



AMERICAN BENEFITS
COUNCIL

January 28, 2016

Submitted electronically via <http://www.regulations.gov>

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

Re: Proposed Rule – Genetic Information Nondiscrimination Act (RIN 3046-AB02)

Dear Ms. Wilson:

We write on behalf of the American Benefits Council (“Council”) to provide comment in connection with the proposed rule (“Proposed Rule”) published in the Federal Register on October 30, 2015 by the Equal Employment Opportunity Commission (“EEOC”). The Proposed Rule would amend the regulations implementing Title II of the Genetic Information Nondiscrimination Act of 2008 (“GINA”) as they relate to employer wellness programs. Specifically, the Proposed Rule addresses the extent to which an employer may offer an employee inducements for the employee’s spouse who is also a participant in the employer’s health plan to provide information about the spouse’s current or past health status as part of a health risk assessment (including a biometric screening) (collectively, “HRA”) administered in connection with the employer’s offer of health services as part of an employer-sponsored wellness program.

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 health and retirement plans that cover more than 100 million Americans.

As we have previously communicated to the EEOC in connection with our comments regarding the proposed rule issued last year by the EEOC under the Americans with Disabilities Act (“ADA”),¹ employers develop and implement wellness strategies with respect to their workforces to improve employee morale and productivity while reducing health care costs. According to the Kaiser Family Foundation’s Employer Health Benefits 2015 Annual Survey,² a majority of large employers offer health screening programs such as HRAs. Given the benefits of these programs for employers and employees, the Council believes that public policy should generally support private sector investment in wellness programs by ensuring employers the flexibility necessary for the design and administration of effective programs.

As discussed in the Council’s recent public policy strategic plan, *A 2020 Vision: Flexibility and the Future of Employee Benefits*, “[a] critical component of encouraging employers to offer meaningful wellness programs is consistent federal policy that promotes the health of Americans and is aligned across multiple agencies and Congress.” We agree with the EEOC’s expressed intent to coordinate any final regulations under the ADA and GINA with regard to wellness programs, given the current uncertainty that exists regarding how the ADA and GINA apply in the context of wellness programs. Most importantly, we strongly urge that any final rules issued under the ADA and GINA be consistent with existing federal laws regarding wellness programs, including, specifically, the rules applicable to wellness programs under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

Congress expressly ratified the existing federal regulatory framework regarding the offering of wellness program incentives by codifying, on a bi-partisan basis, as part of the Patient Protection and Affordable Care Act (“ACA”), the rules previously issued by the departments of Labor, Health and Human Services, and the Treasury (“Departments”) pertaining to wellness programs under HIPAA. Aligning any final rulemakings under the ADA and GINA with the HIPAA rules would help to create a consistent statutory and regulatory federal policy with respect to wellness programs.

As a threshold matter, we believe the EEOC lacks clear jurisdictional authority under Title II of GINA to regulate the design and operation of group health plans, as more fully discussed below. The firewall set forth in Title II of GINA was intended to ensure that employer conduct related to group health plan violations of GINA is the exclusive jurisdiction of Title I.

¹ See Council Comment Letter dated June 19, 2015, available at <http://www.americanbenefitscouncil.org/pub/a6c42d62-c584-b9d7-b53e-482954d95b7d>.

² Kaiser Family Foundation, *Employer Health Benefits 2015 Annual Survey*.

To the extent the EEOC nonetheless asserts jurisdiction and proceeds with this rulemaking, we provide specific comments below and summarize here:

