

WHAT YOU NEED TO KNOW



Final Rules Impose New Requirements on Wellness Programs under the ADA, GINA

In May 2016, the Equal Employment Opportunity Commission (EEOC) issued two final rules, one to amend regulations and provide [guidance on implementing Title I of the Americans with Disabilities Act \(ADA\)](#) as it relates to employer wellness programs, and one to amend the [regulations implementing Title II of the Genetic Information Nondiscrimination Act \(GINA\)](#) as they relate to employer wellness programs that are part of group health plans. Wellness programs are regulated by a plethora of federal regulations, and compliance with one set of regulations does not mean a wellness program is compliant with all regulations. Employers should use caution with plan design changes to ensure compliance across all regulations.

Both rules go into effect on July 18, 2016, and employers must comply as of the first date of the plan year beginning on or after January 1, 2017.

The EEOC's main concern is with an employer's use of disability-related inquires, primarily through health risk assessments (HRAs) and medical examinations, such as biometric screenings. Employers that offer or encourage employees to undergo HRAs or biometric screenings should be very careful to ensure they are complying with these new regulations. The EEOC is concerned that some incentives, offered in conjunction with HRAs or biometric screenings, will render a "voluntary" wellness program involuntary by virtue of the incentive.

These final rules apply to both wellness programs that are part of or are provided by a group health plan; or by a health insurance issuer (carrier) offering group health insurance in conjunction with a group health plan; or wellness incentives that are offered as a benefit of employment by employers that do not sponsor a group health plan or group health insurance. Practically speaking, they apply to all wellness programs, regardless of their attachment to a fully insured or self-funded group health plan.

The final rules provide clarity to the meaning of a "voluntary" program, further rules on the calculation of the incentive limits, and further restrictions on smoking cessation wellness programs that include any sort of medical screening.

Neither the employee nor the employee's spouse who is participating in a wellness program may earn a wellness program reward (or avoid a penalty) by submitting an attestation that they are under the treatment of a physician and that their physician is treating them for identified health risks. The EEOC has determined that this circumvents the "reasonable design" requirements of a wellness program.

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The EEOC has already begun litigation against well-known employers with HRAs and biometric screening programs that do not meet the new requirements. Some federal courts have issued rulings in favor of the employers, and against the EEOC. The final rules acknowledge the rulings and state that the agency disagrees with the judicial decisions. Employers that wish to rely on the court rulings rather than federal guidance should only do so after discussion with their legal counsel.

History of Wellness Programs

Rules for wellness programs have been in effect since 2007, with additional rules that went into effect for the 2014 plan year under the Patient Protection and Affordable Care Act (ACA). Wellness programs are either “participatory” or “health-contingent.” A participatory program is one that either has no reward or penalty (such as providing free flu shots) or simply rewards participation (such as a program that reimburses the cost of a membership to a fitness facility or the cost of a seminar on nutrition).

Health-contingent wellness programs are either classified as “activity only” or “outcome based.” Health-contingent wellness programs are programs that base incentives or requirements in any way on an employee’s health status. Health status includes things like body mass index (BMI), blood glucose level, blood pressure, cholesterol level, fitness level, regularity of exercise, and nicotine use.

A wellness program with health-contingent requirements must meet all of these basic requirements:

- Give employees a chance to qualify for the incentive at least once a year; and
- Cap the incentive at 30 percent of the total cost of employee-only coverage under the plan, including both the employee and employer contributions, with a 50 percent cap for tobacco cessation or reduction; and
- Be reasonably designed to promote health or prevent disease; and
- Provide that the full reward must be available to all similarly situated individuals with a “reasonable alternative” method of qualifying for the incentive for some individuals; and
- Describe the availability of the alternative method of qualifying for the incentive in written program materials.

Terminology

In the final rule, “group health plan” refers to both insured and self-insured group health plans. All of the changes relate to “employee health programs,” regardless of whether they are offered as part of or outside of a group health plan or group health insurance coverage. The term “incentives” includes financial and in-kind incentives for participation such as awards of time off, prizes, or other items of value.

