

Summary of GINA Regulations

On October 7, 2009, the Departments of Treasury, Labor and Health and Human Services issued regulations implementing the requirements of Title I of the Genetic Information Nondiscrimination Act ("GINA"). The rules generally prohibit group health plans from taking certain actions based on an individual's genetic information. Because the term "genetic information" is broadly defined to include family medical history, many current health risk assessment ("HRA") practices will need to be revised. The GINA rules are effective for plan years beginning on or after December 9, 2009. This email summarizes the new rules. [1]

What are the GINA rules? The GINA rules include three specific prohibitions affecting group health plans:

Rule #1 - A group health plan can't adjust premium or contribution amounts for the plan, or for any group of similarly situation individuals under the plan, on the basis of genetic information.

Rule #2 - A group health plan can't request or require an individual or a family member of the individual to undergo a genetic test.

Rule #3 - A group health plan can't collect genetic information for underwriting purposes or prior to an individual's effective date of coverage.

Most employer-sponsored health plans won't have problems with the first two rules, because the actions prohibited by those rules aren't common. However, many employer-sponsored health plans will experience problems with Rule #3 if they are rewarding, or penalizing, plan participants who complete HRAs that include questions

about family medical history (which, as noted below, is treated as genetic information).

How is genetic information defined? The term "genetic information" means information about an individual's genetic tests, the genetic tests of the individual's family members, the manifestation of a disease or disorder in the individual's family members or a request for, or receipt of, genetic services (or participation in clinical research which includes genetic services) by the individual or the individual's family members. This definition includes references to several other defined terms:

The term "family member" means dependents and first-degree, second-degree, third-degree and fourth-degree relatives. Essentially, this includes any relative of an individual within four degrees of relationship.

- The term "genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes (but not an analysis of proteins or metabolites directly related to a manifested disease).
- The term "genetic services" means a genetic test, genetic counseling or genetic education.
- The term "manifestation" or "manifested" means that an individual has been or could reasonably be diagnosed with a disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved.

HRAs typically include questions about family medical history. These questions solicit information about whether a family member has, or had, a specific disease or condition. Thus, these questions relate to the manifestation of a disease or disorder in a family member and are treated as genetic information.

When will an HRA violate Rule #3? An HRA offered in conjunction with a group health plan will violate Rule #3 if the HRA collects family medical history for underwriting purposes or if the HRA collects family medical history prior to the effective date of an individual's enrollment in the plan. The term "underwriting purposes" means: (1) eligibility and enrollment determinations, including cost-sharing changes linked to completion of an HRA or participation in a wellness program; (2) premium or contribution determinations, including premium or contribution differentials linked to completion of an HRA or participation in a wellness program; (3)

preexisting condition exclusions; and (4) other activities related to the creation, renewal or replacement of health insurance or health benefits. [2] Thus, if an HRA collects family medical history and the group health plan provides an incentive bonus for an individual who completes the HRA (or penalizes an individual who doesn't complete the HRA), then the family medical history is being collected for underwriting purposes.

Do the regulations include examples? The GINA rules include a series of examples illustrating situations where group health plans with HRAs either satisfy or violate the requirements of Rule #3:

Example #1 - A group health plan provides a premium reduction for individuals who complete an HRA following enrollment. The HRA requests information about an individual's family medical history. This plan VIOLATES Rule #3 because it collects genetic information for underwriting purposes (i.e., the completion of the HRA with family medical history doesn't affect enrollment status but does result in a premium reduction).

Example #2 - A group health plan does not provide a premium reduction for individuals who complete an HRA following enrollment. The HRA requests information about a family's medical history. This plan SATISFIES Rule #3 because it does not collect genetic information for underwriting purposes (i.e., the completion of the HRA with family medical history doesn't affect enrollment status or premiums), nor does it collect genetic information prior to an individual's effective date of coverage.

Example #3 - A group health plan asks individuals to complete an HRA prior to enrollment. The HRA includes questions about an individual's family medical history. This plan VIOLATES Rule #3 because it collects genetic information prior to an individual's enrollment.

Example #4 - A group health plan does not provide a premium reduction for individuals who complete an HRA following enrollment. Instead, individuals completing the HRA may become eligible for enrollment in a disease management program. The HRA includes questions about an individual's family medical history. This plan VIOLATES Rule #3 because it collects genetic information for underwriting purposes (i.e., eligibility for enrollment in the disease management program).

Example #5 - A group health plan asks individuals to complete two separate HRAs after enrollment. HRA #1 does not ask about an individual's family medical history, or about the individual's genetic tests. Individuals who complete HRA #1 receive a reward. HRA #2 asks about an individual's family medical history and about the individual's

genetic tests. Individuals who complete HRA #2 do not receive a reward. This plan SATISFIES Rule #3 because HRA #1 doesn't collect genetic information at all (so it's ok for the plan to offer a reward for completing that HRA), HRA#2 doesn't collect genetic information for underwriting purposes (because completion of that HRA doesn't result in a reward) and neither HRA requests genetic information prior to the individual's effective date of coverage.

