FREQUENTLY ASKED QUESTIONS ABOUT THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

May 2008

Introduction

Congress recently approved, and the President is scheduled to sign on May 21st, H.R. 493, the "Genetic Information Nondiscrimination Act of 2008" ("GINA").[1] The law is intended, according to the congressional findings in Section 2, to replace the "existing patchwork of State and Federal laws," and establish "a national and uniform basic standard....to fully protect the public from discrimination and allay their concerns about the potential for discrimination..."

The core provisions of this new law focus on: (1) prohibiting health insurance plans from underwriting on the basis of predictive genetic information; (2) barring discrimination in employment based on genetic information; and (3) establishing new confidentiality protections for genetic information.

The following "Frequently Asked Questions" ("FAQs") provide an overview of the key provisions of this new law.

These FAQs are intended to provide an overview of the Act specifically as it applies to health insurance plans, but are not intended as a substitute for legal advice, and you should consult your counsel for specific guidance.

1. What is the basic structure of the new law?

GINA addresses discrimination in both health insurance and employment on the basis of genetic information. The new law also places restrictions on the collection and use of genetic information.

Title I, Genetic Nondiscrimination in Health Insurance, amends the Employee Retirement Income Security Act (ERISA), Public Health Service Act (PHSA), Internal Revenue Code, and Social Security Act. The Title applies to the following health insurance plans:

- ERISA group health plans (regardless of the number of participants who are current employees).
- Health insurance issuers offering health insurance coverage in connection with a group health plan ("group market insurers").
- Health insurance issuers offering insurance coverage in the individual market ("individual market insurers").

[1] In addition to the passage of GINA, Congress subsequently approved H. Con. Res. 340 which makes minor changes to the implementation of the GINA provisions applicable to Medicare supplemental policies.

- Issuers of Medicare supplemental policies ("Medicare supplemental insurers").
- Non-federal governmental plans.[2]

Title II, "Prohibiting Employment Discrimination on the Basis of Genetic Information," addresses the use of genetic information in connection with the compensation, terms, conditions or privileges of employment and applies to the following:

- Employers.
- Employment agencies.
- Labor organizations.
- Employee and apprenticeship training programs.

Title I of GINA

2. Are certain types of health coverage exempted from GINA?

Yes. GINA generally has the same scope of application as the group and individual market rules under HIPAA. As a result, GINA does not apply to "excepted benefits" as defined in HIPAA, including workers compensation coverage, liability coverage, limited scope dental and vision benefits, long-term care benefits, coverage for a specific disease or illness, hospital indemnity insurance, and supplemental insurance.

However, Medicare supplemental policies are specifically ***included*** under GINA.

3. What kinds of information are covered by the new law?

GINA applies to "genetic information," "genetic tests," and "genetic services."

Genetic information is any information about an individual's genetic tests, the genetic tests of his or her family members, and the manifestation of a disease or disorder in his or her family members.[3] Genetic information does not include information about a manifested condition of the individual or information about age or sex.

The definition also applies to the ***genetic information of a fetus or embryo*** with respect to:

- An individual or family member who is a pregnant woman.
- An individual or family member utilizing reproductive technology (including any legally held embryo).

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[2] "Non-federal governmental plans" are allowed to opt-out of the HIPAA group rules (*see* 42 U.S.C. §300gg-21). Under GINA, such plans must comply with all of the GINA provisions applied to group health plans as well as the HIPAA group market rules prohibiting the use of genetic information for purposes of setting premiums or eligibility.
[3] The term "manifestation of a disease or disorder," which is used throughout Title I, is not defined.

Genetic tests are any analysis of human DNA, RNA, chromosomes, proteins or metabolites that detects genotypes, mutations or chromosomal changes.

Genetic tests do not include an analysis of proteins or metabolites:

- that does not detect genotypes, mutations or chromosomal changes; or
- that is directly related to a manifested disease, disorder or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

Genetic services are: (a) a genetic test; (b) genetic counseling (including obtaining, interpreting or assessing genetic information); or (c) genetic education.

