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Wellness Program Compliance – It’s Time to Review Your Program Under New ADA and GINA Final Rules (and HIPAA and...)

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On May 17, 2016, the EEOC issued new rules regarding the nondiscrimination requirements applicable to certain wellness programs under the Americans with Disabilities Act of 1990 (“ADA Final Rule”) and the Genetic Information Nondiscrimination Act of 2008 (“GINA Final Rule” and, collectively, the “Final Rules”). The Final Rules address how employers can design wellness programs to remain “voluntary,” as required under the laws, but still include common features such as offering an incentive (e.g., reduced health plan premiums, or a gift card) for:

- An employee or dependent to submit to a medical examination (e.g., biometric screening) or respond to a disability-related inquiry (ADA), and
- An employee’s spouse to participate in a program that requires disclosure of the spouse’s manifestation of disease or disorder (GINA).

The rules include new requirements related to incentive limits and notice provisions that are effective for employers’ upcoming plan years (i.e., the plan year starting on or after January 1, 2017). Other clarifications in the rules, such as those relating to reasonable plan design, are effective immediately. In order to be ready for the next upcoming open enrollment period and plan year, we encourage employers to thoroughly review their wellness program for compliance with all applicable rules now. A chart summarizing the applicable rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Genetic Information Nondiscrimination Act of 2008 (GINA), and the Americans with Disabilities Act of 1990 (ADA) appears at the end of this alert.

New Final Rules

To educate employees on health and disease prevention, and manage employers’ cost of medical benefits, many employers are offering wellness programs that request employees, and sometimes their spouses or children, to complete health risk assessments (HRAs) and/or biometric screenings, or to provide other health-related information. To promote participation, many wellness programs offer incentives. As wellness programs have grown in popularity, the Department of Labor, Department of Health and Human Services, Treasury Department and Equal Employee Opportunity Commission (EEOC) have continued to monitor and regulate employer-

sponsored wellness programs to ensure that wellness programs do not result in discriminatory employment practices. Specifically, the federal agencies have issued regulations and guidance on nondiscrimination requirements that apply to wellness programs under HIPAA, ADA, and GINA. The requirements of the Final Rules are the focus of this alert:

ADA Final Rule – Title I of the ADA prohibits employers from discriminating against individuals on the basis of disability in regard to terms, conditions and privileges of employment, and generally restricts employers from making disability-related inquiries or requiring medical examinations. There is an exception to this general prohibition that allows an employer to make disability-related inquiries of an employee or request an employee to complete a medical examination in connection with a voluntary employee health program, including a voluntary wellness program.

GINA Final Rule – Title II of GINA generally prohibits the use of genetic information in employment decisions; restricts employers from requesting, requiring or purchasing genetic information; and strictly limits the disclosure of genetic information. There is an exception to this general prohibition that permits an employer to request genetic information from an employee in connection with a wellness program, provided certain requirements are met. One of the requirements is that an employer cannot offer an incentive for an individual to provide genetic information, and if an employer offers an incentive for completing a HRA that includes questions about genetic information, the HRA must clearly state that the individual will be eligible to receive the incentive even if he or she does not complete the questions about genetic information. Under GINA, “genetic information” includes, among other things, information about the manifestation of a disease or disorder in family members (including the spouse) of an individual.

The GINA Final Rule clarifies that, despite the general prohibition on offering incentives for providing genetic information (which includes family medical history), an employer can offer a limited incentive to an employee whose spouse provides information about the spouse’s manifestation of disease or disorder as part of a HRA or completes a biometric screening, as long as certain requirements are met.

Both the ADA Final Rule and the GINA Final Rule may apply to an employer-sponsored wellness program regardless of whether the wellness program is itself a group health plan (although most are). The EEOC makes it clear that the Final Rules apply if the wellness program offers incentives in exchange for employees to provide disability-related information or to complete medical examinations (ADA), or in exchange for an employee's spouse to provide information about his or her manifestation of disease or disorder (GINA).

