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GINA REGULATIONS FOR GROUP HEALTH PLANS

The Genetic Information Nondiscrimination Act (GINA) (Public Law 110-233) was enacted on May 21, 2008. Title I of the Act prohibits discrimination in health coverage based on genetic information.[1] GINA is effective for plan years beginning on or after May 21, 2009 (January 1, 2010 for calendar-year plans).

The Departments of Labor, Treasury and Health and Human Services recently issued joint interim final regulations on GINA's group health plan requirements.[2] **These regulations are effective for plan years beginning on or after December 7, 2009 (January 1, 2010 for calendar-year plans)**.

A copy of the rule is available at: http://frwebgate6.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=104790510410+1+2+0&WAISaction=retrieve

Brief Summary – Compliance Issues

GINA imposes significant changes to group health plans that provide a health risk assessment or other wellness program where genetic information (including family medical history) is collected from plan participants and beneficiaries. In particular, GINA prohibits:

- Tying a financial reward or additional benefits to a health risk assessment that contains family medical history questions, and
- Requesting or requiring completion of a heath risk assessment that includes genetic information (including family medical history) in connection with enrollment.

Moreover, other wellness program components, like biometric testing, may be impacted by these requirements if genetic tests are conducted or if the program collects genetic information with enrollment or otherwise incentivizes individuals to provide such

[1] Title II of GINA prohibits discrimination in employment based on genetic information. This Title is under the jurisdiction of the Equal Employment Opportunity Commission (EEOC), which issued a notice of proposed rule making March 2, 2009. This summary does not address Title II requirements.

[2] Health and Human Services also issued additional GINA regulations that affect the HIPAA Privacy Rule. These regulations are in proposed format and will be addressed in a later technical bulletin. A copy of the proposed rule is available at: http://frwebgate6.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=104790510410+2+2+0&WAISaction=retrieve

information. Employers will need to conduct a careful review of current practices to ensure compliance with the regulations.

The following summarizes the GINA requirements in more detail.

Overview

GINA prohibits a group health plan or health insurance issuer in the group market from:

- Increasing the group premium or contribution amounts based on genetic information;
- Requesting or requiring an individual to undergo a genetic test; and
- Requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

Definitions

Genetic information is defined, with respect to the individual, as:

- Information about the individual's genetic tests or the genetic tests of a family member;[3]
- The manifestation of a disease or disorder in a family member of an individual (i.e. family medical history); or
- Any request for, or receipt of genetic services by the individual or family member.

A *genetic test* means an analysis of human DNA, RNA, chromosomes, proteins or metabolites, if it detects genotypes, mutations or chromosomal changes. It does not include tests or analysis related to a manifested disease, disorder or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise.

Examples of a *genetic test* include (but are not limited to):

- BRCA1 or BRCA2 test; or
- Tests to determine whether an individual has a genetic variant associated with hereditary colorectal cancer.

Genetic tests do not include:

- Complete blood counts;
- HIV tests;
- Cholesterol tests;
- Liver function tests; or

[3] The term *family member* is to be broadly construed. It includes any individual who is a dependent of the employee under the special enrollment rules and any other individual that is a first, second, third or fourth-degree relative of the individual or of the dependent of the individual. Examples:

- First-degree relatives: parents, spouses, siblings and children.
- Second-degree relatives: grandparents, grandchildren, aunts/uncles and nephews/nieces.
- Third-degree relatives: great-grandparents, great-grandchildren, great aunts/uncles, and first cousins.
- Fourth-degree relatives: great-great grandparents, great-great grandchildren and children of first cousins.

- Alcohol or drug tests.

To *collect* means to request, require or purchase information.

No Group Plan Discrimination Based on Genetic Information

Group health plans and health insurance issuers may not adjust premium or contribution amounts for any employer, or group of similarly situated individuals covered under the plan, based on genetic information.[4]

Group health plans may continue to increase premiums based on the existence of a disease or disorder manifested in a participant or beneficiary (i.e. existing medical conditions within the group may cause plan costs to increase). However, this presence of a disease or disorder in one individual may not be used as genetic information about other group members to further increase premiums.

Limitation on Requesting or Requiring Genetic Information

A group health plan may not request or require an individual to undergo a genetic test.

A limited exception permits a plan to request participants or beneficiaries undergo a genetic test for research purposes. This exception is very narrow and specific conditions must be satisfied in order for it to apply.[5]

Nothing in this requirement will preclude a doctor or other health care professional from recommending a genetic test to a plan participant or beneficiary. Further, the group health plan is not prohibited from using genetic information for payment purposes, as long as the plan uses only the minimum amount of information necessary to make a payment determination in accordance with the HIPAA Privacy Rule.

