

October 15, 2009

MEMORANDUM TO CLIENTS

RE: New Interim Final Regulation on Genetic Information Nondiscrimination Act (GINA) (including new restrictions on Health Risk Assessments)

The Genetic Information Nondiscrimination Act of 2008 ("GINA"), signed into law on May 21, 2008, prohibits group health plans, health insurers, and employers from discriminating against individuals on the basis of their genetic information.¹ On October 10, 2008, the Internal Revenue Service ("IRS"), Department of Labor ("DOL"), and Centers for Medicare and Medicaid Services ("CMS") (collectively, "the agencies") published a request for information soliciting comments on Title I of GINA, which prohibits discrimination in health coverage based on genetic information. Last week, after consideration of comments received and consultation with other government agencies, the agencies published interim final regulations implementing Title I of GINA.² These regulations are more restrictive than anticipated, particularly with respect to the use of health risk assessments ("HRAs"). For group health plans, these regulations are effective for plan years beginning on or after December 7, 2009. Comments on these regulations are due on or before January 5, 2010.

The new interim final regulations implementing Title I of GINA include number of provisions that will be of interest to health plans and plan sponsors, the most significant of which we discuss below.

General Rule*Prohibited Discrimination*

Title I of GINA provides that health plans and health insurers may not:

- Adjust premium or contribution amounts on the basis of genetic information;
- Request or require that an individual or the individual's family member undergo a genetic test;
- Request, require, or purchase genetic information for underwriting purposes; or
- Request, require, or purchase genetic information with respect to any individual prior to, or in connection with, the individual's enrollment in a group health plan.

¹ We provided an overview of GINA's structure and basic requirements in a memorandum issued July 2, 2008. <http://www.groom.com/resources-89.html>.

² The Equal Employment Opportunity Commission ("EEOC") released proposed regulations implementing Title II of GINA, which covers genetic nondiscrimination in employment, on March 9, 2009. To date, the EEOC has not released final regulations implementing Title II.

Definitions

As detailed in our July 2008 memorandum, the key to understanding GINA's requirements lies in a careful review of its definitions. Significantly, the new regulations provide guidance on the following GINA terms.

Genetic Information

GINA defines "genetic information" as, with respect to any individual, information about the individual's genetic tests, the genetic tests of family members of the individual, the manifestation of a disease or disorder in family members of the individual, and any request for, or receipt of, genetic services, or participation in clinical research that includes genetic services, by the individual or any family member of the individual. The new regulations also provide that "genetic information" includes genetic information of any fetus carried by a pregnant woman or a family member of a pregnant woman and, with respect to an individual or a family member of the individual who is utilizing an assisted reproductive technology, genetic information of any embryo legally held by the individual or family member. The regulations provide that "genetic information" does not include information about the sex or age of an individual.

The Preamble to the new regulations clarifies that "genetic information" includes family medical history. Therefore, a request for family medical history on an HRA would constitute a request for genetic information for GINA purposes.

Underwriting Purposes

The regulations define "underwriting purposes" broadly to include, with respect to any group health plan or health insurance coverage offered in connection with a group health plan:

- (a) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);
- (b) The computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);
- (c) The application of any preexisting condition exclusion under the plan or coverage; and
- (d) Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

Observation: In this definition, the agencies take the view that providing a monetary incentive for completing an HRA that requests family medical history would fall under categories (a) and (b) above and therefore, violate GINA's prohibition on requesting genetic information for

"underwriting purposes." The Preamble notes that, although the agencies did receive comments urging an exception to allow wellness programs to provide rewards for completing HRAs that request genetic information, the agencies ultimately decided not to allow such an exception. This broad definition of "underwriting purposes," therefore, restricts the ability of group health plans to provide incentives, such as premium discounts, for completing HRAs that include questions about genetic information, including family medical history. This restriction would apply to calendar year plans as of 01/01/2010.

