VI. Modifications to the HIPAA Privacy Rule Under GINABack to Top

A. Background

The Genetic Information Nondiscrimination Act of 2008 ("GINA"),Public Law 110-233, 122 Stat. 881, prohibits discrimination based on an individual's genetic information in both the health coverage and employment contexts. With respect to health coverage, Title I of GINA generally prohibits discrimination in premiums or contributions for group coverage based on genetic information, proscribes the use of genetic information as a basis for determining eligibility or setting premiums in the individual and Medicare supplemental (Medigap) insurance markets, and limits the ability of group health plans, health insurance issuers, and Medigap issuers to collect genetic information or to request or require that individuals undergo genetic testing. Title II of GINA generally prohibits use of genetic information in the employment context, restricts employers and other entities covered by Title II from requesting, requiring, or purchasing geneticinformation, and strictly limits such entities from disclosing genetic information. The Departments of Labor, Treasury, and Health and Human Services (HHS) are responsible for administering and enforcing the GINA Title I nondiscrimination provisions, and the Equal Employment Opportunity Commission (EEOC) is responsible for administering and enforcing the GINA Title II nondiscrimination provisions. [13]

In addition to these nondiscrimination provisions, section 105 of Title I of GINA contains new privacy protections for genetic information, which require 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. [14]

B. Overview of the Proposed Rule

On October 7, 2009, the Department published a notice of proposed rulemaking (NPRM or "proposed rule") to strengthen the privacy protections for genetic information under the HIPAA Privacy Rule by implementing the protections for genetic information required by GINA [15] and making related changes to the Rule. In particular, in accordance with section 105 of GINA and the Department's general authority under sections 262 and 264 of HIPAA, the Department proposed to: (1) Explicitly provide that genetic information is health information for purposes of the Privacy Rule; (2) prohibit all health plans covered by the HIPAA Privacy Rule 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

changes to definitions and other provisions of the Rule; and (5) make technical corrections to update the definition of "health plan."

The 60-day public comment period for the proposed rule closed on December 7, 2009, and the Department received approximately twenty-five comments in response to its proposal. [16] After considering the public comments, the Department is issuing this final rule to strengthen the privacy protections for genetic information in accordance with GINA and the Department's general authority under sections 262 and 264 of HIPAA. In developing this rule, the Department consulted with the Departments of Labor and Treasury, as required by section 105(b)(1) of GINA, to ensure, to the extent practicable, consistency across the regulations. In addition, the Department coordinated with the EEOC in the development of these regulations.

The provisions of the proposed rule and the public comments received that were within the scope of the proposed rule are described in more detail below in the section-by-section description of the final rule.

C. Section-by-Section Description of Final Rule and Response to Public Comments

1. Scope: Extension of Required Protections to All Health Plans Subject to the HIPAA Privacy Rule

Proposed Rule

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. Section 105 of GINA provides that the terms "group health plan" and "health insurance coverage" have the meanings given such terms under section 2791 of the Public Health Service Act (PHSA) (42 U.S.C. 300gg-91), and that the term "medicare [sic] supplemental policy" has the meaning given such term in section 1882(g) of the Social Security Act. In addition, the term "health insurance issuer," as defined at 42 U.S.C. 300gg-91, includes a health maintenance organization (HMO). These four types of entities (i.e., group health plans, health insurance issuers, and health maintenance organizations, as defined in the PHSA, as well as issuers of Medicare supplemental policies), correspond to the types of covered entities listed at subparagraphs (i) through (iii) and (vi) of paragraph (1) of the definition of "health plan" at § 160.103 in the HIPAA Privacy Rule, issued under HIPAA's Administrative Simplification provisions. These also are the entities to which HIPAA's nondiscrimination provisions apply and to which the nondiscrimination provisions of GINA Title I were directed.

However, in addition to these four types of entities, the HIPAA Privacy Rule also includes a number of other entities within the definition of "health plan": (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 (as the term “medical care” is defined in section 2791(a)(2) of the PHSA, 42 U.S.C. 300gg-91(a)(2)). This last category includes, for example, certain “excepted benefits” plans described at 42 U.S.C. 300gg-91(c)(2), such as limited scope dental or vision benefits plans. See the definition of “health plan” at § 160.103.

In the NPRM, the Department, using both its authority under GINA as well as its broad authority under HIPAA, proposed to apply the prohibition 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. As explained in the proposed rule, the HIPAA Administrative Simplification provisions provide the Secretary withbroad authority to craft privacy standards that uniformly apply to all health plans, regardless of whether such health plans are governed by other portions of the HIPAA statute. In addition, the Department indicated in the proposed rule that nothing in GINA explicitly or implicitly curtails this broad authority of the Secretary to promulgate privacy standards for any and all health plans that are governed by the HIPAA Administrative Simplification provisions.

Under the Privacy Rule, and consistent with HIPAA, an individual's privacy interests and rights with respect to the use and disclosure of protected health information are protected uniformly without regard to the type of health plan that holds the information. Thus, under the Privacy Rule, individuals can expect and benefit from privacy protections that do not diminish based on the type of health plan from which they obtain health coverage. In developing the proposed rule, the Department believed that individuals' interests in uniform protection under the Privacy Rule against the use or disclosure of their genetic information for underwriting purposes would outweigh any adverse impact on health plans that are not covered by GINA, particularly since it was not expected that all of the health plans subject to the Privacy Rule use or disclose protected health information that is genetic information for underwriting (or even perform underwriting generally, in the case of some of the public benefit plans). For these reasons, the Department proposed to apply the prohibition on using or disclosing protected health information that is genetic information for underwriting purposes to all health plans that are HIPAA covered entities.