- Final ADA and GINA rules should directly link any incentive limitations with those applicable under HIPAA so that they reflect any fluctuation in the limits imposed by HIPAA.
- The incentive permitted under GINA should equal 30% of the cost of enrolled coverage less the *actual* incentive available to the employee under the ADA (which may be less than 30% of the cost of self-only coverage), rather than 30% of the cost of enrolled coverage less the *maximum* incentive available to the employee under the ADA (which is 30% of the cost of self-only coverage).
- The final GINA rule should clarify that an incentive that is provided as a result of a spouse's completion of an HRA is attributable to such spousal action for purposes of GINA (and thus eligible for the GINA incentive limitation as opposed to the ADA incentive limitation applicable to employee action) regardless of how the incentive is made available (*e.g.*, a contribution to an employee's health savings account).
- The final GINA rule should allow an employee's adult child to receive an incentive for completing an HRA that requests information on such adult child's current or past health status.
- The final GINA rule should clarify that a single authorization by the employee will cover both the employee's completion of an HRA and the spouse's completion of an HRA, and that a separate spousal authorization is not required.
- Consistent with the Council's prior comments regarding the ADA, tobacco cessation programs should not be subject to any incentive limit under the final GINA rule. Rather, their incentive limits should be governed by HIPAA (if applicable).
- Wellness programs that are not part of a group health plan should not be subject to more onerous incentive limitations than those that are part of a group health plan. The Council believes that such wellness programs should not be subject to incentive limitations at all. However, if the EEOC believes that such programs should be subject to incentive limits for completion of spousal HRAs, they should be able to offer incentives that are at least as generous as those offered in connection with a wellness program that is part of a group health plan.

- The final GINA rule should not require employers to offer an incentive to persons who choose not to disclose requested information in any event.
- Sufficient procedural safeguards are already in place to ensure that wellness programs do not shift costs to employees with spouses who have health issues. Accordingly, the Council does not believe that any additional safeguards need to be included in the final GINA rule.
- HIPAA provides for sufficient data protection and adequately addresses privacy concerns in connection with wellness programs, particularly those offered as part of a group health plan. Accordingly, the Council does not believe the final GINA rule should specifically address data protection and privacy issues.
- The Council urges any final rule be made applicable no sooner than the first day of the plan year beginning on or after the date that is 12 months after issuance of both the ADA and GINA final rules. The EEOC should allow sufficient time for employers to bring their wellness programs into compliance with the final GINA rule before making the final rule applicable. In addition, the EEOC should establish an enforcement safe harbor for periods prior to the applicability date of the final rule.

BACKGROUND REGARDING LAWS AND GUIDANCE APPLICABLE TO WELLNESS PROGRAMS

Application of HIPAA and the ADA to Wellness Programs

The Council submitted a comment letter to the EEOC with regard to the proposed ADA rule. The letter includes a detailed discussion of the application of the ADA and HIPAA to wellness programs.³

Application of GINA to Wellness Programs

1. Summary of Statute and Prior Guidance

Title I of GINA prohibits discrimination based on genetic information in health coverage (i.e., discrimination based on genetic information by group health plans and health insurance issuers). Title I is the jurisdiction of the Departments and is not the focus of the Proposed Rule. Interim final rules implementing Title I were issued by the Departments in 2009 and do not specifically address the issue of spousal HRAs.

³ See Council Comment Letter dated June 19, 2015, available at <http://www.americanbenefitscouncil.org/pub/a6c42d62-c584-b9d7-b53e-482954d95b7d>.

Title II of GINA is the jurisdiction of the EEOC and restricts employers from requesting, requiring, or purchasing genetic information, with certain limited exceptions. For this purpose, “genetic information” includes (1) information about an individual’s genetic tests, (2) information about the genetic tests of a family member, (3) information about the manifestation of a disease or disorder in family members of an individual (i.e., family medical history), (4) requests for and receipt of genetic services by an individual or a family member, and (5) genetic information about a fetus carried by an individual or family member or of an embryo legally held by the individual or family member using assisted reproductive technology. For this purpose, “family member” includes a spouse.

An exception to the general prohibition on employers requesting, requiring, or purchasing genetic information is available to employers that offer health or genetic services, including those offered as part of wellness programs. Employers may request genetic information as part of these programs, so long as certain requirements are satisfied. Under the current GINA Title II regulations, a wellness program cannot condition inducements to employees on the provision of genetic information (based on the Title I prohibition against adjusting premium or contribution amounts based on genetic information).

As noted above, Title II of GINA is the jurisdiction of the EEOC and applies to employers. Title I of GINA regulates group health plans, *including with respect to the design and implementation of wellness programs*, and is subject to the jurisdiction of the Departments. Section 209(a)(2)(B)(i) of GINA Title II imposes an express “firewall” between Title I and Title II of GINA, stating that nothing in Title II “shall be construed to ... provide for enforcement of, or penalties for violation of, any requirement or prohibition applicable to any employer ... subject to enforcement for a violation under ... the amendments made by” Title I of GINA.

