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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

October 30, 2009

The Honorable Hilda Solis Secretary U.S. Department of Labor 200 Constitution Avenue NW Washington D.C. 20210

The Honorable Kathleen Sebelius Secretary U.S. Department of Health and Human Services 200 Independence Avenue SW Room 639G Washington D.C. 20201

The Honorable Timothy Geithner Secretary U.S. Department of Treasury 1500 Pennsylvania Avenue NW Washington D.C. 20220

Dear Honorable Sccretaries Solis, Sebelius, and Geithner:

I write to express our serious concerns about the adverse impact of the interim final rules under Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA) on employer-sponsored wellness programs and to request that you postpone the implementation and enforcement date of the regulations to better align the definition of "underwriting purposes" with Congressional intent so that the regulations effectively prevent discrimination without significantly compromising health care and employer-sponsored wellness programs.

We fully support the law's intent to prevent discrimination in employment and health coverage based on genetic information, however, overly broad medical underwriting definitions in the interim final rules will severely limit the ability of group health plans to promote voluntary wellness programs and ensure the most effective treatments and the practice of evidence-based personalized medicine. Furthermore, the late issuance of the regulations, which were due out in May but only released in October, does not provide sufficient time for employer-sponsored health plans to comply with the rules by the effective date of December 7, 2009.

We believe that a one year delay in the effective date will ensure the continuation of wellness and disease management programs, which help improve the quality and safety of care and also possibly "bend the cost curve" by making certain that care is matched to what will work best for each and every patient.

The Honorable Secretaries Solis, Sebelius, and Geithner: Page 2
October 30, 2009

The Business Group represents over 280 members, mostly very large employers, who provide health coverage to more than 55 million U.S. employees, retirces, and their families. We are the nation's only non-profit organization devoted exclusively to finding innovative and forward-thinking solutions to large employers' most important health care and related benefits issues. In addition to large public sector employers, Business Group members include 130 of the Fortune 500 companies with 58 members among the Fortune 100.

Overly Broad Definition of "Underwriting Purposes"

As you are aware, group health plans use self-informed voluntary health assessments to identify people with health risks and offer them programs and benefits that will reduce those risks. Health assessments and free health coaching by health professionals provide opportunities for referral to preventive care, disease management programs, health promotion and wellness programs, and other behavioral change initiatives. Health professionals use this information, most often provided to third parties and never seen by the plans themselves, exclusively to provide more effective treatment and services to participants to improve their health and maximize their use of benefits, not to discriminate in employment or health coverage.

The interim final rules, using an overly broad definition of "underwriting purposes", prohibit asking family medical history questions of group health plan participants when plans provide rewards for completing health risk assessments. The rules consider such questions "requesting genetic information for underwriting purposes" and the fact that rewards are only conditioned on the completion of the health assessments (and not based on any actual answers provided) is immaterial.

The rules further state that, though providing rewards in these instances does <u>not</u> violate the Health Insurance Portability and Accountability (HIPAA) 2006 final nondiscrimination rules for wellness programs, such practices <u>will</u> violate GINA. This inconsistency with HIPAA nondiscrimination rules has created confusion among group health plans and had a chilling effect on employer-sponsors, many of whom have scaled back their wellness activities.

We do not believe that Congressional intent in GINA was to contradict HIPAA or consider this practice "medical underwriting". We urge you to revise the interim final rules to better reflect Congressional intent

Defining Disease Management Programs as Rewards

The new rules also prohibit group health plans from using health risk assessments containing family medical history questions to identify at-risk plan participants who may benefit from disease management programs. The regulations consider eligibility for disease management programs, based on the completion of such health risk assessments, a "reward" and prohibited under GINA. Disease management programs are just like

The Honorable Secretaries Solis, Sebelius, and Geithner: Page 3 October 30, 2009

health services in that they are aimed at helping patients, usually with serious and complex medical conditions, obtain the support they need and ensure that the patient is able to get better if possible or get symptom relief if improvement is unlikely.

This interpretation will severely impair the ability of group health plans to use disease management to improve quality, care coordination, and medical outcomes and to initially identify those who can most benefit from these valuable programs.

<u>Late Issuance of Regulations Imposes Significant Burdens on Employer-sponsored</u> Group Health Plans

The new regulations for Title I of GINA become effective for group health plans beginning on or after December 7, 2009. Many employer-sponsors are well into their annual open enrollment for group health plans on a calendar year basis beginning January 1, 2010. Many have already printed health risk assessments requesting information about family medical history, distributed them to plan participants, and added incentives for their completion.

The regulations were due on May 21, 2009 but were not released until October 1, 2009 — a delay of over four months during which time employer-sponsors were solidifying their renewal terms for the January 2010 to January 2011 plan year. The overly broad interpretation of "underwriting purposes" to include questions about family medical history after the effective dates of coverage, and defining eligibility to participate in a disease management program as a "reward", could not be anticipated. Interrupting the open enrollment process and modifying health risk assessments to eliminate questions about family medical history will not only cause a significant administrative burden on employer-sponsors, but will also significantly impair the ability of group health plans to identify at-risk plan participants and provide additional disease management resources.

We urge you to consider a one year delay in implementation and enforcement of these new regulations in order to assess the impact on wellness initiatives and disease management programs and urge you to revise the definition of "underwriting purposes" in GINA to ensure such valuable programs continue to be available to employer-sponsored group health plans. Thank you, again, for your consideration of these important issues.

Please contact me or Steven Wojcik, Vice President of Public Policy, at 202.585.1812 if you have questions or would like to discuss our concerns in further detail.

Sincerely,

Helen Darling President

Acla Darlis

The Honorable Secretaries Solis, Sebelius, and Geithner: Page 4
October 30, 2009

cc: Phyllis Borzi, Assistant Secretary, Employee Benefits Security Administration Charlene M. Frizzera, Acting Administrator, Centers for Medicare & Medicaid Services
Douglas Shulman, Commissioner of Internal Revenue
Georgina Verdugo, Director, Office of Civil Rights