4. What is a "family member?"

A ***family member*** is:

- A dependent of an individual (because of marriage, birth, adoption or placement for adoption).
- Any first, second, third or fourth-degree relative of the individual or his or her dependents.

5. How does GINA affect underwriting?

As discussed below, GINA generally prohibits health insurance plans from setting premium or contribution amounts, denying eligibility or excluding coverage based on genetic information. In addition, GINA restricts the use of genetic information for "underwriting purposes" (Discussed in Question 8).

GINA prohibits ***group health plans*** and ***group market insurers*** from adjusting premium or contribution amounts ***for the group*** based on genetic information of an individual enrolled in the plan.[4]

Individual market insurers may not establish rules for eligibility (including continued eligibility) of any individual based on genetic information. In addition, health insurers in the individual market may not set premium or contribution amounts or establish preexisting condition exclusions for any individual based on genetic information.

Medicare supplemental insurers may not deny or condition the issuance or effectiveness of a policy, discriminate in the pricing of a policy or impose any pre-existing condition exclusion based on genetic information.

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[4] Existing HIPAA group rules prohibit the use of genetic information to deny coverage or adjust the premium rates of an individual within the group (*see* 29 USC §1182 and 42 USC §300gg-1).

6. Are any underwriting practices recognized by GINA?

Group market insurers are allowed to increase premiums for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan.

Individual market insurers may adjust premium or contribution amounts, establish eligibility rules or impose preexisting condition exclusions based on the manifestation of a disease or disorder for an individual or for a family member that is covered by the individual's policy.

Medicare supplemental insurers are permitted to deny or condition the effectiveness of coverage or increase premiums for an individual based on the manifestation of a disease or disorder under certain conditions. The Social Security Act, however, prohibits the use of health status as an underwriting factor and limits the use of preexisting condition exclusions if the individual enrolls during the first six months after they become eligible for Medicare (*see* 42 USC §1395ss).

As explained in Question 7 below, however, health insurance plans may not use the fact that an individual has a manifested disease or disorder as the reason to underwrite any family member based on genetic information.

7. What are examples of underwriting practices that are permitted or not permitted under GINA?

Example A

Bob Smith applies for health coverage under his employer's group health plan provided by XYZ Health Insurance Company. The health insurer is aware that Bob has tested positive for the genetic marker for Huntington disease even though he has not demonstrated any symptoms of the disease. In addition, Bob has symptoms of diabetes.

The Health Insurance Company is not allowed to establish the premium or contribution amounts for the group health plan based on the presence of the genetic marker. In addition, the HIPAA group market rules generally prohibit the Health Insurance Company from denying coverage or from setting Bob's premiums based on his health status (i.e., his diabetes).

Example B

Bob Smith applies for an individual health insurance policy from XYZ Health Insurance Company. The health insurer is aware of the presence of the genetic market for Huntington disease as well as his diabetes symptoms.

The Health Insurance Company is prohibited from denying Bob coverage or from setting his premiums based on the presence of the genetic marker. However, the Health Insurance Company is allowed to deny coverage (or to exclude coverage for diabetes) and may establish premium or contribution rates based on his disease condition.

Example C

Bob Smith applies for individual health insurance coverage under a family plan for himself and for his two children from XYZ Health Insurance Company. The health insurer is aware that Bob has exhibited symptoms for Huntington disease although his children do not exhibit any symptoms of the disease.

The Health Insurance Company is permitted to deny or exclude coverage and may establish premium or contribution amounts for the insurance policy based on Bob's Huntington disease. The insurer may not, however, assume that Bob's disease will be inherited by his children and deny or exclude coverage for the children based on Bob's condition.

8. Are health insurance plans restricted from obtaining genetic information?

GINA prohibits health insurance plans from requesting, requiring or purchasing an individual's genetic information prior to enrollment or for underwriting purposes.