2. Summary of Proposed Rule

Under the Proposed Rule, an employer may offer, as part of its health plan, an inducement for an employee’s spouse’s “health information,” when the spouse (1) is covered under the employer’s health plan, (2) receives health or genetic services offered by the employer, including as part of a wellness program, and (3) provides information about his or her current or past health status as part of an HRA. However, no inducement may be offered in return for the spouse providing his or her own genetic information, including the results of his or her genetic tests.

The spousal HRA may take the form of a medical questionnaire, a medical examination (*e.g.*, blood pressure or glucose testing), or both, and it must otherwise satisfy the requirements applicable to employee HRAs under existing Title II rules, including that the spouse provide prior, knowing, voluntary, and written authorization

and that the authorization form describe the confidentiality prohibitions and restrictions on the disclosure of genetic information. It also has to be administered as part of the spouse's receipt of genetic services offered by the employer (e.g., participation in a wellness program).

The Proposed Rule outlines the maximum inducement that may be offered for spousal health information, based on the cost of coverage in which the employee is enrolled. The Proposed Rule does not, however, separately address the amount of inducement, if any, that may be offered for spousal health information for a wellness program that is not part of a group health plan.

Per the Proposed Rule, the total permitted inducement, together with any inducements permitted under the ADA proposed rule for an employee's participation in a wellness program that asks disability-related questions or requires medical examinations, may not exceed 30% of the total cost of the coverage under the plan in which an employee and the spouse are enrolled. The maximum amount of the inducement that may be attributable to the employee's spouse completing an HRA may not exceed 30% of the total cost of coverage for the plan in which the employee and spouse are enrolled, less 30% of the total cost of self-only coverage.

The Proposed Rule makes clear that no inducements may be offered for the provision of an employee's child's genetic information or health information. This would appear to apply to adult children as well as minor-age children. In addition, any health or genetic services in connection with which an employer requests the employee's genetic information (including the spouse's health information) must be reasonably designed to promote health or prevent disease.

SPECIFIC COMMENTS ON THE PROPOSED RULE

The EEOC Lacks Jurisdiction to Regulate Group Health Plan Conduct under Title II of GINA

As noted above, the Proposed Rule is expressly promulgated under the authority granted to the EEOC by Title II of GINA. Title II applies to employer conduct, and, per the terms of the statutory firewall, does not reach group health plans. Specifically, Section 209(a)(2)(B)(i) of GINA Title II states that nothing in Title II "shall be construed to ... provide for enforcement of, or penalties for violation of, any requirement or prohibition applicable to any employer ... subject to enforcement for a violation under ... the amendments made by" Title I of GINA. The express reference to "employer" in Section 209(a)(2)(B)(i) versus the "group health plan" should be read to clearly indicate that Congress intended for employer conduct, including with respect to the design and administration of a group health plan, to remain solely the purview of Title I. Accordingly, it is the Council's belief that, per Congress's pronouncement, the EEOC

should focus on employer conduct not otherwise part of, or connected to, the design and implementation of employer-sponsored group health plans (including wellness programs connected thereto), with the Departments retaining jurisdiction over group health plans and related employer conduct.

When Congress enacted GINA, it took the unique step of adopting Title II, which prohibits discrimination based on genetic information in *employment* while, at the same time, adopting via Title I of GINA a comprehensive scheme barring discrimination based on genetic information by *group health plans and issuers* under the Employee Retirement Income Security Act, the Internal Revenue Code, and the Public Health Service Act. The firewall was purposely enacted by Congress to clarify that Title I of GINA establishes the exclusive rules and remedies for genetic discrimination by group health plans or issuers and that Title II of GINA is not intended to be enforced against group health plans or to insurers.

The Council strongly urges the EEOC to reconsider its actions to enforce issues relating to spousal HRAs under group health plans and to promulgate rules relating to group health plans under Title II of GINA. Congress clearly intended the jurisdiction of Title I of GINA and Title II of GINA to be mutually exclusive so as to not expose employers to litigation under the separate titles for the very same acts (*e.g.*, the health plan, which is financed by the employer, and the employer are both sued for a health plan eligibility provision that violates GINA).

