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BENEFITS BRIEF

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EEOC Releases Final Rules on Wellness Programs

On May 17, 2016, the Equal Employment Opportunity Commission ("EEOC") published a final rule on wellness programs under the Americans with Disabilities Act ("ADA") (81 Fed. Reg. 31126) as well as a companion rule under the Genetic Information Nondiscrimination Act ("GINA") (81 Fed. Reg. 31143).

The final rule under the ADA addresses the extent to which employers may use incentives to encourage employees to participate in wellness programs that include disability-related inquiries and/or medical examinations. It generally finalizes, with some notable changes, the provisions of the proposed rule, issued in April 2015.[1] The final rule under GINA addresses the extent to which employers may offer employees inducements where the employee's spouse completes a health risk assessment and/or takes a biometric screening (together, an "HRA"). It generally finalizes, with some significant changes, the provisions of the proposed rule, issued in October 2015.[2]

Both final rules apply to employee health programs broadly, regardless of whether they are part of a group health plan or a stand-alone wellness program. In addition, the incentive limit applies 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. As discussed below, the incentive limit also applies regardless of whether the program is a participation-only or health contingent program for purposes of the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA").

Background

1. Application of the ADA to Wellness Programs

The ADA generally prohibits an employer from making disability-related inquiries or requiring medical examinations. There are, however, two notable statutory exceptions to this limitation.

The first exception permits voluntary medical examinations and medical histories that are part of an employee health program (including wellness programs) available to employees at the work site. EEOC enforcement guidance issued in 2000 indicates that a program is "voluntary" if the employer neither requires participation nor penalizes employees who do not participate. The final rule, discussed below, discusses the criteria wellness programs must satisfy in order to be considered "voluntary."

[1] *See* Groom Benefits Brief, EEOC Releases Proposed Rule on Wellness Programs (April 27, 2015), available at http://www.groom.com/resources-965.html.

[2] *See* Groom Benefits Brief, EEOC Releases Proposed GINA Rule on Wellness Programs (Nov. 19, 2015), available at http://www.groom.com/resources-1016.html.

The second exception is a safe harbor for "bona fide benefit plans". The safe harbor provision of the ADA states, in pertinent 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." Courts have, in recent years, applied the bona fide benefit plan safe harbor in the context of wellness programs to find that the program at issue did not violate the ADA. *See Seff v. Broward County*, 691 F.3d 1221 (11th Cir. 2012), and *EEOC v. Flambeau, Inc*., 131 F.Supp.3d 849 (W.D. Wis. 2015). In the preamble to the final rule and in the final rule itself, 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. It will be very interesting to see the extent to which trial courts defer to the EEOC's interpretation of the bona fide benefit plan safe harbor as being unavailable to employers in defense of their wellness programs.

2. Application of Title II of GINA to Wellness Programs

Among other things, Title II of GINA restricts employers from requesting, requiring, or purchasing genetic information, with certain limited exceptions. "Genetic information" includes, among other things, information about the manifestation of a disease or disorder in family members of an individual (i.e., family medical history). For this purpose, "family member" includes a spouse.

An exception to this restriction is available to employers that offer health or genetic services, including those offered as part of voluntary wellness programs. They may request genetic information as part of these programs, so long as certain requirements are satisfied. Under the current GINA Title II regulations, the wellness program cannot condition inducements to employees on the provision of genetic information.

The current Title II regulations have raised significant questions as to whether incentives may be offered to spouses for completing HRAs that request health information. This is because, when an employer requests information from an employee's spouse about the spouse's current or past health status, this request itself may be considered a request for the employee's genetic information (i.e., an inquiry regarding the manifestation of a disease or disorder in a family member). This is due to the fact that GINA and the implementing regulations define "genetic information" by reference to a "family member," the latter of which is defined to include an individual's spouse.

ADA Final Rule

1. "Employee Health Programs" Involving a Disability-Related Inquiry or Medical Examination Are Subject to the Final Rule.

Unlike the proposed rule, 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 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.

2. Employee Health Programs Must Be "Reasonably Designed to Promote Health or Prevent Disease."

The final rule imposes a requirement that each employee health 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 to participatory-only programs. The final rule provides that the reasonable design requirement is satisfied if a program:

- Has a reasonable chance of improving the health of, or preventing disease in, participating employees;
- Is not overly burdensome;
- Is not a subterfuge for violating the ADA or other laws prohibiting employment discrimination; and
- Is not highly suspect in the method chosen to promote health or prevent disease.

According to the final rule, 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" are not 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."

