



January 1, 2010

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration, Room N-5653
United States Department of Labor
200 Constitution Avenue, NW
Washington D.C. 20210

Attention: RIN 1210-AB27
Interim Final Rules – Genetic Information Nondiscrimination Act of 2008

The National Business Group on Health appreciates the opportunity to respond to the Request for Information on Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA). I write to express our serious concerns about the adverse impact of the interim final rules on employer-sponsored wellness and disease management programs.

The National Business Group on Health represents approximately 300, primarily large, employers who voluntarily provide health benefits and other health programs to over 55 million American employees, retirees, and their families.

We request that you reissue the regulations to provide for both an “underwriting purposes” exception for incentives provided for the completion of health risk assessments (HAs) and a “medical necessity” exception for disease management programs.

We believe that neither of these exceptions will, in any way, diminish GINA’s ability to prevent discrimination based on genetic information. We think, if you will consider our suggestions, that these exceptions will preserve the ability of employer-sponsored group health plans to more adequately address the health concerns of plan participants and employees. Such exceptions are in agreement with other directions conveyed in the interim final rules (and providing these two exceptions will clarify any possible internal inconsistencies in the rules).

“Underwriting Purposes” Exception for Incentives for Completing HAs

The “underwriting purposes” exception would apply to group health plans that incentivize participants to complete HAs that may include family medical history questions (or other questions requesting genetic information). The exception would also apply to group health plans evaluating completed HAs to determine participants who can benefit medically by treatment coordinated through disease management programs.

Example 6 [FR51682] indicates that disease management programs provide an “enhanced benefit” of lower annual deductibles for medical services and supplies even when

treatment is not “condition specific” and facilitated through disease management programs. We are unaware of any disease management programs that include group health plan provisions for required annual deductibles, nor any disease management programs that are not subsidiary components (even with third party administration) of group health plans (that provide all health care benefits and typically use subsidiary programs).

Incentives or rewards for completion of HAs are provided by group health plans (not disease management programs) and employer-sponsors’ formal written plans already contain eligible benefit provisions specifying the procedures participants must follow in order to receive benefits. As benefits differ based on the very nature of medical treatment, there are different procedures participants must follow to receive certain benefits (whether one arbitrarily defines them as “enhanced” or “additional”).

Lower annual deductible levels, differential premium arrangements, reduced co-pay or coinsurance requirements, increased employer contributions to individual health accounts, cash awards, gifts, etc. are all eligible *benefits* under group health plans and written plan documents outline the procedures participants must follow in order to receive these *benefits*.

GINA prohibits collecting genetic information for underwriting purposes (FR51668] that includes rules for determining eligibility (with respect to coverage under any group health plan or health insurance coverage), computation of premium or contribution amounts, and other (vaguely defined) activities related to the renewal or replacement of a contract of health insurance or health benefits (Public Law 110-233 at 122 STAT. 886).

When wellness (or disease management) programs provide rewards for completing HAs that request family medical history (or other genetic information) and the rewards are not based on the outcome of the assessments and do not otherwise violate HIPAA, there is no collection of genetic information for underwriting purposes. Participants (already enrolled in group health plans) are seeking benefits under the plans by completing HAs. The only criteria for incentives or rewards is a “complete health assessment” irrespective of whatever specific answers participants provide and no incentives or rewards are given based on family medical history (or other genetic information).

We do not understand why the “interim final regulations do not provide an exception from underwriting for rewards provided by wellness programs” [FR51669] when group health plans do not actually provide any incentives or rewards based on family medical history (or other genetic information).

We realize that many organizations have submitted written comments pointing out the non-traditional and “overly broad” definition of “underwriting purposes” contained in

GINA. We simply wish to point out that employer-sponsored group health plans providing incentives or rewards for completion of health assessments (containing family medical questions) do not provide incentives or rewards *on the basis of any genetic information disclosed (nor any other answers to any other questions in the HAs)*. Applying the interim final rules to interpret that genetic information is *used for* underwriting purposes, when it is not, is an oversight that should be corrected. If your agency is in disagreement, then we would suggest a significant clarification.

“Medical Necessity” Exception for Disease Management Programs

Health assessments that include questions about family medical history are vital for identifying plan participants who may particularly benefit from wellness initiatives and disease management programs. Without family medical history, plans will lose information about a key risk factor, often the only one present, that identifies plan participants at higher risk for cardiovascular disease, some cancers, diabetes or other major chronic conditions who could benefit from early intervention to stave off debilitating disease, death, and the development of other risk factors.

