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December 3, 2009

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

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

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

Attention: Genetic Information Nondiscrimination Act Interim Final Rules

Dear Secretaries Geithner, Sebelius and Solis:

DMAA: The Care Continuum Alliance respectfully submits the following comments in response to the Interim Final Rules on Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA) issued October 7, 2009.

First and foremost, DMAA: The Care Continuum Alliance fully supports the original intent of GINA to guard against the improper use of genetic information in hiring practices and in the provision and pricing of health insurance. We strongly support efforts to ensure the privacy and confidentiality of the medical record and personal health information. However, we have significant concerns with the GINA interim final rules, which undermine the Administration's stated goals for health care reform to promote wellness and disease prevention, engage individuals in their own health, improve health care quality and control health care costs.

*The recently released interim final rules go far beyond the original intent of the legislation and threaten to significantly and adversely impact employer-sponsored*

*wellness and health promotion programs. Specifically, DMAA believes the definition of "underwriting purposes" included in the interim final rules far exceeds Congressional intent and will have dramatic and unintended consequences on programs designed to support at-risk and chronically ill individuals.*

DMAA believes there is ample middle ground to balance privacy and confidentiality concerns with the Administration's stated goals for health care reform. As such, DMAA respectfully requests a delay in the implementation and enforcement of the definition of "underwriting purposes" until such time as the joint agencies are able to review the underlying statutory intent and better understand the unintended and negative impact the Title I interim final rules will have on the use of health risk assessments and employer-sponsored wellness and disease management programs.

Specifically, the definition of "underwriting purposes" included in the Title I statute includes:

> *"(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage."*

The GINA Title I interim final rule expands upon the statutory definition of "underwriting purposes" in *(A)* to include the following language:

> *"These interim final regulations clarify that underwriting purposes includes changing deductibles or other cost-sharing mechanisms, or providing discounts, rebates, payments in kind or other premium differential mechanisms in return for activities such as completing health risk assessment (HRA) or participating in a wellness program."*

The underlying GINA Title I statute contains no references to the use of incentives or health risk assessments and wellness programs. DMAA believes this "clarification" in the Title I interim final rule clearly exceeds statutory intent and recommends that this clarifying language be removed.

Further, the definition of "underwriting purposes" included in the Title I statute continues:

> *"(B) The computation of premium or contribution amounts under the plan or coverage."*

The GINA Title I interim final rule again expands upon the statutory definition of "underwriting purposes" in *(B)* to include the following language:

> *"(including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program."*

Again, the underlying GINA Title I statute contains no references to the use of incentives or health risk assessments and wellness programs. DMAA believes this additional language in the Title I interim final rule clearly exceeds statutory intent and recommends that this additional language be removed.

The Title I interim final rules, in effect, prohibit the use of HRAs for collection of family medical history to identify candidates for wellness and disease management services

and enroll them in these valuable programs, which it defines as “benefits” (and, therefore, underwriting purposes).

Respectfully, we submit that this provision of the interim final rule is fundamentally flawed: wellness and disease management programs or protocols are not separate "benefits" for which a separate eligibility determination is required. Rather, every participant in a group health plan is already eligible for all the benefits the plan offers – disease management included. That this is the case is demonstrated in the underlying structure of virtually every group medical plan, wherein "eligibility" and plan eligibility issues are treated separately from benefits. Once an individual is eligible to participate, he or she has access to any benefit he or she might require. Thus, for example, a participant is eligible for in-patient coverage under the employer's plan, but won't need to access that benefit until he or she needs an in-patient procedure. When this individual becomes sick or injured, the plan does not make a new or separate eligibility determination. Rather, it has to determine whether in-patient treatment is appropriate under the circumstances. Similarly, each participant in a plan with a disease management feature is already eligible for that feature. The plan merely needs to determine whether that particular benefit is appropriate under the circumstances.

Health risk assessments (HRAs) that consider family medical history are important tools for making such determinations with respect to wellness and disease management programs. Prohibiting the collection of family medical history in HRAs increases the likelihood that those who could benefit from wellness, prevention and disease management will fall through the cracks, leading to a greater incidence of chronic disease and higher health care spending as these individuals develop costly conditions that might otherwise have been prevented. Numerous studies and peer-reviewed literature substantiate the value and importance of family medical history in determining an individual’s risk of developing certain chronic conditions, such as diabetes, heart disease, stroke and cancer. Also, the Centers for Disease Control and Prevention and the Office of the Surgeon General have made awareness of family medical history a key element of federal prevention initiatives.

Further, in their current form, the GINA Title I interim final rules will be detrimental to employer sponsored wellness programs by the unwarranted expansion of “underwriting purposes” to include the use of incentives commonly employed to increase participation. In this definition, the interim final rules pronounce that providing a monetary incentive for completing an HRA that requests family medical history would fall under categories *(A)* and *(B)* above and, therefore, violate GINA’s prohibition on requesting genetic information for “underwriting purposes.” The interim final rule’s preamble notes that the agencies decided against commenter requests for an exception that would allow wellness programs to provide rewards for completing HRAs that request genetic information. DMAA finds it difficult to reconcile this decision not to allow exceptions for wellness programs with the fact that the interim final rules permit requests for genetic information in an HRA, including family medical history, as long as no incentive is offered for completing it.

**DMAA respectfully requests that the joint agencies review and reverse this decision and allow:**

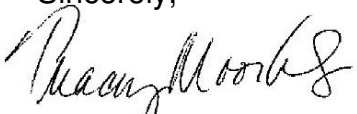
1) **the use of HRAs with family medical history to identify and enroll individuals in wellness and disease management programs; and**
2) **the use of incentives for completion of an HRA (including those with questions pertaining to family medical history), as well as for participation in wellness and disease management programs.**

If implemented in current form, these regulations will significantly and adversely impact employer-sponsored programs aimed at providing health support for individuals at risk for or currently managing chronic disease. The absence, or reduction, of these programs will have immediate impact on the cost of health care incurred by employers, the productivity of the American workforce and the overall use of health care resources in this country.

DMAA members provide services along the entire continuum of care for chronic disease, from wellness to complex care management. DMAA members include wellness, disease management and population health management organizations, health plans, labor unions, employer organizations, pharmaceutical manufacturers, pharmacy benefit managers, health information technology innovators and device manufacturers, physician groups, hospitals and hospital systems, academicians and others. These diverse organizations share DMAA's vision of aligning all stakeholders to improve the health of populations. Our members seek to improve health care quality and contain health care costs by providing targeted interventions and services to individuals who are well, at-risk or managing one or more chronic conditions.

Thank you for the opportunity to submit comments on this important issue. DMAA looks forward to working with your agencies to craft a reasonable solution that adheres to the intent of the underlying GINA statute, yet enables the continued use of important wellness and disease management programs.

Sincerely,



Tracey Moorhead
President and CEO

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