

MEMORANDUM TO CLIENTS

RE: Genetic Information Nondiscrimination Act ("GINA")

On May 21, 2008, President Bush signed the Genetic Information Nondiscrimination Act of 2008 (Pub. L. No. 110-233) ("GINA") into law. GINA prohibits discrimination on the basis of individuals' genetic information by group health plans, health insurers, and employers and consists of two titles: Title I, which covers genetic nondiscrimination in health insurance and Title II, which covers genetic nondiscrimination in employment. GINA contains a number of provisions that will be of interest to health plans and plan sponsors, which we discuss in greater detail below.

Title I: Genetic Nondiscrimination in Health Insurance

Before GINA's enactment, nondiscrimination provisions under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") already prohibited health plans and insurers from establishing eligibility rules or charging higher premiums or contributions on the basis of "health factors," including genetic information. However these nondiscrimination provisions did not prohibit setting group premium rates on the basis of health factors. GINA extends HIPAA by prohibiting health plans and insurers from setting group premium rates on the basis of genetic information and includes a myriad of other specific prohibitions related to genetic information.

Prohibited Discrimination

The statutory structure of Title I of GINA is similar to that of HIPAA in that it consists of amendments to Part 7 of the Employee Retirement Income Security Act of 1974 ("ERISA"), the Public Health Service Act ("PHSA") (both individual and group market provisions), and the Internal Revenue Code of 1986 ("Code"). GINA also applies to Medigap policies, which may be underwritten in limited circumstances. Together, these amendments prohibit discrimination based on certain uses of "genetic information" by group health plans and insurers.

The key to understanding GINA, as with many statutes, lies in a careful review of its definitions. Title I defines "genetic information" to include information about an individual's genetic tests, genetic tests of an individual's family members, and manifestation of a disease or disorder in family members of an individual. "Genetic information" does not include information on the manifestation of a disease or disorder in an individual covered by a plan, and therefore allows for increasing premiums based on manifestation of a disease or disorder in an individual. However, manifestation of a disease or disorder in the individual's family member cannot be the basis for an increase in premiums.

Specific prohibitions under Title I of GINA provide 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 under go 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 the individual's enrollment in a group health plan.

Because "genetic information" includes information on manifested diseases in family members, GINA's prohibition on requesting genetic information for underwriting purposes could impact the use of family histories in medical questionnaires, a practice particularly common in the individual market.

Exceptions/Rules of Construction

Many of GINA's specific prohibitions include rules of construction designed to allow certain existing underwriting practices that would otherwise not be permitted under the prohibitions. For example, one rule of construction under Title I specifies that the prohibition on adjusting premiums and contributions on the basis of genetic information does not prohibit health plans and insurers from increasing premiums based on manifestation of a disease or disorder in any individual enrolled in a health plan. This rule of construction also allows collection of genetic information for underwriting purposes and prior to enrollment with respect to manifestation of a disease or disorder in all family members enrolled in a plan. This provision was needed because the manifestation of a disease or disorder in a family member would otherwise be genetic information. This provision also allows use of a medical questionnaire requesting information on manifested diseases or disorders in an individual prior to that individual's enrollment. However, manifestation of a disease or disorder in one family member covered by a plan cannot be used as genetic information about other family members covered by the plan to increase premiums. Another important provision provides that while health plans and health insurers may not request or require genetic tests, the definition of "genetic test" does not include tests for manifested diseases or disorders.

Another rule of construction in Title I of GINA provides that although health plans and health insurers may not request or require that an individual or the individual's family member undergo a genetic test, health plans and health insurers may obtain results of genetic tests in making determinations regarding payment (as defined in the regulations promulgated under HIPAA's privacy provisions, or "Privacy Rule"). In addition, health plans and health insurers may not request, require, or purchase genetic information for underwriting purposes, but they will not be considered to have violated Title I if they obtain genetic information that is incidental to requesting, requiring, or purchasing other information concerning individuals.

Other Significant Title I Provisions

Scope of Title I. Title I does not have a small plan exception and does not provide an opt-out for non-federal governmental plans under the Public Health Service Act.

Enforcement & New Civil Penalty Under ERISA. With respect to health plans, ERISA's existing enforcement scheme applies to Title I violations. Thus, individuals may bring suit under ERISA section 502 to enforce Title I and health plan provisions.

In addition, Title I creates a new civil penalty under ERISA for Title I violations. A new Section 502(a)(9) of ERISA allows a penalty of \$100 per participant per day for failure to comply with Title I requirements, with a minimum penalty of \$2,500 if the failure is not corrected before the date the plan at issue receives notice of the violation from the Secretary of Labor. If the violation is more than de minimis, the minimum penalty is \$15,000. However, 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 penalty also does not apply if the failure was due to reasonable cause and is corrected

within 30 days of the date that the person otherwise liable for the penalty knew, or exercising reasonable diligence would 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. The Secretary also may waive all or part of the penalty if the failure was due to reasonable cause and the penalty would be excessive relative to the failure.

HIPAA Privacy Rule Amendments. Title I requires that the Secretary of Health and Human Services revise the HIPAA Privacy Rule such that (a) genetic information is treated as "protected health information" and (b) group health plans, health insurers, and Medigap policy issuers are prohibited from using or disclosing genetic information for underwriting purposes. Title I requires that notice of these Privacy Rule revisions be published in the Federal Register within 60 days of the date of GINA's enactment (by July 20, 2008).