Group health plans are allowed to require genetic testing and genetic information when participants seek benefits and genetic tests or information are required to demonstrate the medical appropriateness of treatments. Plans may deny or refuse payment if participants do not undergo appropriate genetic tests to determine medical appropriateness [FR51667]. Group health plans are limited to requesting the minimum amount of genetic information (e.g.; family medical history) necessary to make medically appropriate benefit determinations. According to the regulations, this exception to determine whether benefits are medically appropriate is not within the meaning of “underwriting purposes nor prior to or in connection with enrollment” [FR51668].

We are unaware of any distinction in the normal administration (and medical case management) of all group health plans between “payment” purposes (after medical services are rendered and claims presented) and the practice of pre-authorization (where there can be no dispute that individuals are “seeking benefits under the plan”). When participants fail to pre-authorize certain types of care, they forfeit conditional claim reimbursements – in the same manner that group health plans are “permitted to condition payment... based on ...appropriateness that depends on... genetic makeup” [Item 4 FR51667].

We cannot understand how plan participants completing HAs in order to learn more about their health; earn incentives and rewards; and potentially participate in disease management programs (focused on their personal medical issues) fails this criterion of “seeking a benefit under the plan”.

Relevant (and quite common) examples are the majority of group health plans that require outpatient laboratory testing before reimbursing expenses for hospital admissions and subsequent surgeries. Participants have their laboratory work done prior to their hospital admissions and surgeries in order to comply with plan requirements and receive eligible benefits. The very fact that participants present to outpatient laboratories prior to surgical suites demonstrates they are “seeking a benefit under the plan” – the same as participants completing HAs.

The interim final rules consider eligibility for disease management programs as incentives or rewards [Example 4 - “additional benefits” at FR51681] but do not adequately address “the application of the medical appropriateness rules to the use of genetic information (e.g.; family medical history) to determine eligibility for a disease management program” [FR51669]. The example in the guidance illustrates a disease management program targeted specifically to early intervention, chronic condition management, etc. for the single medical condition of diabetes [Example 4 – “enhanced benefits” at FR51682].

Disease management programs that do not specifically target only one medical condition (such as diabetes), provide incentives for completion of HAs, and request family medical history (or other genetic information) are not granted this exception. The guidance appears to rely on defining distinct eligibility provisions for disease management programs separate and apart from the group health plan providing all benefits.

Furthermore, the determination that eligibility for disease management programs (based on medical appropriateness) somehow represents “additional” or “enhanced” benefits under group health plans is arbitrary. One might ask if reimbursement of the charges of a radiologist to interpret x-rays is an “additional” or “enhanced” benefit provided by plans as opposed to only providing reimbursement for the x-rays themselves.

We believe that *any* benefits under group health plan coverage can arbitrarily be labeled “additional” or “enhanced” because, in most cases, the benefits provided vary among participants *because of the very nature of medical treatment.*

Example 5 [FR51682] indicates plans (it is unclear if the reference is to group health plans or their subsidiary disease management programs) violate GINA when requesting genetic information to determine medical appropriateness when such requests are not limited to only those participants where it is necessary to make medically appropriate determinations (i.e.; entry into disease management programs).

When applied to all similarly situated participants, group health plans determine medical appropriateness for disease management programs in each and every individual case (i.e.; they determine that some participants will benefit from, and should be enrolled in,

disease management programs while other participants will not benefit and disease management is not medically appropriate.

Enrollment in disease management programs (as eligible benefits provided by group health plans) does not differ from any other eligible benefits. *Group health plans determine all benefits, and the eligibility for those benefits defined in plan provisions, based on "medical appropriateness"* and we feel disease management programs should not be limited in the guidance to one focus disease.

Failing, in the interim final rules, to provide a medical appropriateness exception for voluntary wellness and disease management programs is inconsistent with the purpose of GINA to "remove barriers that impede... providing patients and physicians with critical knowledge to facilitate early intervention often before disease symptoms are manifested" [FR51671]. The rules provide a narrow exception for disease management programs when the programs only focus on one medical condition; creating a barrier GINA has been designed to eliminate.

Thank you, again, for your consideration of these important issues.

Please do not hesitate to contact me or Steven Wojcik, Vice President of Public Policy, at 202.585.1812 if you have questions or would like to discuss this feedback in further detail.

Sincerely,



Helen Darling
President

cc: Nancy-Ann DeParle, Counselor to the President and Director, White House
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