Overview of Public Comments

The Department received comments both in support of and against the proposed application of the prohibition on using or disclosing genetic information for underwriting purposes to all health plans covered by the Privacy Rule. Several commenters agreed that the extension of the proposed requirements to all health plans is an appropriate exercise of the Secretary's discretion under HIPAA and is necessary to protect the privacy interests of all individuals without regard to the type of health plan holding individuals' health information, and stated that such an extension would further encourage individuals to take advantage of genetic services. In addition, one commenter in support of the proposal indicated that sixteen States also regulate the use of genetic information in disability insurance, and ten States regulate its use in long-term care insurance, and it is expected that these numbers will continue to increase. The commenter stated that as States move forward in this area it was appropriate for the Federal government to do so as well. However, this and one other commenter, while generally in support of extending the prohibition on using or disclosing genetic information for underwriting to all health plans, also recommended that the Department monitor the impact of such a prohibition on long-term care insurers.

A few commenters did not support the Department's proposal and argued that the prohibition against using or disclosing genetic information for underwriting purposes in the Privacy Rule should apply only to those plans to which GINA expressly applies. Commenters argued that applying the prohibition beyond the health plans identified in GINA was contrary to GINA and its intent.

Certain commenters expressed particular disagreement and concern with applying the prohibition on the use of genetic information for underwriting to long-term care insurers. One commenter argued that there was clear Congressional intent in the legislative history of GINA to exempt “excepted benefits,” particularly long-term care insurance, from any prohibitions under GINA and thus, the Privacy Rule should not apply the prohibition on underwriting with genetic information to issuers of long term care policies. The commenter also argued that the GINA prohibition should not apply to long-term care insurers because long-term care plans have different characteristics from other health plans and applying the GINA prohibition to long-term care insurers would jeopardize the ability of long-term care insurers to adequately underwrite and thus, the viability of the long-term care insurance market. The commenter explained that this would be due to the fact that when underwriting, long term care insurers look to determine an individual's probability of needing long-term care in the future and diagnosis of a particular condition is not the only way this may be determined and in some cases may not even be relevant to such a determination. The Department also heard similar concerns about the potential negative impact of an underwriting prohibition on the economic viability of the long-term market, from certain members

of Congress who wrote to the Secretary on this issue, as well as from certain outside parties during fact finding meetings held by the Department.

Final Rule

The final rule adopts the approach of the proposed rule to apply the prohibition on using or disclosing protected health information that is genetic information for underwriting purposes to all health plans that are covered entities under the HIPAA Privacy Rule, including those to which GINA does not expressly apply, except with regard to issuers of long term care policies. We continue to disagree with the commenters that stated such an extension would conflict with GINA and is outside the scope of our authority. As explained more fully in the proposed rule, the Department has broad authority under HIPAA to regulate a health plan's uses and disclosures of protected health information, including genetic information, to protect an individual's privacy interests. See 74 FR 51698, 51699-51700. It does not follow that by exempting "excepted benefits" from the prohibitions under GINA that Congress intended to restrict the Department's broad authority under HIPAA. Further, there is no conflict with GINA in extending the same privacy protections outlined in GINA to those health plans that are not covered by GINA but are otherwise covered by the HIPAA Privacy Rule. GINA and section 264 of HIPAA are not irreconcilably inconsistent but rather operate concurrently without conflict. Lastly, GINA did not override HIPAA, and did not displace the Department's authority to prohibit uses and disclosures of genetic information that GINA does not otherwise prohibit. Therefore, nothing in GINA explicitly or implicitly curtails the broad authority of the Secretary to promulgate privacy standards for any and all health plans that are governed by the HIPAA Administrative Simplification provisions.

We also continue to believe that individuals have a strong privacy interest in not having their genetic information used in an adverse manner for underwriting purposes and to believe that this privacy interest outweighs any adverse impact on most health plans covered by the Privacy Rule. With respect to most health plans not subject to GINA, the public comment did not indicate that a prohibition on using genetic information for underwriting would have significant adverse impacts on the viability of these plans. Nor did the public comment generally provide information showing that these health plans actually use or disclose protected health information that is genetic information for underwriting, or plan todo so in the future (or even perform underwriting generally, in the case of some of the public benefit plans).

However, as indicated above, the Department did hear from a number of sources about the potential adverse impact a prohibition on using genetic information for underwriting would have on the ability of a long-term care insurer to effectively underwrite and thus, on the viability of the long-term care insurance market generally. The Department recognizes the importance of long-term care insurance coverage and

the need to ensure its continued availability. The Department also acknowledges that, at this time, it does not have the information necessary to more precisely and carefully measure the extent of such an impact on the long-term market in order to appropriately balance an individual's privacy interests with such an impact. Thus, this final rule excludes long-term care plans from the underwriting prohibition.

While we exempt long-term care plans from the underwriting prohibition in this final rule, we continue to believe an individual has a strong privacy interest in the way his or her genetic information is used for the underwriting of long-term care insurance. At the current time, however, we do not have sufficient information to determine the proper balance between the individual's privacy interests and the industry's concerns about the cost effects of excluding genetic information. For that reason, we are looking into ways to obtain further information on this issue, such as through a study by the National Association of Insurance Commissioners (NAIC) on the tension between the use of genetic information for underwriting and the associated privacy concerns in the context of their model long-term care rules. Based on the information the Department may obtain, the Department will reassess how best to move forward in this area in the future.

Long-term care plans, while not subject to the underwriting prohibition, continue to be bound by the Privacy Rule, as are all other covered health plans, to protect genetic information from improper uses and disclosures, and to only use or disclose genetic information as required or expressly permitted by the Rule, or as otherwise authorized by the individual who is the subject of the genetic information.

2. Section 160.101—Statutory Basis and Purpose

We have revised § 160.101, which describes the statutory basis of the HIPAA Rules, to include a reference to section 1180 of the Social Security Act, as added by section 105 of GINA (Pub. L. 110-233).

