BlueCross BlueShield Association

An Association of Independent
Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4780
Fax 202.626.4833

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Daniel J. Maguire
Director
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N–5653
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

Submitted via Regulations.gov, RIN 1210-AB27

RE: Interim Final Rules under the Genetic Information Nondiscrimination Act

Dear Mr. Maguire:

The Blue Cross and Blue Shield Association (BCBSA), which represents the 39 independent, community-based and locally operated Blue Cross and Blue Shield Plans (Plans), is pleased to submit comments on the interim final rules under Title I of the Genetic Information Nondiscrimination Act (GINA), as published in the *Federal Register* on October 7, 2009 (74 Fed. Reg. 51664).

Plans collectively provide healthcare coverage for 100 million people or one-in-three Americans, in all 50 states, the District of Columbia, and Puerto Rico and in all markets, including the individual, small group, large employer, and national account markets. Plans also participate in government programs, such as Medicare, Medicare Advantage, Part D, and the Federal Employees Health Benefits Program.

BCBSA worked closely with Congress to enact the GINA legislation. BCBSA supports GINA because it protects consumers and encourages patients to obtain appropriate genetic testing to take advantage of prevention and effective treatment – versus delaying potentially life-saving care.

In summary, BCBSA recommends that the interim final rule be improved in five ways:

- Providing adequate time for compliance.

- Permitting use of family history in connection with wellness and disease management programs.

- Permitting health care professionals to ask about family health history when providing services as part of wellness and disease management programs.

- Permitting the use of family history in connection with wellness and disease management programs during open enrollment periods.

- Avoiding limits on health care provider diagnoses in the definition of “manifestation or manifested” in relation to diseases or disorders.

1. Adequate Time for Compliance Should Be Provided

It is typical for new group health plan and health insurer requirements to be implemented for plan years that begin a year after the requirement is finalized. This is the case with GINA itself (§ 101(f)(2), 29 U.S.C. § 1132 note), and another example is Michelle’s Law on student dependent health coverage (Pub. L. No. 110-381) (§ 2(d), 26 U.S.C. § 9813 note).

Allowing this time for compliance is very important for group health plan and health insurer regulation because this business is document-intensive. Various kinds of disclosures must be provided to enrollees and must be amended, and employer and health insurer personnel responsible for providing coverage information to enrollees must be trained in new requirements.

The way in which the interim final rules are being put into effect illustrate the problems of too little time for compliance. DOL was required by GINA to have final rules in place by a year after enactment of GINA (*i.e.,* by May 21, 2009) (GINA § 101(f)(1), 29 U.S.C. § 1132 note), but the interim final rules were not released to the public until they appeared online on October 1, 2009. At this time, many group health plans had already prepared for and some had already begun their open enrollment for the 2010 plan year. Imposing new rules in the middle of the open enrollment process has created confusion and additional expenses for group health plans.

DOL stated publicly in industry meetings and seminars that group health plans and insurers should have been aware that certain activities, such as administration of wellness and disease management programs, would be restricted by the interim final rules because it should have been obvious by reading GINA.

BCBSA feels that not all of the new requirements in the interim final rules could have been known from an actual reading of GINA. For example, the interim final rules do not permit the collection of genetic information by a group health plan or a health insurer to be considered incidental and not in violation unless the plan or insurer tells individuals not to submit genetic information (29 C.F.R. § 2590.702-1(d)(2)(ii)(B), 74 Fed. Reg. 51686). However, GINA itself does not contain this

additional disclosure requirement. It merely states that incidental collection of genetic information is not a violation if the genetic information is not used for "underwriting purposes" (GINA § 101(b), 29 U.S.C. § 1182(d)(3)).

Group health plans and health insurers would not have realized the need for an additional warning requirement by reading the legislative history of GINA:

> The committee understands that genetic information permeates health information and that covered entities may inadvertently or unintentionally acquire genetic information. For instance, a health insurance issuer may purchase another health plan and all of its medical records, or request medical records or previously taken lab tests for purposes of underwriting. *Or, in filling out an application for insurance that includes a medical questionnaire, an individual may voluntarily offer additional health information, such as family medical information which is considered genetic information under this bill.* Thus, a provision addressing "incidental collection" is included in the legislation that makes it clear that if a plan, or an issuer obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an individual, such request, requirement, or purchase shall not be considered a violation if it is not obtained for purposes of underwriting and any genetic information obtained incidentally is not used or disclosed in violation of the HHS medical privacy regulations.