Effective Dates and Issuance of Regulations. Title I is effective for plan or policy years beginning after the date that is 1 year after the date of GINA's enactment, i.e., plan years beginning after May 21, 2009. Amendments to the Privacy Rule required by Title I are effective 1 year after the date of GINA's enactment (May 21, 2009).

Title I requires that the Department of Labor, Department of Health and Human Services, and Treasury Department issue regulations to carry out the amendments made by Title I within 1 year after the date of GINA's enactment (by May 21, 2009). However, because of the scope and complexity of these amendments, it is unlikely that these regulations will be issued on time.

Title II: Prohibiting Employment Discrimination on the Basis of Genetic Information

Prohibited Discrimination

Title II of GINA generally prohibits employment discrimination on the basis of genetic information. Its statutory structure is similar to that of Title VII of the Civil Rights Act of 1964 ("Title VII") in that it prohibits "unlawful employment practices" and contains a similar enforcement mechanism to that under Title VII. Specifically, under Title II of GINA, it is an unlawful employment practice for an employer, employment agency, labor organization, or training program to:

- Fail, refuse to hire, discharge, or otherwise discriminate against an employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, based on the employee's genetic information or
- Request, require, or purchase genetic information with respect to an employee or a family member of an employee.

Title II's definition of "genetic information" is similar to that under Title I. Title II also allows certain exceptions to the prohibition on requesting, requiring, or purchasing genetic information in circumstances such as:

- Where an employer inadvertently requests or requires family medical history of an employee or the employee's family member;
- Where health or genetic services are offered by the employer, including such services offered as part of a wellness program, provided certain requirements are met;

- Where an employer requests or requires family medical history from an employee to comply with the certification requirements of the Family and Medical Leave Act of 1993 ("FMLA") or state family and medical leave laws;
- Where an employer purchases documents that are commercially and publicly available that include family medical history;
- Where the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace, provided certain requirements are met; or
- Where the employer conducts DNA analysis for law enforcement purposes.

Confidentiality of Genetic Information

Title II also provides that if an employer, employment agency, labor organization, joint labor-management committee has an employee's genetic information, that information must be maintained on separate forms and in separate medical files and be treated as a confidential medical records of the employee. An employer, employment agency, labor organization, joint labor-management committee will be considered in compliance with this requirement if the genetic information is maintained with and treated as a confidential medical record under the Americans with Disabilities Act.

In addition, Title II prohibits an employer, employment agency, labor organization, joint labor-management committee from disclosing an employee's genetic information, with certain exceptions (such as in response to a court order or for purposes of FMLA certification).

Remedies and Enforcement

Title II of GINA establishes an enforcement mechanism with a private right of action and remedies similar to those available under Title VII but, unlike Title VII, does not allow a cause of action based on disparate impact. While Title II was designed to prohibit discrimination based on genetic information in the employment context, there was significant concern during the legislative process that Title II's enforcement and remedies provisions could also apply to health plans.

The possibility that Title II could provide a remedy for health plan violations arose because "compensation, terms, conditions, or privileges of employment" has been construed to include employer-provided benefits under Title VII and other discrimination statutes. Thus, taken on its own, Title II's prohibition on discrimination in "compensation, terms, conditions, or privileges of employment" could be extended to health plans or plan sponsors. Importantly, plaintiffs will have an incentive to pursue Title II remedies in lieu of the ERISA remedies under Title I because the Title II remedies include compensatory damages (subject to limits).

However, Title II includes a much fought-over "firewall" that is intended to limit the possibly overlapping remedies under Title I and Title II. The idea behind the firewall is that health plans are exclusively regulated under Title I, and employers should not be subject to suit under Title II for actions regulated under Title I. The key firewall provisions are as follows:

- Title II contains a rule of construction providing that Title II is not to be construed to "provide for enforcement of, or penalties for violation of, any requirement or prohibition applicable to any employer, employment agency, labor organization, or joint labor-management committee subject to enforcement for a violation under [Title I]." This provision appears to preclude employers from being sued under Title II for violating provisions enforced under Title I.

- Title II also provides that with respect to a health plan or health insurer, Title II "does not prohibit any activity of such plan or issuer that is authorized for the plan or issuer under and provision of law referred to in clauses (i) through (iv) of subsection (a)(2)(B)" (which clauses include Title I). This provision appears to protect group health plans and health insurers from being sued under Title II for actions regulated by Title I and the existing legal provisions related to genetic information.

As noted, the intent of these provisions appears to be to preclude dual enforcement under Title II and Title I for the same acts. However, other interpretations are possible, and the issue may be litigated in the future.

Effective Dates and Issuance of Regulations

Title II is effective 18 months after the date of GINA's enactment, i.e., November 21, 2009. Title I also requires that the EEOC issue regulations to carry out Title II within 1 year after the date of GINA's enactment (by May 21, 2009).

* * *

Authors: Jon Breyfogle and Debbie Leung

If you have any questions, please contact your regular Groom contact or any of the health team attorneys listed below:

Jon W. Breyfogle	jwb@groom.com	(202) 861-6641
Gina M. Boscarino	gmb@groom.com	(202) 861-6645
Jenifer Cromwell	jac@groom.com	(202) 861-6329
Thomas F. Fitzgerald	tff@groom.com	(202) 861-6621
Christine L. Keller	clk@groom.com	(202) 861-9371
Debbie Leung	dgl@groom.com	(202) 861-2601
Heather E. Meade	hem@groom.com	(202) 861-0179
Christy A. Tinnes	cat@groom.com	(202) 861-6603
Donald G. Willis	dgw@groom.com	(202) 861-6332