Underwriting purposes are:

- Rules for determining the eligibility for health insurance coverage or benefits.
- Composition of premium or contribution amounts.
- Application of pre-existing condition exclusions.
- Other activities related to the creation, renewal or replacement of health insurance coverage or benefits.

9. Does GINA make any changes to the HIPAA privacy rule?

Yes. GINA amends the HIPAA privacy standards by requiring the Department of Health and Human Services to revise the HIPAA privacy rule to:

- Treat genetic information as "health information."
- Restrict the collection and use of genetic information by "covered entities" that are ***group health plans***, ***group market insurers***, ***individual market insurers*** or ***Medicare supplemental insurers*** consistent with the provisions of GINA.

These changes must be made within one year of the date of enactment.

10. Are health insurance plans allowed to request or require genetic tests?

In general, health insurance plans may not request or require an individual or a family member to undergo a genetic test.

11. When are health insurance plans permitted to obtain or use genetic information?

There are a number of situations under which a health insurance plan is allowed to obtain or use genetic information, including the results of a genetic test.

Disease Management and Prevention

A health insurance plan may make an individual aware that he or she or a family member may want to undergo a genetic test for purposes of disease management or prevention. The health insurance plan may not request or require that the test be taken and the test results may not be used for underwriting purposes.

Payment

Health insurance plans may obtain and use the results of a genetic test in making a payment determination, provided that only the "minimum necessary" amount of information is requested.[5]

Research

Health insurance plans may request that an individual undergo a genetic test for research purposes if the following requirements are met:

- The request is made in writing.
- The individual (or his or her guardian) is informed that compliance with the request is voluntary and that they will not be penalized if they do not undergo the test.
- Any genetic information that is collected may not be used for underwriting purposes.
- The health insurance plan notifies the Department of Labor (in the case of group health plans or group market insurers) or the Department of Health and Human Services (in the case of health insurers in the group and individual market and issuers of Medicare supplemental coverage) in writing about the research request.
- The health insurance plan complies with all other state and federal requirements related to research (including federal standards for research involving human subjects).

12. Are health care providers permitted to ask their patients to take a genetic test?

Yes. A health care professional who is providing health care services to an individual may request (but not require) that he or she undergo a genetic test.

[5] "Payment" is defined in the HIPAA privacy rule including claims and billing activities, utilization review, and medical necessity determinations (*see* 45 CFR §164.501).

13. What are some examples of how health insurance plans are allowed or not allowed by GINA to collect or use genetic information?

Example A

Jane Smith is applying for a policy of individual health insurance from XYZ Health Insurance Company. The insurer may not ask Jane Smith or any of her family members to complete a genetic test as part of the application process or as a condition for providing coverage. In addition, the application may not ask any questions about the Jane Smith's family health history. A health insurer may request genetic information following enrollment so long as the request is not for underwriting purposes.

Example B

Jane Smith applies for health insurance coverage through her employer from XYZ Health Insurance Company. The Health Insurance Company may not request, purchase or otherwise obtain any genetic information from Jane Smith prior to her enrollment or at any time for underwriting purposes.

Example C

XYZ Health Insurance Company offers its members the opportunity to establish a personal health record (PHR) that is populated with administrative and clinical data as well as information provided by the member in response to a health risk assessment (HRA). One of the HRA questions asks about the health history of family members, for example, if any parent had cancer.

Because the answer discloses details about the manifestation of a disease or disorder in a family member, the information is considered genetic information. However, the question is permitted because the request for genetic information is not for underwriting purposes and it is made after the individual is enrolled with the health insurer. In addition, the PHR could include the results of genetic tests or information on genetic services as long as the Health Insurance Company does not use the information for underwriting purposes.

