GINA, HIPAA, and Your DNA: A Privacy Love Story

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The HIPAA Privacy Rule encompasess a variety of health information requirements. When the Department of Health and Human Services (HHS) released its final HIPAA/HITECH Act\(^1\) regulations on January 25, 2013, those regulations made clear, once again, what employers have long been aware of—an individual’s genetic information is health information under the HIPAA Privacy Rule and group health plans cannot use or disclose genetic information for underwriting purposes.

Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination in premiums or contributions for group health coverage based on genetic information. Title I of GINA also limits a group health plan’s ability to collect genetic information or require an individual to undergo genetic testing. With respect to the privacy of genetic information, Title I of GINA requires the HHS Secretary to revise the Privacy Rule to set forth that genetic information is health information and that group health plans cannot use or disclose genetic information for underwriting purposes. The final regulations are effective on March 26, 2013 and covered entities must comply with the applicable requirements by September 23, 2013.

This Aon Hewitt bulletin briefly describes the final regulations’ guidance regarding the protection of genetic information that is protected health information (PHI).

HIPAA’s Protection of Genetic Information

Health plans that are covered entities under the HIPAA Privacy Rule are prohibited from using and disclosing PHI that is genetic information for underwriting purposes. All health plans that are covered entities under the HIPAA Privacy Rule are impacted by this rule (including plans that provide “excepted benefits” such as a limited-scope dental or vision plans), but long-term care plans are specifically excluded. However, long-term care plans must still use or disclose genetic information in accordance with the HIPAA Privacy Rule, and safeguard this information from improper uses and disclosures.

Underwriting Purposes

A group health plan may not use or disclose genetic information for “underwriting purposes,” which includes:

- Rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy (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);
- Computation of premium or contribution amounts under the plan, coverage, or policy (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);

\(^1\) Health Information Technology for Economic and Clinical Health (HITECH) Act
Application of any pre-existing condition exclusion under the plan, coverage, or policy; and

Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

However, a group health plan may use the minimum necessary amount of genetic information to determine the medical appropriateness of providing a benefit under a plan, when an individual seeks a benefit under such plan.

Examples of the prohibition on the use and disclosure of PHI that is genetic information for underwriting purposes include:

- A health insurer, with respect to an employer-sponsored group health plan, uses an individual's family medical history or genetic test results maintained in the group health plan's claims experience to adjust the plan's blended, aggregate premium rate for the upcoming year. Result? The health insurer is using PHI that is genetic information for underwriting purposes in a manner that violates the Privacy Rule.

- A group health plan uses an individual's family medical history provided by an individual, incidental to the collection of other information on a health risk assessment, to provide a premium reduction to the individual. Result? The health insurer is using PHI that is genetic information for underwriting purposes in a manner that violates the Privacy Rule.

The prohibition on the use or disclosure of PHI that is genetic information for underwriting purposes applies to all genetic information from the final regulations' compliance date (September 26, 2013) forward, regardless of when or where the genetic information originated.

Health Risk Assessments and Disease Management Programs

Despite concerns from commenters on the definition of "underwriting purposes" and the impact on health risk assessments and wellness and disease management programs, HHS did not exclude wellness programs and the use of health risk assessments from this definition. The preamble to the final regulations notes that health plans may continue to provide incentives for wellness program participation and health risk assessment completion in a way that does not involve the use or disclosure of genetic information. For example, a health plan may request family medical history through a health risk assessment that is completed after and unrelated to health plan enrollment, and that is not tied to any reward.

Additional Modifications and/or Updates Under the Final Regulations

With respect to the protection of genetic information, the final regulations make the following modifications and/or updates to the HIPAA Privacy Rule:

- The definition of "health information" is updated to include "genetic information."

- The final regulations adopt the definitions of "genetic information," "genetic service," "genetic test," "manifestation or manifested," and "family member." For example:
Genetic information is information about an individual’s genetic tests, the genetic tests of an individual’s family members, the manifestation of a disease or disorder in an individual’s family members, or any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services by the individual or any family member of the individual. Genetic information does not include information about an individual’s medical tests or his or her manifested diseases, disorders, or conditions.

A genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. For example, a test to determine if an individual has the BRCA1 or BRCA2 variant (gene variant associated with breast cancer) is a genetic test.

Genetic information and genetic tests do not include HIV tests, complete blood counts, cholesterol or liver function tests, or drug or alcohol tests.

Genetic services mean a genetic test, genetic counseling, and genetic education.

- Even though some underwriting activities may fall within payment or health care operations purposes under the Privacy Rule, the final regulations set out that health plans cannot use or disclose PHI that is genetic information for underwriting purposes.

- Under the Privacy Rule, a group health plan or insurer with respect to the group health plan may provide summary health information to the plan sponsor if this information is requested to: 1) obtain premium bids from health plans providing health insurance coverage under the group health plan; or 2) for modifying, terminating, or amending the group health plan. Pursuant to the final regulations, a disclosure of PHI that is genetic information would not be permitted for underwriting purposes.

- If a group health plan intends to use or disclose PHI for underwriting purposes, then plan sponsors must include a statement in the group health plan’s HIPAA Notice of Privacy Practices (HIPAA Notice) that the plan is prohibited from using or disclosing PHI that is genetic information for such purpose. If the plan sponsor already modified the group health plan’s HIPAA Notice to reflect this prohibition and distributed the HIPAA Notice, then the HIPAA Notice does not need to be updated and redistributed again if the prior changes are consistent with the provisions of the final regulations.

Next Steps for Employer Group Health Plans and Plan Sponsors

Health plans and their plan sponsors should review and update the health plan’s HIPAA privacy policies and procedures to reflect that PHI that is genetic information will not be used or disclosed for underwriting purposes.

To the extent that their HIPAA Notice has not already been updated consistent with the final regulations, plans and sponsors should also review and revise the health plan’s HIPAA Notice to reflect that PHI that is genetic information will not be used or disclosed for underwriting purposes.

Resources


Aon Hewitt’s bulletin on the final regulations’ guidance on the new rules, notice, and agreements required by employer-sponsored group health plans is available at:

For additional information regarding the final regulations, please contact your Aon Hewitt Legal Consultant.
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