Prohibition on the Collection of Genetic Information

GINA also prohibits a group health plan from collecting genetic information (including family medical history) *prior to or in connection with enrollment*, or for *underwriting purposes*.

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[4] GINA requirements expand on the HIPAA nondiscrimination rules. HIPAA prohibits a group health plan (or health insurance issuer) from discriminating against an individual with respect to eligibility, benefits, or premiums in a group health plan based on a health factor (defined to include genetic information). HIPAA also prevents the group health plan (or health insurance issuer) from imposing pre-existing condition exclusions on an individual based solely on genetic information.

[5] In order to claim the research exception all of the following must be satisfied:

- Research is in accordance with Federal regulations and applicable state and local law;
- A written request for participation in research;
- Genetic information collected pursuant to the research exception may not be used for underwriting purposes;
- Appropriate notice is provided to requisite federal agencies in compliance with the law.

Underwriting Purposes

Underwriting purposes means, with respect to the group health plan:[6]

- Rules for, and determination of, eligibility for benefits (including enrollment and continued eligibility) offered under the plan;
- Computation of premium or contributions amounts;
- Applicability of pre-existing condition exclusions;
- **Changing deductibles or other cost-sharing mechanisms, or providing 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;** and
- Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

Thus, GINA prohibits plans and health insurance issuers from offering individuals rewards in return for completion of a Health Risk Assessment that collects genetic information, including family medical history.

Example 1

Facts: A group health plan provides a premium reduction to enrollees who complete an HRA. The HRA is requested to be completed after enrollment. Whether or not it is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The HRA includes questions about the individual's family medical history.

Conclusion: The HRA includes a request for genetic information (that is, the individual's family medical history). Because completing the HRA results in a premium reduction, the request for genetic information is for underwriting purposes. Consequently, the request violates the prohibition on the collection of genetic information.

The conclusion in *Example 1* changes if the plan did not offer a premium reduction or any other reward for completing the HRA. Under that scenario, the request is not for underwriting purposes, nor is it prior to or in connection with enrollment. Therefore, it does not violate the prohibition on the collection of genetic information.

What about providing individuals with a gift card or cash to complete an HRA with family medical history questions?

While the regulations do not contain this specific example, based on the regulatory language, such a payment would likely constitute a *rebate* or *payment in kind* for providing genetic information, and thus violate GINA.

[6] *Underwriting purposes* does not include situations where an individual seeks a benefit under the group health plan that may be limited or excluded based on whether the benefit is medically appropriate. If the benefit is conditioned upon medical appropriateness and such determination is based on genetic information, the plan is permitted to condition the benefit on genetic information. Only the minimum amount of genetic information necessary to determine medical appropriateness is permitted to be used by the plan. This is a very narrow exception and if the individual is not seeking a benefit, then this medical appropriateness exception will not apply.

Additionally, GINA is violated if the information contained in an HRA with family medical history questions is used to determine eligibility for additional benefit programs (e.g. a disease management program) offered under the group health plan.[7]

Consider the example of an individual who completes a health risk assessment and answers questions revealing a family medical history of diabetes (even though the individual is not a diabetic). Based on these answers, the individual becomes eligible for a disease management program. This design is prohibited as the questions about family medical history would constitute a request for genetic information for underwriting purposes.

Prior to or in Connection with Enrollment

A group health plan requesting completion of an HRA with family medical history questions prior to (or in connection with) enrollment will violate GINA.

Example 2

Facts: A group health plan requests that enrollees complete an HRA prior to enrollment, and includes questions about the individual's family medical history. There is no reward or penalty for completing the HRA.

Conclusion: Because the HRA includes a request for genetic information (that is, the individual's family medical history), and requests the information prior to enrollment, the request violates the prohibition on the collection of genetic information.

There is an exception for genetic information that is obtained incidental to the collection of other information concerning the individual, so long as the information was not collected for underwriting purposes. However, if it is reasonable to expect an individual may provide health information in his/her response, the materials must state the individual should not provide genetic information.

Example 3

Facts: A group health plan waives its annual deductible for enrollees who complete an HRA. The HRA is requested to be completed after enrollment. Whether or not the HRA is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The HRA does not include any direct questions about the individual's genetic information (including family medical history). However, the last question reads, "Is there anything else relevant to your health that you would like us to know or discuss with you?"

