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29 CFR Part 2590

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45 CFR Parts 144, 146, and 148

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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

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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 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
- 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 regulations[7] provides most of the definitions used in GINA.[8] Some of these definitions repeat the statutory language, while others include regulatory clarifications.

[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, 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.

[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

[9] This 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.

[10] This 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 test [11] 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.

individual seeks a benefit under a plan or coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate (and a determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes).

Underwriting purposes is defined under GINA and in these interim final regulations as including, with respect to group health plan coverage, rules for and determinations of eligibility (including enrollment and continued eligibility), computation of premium or contribution amounts, and application of preexisting condition exclusions. Under GINA, the definition of underwriting is broader than merely activities relating to rating and pricing a group policy. These interim final regulations clarify that underwriting purposes includes changing deductibles or other cost-sharing mechanisms, or providing discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program.

GINA and paragraph (d) of the interim final regulations provide that plans and issuers are only prohibited from collecting genetic information for underwriting purposes or prior to or in connection with enrollment. Where an individual seeks a benefit under the plan, requesting family medical history or other genetic information to make a determination whether the benefit is medically appropriate for purposes of payment is neither for underwriting purposes nor prior to or in connection with enrollment. Therefore, although the statutory payment exception only applies to requests for individuals to undergo genetic tests, these interim final regulations provide it is permissible for a plan or issuer to request the minimum amount of genetic information necessary to make determinations regarding payment. Specifically, these interim final regulations provide that, if an individual seeks a benefit under a plan or coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. However, a plan or issuer is permitted to request only the minimum amount of information necessary to determine medical appropriateness.

These interim final regulations provide clarifications of the statutory prohibition against a plan or issuer collecting genetic information prior to or in connection with enrollment. Under the interim final regulations, a collection of genetic information with respect to an individual is considered prior to enrollment if it is before the individual's effective date of coverage under the plan or health insurance coverage. The determination of whether a plan or issuer is collecting information before the individual's effective date of coverage is made at the time of collection. Providing that the determination is made at the time of collection means that if a plan or issuer collects genetic information with respect to an individual in circumstances that otherwise would not render the collection impermissible and at that time it is not being collected in connection with a future enrollment, the fact that a future enrollment may occur does not mean, for purposes of this rule, that the genetic information was collected before the enrollment. Thus, for example, if a plan collected genetic information with respect to an individual after initial enrollment (and not for underwriting purposes), and the individual later dropped coverage but then still later reenrolled in the plan, the collection of genetic information after the initial enrollment would not be considered prior to the reenrollment.

Similarly, if a plan affirmatively requires individuals to reenroll on an annual basis or allows individuals to change their enrollment, a collection of genetic information made after a current enrollment will not be considered made prior to a subsequent enrollment unless the collection of information is or will be used to affect that subsequent enrollment. Moreover, if genetic information is collected permissibly under one plan, the information is transferred to a second plan in connection with a merger or acquisition after this collection, and individuals covered under the first plan are enrolling for the first time in the second plan, the transfer of information to the second plan will not be considered a collection prior to the effective date of coverage under the second plan if the collection of information does not affect the enrollment status of individuals enrolling in the second plan.

These interim final regulations include the statutory exception (to the prohibition against collections of genetic information prior to or in connection with enrollment) for genetic information that is collected incidental to the collection of other information and is not used for underwriting purposes. Some commenters suggested that some questions that are typically included in some HRAs and similar documents could easily result in an individual providing genetic information, even if the question does not mention genetic tests or family medical history explicitly. An example given was, ''Have you had any laboratory tests in the past 2 years?'' These commenters suggested plans and issuers should be required to inform individuals that they should not reveal genetic information.

The interim final regulations clarify that if it is reasonable to anticipate that health information will be received as part of the collection of information, the incidental collection exception does not apply unless the collection explicitly states that genetic information should not be provided. If, in connection with a collection of information, it is reasonable to anticipate that health information will be received and the collection explicitly states that genetic information should not be provided, any genetic information provided will be considered within the incidental exception, as long as it is not used for underwriting purposes.

In response to the RFI, a number of comments were received concerning the application of the prohibition on requesting genetic information for underwriting purposes to plans and issuers that reward individuals for completing HRAs. Of particular concern are wellness programs including HRAs that request information about an individual's family medical history. Another concern is the application of the prohibition on requesting genetic information for underwriting purposes to screening processes for disease management programs that use genetic tests or family medical histories to identify individuals that can benefit from the program.

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

Some comments received in response to the RFI urged strongly that a

regulatory exception should allow wellness programs to provide rewards for completing HRAs that request such information, notwithstanding the statutory prohibition on collecting genetic information.[12] Other comments suggested equally strongly that the regulations clarify that wellness programs may not collect such information as a condition for rewards. These interim final regulations do not provide an exception from underwriting for rewards provided by wellness programs, regardless of the amount of the reward. Examples generally illustrate that any reward given for the completion of an HRA that solicits information about the individual's family medical history violates the requirements of paragraph (d).

However, plans and issuers can collect genetic information through HRAs under GINA in certain circumstances. A plan or issuer can collect genetic information through an HRA as long as no rewards are provided (and if the request is not made prior to or in connection with enrollment). A plan or issuer can also provide rewards for completing an HRA as long as the HRA does not collect genetic information. Several examples are provided in these interim final regulations to illustrate these points. In one example, a plan administers two distinct HRAs, one that does not request genetic information and one that does. A reward is provided for completing the HRA that does not solicit genetic information; the instructions for the other HRA make clear that completion of the HRA is wholly voluntary and will not affect the reward given for completion of the first HRA. The example concludes that neither HRA violates the rules against collecting information for underwriting purposes or prior to or in connection with enrollment. Finally, another example illustrates the application of the exception for information obtained incidentally in the context of the acquisition of one issuer by another. The Departments invite comment on ways in which participation in HRAs can be encouraged while complying with the statutory prohibition on using genetic information for underwriting purposes.

[12] Earlier bills (for example, S.358, 110th Cong. (as reported by S. Comm. on Health, Education, Labor, and Pensions) March 29, 2007; H.R. 493, 110th Cong. (as reported by H. Comm. on Energy and Commerce) March 29, 2007) included exceptions for wellness programs in both the Title I health coverage provisions and the Title II employment provisions. As enacted, GINA only includes an exception for wellness programs in the Title II employment provisions.

6. Medical Appropriateness

Paragraph (e) of these interim final regulations provides examples illustrating how medical appropriateness is determined, in connection with both the payment exception under paragraph (c) and the prohibition against collecting genetic information for underwriting purposes under paragraph (d). Examples illustrate the minimum amount of genetic information necessary to determine payment, the restriction of benefits to medically appropriate treatment, and the application of the medical appropriateness rules to the use of genetic information to determine eligibility for a disease management program.

7. Special Rules Related to Very Small Group Health Plans

Generally, the provisions of HIPAA titles I and IV, as amended, do not apply to a group health plan for a plan year if the plan is a very small group health plan; that is, on the first day of the plan year, the group health plan has fewer than 2 participants who are current employees. GINA and these interim final regulations provide that this exception for very small group health plans is not available for the genetic information provisions in Subtitle K of the Code, Part 7 of Subtitle B of Title I of ERISA, and Title XXVII of the PHS Act.

8. Treatment of Non-Federal Governmental Plans

Section 2721(b)(2) of the PHS Act permits the sponsor of a self-funded non-Federal governmental plan as defined in 45 CFR 144.103 to elect to exempt the plan from most of the requirements of Title XXVII of the PHS Act. This is referred to herein as the ''opt-out election.'' However, section 2721(b)(2)(C)(ii) states that no opt-out election is available with respect to the requirements for certification and disclosure of creditable coverage. The PHS Act regulations at 45 CFR 146.180 implement the foregoing opt-out rules under section 2721.

Section 102(c) of GINA added a second limitation on the opt-out rights of a self-funded non-Federal governmental plan sponsor. Section 2721(b)(2)(D) of the PHS Act precludes any exemption election by a self-funded non-Federal governmental plan sponsor from GINA's requirements. The Centers for Medicare & Medicaid Services (CMS) amended 45 CFR 146.180(h) accordingly.

CMS made certain additional conforming changes to other provisions of 45 CFR 146.180. In particular, CMS deleted the reference in 45 CFR 146.180(h) to CMS enforcement under 45 CFR 146.180(k) because paragraph (k) makes clear that CMS enforces all requirements of part 146 that apply to non-Federal governmental plans. CMS also revised the last sentence of 45 CFR 146.180(k), which refers to the imposition of a civil money penalty, by replacing ''under § 150.305'' with ''under subpart C of part 150'' because subpart C includes multiple sections that govern imposition of a civil money penalty, while 45 CFR 150.305 only applies to a determination of which entity is liable for a civil money penalty.

B. Individual Market

The regulations at 45 CFR Part 148 implement the individual market requirements of Title XXVII of the PHS Act. Section 102(b) of GINA added a new section 2753 (42 U.S.C. 300gg–53) to Title XXVII to prohibit discrimination on the basis of genetic information in the individual health insurance market. Section 2753 of the PHS Act generally parallels the group market genetic nondiscrimination provisions GINA added to the Code, ERISA and the PHS Act. Section 2753 and the interim final regulations prohibit issuers in the individual market from collecting genetic information prior to or in connection with such enrollment, and at any time for underwriting purposes. Section 2753 and the interim final regulations also prohibit issuers from requesting or requiring genetic tests. The exceptions and rules of construction that apply to the foregoing requirements in the group market (for example, the rule for incidental collections of genetic information and the research exception to the rule against requiring genetic tests) also apply in the individual market.

Since individual market issuers were not subject to the Federal HIPAA nondiscrimination requirements applicable to issuers in the group market, it was necessary for GINA to amend the PHS Act in order to have similar protections against genetic discrimination applicable in both markets. Thus, new section 2753 of the PHS Act prohibits issuers of individual health insurance policies from using genetic information as a basis for making eligibility or premium determinations, or for imposing preexisting condition exclusions. Issuers in the individual market may continue to establish rules for eligibility, increase premiums, and impose preexisting condition exclusions based on the manifestation of a disease or disorder in an individual, or in a family

member covered under the policy that covers the individual. However, they cannot use a manifestation of a disease or disorder in one individual as genetic information about family members covered under the same policy or another policy in order to further increase premiums.

These interim final regulations add a new § 148.180 to subpart C of part 148 to implement section 2753 of the PHS Act. To the extent that the provisions of section 2753 parallel the GINA amendments to section 2702 of the PHS Act which govern the group market, § 148.180 restates the corresponding group market provisions (with conforming changes and technical corrections appropriate to the individual market) rather than incorporating the group market provisions by reference.

As discussed above, GINA amended the Social Security Act to include genetic nondiscrimination provisions that apply to issuers of Medigap policies. The PHS Act regulations at 45 CFR 148.220 state that Medigap policies are excepted benefits. Nevertheless, because Medigap policies are subject to GINA under the Social Security Act and NAIC model regulation, CMS made clarifying changes to § 148.220 to emphasize the foregoing.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS to promulgate any interim final rules that they determine are appropriate to carry out the provisions of Chapter 100 of Subtitle K of the Code, Part 7 of Subtitle B of Title I of ERISA, and Part A of Title XXVII of the PHS Act, which include the provisions of GINA.

Under Section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

These rules are being adopted on an interim final basis because the Secretaries have determined that without prompt guidance some members of the regulated community may not know what steps to take to comply with the requirements of GINA, which may result in an adverse impact on participants and beneficiaries with regard to their health benefits under group health plans and the protections provided under GINA. Moreover, GINA's requirements will affect the regulated community in the immediate future.

The requirements of sections 101 through 103 of GINA are effective for all group health plans and for health insurance issuers offering coverage in connection with such plans for plan years beginning after May 21, 2009. Plan administrators and sponsors, issuers, and participants and beneficiaries will need guidance on how to comply with the new statutory provisions. As noted earlier, these interim rules take into account comments received by the Departments in response to the request for information on GINA published in the **Federal Register** on October 10, 2008 (73 FR 60208). For the foregoing reasons, the Departments find that the publication of a proposed regulation, for the purpose of notice and public comment thereon, would be impracticable, unnecessary, and contrary to the public interest.

IV. Economic Impact and Paperwork Burden

A. Summary—Department of Labor and Department of Health and Human Services

As discussed above, Title I of GINA generally prohibits group health plans and health insurance issuers in both the group and individual markets from discriminating based on genetic information, requesting or requiring an individual to undergo a genetic test, and collecting genetic information prior to or in connection with enrollment or for underwriting purposes. The Departments have crafted these interim final regulations to secure the protections from discrimination intended by Congress in as economically efficient a manner as possible. Although the Departments are unable to quantify the regulations' economic benefits, they have quantified their costs and have provided a qualitative discussion of some of the benefits that may stem from this rule.

