May 17, 2016

SUMMARY OF EEOC FINAL REGULATIONS GOVERNING TREATMENT OF WELLNESS PROGRAMS UNDER ADA AND GINA

On May 16, 2016, the U.S. Equal Employment Opportunity Commission (EEOC) released long-awaited final wellness plan regulations under Title I of the Americans with Disabilities Act (ADA) and under Title II of the Genetic Information Nondiscrimination Act (GINA).

In addition to the final regulations themselves, the EEOC also released:

- A news release announcing the issuances
- A question-and-answer document on the ADA rules
- A question-and-answer document on the GINA rules

While the final regulations provide important guidance as to how employer wellness programs can comply with the ADA and GINA, there are areas where the regulations do not align with existing HIPAA wellness plans rules as discussed below. These are areas where the Council will continue to advocate for greater consistency of federal wellness plan regulation.

Both the ADA and GINA regulations were published in the Federal Register on May 17, 2016. The EEOC previously issued proposed regulations with respect to ADA and GINA on April 20, 2015, and October 30, 2015, respectively. The Council submitted extensive comments with respect to both proposed rules on a range of issues of concern to plan sponsors:

- Council Comments to EEOC on Proposed Regulations Regarding Wellness Programs and the Americans with Disabilities Act

- Council Letter to EEOC Regarding Proposed GINA Title II Regulations

The final regulations' new notice requirements and rules regarding the use of financial inducements will apply to plan years beginning on or after January 1, 2017. According

to the EEOC, the rest of the provisions in the final regulations clarify existing obligations and apply both before and after the publication of the final regulation.

ADA Final Regulations

The final ADA rule addresses the extent to which employers may use incentives to encourage employees to participate in wellness programs that ask them to respond to disability-related inquiries and/or undergo medical examinations under the ADA. Such inquiries or medical examinations would include medical questionnaires, health risk assessments (HRAs) and biometric screening.

The incentive limits in the final rule apply regardless of whether the wellness program is:

1. offered only to employees enrolled in an employer-sponsored group health plan,
2. offered to all employees whether or not they are enrolled in such a plan, or
3. offered as a benefit of employment where an employer does not sponsor a group health plan or group health insurance coverage.

Key provisions of the final ADA regulations include:

Application limited to programs involving a disability-related inquiry or medical examination: The final rule makes clear that *all* of the provisions of the final rule, including the requirement to provide a notice and limitations on incentives, apply to all employee health programs that ask employees to respond to disability-related inquiries and/or undergo medical examinations – regardless of whether they are included as part of a group health plan or a stand-alone wellness program. Significantly, wellness programs that *do not include* disability-related inquiries or medical examinations are not subject to this final rule, although such programs must be available to all employees and must provide reasonable accommodations to employees with disabilities.

The wellness program must be reasonably designed: The final rule imposes a requirement that each wellness program be reasonably designed. This requirement is similar to that imposed under HIPAA with respect to health-contingent programs – however, the ADA's reasonable design requirement applies not only to health-contingent programs, but also participatory-only programs as well.

Generally, to be reasonably designed, the program must have a reasonable chance of improving the health of, or preventing disease in, participating employees and must not be overly burdensome, a subterfuge for violating the ADA or other laws prohibiting employment discrimination, or highly suspect in the method chosen to promote health or prevent disease. Imposing a penalty on an individual solely for failing to achieve a particular health outcome "would, in many instances, discriminate against individuals based on disability." Additionally, programs consisting of a measurement, test,

screening, or collection of health-related information "without providing results, follow-up information, or advice designed to improve the health of participating employees, would not be reasonably designed to promote health or prevent disease, unless the collected information actually is used to design a program that addresses at least a subset of conditions identified."

The program must be voluntary: As with the proposed rule, the final rule also requires that a program be "voluntary." To be a voluntary program:

- An employer may not require employees to participate in the program (unchanged from proposed rule).

- An employer may not deny coverage under any group health plan to employees for non-participation (unchanged from proposed rule) or limit the extent of benefits (except for permitted incentives subject to limitations, described below).