Example D

Jane Smith is enrolled as a member of XYZ Health Insurance Company through her employer. Her family physician, as part of her treatment, is aware of a family history of breast cancer. The physician asks Jane to undergo a test to determine if she has a genetic marker for breast cancer. This request by Jane's physician is allowed by GINA, although the physician can not require her to undergo the test. In addition, the health insurer may ask the doctor to provide information about her family history or to indicate whether a person has undergone the necessary test to determine payment for appropriate treatment. For example, a health insurance plan may obtain and use the results of a genetic test prior to approving coverage for herceptin treatment for breast cancer.

14. Who is responsible for enforcing the requirements of Title I?

- The Department of Labor will enforce the provisions of Title I in the case of ***group health plans*** and ***group market insurers***.
- The Department of Health and Human Services will enforce Title I requirements as applied to ***group and individual market insurers*** and ***Medicare supplemental insurers***.
- The Department of Health and Human Services will also enforce the HIPAA privacy rule provisions applicable to the "covered entities" subject to GINA.
- The Department of the Treasury is responsible for enforcing certain tax code provisions applicable to ***group health plans***.

15. What are the penalties for non-compliance with GINA?

In the case of a ***group health plan*** or a ***group market insurer*** the Department of Labor may impose the following penalties:

- $100 per day for each participant or beneficiary for whom each violation relates during the period the group health plan or health insurance issuer is in noncompliance.
- A minimum penalty of $2,500 may be imposed.
- For more than *de minimis* penalties, the minimum penalty that may be imposed is $15,000.
- For unintentional noncompliance (i.e., failures due to reasonable cause and not to willful neglect), the maximum annual penalty is the lesser of 10 percent of the amount paid or incurred by the plan sponsor during the preceding taxable year for group health plans, or $500,000.

The Department of Labor may waive all or part of the penalties if the failure is due to reasonable cause and not willful neglect.

The Department of Health and Human Services may impose similar penalties (and may waive the penalties) in the case of GINA violations by a ***group market insurer*** or an ***individual market insurer***.

The Department of the Treasury may impose tax penalties for violations of GINA by a ***group health plan.***

Penalties are not specified in GINA for ***Medicare supplemental insurers***; however, there are existing penalties in the Social Security Act (*see* 42 USC §1395ss (s)(4)).

16. Which agencies are expected to draft regulations for the GINA provisions?

GINA requires the Departments of Labor, Health and Human Services, and the Treasury to draft regulations with respect to the provisions applicable to ***group health plans*** and ***group market***

insurers. The agencies are required to coordinate their regulations, rulings, interpretations, and enforcement activities.

The Department of Health and Human Services will draft regulations or other guidance for ***individual market insurers*** and ***Medicare supplemental insurers***.

The agencies are required to approve these regulations within one year of enactment.

17. What about the impact on Medigap?

As discussed above, the limitations on using genetic information and requesting or requiring genetic tests apply to ***Medicare supplemental insurers.***

The National Association of Insurance Commissioners (NAIC) is given until October 1, 2008 to adopt changes to the Model Regulations applicable to Medigap policies. If the NAIC does not act, the Department of Health and Human Services has until July 1, 2009 to issue regulations with the required changes. States are given a period of time to adopt laws incorporating these changes.

18. Does GINA preempt state laws with respect to the collection or use of genetic information?

GINA follows the HIPAA preemption test with respect to the group and individual market rules. As a result, the GINA provisions that relate to underwriting preempt state laws that "prevent the application of" the GINA requirements with respect to ***group health plans***, ***group market insurers***, and ***individual market insurers.***

In addition, the GINA provisions regarding the use of genetic information are incorporated into the HIPAA privacy rule. The privacy rule generally does not preempt "more stringent" state laws (e.g., laws that provide greater restrictions on disclosure of health information). As a result, it is possible that some state laws that place additional restrictions on the use or disclosure of genetic information by a health insurance plan will not be preempted.

19. When do the provisions of Title I go into effect?

The provisions of Title I go into effect one year after enactment, that is May 2009. The GINA provisions that are applicable to group health plans and to health insurance issuers providing insurance to group health plans are effective for plan years beginning after the effective date.