One potential benefit associated with GINA and these interim final regulations is that genetic testing and research may expand when discrimination based on genetic information and the collection of such information is prohibited, if these protections allay individuals' fears of adverse health coverage-related consequences from undergoing genetic testing and participating in research studies examining genetic information. An increase in genetic testing and research, in turn, could provide greater knowledge regarding the genetic basis of disease, which could facilitate the early diagnosis and treatment of individuals with a genetic predisposition toward developing certain diseases and disorders and may allow scientists to develop new medicines, treatments, and therapies that could enhance the health and welfare of Americans.

B. Statement of Need for Regulatory Action

Congress directed the Departments to issue regulations implementing the GINA provisions not later than 12 months after the date of enactment. In response to this Congressional directive, these interim final regulations clarify and interpret the GINA nondiscrimination provisions under section 702 of ERISA, sections 2702 and 2753 of the PHS Act, and section 9802 of the Code. These regulations are needed to secure and implement GINA's nondiscrimination provisions and ensure that the rights provided to participants, beneficiaries, and other individuals under GINA are fully realized. The Departments' assessment of the expected economic effects of these interim final regulations is discussed in detail below.

C. Executive Order 12866—Department of Labor and Department of Health and Human Services

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Departments must determine whether a regulatory action is ''significant'' and therefore subject to the requirements of the Executive Order and review by the Office of Management and Budget (OMB). Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of the Executive Order, the Departments have determined that this action raises novel policy issues arising out of legal mandates. Therefore, the interim final regulations are ''significant'' and subject

to OMB review under Section 3(f)(4) of the Executive Order. Accordingly, the Departments have undertaken, as described below, an assessment of the costs and benefits of the regulation. Over the 10-year period of 2010 to 2019, the present value of the costs, using a discount rate of 7 percent, is estimated to be $294.8 million in 2009 Dollars, as is shown in Table 1.

All other numbers included in the text are not discounted.

TABLE 1—TOTAL DISCOUNTED COSTS OF RULE

[In millions of 2009 dollars]

Year	Wellness plan review	Individual market review	Medical record review	Research disclosure	Total costs—discounted at 7%
	(B)	(C)	(D)	(E)	B + C + D + E
2010	$2.0	$5.3	$38.3	$0	$45.5
2011			35.8		35.8
2012			33.4		33.4
2013			31.2		31.2
2014			29.2		29.2
2015			27.3		27.3
2016			25.5		25.5
2017			23.8		23.8
2018			22.3		22.3
2019			20.8		20.8
Total with 7% Discounting					294.8
Total with 3% Discounting					356.8

Note: The displayed numbers are rounded and therefore may not add up to the totals. They are discounted using a 7 percent discount rate unless otherwise noted.

The Departments performed a comprehensive, unified analysis to estimate the costs and, to the extent feasible, provide a qualitative assessment of benefits attributable to the statute and regulations for purposes of compliance with Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act. The Departments' assessment and underlying analysis is set forth below.

1. Affected Entities and Other Assumptions

The Departments estimate that 137.1 million participants and beneficiaries [13] are covered by nearly 2.5 million private sector group health plans and 31.7 million individuals are covered by individual health insurance policies.[14] The Departments also estimate that approximately 630 insurers will be are affected by GINA, consisting of approximately 460 insurers offering coverage in connection with insured group health plans and approximately 490 health insurance issuers offering policies in the individual health insurance market.[15]

2. Benefits

One potential benefit associated with GINA and these interim final regulations is that genetic testing and research may increase if the protections provided under GINA allay the public's concerns that health plans and insurers will use genetic information to discriminate based on the collection and disclosure of such information. Comments received in response to the RFI indicate that genetic testing and research currently are being underutilized. A major reason cited for the lack of genetic testing is the public's fear of adverse employment-related or health coverage-related consequences associated with having genetic testing or participating in research studies that examine genetic information. Removing barriers that impede the growth of genetic testing and research has the potential to improve health and save lives by providing patients and physicians with critical knowledge to facilitate early intervention often before disease symptoms are manifested. It also could expand the development of scientific research, which could result in the development of new medicines, therapies, and treatments for diseases and disorders.

Additional economic benefits may derive directly from the improved clarity provided by the interim final regulations, which will reduce uncertainty and help group health plan sponsors and health insurers comply with GINA's requirements in a cost effective manner. Moreover, the prohibitions enacted in GINA and these interim final regulations should provide a benefit to individuals with genetic predispositions for diseases by decreasing the number of individuals that are denied coverage under a group health plan or priced out of the individual health insurance market.[16]

Currently, the Departments are unable to quantify these benefits, because relatively few genetic tests and research studies are performed in the private sector [17] and a limited number of genetic tests are available. As stated above, the Departments expect the number of genetic tests and research studies to increase in the near future. The Departments, however, lack sufficient information to project the trajectory of this increase.

3. Costs

a. Health Risk Assessments

As discussed above, GINA and these interim final regulations prohibit group health plans and health insurance issuers offering coverage in the group and individual health insurance markets from collecting genetic information in

[13] Departments' estimates based on the March 2007 Current Population Survey.

[14] Departments' estimates based on the March 2008 Current Population Survey.

[15] Estimates are from 2007 NAIC financial statements data and the California Department of Managed Healthcare (*http://wpso.dmhc.ca.gov/hpsearch/viewall.aspx*).

[16] When scoring the GINA bill the Congressional Budget Office estimated that the bill would increase health insurance coverage by about 600 people a year with most being in the individual market. Congressional Budget Office Cost Estimate, H.R. 493 Genetic Information Nondiscrimination Act of 2007, April 12, 2007.

[17] Pollitz, Karen, *et. al.* ''Genetic Discrimination in Health Insurance: Current Legal Protections and Industry Practices.'' *Inquiry* 44:350–368 (Fall 2007).

connection with or prior to enrollment and for underwriting purposes. Comments received in response to the RFI indicate that the immediate impact of GINA and these interim final regulations on group health plans and health insurance issuers providing group health coverage should be minimal. Plans and issuers commented that they do not collect or use genetic information for underwriting purposes because pre-GINA laws and regulations prohibit them from discriminating against individuals based on any health status-related factors, including genetic information.[18]

Currently, many group health plans request family medical history information to be provided in response to questions on HRAs that are completed by new employees before enrollment in the plan and as part of open enrollment for current employees. HRAs are used in connection with wellness and disease management programs to identify individuals at risk for certain conditions and provide an opportunity for preventive treatment service referrals, disease management, and other behavioral change initiatives that are focused on creating higher quality medical outcomes. Some group health plans provide rewards and incentives to employees who complete HRAs, such as premium reductions, lower deductibles, and cash bonus payments.

The Departments expect that most of the cost of complying with GINA and these interim final regulations will be concentrated among the approximately 30,000 group health plans [19] that are associated with wellness and disease management programs that provide rewards and incentives to employees that complete HRAs. These plans will have to conduct a compliance review to ensure that their HRAs and any associated policies and procedures comply with GINA's prohibition on using genetic information prior to or in connection with enrollment or for underwriting purposes and to make any necessary changes to their HRAs and policies and procedures.

The Departments assume that insured plans will rely on the health insurance issuer providing coverage to ensure compliance and that self-insured plans will rely on wellness vendors and other service providers to ensure compliance. These interim final regulations provide several examples illustrating the application of the regulations to HRAs, which are intended to reduce the compliance burden. Moreover, the per plan compliance cost is expected to be low, because vendors and insurers will be able to spread these costs across multiple client plans.[20]

The Departments assume that the average burden per plan will be one-half hour of a legal professional's time at an hourly labor rate of $116,[21] and one-half hour of a clerical staff's time at an hourly labor rate of $26 to conduct the compliance review and make the needed changes to the HRAs. This results in a total cost of $2.1 million ($1.7 for legal services, and $0.4 million for clerical services) in the first year. The Departments invite public comments on this estimate.

To the extent that GINA and these interim final regulations prohibit group health plans and issuers from incentivizing employees to complete HRAs requesting genetic information, including family medical history, and response rates for HRAs drop as a consequence, a cost may be incurred that is associated with the forgone benefits of identifying disease risks early and preventing their onset. The Departments do not have adequate data to determine whether these forgone benefits would materialize, and, if so, what their extent may be. However, the Departments invite public comments on this issue, including evidence-based estimates of what the extent of these forgone benefits may be, if any, and ways in which these public health benefits may be realized while complying with the statutory prohibition on using genetic information for underwriting purposes.

b. GINA's Impact on the Individual Health Insurance Market

The Department of Health and Human Services expects that the individual health insurance market will incur higher costs of complying with these interim final regulations than group health plans. The Departments assume that health insurance issuers in the individual market will have to review their applications and underwriting policies and procedures to ensure that genetic information is not collected or used for underwriting purposes. Issuers also will need to train underwriters to avoid using genetic information in underwriting. The Departments estimate that the approximately 490 issuers in the individual health insurance market will spend approximately 100 hours in-house each conducting a compliance review, modifying their applications and policies and procedures, and drafting training materials and providing training sessions for underwriters to ensure compliance with GINA and these interim final regulations at a labor rate of $116. This results in a total cost of about $5.6 million. The Departments invite public comments on this estimate.

One comment received in response to the RFI indicated that underwriters in the individual health insurance market request medical records from medical service providers for approximately 20 percent of applicants.[22] It is likely that most of these medical records contain information relating to family medical history. In a survey, 16 of 23 senior medical underwriters reported that while investigating an applicant's medical history, they had encountered genetic information about an applicant at least once in the applicant's history.[23] As explained earlier, these interim final regulations would require health insurance issuers in the individual market to explicitly state that genetic information—including family medical history—should not be provided when an issuer requests medical records from medical services providers for underwriting purposes. In turn, issuers may request that medical services providers redact any family medical history information regarding an applicant that is contained in medical records requested by an issuer to ensure that the provisions of GINA and these interim final regulations are not violated. However, as explained earlier under the discussion of the incidental collection exception, if medical services providers do not comply with the issuers' requests to redact such information, the collection of genetic information would count as an ''incidental collection'' of genetic information on the part of issuers, and these interim final regulations would

[18] *See e.g.,* Comments from BlueCross BlueShield Association, pg. 3 (*http://www.dol.gov/ebsa/pdf/cmt-12190808.pdf*) and Society for Human Resource Management, pg. 2 (*http://www.dol.gov/ebsa/pdf/cmt-12190813.pdf*).

[19] This estimate is based on the Kaiser Family Foundation Survey, Employer Health Benefits 2008 Annual Survey: Wellness Programs and Employer Opinions, section 12, which estimates that 10% of plans have health risk assessment and 12% of those offer a financial incentive to employees that complete HRAs (2.5 million group health plans × 10% of plans have health risk assessments × 12% of those plans that offer financial rewards and incentives = 30,000 plans).

[20] There are about 30,000 plans with health risk assessments and about 460 insurers in the group market; this is an average of 65 plans per insurer.

[21] EBSA estimates based on the National Occupational Employment Survey (May 2007, Bureau of Labor Statistics) and the Employment Cost Index June 2008, Bureau of Labor Statistics).

[22] This comment may be accessed at the following URL: *http://www.dol.gov/ebsa/regs/cmt-geneticinfoND.html.*

[23] Pollitz, Karen, *et al.,* ''Genetic Discrimination in Health Insurance: Current Legal Protections and Industry Practices.'' Inquiry, 44: 350–368 (Fall 2007).

not be violated so long as the issuers do not use the genetic information for underwriting purposes.

The Departments assume that medical service providers will be responsible for redacting genetic information from medical records before submitting the records to insurers, and that trained medical staff will be used for this purpose. The Departments estimate that, on average, health insurance issuers will request 3 million medical records per year, and that medical records staff will spend one-half hour per request redacting genetic information from requested medical records, at a labor rate of $26 per hour. This results in a total annual cost of nearly $41 million. The Departments invite public comments on this estimate.

c. Research Exception

As discussed above, GINA and these interim final regulations provide an exception to the limitations on requesting or requiring genetic testing, which allows a group health plan or group health insurance issuer to request, but not require, a participant or beneficiary to undergo a genetic test [24] 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. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), participants in the research must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any penalty or loss of benefits to which the subject is otherwise entitled, and participation may be discontinued at any time without penalty or loss of benefits to which the subject is entitled when the participant's informed consent is sought (the participant disclosure).[25] These interim final regulations provide that when participants receive the participant disclosure required under 45 CFR 46.116(a)(8) when their informed consent is sought, 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*).

