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January 29, 2010

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 relating to the Interim Final Rules on Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA) issued on October 7, 2009 (the "interim final rules"). These comments supplement and expand upon our previous comment letter dated December 3, 2009. The purpose of these supplementary comments is to suggest specific changes to the interim final regulation, which in our view will more accurately reflect legislative intent.

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.

We reiterate and reaffirm our unqualified support of GINA's stated goals of guarding against the improper use of genetic information in the pricing of health insurance, and we strongly support efforts to ensure the privacy and confidentiality of medical records and personal health information.

We remain concerned, however, that the definition of "underwriting" included in the interim final regulations goes beyond the original intent of the legislation thereby adversely affecting employer-sponsored wellness and health promotion programs to the detriment of at-risk and chronically ill individuals.

Background

GINA § 101 defines the term "underwriting purposes" as follows:

> UNDERWRITING PURPOSES- The term "underwriting purposes" means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan--
>
> (A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;
>
> (B) the computation of premium or contribution amounts under the plan or coverage;
>
> (C) the application of any pre-existing condition exclusion under the plan or coverage; and
>
> (D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits."

This definition is undeniably broad, and the interim final rule's definition tracts the statute closely (*see, e.g.*, Treas. Reg. § 54.9802-3T(d)(1)(ii)). The net effect of the interim final rule is to further broaden this definition, however, by confusing "eligibility" determinations with "medical appropriateness" determinations. Specifically, the interim final rule treats a wellness or disease management program under an employer-sponsored group health plan as a separate arrangement with its own, separate eligibility requirements. But wellness or disease management programs are not a separate plan; they are, rather, a *feature* of the underlying group medical plan.

An individual who satisfies the eligibility requirements of his or her employer's group health plan thereby gains access to all of the medical benefits offered by the plan. These benefits typically include hospital and physician services, preventative care, and durable medical equipment, etc., and they may include prescription drug coverage, mental health and substance abuse benefits and well-baby care, among other things. The plan's benefits might also include a disease management program. As such, any determination of the need for disease management program benefits is not made under "rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage" within the meaning of GINA § 101. Rather, eligibility for the plan's disease management feature is already established by an individual's status as a participant in the plan. As a consequence, whether the individual might benefit from participation in a disease management program is a question of medical appropriateness, not underwriting.

Treas. Reg. § 54.9802-3T(d)(1)(iii) sets out rules under which genetic information may be used for determinations of medical appropriateness. Generally, when making determinations of medical appropriateness a plan may limit or exclude a benefit on the basis genetic information, provided that the plan requests only the minimum amount of genetic information necessary for that purpose.

Treas. Reg. § 54.9802-3T(d)(1)(iii) clarifies that medical appropriateness determinations do not constitute underwriting as follows:

> "If an individual seeks a benefit under a group health plan, the plan may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes."

As presently constituted, the interim final rule limits the application of the medical appropriateness exception to instances where a participant "seeks" a benefit. Thus, in the absence of an affirmative request for benefits, the medical appropriateness rules don't apply. But the requirement of an affirmative request (i.e., that a participant seek a benefit) does not appear in the statute. It is rather regulatory gloss that implements a rule of construction. It is also unnecessary, in our view.

In the case of a major trauma (e.g., an individual who has just been in a serious accident), an individual is deemed to be "seeking" a medical benefit simply by virtue of presenting at an emergency room irrespective of whether he or she is conscious. Similarly, an individual may not know that he or she might have a need for a disease management program, but the long-term consequences may well be every bit as important as an immediate major trauma. To impose a requirement that an individual affirmatively request access to a disease management program is unsupported by the statute and goes too far—particularly (as we demonstrate in the our recommendations below) in light of the other protections established under the interim final rule.

Proposed Changes to the Interim Final Rule

Evidence demonstrates that disease management programs can lower long-term medical costs and improve health care status. Provided a health risk assessment is administered after enrollment (thereby ensuring that it does not taint the enrollment process), there should be no reason to bar questions about family medical history for the purpose of identifying disease management program candidates.

Under the rule as currently constituted, a group health plan is allowed to send out a notice to all participants that describes the program, explains its terms, and invites interested individuals to contact the plan. But this approach is inefficient at best and harmful at worst. Participants are bombarded with workplace notices of all kinds. A generic notice is unlikely to stir an individual to act, particularly if he or she is unaware that he or she might be at risk. In contrast, a targeted notice in response to a individualized notice generated in response to specific questions in a health risk assessment are for more likely to result in the individual taking action.

