ABA Section of Taxation
Employee Benefits Committee
Health Plan Design and Compliance Update
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Landmark Genetic Nondiscrimination Legislation

On May 21, 2008, President Bush signed the Genetic Information Nondiscrimination Act of 2008 ("GINA"), which Congress passed in late April. GINA sets forth new nondiscrimination prohibitions that apply to group health plans, health insurance companies and employers.

Group Health Plans and Health Insurers

Plans and Insurers Affected

Title I of GINA applies to group health plans and health insurers offering health coverage. GINA applies to group health plans for plan years beginning at least one year after the date of enactment (i.e., for calendar year plans January 1, 2010). For individual health insurance GINA applies to coverage offered, issued or in effect after the date that is one year after enactment.

New Prohibitions

GINA amends ERISA and the Code to establish a number of new prohibitions, as follows:

- **Premiums.** Currently, the HIPAA nondiscrimination regulations prevent group health plans from taking into account genetic information when setting an individual's premiums. GINA moves the line a step farther by prohibiting group health plans from adjusting premiums or employer contribution amounts for the group as a whole on the basis of genetic information. However, GINA does not prevent the premium or contribution of the group from being adjusted on the basis of the actual manifestation of any disease or disorder of an individual covered by the plan.
- **Genetic Testing.** GINA prohibits group health plans from requesting or requiring an individual or a family member to undergo a genetic test.
- **Underwriting.** GINA prohibits group health plans from requesting, requiring or purchasing genetic information for underwriting purposes. Underwriting is defined to include determination of eligibility for benefits, computation of a premium or contribution under the plan, the application of a pre-existing condition exclusion and other activities relating to the creation, renewal or replacement of coverage.
- **Enrollment.** In addition to the underwriting prohibition, a group health plan is also prohibited from requesting, requiring or purchasing genetic information for any purpose before an individual's enrollment under the plan.

HIPAA Privacy Regulations

Currently, the HIPAA privacy regulations include genetic information within an individual's protected health information ("PHI"). GINA directs the Department of Health and Human Services to amend the HIPAA privacy regulations to provide that genetic information be treated as a special class of PHI, and that consistent with the prohibitions above, group health plans and health insurers be prohibited from using or disclosing genetic information for underwriting purposes.

Genetic Information

GINA applies to "genetic information," which includes any of the following information –

- **Genetic Tests of an Individual or Family Member.** Genetic tests are analyses of an individual's DNA, RNA, chromosomes, proteins or metabolites that detect genotypes, mutations or chromosomal changes.
- **Family Medical Histories.** The manifestation of diseases or disorders among an individual's family members are part of the individual's genetic information.
- **Genetic Services.** Information obtained through genetic services or participation in clinical research that includes genetic services is genetic information. Genetic services may consist of genetic tests, genetic counseling (including obtaining, interpreting or assessing genetic information), or genetic education.

Family members include immediate family members and extended family members, up to the fourth degree of kinship. In addition, the genetic information of a pregnant woman or an individual using assisted reproductive technology also includes the genetic information of the fetus or embryo. However, the age and sex of an individual are not considered to be genetic information.

Enforcement

Violations of the above rules can result in penalties of $100 per day per individual beginning with the first day the violation occurs and ending on the date the violation is corrected. If a violation is not corrected before receiving notice of the violation, there will be a minimum penalty of $2,500 with respect to any participant or beneficiary. If the violation is considered to be more than de minimis, the minimum penalty will be increased to $15,000. Further, there is a maximum penalty with respect to failures that are due to reasonable cause and not to willful neglect of the lesser of 10% of the aggregate amount paid by the plan sponsor during the preceding taxable year for its group health plans or $500,000.

These penalties will not be imposed if the Secretary of Labor or Treasury (as applicable) determines that the party did not know, and would not have known through the exercise of reasonable diligence, of the violation. In the case of violations due to reasonable cause, the penalties will not be imposed if the violations are corrected within 30 days of when the party first knew, or should have known through the exercise of reasonable diligence, of the violation. The Secretary may waive any penalty to the extent that the penalty would be excessive in relation to the violation.

Implications

The Department of Labor, the Internal Revenue Service and the Department of Health and Human Services must revise the HIPAA nondiscrimination regulations and the HIPAA privacy regulations to take into account the new prohibitions imposed by GINA. Before that occurs, some plan sponsors and third party administrators have already begun to assess the implications of GINA. It is clear that the

regulations will need to address a number of interesting and hard issues. At this point, GINA appears to have the most effect on wellness plans and other disease management activities.

Health Risk Assessments (HRAs). Under GINA it appears that an HRA used prior to enrollment or an HRA used for purposes of underwriting at any time cannot include questions regarding the manifestations of a genetic disease or disorder of family members. Such questions may include whether the individual's family members have had cancer, heart disease or any other hereditary disease or disorder. Even if GINA would not prohibit such questions in an HRA, the mere collection of this information may raise implications regarding the storage and later use of the information.

Predictive Modeling. Some third party administrators provide predictive modeling services to wellness plan participants. This would include an analysis of health data (which may include both health claims and information from HRAs), which then predicts an individual's chances of contracting a disease or disorder. Although not an actual genetic test, it is unclear whether this type of analysis will be considered a genetic test in the regulations, or whether its use would just be prohibited for underwriting purposes.

Interaction of Health Plan and Employer Penalties

Title II of GINA generally prohibits employers, employment organizations and labor organizations from discriminating against employees or prospective employees on the basis of genetic information. The business community had sought to insert a "firewall" between the penalties for health plans and penalties for employers so that an employer would not be subject to penalties under both provisions with respect to the same conduct. GINA provides in Section 209(a)(2)(B) that the employment prohibitions of Title II should not be construed to provide for the enforcement of, or penalties for, violation of any requirement applicable to group health plans under Title I. While this provision may properly be read to provide that the remedies under Title II will not apply to any conduct that is subject to Title I, it leaves open the possibility that an employer could be subject to the penalties under Title I and Title II for conduct regarding a group health plan if the conduct violates the requirements of both Title I and Title II.