Drinker Biddle Note on Court Challenges to EEOC's ADA Final Rule: *The EEOC's rules applying the ADA to wellness programs are the subject of on-going litigation. Recently, in EEOC v. Flambeau, Inc., a federal district court ruled against the EEOC's position that the ADA's bona fide benefit plan safe harbor provision permitting plan sponsors to ask disability-related questions or require medical examinations for underwriting, classifying or administering risks associated with insurance plans does not apply to wellness programs. In Flambeau, the court held that the bona fide benefit plan safe harbor permitted the employer to require that employees participate in a biometric screening in order to enroll in medical plan coverage. Consistent with its position in the Final Rules, the EEOC is appealing the Flambeau decision to the Court of Appeals for the Seventh Circuit.*

Requirements for Wellness Programs

To fit within the exceptions to the ADA and GINA prohibitions described above (i) wellness programs (whether part of a group health plan or otherwise) must be voluntary and reasonably designed to promote health or prevent disease; (ii) as applicable, employees must be given proper notice (ADA) or an authorization must be obtained (GINA); (iii) only limited incentives can be offered; and (iv) information obtained must be kept confidential.

Voluntary and Reasonable Design Requirements

A wellness program is reasonably designed to promote health or prevent disease if it:

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

A wellness program is not reasonably designed to promote health or prevent disease if it:

- Exists merely to shift costs to employees based on their health;
- Is used only to predict an employer's future health costs;
- Imposes on employees unreasonably intrusive procedures, overly burdensome amount of time for participation, or significant costs for medical exams; or
- Collects health-related information without providing results, follow up information, or advice designed to improve the health of participating employees.

A wellness program is *voluntary* if it:

- Does not require employees to participate;
- Does not deny coverage under any of the employer's group health plan options, or limit benefits for individuals who choose not to participate in the wellness program;
- Does not take adverse employment action, retaliate, interfere with, coerce, intimidate, or threaten employees who choose not to participate or fail to achieve certain health outcomes; and
- For purpose of the ADA Final Rule, provides a notice meeting the requirements below.

Drinker Biddle Note about Limiting Medical Plan Options: *Medical plans that have limited options available to an employee who does not participate in a biometric screening or other medical exam, or whose spouse refuses to provide information about the spouse's manifestation of disease or disorder (e.g., limiting enrollment to a high deductible health plan, and not permitting enrollment under the employer's PPO option) will not be permitted under the Final Rules.*

Notice and Authorization Requirements

ADA Notice Requirement – The ADA Final Rule requires that an employer that makes disability-related inquiries or requests employees to complete a medical examination as part of a wellness program provide employees with a notice that:

1. Is written in a manner that the employee is reasonably likely to understand;
2. Describes the type of medical information that will be obtained and the specific purposes for which it will be used; and
3. Describes the disclosure restrictions on the information, with whom the information will be shared, and the methods the employer will use to ensure that medical information is not improperly disclosed.

The EEOC will post a sample notice on its website within 30 days of the Final Rules' publication.

GINA Notice/Authorization Requirement – The GINA Final Rule does not impose new notice or authorization requirements when an employer offers employees an incentive for an employee's spouse to provide information about the spouse's manifestation of disease or disorder as part of a HRA. Rather, the GINA Final Rule affirms that the notice and authorization requirements in the existing regulations implementing Title II of GINA, which apply to an employee's provision of genetic information as part of a wellness program, also apply when a spouse provides information about the spouse's manifestation of disease or disorder. Specifically, the spouse must provide "prior, knowing, voluntary, and written authorization," using an authorization form that:

1. Is written so that the individual from whom authorization is being obtained is reasonably likely to understand it;
2. Describes the type of information that will be obtained and the general purposes for which it will be used; and

3. Describes the confidentiality protections and restrictions on disclosure of genetic information.

Drinker Biddle Note: Many employers have modified their wellness programs to not seek an employee's genetic information. Thus, such programs would not have had to obtain authorization from an employee. However, if a wellness program extends to employees' spouses and collects information about a spouse's manifestation of disease or disorder, the employer will have to obtain the spouse's authorization under the above rules.

