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Part II

Department of the Treasury
Internal Revenue Service
26 CFR Part 54

Department of Labor
Employee Benefits Security
Administration
29 CFR Part 2590

**Department of Health and
Human Services**
Centers for Medicare & Medicaid Services
45 CFR Parts 144, 146, and 148
Office of the Secretary
45 CFR Parts 160 and 164

**Prohibiting Discrimination Based on
Genetic Information; Interim Final Rules;
HIPAA Administrative Simplification;
Genetic Information Nondiscrimination
Act; Proposed Rules**

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

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DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AB27

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****45 CFR Parts 144, 146, and 148**

RIN 0938-AP37

Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008. These provisions prohibit discrimination based on genetic information in health insurance coverage and group health plans.

DATES: *Effective Date:* These interim final regulations are effective on December 7, 2009.

Comment Date. Comments are due on or before January 5, 2010.

Applicability Dates: Group market rules. These interim final regulations for the group market apply to group health plans and group health insurance issuers for plan years beginning on or after December 7, 2009.

Individual market rules. These interim final regulations for the individual market apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after December 7, 2009.

ADDRESSES: Written comments may be submitted to any of the addresses

specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB27, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* E-OHPSCA.EBSA@dol.gov.

- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: RIN 1210-AB27.

Comments received by the Department of Labor will be posted without change to <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210, including any personal information provided.

Department of Health and Human Services (HHS). Comments to HHS, identified by CMS-4137-IFC, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4137-IFC, P.O. Box 8017, Baltimore, MD 21244-8010.

- *Hand or courier delivery.* Comments may be delivered to either 7500 Security Boulevard, Baltimore, MD 21244-1850 or Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. For delivery to Baltimore, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. For delivery to Washington, because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping in and retaining an extra copy of the comments being filed.

All submissions submitted to HHS will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters for the Centers for

Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786-7195.

Internal Revenue Service. Comments to the IRS, identified by REG-123829-08, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* CC:PA:LPD:PR (REG-123829-08), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

- *Hand or courier delivery:* Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-123829-08), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT:

Amy Turner, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335. Russ Weinheimer, Internal Revenue Service, Department of the Treasury, at (202) 622-6080. Adam Shaw, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (877) 267-2323, extension 61091.

Customer Service Information:

Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws, including the nondiscrimination protections, may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (<http://www.dol.gov/ebsa>). In addition, individuals may request a copy of CMS's publication entitled "Protecting Your Health Insurance Coverage" by calling 1-800-633-4227.

SUPPLEMENTARY INFORMATION:**I. Background**

The Genetic Information Nondiscrimination Act of 2008 (GINA), Public Law 110-233, was enacted on May 21, 2008. Title I of GINA amended the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHS Act), the Internal Revenue Code of 1986 (Code), and the Social Security Act (SSA) to prohibit discrimination in health coverage based on genetic information. GINA builds on existing protections

added by titles I and IV of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).¹ Specifically, the HIPAA portability provisions already prohibit a group health plan or group health insurance issuer from imposing a preexisting condition exclusion based solely on genetic information. See the 2004 final HIPAA portability regulations, published in the *Federal Register* on December 30, 2004 (69 FR 78720). In addition, the HIPAA nondiscrimination provisions already prohibit a group health plan or group health insurance issuer from discriminating against an individual in eligibility, benefits, or premiums based on genetic information (and other health factors) of the individual or a dependent of the individual. See the 2006 final HIPAA nondiscrimination regulations, published in the *Federal Register* on December 13, 2006 (71 FR 75014).

Sections 101 through 104 of Title I of GINA prohibit group health plans, health insurance issuers in the group and individual markets,² and issuers of Medicare supplemental (Medigap) policies from discriminating based on genetic information, and from collecting such information.³ Section 105 of Title I adds section 1180 of the SSA to require HHS to revise the HIPAA privacy regulations to clarify that genetic information is health information under the rule and to prohibit the use or disclosure of genetic information for underwriting purposes.⁴ Title II of GINA prohibits discrimination in employment based on genetic information, and limits the acquisition and disclosure by employers and other entities covered by GINA Title II of such information.⁵ These interim final

¹ These HIPAA provisions generally apply to group health plans and health insurance coverage in the group and individual markets.