Nonetheless, to the extent that the EEOC believes it has statutory authority to issue rules regarding spousal HRAs that are part of a group health plan, below are the Council's comments on the Proposed Rule.

Clarification Regarding Determination and Application of the Incentive Limitation

As discussed above, the Proposed Rule provides that a covered entity may offer an inducement to an employee whose spouse (1) is covered under the employee's health plan, (2) receives health or genetic services offered by the employer, including as part of a wellness program, and (3) provides information about his or her current or past health status as part of an HRA or biometric screening.

The Proposed Rule provides that the total inducement to the employee and spouse may not exceed 30% of the total annual cost of coverage for the plan in which the employee and any dependents are enrolled. The Proposed Rule provides that the maximum share of the inducement attributable to the employee's participation in the wellness program is equal to 30% of the cost of self-only coverage (in line with the ADA proposed rule), and that the maximum share of the inducement attributable to the spouse's participation in the wellness program is equal to 30% of the total cost of coverage for the plan in which the employee and any dependents are enrolled minus 30% of the total cost of self-only coverage (*i.e.*, minus the maximum ADA incentive). In

addition, the Proposed Rule states that an incentive cannot be provided to an employee's child for the provision of information regarding his or her current or past health status.

1. Harmonization with HIPAA

The Council urges the EEOC to harmonize final rulemaking under GINA with not only the ADA, but also with existing HIPAA rules regarding the use of financial incentives.

As noted above, Congress largely codified the rules applicable to wellness programs under HIPAA as part of the ACA and, in fact, increased the maximum permitted incentive for such programs from 20% to 30%, and up to 50% where the Departments determine it is appropriate. The Departments have issued final regulations providing for an incentive limit equal to 30% of the cost of self-only coverage (or enrolled coverage if dependents may participate in the wellness program) and an increased incentive limit equal to 50% to the extent the excess relates to tobacco cessation programs. The Departments could, in future rulemaking, increase the incentive limit in other areas up to 50%.

The Council supports the 30% incentive limit under the Proposed Rule. We believe, however, that the incentive limit in any final rulemakings under GINA and/or the ADA should be directly linked to the HIPAA regulations such that the limits under GINA and/or the ADA will mirror any changes to the HIPAA limit. Congress granted the Departments authority to increase rewards under HIPAA to up to 50% of the total cost of coverage – which the regulators have done in the case of tobacco cessation programs. The discretion given to the Departments to increase the limit up to 50% reflects Congressional support for a higher limit for wellness programs.

As set out in the proposed rules, the incentive limit under the ADA and GINA would remain static even if the Departments increased the permitted incentives under HIPAA, resulting in a disconnect between the permitted incentives under HIPAA and the permitted incentives under the ADA and GINA. Accordingly, any such increase under HIPAA would essentially be rendered ineffective since employers would be bound by the lower ADA and GINA thresholds.

Consistent federal policy is critical to the promotion of employer-based wellness programs, and the EEOC should presume that Congress, in passing the HIPAA, ACA, ADA, and GINA statutes, did not intend for these laws or their regulatory implementation to conflict with each other.

In this regard, the Council requests that the maximum incentive limits for purposes of the ADA and GINA cross-reference the limitation imposed by the HIPAA regulations such that any such limits will fluctuate in accordance with any changes made by the

Departments to the HIPAA limitation. The HIPAA limit was statutorily enacted by Congress as part of the ACA, showing its broad support for wellness programs. The discretion given to the Departments to increase the limit up to 50% reflects Congressional support for a higher limit. A disconnect in the event that the Departments increase the HIPAA limit would be inconsistent with Congressional intent and create significant unnecessary administrative complexity for employers and group health plans.

2. The Incentive Limit Under GINA Should Only Be Reduced by the Actual Incentive Available Under the ADA

The Council requests clarification in final rulemaking that the incentive permitted under GINA equals 30% of the cost of enrolled coverage less the actual incentive available to the employee under the ADA (which may be less than 30% of the cost of self-only coverage), rather than 30% of the cost of enrolled coverage less the maximum incentive available to the employee under the ADA (which is 30% of the cost of self-only coverage). The text of the Proposed Rule appears to provide otherwise, which would create an even greater disconnect between the HIPAA incentive limits and those under the ADA and GINA. Such a result would be contrary to prior Congressional pronouncements in the ACA with respect to HIPAA that allow the maximum incentive with respect to the employee and the spouse to be 30% of the cost of enrolled family coverage.

