



AMERICAN BENEFITS
COUNCIL

May 1, 2009

Mr. Stephen Llewellyn, Executive Officer
Executive Secretariat
Equal Employment Opportunity Commission
131 M Street, N.E., Suite 6NE03F
Washington, DC 20507

**Re: Comments – Proposed Rule Implementing Title II of the
Genetic Information Nondiscrimination Act (RIN 3046-AA84)**

Dear Mr. Llewellyn:

The American Benefits Council (the "Council") appreciates the opportunity to comment on the Equal Employment Opportunity Commission's ("Commission's") proposed rule implementing Title II of the Genetic Information Nondiscrimination Act ("GINA"). 74 Fed. Reg. 9056 (March 2, 2009).

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly, or provide services to, retirement and health plans that cover more than 100 million Americans.

The Council supports the general intent of GINA to protect individuals against discrimination based on genetic information. We are concerned, however, about the potential for implementing regulations to impede legitimate benefit plan practices, particularly with respect to wellness programs, which many of our members offer as a means of improving health and lowering costs.¹

¹The Council also provided comment on a Request for Information regarding Title I of GINA issued by the Departments of Labor, Health and Human Services and Treasury. 73 Fed. Reg. 60209 (October 10, 2008). Title I establishes comprehensive rules barring discrimination based on genetic information for group health plans and broadly prohibits using genetic information in setting plan premiums and contributions, requesting or requiring genetic testing, and collecting genetic information.

The comments below focus on two aspects of the proposed rules for Title II:

- the Commission's request for specific comments regarding how the term "voluntary" should be defined for purposes of the American with Disabilities Act's (ADA's) application to wellness programs; and
- the "firewall" rule of construction between Titles I and II as set out in section 209(a)(2)(B) and (c) of GINA.

Request for Comments on Scope of "Voluntary"

Title II of GINA, along with the proposed rule, provides that an employer may not request, require, or purchase genetic information of an individual, unless the action falls under a specific exception. 29 CFR § 1635.8(a). One of these exceptions is where an employer offers health or genetic services, including such services offered as part of a "voluntary wellness program." 29 CFR § 1635.8(b)(2). In that case, the employer would be permitted to request, require, or purchase genetic information, as long as:

- the individual provides knowing, voluntary, and written authorization that describes the purpose of the wellness program and any disclosure restrictions;
- the genetic information only is provided to a licensed health care professional or genetic counselor; and
- any genetic information obtained is only used for wellness program purposes and only is disclosed to the employer in aggregate terms.

29 CFR § 1635.8(b)(2)(i)-(iii).

In the preamble to the proposed rule, the Commission explains that the wellness program seeking medical information must be voluntary, a requirement set for in the ADA. The Commission noted that according to Enforcement Guidance, a wellness program is voluntary "as long as an employer neither requires participation nor penalizes employees who do not participate." (citing Commission's Enforcement Guidance on Disability-Related Inquiries and Medical Examination of Employees Under the ADA, Q&A 22 (July 27, 2000)). The preamble also states that the Commission has not further addressed how the term "voluntary" should be defined for purposes of the ADA's application to wellness programs and invites specific comment on the scope of this term.

Background: HIPAA Nondiscrimination & Wellness Regulations Applicable to Wellness Programs

The Departments of Treasury, Health and Human Services, and Labor have promulgated nondiscrimination regulations based on genetic information and the application to wellness programs offered by employer group health plans under the Health Insurance Portability and Accountability Act ("HIPAA"). *See* 71 Fed. Reg. 75014 (Dec. 13, 2006).² HIPAA defines a "group health plan" as an employee welfare benefit plan that provides medical care. ERISA § 733(a).

The HIPAA nondiscrimination rules provide that a group health plan may not discriminate in health plan eligibility or application of benefits based on an individual's "health factor." 29 CFR § 2590.702(b), (c). The regulations define "health factor" to including genetic information. 29 CFR § 2590.702(a)(1)(vi).

A health plan is permitted, however, to vary benefits or premiums/contributions in connection with a wellness program that satisfies certain requirements under HIPAA. Under these requirements, any "reward" for satisfying the conditions of the wellness program cannot exceed 20 percent of the cost of employee-only coverage.³ 29 CFR § 2590.702(f)(2)(i). The Preamble to the HIPAA regulations explains:

Comments suggested that plans and issuers have a greater opportunity to encourage healthy behaviors through programs of health promotion and disease prevention if they are allowed flexibility in designing such programs. The 20 percent limit on the size of the reward in the final regulations allows plans and issuers to maintain flexibility in their ability to design wellness programs, while avoiding rewards or penalties so large as to deny coverage or create too heavy a financial penalty on individuals who

² The HIPAA nondiscrimination rules are a part of the Internal Revenue Code ("Code"), Public Health Service Act ("PHSA"), and the Employee Retirement Income Security Act ("ERISA"). The HIPAA nondiscrimination and wellness regulations were issued jointly by the Departments of Treasury, Health and Human Services, and Labor. The "group health plan" rules apply to both group health plans and health insurance issuers offering coverage in connection with group health plans. For ease of reading, we are citing to the Department of Labor regulations under ERISA and simply referencing group health plans, although the regulations under the Code and PHSA, and their applicability to both health plans and insurers, are identical.

