Wellness Plans: Final ADA and GINA Regulations

The EEOC has released final regulations addressing ADA and GINA requirements on wellness programs. The regulations address plans that provide incentives for undergoing medical examinations and responding to disability-related inquiries (ADA) and incentives that are offered in exchange for information about a spouse’s health (GINA). Generally, these final rules adhere to the principles established in the 2015 proposed regulations, but they also refine some requirements. Together with the HIPAA regulations, they help establish the legal framework for employer wellness programs.

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Background

Employers must comply with a plethora of laws and regulations when implementing wellness programs, including the Americans with Disabilities Act (ADA), the Genetic Information Nondiscrimination Act (GINA) and HIPAA. For more detailed information about the general provisions of ADA and GINA and wellness programs (as well as the interplay of other laws like HIPAA), see our December 9, 2015 FYI In-Depth.

ADA

Title I of the ADA, enforced by the Equal Employment Opportunity Commission (EEOC), prohibits employment discrimination on the basis of disability. The ADA requires employers to provide reasonable accommodations to allow employees with disabilities equal access to benefits offered to employees without disabilities. Denying an employee any term, condition or privilege of employment (e.g., coverage under a more robust health benefit option or other wellness reward) because of an actual or perceived physical or mental impairment, or because of the employee’s association or relationship with a person with a known disability (e.g., a spouse), could violate the ADA.

Generally, the ADA prohibits employers from requiring a medical examination or inquiring about either the existence of or the nature or severity of an employee’s disability, unless the requirement or inquiry is job-related. However, the ADA allows such exams and inquiries if they are part of either one of the following:
**“Bona fide benefit plan” — i.e., insured and self-insured health plans that are based on underwriting risks, classifying risks, or administering such risks, and not subterfuge for discrimination**

**Voluntary employee health program under which any medical records acquired are kept confidential and separate from personnel records**

In April 2015, the EEOC issued proposed regulations addressing the extent to which a wellness program that includes medical examinations and/or disability-related inquiries can provide incentives and fall within the voluntary employee health program exception. Under the proposed regulations, such programs are permitted as long as they are reasonably designed, voluntary, meet confidentiality and notice requirements and, if part of a group health plan, generally limit any incentive to 30% of the cost of employee-only coverage.

**GINA**

GINA, also enforced by the EEOC, prohibits discrimination on the basis of an individual’s “genetic information” by group health plans, insurers and employers. Title II of GINA bars employment discrimination based on genetic information. Additionally, it prohibits employers from requesting, requiring or purchasing an employee’s or a family member’s genetic information, except in certain limited circumstances. Under GINA, information about the current or past health status of a spouse or other family member is considered “genetic information” of the employee.

In October 2015, the EEOC issued proposed regulations that would allow employers that offer wellness programs as part of a group health plan(s) to provide limited financial and other inducements in exchange for an employee’s spouse providing information about his or her current or past health status.

**HIPAA**

HIPAA generally prohibits a group health plan from discriminating against individual participants and beneficiaries with respect to eligibility, benefits or premiums based on a health factor. The HIPAA nondiscrimination regulations include an exception for wellness programs that meet certain requirements. The requirements differ depending on whether the wellness program is participatory or health-contingent. Health-contingent programs — activity-only and outcome-based — require an individual to satisfy a standard related to a health factor to obtain a reward and must comply with five requirements related to: the opportunity to qualify for the reward; the size of the reward; reasonable design; uniform availability and reasonable alternative standard; and notice of the alternative standard. Participatory programs are not subject to the heightened scrutiny applied to health-contingent programs. For more information on the HIPAA nondiscrimination rules, see our [December 9, 2015 FYI In-Depth](#).
Final Regulations

On May 16, 2016, the EEOC issued a news release, final regulations and Q&As addressing the extent to which the ADA permits employers to use incentives to encourage employees to participate in wellness programs that include disability-related inquiries and/or medical examinations. On the same day, it issued final regulations and Q&As under GINA, focusing on the use of incentives in return for a spouse’s information about his or her current or past health status.

ADA

The final regulations largely confirm the principles set out in the proposed regulations, but they also reflect some changes based on comments the EEOC received. Generally, a wellness program that includes medical examinations or disability-related inquiries complies with the ADA if it is reasonably designed and voluntary, limits the size of any incentive, provides written notice, and maintains confidentiality of information gathered. Like the proposed regulations, these final regulations are modeled on the principles established in the HIPAA nondiscrimination rules, but contain some distinct differences.