Final Rule – Americans with Disabilities Act

Title I of the ADA applies to employers with 15 or more employees, prohibits discrimination against people with disabilities, and requires equal opportunity in promotion and benefits, among other things. The final rule provides guidance on the extent to which employers may use incentives to encourage employees to participate in wellness programs that include disability-related inquiries or medical examinations.

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The ADA restricts employers from obtaining medical information from employees by generally prohibiting them from making disability-related inquiries or requiring medical examinations, with an exception for voluntary medical examinations for wellness programs.

Additionally, the ADA requires employers to provide reasonable accommodations (modifications or adjustments) to enable individuals with disabilities to have equal access to fringe benefits, such as general health and educational wellness programs, which are offered to individuals without disabilities. The EEOC has decided that allowing certain incentives related to a wellness program, while limiting them to prevent economic coercion that could make the program involuntary, is the best way to achieve the purposes of the wellness program provisions of both the ADA and HIPAA.

The EEOC's final rule relating to the ADA focuses on reasonable design, the meaning of voluntary, the permitted incentives, and confidentiality requirements.

The final rule defines a voluntary wellness program as one that:

1. Does not require employees to participate;
2. Does not deny coverage under any of its group health plans or particular benefits packages within a group health plan for non-participation; and
3. Does not take any adverse employment action or retaliate against, interfere with, coerce, intimidate, or threaten employees within the meaning of Section 503 of the ADA.

Using a Wellness Program as a “Gatekeeper” for a More Comprehensive Group Health Plan

The second requirement of a voluntary wellness program prohibits the outright denial of access to a benefit available by virtue of employment. When an employer denies access to a health plan because the employee does not answer disability-related inquiries, e.g., HRAs, or undergo medical examinations, this is discrimination by virtue of requiring the employee to answer questions or undergo medical examinations that are not job-related and consistent with business necessity, and is not voluntary.

Practically speaking, this means employers cannot offer a “basic” group health plan and a more comprehensive group health plan, with the comprehensive health plan only being offered to employees who participate in the wellness program that involves an HRA or biometric screening. Similarly, lower deductibles or out-of-pocket costs cannot be offered only to individuals who participate in a group health plan that involves an HRA or biometric screening.

Incentives

The maximum allowable incentive (including in-kind incentives) for wellness programs that include HRAs or medical exams or for health-contingent programs that require participants to satisfy a standard related to a health factor may not exceed:

- 30 percent of the total cost of self-only coverage (including both the employee's and employer's contribution) where participation in a wellness program depends on enrollment in a particular health plan;

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- 30 percent of the total cost of self-only coverage when the covered entity offers only one group health plan and participation in a wellness program is offered to all employees regardless of whether they are enrolled in the plan;
- 30 percent of the total cost of the lowest cost self-only coverage under a major medical group health plan where the covered entity offers more than one group health plan but participation in the wellness program is offered to employees whether or not they are enrolled in a particular plan;
- 30 percent of the cost to a 40-year-old nonsmoker of the second-lowest-cost Silver Plan (available under the ACA) in the location that the employer identifies as its principal place of business, where the covered entity does not offer a group health plan or group health insurance coverage.

Smoking Cessation Limits

Generally wellness program rewards or penalties can be as much as 30 percent of the cost of coverage if the incentive is not related to tobacco usage. If there are multiple parts to the program (such as meeting certain BMI, blood pressure, cholesterol, and exercise targets), the maximum total reward or penalty for all parts of the program is 30 percent. However, the reward or penalty for not using tobacco can be up to 50 percent of the cost of coverage.

The final rule clarified that smoking cessation programs that ask employees whether they use tobacco, or whether or not they ceased using tobacco at the conclusion of a program, is not a program that includes disability-related inquiries or medical exams.