The Departments estimate that up to five entities (consisting of group health plans and health insurance issuers in the group and individual markets) will use the genetic research exception and assume that the requirements of 45 CFR Part 46 will be satisfied. Based on the foregoing, the Departments assume that all group health plans and group health insurance issuers using the exemption will not have to send a disclosure to participants in the genetic research, because they will comply with the requirements of 45 CFR Part 46.116(a)(8). Therefore, the only incremental cost imposed by these interim final regulations will be for the group health plans and group health issuers to send the Notice to the appropriate Department.[26] Because this cost is de minimis, it has not been included in this Regulatory Impact Analysis.

4. Uncertainty

a. Adverse Selection

GINA's prohibition on the use and collection of genetic information could increase the potential for adverse selection in the individual health insurance market. Adverse selection arises when individuals seeking coverage have information about their health risks that issuers do not know.[27]

Such information asymmetry can prevent the insurer from assessing the individual's risk accurately enough to determine the appropriate premium to charge. On average, if issuers do not accurately assess the risks they assume, they will pay more in claims than they receive in premiums. To eliminate this shortfall, issuers may be forced to raise premiums for all insureds. If issuers raise premiums for all insureds, those with a perceived low risk of needing medical care might drop their coverage. This outcome in serious cases may lead to a continued cycle of across-the-board premium increases.

The Departments are not able to measure the extent to which GINA might lead to adverse selection and thereby raise premiums in the individual health insurance market, or whether GINA protections of genetic information will increase the total number of persons insured under individual health insurance policies relative to the number that might leave the market due to increased premiums. Currently, with few tests being performed, the Departments expect the impact to be minimal; however, as the number of tests increases, the effects of adverse selection on the individual health insurance market also could increase and the impact of adverse selection could grow.

b. Impact of GINA on Health Care Expenditures

Another uncertainty associated with GINA and these interim final regulations is whether total health care expenditures will increase or decrease. Whether expenditures will increase or decrease is dependent on a number of factors such as the following: The cost and predictive power of tests, how widely the tests are performed among the population, whether detected gene abnormalities are based on a single gene

[24] Comments indicated that at least one issuer is engaging in a long-term research study involving genetic testing. Others may be planning similar research.

[25] The regulations at 45 CFR 46.116(c) and (d) provide for the waiver or alteration of the requirements for obtaining informed consent in certain cases. However, given the second condition established for this research exception under GINA, it is unlikely that a waiver of informed consent could be granted under 45 CFR 46.116(c) or (d). According to 45 CFR 46.116(c) and (d), one of the conditions that must be met in order for a waiver to be granted is that the research could not practicably be carried out without the waiver. The second condition of this research exception under GINA states that a plan or issuer may request, but not require, that a participant or beneficiary undergo genetic testing for research purposes only if the plan or issuer makes the request in writing and clearly indicates that compliance with the request is voluntary. Since it is difficult to envision a circumstance where it would be the case that research could not be practicably carried out without a waiver of informed consent under 45 CFR 46.116(c) or (d), and yet be able to satisfy the second condition of this research exception under GINA, we expect that for research studies conducted under the research exception under GINA, it is unlikely that informed consent could be waived under 45 CFR 46.116(c) or (d).

[26] The instructions to the Notice will specify the appropriate Department to which the Notice should be submitted.

[27] For example, individuals who obtain results from genetic tests indicating the risk of contracting a serious medical condition could benefit financially by ''choosing the timing of purchases, and the type and level of benefits purchased. This biased selection would have a direct impact on premium rates, ultimately raising the cost of insurance to everyone.'' American Academy of Actuaries, ''Genetic Information and Medical Expense Insurance,'' June 2000.

or also involve environmental and other confounding factors which lower the predictive value of the test and treatment, and whether treatments for detected gene abnormalities are less costly than treatments for the manifested disease.

Genetic testing typically is not covered under individual health insurance policies; group health plans are far more likely to cover both the tests and associated treatments.[28] As the number of genetic tests performed increases, the Departments expect group health care premiums will rise to offset the increased costs to insurers, and any increase or decrease in overall expenditures is expected to result in increased or decreased premiums for the group market.

D. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Because these rules are being issued as interim final regulations, the RFA does not apply and the Departments are not required to either certify that the rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments expect the rules to reduce the compliance burden imposed on plans and insurers by clarifying definitions and terms contained in the statute and providing examples of acceptable methods to comply with specific provisions. Based on the foregoing, and as further discussed below, the Departments hereby certify that the rule will not have a significant economic impact on a substantial number of small entities.[29]

The Departments expect most of the cost of complying with GINA and the rules to be concentrated among group health plans associated with wellness and disease management programs providing rewards and incentives to employees who complete Health Risk Assessments (HRAs). The Departments estimate that approximately 15,000 (out of 2.4 million) small plans (or 0.00625 of all group health plans) will need to review their HRAs to ensure that genetic information is not used prior to or in connection with enrollment or for underwriting purposes and to make any necessary changes to forms and policies and procedures. This process is estimated to require one-half hour of a legal professional's time at an hourly labor rate of $116 and one-half hour of a clerical staff member's time at an hourly labor rate of $26 resulting in an average cost to the plans of $71 ($58 + $13).

Health insurers in both the group and individual health insurance markets will have to ensure compliance with the GINA and the rules. For this purpose, using the Small Business Administration's definition of a small business as a business with less than $7 million in revenues, premiums earned as a measure of revenue, and data obtained from the National Association of Insurance Commissioners, the Departments estimate that approximately 75 out of 630 insurers had revenues of less that $7 million, and, of these, about 25 had revenues of less than $1 million.

The Departments estimate that each insurer on average would spend 100 hours of professional time at an hourly labor rate of $116 to revise policies and procedures and train underwriters about GINA. This would result in an estimated one time average cost of $11,600 per insurer. For the approximately 25 insurers with revenues of less than $1 million, this burden could be more than one percent of premiums. However, the estimated costs are an average cost for plans of all sizes, and the Departments expect small insurers to have lower implementation costs, because they have fewer underwriters and other staff members to train.

The Departments invite public comments on this certification.

E. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these interim final regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

F. Paperwork Reduction Act

1. Department of Labor and Department of the Treasury

As part of their continuing efforts to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

As discussed above, GINA and these interim final regulations provide an exception to the limitations on requesting or requiring genetic testing that allow a group health plan or group health insurance issuer to request, but not require, a participant or beneficiary to undergo a genetic test[30] if all of the following conditions of the research exception set forth in 29 CFR 2590.702–1(c)(5) 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. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), a participant must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any penalty

[28] American Academy of Actuaries, *Genetic Information and Medical Expense Insurance.* June 2000.

[29] For purposes of this certification, the Departments continue to consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans which cover fewer than 100 participants. The Departments consulted with the Small Business Administration in making this determination as required by 5 U.S.C. 601(3) and 13 CFR 121.903(c).

[30] Comments indicated that at least one issuer is engaging in a long-term research study involving genetic testing. Others may be planning similar research.

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 (the participant disclosure).[31] These interim final regulations provide that when the participant disclosure is received by participants when their informed consent is sought, 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*).

Two information collection requests (ICRs) are associated with the genetic research exception—the participant disclosure and the Notice. The Departments estimate that up to three entities will take advantage of the research exception, and that all of the entities will comply with the requirements of 45 CFR Part 46, including providing the participant disclosure.

The Departments are not soliciting comments concerning an ICR pertaining to the participant disclosure, because these interim final regulations provide that group health plans and group health insurance issuers meeting the requirements of 45 CFR Part 46 are not required to provide additional disclosures, and the Departments have assumed that all entities using the research exemption will meet these requirements. The costs and burdens associated with complying with the participant disclosure requirement already are accounted for in the information collection request for the informed consent requirements contained in 45 CFR Part 46 approved under the Department of Health and Human Services' OMB Control Number (0990–0260).

Currently, the Departments are soliciting comments concerning the Notice. The Departments have submitted a copy of these interim final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Departments and OMB are particularly interested in comments that:

• Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, for example, by permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer for the Employee Benefits Security Administration either by fax to (202) 395–7285 or by e-mail to *oira_submission@omb.eop.gov*. Although comments may be submitted through December 7, 2009, OMB requests that comments be received within 30 days of publication of these interim final regulations to ensure their consideration. A copy of the ICR may be obtained by contacting the PRA addressee: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers. *E-mail: ebsa.opr@dol.gov*. ICRs submitted to OMB also are available at reginfo.gov (*http://www.reginfo.gov/public/do/PRAMain*).

The Departments estimate that completing and mailing the Notice will require 15 minutes of clerical time at an hourly rate of $26 per hour. Therefore, the total hour burden associated with completing the Notice is estimated to be 0.75 hours of clerical time. The cost burden consists of material and mailing cost to mail the two-page Notice and is estimated to total $20. Although the Departments share the burden for this ICR, the Departments have agreed to allocate the hour and cost burden associated with the rule entirely to the Department of Labor, because it is so minimal. The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.[32]

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, Department of the Treasury.

Title: Notice of Research Exception under the Genetic Information Nondiscrimination Act.

OMB Number: 1210–NEW.

Affected Public: Business or other for-profit; not-for-profit institutions.

Respondents: 3.

Responses: 3.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 0.75 hours.

Estimated Total Annual Burden Cost: $20.

2. Department of Health and Human Services

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

[31] While 45 CFR 46.116(c) and (d) permit a waiver of the disclosure otherwise required under 45 CFR 46.116(a)(8), it is unlikely that such a waiver could be granted for research studies conducted under the research exception under GINA. *See* footnote 25.

[32] 5 CFR 1320.1 through 1320.18.

a. ICRs Regarding Additional Requirements Prohibiting Discrimination Based on Genetic Information (§ 146.122)

As stated in the interim final regulations at 45 CFR 146.122(c), there are limitations on requesting or requiring genetic testing. The interim final regulations at 45 CFR 146.122(c)(1) state that a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not request or require an individual or a family member of the individual to undergo a genetic test. Section 146.122(c)(5) explains the research exception with respect to the limitations on requesting or requiring genetic testing as defined in 45 CFR 146.122(c)(1). Specifically, 45 CFR 146.122(c)(5) states that a plan or issuer may request, but not require, that a participant or beneficiary undergo a genetic test if all of the following conditions are met:

- 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. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), a participant must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any 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 (the participant disclosure).[33] These interim final regulations provide that when the participant disclosure is received by participants when their informed consent is sought, 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*).

There are two information collection requirements associated with obtaining a GINA research exception. The first is the informed consent requirement as described above. To comply with the informed consent requirements of 45 CFR 46.116(a)(8), a participant must receive a disclosure that participation in the research is voluntary, refusal to participate cannot involve any 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 (the participant disclosure).[34] These interim final regulations provide that when the participant disclosure is received by participants when their informed consent is sought, no additional disclosures are required for purposes of the GINA research exception.

The burden associated with this requirement is the time and effort necessary to develop, draft, and disseminate the information consent notice to patients. While this requirement is subject to the PRA, the associated burden is already approved under OMB control number 0990–0260. We are not soliciting comments on this requirement at this time.

The second information collection requirement associated with obtaining a GINA research exception is the Notice of Research Exception under the Genetic Information Nondiscrimination Act (the Notice). The burden associated with this requirement is the time and effort necessary for a plan or issuer to complete a copy of the Notice and submit it to CMS. CMS also estimates that completing and mailing the Notice will require 15 minutes of clerical time at an hourly rate of $26 per hour. Therefore, the total hour burden associated with completing the Notice is estimated to be 0.5 hours of clerical time. The cost burden consists of material and mailing cost to mail the two-page Notice and is estimated to total $13.

b. ICRs Regarding Prohibition of Discrimination Based on Genetic Information (§ 148.180)

The information collection requirements affecting the individual health insurance market as stated in 45 CFR 148.180 mirror the information collection requirements affecting the group health insurance market as stated in 45 CFR 146.122. The burden is discussed in detail in section IV.F.2.A. of this preamble. As stated in section IV.F.2.A., we expect no more than a combined total of 2 entities between the group health insurance market and the individual health insurance market to be subject to the information collection requirements contained in this interim final rule.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

OMB control No.	Regulation section(s)	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
0938–New	45 CFR 146.122	2	2	.25	.50
	45 CFR 148.180				

We have submitted a copy of this interim final rule to OMB for its review and approval of the aforementioned information collection requirements. These requirements are not effective until approved by OMB. Although comments may be submitted through December 7, 2009, OMB requests that comments be received within 30 days of publication of these interim final regulations to ensure their consideration.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the

[33] While 45 CFR 46.116(c) and (d) permit a waiver of the disclosure otherwise required under 45 CFR 46.116(a)(8), it is unlikely that such a waiver could be granted for research studies conducted under the research exception under GINA. *See* footnote 25.

