EEOC Issues Final Wellness Rules under ADA and GINA

On May 17, the Equal Opportunity Employment Commission (“EEOC”) published two sets of final rules applicable to employer-sponsored wellness programs – one under the Americans with Disabilities Act (“ADA”) and the other under the Genetic Information Nondiscrimination Act (“GINA”). The final rules closely follow the proposed regulations issued in 2015 (April 2015 for the proposed ADA regulations and October 2015 for the proposed GINA regulations) with several important changes and a number of clarifications. Below we summarize both sets of final rules and indicate which provisions are clarifications of existing requirements and which are changes from the 2015 proposed regulations. One major change is that the ADA and GINA rules apply to all wellness programs, not just programs that are tied to a group health plan or constitute a health plan. As a result, even employers that do not offer a group health plan, but do offer a wellness program, are subject to the ADA and GINA rules. Employers that are currently in the process of designing or modifying a wellness program will want to review these final rules early in the design process in order to ensure compliant programs.

Final ADA Rules

The ADA was enacted to prohibit discrimination against individuals with disabilities. The law applies to employers with 15 or more employees2 and prohibits employment discrimination, including discrimination based upon a disability in an employer-sponsored wellness program. The proposed regulations issued in April 2015 were the first formal guidance on wellness programs from the EEOC since 1991. In general, employers are not permitted to make disability-related inquiries or require medical examinations (including biometric testing) with limited exceptions. One of the exceptions is an employer-sponsored wellness program that satisfies the following requirements: (1) the program must be reasonably designed; (2) the program must be “voluntary”; (3) employees must be provided with a notice that contains certain information; (4) the information obtained by the wellness program must adhere to strict standards for confidentiality; and (5) there is a limit on the amount of incentives that may be offered for participation. (Note: The ADA rules do not apply to wellness programs that do not include disability-related inquiries or medical exams. Nor do the rules apply to spouses or dependents.) The ADA also contains a reasonable accommodation requirement – i.e., the program must be available to employees with disabilities such as providing large print materials for employees with limited vision.

1 Wellness programs that are, or are part of, a group health plan are also subject to HIPAA requirements. This Technical Bulletin does not cover HIPAA rules for wellness programs. Click here to access our wellness toolkit which contains information on current HIPAA rules. The toolkit also includes information on the proposed regulations issued in 2015, but we will update the toolkit to reflect the final rules in the near future.

2 The ADA also applies to employment agencies, labor organizations and joint-management committees.
**The Program Must Be Reasonably Designed**

In order to meet this standard, the program must have a reasonable chance of improving the health of (or preventing disease in) participating employees, must not be overly burdensome, must not be a subterfuge for violating the ADA or other laws that prohibit employment discrimination, and may not be highly suspect in the method chosen to promote health or prevent disease. A program that collects health information or uses tests or screening that does not provide results, follow up information, or advice designed to improve employees’ health is not considered to be reasonably designed.

The final rules clarify that a program is not reasonably designed if it: (1) does not use collected information to address at least a subset of conditions identified (which could take the form of advice to individual employees or programs to address health issues of a group of employees), (2) the program exists mainly to shift costs to targeted employees based on their health, or (3) is used simply to give the employer information to estimate future healthcare costs. An employer could, for example, collect and use aggregate information from employee Health Risk Assessments (“HRAs”) to design and offer programs aimed at specific conditions prevalent in the workplace such as diabetes or hypertension. The requirement that a wellness program must be reasonably designed applies to all wellness plans that include disability-related inquiries or medical exams, including those that are participatory only. For example, a wellness program that provides an incentive just for completing an HRA would be participatory only. If it includes questions about an employee’s medical conditions (such as whether the employee has diabetes or hypertension), rather than just lifestyle (such as whether an employee exercises regularly), the HRA includes disability-related inquiries and is subject to the ADA rules. Wellness programs that do not include disability-related inquiries or medical exams are not subject to the ADA rules, but must be available to all employees (or a reasonable class of employees such as all full-time employees) and must provide reasonable accommodation to employees with disabilities.