² Rules on GINA's application in the individual market are solely within the jurisdiction of the Centers for Medicare & Medicaid Services at the Department of Health and Human Services and are discussed later in this preamble.

³ This regulation does 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.

⁴ The HIPAA privacy provisions are administered by the Office for Civil Rights within HHS, and will be the subject of a separate rulemaking.

⁵ Title II of GINA is under the jurisdiction of the Equal Employment Opportunity Commission,

regulations only interpret Sections 101 through 103 of Title I of GINA, which added provisions to Subtitle K of the Code, Part 7 of Subtitle B of Title I of ERISA, and Title XXVII of the PHS Act.⁶ References to GINA in the remainder of this preamble refer to the group market provisions of sections 101 through 103 of GINA, unless the context clearly indicates otherwise.

On October 10, 2008, the Departments published in the *Federal Register* (73 FR 60208) a request for information (RFI) soliciting comments on the requirements of sections 101 through 104 of GINA. In addition, the Departments consulted with and obtained technical guidance from the scientific community, including the National Human Genome Research Institute within the National Institutes of Health and the Office for Human Research Protections, both within HHS. The Departments also coordinated with the Equal Employment Opportunity Commission (EEOC), which has responsibility for Title II of GINA, and the Office for Civil Rights within HHS, which has responsibility for section 105 of GINA.

After consideration of the comments received in response to the RFI and based on the consultations with other government agencies, the Departments are publishing these interim final regulations. For the group market, these regulations become applicable to plans and issuers on the first day of the plan year beginning on or after December 7, 2009. For the individual market, these regulations become applicable with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after December 7, 2009.

II. Overview of the Regulations

A. Group Market

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:

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

which issued a notice of proposed rulemaking on March 2, 2009, 74 FR 9056.

⁶ Compliance with GINA sections 101 through 103 is not determinative of compliance with any other provision of GINA or any other State or Federal law, including the Americans with Disabilities Act.

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

These three general prohibitions are subject to rules of construction or exceptions included in the statute which are discussed in further detail later in this preamble.

1. Conforming Changes to Existing Regulations

Sections 9801 and 9802 of the Code, 701 and 702 of ERISA, and 2701 and 2702 of the PHS Act, as originally added by HIPAA, included requirements pertaining to genetic information but did not define the term. The 2004 final HIPAA portability regulations included a definition of genetic information.

GINA contains a statutory definition of genetic information that differs from the definition in the 2004 final HIPAA portability regulations. These interim final regulations revise the existing regulations' definition of genetic information at 26 CFR 54.9801-2, 29 CFR 2590.701-2, and 45 CFR 144.103, to conform to the new statutory definition.

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. Therefore, these interim final regulations amend the 2006 regulations to add clarifying cross-references. See 26 CFR 54.9802-1(c)(2)(i) and (iii), 29 CFR 2590.702(c)(2)(i) and (iii), and 45 CFR 146.121(c)(2)(i) and (iii).

2. Definitions

Paragraph (a) of these interim final regulations⁷ provides most of the definitions used in GINA.⁸ Some of these definitions repeat the statutory language, while others include regulatory clarifications.

⁷ Because substantively similar regulation text is published separately by the three Departments, and the section numbers will all be different, the preamble refers only to the paragraph designations within those sections.

⁸ The same definitions apply to the individual market regulations under GINA, which are discussed later in this preamble, to the extent that they are not inconsistent with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market.

a. Collect

The interim final regulations add the defined term "collect." While "collect" was not defined in the statute, this term was added to paraphrase the longer phrase "request, require or purchase." Thus, under the interim final regulations, "collect" means, with respect to information, to request, require, or purchase such information.

b. Family Member

GINA adds a definition of family member to sections 9832 of the Code, 733 of ERISA, and 2791 of the PHS Act. The definition of family member determines the application of GINA in two ways. First, the definition of genetic information for an individual includes information about the manifestation of a disease or disorder in family members of the individual. Also, a plan or issuer generally may not request or require an individual or family member of the individual to undergo a genetic test.

The statute defines a family member with respect to any individual as a dependent of such individual (as such term is used for purposes of sections 9801(f)(2) of the Code, 701(f)(2) of ERISA, and 2701(f)(2) of the PHS Act (the dependent special enrollment rules)),⁹ and any other individual that is a first-, second-, third-, or fourth-degree relative of the individual or of the dependent of the individual. The legislative history suggests that the term "family member" be broadly construed: "In general, it is intended that the term 'family member' be interpreted broadly so as to provide the maximum protection against discrimination." House Report 110-28, Part 2 at 27.