Limits on Incentives

The ADA Final Rule limits the amount of the incentive that an employer can offer for an employee to respond to disability-related inquiries or complete medical examinations in connection with a wellness program, without causing the wellness program to be "involuntary" and therefore violate the ADA nondiscrimination requirements. Similarly, the GINA Final Rule limits the amount of the incentive that an employer can offer for an employee's spouse to answer questions about his or her manifestation of disease or disorder, without causing the wellness program to violate the GINA nondiscrimination requirements.

Under both the ADA Final Rule and the GINA Final Rule, the amount of the incentive cannot exceed 30 percent of the total cost of self-only coverage. "Total cost" means the employee contribution plus the employer contribution for coverage, and the 30 percent limit is applied as follows:

- If participation in a wellness program is limited to employees enrolled in a group health plan, 30 percent of the total cost of self-only coverage for the group health plan option in which the employee is enrolled.
- If the employer offers only one group health plan option and participation in the wellness program is open to all employees (regardless of whether an employee enrolls in the group health plan), 30 percent of the total cost of self-only coverage for the single group health plan option.
- If the employer offers more than one group health plan option and participation in the wellness program is open to all employees (regardless of whether an employee enrolls in the group health plan), 30 percent of the total cost of self-only coverage for the lowest cost group health plan option offered by the employer.
- If the employer does not offer a group health plan, 30 percent of the total cost of self-only coverage for the second lowest cost Silver Plan for a 40-year-old non-smoker on the state or federal health care exchange in the location that the employer identifies as its principal place of business.

Drinker Biddle Note on Tobacco Cessation Programs: The ADA Final Rule applies the 30 percent incentive limit to wellness programs that require employees to complete a medical examination to test for the presence of nicotine or tobacco. However, the ADA Final Rule reaffirms that a tobacco cessation wellness program that does not involve a medical examination (e.g., merely asking an employee if he or she uses tobacco) is not subject to the 30 percent incentive limit. In that case, the higher 50 percent limit under the HIPAA wellness program. nondiscrimination rules applies.

Some important points about GINA:

- The GINA Final Rule reaffirms that asking an employee's spouse if he or she uses tobacco or requiring a spouse to submit to a blood test to measure nicotine levels are not requests about the spouse's manifestation of disease or disorder. GINA does not apply to such inquiries.
- The GINA Final Rule prohibits an employer from offering incentives for an employee's spouse to provide the spouse's own genetic information (including results of the spouse's genetic tests) and against offering incentives for information about the manifestation of disease or disorder of the employee's children, or for genetic information about an employee's children, including adult children.

Confidentiality Protections

Existing rules under the ADA and GINA prohibit the disclosure of an employee's medical information (ADA) and individually identifiable genetic information about employees or their family members participating in health or genetic services (GINA). The Final Rules include a few additional requirements related to confidentiality:

- ADA Final Rule: Medical information or history collected by a wellness program may be disclosed to an employer only in aggregate terms that do not disclose and are not reasonably likely to disclose the identity of specific employees (except as necessary to administer the plan).
- ADA Final Rule, GINA Final Rule: An employer may not require an employee to agree to the sale, exchange, transfer, or other disclosure of health information or waive any confidentiality protections as a condition for participating in or receiving an incentive under the wellness program.

Drinker Biddle Note on Best Practices to Protect Confidentiality: The EEOC urges employers to adopt best practices to protect confidentiality of medical information and genetic information. The EEOC suggests that such practices include adoption and communication of strong privacy policies, training for individuals who handle confidential medical information, encryption of electronic files, and policies that require prompt notification of employees whose information is compromised if data breaches occur. This is a good time for employers to also review their HIPAA privacy and security compliance for their group health plans (including wellness programs) generally.