[34] While 45 CFR 46.116(c) and (d) permit a waiver of the disclosure otherwise required under 45 CFR 46.116(a)(8), it is unlikely that such a waiver could be granted for research studies conducted under the research exception under GINA. *See* footnote 25.

ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–4137–IFC;

Fax: (202) 395–7285; or

E-mail: *OIRA_submission@omb.eop.gov.*

Please reference ''ICRs Regarding Prohibition of Discrimination Based on Genetic Information (§ 148.180)'' when submitting your comments.

G. Congressional Review Act

These interim final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review.

H. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, these interim final regulations do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, nor do they include mandates which may impose an annual burden of $100 million or more (as adjusted for inflation) on the private sector.

I. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments' view, these interim final regulations have federalism implications, because they have direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. However, in the Departments' view, the federalism implications of these regulations are substantially mitigated because, with respect to health insurance issuers, the Departments expect that the majority of States will enact laws or take other appropriate action resulting in their meeting or exceeding the Federal GINA standards prohibiting discrimination based on genetic information.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, HIPAA added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting State requirements for group health insurance coverage. This amendment applies to the GINA nondiscrimination provisions. With respect to these provisions, States may continue to apply State law requirements except to the extent that such requirements prevent the application of the portability, access, and renewability requirements of HIPAA, which include GINA's nondiscrimination requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to ''prevent the application of'' GINA, and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

GINA provides the Secretary of Labor with the express authority to impose a penalty against any health insurance issuer offering health insurance to a group health plan covered by ERISA for any failure by the issuer to meet the GINA requirements. The States may enforce the provisions of GINA as they pertain to issuers, but the Secretary of HHS is required to enforce any provisions that a State fails to substantially enforce. This relates to HHS' responsibility to enforce the HIPAA nondiscrimination provisions. In exercising its responsibility, HHS works cooperatively with the State for the purpose of addressing the State's concerns and avoiding conflicts with the exercise of State authority. HHS has developed procedures to implement its enforcement responsibilities, and to afford the States the maximum opportunity to enforce HIPAA's requirements in the first instance. HHS' procedures address the handling of reports that States may not be enforcing HIPAA's requirements, and the mechanism for allocating enforcement responsibility between the States and HHS. In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Department of Labor and HHS have engaged in numerous efforts to consult with and work cooperatively with affected State and local officials. It is expected that the Departments will act in a similar fashion in enforcing the GINA requirements.

In addition, the Departments specifically consulted with the National Association of Insurance Commissioners (NAIC) in developing these interim final regulations. Through the NAIC, the Departments sought and received the input of State insurance departments regarding certain insurance rating practices. The Departments have also cooperated with the States in several ongoing outreach initiatives, through which information on GINA is shared among Federal regulators, State regulators, and the regulated community.

Throughout the process of developing these interim final regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to GINA, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress's intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these regulations, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached interim final regulations in a meaningful and timely manner.

V. Statutory Authority

The Department of the Treasury temporary and final regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec.101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note);

sec. 101(f), Public Law 110–233, 122 Stat. 881; Secretary of Labor's Order 1–2003, 68 FR 5374 (Feb. 3, 2003).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as added by Public Law 104–191, and amended by Public Law 104–204, Public Law 105–277, and Public Law 110–233.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Parts 144, 146, and 148

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Amendments to the Regulations

Internal Revenue Service

26 CFR Chapter 1

■ Accordingly, 26 CFR Part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by adding an entry for § 54.9802–3T in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Section 54.9802–3T also issued under 26 U.S.C. 9833. * * *

■ **Par. 2.** Section 54.9801–1 is amended by revising paragraph (a) and adding paragraph (b)(6) to read as follows:

§ 54.9801–1 Basis and scope.

(a) *Statutory basis.* This section and sections 54.9801–2 through 54.9801–6, 54.9802–1, 54.9802–2, 54.9802–3T, 54.9811–1, 54.9812–1T, 54.9831–1, and 54.9833–1 (portability sections) implement Chapter 100 of Subtitle K of the Internal Revenue Code of 1986.

(b) * * *

(6) Additional requirements prohibiting discrimination based on genetic information.

* * * * *

■ **Par 3.** Section 54.9801–2 is amended by revising the introductory text and revising the definition of Genetic information to read as follows:

§ 54.9801–2 Definitions.

Unless otherwise provided, the definitions in this section govern in applying the provisions of § 54.9801–1, this section, §§ 54.9801–3 through 54.9801–6, 54.9802–1, 54.9802–2, 54.9802–3T, 54.9811–1, 54.9812–1T, 54.9831–1, and 54.9833–1.

* * * * *

Genetic information has the meaning given the term in § 54.9802–3T(a)(3).

* * * * *

■ **Par 4.** Section 54.9802–1 is amended by revising paragraphs (a)(1)(vi), (c)(2)(i), the introductory text of paragraph (c)(2)(iii), and paragraph (c)(2)(iii) *Example 1* to read as follows:

§ 54.9802–1 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) * * * (1) * * *

(vi) Genetic information, as defined in § 54.9802–3T.

* * * * *

(c) * * *

(2) *Rules relating to premium rates*—

(i) *Group rating based on health factors not restricted under this section.* Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan. But *see* § 54.9802–3T(b), which prohibits adjustments in group premium or contribution rates based on genetic information.

* * * * *

(iii) *Examples.* The rules of this paragraph (c)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan and purchases coverage from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual F had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of F's claims experience.

(ii) *Conclusion. See Example 1* in 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) for a conclusion that the issuer does not violate the provisions of 29 CFR 2590.702(c)(2) and 45 CFR 146.121(c)(2) similar to the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for F than for a similarly situated individual based on F's claims experience. (However, those examples conclude that if the issuer used genetic information in computing the group rate, it would violate 29 CFR 2590.702–1(b) or 45 CFR 146.122(b).)

* * * * *

■ **Par. 5.** Section 54.9831–1 is amended by revising paragraph (b) to read as follows:

§ 54.9831–1 Special rules relating to group health plans.

* * * * *

(b) *General exception for certain small group health plans.* (1) Subject to paragraph (b)(2) of this section, the requirements of §§ 54.9801–1 through 54.9801–6, 54.9802–1, 54.9802–2, 54.9811–1, 54.9812–1T, and 54.9833–1 do not apply to any group health plan for any plan year if, on the first day of the plan year, the plan has fewer than two participants who are current employees.

(2) The exception of paragraph (b)(1) of this section does not apply with respect to the following requirements:

(i) Section 54.9801–3(b)(6).

(ii) Section 54.9802–1(b), as such paragraph applies with respect to genetic information as a health factor.

(iii) Section 54.9802–1(c), as such paragraph applies with respect to genetic information as a health factor.

(iv) Section 54.9802–1(e), as such paragraph applies with respect to genetic information as a health factor.

(v) Section 54.9802–3T(b).

(vi) Section 54.9802–3T(c).

(vii) Section 54.9802–3T(d).

(viii) Section 54.9802–3T(e).

* * * * *

■ **Par. 6.** Section 54.9802–3T is added to read as follows:

§ 54.9802–3T Additional requirements prohibiting discrimination based on genetic information (temporary).

(a) *Definitions.* Unless otherwise provided, the definitions in this paragraph (a) govern in applying the provisions of this section.

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

(2) *Family member* means, with respect to an individual —

(i) A dependent (as defined for purposes of § 54.9801–2) of the individual; or

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

(A) First-degree relatives include parents, spouses, siblings, and children.

(B) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.

(C) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(D) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

(3) *Genetic information* means—

(i) Subject to paragraphs (a)(3)(ii) and (a)(3)(iii) of this section, with respect to an individual, information about—

(A) The individual's genetic tests (as defined in paragraph (a)(5) of this section);

(B) The genetic tests of family members of the individual;

(C) The manifestation (as defined in paragraph (a)(6) of this section) of a disease or disorder in family members of the individual; or

(D) Any request for, or receipt of, genetic services (as defined in paragraph (a)(4) of this section), or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

(ii) The term *genetic information* does not include information about the sex or age of any individual.

(iii) The term *genetic information* includes—

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

(B) With respect to an individual (or a family member of the individual) who is utilizing an assisted reproductive technology, genetic information of any embryo legally held by the individual or family member.

(4) *Genetic services* means—

(i) A genetic test, as defined in paragraph (a)(5) of this section;

(ii) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(iii) Genetic education.

(5)(i) *Genetic test* means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. However, a genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. Accordingly, a test to determine whether an individual has a 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. However, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test.

(ii) The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* Individual A is a newborn covered under a group health plan. A undergoes a phenylketonuria (PKU) screening, which measures the concentration of a metabolite, phenylalanine, in A's blood. In PKU, a mutation occurs in the phenylalanine hydroxylase (PAH) gene which contains instructions for making the enzyme needed to break down the amino acid phenylalanine. Individuals with the mutation, who have a deficiency in the enzyme to break down phenylalanine, have high concentrations of phenylalanine.

(ii) *Conclusion.* In this *Example,* the PKU screening is a genetic test with respect to A because the screening is an analysis of metabolites that detects a genetic mutation.

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

(ii) The rules of this paragraph (a)(6) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual A has a family medical history of diabetes. A begins to experience excessive sweating, thirst, and fatigue. A's physician examines A and orders blood glucose testing (which is not a genetic test). Based on the physician's examination, A's symptoms, and test results that show elevated levels of blood glucose, A's physician diagnoses A as having adult onset diabetes mellitus (Type 2 diabetes).

(ii) *Conclusion.* In this *Example 1,* A has been diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved. The diagnosis is not based principally on genetic information. Thus, Type 2 diabetes is manifested with respect to A.

Example 2. (i) *Facts.* Individual B has several family members with colon cancer. One of them underwent genetic testing which detected a mutation in the MSH2 gene associated with hereditary nonpolyposis colorectal cancer (HNPCC). B's physician, a health care professional with appropriate training and expertise in the field of medicine involved, recommends that B undergo a targeted genetic test to look for the specific mutation found in B's relative to determine if B has an elevated risk for cancer. The genetic test with respect to B showed that B also carries the mutation and is at increased risk to develop colorectal and other cancers associated with HNPCC. B has a colonoscopy which indicates no signs of disease, and B has no symptoms.

(ii) *Conclusion.* In this *Example 2,* because B has no signs or symptoms of colorectal cancer, B has not been and could not reasonably be diagnosed with HNPCC. Thus, HNPCC is not manifested with respect to B.

Example 3. (i) *Facts.* Same facts as *Example 2,* except that B's colonoscopy and subsequent tests indicate the presence of HNPCC. Based on the colonoscopy and subsequent test results, B's physician makes a diagnosis of HNPCC.

(ii) Conclusion. In this *Example 3,* HNPCC is manifested with respect to B because a health care professional with appropriate training and expertise in the field of medicine involved has made a diagnosis that is not based principally on genetic information.

Example 4. (i) *Facts.* Individual C has a family member that has been diagnosed with Huntington's Disease. A genetic test indicates that C has the Huntington's Disease gene variant. At age 42, C begins suffering from occasional moodiness and disorientation, symptoms which are associated with Huntington's Disease. C is examined by a neurologist (a physician with appropriate training and expertise for diagnosing Huntington's Disease). The examination includes a clinical neurological exam. The results of the examination do not support a diagnosis of Huntington's Disease.

(ii) *Conclusion.* In this *Example 4,* C is not and could not reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is not manifested with respect to C.

Example 5. (i) *Facts.* Same facts as *Example 4,* except that C exhibits additional neurological and behavioral symptoms, and the results of the examination support a diagnosis of Huntington's Disease with respect to C.

(ii) *Conclusion.* In this *Example 5,* C could reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is manifested with respect to C.

(7) *Underwriting purposes* has the meaning given in paragraph (d)(1) of this section.

(b) *No group-based discrimination based on genetic information*—(1) *In general.* For purposes of this section, a group health plan must not adjust premium or contribution amounts for any employer, or any group of similarly situated individuals under the plan, on the basis of genetic information. For this purpose, ''similarly situated individuals'' are those described in § 54.9802–1(d).

(2) *Rule of construction.* Nothing in paragraph (b)(1) of this section (or in paragraph (d)(1) or (d)(2) of this section) limits the ability of a group health plan to increase the premium for an

employer or for a group of similarly situated individuals under the plan based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such a case, however, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members to further increase the premium for an employer or a group of similarly situated individuals under the plan.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

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

(ii) *Conclusion. See Example 1* in 29 CFR 2590.702–1(b)(3) or 45 CFR 146.122(b)(3) for a conclusion that the issuer violates the provisions of 29 CFR 2590.702–1(b) or 45 CFR 146.122(b) similar to the requirements of this paragraph (b) because the issuer adjusts the premium based on genetic information. However, if the adjustment related solely to claims experience, the adjustment would not violate the requirements of 29 CFR 2590.702–1 or 45 CFR 146.122 similar to the requirements of this section (nor would it violate the requirements of paragraph (c) of 29 CFR 2590.702 or 45 CFR 146.121 similar to the requirements of paragraph (c) of § 54.9802–1, which prohibits discrimination in individual premiums or contributions based on a health factor but permits increases in the group rate based on a health factor).