Sections 9801(f)(2) of the Code, 701(f)(2) of ERISA, and 2701(f)(2) of the PHS Act provide special enrollment rights to certain dependents that are eligible for coverage under a group health plan due to such family events as birth, adoption, or marriage. The statutory provisions of neither HIPAA nor GINA define dependent, but the term is defined in the 2004 final HIPAA portability regulations as any individual who is or may become eligible for coverage under the terms of a group health plan because of a relationship to a participant. This makes clear that it is necessary to consult the plan document and other applicable law to determine dependent status for purposes of GINA.

In determining who is a first-, second-, third-, or fourth-degree relation

of an individual, the interim final regulations treat relatives by affinity (such as by marriage or adoption) the same as relatives by consanguinity (relatives who share a common biological ancestor, or blood relatives). The definition also treats relatives who are not full blood relatives (such as half siblings) the same as full blood relatives. In addition, the interim final regulations provide non-exhaustive lists of individuals who are first-, second-, third-, or fourth-degree relatives. The Departments invite public comments on this definition.

c. Genetic Information

The interim final regulations contain a definition of genetic information that restates and reorganizes the statutory provisions. Genetic information is defined, with respect to an individual, as information about the individual's genetic tests or the genetic tests of family members, the manifestation of a disease or disorder in family members of such individual (that is, family medical history), or any request of or receipt by the individual or family members of genetic services. The definition further clarifies that genetic information does not include information about the sex or age of any individual. It also clarifies how GINA applies to genetic information about a fetus or embryo. As previously noted, this definition is a change from the definition of genetic information that applied under the 2004 final HIPAA portability regulations.

d. Genetic Services

An individual's genetic information includes any request for or receipt of genetic services by such individual, or a family member. These interim final regulations follow the statutory definition. "Genetic services" means a genetic test, genetic counseling, or genetic education.

e. Genetic Test

GINA adds a definition of genetic test to sections 9832 of the Code, 733 of ERISA, and 2791 of the PHS Act.¹⁰ These interim final regulations repeat the statutory language, which provides that a genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if it detects genotypes, mutations, or chromosomal changes.

The interim final regulations also follow the statutory language providing

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

The interim final regulations include examples of certain tests that currently are regarded as genetic or non-genetic tests, as the case may be, based on research including consultations with representatives from the scientific community. However, due to rapidly evolving scientific knowledge, it is not an exhaustive list.

f. Manifestation or Manifested

The concept of manifestation of a disease arises in three contexts. First, a plan or issuer may increase the premium or contribution amount for a group health plan based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. Second, the definition of genetic information for an individual includes information about the manifestation of a disease or disorder in family members of such individual. Finally, the definition of genetic test excludes an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could be reasonably detected by a health care professional with appropriate training and expertise in the field of medicine involved.

The interim final regulations add a definition of manifestation or manifested. A disease, disorder, or pathological condition is manifested when an individual has been or could reasonably be diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved. However, the definition further provides that a disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information.

g. Underwriting Purposes

GINA includes a definition of underwriting purposes. This term is discussed later in this preamble, in connection with the discussion of the prohibition on collecting genetic information.

3. Prohibition on Adjusting Group Rates

GINA and these interim final regulations expand the HIPAA prohibitions against discrimination

⁹This definition of the term "dependent" is solely for purposes of interpreting sections 101 through 103 of GINA, and is not relevant to interpreting the term under Title II of GINA, which is under the jurisdiction of the EEOC.

¹⁰This definition of the term "genetic test" is solely for purposes of interpreting Title I of GINA, and is not relevant to interpreting the term under Title II of GINA, which has a different statutory definition.

based on health factors, by prohibiting 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. This prohibition against discrimination is distinct from the prohibition on requesting or requiring an individual to undergo a genetic test and the prohibition on collecting genetic information. Therefore, even when a plan or issuer has lawfully obtained genetic test results or other genetic information (for example, an acquisition that took place prior to GINA's effective date), the plan or issuer is still prohibited—under GINA and paragraph (b) of these interim final regulations—from using that information to discriminate.

