

**A BRIEF SUMMARY OF PORTIONS OF REGULATIONS
PROMULGATED UNDER THE
GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008 (“GINA”)**

**Pub.L. 110-233, 122 Stat. 881
Signed into Law on May 21, 2008**

**Thomas L. Shaevsky
Butzel Long, a professional corporation**

October 12, 2009

I. Purpose

Many genetic tests now exist that can inform individuals whether they may be at risk for developing a specific disease or disorder. But just as the number of genetic tests increase, so do the concerns of the general public about whether they may be at risk of losing access to health coverage or employment if insurers or employers have their genetic information. Congress enacted GINA to address these concerns, by prohibiting discrimination based on genetic information and restricting acquisition and disclosure of such information, so that the general public would not fear adverse employment- or health coverage-related consequences for having a genetic test or participating in research studies that examine genetic information. See Preamble to proposed Equal Employment Opportunity Commission regulations.

II. Different Titles in GINA

A. Title I

GINA Title I applies to group health plans sponsored by private employers, unions, and state and local government employers; issuers in the group and individual health insurance markets; and issuers of Medicare supplemental (Medigap) insurance. Sections 1010 through 104 of Title I generally prohibit discrimination in group premiums based on genetic information and the use of genetic information as a basis for determining eligibility or setting premiums in

the individual and Medigap insurance markets, and place limitations on genetic testing and the collection of genetic information in group health plan coverage, the individual insurance market, and the Medigap insurance market. Title I also provides a clarification with respect to the treatment of genetic information under privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Title I is effective for group health plans for plan years beginning after May 21, 2009 (i.e., for plan years beginning after the date that is 1 year after the date of enactment). With respect to health insurance coverage offered, sold, issued, renewed, in effect or operated in the individual market, Title I is effective after May 21, 2009 (i.e., after the date that is 1 year after the date of enactment).

Title I is administered by U.S. Department of Health and Human Services (“HHS”), U.S. Department of Labor (“DOL”) and U.S. Department of Treasury.

Title I of GINA amended Part 7 of Subtitle B of Title I of the Employee Retirement Income Security Act of 1974 (ERISA), Title XXVII of the Public Health Service Act (PHS Act), Subtitle K of the Internal Revenue Code of 1986 (Code), and added Section 1180 to the Social Security Act (SSA) to prohibit discrimination in health coverage based on genetic information.

While GINA does not mandate any specific benefits for health care services related to genetic tests, diseases, conditions, or genetic services, GINA establishes rules that generally prohibit a group health plan and a health insurance issuer in the group market from:

1. Increasing the group premium or contribution amounts based on genetic information;
2. Requesting or requiring an individual or family member to undergo a genetic test; and

3. Requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

Sections 9802 of the Code, 702 of ERISA, and 2702 of the PHS Act, and the 2006 final HIPAA nondiscrimination regulations prohibit discrimination based on a health factor. GINA retained the prohibition against increasing an individual's premium or contribution amounts based on genetic information, and added a new provision to prevent plans and issuers from adjusting premium or contribution rates at the group level based on genetic information of one or more individuals in the group.

B. Title II

Title II of GINA prohibits use of genetic information in the employment context, restricts the deliberate acquisition of genetic information by employers and other entities covered by Title II, and strictly limits such entities from disclosing genetic information. The law incorporates by reference many of the familiar definitions, remedies, and procedures from Title VII of the Civil Rights Act of 1964, as amended and other statutes protecting federal, state, and Congressional employees from discrimination.¹ Title II is effective November 21, 2009 (18 months after date of enactment).

Title II is administered by the Equal Employment Opportunity Commission ("EEOC").

¹ Currently, Executive Order 13145 prohibits federal executive branch agencies from discriminating against applicants and employees on the basis of genetic information and limits access to and use of genetic information. Upon its effective date in November 2009, GINA will protect federal employees from genetic discrimination.

III. Regulations

A. Title II

EEOC issued proposed regulations on March 2, 2009 (74 Federal Register 9056). EEOC coordinated with DOL, HHS, and Treasury in issuing proposed regulations. The EEOC proposed regulations are not discussed in this summary.