3. Section 160.103—Definitions

The final rule modifies § 160.103 of the Privacy Rule to: (1) Revise the definition of "health information" to make clear that the term includes "genetic information;" (2) add definitions for the GINA-related terms of "family member," "genetic information," "genetic services," "genetic test," and "manifestation or manifested;" and (3) make technical corrections to the definition of "health plan." With respect to the GINA-related terms, the final rule adopts definitions that are generally consistent with the definitions of such terms promulgated in the implementing regulations for sections 101-103 of GINA. This will facilitate compliance for those health plans subject to both the privacy as well as the nondiscrimination provisions of GINA.

a. Definition of "Health information"

Proposed Rule

Prior to enactment of GINA, the Department issued guidance that genetic information is health information protected by the Privacy Rule to the extent that such information is individually identifiable and held by a covered entity (subject to the general exclusions from the definition of "protected health information"). [17] Section 105 of GINA requires the Secretary to revise the Privacy Rule to make clear that genetic information is health information under the Rule. Thus, the Department proposed to modify the definition of "health information" at § 160.103 to explicitly provide that such term includes genetic information.

Overview of Public Comments

The Department received a few comments expressing specific support for and one comment against the proposed inclusion of the term "genetic information" in the definition of "health information." The commenters supporting the revision to the definition of "health information" indicated that such an inclusion was necessary to clarify that genetic information is health information. The commenter against the proposed inclusion to the definition argued that although GINA directs the Department to treat genetic information as health information, the language of GINA does not require a change to the definition of "health information," and this change would create costs for health plans, which would have to update all their policies and procedures to reflect the change.

Final Rule

The final rule adopts the proposed modification to the definition of "health information" at § 160.103. This modification to the definition is a necessary clarification to the Privacy Rule based on the statutory language. Given that revising the definition of "health information" to include genetic information does not substantively change the scope of the Privacy Rule, it is unclear why such a change alone would require revisions to a health plan's policies and procedures. Health plans that perform underwriting will otherwise need to revise their policies and procedures as necessary to comply with this final rule, as well as the modifications to the HIPAA Rules required by the Health Information Technology for Economic and Clinical Health (HITECH) Act. Thus, to the extent the concern about this modification stems from the fact that a health plan's policies and procedures quote the prior regulatory definition of "health information," the health plan can revise the definition at the time it is otherwise updating its policies and procedures to comply with these rules.

b. Definition of "Genetic Information"

Proposed Rule

The term “genetic information” is defined in GINA and establishes what information is protected by the statute. Section 105 of GINA provides that the term “genetic information” in section 105 shall have the same meaning given the term in section 2791 of the PHSA (42 U.S.C. 300gg-91), as amended by section 102 of GINA. Section 102(a)(4) of GINA defines “genetic information” to mean, with respect to any individual, information about: (1) Such individual's genetic tests; (2) the genetic tests of family members of such individual; and (3) the manifestation of a disease or disorder in family members of such individual (i.e., family medical history). GINA also provides that the term “genetic information” includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by suchindividual or family member of such individual. GINA expressly provides that the term “genetic information” shall not include information about the sex or age of any individual. This basic definition of “genetic information” in section 102(a)(4) of GINA (and that is to apply for purposes of section 105) is also expanded by section 102(a)(3), which provides that any reference to genetic information concerning an individual or family member in the PHSA shall include: with respect to an individual or family member of an individual who is a pregnant woman, the genetic information of any fetus carried by such pregnant woman; and with respect to an individual or family member utilizing an assisted reproductive technology, the genetic information of any embryo legally held by the individual or family member. The Department proposed to include this statutory definition of “genetic information” in § 160.103.

Overview of Public Comments

Most commenters did not address the proposed definition of “genetic information” in their comments on the proposed rule. However, one commenter stated that it was unclear what information may fall within the scope of the term “genetic information” and whether such term may be construed to include traditional medical information or medical tests used in underwriting today.

Final Rule

The final rule adopts without modification the definition of “genetic information” proposed in the NPRM. This definition is consistent with the definition found in the implementing regulations for sections 101-103 of GINA and with which compliance is already required by most health plans. The term “genetic information” includes information about the genetic tests of the individual or of the individual's family members and about diseases or disorders manifested in an individual's family members (i.e., family health history). Thus, information about manifested diseases, disorders, or conditions of the individual or medical tests that do not meet the rule's definition of “genetic test,” such as HIV tests, complete blood counts, cholesterol or

liver function tests, or tests to detect for the presence of alcohol or drugs, are not genetic information, and such information may be used or disclosed for underwriting purposes. Conversely, family health histories and information about genetic tests, such as tests to determine whether an individual or family member has a gene variant associated with breast cancer, are genetic information, and such information may not be used or disclosed for underwriting purposes. The definitions of "manifestation or manifested" and "genetic test" are discussed more fully below.

c. Definition of "Genetic Test"

Proposed Rule

As explained above, GINA provides that the term "genetic information" includes information about an individual's genetic tests or the genetic tests of family members of the individual. Section 105 of GINA provides that the term "genetic test" shall have the same meaning as the term has in section 2791 of the PHSA (42 U.S.C. 300gg-91), as amended by section 102 of GINA. Section 102(a)(4) of GINA amends section 2791(d) of the PHSA to define "genetic test" to mean "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes." GINA further clarifies that the term "genetic test" does not include an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes, nor does it include an analysis of proteins or metabolites 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.
Consistent with the statutory definition, the Department proposed to define "genetic test" at § 160.103 as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes, and to provide in the definition that "genetic test" does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. While the statute refers to a "manifested" disease as one that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved, the statute does not define "manifested." Consequently, for clarity, the Department proposed a definition of "manifested," as described below.

Overview of Public Comments

The Department received one comment requesting that the Department include examples within the regulatory text of the definition and another comment stated that it is not clear what constitutes a genetic test under the definition.