- An employer may not take any adverse action, retaliate against, or coerce employees who choose not to participate (unchanged from proposed rule).

- An employer must satisfy a specific notice requirement (described below; applicability is different from that specified in proposed rule).

Cannot deny access to a group health plan for failure to participate in the wellness program: As part of the "voluntary" requirement described above, the final rule provides that a program *cannot* deny access to a group health plan to an employee solely because he or she fails to participate in a wellness program. This requirement could limit the ability to design a wellness program that bases eligibility for a particular health plan on completing and HRA or undergoing biometric screenings (sometimes called "gateway plans").

New ADA incentive limitations generally do not align with HIPAA's rules: The final rule reaffirms that an employer may offer incentives, whether in the form of a reward or penalty, to promote an employee's participation in a wellness program that includes disability-related inquiries and/or medical examinations as long as participation is voluntary. However, the final rule limits the use of incentives *with respect to the employee only* to no more than 30% of the total cost of self-only coverage in which the employee is enrolled (as discussed below). The final rule does not govern the financial incentives used with respect to the spouse (however, the final GINA rule does limit the use of incentives with respect to spousal health risk assessments (HRAs). The final rule does not impose an affordability standard as was suggested as a possibility in the proposed rule and does not exempt the value of de minimis incentives from the 30% limit on incentives for wellness programs that include disability-related questions and/or medical examinations.

Calculation of incentive limitations:

- Where participation in a wellness program depends on enrollment in a particular group health plan, the employer may offer an incentive of up to 30% of the total cost of self-only coverage under that plan.

- Where an employer offers a single group health plan but participation in the wellness program does not depend on the employee's enrollment in that plan, an employer may offer an incentive of up to 30% of the total cost of self-only coverage under that plan.

- Where an employer has more than one group health plan but participation in the wellness program does not depend on the employee's enrollment in any plan, the employer may offer an incentive of up to 30% of the total cost of the lowest cost self-only coverage under a major medical group health plan offered by the employer.

- Where an employer does not offer a group health plan or group health insurance coverage the rule uses the cost of the second-lowest cost Silver Plan for a 40-year-old non-smoker available through the exchange in the location that the employer identifies as its principal place of business as a benchmark for setting the incentive limit.

Incentives for tobacco cessation programs: The final rule, like the proposed rule, provides that a smoking cessation program that merely asks employees whether or not they use tobacco (or ceased using tobacco up on completion of a program) is not an employee health program that includes disability-related inquiries or medical examinations and thus the 30% incentive limit does not apply. Under the final ADA regulations, any biometric screening or other medical procedure that tests for the presence of nicotine or tobacco would be subject to the 30% incentive limit. This is lower than the 50% incentive limit for tobacco cessation programs currently permitted under HIPAA regulations.

Enhanced notice requirement: The final rule requires an employer to provide a notice that is written in language reasonably likely to be understood by the employee from whom the medical information is being obtained and that clearly explains what medical information will be obtained, how the medical information will be used, who will receive the medical information, the restrictions on its disclosure, and the methods the covered entity uses to prevent improper disclosure of medical information. This requirement applies to all wellness programs that ask employees to respond to disability-related inquiries and/or undergo medical examinations; regardless of whether such programs relate to a group health plan (this is a change from the proposed rule, which would have applied the notice requirement only to wellness programs offered in connection with group health plans). The EEOC will be posting a sample notice on its website within 30 days of the final rule's publication.

Confidentiality requirements: In addition to existing requirements, information obtained in connection with an employee health program subject to the final rule regarding the medical information or history of any individual may only be provided to an ADA covered entity in aggregate terms that do not disclose, or are not reasonably likely to disclose, the identity of any employee. In addition, an employer cannot require an employee to agree to the sale, exchange, sharing, transfer or other disclosure of medical information (with certain exceptions) or to waive any confidentiality provisions in this part as a condition for participating in a wellness program or earning any related incentive.