GINA and these interim final regulations also provide that the prohibition on adjusting premiums or contributions based on genetic information does not limit the ability of a plan or issuer to increase the premium or contribution amount for a group health plan based on the manifestation of a disease or disorder of an individual enrolled in the plan. However, a plan or issuer may not use the manifested disease or disorder of one individual as genetic information about other group members to further increase the premium or contribution amount. Moreover, the prohibitions on adjusting premium or contribution amounts based on genetic information do not prohibit a plan or issuer from including costs associated with providing benefits for covered genetic tests or genetic services within the costs of providing other benefits in determining premiums or contribution amounts. In particular, a plan or issuer is not required to reduce the aggregate costs of providing health benefits for the year by those costs relating to benefits for genetic tests and services when adjusting group rates. These interim final regulations also make conforming changes to the existing HIPAA nondiscrimination regulations regarding the ability to adjust premium or contribution amounts based on a health factor.

4. Limitation on Requesting or Requiring Genetic Testing

GINA generally prohibits plans and issuers from requesting or requiring individuals or their family members to undergo a genetic test. There are three exceptions to this prohibition, for certain health care professionals, for determinations regarding payment, and for research.

The first exception allows a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test. The health care professional must actually be providing health care services to the individual for the exception to apply. Thus, for example, the performance of claims review by a health care professional would never be considered providing health care services to an individual. The term "health care professional" is not limited to physicians.

The second exception allows a plan or issuer to obtain and use the results of a genetic test to make a determination regarding payment. For this purpose, payment is defined by reference to 45 CFR 164.501 of the HIPAA privacy regulations. However, plans and issuers are only permitted to request the minimum amount of information necessary to make this determination. These interim final regulations incorporate the standard set forth at 45 CFR 164.502(b) of the HIPAA privacy regulations to determine the minimum amount of information necessary.

In some cases, the appropriateness of certain courses of treatment for a patient depends on the patient's genetic makeup. A plan or issuer is permitted to condition payment for an item or service based on medical appropriateness that depends on an individual's genetic makeup. Under these narrow circumstances, a plan or issuer may condition payment on the outcome of a genetic test, and may refuse payment for the item or service if the individual does not undergo the genetic test. Any information received by the plan to make a determination regarding payment, including the results of a genetic test, must be used in accordance with these interim final regulations and the 2006 final HIPAA nondiscrimination regulations.

Under the third exception relating to the limitation on requesting or requiring genetic testing, a group health plan or group health insurance issuer is permitted to request, but not require, that a participant or beneficiary undergo a genetic test¹¹ if all of the following

conditions of the research exception are satisfied:

- The request must be made pursuant to research that complies with 45 CFR Part 46 (or equivalent Federal regulations) and any applicable State or local law or regulations for the protection of human subjects in research. Moreover, to comply with the informed consent requirements of 45 CFR 46.116(a)(8), an investigator seeking the informed consent of a human subject must provide the subject with a statement that participation in the research is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is entitled, except in limited circumstances in which an institutional review board has approved a waiver or alteration of this requirement under the requirements of 45 CFR 46.116(c) or (d). For research in which the investigator provides subjects with the statement required under 45 CFR 46.116(a)(8) when seeking their informed consent, no additional disclosures are required for purposes of the GINA research exception.

- The plan or issuer must make the request in writing and must clearly indicate to each participant or beneficiary (or in the case of a minor child, to the legal guardian of such beneficiary) to whom the request is made that compliance with the request is voluntary and noncompliance will have no effect on eligibility for benefits or premium or contribution amounts.

- None of the genetic information collected or acquired as a result of the research may be used for underwriting purposes.

- The plan or issuer must complete a copy of the "Notice of Research Exception under the Genetic Information Nondiscrimination Act" (the Notice) and provide it to the address specified in its instructions. The Notice and instructions are available on the Department of Labor's Web site (<http://www.dol.gov/ebsa>).

5. Prohibition on Collection of Genetic Information

Paragraph (d) of these interim final regulations describes the statutory prohibitions against plans or issuers collecting genetic information, either for underwriting purposes or prior to or in connection with enrollment; sets forth the statutory definition of underwriting purposes; and clarifies that, if an

¹¹ Comments indicated that at least one issuer is engaging in a long-term research study involving

genetic testing. Others may be planning similar research.

