COVER LETTER

November 23, 2009

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

Ladies and Gentlemen:

Nationwide is pleased to have the opportunity to submit the following 2 responses to the request for comments related to the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 ("GINA").

The first response is from Nationwide Mutual Insurance Company, as an employer and sponsor of various wellness program offerings designed to provide access to resources and tools to help our employees manage their health. The second response is from Nationwide Better Health, Inc., which is a part of the Nationwide family of companies and offers a wide array of health and productivity services for employers.

We are submitting 2 separate responses because, although the perspective set forth by Nationwide in the first response is illustrative of Nationwide Better Health's customer-base, we believe that, from a clinical standpoint, it is important for you to also carefully consider the perspective of a health management company.

Thank you for your time and consideration. We appreciate the opportunity to comment.

Sincerely,

Jennifer A. Nickell-Thomas

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Nationwide is pleased to have the opportunity to respond 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.

The interim final rules implement provisions of GINA that prohibit group health plans and health insurance issuers from discriminating on the basis of genetic information. In this respect, 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."

As you are aware, comments have been specifically requested related to the cost associated with lower response rates for Health Risk Assessments ("HRAs") by disallowing certain "underwriting" incentives and the forgone benefits of identifying disease risks early and preventing their onset. In this respect, Nationwide does provide financial incentives in order to encourage participation by our employees to complete an HRA and we believe that these incentives do motivate our employees to participate.

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The interim final rules under Title I of GINA would preclude our ability, as well as other employers' abilities, to provide such financial incentives to our employees who complete an HRA that requests family medical history. And, if this rule is implemented, completion rates of our HRAs will suffer significantly, and participation in our wellness programs will decline, which we believe will result in higher health care costs for our employees and their families.

Over the past 5 years, Nationwide has developed a highly sophisticated and comprehensive health care strategy, which includes components designed to help our employees and their family members stay healthy or get healthier. Modifying this strategy in the manner contemplated by the interim rules will result in significant cost and administrative burden, especially in what appears to be an extremely short compliance timeframe.

Part of this strategy involves continued investment in our *My Health* program, which provides access to resources and tools that help to manage health by focusing on wellness, prevention, and disease management. The *My Health* program has been offered to our employees and their families for over 4 years now and the various resources and tools offered through the program have been designed to address potential health problems, often before they develop into more deadly chronic disease. These efforts to encourage and guide healthy behavior, which have become increasingly popular within our workforce, have helped to control our health care costs while improving quality of life for our employees.

Participation in the *My Health* program is entirely voluntary and only data in the aggregate is shared with Nationwide. Nationwide adheres to strict confidentiality, privacy, and security protections that have been instituted, in part, to help alleviate employee apprehension of perceived discrimination or stigmatization associated with participation in the program.

The cornerstone of the *My Health* program is an HRA administered by Nationwide Better Health, a health management company and service provider to many employers like Nationwide. The goal of the *My Health* program HRA, and HRAs in general, is to both: (1) reduce health care costs; and (2) provide the individual who takes the HRA with basic awareness and educational information on their overall health and to risk stratify and triage them to interventions that are most appropriate based on their specific situation.

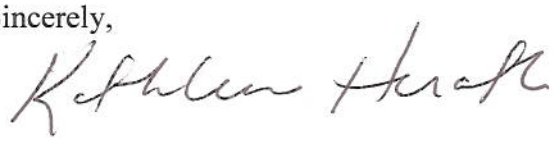
A key element of the HRA is a series of questions designed to gather family medical history. Answers to the family medical history questions in the HRA are used to: (1) inform the participant of their future risk for certain specific chronic conditions (namely, cardiovascular disease, diabetes and cancer); (2) set goal values for certain risk factors (e.g., goal LDL (or "bad") cholesterol); and (3) determine if the individual requires medical clearance before embarking on an exercise program.

Wellness, prevention and disease management programs are one of the few effective resources available to us to help control our soaring health care costs for our employees and their families. Moreover, participation in these programs is generally met with enthusiasm by our employees, who are often relieved to be encouraged 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.

Again, it is our belief that preventing the use of financial incentives to garner family medical history in an HRA will discourage healthy behaviors and ultimately increase, rather than lower, health care costs.

We appreciate this opportunity to provide comments and would be happy to further discuss our concerns with you.

Sincerely,



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Ladies and Gentlemen:

Nationwide Better Health, Inc., as a health management company and service provider to many employers, is pleased to have the opportunity 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.