S. Rep. No. 110-48, at 26-27 (2007) (emphasis added).

Congress did not include any additional notice requirement for group health plans and health insurers to avail themselves of the "incidental collection" exception in either GINA or reports on GINA, so many employers and affected entities did not anticipate this new requirement as added in the interim final rules.

This is only one example of the how inadequate time for implementation causes serious problems for compliance.

Recommendation: DOL should grant an additional year for group health plans to come into compliance.

2. Family History Questions in Health Risk Assessments Do Not Involve "Underwriting Purposes" as Defined in GINA

DOL's definition of "underwriting purposes" unnecessarily restricts the use of wellness and disease management programs that benefit group health plan participants.

Here is how the interim final rules change the definition of "underwriting purposes" in GINA (language added by interim final rules underlined):

> Underwriting purposes means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—
>
> Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage as described in § 2590.702(b)(1)(ii) of this Part (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);
>
> The computation of premium or contribution amounts under the plan or coverage (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);
>
> The application of any preexisting condition exclusion under the plan or coverage; and
>
> Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

See GINA § 101(d) (29 U.S.C. § 1191b(d)(9)); 29 C.F.R. § 2590.702-1(d)(1)(ii) (74 Fed. Reg. 51685).

Proper Definition of "Underwriting Purposes" as to Premiums and Contributions. The interim final rules define "underwriting purposes" as to the computation of premium or contribution amounts more broadly than the statute requires by referring to health risk assessments (HRAs) for wellness programs and fail to give proper consideration to the purpose of rewards that are provided.

A proper definition of "underwriting purposes" in relation to premiums and contributions would:

- *Recognize that "Underwriting Purposes" is Limited to Determining Acceptability of Risk.* DOL should give proper weight to the statutory phrase "for the purpose of underwriting" and that GINA's definition of "underwriting purposes" is limited to "…activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits." 29 U.S.C. § 1191b(d)(9)(D). GINA views "underwriting" as the process of determining the acceptability of an insurance risk and what premium is to be charged.

  - Thus, DOL should recognize that the only time a group health plan or health insurer should be viewed as collecting family history information for the purpose of computing contributions or premiums is if the plan or health insurance issuer is actually using that information to discriminate against the individual by using family history information that was supplied (*e.g.,* by increasing their premiums or reducing coverage based on the family medical history).

- *Provide that Monetary Rewards for Completing HRAs that Involve Family History Are Not "Premiums" or "Contributions."* Congress and DOL do not define "premium," the ordinary meaning of which is "[t]he periodic payment required to keep an insurance policy in effect" (*Black's Law Dictionary* (9th Ed. 2009) 1300). A "contribution" is not defined by GINA, ERISA, or regulation, but is generally defined as the equivalent of premium for a self-insured group health plan.[1] The interim final rules do not articulate a reason why monetary rewards for completing an HRA are part of the premium or contribution for coverage. Therefore, this restriction is beyond the authority granted by GINA.

  - DOL should recognize that, where the HRA is voluntary and the reward is provided to anyone who fills out the HRA, group health plans and health insurers are not giving a premium discount or reward for the purpose of underwriting, because the discount or reward is available to everyone in the same amount and is based upon the act of filling out the form. No adjustment to premiums or contributions is made in response to the information that is actually provided on the form (*i.e.,* the content of the form and the answers to the family medical history questions). Therefore, any discount or reward for filling out the form is not for the purpose of computing a contribution or premium – even if the incentive is in the form of a minimal premium discount, and especially if the incentive has nothing to do with the premium or contribution. Rather, it is for the purpose of getting individuals to complete the form (and, depending on the answers, to receive additional services).