However, tobacco or smoking cessation programs that include a medical exam or biometric screening that tests for the presence of nicotine or tobacco would be subject to the 30 percent limits, not the higher 50 percent limit. Calculation of the incentive limit follows four methods outlined above.

Reasonable Alternatives

Reasonable alternatives must be provided for employees for whom it is unreasonably difficult due to a medical condition to complete the disability-related inquiry such as an HRA or biometric screening due to a medical condition. An example would be an individual who has a medical condition that makes a blood draw a risky procedure.

Notice Requirement

Furthermore, to be a voluntary program, employers must provide a notice that clearly explains what medical information will be obtained, who will receive that medical information, how the medical information will be used, the restrictions on its disclosure, and the methods the covered entity will employ to prevent improper disclosure of the medical information. The employer must also notify the employee whether it complies with privacy and security measures established by HIPAA. The information must be written so that the employee whose medical information is being obtained is reasonably likely to understand it.

The EEOC intends to publish a sample notice on its website that satisfies these requirements.

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Use of Information

Under the final rule, a wellness program with a biometric screening or HRA requirement will not be able to show that it is reasonably designed to promote health if it merely claims that the collection of information is useful. Conversely, asking employees to complete an HRA in order to alert them to health risks they might have been unaware of would meet the standard of promoting health. Employers that use aggregated information from HRAs or biometric screening to design programs to meet the needs of their employee population (for example a program for individuals with diabetes or high blood pressure) would be sufficient. Collecting information without meaningful follow-up and advice is not sufficient. Employers must ensure that any wellness program involving medical screenings or HRAs is sufficient to promote health; any program that merely collects information should be avoided.

Confidentiality

Medical records developed in the course of wellness programs (and other voluntary health services generally) must be maintained in a confidential manner. Covered entities may not require employees to agree to the sale, exchange, sharing, transfer, or disclosure of information (except as required to carry out the wellness program) or to waive confidentiality in any way. If the wellness program is part of the group health plan, it is subject to HIPAA's privacy, security, and breach notification rules.

Individuals who handle medical information that is part of an employee health program should not be responsible for making decisions related to employment, such as hiring, termination, or discipline. If an employer uses a third-party vendor, it should be familiar with the vendor's privacy policies for ensuring the confidentiality of medical information. Employers that administer their own wellness programs need adequate firewalls in place to prevent unintended disclosure of information.

Safe Harbor

The ADA provides an insurance "safe harbor" that prohibits insurers or benefit plan administrators 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. Essentially, the safe harbor permits insurers and employers to treat individuals differently based on disability, but only in certain justified situations according to accepted principles of risk classification. However, the EEOC notes that this safe harbor relates to underwriting and rate-making that was in place before the ADA and does not apply to the wellness programs that involve disability-related inquiries and medical examinations. The EEOC's position on the applicability (or lack thereof) of the safe harbor is contradictory to two federal court rulings. Risk-adverse employers should exercise caution and consult with legal counsel if they are contemplating following the court rulings rather than the regulations.

Final Rule – GINA

Current wellness program rules provided by other federal agencies allow employers to extend the financial incentives of a wellness program to spouses and children of an employee, so long as the spouse and children are permitted to participate in the wellness program. GINA prohibits discrimination in insurance and employment on the basis of genetic information.

The statute and the EEOC's GINA regulations say that "genetic information" includes, among other things, information about the "manifestation of a disease or disorder in family members of an individual." Family members include certain blood relatives, like parents, grandparents, and children, but also include

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spouses and adopted children. This is because when Congress defined family members, it included two very specific provisions – one that covers blood relatives and a second that refers to "dependents" within the meaning of the Employee Retirement Income Security Act (ERISA). The section of ERISA referenced in GINA defines dependents to include spouses and adopted children.