³ The other requirements that a health-based wellness program must meet are: (1) the program must be reasonably designed to promote health and prevent disease; (2) the program must give individuals the opportunity to qualify annually; and (3) the program must provide a reasonable alternative standard, not based on a health factor, for individuals for whom it is medically inadvisable to achieve the initial standard. 29 CFR § 2590.702(f)(2)(ii)-(v).

do not satisfy an initial wellness program standard that is related to a health factor. 71 Fed. Reg. at 75018 (Dec. 13, 2006).

The regulations establish two categories of wellness programs in applying these rules:

- (1) Health-Based Standard – If any of the conditions for obtaining a reward under the wellness program are contingent on an individual satisfying a standard based on a health factor, the wellness program must meet both the general HIPAA nondiscrimination rules and the specific HIPAA wellness program restrictions (*i.e.*, the 20% reward limit). For example, if a wellness program offers a lower deductible for individuals who have low cholesterol; this would be a program whose rewards are based on an individual's health factor, so this program would be subject to the HIPAA nondiscrimination rules, plus the additional HIPAA wellness program restrictions. In this case, the deductible reward would be limited to 20% of the cost of coverage.
- (2) Participation-Only Standard – If none of the conditions for obtaining a reward under the wellness program are based on an individual satisfying a standard based on a health factor (*i.e.*, the only requirement is that the individual merely participate), the wellness program must meet the general HIPAA nondiscrimination rules, but would not be required to meet the specific HIPAA wellness program restrictions. For example, if a wellness program offers a premium reduction for individuals who complete a health risk assessment, this would not be a program that is based on an individual's health factor because the only requirement is that the individual merely participate. This program would be subject to HIPAA's general nondiscrimination rules (*i.e.*, the plan could not use information collected to discriminate against the individual based on a health factor), but the program would not be subject to the additional HIPAA wellness program restrictions.

Comment

The Council recommends that the Commission build on the framework already established under the HIPAA nondiscrimination and wellness regulations in determining the scope of “voluntary” for purposes of the ADA’s application to wellness plans and section 1635.8(b)(2) of the proposed regulation. These standards were issued in order to protect individuals from discrimination in the health plan context based on any individual health factor, including genetic information. Health plans have designed their wellness programs within these parameters, and the requirements under HIPAA offer a bright line test that both health plans and the Commission can follow.

Using the framework currently in place would make administration easier for both health plans and the Commission and would support the policy goals of GINA that neither a health plan nor employer should be able to use genetic information to discriminate against an individual.

Under this framework, we recommend that the Commission also look to the two categories of wellness programs: (1) health-based, and (2) participation-based. Having a "one size fits all" definition of "voluntary" that does not recognize these two categories would require every group health plan to re-examine their wellness programs and comply with two potentially conflicting standards under HIPAA and GINA.

For the first category – *health-based wellness programs* – we recommend that the Commission adopt the rule under the HIPAA wellness program regulations that a wellness program will be considered "voluntary" if the rewards under the program are limited to 20% of the cost of coverage. We understand that the Commission has considered this approach in recent guidance regarding health risk assessments for ADA purposes. Letter from Peggy R. Mastrianni, ADA: Disability-Related Inquiries and Medical Examinations; Health Risk Assessment (Mar. 6, 2009).

For the second category – *participation-based wellness programs* – we recommend that the Commission also adopt HIPAA's approach – that these wellness programs are subject to the HIPAA nondiscrimination requirements, but are not subject to the additional wellness program requirements. In this case, the health plan is not acting on any particular health standard or health information obtained, but is providing a reward merely on participation. The 20% limit would not apply, but the health plan still would be prohibited from any form of discrimination based on an individual's health factor. This category (along with the first category) would be dovetailed with the requirements already in GINA – that the individual authorizes participation (and such authorization includes required disclosures) and that any information obtained as part of the wellness program only may be used for purposes of the wellness program and may not be disclosed to the employer, except in aggregate form.

We also note that any information obtained in connection with a group health plan's wellness program is protected by the HIPAA privacy regulations. 45 CFR Parts 160-164. We understand that a legitimate concern under GINA (as well as the ADA) is that an employer not be able to access an individual's health information or use it to discriminate for employment purposes. The HIPAA privacy rules clearly apply to a wellness program that is part of a health plan. The privacy rules require that a health plan only may use or disclose individually identifiable health information for the health plan purposes of treatment, payment of benefits, or health care operations of the health plan. The HIPAA privacy rules prohibit the health plan from disclosing individually identifiable health information to the employer for an employment purpose; the plan only is permitted to disclose information to the employer for very specific plan purposes, such as administering the health plan or making plan design decisions (and

even then, the plan only may disclose certain minimally necessary information). *See* 45 CFR § 164.504(f).

