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New ADA and GINA Wellness Regulation Changes Complicate Wellness Program Compliance Analysis and Risks

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Wellness programs should all be reviewed considering the Americans with Disabilities Act ("ADA") and the Genetic Information Nondiscrimination Act ("GINA") regulatory changes because noncompliance with the new requirements do not carry just the HIPAA and ACA penalties, but the penalties for violation of the ADA and GINA which may include punitive damages awards that are generally not covered by most employment practices insurance.

Effective Date

The new requirements apply regardless of whether the wellness program is part of a health plan or a free standing wellness plan. The protection some courts had recognized for integration of the wellness program in the health plan is eliminated by these regulations which are in effect on and after January 1, 2017.

For calendar year plans, this means it will apply for all of plan year 2017 and must be considered as you prepare for annual enrollment for 2017.

For fiscal year plans these limits will apply in the middle of the plan year because the application of the rules to employers is effective on January 1, 2017 and there is no delay to the beginning of a plan year. This may change the amount of the payroll deductions must be processed in the middle of the plan year and necessitate communications with employees about a mid-year change in the wellness program benefits and changes in their payroll deductions. Because state payday laws, and possibly other contractual requirements, may require advance authorization of payroll deductions employers who have fiscal year plans may want to consider this regulations' impact on the payroll deductions on January 1 when drafting the payroll deduction authorizations and notifications for the fiscal year containing January 1, 2017.

Employers Subject to the ADA and GINA

It is important to remember that the ADA and GINA apply to employers who employ fifteen or more employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year. Thus, wellness programs for employers with fewer than fifteen employees in the current or preceding calendar year in less than the requisite number of weeks may be able to not be concerned with these rules, but each employer's situation needs to be reviewed. Employers who are close to being subject to these rules will need to monitor the thresholds for being subject to these rules as they are triggered as soon as the threshold is crossed and there is no delay until the next plan year begins.

Incentive Limitations

Incentives provided for wellness programs to be compliant with the ADA and GINA regulations will need to be more limited than permitted under the ACA. *Even though more generous wellness incentives are permitted under the ACA, noncompliance with the ADA or GINA requirements will carry stiffer sanctions for the employer. The incentive limitations under the ADA and GINA requirements are lower, more complex and require different calculations and analysis than the limits and analysis under HIPAA and the ACA wellness program rules.* Generally the limit is 30% of the self-only coverage cost, but what is the self-only coverage cost changes based upon the design of the medical and wellness plan. The calculation of the limits vary based on whether the wellness program is offered to the employee only or if the spouse might also participate, whether the wellness is only offered to participants in the one medical option offered by the employer, if there is one medical option and the wellness incentive is available to all employees and not just those enrolled, if there are multiple medical options and the wellness program is offered to all employees or if it is offered when there is no group major medical plan offered. *The ADA regulation limitations on the wellness program incentives or penalties apply to any wellness programs regardless of whether they are participatory or health status contingent under the HIPAA and ACA standards as a limitation on the total incentive or penalty if the ADA is implicated due to the questions asked or a medical examination/test. Compliance with the GINA regulations discussed below permits extending the incentive to the spouse if the spouse participates in the compliant wellness program.*

Smoking Cessation

Smoking cessation programs have higher limits on the incentives that may be provided under the ACA, there is no increase in the limits under the ADA regulations for smoking cessation programs; however, if the employer only asks if the employee is using tobacco and does not test, the ADA regulations do not apply to a mere question on tobacco use because it does not ask a disability related inquiry (assuming none of the other components include a medical exam or disability related inquiry).

However, if there is a test to determine if tobacco was used, that would be a disability related medical examination and the wellness program incentive would be subject to the lower limitation for wellness program incentives under the ADA regulations.