B. Title I

1. Interim Final Regulations (GINA Sections 101-103)²

On October 7, 2009, HHS, DOL and Treasury issued joint interim final rules pursuant to Sections 101 through 103 of GINA (74 Federal Register 51664). The rules are effective December 7, 2009. Treasury Regulations 54.9802-3T is the primary Treasury regulation, DOL Regulation 2590.702-1 is the primary DOL regulation, and HHS Regulation 146.122 is the primary HHS regulation. All of these regulations are substantially similar. HHS Regulation 146.180 pertains to treatment of non-Federal governmental plans. HHS regulations 148.101, 148.102, 148.120 and 148.180 pertain to requirements for the individual health insurance market.

a. No group-based discrimination based on genetic information

GINA and the interim final regulations expand the HIPAA prohibitions against discrimination based on health factors, by prohibiting

² Section 104 of Title I of GINA pertains to amendments to Title XVIII of the Social Security Act relating to Medigap. The interim final regulations do not address the application of GINA to Medigap issuers, which are subject to provisions in section 1882 of the SSA that are implemented by the Centers for Medicare & Medicaid Services (CMS), and incorporate by reference certain provisions in a model regulation of the National Association of Insurance Commissioners (NAIC). The model regulation adopted by the NAIC on September 24, 2008 was published by CMS in the Federal Register on April 24, 2009 at 74 FR 18808. This regulation also does not address the additional enforcement authority given to the Secretaries of Labor and HHS, relating to the use of genetic information, which will be addressed in future regulatory guidance.

group health plans and health insurance issuers offering health coverage in connection with a group health plan from adjusting premium or contribution amounts for a group health plan or group of similarly situated individuals on the basis of genetic information. This is a change from prior law, which allowed plans and issuers to adjust premium or contribution amounts for the group health plan or a group of similarly situated individuals (but not for individuals within the group) based on genetic information, as well as other health factors.

More specifically, a group health plan must not adjust premium or contribution amounts for any employer, or any group of similarly situated individuals under the plan, on the basis of genetic information. A group health plan can still increase the premium for an employer or for a group of similarly situated individuals under the plan based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such a case, however, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members to further increase the premium for an employer or a group of similarly situated individuals under the plan.

Example 1. Facts. An employer sponsors a group health plan that provides coverage through a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan and other health status information of the individuals, including genetic information. The issuer finds that three individuals covered under the plan had unusually high claims experience. In addition, the issuer finds that the genetic information of two other individuals indicates the individuals have a higher probability of developing certain illnesses although the illnesses are not manifested at this time. The issuer quotes the plan a higher per-

participant rate because of both the genetic information and the higher claims experience.

Conclusion. The issuer violates the provisions of 26 CFR 54.9802-3T(b), 29 CFR 2590.702-1(b) and 45 CFR 146.122(b) because the issuer adjusts the premium based on genetic information. However, if the adjustment related solely to claims experience, the adjustment would not violate the requirements of 26 CFR 54.9802-3T(b), 29 CFR 2590.702-1 or 45 CFR 146.122.

Example 2. (i) Facts. An employer sponsors a group health plan that provides coverage through a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan and other health status information of the individuals, including genetic information. The issuer finds that Employee A has made claims for treatment of polycystic kidney disease. A also has two dependent children covered under the plan. The issuer quotes the plan a higher per-participant rate because of both A's claims experience and the family medical history of A's children (that is, the fact that A has the disease).

(ii) Conclusion. The issuer violates the provisions of 26 CFR 54.9802-3T(b), 29 CFR 2590.702-1(b) and 45 CFR 146.122(b) by taking the likelihood that A's children may develop polycystic kidney disease into account in computing the rate for the plan, the issuer adjusts the premium based on genetic information relating to a condition that has not been manifested in A's children. However, the issuer does not violate the requirements of these regulations by increasing the premium based on A's claims experience.

b. Limitation on requesting or requiring genetic testing.

A group health plan must not request or require an individual or a family member of the individual to undergo a genetic test. However, a health care professional who is providing health care services to an individual can still request that the individual undergo a genetic test.

Example 1. (i) Facts. Individual A goes to a physician for a routine physical examination. The physician reviews A's family medical history and A informs the physician that A's mother has been diagnosed with Huntington's Disease. The physician advises A that Huntington's Disease is hereditary and recommends that A undergo a genetic test.