**The Program Must Be Voluntary**

Both the proposed regulations and final rules state that a wellness program will be considered voluntary if the employer:

- Does not require employees to participate;
- Does not deny coverage under any of its group health plans, or particular benefit packages within a group health plan, for non-participation, or otherwise limit the extent of benefits for employees who do not participate;
- Does not take any adverse employment action or retaliate against, interfere with, coerce, intimidate, or threaten employees in violation of the ADA; and
- Provides employees with a notice containing certain information relating to the program.

In the preamble of the final rules, the EEOC notes that some commenters asked that the EEOC permit group health plans to base eligibility for a particular health plan on completing a HRA or undergoing biometric screenings (sometimes called a gateway plan). However, the EEOC declined to do so, but noted that employers may offer incentives up to 30 percent of the total cost of self-only coverage based on participation in a wellness program. As a result, an employee who chooses a more comprehensive health plan, but declines to participate in a wellness program, could pay more for the comprehensive coverage than an employee who participates in the wellness program.
The EEOC also expanded upon its interpretation of the safe harbor provision under the ADA reaffirming their position that the insurance safe harbor is not available for wellness programs. This issue had been addressed by several courts prior to the issuance of these regulations and is likely to be the subject of additional litigation.

**ADA Insurance Safe Harbor**

As stated in the preamble to the final rules, the ADA safe harbor provision applicable to insurance states that an insurer or any entity that administers benefits 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 risk that are based on or not inconsistent with state law.” The EEOC believes that:

1. Reading the insurance safe harbor provision as applicable to wellness programs, and thus permitting incentives greater than the final rules permit or even to permit practices such as requiring employees to participate in wellness program in order to maintain their health insurance, would render U.S.C. Code Section 12112(d)(4)(B) unnecessary.

2. The safe harbor is intended to be narrow based upon legislative history. When the ADA was enacted, insurers and health plans were permitted to use practices such as charging more for individuals with certain health conditions. The safe harbor permitted insurers (and plans) to charge more for individuals with certain health conditions, but limited the practice to situations where the difference in premiums is based on sound actuarial principles. The intent was to permit insurers and plans to use health information for underwriting and risk classification. (Note: PPACA prohibits insurers and plans from charging individuals higher rates based on increased risks associated with medical conditions.)

3. Two recent ADA cases involving wellness programs were decided wrongly by the courts because in neither case did the employer use the wellness program data to determine insurability or to calculate insurance rates based on risk associated with certain conditions – practices that the EEOC believe the safe harbor provision was intended to permit.

The EEOC also addresses the safe harbor in question #6 in its final rules Questions & Answers document by stating that insurers (and plan sponsors) may use information about risks posed by certain health conditions to make decisions about insurability and the cost of insurance as long as these practices are consistent with laws governing insurance and are not a subterfuge to evade the ADA’s requirements. The EEOC also states that the safe harbor provision does not apply to employer-sponsored wellness programs since employers are not collecting or using information to determine whether employees with certain health conditions are insurable or to set insurance premiums. (Note: Many of the practices the safe harbor permitted when the ADA was enacted, such as increasing premiums for individuals with certain health conditions, are now prohibited by the Patient Protection and Affordable Care Act (“PPACA”.)

Based on the EEOC’s comments in the preamble and question #6, it appears likely that the EEOC will continue to challenge employers who rely on the insurance safe harbor when designing their wellness

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3 U.S.C. Code Section 12112(d)(4)(B) - “A covered entity may conduct voluntary medical examinations, including voluntary medical histories, which are part of an employee health program available to employees at that work site. A covered entity may make inquiries into the ability of an employee to perform job-related functions.”
programs. Employers that want to use the safe harbor when designing their wellness program should discuss the EEOC’s position and their program design with an attorney with appropriate experience before proceeding.

**Notice Requirement**

Employees must be provided with a notice that describes the information to be collected, how it will be used, with whom it will be shared, how it will be kept confidential, the restrictions on uses and disclosures, and the methods the employer has implemented to prevent improper disclosure of medical information. Employers that have already provided employees with notices will need to provide a revised notice if the existing notice does not contain all of the necessary information. The EEOC has promised to provide employers with a model notice on its website within 30 days after the date the final rules were published in the Federal Register (May 17, 2016).