Application of other EEOC-enforced nondiscrimination rules: The preamble provides that compliance with the final rule does not relieve a covered entity of its obligation to comply with other employment nondiscrimination laws. In addition, even if an employer's wellness program complies with the incentive limits set forth in these regulations, the employer would violate Title VII or the ADEA if the program discriminates on the basis of race, sex (including pregnancy, gender identity, transgender status, and sexual orientation), national origin, age, or any other grounds prohibited by those statutes. Finally, the preamble notes that if a wellness program requirement (such as achieving a particular blood pressure) disproportionately affects individuals on the basis of some protected characteristic, an employer may be able to avoid a disparate impact claim by offering and providing a reasonable alternative standard.

EEOC interpretation of the ADA's statutory "bona fide benefit plan" safe harbor: The statutory text of the ADA contains a safe harbor for "bona fide benefit plans." The safe harbor provision states, in part, that an insurer or any entity that administers benefit plans is not prohibited from "establishing, sponsoring, observing or administering the terms of a bona fide benefit plan based on underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with state law." In the preamble, the regulatory text, and the interpretive guidance accompanying the final regulations, the EEOC asserts its authority to interpret the bona fide benefit plan safe harbor and reaffirms its position that the safe harbor does not apply to an employer's decision to offer rewards or impose penalties in connection with wellness programs that include disability-related inquiries or medical examinations.

Courts have, in recent years, applied the bona fide benefit plan safe harbor in the context of employer-sponsored wellness programs. In *Seff v. Broward County* and most recently, *EEOC v. Flambeau, Inc*, the courts ruled in favor of employers, holding that the ADA safe harbor applied to employer wellness plans. An appeal in *Flambeau* by the EEOC is currently pending with U.S. Court of Appeals for the Seventh Circuit. The Council is submitting an amicus brief in support of the argument that the lower court correctly held that the safe harbor does apply to employer wellness plans.

GINA FINAL REGULATIONS

The GINA final regulations issued on May 16, 2016 resolve a long-standing question regarding the extent to which an employer may offer an incentive to an employee for the employee's spouse to provide information about the spouse's health status on a health risk assessment (HRA). The regulations clarify that employers may provide a limited inducement to an employee whose spouse provides current or past health status information as part of a wellness program.

GINA's statutory text (and related implementing regulations) defines "genetic information" to include medical information with respect to a "family member" – the latter of which was defined by Congress to include an individual's "spouse". There has been on-going uncertainty as to whether providing a financial incentive to a spouse to complete an HRA regarding the spouse's own medical information could constitute genetic information to the employee/individual. The final regulations make clear that such practices generally will not give rise to a GINA violation so long as the requirements of the final rule are satisfied.

The GINA final rule regarding the use incentive limitations in connection with spousal HRAs is applicable for plan years beginning on or after January 1, 2017. The guidance states that other parts of the rule that are clarifications of existing obligations, such as provisions requiring confidentiality of current or past health status information about employees' spouses and other genetic information about employees and their family members, already apply to wellness programs.

Key provisions of the final GINA regulations include:

The final GINA rule applies broadly to wellness programs whether offered as part of a group health plan: The preamble states that the EEOC has decided that all of the provisions in this rule apply to all employer-sponsored wellness programs that request genetic information. This means that the final rule applies to employer-sponsored wellness programs regardless of whether they are related to a group health plan.

Reasonable design requirement: The final rule retains the provision providing that employers may request, require, or purchase genetic information as part of health or genetic services only when those services, including any acquisition of genetic information that is part of those services, are "reasonably designed" to promote health or prevent disease. Notably, the final rule clarifies that programs consisting of a measurement, test, screening, or collection of health-related information without providing results, follow-up information, or advice designed to improve the participant's health would not be reasonably designed to promote health or prevent disease, unless the collected information is actually used to design a program that addresses at least a subset of conditions identified.

The final rule imposes maximum incentive limitations that mirror ADA limits for employee incentives: However, they do not align with existing HIPAA rules. The final ADA rule limits the maximum share of the inducement attributable to the employee's participation in an employer-sponsored wellness program (or multiple employer-sponsored wellness programs that request such information) to no more than 30% of the cost of self-only coverage. The maximum total inducement for a spouse to provide information about his or her manifestation of a disease or disorder will also be 30% of the total cost of (employee) self-only coverage, so that the combined total inducement will be no more than twice the cost of 30% of self-only coverage.