3. An Incentive for Completion of a Spousal HRA Should Be Attributable to the Spouse

The Proposed Rule would apply incentive limits based on the use of spousal HRAs. Longstanding practice is to, in many instances, provide for a combined financial incentive, or, alternatively, distinct incentives, based on both the employee's and the spouse's actions with regard to a wellness program. Such an incentive is frequently credited to a common fund or a notional account in the name of the employee, such as a health savings account or a health reimbursement account. The Council requests clarification that, in determining compliance with any incentive limitation under GINA, the amount attributable to the spouse versus the employee will be the additional incentive provided as a result of the spouse's actions without regard to the form of the incentive or where it is credited.

4. Adult Children Should Be Eligible for an Incentive upon Completion of an HRA

As noted above, the Proposed Rule does not permit incentives to be provided to employees' children for completion of an HRA that requests information regarding current or past health status of the employee, including adult children.

The Council urges the EEOC to expand its rule regarding spousal incentives to also include adult children. Although the Council understands that the link between an employee's genetic information and a child's genetic information is greater than that between an employee's genetic information and a spouse's genetic information, we believe the benefits of incentivizing adult children to participate in wellness programs outweigh the potential downsides of collecting such children's information – the objectives of a wellness program are better served where an incentive may be offered to all participating individuals who have reached the age of majority. The same policy argument that should allow for the use of permitted financial incentives with respect to spousal HRAs applies with respect to adult children. As described below, it is the act of completing the HRA that is of the greatest value, because it is in completing the HRA that the individual considers his or her own health status, medical needs, fitness and eating habits, and general well-being. The value and benefit of completing the HRA applies with equal force to adult children as to a spouse.

Further, given the Congressional mandate as part of the ACA that employers must allow adult children up to age 26 to enroll in employer-sponsored plans, the Council believes those adult children should be entitled to fully participate in, and benefit from, all aspects of the health and wellness benefits offered by the employer, including any wellness programs. If an adult child were not enrolled in his or her parent's coverage, he or she would be a primary enrollee in another plan and eligible to participate in any HRA (and receive any incentive) offered under such other plan. Accordingly, the Council urges the adoption of a rule that would allow the use of incentives with respect to adult-age children (i.e., children who have attained the age of 18).

Employers fully understand that they are not to use genetic information to discriminate against an employee or his or her family members, and there are very significant existing safeguards in place to keep employers from engaging in such prohibited conduct.

A Separate Prior, Written Authorization by the Spouse Should Not Be Required

The Proposed Rule provides that the HRA must otherwise comply with the already existing requirements of 29 CFR § 1635.8(b)(2)(i) (i.e., the written authorization requirement in the current GINA regulations) in the same manner as if completed by the employee. Among other things, current 29 CFR § 1635.8(b)(2)(i) requires that an individual provide prior knowing, voluntary, and written authorization, which may include authorization in electronic format. The preamble to the Proposed Rule states that a separate authorization for the acquisition of this information from the employee is not necessary, but is needed from the spouse.

The Council urges the EEOC to provide in final rulemaking that a separate authorization by the spouse is not required. Any such required authorization would unduly complicate the operation of wellness programs by adding yet another

administrative burden to the administration of a wellness program. As an alternative, the Council requests that the EEOC provide as part of final rules that only one authorization by the employee is necessary for the use of both an employee HRA and a spousal HRA so long as the authorization makes clear to the employee that the program will also be requesting permitted health information from the spouse.

In response to the EEOC's specific request for comments on whether the proposed authorization requirement should apply only to wellness programs that offer more than de minimis rewards or penalties to employees whose spouses provide information about current or past health status as part of an HRA, the Council reiterates its belief that a separate authorization requirement should not apply to spousal HRAs at all. In such case, a definition of "de minimis" would not be necessary.

Application to Tobacco-Related Programs

The ADA proposed rule states in interpretive guidance that tobacco cessation programs that do not include disability-related inquiries or medical examinations are not subject to the incentive limits imposed by the ADA proposed rule and may instead utilize a higher limit as allowed by HIPAA regulations.