The EEOC considered, but rejected, a request to exclude from the notice requirement wellness programs that provide only “de minimis” incentives. Although the rules do not include an example of a “de minimis” incentive, the Questions & Answers document that accompanies the rules include a reference to items of value – including “trinket” gifts. As a result, it appears that the notice requirement will apply if the program provides any incentive regardless of how small it may seem. In the preamble, the EEOC states that it did not include a “de minimis” exception because none of the commenters provided a workable definition of “de minimis.”

**Change** – Under the proposed rule, the notice requirement only applied to wellness programs that are, or are part of, a group health plan. The final regulations include a notice requirement for wellness programs that are separate from a group health plan if they include either disability-related inquiries or medical exams. **Applicable for plan years beginning on or after January 1, 2017.**

**Maximum Incentive**

The maximum incentive an employer may offer for participation in its wellness program(s) is 30% of the total cost (employer and employee amounts) of self-only coverage. (Note: The ADA applies to employees, not spouses and dependents. As a result, the ADA rules do not address incentives for family members.) The final rules include specific instructions governing how the 30% is to be calculated:

- If participation in the wellness program is dependent upon enrollment in a particular group health plan, then the incentive is limited to 30% of the total cost under that plan.

- If participation in the wellness program is not dependent upon enrollment in the employer’s group health plan and the employer offers only one group health plan, the 30% is based on the total cost of self-only coverage under that group health plan.

- If participation in the wellness program is not dependent upon enrollment in a particular group health plan and the employer offers more than one group health plan, the 30% must be calculated using the cost for the least expensive group health plan. For example, if the employer offers three group health plans with premiums for self-only coverage ranging from $5,000 to $8,000 and participation in the wellness program is not tied to enrollment in any particular plan, the 30% must be calculated using the $5,000 health plan (i.e., the maximum would be 30% of $5,000).
• If the employer offers a wellness program, but does not offer a group health plan, the 30% must be calculated using the cost of self-only coverage for a 40-year-old non-smoker under the second lowest cost Silver plan available through the state or federal Marketplace in the location that the employer identifies as its principal plan of business.

• The maximum incentive related to smoking cessation is limited to 30% of self-only coverage if the program includes biometric screening or another medical procedure that tests for the presence of nicotine or tobacco. If the wellness program does not include any disability-related inquiries or medical exams, the ADA 30% limit would not apply and the employer may offer an incentive up to the 50% level permitted by HIPAA.

**Change** – The proposed regulations limited the maximum incentive to 30% of the cost of coverage, but did not provide detailed guidance on how to calculate the 30%. The final rules include that guidance. 

**Applicable for plan years beginning on or after January 1, 2017.**

**Clarification** – Incentives include both financial incentives such as reduced contributions as well as non-financial incentives such as use of a parking spot. Employers may use any reasonable method to value non-financial incentives. **Applicable now.**

The EEOC considered, but rejected the idea of tying the maximum incentive to the “affordability” threshold under PPACA.

**Confidentiality Requirement for Medical Information**

Employers sponsoring wellness programs are required to take steps to protect the confidentiality of the information acquired through their wellness programs. Information regarding the medical condition or history of any employee must be collected and maintained on separate forms and in separate medical files that are treated as confidential medical records. Moreover, information regarding the medical history of any employee may not be used for any purpose inconsistent with the ADA. Medical information collected through an employee health program may only be provided to an employer subject to the ADA in aggregate terms that do not disclose, and are not likely to disclosure, the identity of specific individuals, except as needed to administer the health plan and as permitted by the ADA. Finally, an employer may not require an employee to agree to the sale, exchange, sharing, transfer or other disclosure of medical information (except to the extent permitted by the ADA to carry out specific activities related to the wellness program) or to waive the confidentiality protections put in place by the ADA as a condition for participating in the wellness program or receiving an incentive. **Note:** HIPAA also prohibits the sale, exchange, sharing transfer, or other disclosure of protected health information unless the patient provides written authorization.