Applicability and Effective Date

Employers with 15 or more employees are subject to the ADA and GINA. The notice and incentive provisions of the ADA Final Rule and the incentive provisions of the GINA Final Rule apply prospectively to wellness programs as of the first day of the first plan year beginning on or after January 1, 2017. The EEOC indicates that all other provisions of the Final Rule are clarifications of existing obligations that apply at, and prior to, issuance of the Final Rules.

Summary of Wellness Program Requirements under HIPAA, ADA and GINA Rules

FAQ	HIPAA	ADA	GINA
Must the wellness program be reasonably designed to promote health or prevent disease?	Yes.	Yes.	Yes.
Is there a specific notice requirement?	Yes. Materials describing the terms of the wellness program must describe the availability of a reasonable alternative standard. Regulations include model notice language.	Yes. Notice explaining the types of medical information collected and how the information can be used and disclosed must be provided. EEOC intends to issue model notice language.	Yes. Notice explaining the types of genetic information collected and how the information can be used and disclosed must be included in the authorization form, if authorization is required.
Must an individual provide prior, written and knowing authorization?	No.	No.	Yes. Spouse's authorization is required if spouse is providing information about manifestation of disease or disorder.
Does the rule include specific confidentiality requirements?	No. However, HIPAA privacy and security requirements generally apply.	Yes.	Yes.
Is there a limit on the amount of the incentive that can be offered for employee participation?	Yes. Generally 30 percent of the total cost of employee-only coverage. 50 percent of the total cost of employee-only coverage for tobacco prevention wellness program.	Yes. 30 percent of the total cost of self-only coverage. For a tobacco cessation wellness program that does not involve medical examinations (e.g., merely asks if an employee uses tobacco), the 50 percent HIPAA limit applies.	N/A. The Final GINA Rule relates to incentives for spouses to provide information about manifestation of disease or disorder. GINA prohibits wellness programs from offering incentives for an employee to provide his or her own genetic information.
Is there a limit on the amount of the incentive that can be offered for spouse and/or dependent participation?	Yes. Limit for the family participants combined is 30 percent of the total cost of the coverage in which the employee and dependents are enrolled. 50 percent of the total cost of the coverage in which the employee and dependents are enrolled for tobacco prevention wellness program.	N/A. The Final ADA Rule relates only to wellness program incentives offered to employees.	Yes. The maximum incentive that can be offered for a spouse to provide information about the manifestation of disease or disorder is 30 percent of the total cost of self-only coverage. However, GINA prohibits wellness programs from offering incentives for information about the manifestation of disease or disorder, or for genetic information, about an employee's children.
How often must an eligible individual be given a chance to qualify for the incentive?	At least once per year.	Not addressed.	Not addressed.
Must the wellness program offer a reasonable alternative standard to qualify for the incentive?	Yes.	Yes. Reasonable accommodations must be offered to enable employees with disabilities to participate.	No.

Other Laws Impact Wellness Program Design Too

The Final Rules provide much needed clarity about how employers can design wellness programs without violating the ADA or GINA. However, compliance with the Final Rules does not necessarily mean a wellness program satisfies the HIPAA wellness program requirements. Employers should review their wellness programs' compliance with the HIPAA wellness program exception to the prohibition on discrimination on the basis of health status, and other applicable laws, and add in any new features as needed to comply with the Final Rules. Our client alert on the final rules under HIPAA may be reviewed here: www.drinkerbiddle.com/resources/publications/2013/Final-Wellness-Program-Rules-New-Requirements-Will-Likely-Require-Changes-to-Outcome-Based-Programs. On the previous page, we provide a summary chart highlighting how the rules apply and compare under HIPAA, ADA and GINA.

If you have any questions or would like assistance with any of the matters discussed in this Alert, contact one of the authors above or any member of our Employee Benefits and Executive Compensation Practice Group.

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