Final Rule

The final rule adopts without modification the definition of "genetic test" as proposed in the NPRM. This definition is consistent with the definition found in the implementing regulations for sections 101-103 of GINA and with which compliance is already required by most health plans. Under this definition, a test to determine whether an individual has a gene variant associated with breast cancer (such as the BRCA1 or BRCA2 variant) is a genetic test. Similarly, a test to determine whether an individual has a genetic variant associated with hereditary nonpolyposis colorectal cancer is a genetic test. Such tests are genetic in nature because they detect genotypes, mutations, or chromosomal changes. In contrast, medical tests that do not detect genotypes, mutations, or chromosomal changes, are not genetic tests. For example, HIV tests, complete blood counts, cholesterol tests, liver function tests, or tests for the presence of alcohol or drugs are not genetic tests. Consistent with the approach taken generally with the HIPAA Privacy Rule, the Department declines to include these examples in the regulatory text. The Department intends to issue future guidance on its web site about this issue.

d. Definition of "Genetic Services"

Proposed Rule

GINA provides that the term "genetic information" includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual. Section 102(a)(4) of GINA defines "genetic services" to mean: (1) A genetic test; (2) genetic counseling (including obtaining, interpreting, or assessing genetic information); or (3) genetic education. Thus, the fact that an individual or a family member of the individual requested or received a genetic test, counseling, or education is information protected under GINA. Genetic counseling and education are means by which individuals can obtain information and support about potential risks for genetic diseases and disorders. The Department proposed to add the statutory definition of "genetic services" to the Privacy Rule.

Overview of Public Comments

The Department received one comment requesting that theDepartment add language to the definition to make clear that the genetic tests, genetic counseling, or genetic education of a family member of an individual are specifically covered by the term.

Final Rule

The final rule adopts without modification the definition of “genetic services” proposed in the NPRM. This definition is consistent with the definition found in the implementing regulations for sections 101-103 of GINA and with which compliance is already required by most health plans. The Department does not believe it necessary to add the term “family member” to the definition of “genetic services” because the definition of “genetic information” makes clear that information about any request for, or receipt of, genetic services by a family member of an individual is protected information.

e. Definition of “Family Member”

Proposed Rule

The term “family member” is used in the definition of “genetic information” in GINA to indicate that an individual's genetic information also includes information about the genetic tests of the individual's family members, as well as family medical history. Section 105 of GINA states that the term “family member” shall have the meaning given such term in section 2791 of the PHSA (42 U.S.C. 300gg-91), as amended by GINA section 102(a)(4), which defines “family member” to mean, with respect to any individual: (1) A dependent (as such term is used for purposes of section 2701(f)(2) of the PHSA, 42 U.S.C. 300gg(f)(2)) of such individual; or (2) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual or of a dependent of the individual. Section 2701(f)(2) of the PHSA uses the term “dependent” to mean an individual who is or may become eligible for coverage under the terms of a group health plan because of a relationship to the plan participant.
The Department proposed to incorporate GINA's definition of “family member” into the Privacy Rule. The proposed rule also clarified within the definition that relatives by affinity (such as by marriage or adoption) are to be treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor) and that, in determining the degree of 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). The NPRM explained that this broad interpretation of “family member” was consistent with GINA's legislative history, which suggests that the term “family member” is to be broadly construed to provide the maximum protection against discrimination. [18] In addition, the Department proposed to include in the definition of “family member” non-exhaustive lists of persons who are first-, second-, third-, or fourth-degree relatives. Finally, within the definition of “family member,” the Department proposed to refer to the definition of “dependent” contained in the implementing regulations at 45 CFR 144.103 rather to the PHSA directly.

Overview of Public Comments

One commenter expressed support for including relatives by affinity and by less than full consanguinity, agreeing that this interpretation is consistent with Congressional intent and provides the most privacy protection for individuals. This commenter also was supportive of including non-exhaustive lists of persons who are first-, second-, third-, and fourth-degree relatives to add clarity to the definition.

Final Rule

As we received only support with regard to the definition of "family member," the final rule adopts without modification the definition of "family member" proposed in the NPRM. This definition also is consistent with the definition found in the implementing regulations for sections 101-103 of GINA and with which compliance is already required by most health plans.

f. Definition of "Manifestation or Manifested"

Proposed Rule

Although not separately defined by GINA, the terms "manifestation" or "manifested" are used in GINA in three important contexts. First, GINA uses the term "manifestation" to incorporate "family medical history" into the definition of "genetic information" by stating that "genetic information" includes, with respect to an individual, the manifestation of a disease or disorder in family members of such individual. Second, GINA uses the term "manifested" to exclude from the definition of "genetic test" those tests that analyze a physical malady rather than genetic makeup by excluding from the definition analyses of proteins or metabolites that are directly related to a manifested disease, disorder, or pathological condition. Third, GINA uses the term "manifestation" to clarify that nothing in Title I of GINA should 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. [19] However, GINA provides that, in such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the plan. Similarly, for the individual health insurance market, GINA clarifies that it does not prohibit a health plan from establishing rules for eligibility for an individual to enroll in coverage or from adjusting premium or contribution amounts for an individual based on the manifestation of a disease or disorder in that individual or in a family member of such individual where such family member is covered under the individual's policy. However, under GINA, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals and to further increase premiums or contribution amounts.

Given the importance of the term “manifested” or “manifestation,” the Department proposed to define the term. Although GINA does not define the term, it is clear from the statutory definition of “genetic test” that a manifested disease or disorder is one “that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.” Accordingly, the proposed rule defined the term “manifestation or manifested” to mean, 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. The proposed definition also provided that a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information. This clarification was included due to the fact that variants of genes associated with diseases have varying degrees of predictive power forlater development of the disease. In some cases, an individual may have a genetic variant for a disease and yet never develop the disease. In other cases, the presence of a genetic variant indicates that the individual will eventually develop the disease, such as is the case with Huntington's disease. However, an individual may obtain a positive test that shows the genetic variant for Huntington's disease decades before any clinical symptoms appear. Under the proposed definition, the presence of a genetic variant alone would not constitute the diagnosis of a disease even in cases where it is certain the individual possessing the genetic variant will eventually develop the disease, such as with Huntington's disease.

