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November 30, 2009

Timothy Geithner  
Secretary  
U.S. Department of Treasury  
1500 Pennsylvania Avenue NW  
Washington, DC 20220

Kathleen Sebelius  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Room 639G  
Washington, DC 20201

Hilda Solis  
Secretary  
U.S. Department of Labor  
200 Constitution Avenue NW  
Washington, DC 20210

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NOV 30 2009 11:59  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Re: RFG-123829-08, CMS-4137-IFC, RIN 1210-AB27 - *Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans (Vol. 74, No. 193) (October 7, 2009)*

Dear Secretaries Geithner, Sebelius and Solis:

Personalized Prevention is a health and wellness company that creates excitement in workplace wellness programs to advance the health and well-being of people around the country. Personalized Prevention is committed to offering employees effective wellness, prevention, and disease management programs. Our company brings industry leading health challenges, screening services, health coaching and disease management programs that help organizations reduce health care costs by cost-effectively enhancing the health and wellness of their employees and members. I appreciate the opportunity to comment on the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 ("GINA") (the "Interim Final Rules").

Personalized Prevention fully supports GINA's intended purpose of prohibiting discrimination on the basis of genetic information with respect to health insurance and employment. However, we believe that the overly broad definition of "underwriting" in the Interim Final Rules far exceeds the original intent of the law and will have significant and unfortunate consequences on wellness, prevention and disease management programs,

and, ultimately, health care costs. Specifically, our company is concerned that the Interim Final Rules prohibit (i) the collection of family medical history as part of a valid Health Risk Assessment (“HRA”) that provides an incentive or is completed during an open enrollment period, and (ii) the use of HRAs that collect family medical history to match individuals with appropriate disease management programs. We believe that rather than apply absolute prohibitions against the use of these tools, there are other appropriate ways to ensure the protections provided under GINA are realized, and we believe the Agencies should take the appropriate time to evaluate these options.

Health risk assessments, routine lab screenings and health coaching programs are powerful ways to help people understand their personal health risks, including risks related to family medical history. These important tools help motivate healthier lifestyles and drive appropriate preventive behavior. Family medical history is a vital piece of the HRA. Answers to a few key family medical history questions can provide a participant critical information about his or her health risks. For example:

- The U.S. Preventive Services Task Force recommends that people at normal risk of colorectal cancer start screening at 50 years of age. Some people with a family history of colorectal cancer are at increased risk of developing this cancer at a young age, and should begin screening before 50 years. If this information is not collected in an HRA, the participant may not be advised to speak to his or her doctor about the best time to initiate screening.
- The U.S. Preventive Services Task Force does not recommend cholesterol screening for men under 35 years old who are at low risk or for women at any age who are low risk. Family history of premature heart disease (<55 years old in first-degree male relative, <65 years old in first-degree female relative) is a major risk factor for coronary heart disease. If that is the only risk factor that a woman or young man has for coronary heart disease, the participant will not be advised to get screened for high cholesterol and they may not take advantage of interventions that could lower their risk of heart attack and stroke.

These are just a few examples of how important family medical history questions are in helping individuals receive accurate risk information and motivating healthier lifestyles and appropriate preventive behavior.

It is important to note as well that, Personalized Prevention does not give our clients, employers who provide HRAs, screening services and other health coaching programs, any individually identifiable family medical history information about their employees. In fact, it is common industry practice that third party wellness companies like our own hold this information confidential from employers.

The option presented by the Interim Final Rules of removing incentives related to the completion of HRAs that contain family history questions will significantly decrease participation in the HRAs we provide. Incentives have been a key driver in encouraging people to take an HRA and to participate in screenings and health coaching programs. A CDC-sponsored employer health and productivity management benchmarking study identified “meaningful incentives,” such as insurance premium discounts for completing an HRA, as a promising practice.<sup>1</sup> Incentives can serve as powerful motivators: A \$25 cash incentive can generally spur a 50 percent HRA participation rate compared with a 10 percent to 15 percent rate in programs without

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<sup>1</sup> Goetzel RZ, Shechter D, Ozminkowski RJ, Marmet PF, Tabrizi MJ, Roemer EC. Promising practices in employer health and productivity management efforts: findings from a benchmarking study. *J Occup Environ Med.* 2007; 49(2):111-30.  
Page - 2 - of 3

incentives.<sup>2</sup> The rules implementing GINA should not restrict incentive programs connected with valid HRAs that include family medical history questions where the family history information is used appropriately to help individuals identify and respond to important health risks.

We believe that there are ways to ensure family medical history information is not used to discriminate in employment or health coverage, while at the same time helping people identify and address health risks through the use of HRAs and health coaching tools. Therefore, we request a delay in the implementation and enforcement of the Interim Final Rules in order for affected parties to explore ways to ensure we protect genetic information, while also encouraging healthier lifestyles through use of valid and effective wellness and prevention tools.

Please feel free to contact me if you have any questions or would like to discuss our concerns in more detail. I can be reached at 210-481-7584.

Sincerely,

Lisa R. Van Ackeren, Esq.  
President & Chief Executive Officer  
Personalized Prevention

cc: Robert Kocher, MD, Special Assistant to the President, National Economic Council, The White House  
Ezekiel Emanuel, MD, Special Advisor for Health Policy, Office of the Director, Office of Management and Budget

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<sup>2</sup> Hunnicutt, D; Toffelman, B. (2006). *WELCOA's 7 Benchmarks*. *WELCOA's Absolute Advantage Magazine*, 6(1), 2-29.