order to preserve the effectiveness of these programs, we request that the Departments clarify that the relevant services would also be granted the health care professional exception, especially where part of a wellness or disease prevention program.

In addition to the ambiguity of the Interim Final Rules regarding employer-sponsored health care professionals, the above major medical center strongly believes that the Rules deviate far from the original intent of GINA and actually misperceive the purpose and goals of collecting genetic information through the completion of an HRA. Genetic information, including family medical history, gathered by tools such as HRAs is used exclusively for the purposes of improving the health status of an employee. This predictive information is used by wellness and disease management programs only to identify and target effective public health and clinical interventions designed to prevent the occurrence of potential future disease as well as better manage costly chronic diseases. Health insurance coverage and/or its cost-sharing provisions nor terms of employment are ever affected by family medical histories. All individual information collected in the HRA of course remains confidential and is never shared with the employer, as required by the Health Insurance Portability and Accountability Act (HIPAA).


**Employer B: Mailstream Management Company**

This NYBGH member, one continually active and successful in managing the health of its employee population, foresees the GINA Interim Final Rules as diminishing the value and effectiveness of its wellness and prevention programs, an important avenue for managing and understanding the health of its workforce. Typically experiencing a greater than 30 percent HRA completion rate, this employer notes that helping employees understand how their own genetic history as well as family medical history relates to their health and health-related choices is extremely important. Equipped with this information, employees are better able to understand their own health situation and prioritize interventions and changes. This employer cites that as a result of the Rules, garnering a complete and accurate picture of their population’s health, accurately forecasting future health trends, and effectively providing treatment in their on-site medical clinics will become more difficult. They anticipate that their company-wide HRA completion rate will plunge to below ten percent and it forces them, furthermore, to take a more generalized approach to managing the health and productivity of their workforce.

**Employer C: Media Corporation**

With an HRA completion rate of over 60 percent, this NYBGH employer member foresees the implementation of the GINA Interim Final Rules as the beginning of a slippery slope of governmental regulation further hindering employer wellness and health promotion initiatives. By providing a financial incentive in the form of a ten percent discount on health insurance premiums, this employer is able to collect useful and actionable information that helps guide the targeting and content of health education programming. The implementation of the Rules will discourage a number of initiatives and reward programs designed to improve the health status of its employees. For instance, programs rewarding employees for achieving outcomes such as quitting smoking, maintaining a healthy weight, reducing cholesterol levels, and/or reducing high blood pressure levels will experience diminished results. This also forces the organization to find alternative methods of identifying future health risks, lowering health costs, and improving the health of its employees.

**CONCLUSION**

Wellness, prevention, and disease management programs are one of the few avenues available to employers in helping to control soaring healthcare costs. These are efforts generally met with enthusiasm by employees, who often appreciate an impetus and encouragement to lead a healthier lifestyle. Some employees are especially grateful to have completed an HRA and to have found out for the first time that they are at risk for certain diseases and that there are steps they can take to minimize their vulnerability. Making these tasks more difficult, such as by preventing the use of financial incentives to garner family medical history in an HRA, is an incomprehensible action in view of the dire necessity of holding down medical costs and encouraging individuals to assume more active control of their health.

Thank you again for providing this opportunity to submit comments. Attached, please find a listing of our membership. Please do not hesitate to contact me or Shawn Nowicki, Director of Health Policy, at 212.252.7440 x227, if you have any further questions or would like to further discuss our feedback in greater detail.

Sincerely,

Laurel Pickering, MPH
Executive Director

Enclosure
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