The GINA Proposed Rule's discussion regarding tobacco cessation programs is limited to a footnote in the preamble, which states that "[a] smoking cessation program that asks employees whether they use tobacco (or whether they ceased using tobacco upon completion of the program) or requires blood tests to determine nicotine levels is not a wellness program that requests genetic information and is therefore not covered by" the Proposed Rule.

The Council requests that the EEOC make clear for purposes of GINA as well as the ADA that all tobacco-related programs can use the higher 50% incentive limitation permitted by HIPAA (to the extent subject thereto) regardless of whether the program uses a biometric screening or a diagnostic test or collects genetic information. As discussed in the Council's comments regarding the proposed ADA regulations, the line-drawing engaged in by the EEOC is unduly restrictive and unnecessary. The EEOC clearly has the authority to permit all tobacco-related programs to utilize a 50% incentive limitation, and we encourage the EEOC to use its authority to provide as much.

If the EEOC does not allow all tobacco-related programs to use the higher 50% incentive limitation, then, at minimum, the Council requests that the EEOC include the text of the aforementioned footnote (providing that a program that asks employees whether they use tobacco or tests for nicotine levels is not a request for genetic information and therefore not subject to the GINA incentive limits) in the text of any final rulemaking and clarify that the same conclusion holds true where a spouse is the individual participating in the tobacco-related program as opposed to the employee.

Permitted Level of Incentives in Wellness Programs Offered Outside of the Group Health Plan Context

The incentive limit imposed by the Proposed Rule appears to apply, by its terms, only to wellness programs offered in connection with a group health plan. Specifically, the Proposed Rule states that “a covered entity may offer, *as part of its health plan*, an inducement” for completion of a spousal HRA that requests information about the spouse’s current or past health status. The Proposed Rule does not address what incentive, if any, may be offered with respect to wellness programs that are offered outside of a group health plan. In this regard, the EEOC specifically requests comment regarding the extent to which the GINA regulations should allow inducements provided as part of wellness programs offered outside of a group health plan.

Consistent with our prior comments regarding the proposed ADA regulations, the Council urges the adoption of final ADA and GINA rules that would not impose a cap on the use of financial incentives with respect to programs that are not part of a group health plan so long as the wellness programs are reasonably designed as otherwise required by HIPAA and the proposed ADA and GINA rules and meet all other applicable requirements under HIPAA, the ADA, GINA, and other federal laws.

If the EEOC concludes that incentive limits should apply to wellness programs that are not part of a group health plan, then the Council believes that employers that sponsor stand-alone wellness programs should be able to use meaningful incentives in connection with their programs to encourage wellness program participation. Wellness programs offered outside of the group health plan context offer valuable benefits to employees and their dependents and should not be treated more onerously than programs offered under group health plans. Accordingly, any limitations made applicable to incentives under stand-alone wellness programs should be no more restrictive than those that apply to wellness programs offered as part of a group health plan.

Persons Who Choose to Not Disclose Requested Information

The EEOC has specifically requested comment on whether employers that offer inducements to encourage the spouses of employees to disclose information about current or past health status must also offer similar inducements to persons who choose not to disclose such information but instead provide certification from a medical professional stating that the spouse is under the care of a physician and that any medical risks identified by that physician are under active treatment.

The Council strongly recommends that the EEOC not adopt such a rule. To the extent a wellness program is a health-contingent program, reasonable alternative standards are already required to be offered under HIPAA. To the extent that a

program is a participatory program, inviting a spouse to merely disclose information in order to obtain an incentive will not harm the spouse. It is the act of considering one's own health status as part of completing the HRA itself that has significant value – value in helping individuals assess their health conditions, medical needs, food and exercise habits, etc. To implement a rule that allows individuals to avoid completing the HRA would completely undermine the use and efficacy of HRAs and, therefore, should be avoided.

Existing federal laws provide robust protections against the prohibited use and safekeeping of this information. As discussed above, under GINA, an employer is prohibited from using such information to adversely affect the employee's employment or the spouse's health coverage. Additionally, other existing requirements, such as the "reasonable design" requirement set forth in the Proposed Rule, should ensure that the design of participatory programs is reasonable and not harmful to spouses who complete an HRA in connection with a participatory wellness program.