Voluntary Employee Health Program versus Bona Fide Benefit Plan. In the final regulations, the EEOC reaffirms its position that the exception for voluntary employee health programs, rather than the bona fide benefit plan safe harbor, applies to a wellness program that includes disability-related inquiries or medical examinations. Despite that, at least two courts have found that the bona fide benefit plan safe harbor applied to an employer’s wellness program. In Seff v. Broward County, employees who did not participate in the wellness program were subject to a premium surcharge. The 11th Circuit Court of Appeals found that because the program was part of a condition or “term” under the County’s group health plan and had the financial objective of enhancing the benefit plan’s cost-effectiveness, it met the bona fide benefit plan safe harbor requirements. In EEOC v. Flambeau, Inc., eligibility for the group health plan coverage was conditioned on completion of a health risk assessment (HRA) and a biometric screening. Persuaded by the 11th Circuit’s ruling in Seff, the district court in Wisconsin held similarly. Neither court addressed the voluntary benefit plan exception. (See our January 19, 2016 For Your Information.)

Comment. The EEOC was a party to the litigation in Flambeau, but not in Seff. In the preamble to the final regulations, the EEOC asserts that these cases were wrongly decided. Likely, this issue will continue to play out in the courts. And we can expect to see more employers design and defend their wellness programs using the bona fide safe harbor (see discussion below under “voluntary”).

Reasonable Design. The final regulations provide that an employee health program must be reasonably designed to promote health or prevent disease, not overly burdensome, and not a subterfuge for violating the ADA or other laws prohibiting employment discrimination.

A reasonably designed wellness program might offer an HRA or biometric screening to alert employees to health risks — such as high cholesterol or blood pressure. Additionally, a program that uses aggregate employee information from such assessments to offer health programs aimed at specific conditions prevalent in the workforce (like diabetes) also would be considered reasonably designed. However, a
program that collects medical information without providing follow-up or advice or requires an overly burdensome amount of time or significant costs would not be considered reasonably designed.

**Voluntary.** Any program that includes disability-related questions or medical examinations, regardless of whether it is part of a group health plan, must be voluntary. Generally, the final regulations provide that such a program will be considered voluntary as long as there is:

- **No requirement to participate.** Employees are not required to take part.
- **No retaliation.** The employer does not take any adverse employment action or retaliate against, interfere with, coerce, intimidate or threaten nonparticipating employees.
- **No denial of coverage or benefit package.** The employer does not penalize employees for nonparticipation by denying coverage under any group health plan or particular benefit packages within a group health plan, or limit the extent of benefits (with the exception of the 30% incentive limit noted below).

**Comment.** The EEOC has consistently expressed disapproval of “gateway” design concepts — where eligibility for health coverage or options under the health plan is conditioned on participation in the wellness program (containing inquiries and/or medical exams). Despite this fact, a Wisconsin employer successfully defended such a design by invoking the bona fide benefit plan exception (mentioned above). The employer maintained that aggregated data collected from the wellness program was used to estimate the cost of providing insurance, setting premiums and copays and for other purposes. It will be interesting to see if more litigation making use of this safe harbor arises and if the courts will agree with the EEOC’s position, especially now that the regulations are final.

**Size of Reward.** The final regulations permit a wellness program to offer limited incentives. A reward includes not only financial incentives (such as lower contributions), but also the avoidance of a penalty (absence of a premium surcharge). As in the proposed regulations, the final regulations provide that the maximum incentive is 30% of the cost of self-only coverage, but explain how to calculate the incentive limit depending on whether access to the wellness program requires enrollment in an employer group health plan. Using HIPAA language, the final regulations state that the maximum incentive that may be offered for a participatory program involving disability-related inquiries or medical examinations or for a health-contingent program that requires participants to satisfy a standard related to a health factor is:

- 30% of the total cost of self-only coverage (employer plus employee contributions) of the group health plan in which the employee is enrolled where participation in the wellness program is conditioned on enrollment in a particular health plan.

**Example.** An employer offers a wellness program with an HRA and biometric screening to employees who enroll in its group health plan and the annual total cost of self-only coverage under the plan is $6,000. The maximum incentive permitted under the wellness program is $1,800 (30% x $6,000). If the employer offers additional incentives for individuals who are identified through the HRA and biometric screening as having health issues, seemingly these amounts also would be included in the $1,800 maximum incentive.
Thus, the employer could offer a $1,000 incentive to employees enrolled in the group health plan who respond to the HRA and obtain a biometric screening. An additional $800 could be offered to employees who are identified as having high cholesterol or high blood pressure to participate in free health education classes (offered through the wellness program).