In summary, we believe that information held by a health plan is protected from use for discriminatory purposes under the current framework of the HIPAA nondiscrimination and wellness rules, and further protected from being disclosed to the employer under the HIPAA privacy rules. As such, we recommend that the Commission build on this existing framework by adopting a safe harbor rule that a covered entity that complies with the HIPAA nondiscrimination and wellness program rules would be deemed to be in compliance with GINA.

Firewall Rule of Construction - Section §209(a)(2)(B) and (c)

Title I of GINA establishes comprehensive rules barring discrimination based on genetic information for group health plans (and insurers issuing group health insurance). Group health plans are broadly prohibited from using genetic information in setting plan premiums and contributions, requesting or requiring genetic testing, and collecting genetic information. There are detailed rules of construction and definitions that apply and there are specific new civil penalties added to both ERISA (and the PHSa) for violations of these new rules by health plans and insurers.

Section 202 of Title II of GINA makes it an unlawful employment practice for an "employer" to discriminate with respect to "compensation, and terms and conditions of employment" because of genetic information. Section 203, 204 and 205 of GINA establish parallel rules for employment agencies, labor organizations and training programs. Section 207 provides that the remedies under the Civil Rights Act will apply to violations of Title II. Because group health plans are likely to be viewed as part of an employee's "compensation and terms and conditions of employment," Title II of GINA created a risk that employers could face "double liability" associated with the group health plans that they sponsor. In response, Congress added the "firewall" rules of construction found in section 209(a)(2)(B) and (c) of GINA.

The intent of section 202 of Title II is to regulate the use of genetic information in the context of traditional employment practices (e.g., hiring, firing, promotions). It was not the goal of Title II to regulate the administration of group health plans that are sponsored by employers (and labor organizations) -- that is left up to Title I. The inclusion of the firewall makes it clear that employers are not subject to claims under Title II that are related to the terms of their group health plans and administration of such plans. The actions of group health plans, and the associated remedies, are exclusively regulated by Title I. Of course, since employers fund group health plans, and employers or their employees serve as fiduciaries to group health plans, they will be exposed to the civil remedies and penalties under ERISA for violation of Title I of GINA. But employers should not be subject to claims under both Title I and Title II for essentially the same actions.

Comment

The firewall rule of construction set out in section 209(a)(2)(B) and (c) of GINA is restated without much elaboration in sections 1635.11(b) and (c) of the proposed regulation. However, the Commission included a well worded clarifying statement in the preamble to the proposed regulation regarding the scope and nature of the GINA firewall which should be expanded upon in the final regulation. 74 Fed. Reg. at 9065.

In this regard, the preamble makes clear the Commission's view that there should be no "double liability" for employers that sponsor group health plans and that employer liability relating to group health plans under Title II should be limited to traditional employment claims, such as where an employer fires an employee based on anticipated high health care costs attributable to their genetic information. (Other examples of similar claims that the Commission might recognize under Title II might include circumstances where an employer fails to promote, fails to hire, or demotes an individual based on expected health insurance costs.) The preamble further clarifies that "acts or omissions relating to health plan" administration "remain subject to enforcement under Title I exclusively."

The Council recommends that the Commission restate its views on the firewall rule of construction in the preamble to the final regulation. More importantly, the Council recommends that the Commission include its interpretation in the text of section 1635.11(b) of the regulation itself. Inclusion in the actual regulation is needed to make certain that the Commission's interpretation of the firewall is given the full deference of a legislative rule, rather than the lesser deference that might be accorded to a preamble statement interpreting the statute and/or the regulation. *See, e.g., Langbecker v. Elec. Data Sys. Corp.*, 476 F.3d 299 (5th Cir. 2007) (Department of Labor preamble language commenting on the scope of section 404(c) of ERISA not accorded deference when left out of its section 404(c) regulation).

In order to add the Commission's interpretation directly to the regulation, we would suggest that the proposed section 1635.11(b) be revised so that the existing provision is renumbered as paragraph "(1) In general", with appropriate renumbering of the existing subparagraphs (1)–(4), and a new paragraph "(2) Application" be inserted at the end of subsection (b) that reads as follows –

(2) Application. The application of (b)(1) is intended to prevent causes of action under Title II of GINA from being asserted against covered entities regarding conduct that is the subject of regulation and enforcement under Title I of GINA or the specified genetic provisions for group health plan coverage under ERISA, the Public Health Service Act or the Internal Revenue Code. Covered entities are subject to causes of action under Title II of GINA when their conduct constitutes traditional employment based discrimination, such as firing an employee based on expected high health

claims based on genetic information. Acts or omissions relating to health plan eligibility, benefits, or premiums, or a health plan's request for or collection of genetic information are subject to enforcement exclusively under Title I of GINA.

* * *

The Council appreciates the opportunity to comment on the Commission's proposed regulations for implementation of Title II of GINA. Please do not hesitate to contact me at 202-289-6700 or kwilber@abcstaff.org with any questions or if we can be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "Kathryn Wilber". The signature is written in a cursive, flowing style.

Kathryn Wilber
Senior Counsel, Health Policy