National Business Group on Health®

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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

January 28, 2016

Submitted electronically via: www.regulations.gov

Bernadette Wilson, Acting Executive Officer
Executive Secretariat, Equal Employment Opportunity Commission
U.S. Equal Employment Opportunity Commission
131 M Street NE
Washington DC 20507

Re: RIN 3046-AB02 – Genetic Information Nondiscrimination Act of 2008

Dear Sir or Madam:

The National Business Group on Health is pleased to respond to the Equal Employment Opportunity Commission's proposed rule regarding Title II of the Genetic Information Nondiscrimination Act of 2008 as it relates to employer wellness programs.

The National Business Group on Health represents 427 primarily large employers, including 70 of the Fortune 100, who voluntarily provide group health plan coverage to over 55 million American employees, retirees, and their families. Our members employ and provide health coverage for employees under a wide variety of work arrangements, including full-time, part-time, seasonal, and temporary. They also often operate multiple lines of business in multiple states and tailor employee work and benefit arrangements to the specific needs of each employee population and line of business.

We commend the Commission's efforts to protect employees from employment discrimination based on genetic information, make regulatory requirements consistent with respect to wellness programs, and reduce administrative burden for employers. Therefore, we support the Commission's proposal to clarify that GINA does not prohibit an employer from offering an employee and spouse an inducement of up to 30% of the total annual cost of coverage for the plan in which the employee and any dependents are enrolled for providing information about current or past health status as part of a health risk assessment.

However, our members remain concerned that some of the Commission's proposals will impede innovation and increase administrative and cost burdens for wellness programs, with little or no benefit to plan participants. We strongly believe that the current HIPAA rules for wellness programs work well both for employers and for employees and protect participants from discrimination on the basis of genetic information. Therefore, we recommend that final regulations:

- **Maintain the distinction between participatory and health-contingent wellness programs such that the limit on wellness incentives does not apply to program components that only require participation, as opposed to a health activity or outcome;**

- **Eliminate apportionment rule in the proposed 29 C.F.R. § 1635.8(b)(2)(iv)(A);**

- **Maintain flexibility to offer wellness incentives for employees' children; and**

- **Provide that complying with the reasonable design standard under 29 C.F.R. § 2590.702(f)(3)(iii) and 29 C.F.R. § 2590.702(f)(4)(iii) will satisfy any reasonable design requirement under GINA.**

We believe that the above approach will allow plan sponsors to develop wellness programs that promote participants' health and productivity while protecting participants from discrimination based on genetic discrimination; promote efficient, uniform plan administration; and reduce the overall costs of health care for plan sponsors and participants. We provide further discussion of these recommendations and responses to the Commission's requests for comments below.

I. Incentive Limits under GINA and Other Federal Laws

As an initial matter, we emphasize the need for (1) clarity and consistency in federal requirements for wellness programs and (2) flexibility to offer innovative plan designs with meaningful incentives that improve employee health and engagement and lower the overall cost of health coverage. As our members continue to implement group health plan requirements under the ACA, ADA, GINA, and other statutes, one of employers' primary concerns is their ability to continue offering high-quality, comprehensive health coverage while complying with ever-increasing regulatory burdens.

Our members view wellness programs as critical tools in increasing participant engagement in health improvement and lowering overall health care costs and because of their large employee populations, are in a unique position to adopt innovative programs that help achieve these goals.[1] However, the risk of violating different regulatory requirements will have a chilling effect on these innovations. Therefore, the Commission's guidance and final regulations should not be overly prescriptive and limit newer program designs, such as those involving employees' family members.

To date, our members have complied in good faith with the wellness program requirements under HIPAA and the ACA, made reasonable accommodations for individuals with disabilities, as required by the ADA, and complied with both GINA and HIPAA regulations, which protect participants from discrimination on the basis of

[1] In our *Large Employers' 2015 Health Plan Design Survey*, 55% of survey respondents indicated that wellness initiatives to improve employee health were the one of the top 3 most effective steps taken to control health care cost increases. 53% of survey respondents indicated that they either have or will expand or increase wellness incentives to engage employees in wellness programs as a strategy for minimizing the ACA's excise tax on high cost health coverage, which will become effective in 2020.

genetic information. Therefore, we recommend that the Commission, in developing GINA guidance and regulations, retain the rules under HIPAA and the ACA to the maximum extent possible. Specifically:

- We recommend that the Commission maintain the distinction between participatory and health-contingent wellness programs such that the limit on wellness inducements does not apply to program components that only require participation, as opposed to a health activity or outcome.

- As noted above, we support the Commission's proposal to clarify that GINA does not prohibit an employer from offering an employee and spouse an inducement of up to 30% of the total annual cost of coverage for the plan in which the employee and any dependents are enrolled for providing information about current or past health status as part of a health risk assessment. Wellness incentives that involve spouses are increasingly popular and, based on our members' experience, have contributed to increased engagement by spouses as well as employees.