Enrolling an Individual in a Disease Management Program Based on an HRA with Family History Questions is not for "Underwriting Purposes." This activity does not involve premium or contribution amounts, excluding preexisting conditions, or any other activities related to the creation, renewal, or replacement of health insurance or benefits. Thus, DOL had to rely on the part of GINA's "underwriting purposes" definition relating to eligibility for this provision (*see* Example 4, 29 C.F.R. § 2590.702-1(d)(3), 74 Fed. Reg. 51686). We have

[1] *See Group Insurance* (William F. Bluhm, Principal Editor, 5th Ed. 2007) 699.

concerns with the DOL's approach as we believe it is not well founded in statute because:

- *Eligibility for Underlying Benefits is not Affected.* Where family history is requested as part of an HRA and is used for the purpose of providing early intervention – *e.g.,* coaching, disease management, etc. – eligibility for the underlying benefits or coverage offered under the group health plan or insurance coverage is not affected. While wellness and disease management programs help reduce medical costs and are legitimately considered part of group health plans' and insurer's medical costs,[2] individuals who participate in coaching and disease management programs are eligible for all of the same benefits under the group health plan or insurance coverage (*e.g.,* inpatient and outpatient coverage, prescription drug benefits) as individuals who do not participate in these programs. The disease management or coaching program is merely one means by which certain HRA participants will be able to more efficiently access the same benefits available to all plan participants.

- *Coaching and Disease Management Programs Are not Benefits in and of Themselves.* Rather, they are services under which an individual receives assistance with accessing benefits that are otherwise available to them under the group health plan. A coaching or a disease management program merely offers more targeted access to benefits. Thus, while these programs help reduce medical costs and are legitimately considered part of group health plans' and insurer's medical costs[3], they are not benefits in and of themselves.

- *Disease Management Programs May Be Accessed in Multiple Ways.* Even if coaching and disease management are viewed as benefits or coverage within the meaning of GINA, as noted above, completing an HRA and providing family history information is only one of many ways to access the coaching and disease management services. Because eligibility for these services is not contingent on providing HRA/family medical history information, requesting and using the information to enroll an individual in a program should not be viewed as affecting eligibility for benefits (all employees are generally eligible for such programs). Rather, provision of family medical history is simply one of many ways that an individual can be automatically enrolled in such a program. Other ways that individuals may be enrolled can include reviews by the health plan of actual claims experience of the individual, physician referral, or individual request.

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[2] *See* NAIC Statement of Statutory Accounting Principles No. 85, noting that disease management and consumer education programs designed to improve health are legitimately classified as cost containment activities.
[3] *Id.*

- *GINA Should Be Interpreted to Permit Additional Benefits.* Importantly, the purpose of a voluntary HRA that provides rewards to anyone who fills out the HRA and additional coaching or disease management programs is to confer additional benefits upon individuals who are at risk for an adverse health condition, not to limit eligibility or benefits for these individuals. Interpreting the statute in a manner that would allow the individuals that GINA was designed to protect to receive additional benefits would be consistent with the HIPAA nondiscrimination rules, which specifically permit more favorable treatment of individuals with adverse health factors. *See* 29 C.F.R. § 2590.702(g).

- *Referring to Existing Rules to Suppress Disease Management Programs is Contrary to the Intent of Congress.* DOL changed GINA's reference to eligibility for benefits in 29 U.S.C. § 1191b(d)(9)(A) by referring to existing rules that extend GINA's definition of "underwriting purposes" beyond the "…creation, renewal, or replacement of a contract of health insurance or health benefits." GINA specifically limits the definition of "underwriting purposes" to these types of activities (29 U.S.C. § 1191b(d)(9)(D)) and DOL has no authority to go beyond those statutory limits.

- *DOL's Position on Use of Family History and Wellness and Disease Programs Conflicts with Other Provisions of the Interim Final Rules.* Assuming DOL is correct in interpreting GINA's definition of "underwriting purposes" as prohibiting the use of family history for wellness and disease management programs because these programs are "benefits" under the group health plan or insurance coverage, this approach conflicts with parts of the interim final rules providing that a determination as to whether a benefit is "medically appropriate" is not for "underwriting purposes" (29 C.F.R. § 2590.702-1(d)(iii), 74 Fed. Reg. 51686).