**Comment.** What components of the wellness program are included in the permitted maximum incentive? Presumably, any incentive amounts that are connected to the information obtained through the disability-related inquiry (HRA) and the medical examination (biometric screening) would be considered an inducement for participation and would be included in this calculation.

- 30% of the total cost of self-only coverage when the employer offers only one group health plan and participation in the wellness program is offered to all employees whether or not they are enrolled in the health plan.

- 30% of the total cost of the lowest cost self-only coverage where the employer offers more than one health plan and participation in the wellness program is offered to employees whether or not they are enrolled in one of the employer’s health plans.

  **Example.** An employer offers two group health plans where the annual total cost of self-only coverage under one is $5,000 and the other is $7,000. All employees, whether or not they are enrolled in the employer’s group health plan, are eligible to participate in the wellness program, which includes a biometric screening. The maximum permitted incentive under the wellness program is $1,500 (30% x $5,000 — the lowest cost self-only coverage).

- 30% of the cost to a 40-year-old non-smoker of the second lowest cost marketplace Silver Plan where the employer’s principal place of business is located if the employer does not offer a group health plan.

**Comment.** It’s important for an employer to be aware of the subtle differences among the categories of incentive limits and to ensure that, based on program design, the incentive does not exceed the limit. That said, these categories don’t appear to address some common wellness program designs. For example, it’s not clear if the EEOC contemplated multiple coverage options offerings where only employees enrolled in the health plan are eligible for the wellness program. The regulations also do not address the situation where multiple wellness programs are offered; nor where the wellness program might differ for different groups of employees (e.g., hourly versus salaried employees). These same questions exist under the GINA regulations (see below). The EEOC is aware there’s some lack of clarity in this area of the regulations, and we hope guidance will be forthcoming soon. In the meantime, employers should consult with trusted advisors and might opt for a more conservative approach for 2017 — limiting the incentive amount to 30% of self-only coverage of the lowest cost plan where multiple coverage options are available.

**Incentives for family members.** In the final regulations, the EEOC explains that the ADA applies only to applicants and employees, and not their spouses and other dependents. Thus, the final rules do not...
address, nor do they apply to, wellness program incentives offered in connection with dependent or spousal participation.

Incentives for tobacco users. As under the proposed regulations, a program that merely asks employees about tobacco use (e.g., an attestation) does not involve a disability-related inquiry or medical examination and, therefore, this ADA incentive limitation does not apply to such a program. However, the limitation does apply if the program involves a biometric screening or other medical examination for the presence of cotinine (which indicates tobacco use).

Comment. Unlike the HIPAA nondiscrimination rules, the ADA does not provide an increased incentive for programs related to tobacco use. Where a wellness program offers screenings for cotinine, either through a medical test or other medical examinations, employers should be aware of this “disconnect” between the HIPAA and ADA final regulations and consider design changes that reconcile the two positions.

Written Notice. The plan must provide employees with a clear, concise, written notice, in a language the employee is reasonably likely to understand, that describes the type of medical information that will be obtained, the purposes for which it will be used, who will receive it, and the restrictions on its disclosure, including the methods used to protect it. If an employer’s current wellness program notices already include this information, the employer need not create a separate notice for its wellness programs that include medical examinations or disability-related questions. Unlike the proposed notice requirement, the final notice requirement applies to all wellness programs that include medical exams or disability-related inquiries, regardless of whether the wellness program is part of a group health plan. The final rule does not include an exception for de minimis amounts nor does it require employees to give prior, written confirmation that their participation is voluntary.

The EEOC provides a sample notice and some Q&As describing the notice requirements:

- Employers can combine notices (e.g., if a HIPAA nondiscrimination notice describing a reasonable alternative standard is required) as long as the notice informs employees what information will be collected, who will receive it, how it will be used, and how it will be kept confidential.
- While the employer is ultimately responsible for ensuring that employees receive the notice, a third party vendor can send it on behalf of the employer.
- Employers do not have to use the precise wording in the EEOC sample notice. The model notice can be modified to accommodate the specific features of a wellness program.
- The first notice must be provided as of the first day of the plan year that begins on or after January 1, 2017. Thereafter, a notice must be given to employees before they provide any health information and with enough time to decide whether to participate in the program.