Conclusion: The plan's request for medical information does not explicitly state that genetic information should not be provided. Therefore, any genetic information collected in response to the question is not within the incidental collection exception and is prohibited.

[7] Such an arrangement would not qualify for the medical appropriateness exception because the individual is not seeking the benefits being provided.

The answer in *Example 3* changes if the last question goes on to state:

"In answering this question, you should not include any genetic information. That is, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk."

In this case, the plan's request for medical information explicitly states that genetic information should not be provided. Therefore, any genetic information collected in response to the question is within the incidental collection exception. However, the plan may not use this information for underwriting purposes.

Avoiding the Application of GINA – Design Options

In order to avoid the application of GINA, the plan sponsor (or insurer) may consider:

- Removing any reward (or additional benefit eligibility) tied to an HRA that asks family history questions; or
- Removing any requests for genetic information (including family medical history questions) from an HRA that is tied to enrollment and/or provides a reward (or additional benefits) for completing of the assessment.

Another option would be to utilize two different HRAs, where each HRA independently satisfies the GINA requirements.

Example 4

Facts: A group health plan requests enrollees to complete two distinct health risk assessments (HRAs) after and unrelated to enrollment. The first HRA instructs the individual to answer only for the individual and not for the individual's family. The first HRA does not ask about any genetic tests the individual has undergone or any genetic services the individual has received. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and the results of genetic tests the individual has undergone. The plan offers no reward for completing the second HRA and the instructions make clear that completion of the second HRA is wholly voluntary and will not affect the reward given for completion of the first HRA.

Conclusion: In this example, no genetic information is collected in connection with the first HRA, which offers a reward, and no benefits or other rewards are conditioned on the request for genetic information in the second HRA. Consequently, the request for genetic information in the second HRA is not for underwriting purposes, and the two HRAs do not violate the prohibition on the collection of genetic information.

Note however, that compliance with the requirements of GINA do not necessarily mean compliance with all federal laws, in particular the Americans with Disabilities Act. Informally, the EEOC has expressed concern about conditioning eligibility for benefits on

completion of an HRA and any financial incentives that may render participation involuntary.[8]

Wellness Programs

In addition to the HRA rules discussed above, plans will want to review other components of a wellness programs in light of these regulations, particularly if the program requires individuals to undergo genetic testing or provide genetic information. For example, a biometric testing program tied to enrollment or financially incentivized should be reviewed to ensure genetic tests are not performed and genetic information is not collected.

Employer Action Items

Employers with upcoming renewals will want to review current programs to address and appropriately modify the HRA and wellness plans prior to renewal. Employers considering implementing an HRA or wellness program should consult with vendors, insurers and their brokers about the impact these rules may have on design options.

Following are some compliance steps that should assist in this process:

- Discuss the new GINA requirements with any third party wellness vendor or HRA provider (or an insurance carrier providing these services) to understand what steps the provider is taking to ensure compliance.

- If providing participants and beneficiaries with an HRA, review the questions asked on the assessment to determine whether family medical history or other genetic information is being collected, particularly if a reward or enrollment is tied to the HRA.
    - If so, review alternative design options in order to comply with the new GINA requirements. This may include removing family history questions, removing the reward, changing the timing of the HRA from enrollment or adopting two HRAs.

- If providing a wellness program, review the plan to determine whether participants and beneficiaries are requested to undergo a genetic test or provide

[8] The ADA limits an employer's ability to obtain medical information from applicants and employees. GINA is narrower than the ADA, being only concerned with genetic information. Generally, the employer may only require medical examinations and make disability related inquiries when it is job related and consistent with business necessity. However, the ADA affords an exception to the general prohibition when such medical exams and disability related inquiries are part of a *voluntary wellness program*. The guidance around what constitutes a *voluntary wellness program* is not clear. However, the final regulations on GINA Title II requirements are expected to address the definition of a voluntary wellness program. Note, in a recent informal EEOC letter, the EEOC indicated a program that requires employees to complete a Health Risk Assessment in order to receive coverage under the group health plan renders the program *involuntary* and would *violate* the ADA because employees choosing not to participate are denied a benefit (i.e. penalized for non-participation) as compared to those employees who participated.[8] *Informal Letter dated March 6, 2009,* www.eeoc.gov/foia/letters/2009/ada_disability_medexam_healthrisk.html

genetic information (e.g. review biometric tests to determine whether genetic testing is a component of the program).

- If collecting health information from participants use the appropriate language to notify individuals that genetic information (including family medical history) should not be provided.

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