Restrictions on Collecting Genetic Information under an HRA

As noted above, GINA prohibits collection of genetic information (1) for underwriting purposes and (2) prior to or in connection with enrollment. The new regulations provide guidance and clarification that could have a significant impact on group health plans, and particularly, on group health plans that use HRAs. Specifically:

- A group health plan cannot request or require genetic information prior to or in connection with an individual's effective date of coverage, and
- A group health plan cannot request or require genetic information for underwriting purposes. As noted above, "underwriting purposes" includes providing monetary incentives for completing HRAs that request genetic information, including family medical history.

Thus, with regard to HRAs:

(1) Any request for genetic information (including family medical history) cannot occur before the effective date of coverage. The Preamble to the GINA regulations states that, for individuals who already are enrolled or who re-enroll on an annual basis, it is permissible to collect genetic information after the initial enrollment, provided the genetic information is not used to affect a subsequent enrollment. However, for new enrollees, genetic information cannot be collected until after the effective date of coverage.

(2) Any request for genetic information (including family medical history) cannot be tied to a reward. However, the regulations provide that a plan sponsor could provide a reward if it:

- Removes any request for genetic information (including family medical history) from the HRA, or
- Separates any requests for genetic information (including family medical history) into a second HRA for which there is no reward and makes clear in the second HRA that completing the second HRA is voluntary and will not affect the reward for the first HRA.

The new regulations also suggest that an HRA should not request genetic information (including family medical history) if the answer may result in the participant being enrolled in a disease management program, even if there is no additional reward involved and the HRA is

completed after enrollment. The Preamble explains that such a request for genetic information would be for "underwriting purposes," which includes "determination of eligibility (including enrollment and continued eligibility) for benefits under the plan." However, a reasonable argument can be made that this rule only prohibits a plan from limiting enrollment in a disease management program to people who complete an HRA (i.e., if there are alternative pathways to enroll in a disease management program, this rule may not apply). In addition, there is an exception to this rule for payments that are based on medical appropriateness.

Observation: This rule may present difficulties for many wellness programs, as wellness programs often identify participants for disease management programs based on genetic information. Therefore, it is difficult to reconcile this rule with the fact that the Preamble and regulations do allow requests for genetic information (including family medical history) in an HRA, as long as no reward is offered for completing the HRA. Commenters should consider raising this issue with the agencies and requesting clarification.

Exceptions to Prohibition on Requesting or Requiring Genetic Testing

As noted above, GINA prohibits a health plan or health insurer from requesting or requiring that an individual or the individual's family member undergo a genetic test. However, the statute provides exceptions to this rule, such as the exception that allows a plan or insurer to obtain and use the results of a genetic test in making a determination regarding payment. Requesting genetic information in this context is permissible, provided the plan or insurer requests only the minimum amount of genetic information needed to make the determination.

In several examples, the new regulations address the situation in which a genetic test is needed to determine medical appropriateness for payment purposes. In one example, a health plan may cover a yearly mammogram for participants and beneficiaries starting at age 40, or age 30 for those with increased risk for breast cancer, including individuals with certain gene mutations. In these circumstances, a plan may ask a participant for evidence of increased risk of breast cancer, such as the results of a genetic test or a family history of breast cancer before paying a claim for a mammogram, provided the policy is applied uniformly to all similarly situated individuals and is not directed at individuals based on any genetic information. The regulations also say that a plan may refuse payment for a service if the individual does not undergo the required genetic test.

Effective Date

For the group market, the regulations are applicable to plans and health insurers on the first day of the plan year beginning on or after December 7, 2009. For the individual market, the regulations are applicable with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated on or after December 7, 2009.

Observation: The effective date may present particular difficulties for group health plans that utilize HRAs, as many calendar year plans have already distributed HRAs that include questions on family medical history as a part of open enrollment for the 2010 plan year. As a result, such plans may risk noncompliance with GINA's prohibition on requesting genetic information prior

to or in connection with enrollment. However, we understand from informal conversations with agency officials that in such cases, plan sponsors are not necessarily in violation of GINA. One example is the case of a plan sponsor that sends out an HRA with questions on family medical history before January 1, 2010 as part of a plan's open enrollment materials and receives all responses prior to January 1, 2010. The plan sponsor will likely be considered in compliance with GINA in such a case, provided information on family medical history is not used for underwriting purposes for 2010 coverage (*i.e.*, no reward or penalty is associated with completing or not completing the HRA). If a reward or penalty is offered for completing an HRA that requests genetic information, a conservative approach for a calendar year plan would be to distribute or collect that reward or penalty before January 1, 2010.