Employers Already Have Sufficient Procedural Safeguards in Place to Ensure that Wellness Programs Do Not Shift Costs to Employees with Spouses Who Have Health Issues

The EEOC specifically requests comments regarding which best practices or procedural safeguards ensure that employer-sponsored wellness programs are designed to promote health or prevent disease and do not operate to shift costs to employees with spouses who have health impairments or stigmatized conditions. Employers utilize a number of best practices or procedural safeguards to ensure that wellness programs are appropriately designed. Compliance with HIPAA, GINA, and the ADA already ensures a sufficient level of protection for employees and program participants. For example, under the HIPAA final rules and under the proposed rules under GINA and the ADA, employers must take care to ensure that programs are reasonably designed to promote health and prevent disease. In addition, with respect to health-contingent programs, HIPAA imposes strict rules on plans in order for such plans to be able to offer a reward.

Regulation of wellness program design, including the establishment of additional procedural rules, goes beyond the intent of GINA, which only focuses on preventing discrimination based on genetic information. We are concerned that any such additional measures would serve to merely increase costs and administrative burdens with respect to wellness programs or lead to reduced utilization.

HIPAA Provides for Sufficient Data Protection and Adequately Addresses Privacy Concerns

The EEOC has specifically requested comment as to whether any final rulemaking under GINA should include more specific guidance to employers regarding how to implement the requirements of [29 CFR § 1635.9\(a\)](#) (e.g., relating to confidentiality of

genetic information) for electronically stored records, and, if so, what procedures are needed to achieve GINA's goal of ensuring the confidentiality of genetic information with respect to electronic records stored by employers.

[29 CFR § 1635.9](#)(a) provides rules regarding the treatment of genetic information that is possessed by a covered entity. Among other things, it requires that genetic information must be maintained separately from personnel files and treated as a confidential medical record. Particularly given that the proposed rule is limited to wellness programs offered in connection with group health plans, the Council believes that HIPAA already imposes more than sufficient data privacy and security requirements. Accordingly, the Council urges the EEOC to provide that, to the extent relevant, compliance with HIPAA's privacy rules will constitute compliance with any privacy rules under GINA.

The EEOC also requests comment regarding whether there are best practices or procedural safeguards to ensure that information about spouses' current health status is protected from disclosure. Again, current employer practices as well as applicable laws and guidance provide sufficient protection for information about spouses' current health status.

Finally, the EEOC has requested comment as to whether any final rulemaking should restrict collection of genetic information to the minimum necessary to directly support the specific program activities. The Council does not believe any specific restriction is necessary, as employers and group health plans are already sufficiently hesitant to collect more information than is needed to carry out the wellness program objectives. The Council believes that the current framework of the ADA and GINA adequately limit the information that may be collected as part of a wellness program and encourages the EEOC to allow wellness programs to continue to request sufficient information to allow employers to understand health trends among their populations.

Sufficient Time Is Needed to Comply with Final Rules and an Enforcement Safe Harbor Is Needed Prior to the Effective Date

It is unclear when any final rulemaking under GINA would become effective. It is also unclear whether and to what extent the EEOC may apply the Proposed Rule in proposed form in the course of undertaking enforcement actions. The Council urges that any final rulemaking not take effect before the first day of the plan year beginning on or after the date that is 12 months after issuance of both the ADA and GINA final rules. Such a rule is needed to give employers time to come into compliance with any new final rules. Additionally, decisions regarding benefit design (including with respect to wellness programs) are made many months (and frequently a year) in advance of the beginning of a plan year.

The Council also requests the EEOC provide a non-enforcement safe harbor under which employers will not run the risk of an EEOC enforcement action based upon this rulemaking project until the final rules become effective. The issuance of such a non-enforcement safe harbor is supported by sound public policy as employers should not be compelled to defend costly enforcement actions against plans that were designed and implemented prior to the promulgation and application of final rules.

* * *

Thank you for considering these comments submitted in response to the Proposed Rule. If you have any questions or would like to discuss these comments further, please contact us at (202) 289-6700.

Sincerely,



Katy Spangler
Senior Vice President
Health Policy



Kathryn Wilber
Senior Counsel
Health Policy