In addition to all the issues Nationwide Mutual Insurance Company and other employers face with concerns on the costs associated with lower participation rates and forgone benefits of identifying disease risk early, we believe there is yet another critical concern associated with an expansive definition of "underwriting purposes" that has not received much consideration: the ***clinical care perspective***, which goes hand-in-hand with delivery of the wellness programs. The interim final rules under Title I of GINA create serious concerns for and undermine the integrity of wellness programs with essentially no distinction between programs that offer "underwriting" incentives versus those that offer cash incentives as illustrated below.

The core of the concern for these wellness programs is the type of incentive provided, which may vary among employers and health plans even though the lifestyle health coaching and disease management programs are essentially the same. We urge you to consider a less expansive definition of "underwriting purpose" or a safe harbor for "underwriting" incentives provided in connection with wellness programs, which would remove the conflict that otherwise significantly impairs the efficacy and value of wellness programs. Alternatively, an exception for wellness vendors (that are not health plans or health issuers) could be made to permit collection of genetic information so long as such information is not disclosed to health plans, health issuers, and employers.

I. Lifestyle Health Coaching and Disease Management Programs

The interim rules do not address lifestyle health coaching and disease management programs that require family medical history to provide appropriate clinical care plans or that could

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incidentally collect family medical history during a coaching session. The examples in the interim rules provide that for an individual seeking a benefit it is permissible for the health plan or health issuer to request genetic information to determine whether the benefit is medically appropriate. However, no example illustrates whether it is permissible under GINA for a health plan or service provider to request or even discuss genetic information where an individual is already enrolled in a disease management program and an "underwriting" incentive is provided for completion of the program. The safe harbor provision for the incidental collection of family medical history is not currently available to a disease management program that provides an incentive (e.g., reduction in pharmacy co-payment or premium reduction) for completion of the program. Arguably, strict adherence to the interim rules would essentially require wellness programs, through the wellness program administrator/vendor, to turn away participants or not document discussions with participants who raise family medical history issues and/or concerns where "underwriting" incentives are provided. From a clinical care perspective, this leaves health management vendors in a precarious situation of balancing competing and conflicting interests: on the one hand, strict legal adherence with the interim rules which leads to providing inadequate clinical education/guidance to individuals, and on the other hand, delivering appropriate meaningful services.

II. Health Risk Assessments (HRAs)

Removal of the family medical history questions diminishes the value of HRAs and the benefit obtained for the individuals taking the HRAs. When asking the family medical history questions in the HRA, the answers are used to (i) inform the participant of their future risk for certain specific chronic conditions (namely, cardiovascular disease, diabetes and cancer), (ii) to set goal values for certain risk factors (e.g., goal LDL (or "bad") cholesterol) and (iii) to determine if the individual requires medical clearance before embarking on an exercise program.

Without the family medical history answers, wellness programs are unable to set appropriate goal values and determine when medical clearances are appropriately required. Answers to family history questions form the basis of national clinical guidelines and are important to at least two fundamental issues.

a. Family medical history needed to follow National Institutes of Health guidance

A prevalent example involves determining the goal level for the LDL (or "bad") cholesterol for a given participant. For such determination, the guidelines from the National Institutes of Health (National Cholesterol Education Program) involve knowing whether a participant has a family history of premature cardiovascular disease. If information on family history of premature cardiovascular disease is not known, the goal we set for LDL cholesterol may be inaccurate. If the person has a positive family history and we set the goal as if they have a negative family history, we may set the goal at too high a value and place the person at risk from an untreated/inadequately treated cardiovascular disease risk factor. If the person has a negative family history and we set the goal as if they have a positive family history, we may set the goal at too low a value. However, this more conservative approach does not potentially place the person at added risk from an untreated/inadequately treated cardiovascular disease risk factor.

b. Family medical history needed to follow American College of Sports Medicine guidance

The second issue relates to determining whether a person requires medical clearance before participating in an exercise program. Based on guidelines from the American College of Sports Medicine, family history of premature cardiovascular disease must be considered together with other risk factors when deciding on the need for medical clearance. If the person has a positive family history and we act as if they have a negative family history, we may tell a person that they do not need medical clearance when in fact they do (and thereby potentially place the person at risk). If the person has a negative family history and we act as if they have a positive family history, we may tell them that they need medical clearance when in fact they don't. However, this more conservative approach, although it inconveniences the participant, it does not place the person at added risk.

In effect, removing the family medical history questions (in order to provide meaningful incentives that impact the health coverage cost) penalizes individuals by providing higher goal levels and requiring medical clearances that may not be necessary.

If the interim rules are implemented, the integrity of wellness programs will suffer significantly, and participation in wellness programs will decline, which we believe will result in higher health care costs for employees and their families.

We appreciate this opportunity to provide comments and would be happy to further discuss our concerns with you.

Sincerely,

Terri L. Hill
President and Chief Executive Officer
Nationwide Better Health, Inc.