(ii) Conclusion. In this Example 1, the physician is a health care professional who is providing health care services to A. Therefore, the physician's recommendation that A undergo the genetic test does not violate this requirement.

Example 2. (i) Facts. Individual B is covered by a health maintenance organization (HMO). B is a child being treated for leukemia. B's physician, who is employed by the HMO, is considering a treatment plan that includes six-mercaptopurine, a drug for treating leukemia in most children. However, the drug could be fatal if taken by a small percentage of children with a particular gene variant. B's physician recommends that B undergo a genetic test to detect this variant before proceeding with this course of treatment.

(ii) Conclusion. In this Example 2, even though the physician is employed by the HMO, the physician is nonetheless a health care

professional who is providing health care services to B. Therefore, the physician's recommendation that B undergo the genetic test does not violate this requirement.

Payment Exception:

A plan can still obtain and use the results of a genetic test in making a determination regarding payment. For this purpose, "payment" has the meaning given such term in 45 CFR 164.501 of the privacy regulations issued under HIPAA. Thus, if a plan conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on the genetic makeup of a patient, then the plan is permitted to condition payment for the item or service on the outcome of a genetic test. The plan may also refuse payment if the patient does not undergo the genetic test.

However, a plan is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in 45 CFR 164.502(b) of the privacy regulations issued under HIPAA.

Research Exception:

A plan may request, but not require, that a participant or beneficiary undergo a genetic test if all of the conditions regarding the research exception are met, such as:

- (i) The research is in accordance with Federal regulations and applicable State or local law or regulations,
- (ii) The plan makes a written request for participation in research,

(iii) Genetic information collected or acquired cannot be used for underwriting, and

(iv) The plan provides applicable notice to Federal agencies.

c. **Prohibition on Collection of Genetic Information and Affect on Health Risk Assessments.**³

A group health plan must not collect genetic information for underwriting purposes.

GINA prohibits collecting genetic information for underwriting purposes. As described below, underwriting purposes is defined broadly to include rules for eligibility for benefits and the computation of premium or contributions amounts, and not merely activities relating to rating and pricing a group policy. Moreover, GINA defines genetic information as including family medical history. Consequently, wellness programs that provide rewards for completing health risk assessments that request genetic information, including family medical history, violate the prohibition against requesting genetic information for underwriting purposes. This is the result even if rewards are not based on the outcome of the assessment, which otherwise would not violate the 2006 final HIPAA nondiscrimination rules regarding wellness programs.

To implement this prohibition, the following definitions are utilized:

1. **Collect** means, with respect to information, to request, require, or purchase such information.

³ Proposed EEOC Regulation 1635.8(b)(2) describes situations where an employer can obtain genetic information as part of a voluntary wellness program.

2. **Underwriting purposes** means, 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 as described in Treasury Reg. 54.9802-1(b)(1)(ii), DOL Reg. 2590.702(b)(1)(ii) and HHS Reg. 146.121(b)(1)(ii) (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.

Medical Appropriateness

If an individual seeks a benefit under a group health plan, the plan may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an individual seeks a benefit under the plan and the plan conditions the benefit based on its medical appropriateness and the

medical appropriateness of the benefit depends on genetic information of the individual, then the plan is permitted to condition the benefit on the genetic information. A plan is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness. The plan may deny the benefit if the patient does not provide the genetic information required to determine medical appropriateness. If an individual is not seeking a benefit, the medical appropriateness exception to the definition of underwriting purposes does not apply.

Prior to or in Connection with Enrollment

A group health plan must not collect genetic information with respect to any individual prior to that individual's effective date of coverage under that plan, nor in connection with the rules for eligibility (as defined in Treasury Reg. 54.9802-1(b)(1)(ii), DOL Reg. 2590.702(b)(i)(ii) and HHS Reg. 146.121(b)(1)(ii)) that apply to that individual. Whether or not an individual's information is collected prior to that individual's effective date of coverage is determined at the time of collection.

Incidental Collection Exception

If a group health plan obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this rule as long as the collection is not for underwriting purposes in violation of the above described rule.