**Clarification** - The final regulations make it clear that a participant may not be required to agree to the sale, exchange, sharing, transfer or other disclosure of medical information in order to participate in the wellness program or receive an incentive. **Applicable now.**

Both the proposed regulations and final rules provide information not only on the specific requirements, but also the best practices. For example as a best practice, an employer must train individuals who handle medical information and have clear privacy policies and procedures regarding the collection, storage, and disclosure of any medical information. In general, individuals who handle medical information obtained from a wellness program should not be responsible for making employment decisions. Employers that
administer their own wellness programs should have adequate firewalls in place to prevent any unintended disclosure of program-related medical information. An employer that uses a third-party vendor to reduce the risk of an impermissible disclosure will want to be familiar with the third-party’s policies for protecting the confidentiality, availability, and integrity of the medical information. Finally, should a breach occur, the breach should be thoroughly investigated and affected employees must be notified. In most cases, the employer’s wellness program will also be subject to the HIPAA privacy, security, and breach notification requirements. The EEOC notes that compliance with the HIPAA rules will likely translate into compliance with the ADA rules.

Clarification - The final rules clarify that an employer may not require an employee to agree to the sale, exchange, sharing, transfer or other disclosure of medical information (except as permitted to carry out wellness plan activities) or to waive confidentiality protections under the ADA as a condition for participating in the wellness program or receiving a wellness program incentive. Applicable now.

Final GINA Rules

In 2008, Congress enacted GINA in response to concerns about the potential misuse of genetic information to discriminate in employment and health insurance. GINA generally applies to employers with 15 or more employees and limits the acquisition and disclosure of genetic information. Employers may not request, require or purchase genetic information unless one of six narrow exceptions applies. One of those exceptions applies when an employee voluntarily accepts health or genetic services offered by an employer, including services offered as part of a wellness program.

GINA defines genetic information very broadly. In general, genetic information includes genetic tests, requests for genetic services, receipt of genetic services, and information about the manifestation of a disease or disorder in an individual’s family member (i.e., family medical history). Genetic information as defined by GINA also includes information about a fetus carried (or embryo legally held) by an individual or family member and information about an individual or family member using assisted reproductive technology. Pursuant to GINA, the term “family member” includes those who are related to the individual by blood or by marriage and includes dependents of an individual through birth, adoption, or placement for adoption. The term also applies to fourth degree relatives, such as a great-great grandchild or the child of a first cousin.

Although it is unlikely that an individual and spouse share genetic material, GINA’s definition of family member includes the individual’s spouse. Prior to the issuance of the proposed regulations in October 2015, there was a concern that requesting health information from an employee’s spouse would be considered genetic information since under GINA medical information about a spouse would be medical information about a family member. Specifically, employers offering wellness programs were concerned that offering spouses an incentive to complete a HRA that includes health questions or undergoing biometric testing would violate GINA. However, both the proposed regulations and final rules permit employers to offer an incentive under a wellness programs as long as the program satisfies specific requirements as noted below.

In order to comply with GINA, the final rules emphasize that the plan must satisfy the following four requirements: (1) there must be a reasonable plan design; (2) participation must be voluntary; (3) any incentive for participation cannot exceed a maximum percentage; and (4) the program must adhere to notice requirements and confidentiality standards. Each of these standards are discussed in greater detail below, and while they are similar to the requirements under the final ADA rules, they are not identical.
Reasonable Plan Design

The wellness program: (1) must be reasonably designed to promote health or prevent disease; (2) must not be overly burdensome; (3) must not be a subterfuge for violating GINA or other laws; and (4) must not be highly suspect in the method chosen. In addition, any program that includes a test, screening, or collection of health-related information without providing participants with results, follow-up information or advice designed to improve the participant’s health is not reasonably designed to promote health or prevent disease. A program is not considered reasonably designed, if it imposes a penalty on (or otherwise disadvantages) an individual because of a spouse’s manifestation of a disease or disorder by preventing or inhibiting the spouse from participating in, or from achieving a certain health outcome. For example, an employer may not deny an incentive to an employee or the employee’s spouse because the spouse has a cholesterol or blood glucose level that the employer considers too high. A program may be reasonably designed even without providing feedback to individual participants, as long as the information collected is actually used to design a program that addresses at least a subset of conditions identified. For example, a program may use the information collected to design and offer a program to address a medical condition such as high cholesterol that may be prevalent among employees and/or family members. However, any program that is used to shift costs to targeted employees, based on their health, is not reasonably designed. Likewise, any program that an employer uses to collect data in order to determine its future health costs is not considered reasonably designed.