20. What's the relationship between Title I and Title II of the Act, and are there circumstances in which employers may be liable for discrimination claims brought against their insurers or health plans?

Both Titles of GINA are careful to distinguish between situations where a group market insurer might be liable for discrimination as opposed to the plan sponsor/employer. Thus, an employer will

not be liable if its health insurer commits the discriminatory act, such as improperly using an individual's genetic information to set a higher rate. While employers might be liable for the discriminatory acts of their agents, the Act is structured so that the health insurer will not be transformed into an agent of the employer for liability purposes, if the employer had nothing to do with the discriminatory act.

Title II of GINA

21. How are employment practices affected by GINA?

Employers, employment agencies, labor organizations, and training programs are prohibited under Title II from taking the following actions based on genetic information about an individual:

- Failing or refusing to hire or discharge any employee.
- Discriminating with respect to the compensation, terms, conditions or privileges of employment.
- Limiting, segregating or classifying the individual in any way that deprives them of employment opportunities.

22. May employers and others collect genetic information?

In general, employers, employment agencies, labor organizations, and training programs may not request, require or purchase genetic information with respect to an individual or family member with certain exceptions:

- The information collection is inadvertent.
- Health or genetic services are offered to an individual, including as part of a wellness program, and:
  - the individual provides prior, knowing, voluntary, and written authorization;
  - only the individual (or family member if they receive the services) and a health care professional involved in providing such services receives individually identifiable information; and
  - the employer receives only aggregated, de-identified information.
- Information is needed to file a request for leave under the Family and Medical Leave Act.
- The employer purchases publicly and commercially available documents that include family medical histories (but not medical databases or court records).
- The information is needed for genetic monitoring of the workplace on the biological effects of toxic substances (subject to additional requirements).
- If the employer is a forensic laboratory that conducts DNA analysis for law enforcement or for purposes of identifying human remains and needs the information for quality control purposes.

23. How does Title II protect the confidentiality of genetic information?

Employers, employment agencies, labor organizations and joint labor-management committees may possess genetic information under the following conditions:

- The information must be maintained in separate forms and in separate medical files.
- The information must be treated as confidential.[6]

24. Are employers, employment agencies, labor organizations, and training programs allowed to disclose genetic information?

Disclosure of genetic information is prohibited except in the following situations:

- To the individual or to a family member at the individual's written request.
- To an occupational or other health researcher in compliance with federal research requirements.
- In response to a court order.
- To a government official investigating violations of Title II of GINA if disclosure is relevant to the investigation.
- In connection with an employee's compliance with the certification provisions of FMLA.
- To a Federal, State or local public health agency if the disclosure concerns a contagious disease that presents an imminent hazard of death or life-threatening illness.

25. May employers, in their role as "covered entities" under the HIPAA privacy rule, disclose genetic information?

Yes. Title II allows an employer group health plan, acting as a "covered entity," to use or disclose genetic information as permitted by the HIPAA privacy rule.

26. What are the remedies imposed on employers for discriminatory actions?

Enforcement for Title II of GINA for private employers is provided by existing procedures, including the Civil Rights Act of 1964. Lawsuits under the concept of "disparate impact" as that term is used in the Civil Rights Act of 1964 are prohibited, with a Commission set up in 6 years to make recommendations as to whether to allow such a cause of action.

[6] Entities meet the "confidentiality" requirement if they follow the requirements for confidential medical records under the Americans with Disabilities Act (ADA) (*see* 42 USC §12112 (d) (3) (B)).

27. Does Title II preempt state causes of action or supplant causes of action under other statutes?

No. Title II (Section 209) specifically provides that nothing in the title "shall be construed to limit the rights or protections of an individual under any other Federal or State statute that provides equal or greater protection to an individual," including the Americans with Disabilities Act and the Rehabilitation Act.

28. When is Title II effective?

The provisions of Title II are effective 18 months after enactment.

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