The incidental collection exception does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly states that genetic information should not be provided.

Example 1. (i) Facts. A group health plan provides a premium reduction to enrollees who complete a health risk assessment. The health risk assessment 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 health risk assessment includes questions about the individual's family medical history.

(ii) Conclusion. In this Example 1, the health risk assessment includes a request for genetic information (that is, the individual's family medical history). Because completing the health risk assessment 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.

Example 2. (i) Facts. The same facts as Example 1, except there is no premium reduction or any other reward for completing the health risk assessment.

(ii) Conclusion. In this Example 2, 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.

Example 3. (i) Facts. A group health plan requests that enrollees complete a health risk assessment prior to enrollment, and includes questions about the individual's family medical history. There is no reward or penalty for completing the health risk assessment.

(ii) Conclusion. In this Example 3, because the health risk assessment 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. Moreover, because it is a request for genetic information, it is not an incidental collection.

Example 4. (i) Facts. The facts are the same as in Example 1, except there is no premium reduction or any other reward given for completion of the health risk assessment. However, certain people completing the health risk assessment may become eligible for additional benefits under the plan by being enrolled in a disease management program based on their answers to questions about family medical history. Other people may become eligible for the disease management program based solely on their answers to questions about their individual medical history.

(ii) Conclusion. In this Example 4, the request for information about an individual's family medical history could result in the individual being eligible for benefits for which the individual would not otherwise be eligible. Therefore, the questions about family medical history on the health risk assessment are a request for genetic information for underwriting purposes and are prohibited. Although the plan conditions eligibility for the disease management program based on determinations of medical appropriateness, the exception for determinations of medical appropriateness does not apply because the individual is not seeking benefits.

Example 5. (i) 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.

(ii) Conclusion. In this Example 5, 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.

Example 6. (i) 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?"

(ii) Conclusion. In this Example 6, 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.

Example 7. (i) Facts. Same facts as Example 6, except that 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."

(ii) Conclusion. In this Example 7, 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 any genetic information it obtains incidentally for underwriting purposes.

Example 8. (i) Facts. Issuer M acquires Issuer N. M requests N's records, stating that N should not provide genetic information and should review the records to excise any genetic information. N assembles the data requested by M and, although N reviews it to delete genetic information, the data from a specific region included some individuals' family medical history. Consequently, M receives genetic information about some of N's covered individuals.

(ii) Conclusion. In this Example 8, M's request for health information explicitly stated that genetic information should not be provided. The collection of genetic information was within the incidental collection exception. However, M may not use the genetic information it obtained incidentally for underwriting purposes.

Examples regarding determinations of Medical Appropriateness

Example 1. (i) Facts. Individual A's group health plan covers genetic testing for celiac disease for individuals who have family members with this condition. After A's son is diagnosed with celiac disease, A undergoes a genetic test and promptly submits a claim for the test to A's issuer for reimbursement. The issuer asks A to provide the results of the genetic test before the claim is paid.

(ii) Conclusion. The issuer is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for the issuer to make a decision regarding the payment of A's claim, the issuer's request for the results of the genetic test violates the rule.

Example 2. (i) Facts. Individual B's group health plan covers a yearly mammogram for participants and beneficiaries starting at age 40, or at age 30 for those with increased risk for breast cancer, including individuals with BRCA1 or BRCA2 gene mutations. B is 33 years old and has the BRCA2 mutation. B undergoes a mammogram and promptly submits a claim to B's plan for reimbursement. Following an established policy, the plan asks B for evidence of increased risk of breast cancer, such as the results of a genetic test or a family history of breast cancer, before the claim for the mammogram is paid. This policy is applied uniformly to all similarly situated individuals and is not directed at individuals based on any genetic information.

(ii) Conclusion. In this Example 2, the plan does not violate the rule. The plan is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the plan requests only the minimum amount of information necessary.

Because the medical appropriateness of the mammogram depends on the genetic makeup of the patient, the minimum amount of information necessary includes the results of the genetic test. Similarly, the plan does not violate the rule because the plan is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and if the genetic information is not used for underwriting purposes).

d. Definitions

Some key definitions used in the regulations are as follows:

Family member means, with respect to an individual --

- (i) A dependent (as defined for purposes of Treasury Reg. 54.9801-2, or DOL Reg. 2590.701-2, or HHS Reg. 144.103) of the individual; or

- (ii) Any other person who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents).
 - (A) First-degree relatives include parents, spouses, siblings, and children.