  - The purpose of asking family history questions is that this is a good way to determine whether an individual is a candidate for a wellness or disease management program. In other words, the question is whether a wellness or disease management program (in the eyes of DOL, a "benefit") is medically appropriate for an individual.

  - DOL should not exclude wellness and disease management programs from the provision in the interim final rules stating that a determination of whether a benefit is medically appropriate is not "underwriting purposes."

Recommendation: DOL should not consider the use of family history questions in HRAs that are part of wellness or disease management programs to be for "underwriting purposes" as defined in GINA.

3. Health Care Professionals Working with a Wellness or Disease Management Program may Request Genetic Information – GINA specifically permits health care professionals providing health care services to an individual to request an individual to take a genetic test. *See* 29 U.S.C. § 1182(c)(2). The interim final rules recognize this, even if the health care professional is employed by an HMO (29 C.F.R. § 2590.702-1(c)(2), (3), 74 Fed. Reg. 51685).

Wellness and disease management programs frequently employ health care professionals to provide services such as counseling, coaching, or onsite health screenings. As part of their services under these programs, health care professionals may ask about family history to better understand individuals' results or provide further coaching or recommendations.

Recommendation: The interim final rules should make it clear that GINA permits health care professionals providing services under wellness and disease management programs to ask about family history.

4. The Use of Family History in Connection with Wellness and Disease Management Programs Should Be Permitted During Open Enrollment Periods

The Prohibition on Collecting Genetic Information Prior to Enrollment Can Be Made More Efficient. Prohibiting the collection of genetic information prior to the enrollee's effective date of coverage makes the process of enrollment inefficient.

- *An alternative interpretation would:* (i) Interpret the statutory phrase "prior to such individual's enrollment under the plan or coverage in connection with such enrollment" (29 U.S.C. § 1182(d)(2)) to read "prior to such individual's enrollment under the plan" or "prior to enrollment in coverage," and (ii) Provide that, as long as information is requested after a participant has selected a medical plan option, and as long as a participant need not complete an HRA in order to be enrolled in the plan, an HRA with family history questions that is completed by any participant during the open enrollment period does not violate the statutory prohibition against requesting genetic information prior to enrollment.

- *This proposed rule makes sense from an administrative standpoint.* It is most efficient for plans or health insurance issuers to provide an HRA for completion during the time that participants are focused on and receiving other information about benefits. Administering the HRA at any other time of year would not only result in additional mailing expenses or e-mail and website traffic, but would also interrupt the workdays of employees at a time that they are not focused on benefits, reducing the likelihood that they will complete the HRA. Further, the interpretation in the regulations that allows an HRA to be provided during open enrollment for an existing enrollee but not for a new enrollee would be expensive and cumbersome

to administer because it would require plans and health insurers to create an entirely new system for treating these two groups separately when, for all other purposes, they can be treated as a single group.

Recommendation: HRAs requesting family history information should be permitted after enrollment, regardless of whether coverage is already in effect.

5. The Definition of "Manifestation or Manifested" Should Be Limited to the Definition Used in GINA

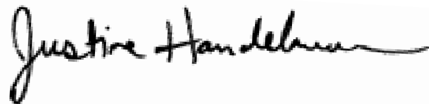
The definition of "manifestation or manifested" in the interim final rules goes beyond GINA to state that a disease or disorder is not manifested if the diagnosis is based principally on genetic information (29 C.F.R. § 2590.702-1(a)(6)(i), 74 Fed. Reg. 51684). GINA provides that manifested diseases or disorders may be used for setting an employer's group premium (29 U.S.C. § 1182(b)(3)(B)) and for establishing eligibility and premiums for individual health insurance policies (42 U.S.C. § 300gg-53(a)(2), (b)(2)), but it does not say anything about how a manifested disease or disorder is diagnosed.

Recommendation: DOL should leave diagnoses to health care professionals, which was the intent of Congress.

In conclusion, BCBSA urges DOL to implement GINA in a way that adheres to the intent of Congress and allows continuation of important disease management and care coordination activities that can help improve care and rein in costs.

Thank you for the opportunity to comment on these issues. Please contact me if additional information is needed on these comments.

Sincerely,



Justine Handelman
Executive Director, Legislative and Regulatory Policy