3. Employee Health Programs 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 (or particular benefits packages within a group health plan) to employees for non-participation (unchanged from proposed rule; generally encompasses common "gatekeeping" practices) 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); and
- An employer must satisfy a specific notice requirement (described below; applicability is different from that specified in proposed rule).

4. Employee Health Programs Must Limit Incentives to be Voluntary

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.

Notably, 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 (as described in more detail below). The final rule does not govern the financial incentives used with respect to the spouse. However, as discussed below, many wellness programs applicable to spouses provide an incentive for the spouse to complete an HRA or otherwise undergo a biometric screen or test. Accordingly, the new GINA final rule will apply to the spouse, which – like the ADA – has been interpreted by the EEOC to only allow for financial incentives up to 30% of the total cost of self-only coverage (by reference to certain plans). Thus, it should be expected that, with respect to many wellness programs that apply to employees and their spouses, the maximum incentive for either the employee or spouse will be 30% of the total cost of self-only coverage.

Limit Applies to Stand-Alone Wellness Programs and Wellness Programs that Are Part of Group Health Plan. The ADA incentive limit with respect to the employee applies 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. Similarly, it applies regardless of whether the program is a participation-only or health-contingent program for purposes of HIPAA.

- 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.

Significantly, the final regulations are not entirely clear on how the financial limits are to be determined where multiple plans are offered, all of which allow for wellness program participation, or where an employer sponsors multiple benefit packages within a given group health plan.

Application to 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 upon 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. Any biometric screening or other medical procedure that tests for the presence of nicotine or tobacco would be subject to the 30% incentive limit.

5. Employers Must Satisfy Certain Notice Requirements

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 providing a sample notice on its website within 30 days of the final rule's publication.

6. Employee Health Programs Must Satisfy Certain 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. An employer also cannot require an employee to agree to the sale, exchange, sharing, transfer or other disclosure of

medical information (with certain exceptions) or to waive certain confidentiality provisions as a condition for participating in a wellness program or earning any incentive related thereto. Significantly, a wellness program that is part of a group health plan likely may satisfy its obligation to comply with the final rule's confidentiality requirements by adhering to the HIPAA privacy rule.

GINA Final Rule

1. **Employer May Offer Inducement to Employee for Employee's Spouse to Provide Information About Spouse's Manifestation of Disease or Disorder as Part of HRA**

The final GINA rule resolves a long-standing question regarding the extent to which an employer may offer an inducement to an employee for the employee's spouse to provide information about the spouse's manifestation of disease or disorder as part of a health risk assessment and/or a biometric screening (together, an "HRA") administered in connection with an employer-sponsored wellness program. The basis for the uncertainty stemmed from the fact that 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". Accordingly, there has been some question 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.

2. **GINA Rule Applies Broadly to Wellness Programs, Whether or Not Offered as Part of a Group Health Plan.**

The preamble states that the EEOC has decided that all of the provisions in the 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.

3. **GINA-Subject Programs Must Satisfy a Reasonable Design Requirement.**

The final rule retains the proposed requirement 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.

4. **GINA-Subject Programs Must Limit Incentives (Maximum Incentive Limitations Mirror ADA).**

The final GINA rule limits the maximum total inducement for a spouse to provide information about his or her manifestation of a disease or disorder to 30% of the total cost of (employee) self-only coverage, similar to the limit imposed on an employee's incentive under the ADA. As a result, the combined total inducement for an employee and his or her spouse will be no more than twice the cost of 30% of self-only coverage.

Significantly, 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. 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 and will be determined based on the same benchmarks of self-only coverage that apply for purposes of the final ADA rule.

5. **GINA-Subject Programs Cannot Deny Access to Group Health Plan Coverage (or a Particular Benefits Package Within a Group Health Plan) 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 (i.e., common "gatekeeping" practices), 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.

6. **GINA-Subject Programs 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.

7. **GINA-Subject Programs Cannot Provide Financial Inducement for Spouse to Provide His or Her 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.

8. **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.

9. **Authorization Requirement Applies to Spouses.**

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.

10. **GINA-Subject Programs 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.

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What's Next?

While the final regulations are technically effective 60 days after publication in the Federal Register, they are generally applicable immediately as the EEOC has characterized the guidance as a clarification of existing law. New expanded notice requirements (under the ADA rules) and the rules regarding the use of financial inducements (under both rules) apply for plan years beginning on or after January 1, 2017.

In light of the foregoing, employers and wellness providers should perform a careful review of their wellness programs to ensure compliance with these new rules. Please contact any of the attorneys in the Health and Welfare Practice Group at Groom Law Group or your regular Groom Law Group attorney for further information.