- (B) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.
- (C) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.
- (D) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

Genetic information means --

- (i) With respect to an individual, information about --
 - (A) The individual's genetic tests;
 - (B) The genetic tests of family members of the individual;
 - (C) The manifestation of a disease or disorder in family members of the individual; or
 - (D) 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.
- (ii) The term genetic information does not include information about the sex or age of any individual.
- (iii) The term genetic information includes --

- (A) With respect to a pregnant woman (or a family member of the pregnant woman), genetic information of any fetus carried by the pregnant woman; and
- (B) 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.

Genetic services means --

- (i) A genetic test;
- (ii) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or
- (iii) Genetic education.

Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes

Manifestation or manifested means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. A disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information.

C. Amendment to Privacy Regulations

1. Background

The "Standards for Privacy of Individually Identifiable Health Information," or "Privacy Rule" was issued on December 28, 2000 (and later amended in August 2002), pursuant to the Administrative Simplification Provisions of Title II, Subtitle F, of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191. Subtitle F of Title II of HIPAA added a new Part C to Title XI of the Social Security Act (sections 1171-1179 of the Act, 42 U.S.C. 1320d-1320d-8). The Privacy Rule is one of a suite of rules required by the Administrative Simplification provisions of HIPAA, and put in place the first national standards for the privacy protection of certain individually identifiable health information (called "protected health information" or "PHI"). The other HIPAA Administrative Simplification Rules provide national standards for electronic health care transactions and code sets, unique health identifiers for employers and health care providers, and the security of electronic PHI. The HIPAA Privacy and other Administrative Simplification Rules currently apply to three types of covered entities: health care providers who conduct covered health care transactions electronically, health plans, and health care clearinghouses.

In addition to the nondiscrimination provisions, Title I of GINA contains certain new privacy protections for genetic information. In particular, section 105 of GINA, entitled "Privacy and Confidentiality," amends Part C of Title XI of the Social Security Act by adding section 1180 to address the application of the HIPAA Privacy Rule to genetic information. Section 1180 requires the Secretary of HHS to revise the Privacy Rule to clarify that genetic information is health information and to prohibit group health plans, health insurance issuers (including HMOs),

and issuers of Medicare supplemental policies from using or disclosing genetic information for underwriting purposes.

2. Proposed regulations (GINA Section 105)

a. In General

Section 105 of GINA requires HHS to modify the Privacy Rule to prohibit "a covered entity that is a group health plan, health insurance issuer that issues health insurance coverage, or issuer of a medicare [sic] supplemental policy" from using or disclosing genetic information for underwriting purposes.

In accordance with section 105 of GINA and HHS's general authority under sections 262 and 264 of HIPAA, on October 7, 2009, HHS issued proposed regulations to modify the HIPAA Privacy Rule to: (1) explicitly provide that genetic information is health information for purposes of the Rule; (2) prohibit health plans from using or disclosing protected health information that is genetic information for underwriting purposes; (3) revise the provisions relating to the Notice of Privacy Practices for health plans that perform underwriting; (4) make a number of conforming modifications to definitions and other provisions of the Rule; and (5) make technical corrections to update the definition of "health plan." 74 Federal Register 51698.

b. Types of plans covered

In addition to group health plans, health insurance issuers, health maintenance organizations, and issuers of medicare supplemental policies (the four categories of health plans), the HIPAA Privacy Rule also applies to many other types of health plans, including: (1) long-term care policies (excluding nursing home fixed-indemnity policies); (2) employee welfare benefit plans or other arrangements that are established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers (to the extent that they are not group health plans

or health insurance issuers); (3) high risk pools that are mechanisms established under State law to provide health insurance coverage or comparable coverage to eligible individuals; (4) certain public benefit programs, such as Medicare Part A and B, Medicaid, the military and veterans health care programs, the Indian Health Service program, and others; as well as (5) any other individual or group plan, or combination of individual or group plans that provides or pays for the cost of medical care including certain "excepted benefits" plans described at 42 U.S.C. 300gg-91(c)(2), such as limited scope dental or vision benefits plans.