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

(ii) *Conclusion. See Example 2* in 29 CFR 2590.702–1(b)(3) or 45 CFR 146.122(b)(3) for a conclusion that the issuer violates the provisions of 29 CFR 2590.702–1(b) or 45 CFR 146.122(b) similar to the requirements of this paragraph (b) because, by taking the likelihood that A's children may develop polycystic kidney disease into account in computing the rate for the plan, the issuer adjusts the premium based on genetic information relating to a condition that has not been manifested in A's children. However, the issuer does not violate the requirements of 29 CFR 2590.702–1(b) or 45 CFR 146.122(b) similar to the requirements of this paragraph (b) by increasing the premium based on A's claims experience.

(c) *Limitation on requesting or requiring genetic testing*—(1) *General rule.* Except as otherwise provided in this paragraph (c), a group health plan must not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test.* Nothing in paragraph (c)(1) of this section limits the authority of a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test.

(3) *Examples.* The rules of paragraphs (c)(1) and (c)(2) of this section are illustrated by the following examples:

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

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

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

(ii) *Conclusion.* In this *Example 2,* even though the physician is employed by the HMO, the physician is nonetheless a health care professional who is providing health care services to B. Therefore, the physician's recommendation that B undergo the genetic test does not violate this paragraph (c).

(4) *Determination regarding payment*—(i) *In general.* As provided in this paragraph (c)(4), nothing in paragraph (c)(1) of this section precludes a plan from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, ''payment'' has the meaning given such term in 45 CFR 164.501 of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if a plan conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on the genetic makeup of a patient, then the plan is permitted to condition payment for the item or service on the outcome of a genetic test. The plan may also refuse payment if the patient does not undergo the genetic test.

(ii) *Limitation.* A plan is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in 45 CFR 164.502(b) of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples. See* paragraph (e) of this section for examples illustrating the rules of this paragraph (c)(4), as well as other provisions of this section.

(5) *Research exception.* Notwithstanding paragraph (c)(1) of this section, a plan may request, but not require, that a participant or beneficiary undergo a genetic test if all of the conditions of this paragraph (c)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local law or regulations.* The plan makes the request pursuant to research, as defined in 45 CFR 46.102(d), 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.

(ii) *Written request for participation in research.* The plan makes the request in writing, and the request clearly indicates to each participant or beneficiary (or, in the case of a minor child, to the legal guardian of the beneficiary) that—

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in § 54.9802–1(b)(1)) or premium or contribution amounts.

(iii) *Prohibition on underwriting.* No genetic information collected or acquired under this paragraph (c)(5) can be used for underwriting purposes (as described in paragraph (d)(1) of this section).

(iv) *Notice to Federal agencies.* The plan completes a copy of the ''Notice of Research Exception under the Genetic Information Nondiscrimination Act'' authorized by the Secretary and provides the notice to the address specified in the instructions thereto.

(d) *Prohibitions on collection of genetic information*—(1) *For underwriting purposes*—(i) *General rule.* A group health plan must not collect (as defined in paragraph (a)(1) of this section) genetic information for underwriting purposes. *See* paragraph (e) of this section for examples illustrating the rules of this paragraph (d)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (d)(1)(iii) of this section, *underwriting purposes* means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage as described in § 54.9802–1(b)(1)(ii) (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(B) The computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(C) The application of any preexisting condition exclusion under the plan or coverage; and

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

(iii) *Medical appropriateness.* If an individual seeks a benefit under a group health plan, the plan may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an individual seeks a benefit under the plan and the plan conditions the benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on genetic information of the individual, then the plan is permitted to condition the benefit on the genetic information. A plan is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness. The plan may deny the benefit if the patient does not provide the genetic information required to determine medical appropriateness. If an individual is not seeking a benefit, the medical appropriateness exception of this paragraph (d)(1)(iii) to the definition of underwriting purposes does not apply. *See* paragraph (e) of this section for examples illustrating the medical appropriateness provisions of this paragraph (d)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment*—(i) *In general.* A group health plan must not collect genetic information with respect to any individual prior to that individual's effective date of coverage under that plan, nor in connection with the rules for eligibility (as defined in § 54.9802–1(b)(1)(ii)) that apply to that individual. Whether or not an individual's information is collected prior to that individual's effective date of coverage is determined at the time of collection.

(ii) *Incidental collection exception*—(A) *In general.* If a group health plan obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (d)(2), as long as the collection is not for underwriting purposes in violation of paragraph (d)(1) of this section.

(B) *Limitation.* The incidental collection exception of this paragraph (d)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly states that genetic information should not be provided.

(3) *Examples.* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides a premium reduction to enrollees who complete a health risk assessment. The health risk assessment is requested to be completed after enrollment. Whether or not it is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The health risk assessment includes questions about the individual's family medical history.

(ii) *Conclusion.* In this *Example 1,* the health risk assessment includes a request for genetic information (that is, the individual's family medical history). Because completing the health risk assessment results in a premium reduction, the request for genetic information is for underwriting purposes. Consequently, the request violates the prohibition on the collection of genetic information in paragraph (d)(1) of this section.

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

(ii) *Conclusion.* In this *Example 2,* the request is not for underwriting purposes, nor is it prior to or in connection with enrollment. Therefore, it does not violate the prohibition on the collection of genetic information in this paragraph (d).

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

(ii) *Conclusion.* In this *Example 3,* because the health risk assessment includes a request for genetic information (that is, the individual's family medical history), and requests the information prior to enrollment, the request violates the prohibition on the collection of genetic information in paragraph (d)(2) of this section. Moreover, because it is a request for genetic information, it is not an incidental collection under paragraph (d)(2)(ii) of this section.

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

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

Example 5. (i) *Facts.* A group health plan requests enrollees to complete two distinct health risk assessments (HRAs) after and unrelated to enrollment. The first HRA instructs the individual to answer only for the individual and not for the individual's family. The first HRA does not ask about any genetic tests the individual has undergone or any genetic services the individual has received. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and the results of genetic tests the individual has undergone. The plan offers no reward for completing the second HRA and the instructions make clear that completion of the second HRA is wholly voluntary and will not affect the reward given for completion of the first HRA.

(ii) *Conclusion.* In this *Example 5,* no genetic information is collected in

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

Example 6. (i) *Facts.* A group health plan waives its annual deductible for enrollees who complete an HRA. The HRA is requested to be completed after enrollment. Whether or not the HRA is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The HRA does not include any direct questions about the individual's genetic information (including family medical history). However, the last question reads, ''Is there anything else relevant to your health that you would like us to know or discuss with you?''

(ii) *Conclusion.* In this *Example 6,* the plan's request for medical information does not explicitly state that genetic information should not be provided. Therefore, any genetic information collected in response to the question is not within the incidental collection exception and is prohibited under this paragraph (d).

Example 7. (i) *Facts.* Same facts as *Example 6,* except that the last question goes on to state, ''In answering this question, you should not include any genetic information. That is, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk.''

(ii) *Conclusion.* In this *Example 7,* the plan's request for medical information explicitly states that genetic information should not be provided. Therefore, any genetic information collected in response to the question is within the incidental collection exception. However, the plan may not use any genetic information it obtains incidentally for underwriting purposes.

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

(ii) *Conclusion.* In this *Example 8,* M's request for health information explicitly stated that genetic information should not be provided. *See Example 8* in 29 CFR 2590.702–1(d)(3) or 45 CFR 146.122(d)(3) for a conclusion that the collection of genetic information was within the incidental collection exception of 29 CFR 2590.702–1(d)(2)(ii) or 45 CFR 146.122(d)(ii) similar to the incidental exception of paragraph (d)(2)(ii) of this section. *See Example 8* in 29 CFR 2590.702–1(d)(3) or 45 CFR 146.122(d)(3) also for a caveat that M may not use the genetic information it obtained incidentally for underwriting purposes.

(e) *Examples regarding determinations of medical appropriateness.* The application of the rules of paragraphs (c) and (d) of this section to plan determinations of medical appropriateness is illustrated by the following examples:

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

(ii) *Conclusion. See Example 1* in 29 CFR 2590.702–1(e) or 45 CFR 146.122(e) for a conclusion under the rules of paragraph (c)(4) of 29 CFR 2590.702–1 or 45 CFR 146.122 similar to the rules of paragraph (c)(4) of this section that the issuer is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for the issuer to make a decision regarding the payment of A's claim, the conclusion in *Example 1* in 29 CFR 2590.702–1(e) or 45 CFR 146.122(e) concludes that the issuer's request for the results of the genetic test violates paragraph (c) of 29 CFR 2590.702–1 or 45 CFR 146.122 similar to paragraph (c) of this section.

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

(ii) *Conclusion.* In this *Example 2,* the plan does not violate paragraphs (c) or (d) of this section. Under paragraph (c), the plan is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the plan requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the genetic makeup of the patient, the minimum amount of information necessary includes the results of the genetic test. Similarly, the plan does not violate paragraph (d) of this section because the plan is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and if the genetic information is not used for underwriting purposes).

Example 3. (i) *Facts.* Individual C was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of C's physician, C has been taking a regular dose of tamoxifen to help prevent a recurrence. C's group health plan adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients, those with certain variations of the gene for making the CYP_2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, the plan does not pay for the tamoxifen prescription.

(ii) *Conclusion.* In this *Example 3,* the plan does not violate paragraph (c) of this section if it conditions future payments for the tamoxifen prescription on C's undergoing a genetic test to determine what genetic markers C has for making the CYP_2D6 enzyme. Nor does the plan violate paragraph (c) of this section if the plan refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for C.

Example 4. (i) *Facts.* A group health plan offers a diabetes disease management program to all similarly situated individuals for whom it is medically appropriate based on whether the individuals have or are at risk for diabetes. The program provides enhanced benefits related only to diabetes for individuals who qualify for the program. The plan sends out a notice to all participants that describes the diabetes disease management program and explains the terms for eligibility. Individuals interested in enrolling in the program are advised to contact the plan to demonstrate that they have diabetes or that they are at risk for diabetes. For individuals who do not currently have diabetes, genetic information may be used to demonstrate that an individual is at risk.

(ii) *Conclusion.* In this *Example 4,* the plan may condition benefits under the disease management program upon a showing by an individual that the individual is at risk for diabetes, even if such showing may involve genetic information, provided that the plan requests genetic information only when necessary to make a determination regarding whether the disease management program is medically appropriate for the individual and only requests the minimum amount of information necessary to make that determination.

Example 5. (i) *Facts.* Same facts as *Example 4,* except that the plan includes a questionnaire that asks about the occurrence of diabetes in members of the individual's family as part of the notice describing the disease management program.

(ii) *Conclusion.* In this *Example 5,* the plan violates the requirements of paragraph (d)(1) of this section because the requests for genetic information are not limited to those situations in which it is necessary to make a determination regarding whether the disease management program is medically appropriate for the individuals.

Example 6. (i) *Facts.* Same facts as *Example 4,* except the disease management program provides an enhanced benefit in the

form of a lower annual deductible to individuals under the program; the lower deductible applies with respect to all medical expenses incurred by the individual. Thus, whether or not a claim relates to diabetes, the individual is provided with a lower deductible based on the individual providing the plan with genetic information.

(ii) *Conclusion.* In this *Example 6,* because the enhanced benefits include benefits not related to the determination of medical appropriateness, making available the enhanced benefits is within the meaning of underwriting purposes. Accordingly, the plan may not request or require genetic information (including family history information) in determining eligibility for enhanced benefits under the program because such a request would be for underwriting purposes and would violate paragraph (d)(1) of this section.

(f) *Effective/applicability date.* This section applies for plan years beginning on or after December 7, 2009.

(g) *Expiration date.* This section expires on or before October 1, 2012.

Linda E. Stiff,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: September 11, 2009.

Michael Mundaca,

Acting Assistant Secretary of the Treasury (Tax Policy).

Employee Benefits Security Administration

29 CFR Chapter XXV

■ For the reasons stated in the preamble, 29 CFR Part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for Part 2590 is amended to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 101(f), Public Law 110–233, 122 Stat. 881; Secretary of Labor's Order 1–2003, 68 FR 5374 (Feb. 3, 2003).

