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October 30, 2009

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

Dear Secretary Solis:

I write on behalf of the **Michigan Purchasers Health Alliance** in regard to recent interim final regulations issued by your departments. The regulations seek to implement Title I of the Genetic Information Nondiscrimination Act (GINA) to prohibit discrimination based on genetic information. ***We respectfully request an immediate moratorium on the implementation and enforcement of these regulations. We further request the creation of a special joint-agency panel to review and understand the impact of these regulations on the use of wellness and chronic disease management programs.***

Michigan Purchasers Health Alliance supports the intent of Title I of GINA to prohibit group health plans and health insurers from taking the following actions: 1) increasing group premiums or contribution amounts based on genetic information; 2) requesting or requiring individuals or their family members to undergo a genetic test; and 3) requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

However, **Michigan Purchasers Health Alliance** *believes the definition of "underwriting" included in the interim final regulations far exceeds Congressional intent and will have dramatic and unintended consequences on programs designed to support at-risk and chronically ill individuals*

As noted, GINA's intent was to prohibit group health plans and insurers from collecting genetic information 1) prior to or in connection with enrollment; and 2) for underwriting purposes. The final interim regulations broadly define "underwriting purposes" to mean rules for determining eligibility (including enrollment and continued eligibility), computation of premium or contribution amounts, and application of pre-existing condition exclusions. This definition 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 a health risk assessment (HRA) or participating in wellness programs. The new regulations clarify that offering reduced premiums or other reward for providing genetic information is an impermissible "underwriting" activity.

Further, the interim final regulations state that a wellness program that provides rewards for completing an HRA that requests family medical history would violate the prohibition against requesting genetic information for underwriting purposes, even if the rewards or incentives are not based on the outcome of the assessment. The interim final regulations provide no exception to this rule, regardless of the amount of the reward or incentive or whether the HRA meets the HIPAA wellness plan requirements.

Finally, and most troubling, the interim final regulations prohibit the use of an HRA to determine whether a participant is eligible for a disease management program if the HRA collects family medical information. This prohibition holds even if the HRA does not otherwise contain a financial reward or incentive.

The prohibition on collecting genetic information for underwriting purposes as defined in the interim final regulations severely impacts the use of HRAs by employers, health plans and population health management organizations, labor unions and others. The HRA is an essential, proven tool to identify individuals who are at-risk for or currently managing chronic illness. The use of sophisticated HRA tools enables targeted programs designed to benefit these individuals and provide services and support based on current health status. It is important to recognize that these tools have been shown to improve health care status and quality and reduce health care costs.

As written, the interim final rule leaves health plans, employers and others with two unworkable options: end incentives for completing an HRA that collects genetic information (including family medical history) or remove questions about genetic information from the HRA. In the former case, participation in wellness and disease management programs will decline, as studies have shown incentives significantly improve wellness program participation; in the latter, the effectiveness of the HRA will be severely diluted, as family history and other genetic information are valuable indicators of chronic disease risk.

Michigan Purchasers Health Alliance believes wellness and disease management programs – and the tools they use, such as HRAs –are consistent with the Administration's health care reform goals of improved quality and reduced costs. As such, the Title I GINA interim final rules directly contradict those goals and should not be permitted to move forward to implementation or enforcement without closer examination and adherence to original Congressional intent.

Michigan Purchasers Health Alliance stands prepared to work closely with your agencies, other Administration officials and Congressional leaders to ensure a mutually agreeable solution to these issues.

Sincerely,

Marilyn H Bell
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