Clarification – Programs that do not provide results, follow-up information, or advice designed to improve the participant’s health would not be reasonably designed unless the information is actually used to design a program that addresses at least a subset of conditions identified. Applicable now.

Participation must be Voluntary

Similar to the final ADA rules, an employer may not deny access to a group health plan, or any package of benefits in the group health plan, to an employee and/or the employee’s family members, or retaliate against an employee, based on a spouse’s refusal to provide information by completing a HRA or undergoing biometric testing.

A wellness program may offer an incentive for spousal participation if the spouse is covered under the employer’s health plan or the spouse receives health or genetic services offered by the employer (including as part of a wellness program). The spouse must be provided with a notice containing specific information and must provide knowing, voluntary, and written authorization.

The employer may not condition participation in a wellness program or eligibility for an incentive on an employee or spouse agreeing to the sale of genetic information or waiving his/her protections under GINA.

Clarification – The final rules make it clear that a participant may not be required to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information in order to participate in the wellness program or receive an incentive. Applicable now.

Maximum Incentives

The maximum incentive that may be offered for spousal participation is 30% of the total cost of self-only coverage. The wellness program may include questions about the spouse’s current or past health status and may include medical exams, such as biometric testing. However, no incentive may be offered for
information about genetic tests taken, genetic services received, or information about the spouse’s family medical history. For example, no incentive may be offered if a HRA includes questions about genetic tests the spouse received or questions about the spouse’s family medical history. Moreover, no incentive may be provided for information about the manifestation of disease or disorder of an employee’s children – either biological or adopted. Similar to the final ADA rules, the final GINA rules include specific guidelines with respect to how employers must calculate the 30% maximum incentive for spousal participation:

- If participation in the wellness program is dependent upon enrollment in a particular group health plan, then the incentive is limited to 30% of the total cost for self-only coverage under that specific plan.

- The maximum incentive for the employee and spouse is 30% of the total cost for self-only coverage for each person. For example, if the total cost for self-only coverage is $6,000, the maximum incentive for the employee would be $1,800 and the maximum incentive for the spouse would be $1,800. Note that even if the plan had a total family coverage cost of $14,000, the cost of self-only coverage is used to determine the maximum incentive.

- If participation in the wellness program is not dependent upon enrollment in the employer’s group health plan and the employer offers only one group health plan, the 30% is based on the total cost of self-only coverage under that group health plan.

- If participation in the wellness program is not dependent upon enrollment in a particular group health plan and the employer offers more than one group health plan, then the 30% must be calculated using the cost for the least expensive group health plan. For example, if the employer offers three group health plans with premiums for self-only coverage ranging from $5,000 to $8,000 and participation in the wellness program is not tied to enrollment in any particular plan, the 30% must be calculated using the $5,000 cost of the least expensive plan (i.e., the maximum incentive would be 30% of $5,000).

- If the employer offers a wellness program, but does not offer a group health plan, the 30% must be calculated using the cost of self-only coverage for a 40-year-old non-smoker under the second lowest cost Silver plan available through the state or federal Marketplace in the location that the employer identifies as its principal plan of business.

Change – Under the proposed regulations the maximum incentive for spousal participation was 30% of the difference between the total cost of coverage for the family unit and self-only coverage. For example if the employee and spouse were enrolled in a plan with premiums of $6,000 for self-only coverage and $15,000 for family coverage, the maximum incentive for the employee would be $1,800 while the maximum incentive for the spouse would be $2,700 (30% of the difference between $15,000 and $6,000). Under the new rules the maximum for spousal participation is $1,800. Applicable for plan years beginning on or after January 1, 2017.

Clarification – Incentives include both financial incentives, such as reduced contributions, as well as non-financial incentives such as the use of a parking spot. Employers may use any reasonable method to value non-financial incentives. Applicable now.
Clarification – The prohibition against incentives for children applies to all children including adopted and adult children. Applicable now.

Clarification – The incentive need not be paid directly to the spouse but may be paid using the method for paying other incentives such as a reduction in required contributions. Applicable now.

Notice Requirement and Confidentiality

GINA requires employers that possess genetic information to maintain that information in medical files that are separate from personnel files. The information must be treated as a confidential medical record with disclosure prohibited except in very limited circumstances. Confidentiality requirements apply to genetic information in both paper and electronic forms. The rules include examples of best practices such as the 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 affected individuals in the event of a breach.