■ 2. Section 2590.701–1 is amended by revising paragraph (b)(6) and adding paragraph (b)(7) to read as follows:

§ 2590.701–1 Basis and scope.

* * * * *

(b) * * *

(6) Additional requirements prohibiting discrimination based on genetic information.

(7) Use of an affiliation period by an HMO as an alternative to a preexisting condition exclusion.

* * * * *

■ 3. Section 2590.701–2 is amended by revising the definition of genetic information to read as follows:

§ 2590.701–2 Definitions.

* * * * *

Genetic information has the meaning given the term in § 2590.702–1(a)(3) of this Part.

* * * * *

■ 4. Section 2590.702 is amended by revising paragraphs (a)(1)(vi), (c)(2)(i), and (c)(2)(iii) to read as follows:

§ 2590.702 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) * * *

(1) * * *

(vi) Genetic information, as defined in § 2590.702–1(a)(3) of this Part.

* * * * *

(c) * * *

(2) * * * (i) *Group rating based on health factors not restricted under this section.* Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan. But *see* § 2590.702–1(b) of this Part, which prohibits adjustments in group premium or contribution rates based on genetic information.

* * * * *

(iii) *Examples.* The rules of this paragraph (c)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan and purchases coverage from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual *F* had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of *F*'s claims experience.

(ii) *Conclusion.* In this *Example 1,* the issuer does not violate the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for *F* than for a similarly situated individual based on *F*'s claims experience. (However, if the issuer used genetic information in computing the group rate, it would violate § 2590.702–1(b) of this Part.)

* * * * *

■ 5. Add § 2590.702–1 to read as follows:

§ 2590.702–1 Additional requirements prohibiting discrimination based on genetic information.

(a) *Definitions.* Unless otherwise provided, the definitions in this paragraph (a) govern in applying the provisions of this section.

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

(2) *Family member* means, with respect to an individual—

(i) A dependent (as defined for purposes of § 2590.701–2 of this Part) of the individual; or

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

(A) First-degree relatives include parents, spouses, siblings, and children.

(B) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.

(C) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(D) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

(3) *Genetic information* means—(i) Subject to paragraphs (a)(3)(ii) and (a)(3)(iii) of this section, with respect to an individual, information about—

(A) The individual's genetic tests (as defined in paragraph (a)(5) of this section);

(B) The genetic tests of family members of the individual;

(C) The manifestation (as defined in paragraph (a)(6) of this section) of a disease or disorder in family members of the individual; or

(D) Any request for, or receipt of, genetic services (as defined in paragraph (a)(4) of this section), or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

(ii) The term *genetic information* does not include information about the sex or age of any individual.

(iii) The term *genetic information* includes—

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

(B) With respect to an individual (or a family member of the individual) who is utilizing an assisted reproductive technology, genetic information of any

embryo legally held by the individual or family member.

(4) *Genetic services* means—

(i) A genetic test, as defined in paragraph (a)(5) of this section;

(ii) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(iii) Genetic education.

(5)(i) *Genetic test* means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. However, a genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. Accordingly, a test to determine whether an individual has a 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. However, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test.

(ii) The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* Individual *A* is a newborn covered under a group health plan. *A* undergoes a phenylketonuria (PKU) screening, which measures the concentration of a metabolite, phenylalanine, in *A's* blood. In PKU, a mutation occurs in the phenylalanine hydroxylase (PAH) gene which contains instructions for making the enzyme needed to break down the amino acid phenylalanine. Individuals with the mutation, who have a deficiency in the enzyme to break down phenylalanine, have high concentrations of phenylalanine.

(ii) *Conclusion.* In this *Example,* the PKU screening is a genetic test with respect to *A* because the screening is an analysis of metabolites that detects a genetic mutation.

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

(ii) The rules of this paragraph (a)(6) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* has a family medical history of diabetes. *A* begins to experience excessive sweating, thirst, and fatigue. *A's* physician examines *A* and orders blood glucose testing (which is not a genetic test). Based on the physician's examination, *A's* symptoms, and test results that show elevated levels of blood glucose, *A's* physician diagnoses *A* as having adult onset diabetes mellitus (Type 2 diabetes).

(ii) *Conclusion.* In this *Example 1, A* has been diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved. The diagnosis is not based principally on genetic information. Thus, Type 2 diabetes is manifested with respect to *A.*

Example 2. (i) *Facts.* Individual *B* has several family members with colon cancer. One of them underwent genetic testing which detected a mutation in the MSH2 gene associated with hereditary nonpolyposis colorectal cancer (HNPCC). *B's* physician, a health care professional with appropriate training and expertise in the field of medicine involved, recommends that *B* undergo a targeted genetic test to look for the specific mutation found in *B's* relative to determine if *B* has an elevated risk for cancer. The genetic test with respect to *B* showed that *B* also carries the mutation and is at increased risk to develop colorectal and other cancers associated with HNPCC. *B* has a colonoscopy which indicates no signs of disease, and *B* has no symptoms.

(ii) *Conclusion.* In this *Example 2,* because *B* has no signs or symptoms of colorectal cancer, *B* has not been and could not reasonably be diagnosed with HNPCC. Thus, HNPCC is not manifested with respect to *B.*

Example 3. (i) *Facts.* Same facts as *Example 2,* except that *B's* colonoscopy and subsequent tests indicate the presence of HNPCC. Based on the colonoscopy and subsequent test results, *B's* physician makes a diagnosis of HNPCC.

(ii) Conclusion. In this *Example 3,* HNPCC is manifested with respect to *B* because a health care professional with appropriate training and expertise in the field of medicine involved has made a diagnosis that is not based principally on genetic information.

Example 4. (i) *Facts.* Individual *C* has a family member that has been diagnosed with Huntington's Disease. A genetic test indicates that *C* has the Huntington's Disease gene variant. At age 42, *C* begins suffering from occasional moodiness and disorientation, symptoms which are associated with Huntington's Disease. *C* is examined by a neurologist (a physician with appropriate training and expertise for diagnosing Huntington's Disease). The examination includes a clinical neurological exam. The results of the examination do not support a diagnosis of Huntington's Disease.

(ii) *Conclusion.* In this *Example 4, C* is not and could not reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is not manifested with respect to *C.*

Example 5. (i) *Facts.* Same facts as *Example 4,* except that *C* exhibits additional neurological and behavioral symptoms, and the results of the examination support a diagnosis of Huntington's Disease with respect to *C.*

(ii) *Conclusion.* In this *Example 5, C* could reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is manifested with respect to *C.*

(7) *Underwriting purposes* has the meaning given in paragraph (d)(1) of this section.

(b) *No group-based discrimination based on genetic information*—(1) *In general.* For purposes of this section, a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not adjust premium or contribution amounts for the plan, or any group of similarly situated individuals under the plan, on the basis of genetic information. For this purpose, ''similarly situated individuals'' are those described in § 2590.702(d) of this Part.

(2) *Rule of construction.* Nothing in paragraph (b)(1) of this section (or in paragraph (d)(1) or (d)(2) of this section) limits the ability of a health insurance issuer offering health insurance coverage in connection with a group health plan to increase the premium for a group health plan or a group of similarly situated individuals under the plan based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such a case, however, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members to further increase the premium for a group health plan or a group of similarly situated individuals under the plan.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

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

(ii) *Conclusion.* In this *Example 1,* the issuer violates the provisions of this paragraph (b) because the issuer adjusts the premium based on genetic information. However, if the adjustment related solely to claims experience, the adjustment would not violate the requirements of this section (nor would it violate the requirements of paragraph (c) of § 2590.702 of this Part,

which prohibits discrimination in individual premiums or contributions based on a health factor but permits increases in the group rate based on a health factor).

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

(ii) *Conclusion.* In this *Example 2,* the issuer violates the provisions of this paragraph (b) because, by taking the likelihood that *A's* children may develop polycystic kidney disease into account in computing the rate for the plan, the issuer adjusts the premium based on genetic information relating to a condition that has not been manifested in *A's* children. However, it is permissible for the issuer to increase the premium based on *A's* claims experience.

(c) *Limitation on requesting or requiring genetic testing*—(1) *General rule.* Except as otherwise provided in this paragraph (c), a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test.* Nothing in paragraph (c)(1) of this section limits the authority of a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test.

(3) *Examples.* The rules of paragraphs (c)(1) and (2) of this section are illustrated by the following examples:

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

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

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

(ii) *Conclusion.* In this *Example 2,* even though the physician is employed by the HMO, the physician is nonetheless a health care professional who is providing health care services to *B.* Therefore, the physician's recommendation that *B* undergo the genetic test does not violate this paragraph (c).

(4) *Determination regarding payment.* (i) *In general.* As provided in this paragraph (c)(4), nothing in paragraph (c)(1) of this section precludes a plan or issuer from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, ''payment'' has the meaning given such term in 45 CFR 164.501 of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if a plan or issuer conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on the genetic makeup of a patient, then the plan or issuer is permitted to condition payment for the item or service on the outcome of a genetic test. The plan or issuer may also refuse payment if the patient does not undergo the genetic test.

(ii) *Limitation.* A plan or issuer is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in 45 CFR 164.502(b) of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples. See* paragraph (e) of this section for examples illustrating the rules of this paragraph (c)(4), as well as other provisions of this section.

(5) *Research exception.* Notwithstanding paragraph (c)(1) of this section, a plan or issuer may request, but not require, that a participant or beneficiary undergo a genetic test if all of the conditions of this paragraph (c)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local law or regulations.* The plan or issuer makes the request pursuant to research, as defined in 45 CFR 46.102(d), 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.

(ii) *Written request for participation in research.* The plan or issuer makes the request in writing, and the request clearly indicates to each participant or beneficiary (or, in the case of a minor child, to the legal guardian of the beneficiary) that—

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in § 2590.702(b)(1) of this Part) or premium or contribution amounts.

(iii) *Prohibition on underwriting.* No genetic information collected or acquired under this paragraph (c)(5) can be used for underwriting purposes (as described in paragraph (d)(1) of this section).

(iv) *Notice to Federal agencies.* The plan or issuer completes a copy of the ''Notice of Research Exception under the Genetic Information Nondiscrimination Act'' authorized by the Secretary and provides the notice to the address specified in the instructions thereto.

(d) *Prohibitions on collection of genetic information*—(1) *For underwriting purposes*—(i) *General rule.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not collect (as defined in paragraph (a)(1) of this section) genetic information for underwriting purposes. *See* paragraph (e) of this section for examples illustrating the rules of this paragraph (d)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (d)(1)(iii) of this section, *underwriting purposes* means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage as described in § 2590.702(b)(1)(ii) of this Part (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(B) The computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(C) The application of any preexisting condition exclusion under the plan or coverage; and

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

(iii) *Medical appropriateness.* If an individual seeks a benefit under a group health plan or health insurance coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an individual seeks a benefit under the plan and the plan or issuer conditions the benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on genetic information of the individual, then the plan or issuer is permitted to condition the benefit on the genetic information. A plan or issuer is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness. The plan or issuer may deny the benefit if the patient does not provide the genetic information required to determine medical appropriateness. If an individual is not seeking a benefit, the medical appropriateness exception of this paragraph (d)(1)(iii) to the definition of underwriting purposes does not apply. *See* paragraph (e) of this section for examples illustrating the medical appropriateness provisions of this paragraph (d)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment.* (i) *In general.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not collect genetic information with respect to any individual prior to that individual's effective date of coverage under that plan or coverage, nor in connection with the rules for eligibility (as defined in § 2590.702(b)(1)(ii) of this Part) that apply to that individual. Whether or not an individual's information is collected prior to that individual's effective date of coverage is determined at the time of collection.

(ii) *Incidental collection exception.*—(A) *In general.* If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (d)(2), as long as the collection is not for underwriting purposes in violation of paragraph (d)(1) of this section.

(B) *Limitation.* The incidental collection exception of this paragraph (d)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly states that genetic information should not be provided.

(3) *Examples.* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides a premium reduction to enrollees who complete a health risk assessment. The health risk assessment is requested to be completed after enrollment. Whether or not it is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The health risk assessment includes questions about the individual's family medical history.

(ii) *Conclusion.* In this *Example 1,* the health risk assessment includes a request for genetic information (that is, the individual's family medical history). Because completing the health risk assessment results in a premium reduction, the request for genetic information is for underwriting purposes. Consequently, the request violates the prohibition on the collection of genetic information in paragraph (d)(1) of this section.

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

(ii) *Conclusion.* In this *Example 2,* the request is not for underwriting purposes, nor is it prior to or in connection with enrollment. Therefore, it does not violate the prohibition on the collection of genetic information in this paragraph (d).