The Requirements

While HIPAA and the ACA divide wellness programs between participatory or health status contingent and smoking cessation, the ADA and GINA are focused on protection of individuals from discrimination based upon a disability or perceived disability and based on genetic information. Once a wellness program is permitted under HIPAA and the ACA, it must also be analyzed to see if it is subject to the ADA or GINA based on the size of the employer, the criteria used, if a medical exam is used or if the questions the participants must answer trigger the applicability of the ADA or GINA.

The wellness program must be voluntary under the ADA. Participation in the wellness program cannot be required as a condition to accessing health coverage or to access certain health options (e.g., an employee cannot be required to participate in the wellness program to access the PPO option, but the HMO option is available without participation). Coverage cannot be limited if the employee chooses not to participate in the wellness program (e.g., wellness participants have a lower deductible). An employer cannot retaliate against an employee who does not participate in the wellness program.

An employer subject to the ADA and GINA requirements, must determine if the wellness program (including any health risk assessment ("HRA") or biometric screening or other medical examination, including a blood draw to determine if a person is using tobacco) might potentially discriminate based on a disability and if it provides a reasonable alternative to meeting the requirement. If subject to the ADA, then the wellness program must meet all of the requirements, including the required notice contents under the final regulations. The wellness program must not be overly burdensome and it cannot place significant costs on the employees to participate and cannot exist mainly to shift costs to employees.

The wellness program must not violate federal nondiscrimination laws and must not discriminate on the basis of race, sex (including pregnancy, gender identity, transgender status, and sexual orientation), color, religion, national origin, or age. Wellness program requirements may not disproportionately affect individuals on the basis of a protected characteristic and employers can prevent such disparate impact claims by offering a reasonable alternative standard. For example if high blood pressure is prevalent in persons of a certain nationality, an alternative standard might be attending a class on lowering high blood pressure risks.

The wellness program also must be reviewed regarding how the data is used. Only the aggregate data may be provided to the employer. The wellness program must satisfy the requirement that it is reasonably designed to promote health or prevent disease under these regulations. Both the ADA and GINA regulations impose confidentiality requirements on the data collected in addition to the HIPAA privacy regulations that apply to group health plans. The ADA regulations prohibit an employer from requiring an employee to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information beyond what is needed for operation of the wellness program as a condition for participating in or receiving a wellness incentive. Security is required for any on-line systems. Reporting of breaches to participants is required. Employers using third party vendors are required to be familiar with the vendor's privacy policies for ensuring confidentiality of the medical records, this implies something more than merely signing a HIPAA business associate agreement. *The ADA confidentiality requirements appear to be intended to co-exist with the HIPAA Privacy regulations when both are applicable with the HIPAA limitations on disclosures prevailing when more restrictive. It is not clear what additional security requirements must be satisfied for online systems. The requirement to be familiar with the vendor's privacy practices to protect the confidentiality of the data is not a standard required under HIPAA Privacy or Security or in the business associate agreement, so this appears to be a requirement above and beyond those already in existence for*

group health plans with a wellness program component that would have been subject to the HIPAA Privacy and Security regulations.

The GINA regulations restrict the gathering of family medical information about diseases or disorders that are genetically identified or manifested in a family member as a "family member" is defined by GINA. Family members under GINA will include persons who may not be genetically related to the employee. Compliance with the GINA regulations permit both an employee and the employee's spouse to receive a reward or avoid a penalty by completing a HRA, if it is voluntary and any information that is requested in the HRA that is also protected by GINA is not required to be completed. Many of the other requirements are similar in that there are confidentiality requirements and the program must be reasonably designed to promote health or prevent disease. Compliance with the GINA requirements is necessary for an employer's wellness program to be able to provide an incentive, but does not increase the level of the incentive that can be provided, instead it permits an incentive to be provided to a spouse who participates in the wellness program in addition to any incentive provided to the employee. Many of the requirements in the proposed regulations continue in the final regulations.

All wellness programs should be reviewed to determine if they comply with the final ADA and GINA regulations.