HHS proposes to apply the prohibition in GINA on using and disclosing protected health information that is genetic information for underwriting to all health plans that are subject to the Privacy Rule, rather than solely to the plans GINA explicitly requires be subject to the prohibition (i.e., the four categories of health plans).

HHS intends to require health plans to comply with these modifications to the privacy standards no later than 180 days from the effective date of such modifications.

c. Definitions

Definitions in the proposed HHS regulations are similar to those in interim final regulations issued pursuant to GINA Sections 101-103. With regard to health information in particular, HHS notes that HHS has always maintained that genetic information is health information protected by the Privacy Rule to the extent such information is individually identifiable and held by a covered entity (subject to the general exclusions from the definition of "protected health information"). Frequently Asked Question number 354, available at <http://www.hhs.gov/ocr/privacy/hipaa/faq/about/354.html>, states:

"Question: Does the HIPAA Privacy Rule protect genetic information? Answer: Yes, genetic information is health information

protected by the Privacy Rule. Like other health information, to be protected it must meet the definition of protected health information: it must be individually identifiable and maintained by a covered health care provider, health plan, or health care clearinghouse. See 45 C.F.R. 160.103.”

Nevertheless, section 105 of GINA requires HHS to revise the Privacy Rule to make clear that genetic information is health information under the Rule. Accordingly, HHS proposes to modify the definition of "health information" at §160.103 to explicitly provide that such term includes genetic information. HHS notes, however, that as before, genetic information, while health information, is only covered by the Privacy Rule to the extent that it meets the definition of "protected health information." That is, the genetic information must be individually identifiable and maintained by a HIPAA covered entity (or business associate of a covered entity) (and not otherwise fall within one of the exceptions to the definition). See the definition of "protected health information" at §160.103.

d. Underwriting

HHS interprets section 105 of GINA as requiring HHS to prohibit a health plan's use or disclosure of genetic information for underwriting purposes, even if an individual has signed an authorization for such purposes pursuant to §164.508. HHS also proposes a conforming change to §164.502(a)(1)(iv) to make clear that an authorization could not be used to permit a use or disclosure of genetic information for underwriting purposes.

Consistent with the statute, however, this prohibition should not be construed to limit the ability of a health plan to adjust premiums or contribution amounts for a group health plan based on the manifestation of a disease or disorder of an individual enrolled in the plan, even though a health plan cannot use the manifestation of a disease or disorder in one

individual as genetic information about other group members and to further increase the premium for the plan.

As an example to demonstrate the proposed prohibition, if a health insurance issuer, with respect to an employer-sponsored group health plan, uses an individual's family medical history or the results of genetic tests maintained in the group health plan's claims experience information to adjust the plan's premium rate for the upcoming year, the issuer would be using PHI that is genetic information for underwriting purposes in violation of proposed §164.502(a)(3). Similarly, if a group health plan uses family medical history provided by an individual incidental to the collection of other information on a health risk assessment to grant a premium reduction to the individual, the group health plan would be using genetic information for underwriting purposes in violation of §164.502(a)(3).

Also, note that the prohibition is limited to health plans. A health care provider may use or disclose genetic information as it sees fit for treatment of an individual. If a covered entity, such as an HMO, acts as both a health plan and health care provider, the covered entity may use genetic information for purposes of treatment, to determine the medical appropriateness of a benefit, and as otherwise permitted by the Privacy Rule, but may not use such genetic information for underwriting purposes. Such covered entities, in particular, should ensure that appropriate staff members are trained on the permissible and impermissible uses of genetic information.

e. Notice of privacy practices

HHS proposes to require health plans that use or disclose PHI for underwriting to include a statement in their Notice of Privacy Practices (“NPP”) making clear that they are prohibited from using or disclosing PHI that is genetic information about an individual for such purposes.

HHS recognizes that revising and redistributing a NPP may be costly for health plans that perform underwriting and thus requests

comment on ways to inform individuals of this change to privacy practices without unduly burdening health plans, particularly given there may be other material changes to the NPP due to the modifications to the Privacy Rule required by the provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act.