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

(ii) *Conclusion.* In this *Example 3,* because the health risk assessment includes a request for genetic information (that is, the individual's family medical history), and requests the information prior to enrollment, the request violates the prohibition on the collection of genetic information in paragraph (d)(2) of this section. Moreover, because it is a request for genetic information, it is not an incidental collection under paragraph (d)(2)(ii) of this section.

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

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

Example 5. (i) *Facts.* A group health plan requests enrollees to complete two distinct health risk assessments (HRAs) after and unrelated to enrollment. The first HRA instructs the individual to answer only for the individual and not for the individual's family. The first HRA does not ask about any genetic tests the individual has undergone or any genetic services the individual has received. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and the results of genetic tests the individual has undergone. The plan offers no reward for completing the second HRA and the instructions make clear that completion of the second HRA is wholly voluntary and will not affect the reward given for completion of the first HRA.

(ii) *Conclusion.* In this *Example 5,* no genetic information is collected in connection with the first HRA, which offers a reward, and no benefits or other rewards are conditioned on the request for genetic information in the second HRA. Consequently, the request for genetic information in the second HRA is not for underwriting purposes, and the two HRAs do not violate the prohibition on the collection of genetic information in this paragraph (d).

Example 6. (i) *Facts.* A group health plan waives its annual deductible for enrollees who complete an HRA. The HRA is requested to be completed after enrollment. Whether or not the HRA is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The HRA does not include any direct questions about the individual's genetic information (including family medical history). However, the last question reads, ''Is there anything else relevant to your health that you would like us to know or discuss with you?''

(ii) *Conclusion.* In this *Example 6,* the plan's request for medical information does not explicitly state that genetic information should not be provided. Therefore, any genetic information collected in response to the question is not within the incidental collection exception and is prohibited under this paragraph (d).

Example 7. (i) *Facts.* Same facts as *Example 6,* except that the last question goes on to state, ''In answering this question, you

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

(ii) *Conclusion.* In this *Example 7,* the plan's request for medical information explicitly states that genetic information should not be provided. Therefore, any genetic information collected in response to the question is within the incidental collection exception. However, the plan may not use any genetic information it obtains incidentally for underwriting purposes.

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

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

(e) *Examples regarding determinations of medical appropriateness.* The application of the rules of paragraphs (c) and (d) of this section to plan or issuer determinations of medical appropriateness is illustrated by the following examples:

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

(ii) *Conclusion.* In this *Example 1,* under the rules of paragraph (c)(4) of this section the issuer is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for the issuer to make a decision regarding the payment of *A's* claim, the issuer's request for the results of the genetic test violates paragraph (c) of this section.

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

(ii) *Conclusion.* In this *Example 2,* the plan does not violate paragraphs (c) or (d) of this section. Under paragraph (c), the plan is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the plan requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the genetic makeup of the patient, the minimum amount of information necessary includes the results of the genetic test. Similarly, the plan does not violate paragraph (d) of this section because the plan is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and if the genetic information is not used for underwriting purposes).

Example 3. (i) *Facts.* Individual *C* was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of *C*'s physician, *C* has been taking a regular dose of tamoxifen to help prevent a recurrence. *C*'s group health plan adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients, those with certain variations of the gene for making the CYP_2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, the plan does not pay for the tamoxifen prescription.

(ii) *Conclusion.* In this *Example 3,* the plan does not violate paragraph (c) of this section if it conditions future payments for the tamoxifen prescription on *C*'s undergoing a genetic test to determine what genetic markers *C* has for making the CYP_2D6 enzyme. Nor does the plan violate paragraph (c) of this section if the plan refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *C.*

Example 4. (i) *Facts.* A group health plan offers a diabetes disease management program to all similarly situated individuals for whom it is medically appropriate based on whether the individuals have or are at risk for diabetes. The program provides enhanced benefits related only to diabetes for individuals who qualify for the program. The plan sends out a notice to all participants that describes the diabetes disease management program and explains the terms for eligibility. Individuals interested in enrolling in the program are advised to contact the plan to demonstrate that they have diabetes or that they are at risk for diabetes. For individuals who do not currently have diabetes, genetic information may be used to demonstrate that an individual is at risk.

(ii) *Conclusion.* In this *Example 4,* the plan may condition benefits under the disease management program upon a showing by an individual that the individual is at risk for diabetes, even if such showing may involve genetic information, provided that the plan requests genetic information only when necessary to make a determination regarding whether the disease management program is medically appropriate for the individual and only requests the minimum amount of information necessary to make that determination.

Example 5. (i) *Facts.* Same facts as *Example 4,* except that the plan includes a questionnaire that asks about the occurrence of diabetes in members of the individual's family as part of the notice describing the disease management program.

(ii) *Conclusion.* In this *Example 5,* the plan violates the requirements of paragraph (d)(1) of this section because the requests for genetic information are not limited to those situations in which it is necessary to make a determination regarding whether the disease management program is medically appropriate for the individuals.

Example 6. (i) *Facts.* Same facts as *Example 4,* except the disease management program provides an enhanced benefit in the form of a lower annual deductible to individuals under the program; the lower deductible applies with respect to all medical expenses incurred by the individual. Thus, whether or not a claim relates to diabetes, the individual is provided with a lower deductible based on the individual providing the plan with genetic information.

(ii) *Conclusion.* In this *Example 6,* because the enhanced benefits include benefits not related to the determination of medical appropriateness, making available the enhanced benefits is within the meaning of underwriting purposes. Accordingly, the plan may not request or require genetic information (including family history information) in determining eligibility for enhanced benefits under the program because such a request would be for underwriting purposes and would violate paragraph (d)(1) of this section.

(f) *Applicability date.* This section applies for plan years beginning on or after December 7, 2009.

■ 6. Section 2590.732 is amended to revise paragraph (b) as follows:

§ 2590.732 Special rules relating to group health plans.

* * * * *

(b) *General exception for certain small group health plans*—(1) Subject to paragraph (b)(2) of this section, the requirements of this part do not apply to any group health plan (and group health insurance coverage) for any plan year, if on the first day of the plan year, the plan has fewer than two participants who are current employees.

(2) The following requirements apply without regard to paragraph (b)(1) of this section:

(i) Section 2590.701–3(b)(6) of this Part.

(ii) Section 2590.702(b) of this Part, as such section applies with respect to genetic information as a health factor.

(iii) Section 2590.702(c) of this Part, as such section applies with respect to genetic information as a health factor.

(iv) Section 2590.702(e) of this Part, as such section applies with respect to genetic information as a health factor.

(v) Section 2590.702–1(b) of this Part.

(vi) Section 2590.702–1(c) of this Part.

(vii) Section 2590.702–1(d) of this Part.

(viii) Section 2590.702–1(e) of this Part.

(ix) Section 2590.711 of this Part.

* * * * *

Signed at Washington, DC, this 21st day of August 2009.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

Department of Health and Human Services

45 CFR Subtitle A

■ For the reasons set forth in the preamble, the Department of Health and Human Services is amending 45 CFR Subtitle A, Subchapter B as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 is revised to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

§ 144.101 Basis and purpose.

■ 2. Section 144.101 is amended by revising paragraph (a) to read as follows:

(a) Part 146 of this subchapter implements sections 2701 through 2723, 2791 and 2792 of the Public Health Service Act (PHS Act, 42 U.S.C. 300gg through 42 U.S.C. 300gg–23, 300gg–91, and 300gg–92.).

* * * * *

■ 3. Section 144.103 is amended by revising the definition of ''genetic information'' to read as follows:

§ 144.103 Definitions.

* * * * *

Genetic information has the meaning specified in § 146.122(a) of this subchapter.

* * * * *

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 4. The authority citation for part 146 is revised to read as follows:

Authority: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92).

■ 5. Section 146.101 is amended by—

■ A. Revising the first sentence of paragraph (a).

■ B. Adding a new paragraph (b)(1)(vii).

The revision and addition read as follows:

§ 146.101 Basis and scope.

(a) * * *. This part implements sections 2701 through 2723, 2791, and 2792 of the PHS Act. * * *

(b) * * *

(1) * * *

(vii) Additional requirements prohibiting discrimination against participants and beneficiaries based on genetic information.

* * * * *

■ 6. Section 146.121 is amended by—

■ A. Revising paragraph (a)(1)(vii).

■ B. Revising paragraph (c)(2)(i).

■ C. Republishing paragraph (c)(2)(iii) (Example 1) (i).

■ D. Revising paragraph (c)(2)(iii) (Example 1) (ii).

The revisions and republication read as follows:

§ 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) * * *

(1) * * *

(vi) Genetic information, as defined in § 146.122(a) of this subchapter;

* * * * *

(c) * * *

(2) * * *

(i) *Group rating based on health factors not restricted under this section.* Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan. But *see* § 146.122(b) of this part, which prohibits adjustments in group premium or contribution rates based on genetic information.

* * * * *

(iii) * * *

Example 1. (i) *Facts.* An employer sponsors a group health plan and purchases coverage from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual *F* had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of *F*'s claims experience.

(ii) *Conclusion.* In this *Example 1*, the issuer does not violate the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for *F* than for a similarly situated individual based on *F*'s claims experience. (However, if the issuer used genetic information in computing the group rate, it would violate § 146.122(b) of this part.)

* * * * *

■ 7. Add a new § 146.122 to read as follows:

§ 146.122 Additional requirements prohibiting discrimination based on genetic information.

(a) *Definitions.* Unless otherwise provided, the definitions in this paragraph (a) govern in applying the provisions of this section.

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

(2) *Family member* means, with respect to an individual—

(i) A dependent (as defined in § 144.103 of this part) of the individual; or

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

(A) First-degree relatives include parents, spouses, siblings, and children.

(B) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.

(C) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(D) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

(3) *Genetic information* means—

(i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, with respect to an individual, information about—

(A) The individual's genetic tests (as defined in paragraph (a)(5) of this section);

(B) The genetic tests of family members of the individual;

(C) The manifestation (as defined in paragraph (a)(6) of this section) of a disease or disorder in family members of the individual; or

(D) Any request for, or receipt of, genetic services (as defined in paragraph (a)(4) of this section), or participation in clinical research which includes genetic

services, by the individual or any family member of the individual.

(ii) The term *genetic information* does not include information about the sex or age of any individual.

(iii) The term *genetic information* includes—

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

(B) With respect to an individual (or a family member of the individual) who is utilizing an assisted reproductive technology, genetic information of any embryo legally held by the individual or family member.

(4) *Genetic services* means —

(i) A genetic test, as defined in paragraph (a)(5) of this section;

(ii) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(iii) Genetic education.

(5)(i) *Genetic test* means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. However, a genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. Accordingly, a test to determine whether an individual has a 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. However, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test.

(ii) The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* Individual *A* is a newborn covered under a group health plan. *A* undergoes a phenylketonuria (PKU) screening, which measures the concentration of a metabolite, phenylalanine, in *A's* blood. In PKU, a mutation occurs in the phenylalanine hydroxylase (PAH) gene which contains instructions for making the enzyme needed to break down the amino acid phenylalanine. Individuals with the mutation, who have a deficiency in the enzyme to break down phenylalanine, have high concentrations of phenylalanine.

(ii) *Conclusion.* In this *Example*, the PKU screening is a genetic test with respect to *A* because the screening is an analysis of metabolites that detects a genetic mutation.

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

(ii) The rules of this paragraph (a)(6) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* has a family medical history of diabetes. *A* begins to experience excessive sweating, thirst, and fatigue. *A's* physician examines *A* and orders blood glucose testing (which is not a genetic test). Based on the physician's examination, *A's* symptoms, and test results that show elevated levels of blood glucose, *A's* physician diagnoses *A* as having adult onset diabetes mellitus (Type 2 diabetes).

(ii) *Conclusion.* In this *Example 1, A* has been diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved. The diagnosis is not based principally on genetic information. Thus, Type 2 diabetes is manifested with respect to *A.*

Example 2. (i) *Facts.* Individual *B* has several family members with colon cancer. One of them underwent genetic testing which detected a mutation in the MSH2 gene associated with hereditary nonpolyposis colorectal cancer (HNPCC). *B's* physician, a health care professional with appropriate training and expertise in the field of medicine involved, recommends that *B* undergo a targeted genetic test to look for the specific mutation found in *B's* relative to determine if *B* has an elevated risk for cancer. The genetic test with respect to *B* showed that *B* also carries the mutation and is at increased risk to develop colorectal and other cancers associated with HNPCC. *B* has a colonoscopy which indicates no signs of disease, and *B* has no symptoms.