Overview of Public Comments

A few commenters expressed support for adopting the proposed definition of “manifestation or manifested” because it would provide clarity to the rule and the scope of the underwriting prohibition. One commenter requested that the Department include the examples provided in the preamble to the proposed rule directly within the regulatory definition. A few commenters raised concerns about the inclusion in the proposed definition of the clarification that “a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.” It was argued that the proposed definition was too narrow because, for some diseases, disorders, or pathological conditions, a genetic test is the primary means of diagnosing the condition and further that genetic tests will more frequently be used to diagnose diseases or conditions in the future given the continuing evolution of genetics. It was also argued that the proposed definition went beyond GINA by indicating how a manifested disease or disorder is diagnosed.

Final Rule

The final rule adopts without modification the definition of “manifestation or manifested” proposed in the NPRM. The definition is consistent with the definition of

"manifestation or manifested" found in the implementing regulations for the non-discrimination provisions of sections 101-103 of GINA and with which compliance is already required for most health plans. In developing this definition, the agencies consulted with technical experts at the National Human Genome Research Institute within the National Institutes of Health (NIH). In addition, for the reasons stated above regarding the varying degrees of predictive power genes provide in terms of ultimate development of a disease, as well as of the fact that a genetic test for a disease may precede clinical signs or symptoms by years or even decades, the Department does not believe that the definition is too narrow but rather that it is consistent with the provisions of GINA that protect genetic information from being used for health coverage determinations. Finally, the definition does not preclude a health care provider from performing one or more genetic tests to confirm a diagnosis so long as the diagnosis is not based solely or principally on the result of the genetic test.
To illustrate the definition, we provide the following examples, which were also included in the NPRM:

- An individual may have a family member that has been diagnosed with Huntington's disease and also have a genetic test result that indicates the presence of the Huntington's disease gene variant in the individual. However, when the individual is examined by a neurologist (a physician with appropriate training and expertise for diagnosing Huntington's disease) because the individual has begun to suffer from occasional moodiness and disorientation (symptoms which are associated with Huntington's disease), and the results of the examination do not support a diagnosis of Huntington's disease, then Huntington's disease is not manifested with respect to the individual. In contrast, if the individual exhibits additional neurological and behavioral symptoms, and the results of the examination support a diagnosis of Huntington's disease by the neurologist, then Huntington's disease is manifested with respect to the individual.

- An individual has had several family members with colon cancer, one of whom underwent genetic testing which detected a mutation in the MSH2 gene associated with hereditary nonpolyposis colorectal cancer (HNPCC). On the recommendation of his physician (a health care professional with appropriate training and expertise in the field of medicine involved), the individual undergoes a targeted genetic test to look for the specific mutation found in the family member of the individual to determine if the individual himself is at increased risk for cancer. The genetic test shows that the individual also carries the mutation but the individual's colonoscopy indicates no signs of disease and the individual has no symptoms. Because the individual has no signs or symptoms of colorectal cancer that could be used by the individual's physician to diagnose the cancer, HNPCC is not a manifested disease with respect to the individual. In contrast, if the individual undergoes a colonoscopy or other medical tests that indicate the presence of HNPCC, and the individual's physician makes a diagnosis of HNPCC, HNPCC is a manifested disease with respect to the individual.

- If a health care professional with appropriate expertise makes a diagnosis based on the symptoms of the patient, and uses genetic tests to confirm the diagnosis, the disease will be considered manifested, despite the use of genetic information. For example, if a

> neurologist sees a patient with uncontrolled movements, a loss of intellectual faculties, and emotional disturbances, and the neurologist suspects the presence of Huntington's disease, the neurologist may confirm the diagnosis with a genetic test. While genetic information is used as part of the diagnosis, the genetic information is not the sole or principal basis for the diagnosis, and, therefore, the Huntington's disease would be considered a manifested disease of the patient.

As with the definition of "genetic test," the Department declines to include these examples in the regulatory text as this is inconsistent with the approach generally taken in the HIPAA Privacy Rule. The Department intends to issue future guidance on its web site with respect to the Rule's protections for genetic information.

g. Definition of "Health Plan"

Proposed Rule

The Department proposed to make technical corrections to update the definition of "health plan" by revising and renumbering the definition to: Include specific reference to the Voluntary Prescription Drug Benefit Program under Part D of title XVIII of the Social Security Act, 42 U.S.C. 1395w-101 through 1395w-152; remove the specific reference to the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)), as this program is now part of the TRICARE health care program under title 10 of the United States Code, and revise the reference to the title 10 health care program accordingly to read more generally "health care program for the uniformed services" rather than "health care program for active military personnel"; and reflect that Part C of title XVIII of the Social Security Act, 42 U.S.C. 1395w-21 through 1395w-28, is now called the Medicare Advantage program.

Overview of Public Comments

The Department did not receive any comments on the proposed technical corrections to the definition of "health plan."

Final Rule

The final rule incorporates the technical corrections to the definition.

4. Section 164.501—Definitions

The Department proposed to modify § 164.501 to add a definition of "underwriting purposes" and to make conforming changes to the definitions of "payment" and "health care operations."

a. Definition of "Underwriting Purposes"

Proposed Rule

Section 105 of GINA provides that the term “underwriting purposes” means, with respect to a group health plan, health insurance coverage, or Medicare supplemental policy: (A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy; (B) the computation of premium or contribution amounts under the plan, coverage, or policy; (C) the application of any pre-existing condition exclusion under the plan, coverage, or policy; and (D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.
The Department proposed to adopt GINA's statutory definition of “underwriting purposes” in § 164.501 of the Privacy Rule, but also proposed to include certain clarifications for consistency with the regulations promulgated to implement the nondiscrimination provisions in sections 101 through 103 of GINA. In particular, the Department proposed to include a parenthetical to explain that the rules for, or determination of eligibility for, or determination of, benefits under the plan include 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. The proposed rule also included a parenthetical to make clear that the computation of premium or contribution amounts under the plan, coverage, or policy includes 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. Finally, we proposed a provision within the definition to clarify that “underwriting purposes” does not include determinations of medical appropriateness where an individual seeks a benefit under the plan, coverage, or policy.