Penalties

Possible penalties for GINA violations include:

- Individuals may bring suit under ERISA § 502 to enforce Title I of GINA.
- A civil penalty under ERISA § 502(a)(9) in the amount of \$100 per participant per day if the failure is not corrected before the date the plan at issue receives notice of the violation from the Secretary of Labor. The penalty does not apply if the person otherwise liable for the penalty did not know, and exercising reasonable diligence would not have known, that the failure existed. The maximum penalty is the lesser of \$500,000 or 10% of the aggregate amount paid or incurred by the plan sponsor during the preceding taxable year for group health plans.
- Liability for excise taxes under section 4980D of the Internal Revenue Code in the amount of \$100 per participant per day if the failure is not corrected before the date the employer receives notice of examination of income tax liability.³ The penalty does not apply if the person otherwise liable for the penalty did not know, and exercising reasonable diligence would not have known, that the failure existed. The maximum penalty is the lesser of \$500,000 or 10% of the aggregate amount paid or incurred by the plan sponsor during the preceding taxable year for group health plans.

Proposed Regulations Modifying the HIPAA Privacy Rule

In addition to the agencies' interim final regulations, the Department of Health and Human Services ("HHS") issued proposed primary regulations with regard to "genetic information" on October 7, 2009. In accordance with GINA's requirements, these proposed regulations revise the HIPAA Privacy Rule such that (a) genetic information is treated as "protected health information" ("PHI") and (b) group health plans, health insurers, and Medigap policy issuers are prohibited from using or disclosing genetic information for underwriting purposes. These proposed regulations also include the following provisions:

³ The IRS has issued final excise tax regulations, which require employers, plans, and other responsible parties to report and pay excise taxes for failures to comply with group health plan requirements, including those under GINA. A summary of these regulations is available at: http://www.groom.com/media/publication/614_Excise%20Tax%20Article.pdf

GROOM LAW GROUP

- Possible Change to Notice of Privacy Practices. For a health plan that uses or discloses PHI for underwriting, HHS proposes to require such a plan to include a statement in its Notice of Privacy Practices that makes clear that the plan is prohibited from using or disclosing PHI that is genetic information about an individual for such purposes.
- Prohibition on Use/Disclosure of PHI that is Genetic Information. Under the proposed regulations, all health plans subject to the HIPAA privacy rule—not just plans subject to GINA—would be prohibited from using and disclosing PHI that is genetic information for underwriting purposes.

Comments on these proposed regulations are due to HHS on or before December 7, 2009.

* * *

Authors: Jon Breyfogle, Thomas Fitzgerald, Chris Keller, Christy Tinnes, and Debbie Leung

If you have any questions or would like our assistance with submitting comments, please contact your regular Groom attorney or any of the Health and Welfare Practice Group attorneys listed below:

Jon W. Breyfogle	jwb@groom.com	(202) 861-6641
Jenifer A. Cromwell	jac@groom.com	(202) 861-6329
Thomas F. Fitzgerald	tff@groom.com	(202) 861-6621
Cheryl Risley Hughes	chughes@groom.com	(202) 861-0167
Christine L. Keller	clk@groom.com	(202) 861-9371
Tammy Killion	tkillion@groom.com	(202) 861-6328
Debbie G. Leung	dgl@groom.com	(202) 861-2601
William F. Sweetnam	wfs@groom.com	(202) 861-5427
Christy A. Tinnes	cat@groom.com	(202) 861-6603
Donald G. Willis	dgw@groom.com	(202) 861-6332
Brigen L. Winters	blw@groom.com	(202) 861- 6618