- In addition, engaging the entire household in wellness reinforces a healthy lifestyle at home and helps all members of the family improve health and make better health choices. For example, some of our members have adopted incentives to increase preventive care for children by offering incentives to complete well-baby visits. Other members offer incentives to participate in exercise programs to combat obesity for all family members. Therefore, we recommend that final regulations maintain flexibility for employers to offer incentives to all family members, including spouses and children.

II. Reasonable Design

As noted above, we believe that the current HIPAA rules for reasonable design and reasonable alternative standards in wellness programs work well both for employers and for employees. First, HIPAA regulations require that a wellness program be "reasonably designed to promote health or prevent disease" and that a wellness program satisfies this requirement if the program (1) has a reasonable chance of improving health or preventing disease, (2) is not overly burdensome, (3) is not a subterfuge for discriminating based on a health factor, and (4) is not highly suspect in methods chosen to promote health or prevent disease.[2] The regulations define "health factors" broadly to include health status, medical condition (including physical and mental illnesses), claims experience, receipt of health care, *genetic information*, evidence of insurability, and disability.[3] Thus, the current reasonable design requirement under HIPAA explicitly prohibits wellness programs from discriminating on the basis of genetic information.

To date, our members have complied in good faith with this rule. Adding another reasonable design requirement, as described in the proposed rule and Preamble, would

[2] 29 C.F.R. § 2590.702(f)(3)(iii); 29 C.F.R. § 2590.702(f)(4)(iii).

[3] 29 C.F.R. § 2590.702(a).

only cause confusion and increase compliance costs without adding meaningful protections for plan participants. We therefore recommend that final regulations either eliminate the proposed reasonable design requirement or provide that complying with the reasonable design standard under 29 C.F.R. § 2590.702(f)(3)(iii) and 29 C.F.R. § 2590.702(f)(4)(iii) will satisfy the reasonable design requirement under GINA.

III. Medical Professional Certification

Because current laws and regulations already prohibit discrimination on the basis of genetic information, it is unnecessary to require programs to offer similar incentives to participants who choose not to disclose information about current or past health and provide certification from a medical professional stating that the employee is under the care of a physician and that any medical risks identified by that physician are under active treatment. We believe that the current rules under HIPAA and the ACA offer ample opportunities for individuals to obtain incentives. Creating an additional "doctor's note" requirement would involve substantial administrative and cost burdens and would not support employers' efforts to develop comprehensive programs that increase employee engagement in health and productivity improvement.

IV. Authorization Requirement

As discussed above, our members support rules that allow for efficient, uniform plan administration. To the extent that the Commission is proposing to eliminate the authorization requirement for *all* plan participants when a wellness incentive is de minimis, we support this proposal.

V. Best Practices and Procedural Safeguards

We think it is important to address the misconception that wellness programs are designed to shift costs to individuals who have health impairments or stigmatized conditions. It is our members' experience that financial incentives such as premium surcharges do not result in substantial cost savings for group health plans. Wellness incentives take many forms, including premium discounts and surcharges, copayment and deductible waivers, health savings account and health reimbursement arrangement contributions, raffles, gift cards, and cash. These financial incentives generally form only part of a comprehensive wellness strategy. Rather than immediate cost savings, the goals for our members' wellness programs include:

- Improving participant health and productivity;
- Increasing workforce readiness and engagement;
- Lowering absenteeism;
- Improving workplace safety;
- Improving employee morale; and
- Reducing overall health care costs for employers and employees.

Additional requirements, such as procedural safeguards, would only limit plan sponsors' ability to modify wellness programs to improve health outcomes, increase participation, and lower overall health care costs in the future.

VI. Confidentiality and Privacy

Although many wellness programs do ask participants to provide health information that is stored electronically (most often through third party vendors), it is important to remember that existing privacy and security rules under HIPAA provide a strict and comprehensive set of protections for that information, including genetic information.

HIPAA's Security Rule establishes a national set of security standards for protecting health information that is held or transferred electronically. Under the Security Rule, any "covered entity" maintaining electronic protected health information—including a group health plan's wellness program and any third party vendors or health care providers that maintain information on behalf of a group health plan—must:

- Ensure the confidentiality, integrity, and availability of all ePHI it creates, receives, maintains, or transmits;
- Identify and protect against reasonably anticipated threats to the security or integrity of the information;
- Protect against reasonably anticipated, impermissible uses or disclosures; and
- Ensure compliance by its workforce.[4]

Likewise, HIPAA's Privacy Rule requires that covered entities, including group health plans and their wellness programs, not use or disclose protected health information (PHI)[5] unless the person who is the subject of that information authorizes such use or disclosure or unless the Privacy Rule explicitly permits or requires such use or disclosure.[6] The Privacy Rule also gives individuals specific enumerated rights with regard to their health information and how it is used.[7]

The Privacy Rule allows group health plans to share PHI with plan sponsors for plan administration functions. However, before plans can do so, they must receive certification from plan sponsors that plan documents have been amended to impose restrictions on the plan sponsors' use and disclosure of the PHI. These restrictions must include a representation that plan sponsors will not use or disclose the PHI for any employment-related action or decision or in connection with any other benefit plan.[8] As noted above, plan sponsors generally use third-party vendors to operate wellness programs. Under this arrangement, plan sponsors can receive health information about plan participants in the aggregate but will not receive individually identifiable health information.