Comment. The Q&As do not specify how often an employer needs to provide this notice to employees. As terms of a wellness program can change from year to year and new employees are offered the program, presumably it’s a best practice to provide this notice to all eligible employees each year.
The EEOC does not mandate a specific format and delivery method of the notice. It can be provided in any format that will be “effective in reaching employees being offered an opportunity to participate in the wellness program,” including in hard copy or by email. But if it is sent electronically, the EEOC indicates that the subject line should clearly identify what information is being communicated (e.g., "Notice Concerning Employee Wellness Program"). The EEOC also recommends that employers avoid sending the notice with a lot of unrelated materials. Finally, the notice should be made available in alternative format, if needed, for employees with disabilities.

Comment. The EEOC warns that if an employee files a charge claiming that he or she was unaware of a particular medical examination conducted as part of a wellness program, it will examine the contents of the notice and all the surrounding facts and circumstances to determine whether the employee understood what information was being collected, how it was being used, who would receive it, and how it would be kept confidential. An employer may decide that it is appropriate to send this notice along with group health plan open enrollment material. While employees are not required to confirm that they received the notice, it is in the employer’s interest, particularly where the notice is included with a packet of information, to have all the material clearly marked and easily understandable.

Confidentiality. The final regulations do not change any of the confidentiality obligations under existing ADA regulations but add two new requirements. Information obtained through the wellness program can be provided to the employer only in aggregate terms and cannot disclose, or be reasonably likely to disclose, the identity of any employee (except as permitted under existing EEOC regulations or as needed to administer the health plan). The final regulations also add that an employer may not require an employee to agree to the disclosure of medical information (e.g., sale, exchange, sharing, or transfer) or to waive any confidentiality protections as a condition of participating in, or earning an incentive under, the wellness program. As provided in the proposed rules, a wellness program that is part of the group health plan generally can comply with confidentiality requirements by satisfying the HIPAA privacy (and security) rule, and employers can comply with their obligations by certifying that personally identifiable information will not be used for employment purposes (and abiding by that certification).

GINA
The final GINA regulations address the extent to which an employer may offer a wellness program with an inducement (financial or in-kind) to an employee for the employee’s spouse to provide information about his or her manifestation of disease or disorder. In contrast to the proposed regulations, these final regulations apply to all wellness programs that request genetic information, regardless of whether they are offered in connection with a group health plan. The final rule retains the requirement that an incentive may not be offered in return for the spouse providing his or her own genetic information or for health information about an employee’s children.

Like the proposed regulations and the ADA regulations, these are modeled on the HIPAA nondiscrimination rules.

Reasonable Design. Adopting the same standard set out in the final ADA regulations, wellness programs must be reasonably designed to promote health or prevent disease. Whether a program meets this requirement is determined based on all relevant facts and circumstances.
A wellness program involving a test or screening would meet this requirement if it uses the information collected to design a program that addresses at least a subset of health conditions the test or screening identifies. In contrast, a wellness program is not reasonably designed if it imposes a penalty on an individual because a spouse’s manifestation of disease or disorder prevents the spouse from achieving a specific health outcome. For example, an employer may not deny an employee a wellness program incentive because the employee’s spouse has a cholesterol level that the employer considers too high.

**Voluntary.** These final regulations do not change the requirement under existing regulations that individuals must provide the genetic information voluntarily — no requirement or penalty may be imposed on an individual who withholds such information. Additionally, while employers may offer financial incentives to encourage participation, they may not offer incentives, no matter the size, specifically for providing genetic information (except as provided for spousal participation). Generally, an employer may offer incentives to encourage individuals to complete an HRA with questions about genetic information (e.g., family medical history) as long as the HRA identifies those questions and clearly states that the incentive is available regardless of whether those questions are answered. (For more information, see our [February 1, 2011 For Your Information](#).)

**Authorization.** The final regulations make clear that when an employer offers an employee an inducement in exchange for a spouse providing information about his or her manifestation of disease or disorder, the spouse must give voluntary, knowing and written authorization before producing the information, but otherwise they add no new notice or authorization requirements. The notice must be clear, concise and easily understood and describe the information that will be obtained, the general purposes for which it will be used and the restrictions that apply to the disclosure of the genetic information. The authorization may be provided by the employee and spouse on the same form.

**Comment.** Note that the notice requirements are similar to that of the ADA, except the ADA regulations do not require prior written authorization.

**Confidentiality.** Individually identifiable information may be provided only to the individual (or family member receiving the genetic services) and the licensed health care professionals or board-certified genetic counselors providing them. Also, the individually identifiable information can be available only for purposes of the services and may not be disclosed to the employer, except in aggregate terms that do not disclose specific individuals’ identity.