Example #6 - A group health plan waives its annual deductible for individuals who complete an HRA after enrollment. The HRA does not ask a specific question about an individual's family medical history, but includes an open question inviting the individual to identify "anything else relevant to your health that you would like us to know." This plan VIOLATES Rule #3 because it collects (or could collect) genetic information for underwriting purposes (i.e., an individual might provide genetic information when completing the HRA, and completion of the HRA results in waiver of the annual deductible).

Example #7 - A group health plan waives its annual deductible for individuals who complete an HRA after enrollment. The HRA does not ask a specific question about an individual's family medical history, but includes an open question inviting the individual to identify "anything else relevant to your health that you would like us to know." The question goes on to state that an individual should not include any genetic information, including family medical history. This plan SATISFIES Rule #3 because it does not collect genetic information - any genetic information provided would be incidental and would not be used for underwriting purposes.

What are the penalties for noncompliance with the GINA rules? For violations associated with ERISA-covered plans, the Department of Labor ("DOL") has authority to assess a \$100 per day per participant penalty until a violation is corrected. This penalty is imposed against the group health plan sponsor. No penalty is imposed if the violation could not have been discovered exercising reasonable diligence, or if the violation is corrected within 30 days of discovery. In addition, the DOL also has authority to waive the penalty. If the violation is not corrected before DOL notifies the plan sponsor, the minimum penalty is \$2,500 (or \$15,000 if the violation is more than "de minimis") and the maximum penalty (if the violation is not due to willful neglect) is the lesser of 10% of the plan sponsor's aggregate previous year spending on health plans or \$500,000. For violations associated with non-ERISA covered plans, the IRS has authority to impose similar excise tax penalties.

What actions should we take to comply with the GINA rules? The principal affect of the GINA rules is to prohibit group health plans from collecting family medical history,

a practice that is very common with most HRAs. Suggested action items include:

- Determine your compliance risk - Review your current HRA practices and determine whether your practices are in potential violation of the GINA rules. If the HRA is linked to a group health plan, if the HRA collects family medical history, and if completion of the HRA affects eligibility, enrollment, cost-sharing, premiums or contributions under the plan or if the HRA must be completed prior to enrollment, then you will need to take corrective action.
- Talk to your HRA vendors - Schedule some time with your HRA vendors to discuss possible "work-around" strategies. For example, it may be possible to disregard the HRA questions relating to family medical history. It may also be possible to revise the HRA so that family medical history is not collected. Other possible strategies include: (1) eliminating any group health plan reward or penalty linked to completion of the family medical history questions on an HRA; or (2) evaluating whether it is possible to uncouple the HRA from your group health plan and instead provide rewards out of general assets[3].
- Communicate your decisions - Tell plan participants what you are doing, or intend to do, regarding GINA compliance. Many participants have already completed HRAs that collected family medical history and you, and your HRA vendors, may need to consider whether that information can be destroyed. Going forward, rewards and penalties for completing an HRA can't be based on family medical history, so that information should not be collected as part of an HRA process. After deciding on an appropriate corrective strategy with your HRA vendors, explain to plan participants what is being done with respect to previously collected family medical history, and what modifications will be made to your HRA practices going forward.
- Review your HIPAA privacy documents - The GINA-related HIPAA privacy revisions appear to require modifications to your HIPAA policies and procedures and HIPAA privacy notice if a group health plan uses or discloses protected health information for underwriting purposes. It is not clear whether this means any protected health information or only protected health information consisting of genetic information (including family medical history). If you modify your HRA practices so that no genetic information is collected for underwriting purposes, then you may not need to modify your HIPAA documents. Assuming this issue is clarified in final regulations, you will have 180 days following publication of the final regulations to modify your HIPAA documents.

Please do not hesitate to contact SBA with any questions or if you require additional information.

[1] Also on October 7, 2009, the Department of Health and Human Services issued regulations proposing GINA-related revisions to the HIPAA privacy rule. The HIPAA privacy revisions prohibit covered entities, including employer-sponsored health plans, from using or disclosing protected health information consisting of genetic information for underwriting purposes. The HIPAA privacy revisions also require covered entities that use protected health information for underwriting purposes to revise their privacy notices and HIPAA policies and procedures to clarify that the entity is prohibited from using genetic information for underwriting purposes. The HIPAA privacy revisions would take effect 180 days after publication of final regulations.

[2] The term "underwriting purpose" does not include a group health plan's determination on whether a benefit is medically appropriate. Thus, if a determination of medical appropriateness depends on genetic information, then the plan is permitted to condition the benefit based on the genetic information.

[3] Title II of GINA seems to permit the limited collection of genetic information as part of certain voluntary wellness programs. However, it is not entirely clear what type of wellness program designs will avoid the Title I prohibitions. In other words, is it possible to design a voluntary wellness program that is not a group health plan? The EEOC administers Title II of GINA but has not addressed this issue.

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