Notably, the final rule differs from the proposed rule, which would have allowed an incentive attributable to the spouse's completion of an HRA equal to 30% of the cost of enrolled coverage less 30% of the cost of self-only coverage. In making the change, the EEOC noted that the proposed rule's apportionment rules were overly complicated and sent the wrong message about the value of employer-sponsored wellness programs for each participating individual. Under the final rule, the maximum incentive that may be attributable to completion of a spousal HRA will equal the maximum incentive that may be attributable to an employee's answering disability-related inquiries and/or undergoing a medical examination.

Under the final rule, incentives for completion of a spousal HRA may not exceed 30% of the total cost of:

- Self-only coverage under the group health plan in which the employee is enrolled, if enrollment in the plan is a condition for participation in the wellness program;

- Self-only coverage under the group health plan offered by the employer, where the employer offers a single group health plan, but participation in a wellness program does not depend on the employee's or spouse's enrollment in that plan;

- The lowest cost self-only coverage under a major medical group health plan offered by the employer, where the employer has more than one group health plan, but enrollment in a particular plan is not a condition for participating in the wellness program; or

- The second lowest cost Silver Plan available on the Exchange for a 40-year-old nonsmoker in the location that the employer identifies as its principal place of business if the employer offers no group health plan.

As with final ADA rule, cannot deny access to group health plan coverage solely for failure to complete an HRA: The final rule contains a clarification that it is a violation of Title II of GINA for an employer to deny access to health insurance or any package of health insurance benefits to an employee and/or his or her family members, or to

retaliate against an employee, based on a spouse's refusal to provide information about his or her manifestation of disease or disorder to an employer-sponsored wellness program.

Cannot provide any financial incentives for use with child HRAs: The final rule provides that no inducements are permitted in return for information about the manifestation of disease or disorder of an employee's children and makes no distinction between adult and minor children or between biological and adopted children. The final rule makes clear that the prohibition extends to adult children.

Cannot provide financial inducement for spouse to provide his or her own genetic information, including genetic tests: The final rule reiterates the long-standing prohibition on providing an inducement in exchange for a spouse (or other) providing his or her own genetic information, including results of his or her genetic tests.

Final rule confirms that information regarding tobacco use is not genetic information: The rules prohibiting the use of inducements apply only to health and genetic services that request genetic information. The final rule confirms that an employer-sponsored wellness program does not request genetic information when it asks the spouse of an employee whether he or she uses tobacco or ceased using tobacco upon completion of a wellness program or when it requires a spouse to take a blood test to determine nicotine levels, as these are not requests for information about the spouse's manifestation of disease or disorder.

Generally no change to existing rules regarding notice and authorization: The final GINA rule reaffirms that when an employer offers an employee an inducement in return for his or her spouse's providing information about the spouse's manifestation of disease or disorder as part of an HRA, the HRA must otherwise comply with the written authorization requirements already applicable to the employee in the same manner as if completed by the employee, including the requirement that the spouse provide prior knowing, voluntary, and written authorization when the spouse is providing his or her own genetic information, and the requirement that the authorization form describe the confidentiality protections and restrictions on the disclosure of genetic information.

The employer must also obtain authorization from the spouse when collecting information about the spouse's manifestation of a disease or disorder, although a separate authorization for the acquisition of this information from the employee is not necessary.

Programs that offer "de minimis" inducements are not excluded from the authorization requirement of the rule. The EEOC notes in the preamble that no commenters offered a workable principle that could be used as the basis for defining which inducements are de minimis and which are not.

Cannot condition receipt of inducement on waiver of confidentiality protections: The final rule prohibits a covered entity from conditioning participation in an employer-sponsored wellness program or an inducement on an employee, an employee's spouse or other covered dependent agreeing to the sale, exchange, sharing, transfer, or other disclosure of genetic information (with limited exception) or waiving certain protections.