ACA section 1557 Final Regulations Impact Health Plans of Health Care Providers Receiving Certain Federal Funds, Health Insurers and Third Party Administrators and Certain Others Who Receive Funds from the Department of Health and Human Services

These regulations apply to a covered entity that receives federal financial assistance from the Department of Health and Human Services ("HHS"), an entity that operates a health program or activity that receives Federal financial assistance, or an entity established under Title I of the ACA that administers a health program or activity, and HHS. A health program is the provision or administration of heath related services, health related insurance coverage or the health related coverage and providing assistance to individuals in to receive such services or coverage. A health program includes a hospital, health clinic, group health plan, health insurance issuer, nursing facility or a residential or community based treatment facility or a similar entity.

Federal financial assistance includes any subsidy, funds made available or federal personnel services, or tax credits that are administered by HHS under the ACA and also to all payments, subsidies or other funds HHS extended to any entity providing health related insurance coverage on the exchanges. Federal financial assistance also includes a contract, that is not a procurement contract, or any other arrangement by which the Federal government provides or otherwise makes available assistance in the form of funds, services, or real or personal property or the use of the same, or funds the Department plays a role in providing or administering. An employer plan for instance would be a covered entity if it were still receiving funds under the Early Retiree Reinsurance Program established under the ACA. Health insurers providing coverage on the exchanges established under the ACA are receiving the advance payment of health care tax credits and other subsidies toward reduced cost sharing for low income enrollees (the subsidies the D.C. District Court recently ruled unconstitutional for the government to fund, but then did not require compliance with its ruling until the appeal is decided- See- *U. S. House of Representatives v. Burwell*, no. 14-1967 (RMC), May 12, 2016)) and will be subject to these new nondiscrimination requirements.

Health care providers who receive funds from HHS which constitute federal financial assistance will be subject to the nondiscrimination requirements in these final regulations with respect to their group health benefit plans. What constitutes federal financial assistance is very fact specific. It clearly includes the Children's Health Insurance Program, the Basic Health Program and student health insurance programs because of the funding for education provided by the federal government. A careful review of an organization's operations and sources of funds is necessary under the new rules to determine if the plan or organization is receiving "Federal financial assistance" and is subject to the new nondiscrimination requirements.

The ACA section 1557 final regulations prohibit discrimination on the basis of race, color, or national origin, age, gender, including gender identity. Any health program subject to these requirements shall provide equal access to its health programs without discrimination on the basis of sex and shall treat an individual consistent with the individual's gender identity, and may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex , to a

transgender individual based on the fact that the individual's sex assigned at birth, is different from the gender to which such health services are ordinarily or exclusively available.

A covered entity must not in providing or administering health-related insurance or coverage, deny, cancel, limit or refuse to issue or renew a health related insurance plan, policy or coverage or impose additional cost sharing or other limitations on the basis of race, color, national origin, sex, age or disability. A covered entity must not deny or limit coverage of a claim or impose additional cost sharing or other limits or restrictions on any health service that is a service ordinarily or exclusively available to individuals of one gender to an individual who is transgender, if that denial or limitation discriminates against a transgender individual.

A covered entity must not have or implement a categorical coverage exclusion or limitation for all health services related to gender transition and must not impose additional cost sharing or other restriction on services related to gender transition if such limitation or denial results in discrimination against a transgender individual. This is not intended to preclude a covered entity from determining if a health service is medically necessary or otherwise meets applicable coverage requirements for any individual claim.

These requirements apply to the group health plans sponsored by entities receiving federal financial assistance and for health insurers offering coverage on the exchanges on the first day of the first plan year beginning on or after January 1, 2017. The regulation includes notification requirements, a required grievance procedure, a provision for health access for persons with limited English proficiency and other requirements.

The regulatory changes keep coming and each change requires analysis to determine if it applies, how it applies, and what options exist. Based upon the recently published regulatory agendas for several federal agencies, this will be an active season for regulatory activity before the end of the term.

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