**Comment.** The final regulations made no changes to the existing confidentiality rules, but the EEOC is encouraging employers to adopt best practices to ensure protection of confidential information. Some suggested practices include adoption and communication of strong privacy policies, training for individuals who handle confidential medical information, encryption of electronic files, and policies for prompt notification of employees whose information is compromised in the event of a data breach.

**Size of Reward.** The final regulations modify the proposed rule on incentive limits by mirroring the ADA final regulations. In this way, the rules coordinate with each other. The incentive limits apply regardless of whether the wellness program is connected to a group health plan. Where an employee and the employee’s spouse can participate in a wellness program, the incentive for *each* may not exceed:
• 30% of the total cost of self-only coverage (employer plus employee contributions) under the plan in which the employee is enrolled where participation in the wellness program is conditioned on enrollment in a particular health plan

   **Example.** An employer offers a wellness program that contains a biometric screening to employees and spouses enrolled in its group health plan. The employee is enrolled in family coverage for an annual total cost of $14,000 (employer and employee contributions). The total cost of self-only coverage under the plan is $6,000. If both the employee and the spouse participate in the wellness program, the total maximum incentive permitted under the wellness program is $3,600 - $1,800 for the employee’s participation (30% x $6,000) and $1,800 for the spouse’s (30% x $6,000).

• 30% of the total cost of self-only coverage when the employer offers only one group health plan and participation in the wellness program does not depend on enrollment in the health plan

• 30% of the total cost of the lowest cost self-only coverage where the employer offers more than one health plan and participation in the wellness program is not conditioned on enrollment in one of the employer’s health plans

   **Example.** An employer offers two group health plans where the annual total cost of self-only coverage under one is $5,000 and the other is $7,000. A wellness program, which includes an HRA, is available to employees and their spouses regardless of their participation in one of the employer’s group health plans. The maximum permitted incentive under the wellness program is $3,000 - $1,500 for the employee’s participation and $1,500 for the spouse’s (30% x $5,000 — the lowest cost self-only coverage).

• 30% of the cost to a 40-year-old non-smoker of the second lowest cost marketplace Silver Plan where the employer’s principal place of business is located if the employer does not offer a group health plan

   **Comment.** Employers extending wellness program rewards for participation of an employee’s child should ensure that incentives are not attached to an HRA, biometric screening or other programs that could elicit genetic information. The exception for spouses doesn’t apply for children. Incentives for a child’s participation, however, would be permissible for participation in other activities designed to promote health or prevent disease, like attending exercise or nutrition classes.

**Applicability Date**

The notice and incentive provisions of the final ADA regulations and the incentive provisions of the final GINA regulations apply for the first day of the first plan year beginning on or after January 1, 2017. The EEOC considers all the other provisions to be clarifications of existing obligations and, therefore, already apply.

**Consequences of Noncompliance**

Employers should keep in mind the consequences of failing to comply with these final regulations. Individuals who believe their rights under the ADA or GINA have been violated can bring a claim against the employer by filing a charge with the EEOC within 180 days of the alleged violation. The EEOC, after investigating the charge, can either
file a lawsuit or issue a “Notice of Right to Sue” letter, allowing the individual who brought the charge to file a lawsuit within 90 days.

Additionally, remedies available under Title VII of the Civil Rights Act of 1964 are available for ADA and GINA violations. So, for employers with more than 500 employees, each individual can recover up to $300,000 in damages from an employer for a successful ADA or GINA claim.

**Comment.** The application of the final regulations — and associated penalties — is subject to federal court challenge. Employers should confer with legal counsel about risks involved with benefit designs that do not comply with the final regulations.

**HIPAA, ADA and GINA**

The table on the following page highlights some of the similarities and differences between HIPAA and the new and requirements under the ADA and GINA. Please note that the table discusses GINA as it relates to spousal information. Existing regulations (issued in 2011) address how GINA applies to the employee’s personal information.
## HIPAA, ADA and GINA
### Brief Comparison of Wellness Plan Regulatory Requirements

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<td>No GHP offered: 30% of total cost self-only coverage for 40-year-old non-smoker purchasing second-lowest-cost Silver Plan in marketplace</td>
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In Closing

A wellness program that provides an incentive in exchange for responding to disability-related questions, having a medical examination or asking a spouse to provide information about his or her manifestation of disease or disorder will comply with the ADA and/or GINA if it is reasonably designed, voluntary, authorized by the spouse (in the case of GINA), maintains confidentiality and limits the amount of the incentive. In light of these final regulations, employers should review their wellness programs to ensure they are compliant.

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