Because disease management is not properly considered "underwriting," there is no need to bar the use of premium discounts, rebates or other rewards already permitted by rules jointly issued by the Treasury Department, the Department of Labor and the Department of Health and Human Services under Title I of the Health Insurance Portability and Accountability Act of 1996. With the judicious use of premium discounts, rebates or other rewards, the success of a wellness or disease management program is made all the more likely. With or without incentives, the individual could choose not to take any action in the matter. Either way, provided the health risk assessment is administered after enrollment in the group health plan, there is no possible adverse consequence to the employee.

Suggested Changes to Temp. Reg. § 54.9802-3T(d)(1)(iii)

The references to a participant "seeking" benefits should be expanded upon, such that a request for admission to a disease management program in response to answers furnished on a health risk assessment should qualify. For example, we suggest that you substitute the following for the fifth sentence of this section:

"An individual is deemed to be seeking benefits under a group health plan if the request for a benefit is as a result of responses voluntarily provided under a health risk assessment that satisfies the requirements of Treas. Reg. §§ 54.9802-1(f)(2) and -3T(d)(2).

In addition, we suggest adding the following as the penultimate sentence:

The minimum necessary standard of this section is deemed satisfied with respect to a health risk assessment provided that questions under the health risk assessment are reasonably calculated to elicit only information concerning a symptom, condition or status relating to the purpose and goals of the disease management program to which the health risk assessment is related.

Suggested Changes to Temp. Reg. § 54.9802-3T(d)(3), Example 4

This section might be revised to read as follows:

Example 4. (i) Facts. The facts are the same as in Example 1, except there is no premium reduction or any other reward given for completion of the health risk assessment. However, certain people completing the health risk assessment may become eligible for additional benefits under the plan by being enrolled in a disease management program based on their answers to questions about family medical history. Other people may become eligible for the disease management program based solely on their answers to questions about their individual medical history. Also, questions on the health risk assessment are limited to those reasonably calculated to elicit information concerning a symptom, condition or status relating to the purpose and goals of the disease management program.

(ii) *Conclusion*. In this Example 4, the request for information about an individual's family medical history is a medical appropriateness determination. Therefore, the questions about family medical history on the health risk assessment are permitted. The exception for determinations of medical appropriateness apply because the individual is deemed to be seeking benefits as a result of his or some voluntary completion of the health risk assessment that is administered after enrollment in the underlying group health plan.

Suggested Changes to Temp. Reg. § 54.9802-3T(e), Example 4

This example might be revised, or a new question and answer added, to read as follows:

Example 4. (i) *Facts*. A group health plan offers a diabetes disease management program to all similarly situated individuals for whom it is medically appropriate based on whether the individuals have or are at risk for diabetes. The program provides enhanced benefits related only to diabetes for individuals who qualify for the program. Certain people completing a health risk assessment, with respect to which there is a premium discount that satisfies the "wellness program" requirements under the Health Insurance Portability and Accountability Act of 1996, may become eligible for the diabetes disease management program based on their answers to questions about family medical history. Individuals interested in enrolling in the program are advised to contact the plan to demonstrate that they have diabetes or that they are at risk for diabetes.

(ii) *Conclusion*. In this Example 4, the plan may condition benefits under the disease management program upon a showing by an individual that the individual is at risk for diabetes, even if such showing may involve genetic information, provided that the questions on the health risk assessment request genetic information only to the extent necessary to make a determination regarding whether the disease management program is medically appropriate for the individual.

Suggested Changes to Temp. Reg. § 54.9802-3T(d)(3)(ii), Example 5

This example should be deleted.

Conclusion

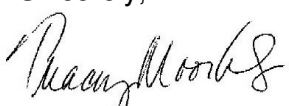
We believe that enrollment in a disease management program is properly viewed as relating to medical appropriateness, and not to underwriting. This is not a question of eligibility; the participant is already eligible to participate in the plan. Rather the question is whether this particular benefit, which is available to all plan participants, is medically appropriate to any particular participant. Viewed in this way, the suggestions set out above fit easily and seamlessly into the final interim rule.

The changes to the interim final rule suggested above are relatively minor: they affect only disease management programs, and they are limited to the use of genetic information disclosed under a health risk assessment that is administered post-enrollment and with other appropriate safeguards. The purpose of this change is to alert individuals of possible health problems in conditions in a way that is reasonably calculated to get their attention, i.e., in response to a specific notice that is tailored to the individual in response that the individual has disclosed voluntarily.

Lastly, and perhaps most importantly, the opportunity for an early warning of a potentially serious medical condition is potentially invaluable. In extreme cases, it is a matter of life and death. That the opportunity might require access to genetic information does not change this fact. It simply means that such access must comport with all applicable requirements of law. In preparing these comments we have endeavored to do just that. GINA's goals are important and laudable; so too is the judicious use of disease management programs. The two are not incompatible as we see it. We hope you agree.

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