Overview of Public Comments

About ten commenters addressed the proposed definition of “underwriting purposes.” Four commenters generally supported the proposed definition. Other commenters expressed concern with the definition's inclusion of discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program. These commenters were concerned that prohibiting the use of genetic information, particularly family health history, for such purposes would have a detrimental impact on wellness and disease management programs. One commenter was concerned that the definition would prohibit dental insurance plans from offering preventive prognostic features to enrollees as part of the plan that test for susceptibility to dental decay and periodontal diseases. Enrollees that test positive would be provided with additional plan benefits as a supplement to the standard benefits to cover more aggressive preventive services. Finally, a few commenters were concerned that the broad definition of “underwriting purposes” would preclude plans from using HRAs and offering wellness programs even if no genetic information is requested or used. For

example, one commenter was concerned that the definition would prohibit the use of "personal habit" information, such as information about smoking, or alcohol or drug use.

Final Rule

The final rule adopts the proposed definition of "underwriting purposes" but moves the definition to within the underwriting prohibition at § 164.502(a)(5)(i). This makes clear that the definition applies only for purposes of the prohibition on a health plan's use or disclosure of genetic information for underwriting purposes. As discussed more fully below with respect to the definition of "health care operations," we move the definition of "underwriting purposes" and retain the term "underwriting" within the definition of "health care operations" in response to several public comments expressing concern that the proposed rule would no longer allow health plans to use or disclose any protected health information (i.e., even non-genetic information) for underwriting. The adopted definition is consistent with the definition promulgated in the interim final regulations to implement sections 101-103 of GINA and with which compliance is already required by most health plans. We decline to exclude wellness programs and the use of HRAs from the definition because, as discussed in the interim final regulations issued by DOL, Treasury, and HHS, GINA Title I does not include an exception for wellness programs. [20] However, we emphasize that health plans may continue to provide incentives for completing HRAs and participating in wellness programs in manners that do not involve the use or disclosure of genetic information. For example, "personal habit" information about an individual, such as smoking status and alcohol and drug use, is not genetic information and thus, may be used by health plans for underwriting purposes. Further, DOL has issued guidance which makes clear that health plans may continue to collect family health history through the use of HRAs that are not tied to any reward. [21]

In addition, the definition of "underwriting purposes" includes an exception for determinations of medical appropriateness where an individual seeks a benefit under the plan, coverage, or policy. Thus, to the extent that an individual is seeking a particular benefit under the plan and the health plan needs genetic information to determine the medical appropriateness of providing the benefit to the individual, the plan may use or disclose the minimum necessary genetic information to determine the medical appropriateness of providing the benefit. For example, if a health plan covers yearly mammograms for individuals under age 40 only in cases where the individual can demonstrate she is at increased risk for breast cancer, the plan can ask an individual under age 40 to provide the results of a genetic test or family health history and use such information to determine medical appropriateness prior to paying a claim for the mammogram. The medical appropriateness exception would also cover situations where a dental plan requires the results of a genetic test prior to offering a

supplemental benefit for more aggressive preventive services to the extent the individual seeks such a benefit. For example, a dental plan may provide information to all of its enrollees about how to take advantage ofsuch a benefit, and when an enrollee contacts the plan about obtaining the benefit, may require the individual to take and provide the results of a genetic test to determine the medical appropriateness of providing the supplemental benefit to the individual.

b. Definition of "Health Care Operations"

Proposed Rule

The definition of "health care operations" at § 164.501 includes at paragraph (3) "underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or benefits * * *." To avoid confusion with the use of both "underwriting" and "underwriting purposes" in the Privacy Rule, and in recognition of the fact that the proposed definition of "underwriting purposes" includes activities that fall within both the definitions of "payment" and "health care operations" in the Rule, the Department proposed to remove the term "underwriting" from the definition of "health care operations." We also proposed to add the term "enrollment" to the express list of health care operations activities to make clear that the removal of the term "underwriting" would not impact the use or disclosure of protected health information that is not genetic information for enrollment purposes. These proposed revisions were not intended to be substantive changes to the definition and thus, health plans would be permitted to continue to use or disclose protected health information, except genetic information, for underwriting purposes.

Overview of Public Comments

The Department received a few comments on the proposed revisions to the definition of "health care operations." One commenter supported the inclusion of the word "enrollment." A few commenters, however, expressed concern and confusion that the removal of the term "underwriting" from the definition of "health care operations" would no longer permit uses or disclosures of even non-genetic protected health information for underwriting.

Final Rule

Due to the confusion and concern expressed by the commenters regarding the removal of the term "underwriting" from the definition, we retain the term "underwriting" within the definition of "health care operations" at § 164.501 However, to make clear that a health plan may continue to use or disclose only protected health information that is not genetic information for underwriting, we include a reference to the prohibition on using or disclosing genetic information for underwriting purposes

within the definition. The final rule also retains the term “enrollment” within the definition because we believe it is helpful to clarify that this is a permitted health care operations activity.

c. Definition of “Payment”

Proposed Rule

The definition of “payment” in the Privacy Rule at § 164.501 includes activities, such as “determinations of eligibility or coverage” by a health plan, some of which may fall within the definition of “underwriting purposes.” To avoid any implication that a health plan would be permitted to use or disclose protected health information for “payment” purposes that are otherwise prohibited by the underwriting prohibition, we proposed to include a cross-reference in the definition of “payment” to the prohibition. Further, we believed the inclusion of such a cross-reference to be necessary to properly align the definition of “payment” in the Privacy Rule with the nondiscrimination provisions of GINA Title I and their implementing regulations. GINA provides a rule of construction at section 102(a)(2), which adds paragraph 2702(c)(3) of the PHSA, to make clear that health plans are not prohibited from obtaining and using the results of a genetic test in making determinations regarding payment, as such term is defined by the HIPAA Privacy Rule. Thus, the proposed exception would make clear that GINA's rule of construction regarding payment does not allow a health plan to use the results of genetic tests for activities that would otherwise constitute “underwriting purposes,” such as for determinations of eligibility for benefits.