When the EEOC issued its Proposed rule in April 2015 to integrate wellness program rules with Title I of the ADA, it expressly provided that financial incentives for wellness programs would be limited to employees only. That is because the current regulations at that time stated that a wellness program cannot require employees to provide genetic information as a condition of receiving incentives, including current or past health status of spouses and family members. This led to the interpretation that GINA prohibited employers from offering wellness program incentives to spouses who are asked to provide their current or past health information. The final rule intends to provide the parameters for an employer to lawfully offer wellness incentives to spouses. GINA's existing confidentiality protections of genetic information apply to the genetic information of all individuals responding to a disability-related inquiry through a voluntary wellness program.

Prohibition on Programs Involving Genetic Information of Children

The EEOC has determined that information about the manifestation of a disease or disorder in an employee's child can more easily lead to genetic discrimination against an employee than information about an employee's spouse. As a result, 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. Practically speaking, the final rule prohibits employers from operating a wellness program that includes disability-related questions, such as HRAs or biometric screenings for children. The GINA rules do not apply to wellness programs that offer inducements for participation in an outcome-based program, such as attending a nutrition program or exercising for a certain amount of time every month.

Spouses

The final rule allows employers to offer limited inducements to obtain information about the "manifestation of a disease or disorder" (via a biometric screening, HRA, or medical examination) from a spouse of a covered employee, in certain situations. General rules about wellness programs continue to apply, including the requirement that the program be reasonably designed. Any wellness program with biometric screenings or HRAs must include follow-up information or advice to individual participants based on the results. The term "spouse" includes both opposite sex and same-sex spouses.

Again, the GINA rules do not apply to wellness programs that offer inducements for participation in an outcome-based program, such as attending a nutrition program or exercising for a certain amount of time every month.

When an employee and the employee's spouse are given the opportunity to enroll in an employer sponsored wellness program, the inducement to each individual may not exceed 30 percent of the total cost of:

- Self-only coverage (including both the employee's and employer's contribution) where participation in a wellness program depends on enrollment in a particular health plan;

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- Self-only coverage when the covered entity offers only one group health plan and participation in a wellness program is offered to all employees regardless of whether they are enrolled in the plan;
- The lowest cost self-only coverage under a major medical group health plan where the covered entity offers more than one group health plan but participation in the wellness program is offered to employees whether or not they are enrolled in a particular plan; or
- The cost to a 40-year-old nonsmoker of the second-lowest-cost Silver Plan (available under the ACA) in the location that the employer identifies as its principal place of business, where the covered entity does not offer a group health plan or group health insurance coverage.

Example: An employee is enrolled in a group health plan through the employer at a total cost (taking into account both employer and employee contributions toward the cost of coverage) of \$14,000 for family coverage. The plan has a self-only option for a total cost of \$6,000, and the employer provides the employee and spouse the option of participating in a wellness program if they participate in the plan. The employer may not offer more than \$1,800 to the employee and \$1,800 to the spouse. The 30 percent limit is based on the \$6,000 cost of self-only coverage rather than the cost of family coverage.

Mirroring the final rule relating to wellness programs and the ADA, the final rule relating to GINA prohibits employers or covered entities from requiring employees to agree to the selling, exchanging, sharing, transferring, or disclosing of information (except as required to carry out the wellness program) or waiving confidentiality in any way. Employers may not condition participation in any group health plan on the participation in a wellness program that makes disability related inquiries, this renders the program involuntary.

Reasonable alternatives must be provided for employees and spouses for whom it is unreasonably difficult due to a medical condition, to complete the HRA or biometric screening due to a medical condition. An example would be an individual who has a medical condition that makes a blood draw a risky procedure.

Further Resources

[Press Release: EEOC Issues Final Rules on Employer Wellness Programs](#)

[GINA FAQ](#), EEOC

[ADA FAQ](#), EEOC

[HIPAA Privacy and Security and Workplace Wellness Program](#), U.S. Department of Health and Human Services

[Affordable Care Act Regulations and Guidance on Wellness Programs](#), U.S. Department of Labor

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