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[4] 45 C.F.R. § 164.306(a).

[5] PHI generally includes any individually identifiable health information. *See* 45 C.F.R. § 160.103.

[6] 45 C.F.R. § 164.502.

[7] *See, e.g.*, 45 C.F.R. § 164.522 (right to request privacy protection for PHI); 45 C.F.R. § 164.524 (right to access PHI); 45 C.F.R. § 164.528 (right to accounting of disclosures of PHI).

[8] *See* 45 C.F.R. § 164.504(f).

In addition, under the Privacy Rule, a group health plan (including its wellness program) must:

- Designate a privacy official who is responsible for implementation and development of privacy policies and procedures;
- Train its employees on its privacy policies and procedures;
- Implement administrative, technical, and physical safeguards to protect the privacy of PHI;
- Provide a process for individuals to make complaints concerning the plan's privacy policies and procedures;
- Develop sanctions for employees or business partners who violate the plan's privacy policy or procedures;
- Mitigate, to the extent practicable, any harm that might occur from improper use or disclosure of PHI;
- Not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against individuals exercising their rights under the Privacy Rule or individuals participating in the filing of a complaint under the Privacy Rule;
- Not require individuals to waive their rights under the Privacy Rule as a condition of treatment, payment, enrollment in a health plan, or eligibility for benefits;
- Implement written policies and procedures with respect to PHI that are designed to comply with the Privacy Rule; and
- Maintain the policies and procedures above in written or electronic form, maintain copies of any communications required to be in writing by the Privacy Rule, maintain copies of any actions that the Privacy Rule requires to be documented, and retain any such copies or records for six years from the date of creation or the date last in effect, whichever is later.[9]

Our members devote considerable resources toward developing and implementing policies and procedures that protect all PHI—not just PHI provided through wellness programs. Given HIPAA's robust privacy protections, security rules, and enforcement mechanisms, we believe that additional requirements in GINA regulations related to confidentiality, privacy, and disclosure of genetic information would only create additional administrative and cost burdens without providing meaningful protection for participants.

VII. Wellness Programs Outside of a Group Health Plan

National Business Group on Health members employ and provide health benefits for employees in many different industries and work arrangements. To accommodate the health care needs of their large and varied employee populations, our members provide a wide variety of health plan options at different cost and coverage levels. Along with health plan options, many of our members offer and are expanding wellness programs with the goal of engaging their employee populations in health and productivity efforts. These wellness programs often involve a number of different components—which may be in or outside the group health plan context—such as:

[9] *See* 45 C.F.R. §§ 164.500-534.

- Disease management programs;
- On-site or near-site health clinics;
- Health risk assessments;
- Biometric screenings;
- Health coaching;
- Information campaigns on healthy lifestyles and nutrition;
- On-site exercise facilities and classes;
- Discounts or company subsidies for off-site exercise facilities and classes;
- Employee assistance programs that address physical and mental health, workplace stress, caregiving challenges, and other issues; and
- Employee fitness challenges such as exercise or weight loss competitions.

Guidance or final regulations should permit plan sponsors to continue offering incentives for wellness program activities outside the group health plan context without additional regulatory requirements. These types of activities—including exercise programs, weight loss challenges, and wellness-themed raffles and prizes—generally do not involve requests for genetic information and are not considered ERISA-covered group health plan benefits. However, they often form part of an overall wellness strategy and have proven effective in increasing employee engagement and participation in other health programs.

VIII. Effective Date

Finally, we recommend that in setting an effective date for final regulations, the EEOC consider the administrative requirements of large, self-insured group health plans. Most of our members implement plan design changes on a plan year basis, which may or may not coincide with the calendar year. In addition, because our members' plans (1) cover large populations, (2) often include different plan options and designs tailored to specific participant populations, and (3) often require coordination with multiple third-party administrators and vendors; our members tend to finalize any plan design changes up to a year before their implementation. Therefore, we recommend that any amendments to GINA regulations related to wellness programs become effective no earlier than the first day of the first plan year beginning 12 months after the issuance of final regulations, which would be consistent with other laws and regulations affecting employer-sponsored plans.

Thank you for considering our comments. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012 if you would like to discuss our comments in more detail.

Sincerely,

Brian Marcotte
President