Overview of Public Comments

The Department received two comments on the proposed change to the definition of “payment,” one supporting the change and one indicating it is unnecessary.

Final Rule

For the reasons described above, the final rule adopts the proposed change to the definition of “payment.”

5. Section 164.502(a)—Uses and Disclosures of Protected Health Information: General Rules

a. Prohibition

Proposed Rule

To implement section 105 of GINA, the Department proposed a new prohibition on health plans using or disclosing protected health information that is genetic

information for underwriting purposes at § 164.502(a)(3). We made clear that such a provision would operate notwithstanding the other provisions in the Privacy Rule permitting uses and disclosures, and proposed a conforming change to § 164.502(a)(1)(iv) to clarify further that an authorization could not be used to permit a use or disclosure of genetic information for underwriting purposes.

Overview of Public Comments

Some commenters expressly supported the proposed modification to the Privacy Rule to include the prohibition, and the proposed clarification that an authorization cannot be used to otherwise permit a prohibited use or disclosure of genetic information. One commenter suggested adding the examples from the preamble to the regulatory text, as well as language to the regulatory text to clarify that the prohibition applies to genetic information obtained by a health plan prior to the passage of GINA.

Final Rule

The final rule adopts the proposed prohibition on a health plan's use or disclosure of genetic information for underwriting purposes, except with regard to health plans that are issuers of long term care policies, as explained above in section VI.C.1 regarding to which plans the final rule applies. This prohibition, located in this final rule at § 164.502(a)(5), applies to all genetic information from the compliance date of these modifications forward, regardless of when or where the genetic information originated. We do not believe a clarification of this fact in the regulatory text is necessary. Consistent with Sec. 101(a) of the statute, 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. Similarly, for the individualhealth insurance market, a health plan is not prohibited from establishing rules for eligibility for an individual to enroll in coverage or from adjusting premium or contribution amounts for an individual based on the manifestation of a disease or disorder in that individual or in a family member of such individual where such family member is covered under the individual's policy, even though the health plan cannot use the manifestation of a disease or disorder in one individual as genetic information about other individuals to further increase premiums or contribution amounts for those other individuals.

To illustrate how the prohibition operates, we reiterate the following examples (but for the reasons explained above, decline to include them in the regulatory text). 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 blended, aggregate premium rate for the upcoming year, the issuer would be using protected health information that is genetic information for underwriting purposes in violation of § 164.502(a)(5)(i). 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)(5)(i).

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, it 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.

6. Section 164.504(f)(1)(ii)—Requirements for Group Health Plans

Proposed Rule

Section 164.504(f)(1)(ii) permits a group health plan, or health insurance issuer or HMO with respect to the group health plan, to disclose summary health information to the plan sponsor if the plan sponsor requests the information for the purpose of obtaining premium bids from health plans for providing health insurance coverage under the group health plan, or for modifying, amending, or terminating the group health plan. As this provision permits activities that constitute "underwriting purposes," as defined by GINA and the proposed rule, the Department proposed to modify § 164.504(f)(1)(ii) to clarify that § 164.504(f)(1)(ii) would not allow a disclosure of protected health information that is otherwise prohibited by the underwriting prohibition.

Overview of Public Comments

The Department received one comment in support of this modification.

Final Rule

The final rule adopts the modification to § 164.504(f)(1)(ii).

7. Section 164.506—Uses and Disclosures To Carry Out Treatment, Payment, or Health Care Operations

Proposed Rule

Section 164.506(a) of the Privacy Rule sets out the uses and disclosures a covered entity is permitted to make to carry out treatment, payment, or health care operations. In light of the fact that the proposed definition of "underwriting purposes" encompasses activities that fall both within the definitions of "payment" and "health care operations" under the Privacy Rule, the Department proposed to add a cross-reference in § 164.506(a) to the new underwriting prohibition to make clear that § 164.506 of the Privacy Rule would not permit health plans to use or disclose an individual's protected health information that is genetic information for underwriting, even though such a use or disclosure is considered payment or health care operations.

Overview of Public Comments

The Department received one comment in support of this modification.

Final Rule

The final rule adopts the modification to § 164.506(a).

8. Section 164.514(g)—Uses and Disclosures for Activities Relating to the Creation, Renewal, or Replacement of a Contract of Health Insurance or Health Benefits

Proposed Rule

Section 164.514(g) of the Privacy Rule prohibits a health plan that receives protected health information for underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract for health insurance or health benefits, from using or disclosing such protected health information for any other purpose (except as required by law) if the health insurance or health benefits are not placed with the health plan. The Department proposed conforming amendments to § 164.514(g) to: (1) Remove the term "underwriting" to avoid confusion given the new definition of "underwriting purposes," which encompasses the activities described above; and (2) make clear that a health plan that receives protected health information that is genetic information for the above purposes is not permitted to use or disclose such information for underwriting purposes. The proposed removal of the term "underwriting" from § 164.514(g) was not intended as a substantive change to the scope of the provision.

Overview of Public Comments

One commenter suggested that the Department reconsider the removal of the term "underwriting" from this section as it could be viewed as a substantive change to the scope of the provision, and expressed concern that the modification would prohibit a health plan from using or disclosing genetic information as required by other law.

Final Rule

The final rule modifies § 164.514(g) to refer to the prohibition, now at § 164.502(a)(5). However, as with the definition of "health care operations," we do not remove the term "underwriting" to avoid unnecessary confusion. We also clarify that a health plan may continue to use or disclose protected health information that is genetic information as required by other law, except to the extent doing so would be inconsistent with the prohibition in GINA and this final rule at § 164.502(a)(5)(i) against using or disclosing genetic information for underwriting purposes.