The exception that allows employers to acquire genetic information as part of a wellness program or health plan requires both a notice to the individual and an authorization. If the spouse is completing a HRA or undergoing biometric testing, the notice must be provided to the spouse and must explain the restrictions on the disclosure of that information, state that individually identifiable genetic information is provided only to the individual receiving the services and the health care professionals or board certified genetic counselors involved in providing services, and that individually identifiable genetic information is only available for the purpose of providing health or genetic services and is not disclosed to the employer except in aggregate form. In addition, the employer must obtain prior knowing, voluntary, and written authorization from the spouse. If the spouse is completing a HRA, a separate authorization from the employees is not required. (If the employee is completing a HRA, the employee must provide the authorization.)

The EEOC considered, but rejected, a request to exclude from the notice requirement wellness programs that provide only “de minimis” incentives. Similar to the ADA rules, incentives include both financial and non-financial incentives. Although the rules do not define “de minimis”, based on the reference to “trinket” gifts in the EEOC’s ADA Questions and Answers, any item of value appears to trigger a notice requirement. In the preamble the EEOC states that it did not include a “de minimis” exception because none of the commenters provided a workable definition of “de minimis.”

The EEOC also considered, but rejected, the addition of a minimum necessary requirement on the collection of genetic information.

Applicability Date

The new provisions in the final ADA rules - the requirement to provide a notice that explains to the employee what information will be collected, how it will be used, with whom it will be shared, how it will be kept confidential, the restrictions on uses and disclosures, and the methods the employer has implement to prevent improper disclosure – will apply on prospectively to wellness programs as of the first day of the plan year that begins on or after January 1, 2017. Similarly, the limits on incentives will also apply prospectively for plan years beginning on or after January 1, 2017. All of the other provisions of the final ADA rules (which only clarify existing obligations) already apply.
The new provisions in the final GINA rules that apply to incentives will only apply prospectively to employer-sponsored wellness programs as of the first day of the plan year that begins on or after January 1, 2017. Similar to the ADA rules, provisions of the final GINA rules which represent clarifications already apply.

**Resources**

In addition to the final regulations, the EEOC has made available on its website Fact Sheets and Questions & Answers for both ADA and GINA. To access this material, click on the links below:

**ADA**

- Small Business Fact Sheet
- Questions & Answers
- Final Regulations

**GINA**

- Small Business Fact Sheet
- Questions & Answers
- Final Regulations

GBS provides a number of materials contained in a toolkit designed to help employers to design compliant wellness programs. Those materials currently include the HIPAA requirements along with the April 2015 proposed ADA regulations and the October 2015 proposed GINA regulations. Click here to access our wellness toolkit. Materials in the toolkit are currently being updated to reflect the final ADA and GINA rules.

**Employer Action Steps**

Employers should review any wellness program currently in existence and any programs under consideration to ensure that those programs will comply with the final regulations. Employers with stand-alone wellness programs (i.e., wellness programs that are not group health plans and are not part of a group health plan) may not have focused on the 2015 proposed ADA and GINA rules which were limited to group health plans and, as a result, may need more time to become familiar with the rules and may have more steps (e.g., may now need to send notices) that they need to take to ensure compliance. Employers with wellness programs that include disability-related inquiries or include biometric testing for employees or spouses or completion of a HRA by spouses should address some key questions:

- Is the program reasonably designed as defined by the final rules?
- Is the program voluntary for both employees and spouses as defined by the rules?
- Do existing notices include all the required information, or will a new notice be required?
- Are the incentives offered no more than the maximum allowed under the final rules?
• Is information obtained – responses to disability-related questions, medical information, and genetic information – maintained in separate medical files and kept confidential?

Gallagher Benefit Services, through its compliance experts and consultants, will continue to monitor developments on healthcare reform legislation and regulation and will provide you with relevant updated information as it becomes available. In the interim, please contact your Gallagher Benefit Services Representative with any questions that you may have.

The intent of this Technical Bulletin is to provide general information on employee benefit issues. It should not be construed as legal advice and, as with any interpretation of law; plans sponsors should seek proper legal advice for the application of these rules to their plans.