9. Section 164.520—Notice of Privacy Practices for Protected Health Information

Proposed Rule

As discussed above in Section IV with regard to the changes made to § 164.520 pursuant to the HITECH Act, § 164.520 of the Privacy Rule sets out the requirements for most covered entities to have and distribute a Notice of Privacy Practices (NPP). With respect to the NPP, the Department believes thatindividuals should be informed of their new rights and protections under this rule with respect to genetic information in the health coverage context. Thus, the Department proposed in § 164.520(b)(1)(iii)(D) to require health plans that use or disclose protected health information for underwriting to include a statement in their NPP that they are prohibited from using or disclosing protected health information that is genetic information about an individual for such purposes. Without such a specific statement, individuals would not be aware of this restriction and the general statements regarding permitted uses and disclosures for treatment, payment, and health care operations in the NPP of a health plan that performs underwriting would not be accurate (i.e., the NPP would state that the health plan may use or disclose PHI for purposes of payment and health care operations, which would not be true with respect to genetic information when the use or disclosure is for underwriting purposes).
The preamble explained that the proposed prohibition on using or disclosing genetic information for underwriting and the proposed requirement to explicitly include a statement regarding the prohibition would represent a material change to the NPP of health plans that perform underwriting, and the Privacy Rule requires at § 164.520(c)(1)(i)(C) that plans provide notice to individuals covered by the plan within 60 days of any material revision to the NPP. As in the NPRM issued to implement HITECH Act provisions, the Department requested comment on ways to inform individuals of this change to privacy practices without unduly burdening health plans and provided several possible alternatives. The Department also explained that the obligation to revise the NPP for the reasons described above would fall only on health plans that intend to use or disclose protected health information for activities that

constitute “underwriting purposes.” Thus, health care providers, as well as health plans that do not perform underwriting, would not be required to revise their NPPs.

Overview of Public Comments

One commenter supported informing individuals in the NPP that health plans are prohibited from using or disclosing genetic information for underwriting purposes. One commenter asked the Department to clarify that where a health plan has already made a change to the NPP to comply with a statute, such as with GINA, and has sent the revised NPP to members, the health plan would not be required to make another change to its NPP to comply with the regulation.

A number of comments addressed the issue of the timing and manner of distributing revised NPPs. In general, commenters recommended various alternatives, including: (1) Require health plans to provide a revised NPP to members in the next annual mailing; (2) require health plans to provide either a revised NPP or a supplement to members in the next annual mailing and to post the revised NPP or supplement on the health plan Web site immediately; (3) retain the existing 60-day deadline for providing a revised NPP to individuals or provide for a 30-day extension; and (4) allow for distribution via electronic processes for more efficient delivery of NPPs to members.

Final Rule

The final rule adopts the requirement for health plans that perform underwriting to include in their NPPs a statement that they are prohibited from using or disclosing genetic information for such purposes, except with regard to issuers of long term care policies, which are not subject to the underwriting prohibition. Health plans that have already modified and redistributed their NPPs to reflect the statutory prohibition are not required to do so again, provided the changes to the NPP are consistent with this rule. We also modify the NPP distribution requirements for health plans where there are material changes. These modifications are discussed above in Section IV with regard to material changes to the NPP resulting from changes pursuant to the HITECH Act.

10. Other Comments

Comment: One commenter requested clarification on preemption with regard to the new underwriting prohibition.

Response: Pursuant to subpart B of Part 160 of the HIPAA Administrative Simplification Rules, to the extent that a provision of State law requires a use or disclosure of genetic information for an activity that would otherwise constitute “underwriting purposes,” such State law would be preempted by the Privacy Rule unless an exception at § 160.203 applies. In contrast, State laws that provide greater

privacy protection for genetic information than the Privacy Rule continue to remain in place.

Comment: One commenter asked how a health care provider should ensure that releasing an individual's information to a health plan will not result in an inappropriate disclosure to the health plan for underwriting purposes. This commenter also asked what the rules are for access to protected health information about an individual by the individual's extended family members seeking to determine if they are affected by a genetic trait.

Response: With respect to the first question, these rules do not apply to health care providers. A covered health provider may continue to disclose protected health information, including genetic information, where doing so meets the minimum necessary standard, to health plans for payment purposes. Under this Rule, the onus is on the health plan to not use or disclose protected health information it receives for such purposes for prohibited underwriting purposes. Further, health plans continue to be required by the Privacy Rule to limit requests of protected health information to the minimum necessary when requesting such information from other covered entities. The regulations implementing sections 101-103 of GINA also restrict the ability of health plans covered by those rules to request genetic information.

With respect to the second question, to the extent that an individual's genetic information is needed for the treatment purposes of a family member, a covered health care provider is permitted to disclose such information, subject to any agreed-upon restriction, to another provider for the treatment of the family member. See FAQ #512 at *http://www.hhs.gov/ocr/privacy/hipaa/faq/right_to_request_a_restriction/512.html*, which makes clear that a health care provider may share genetic information about an individual with providers treating family members of the individual who are seeking to identify their own genetic health risks, provided the individual has not requested and the health care provider has not agreed to a restriction on such disclosure.

Comment: One commenter requested that the rule require that health plans conducting or sponsoring research involving genetic information provide research participants with an explicit statement to ensure the individuals understand that such information may not and will not be used for underwriting purposes.

Response: We decline to require such a statement. The regulations implementing sections 101-103 of GINA already require a statement to that effect as a condition of the health plan requesting that a research participant undergo a genetic test as part of the research. See, e.g., 45 CFR 144.122(c)(5). Further, this rule requires that health plans that perform underwriting inform individuals through their NPPs that theplans may not use or disclose genetic information for such purposes.

Comment: One commenter asked that the HIPAA de-identification standard be strengthened to provide better protection for health information, including genetic information.

Response: The Privacy Rule's de-identification standard is outside the scope of this rulemaking.