(ii) *Conclusion.* In this *Example 2,* because *B* has no signs or symptoms of colorectal cancer, *B* has not been and could not reasonably be diagnosed with HNPCC. Thus, HNPCC is not manifested with respect to *B.*

Example 3. (i) *Facts.* Same facts as *Example 2*, except that *B's* colonoscopy and subsequent tests indicate the presence of HNPCC. Based on the colonoscopy and subsequent test results, *B's* physician makes a diagnosis of HNPCC.

(ii) *Conclusion.* In this *Example 3*, HNPCC is manifested with respect to *B* because a health care professional with appropriate training and expertise in the field of medicine involved has made a diagnosis that is not based principally on genetic information.

Example 4. (i) *Facts.* Individual *C* has a family member that has been diagnosed with Huntington's Disease. A genetic test indicates that *C* has the Huntington's Disease gene variant. At age 42, *C* begins suffering from occasional moodiness and disorientation, symptoms which are associated with Huntington's Disease. *C* is examined by a neurologist (a physician with appropriate training and expertise for diagnosing Huntington's Disease). The examination includes a clinical neurological exam. The results of the examination do not support a diagnosis of Huntington's Disease.

(ii) *Conclusion.* In this *Example 4, C* is not and could not reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is not manifested with respect to *C.*

Example 5. (i) *Facts.* Same facts as *Example 4*, except that *C* exhibits additional neurological and behavioral symptoms, and the results of the examination support a diagnosis of Huntington's Disease with respect to *C.*

(ii) *Conclusion.* In this *Example 5, C* could reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is manifested with respect to *C.*

(7) *Underwriting purposes* has the meaning given in paragraph (d)(1) of this section.

(b) *No group-based discrimination based on genetic information*—(1) *In general.* For purposes of this section, a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not adjust premium or contribution amounts for the plan, or any group of similarly situated individuals under the plan, on the basis of genetic information. For this purpose, ''similarly situated individuals'' are those described in § 146.121(d) of this part.

(2) *Rule of construction.* Nothing in paragraph (b)(1) of this section (or in paragraph (d)(1) or (d)(2) of this section) limits the ability of a health insurance issuer offering health insurance coverage in connection with a group health plan to increase the premium for a group health plan or a group of similarly situated individuals under the plan based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such a case, however, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members to further increase the premium for a group health plan or a group of similarly situated individuals under the plan.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that provides coverage through a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan and other health status information of the individuals, including genetic information. The issuer finds that three individuals covered under the plan had unusually high claims experience. In addition, the issuer finds that the genetic

information of two other individuals indicates the individuals have a higher probability of developing certain illnesses although the illnesses are not manifested at this time. The issuer quotes the plan a higher per-participant rate because of both the genetic information and the higher claims experience.

(ii) *Conclusion.* In this *Example 1*, the issuer violates the provisions of this paragraph (b) because the issuer adjusts the premium based on genetic information. However, if the adjustment related solely to claims experience, the adjustment would not violate the requirements of this section (nor would it violate the requirements of paragraph (c) of § 146.121 of this part, which prohibits discrimination in individual premiums or contributions based on a health factor but permits increases in the group rate based on a health factor).

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

(ii) *Conclusion.* In this *Example 2*, the issuer violates the provisions of this paragraph (b) because, by taking the likelihood that *A's* children may develop polycystic kidney disease into account in computing the rate for the plan, the issuer adjusts the premium based on genetic information relating to a condition that has not been manifested in *A's* children. However, it is permissible for the issuer to increase the premium based on *A's* claims experience.

(c) *Limitation on requesting or requiring genetic testing*—(1) *General rule.* Except as otherwise provided in this paragraph (c), a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test.* Nothing in paragraph (c)(1) of this section limits the authority of a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test.

(3) *Examples.* The rules of paragraphs (c)(1) and (2) of this section are illustrated by the following examples:

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

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

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

(ii) *Conclusion.* In this *Example 2,* even though the physician is employed by the HMO, the physician is nonetheless a health care professional who is providing health care services to *B.* Therefore, the physician's recommendation that *B* undergo the genetic test does not violate this paragraph (c).

(4) *Determination regarding payment.*

(i) *In general.* As provided in this paragraph (c)(4), nothing in paragraph (c)(1) of this section precludes a plan or issuer from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, ''payment'' has the meaning given such term in § 164.501 of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if a plan or issuer conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on the genetic makeup of a patient, then the plan or issuer is permitted to condition payment for the item or service on the outcome of a genetic test. The plan or issuer may also refuse payment if the patient does not undergo the genetic test.

(ii) *Limitation.* A plan or issuer is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in § 164.502(b) of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples. See* paragraph (e) of this section for examples illustrating the rules of this paragraph (c)(4), as well as other provisions of this section.

(5) *Research exception.* Notwithstanding paragraph (c)(1) of this section, a plan or issuer may request, but not require, that a participant or beneficiary undergo a genetic test if all of the conditions of this paragraph (c)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local law or regulations.* The plan or issuer makes the request pursuant to research, as defined in § 46.102(d) of this subtitle, that complies with part 46 of this subtitle or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) *Written request for participation in research.* The plan or issuer makes the request in writing, and the request clearly indicates to each participant or beneficiary (or, in the case of a minor child, to the legal guardian of the beneficiary) that –

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in § 146.121(b)(1) of this part) or premium or contribution amounts.

(iii) *Prohibition on underwriting.* No genetic information collected or acquired under this paragraph (c)(5) can be used for underwriting purposes (as described in paragraph (d)(1) of this section).

(iv) *Notice to Federal agencies.* The plan or issuer completes a copy of the ''Notice of Research Exception under the Genetic Information Nondiscrimination Act'' authorized by the Secretary and provides the notice to the address specified in the instructions thereto.

(d) *Prohibitions on collection of genetic information.*

(1) *For underwriting purposes.*

(i) *General rule.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not collect (as defined in paragraph (a)(1) of this section) genetic information for underwriting purposes. *See* paragraph (e) of this section for examples illustrating the rules of this paragraph (d)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (d)(1)(iii) of this section, *underwriting purposes* means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage as described in § 146.121(b)(1)(ii) of this part (including changes in deductibles or other cost-

sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(B) The computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(C) The application of any preexisting condition exclusion under the plan or coverage; and

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

(iii) *Medical appropriateness.* If an individual seeks a benefit under a group health plan or health insurance coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an individual seeks a benefit under the plan and the plan or issuer conditions the benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on genetic information of the individual, then the plan or issuer is permitted to condition the benefit on the genetic information. A plan or issuer is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness. The plan or issuer may deny the benefit if the patient does not provide the genetic information required to determine medical appropriateness. If an individual is not seeking a benefit, the medical appropriateness exception of this paragraph (d)(1)(iii) to the definition of underwriting purposes does not apply. *See* paragraph (e) of this section for examples illustrating the medical appropriateness provisions of this paragraph (d)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment.* (i) *In general.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not collect genetic information with respect to any individual prior to that individual's effective date of coverage under that plan or coverage, nor in connection with the rules for eligibility (as defined in § 146.121(b)(1)(ii) of this part) that apply to that individual. Whether or not an individual's information is collected prior to that individual's effective date of coverage is determined at the time of collection.

(ii) *Incidental collection exception.*

(A) *In general.* If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (d)(2), as long as the collection is not for underwriting purposes in violation of paragraph (d)(1) of this section.

(B) *Limitation.* The incidental collection exception of this paragraph (d)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly states that genetic information should not be provided.

(3) *Examples.* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides a premium reduction to enrollees who complete a health risk assessment. The health risk assessment is requested to be completed after enrollment. Whether or not it is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The health risk assessment includes questions about the individual's family medical history.

(ii) *Conclusion.* In this *Example 1*, the health risk assessment includes a request for genetic information (that is, the individual's family medical history). Because completing the health risk assessment results in a premium reduction, the request for genetic information is for underwriting purposes. Consequently, the request violates the prohibition on the collection of genetic information in paragraph (d)(1) of this section.

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

(ii) *Conclusion.* In this *Example 2*, the request is not for underwriting purposes, nor is it prior to or in connection with enrollment. Therefore, it does not violate the prohibition on the collection of genetic information in this paragraph (d).

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

(ii) *Conclusion.* In this *Example 3*, because the health risk assessment includes a request for genetic information (that is, the individual's family medical history), and requests the information prior to enrollment, the request violates the prohibition on the collection of genetic information in paragraph (d)(2) of this section. Moreover, because it is a request for genetic information, it is not an incidental collection under paragraph (d)(2)(ii) of this section.

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

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

Example 5. (i) *Facts.* A group health plan requests enrollees to complete two distinct health risk assessments (HRAs) after and unrelated to enrollment. The first HRA instructs the individual to answer only for the individual and not for the individual's family. The first HRA does not ask about any genetic tests the individual has undergone or any genetic services the individual has received. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and the results of genetic tests the individual has undergone. The plan offers no reward for completing the second HRA and the instructions make clear that completion of the second HRA is wholly voluntary and will not affect the reward given for completion of the first HRA.

(ii) *Conclusion.* In this *Example 5*, no genetic information is collected in connection with the first HRA, which offers a reward, and no benefits or other rewards are conditioned on the request for genetic information in the second HRA. Consequently, the request for genetic information in the second HRA is not for underwriting purposes, and the two HRAs do not violate the prohibition on the collection of genetic information in this paragraph (d).

Example 6. (i) *Facts.* A group health plan waives its annual deductible for enrollees who complete an HRA. The HRA is requested to be completed after enrollment. Whether or not the HRA is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The HRA does not include any direct questions about the individual's genetic information (including family medical history). However, the last

question reads, ''Is there anything else relevant to your health that you would like us to know or discuss with you?''

(ii) *Conclusion.* In this *Example 6*, the plan's request for medical information does not explicitly state that genetic information should not be provided. Therefore, any genetic information collected in response to the question is not within the incidental collection exception and is prohibited under this paragraph (d).

Example 7. (i) *Facts.* Same facts as *Example 6*, except that the last question goes on to state, ''In answering this question, you should not include any genetic information. That is, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk.''

(ii) *Conclusion.* In this *Example 7*, the plan's request for medical information explicitly states that genetic information should not be provided. Therefore, any genetic information collected in response to the question is within the incidental collection exception. However, the plan may not use any genetic information it obtains incidentally for underwriting purposes.

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

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

(e) *Examples regarding determinations of medical appropriateness.* The application of the rules of paragraphs (c) and (d) of this section to plan or issuer determinations of medical appropriateness is illustrated by the following examples:

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

(ii) *Conclusion.* In this *Example 1*, under the rules of paragraph (c)(4) of this section the issuer is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for the issuer to make a decision regarding the payment of *A*'s claim, the issuer's request for the results of the genetic test violates paragraph (c) of this section.

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

(ii) *Conclusion.* In this *Example 2*, the plan does not violate paragraphs (c) or (d) of this section. Under paragraph (c), the plan is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the plan requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the genetic makeup of the patient, the minimum amount of information necessary includes the results of the genetic test. Similarly, the plan does not violate paragraph (d) of this section because the plan is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and if the genetic information is not used for underwriting purposes).

Example 3. (i) *Facts.* Individual *C* was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of *C*'s physician, *C* has been taking a regular dose of tamoxifen to help prevent a recurrence. *C*'s group health plan adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients, those with certain variations of the gene for making the CYP_2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, the plan does not pay for the tamoxifen prescription.

(ii) *Conclusion.* In this *Example 3,* the plan does not violate paragraph (c) of this section if it conditions future payments for the tamoxifen prescription on *C*'s undergoing a genetic test to determine what genetic markers *C* has for making the CYP_2D6 enzyme. Nor does the plan violate paragraph (c) of this section if the plan refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *C.*

Example 4. (i) *Facts.* A group health plan offers a diabetes disease management program to all similarly situated individuals for whom it is medically appropriate based on whether the individuals have or are at risk for diabetes. The program provides enhanced benefits related only to diabetes for individuals who qualify for the program. The plan sends out a notice to all participants that describes the diabetes disease management program and explains the terms for eligibility. Individuals interested in enrolling in the program are advised to contact the plan to demonstrate that they have diabetes or that they are at risk for diabetes. For individuals who do not currently have diabetes, genetic information may be used to demonstrate that an individual is at risk.

(ii) *Conclusion.* In this *Example 4*, the plan may condition benefits under the disease management program upon a showing by an individual that the individual is at risk for diabetes, even if such showing may involve genetic information, provided that the plan requests genetic information only when necessary to make a determination regarding whether the disease management program is medically appropriate for the individual and only requests the minimum amount of information necessary to make that determination.

Example 5. (i) *Facts.* Same facts as *Example 4*, except that the plan includes a questionnaire that asks about the occurrence of diabetes in members of the individual's family as part of the notice describing the disease management program.

(ii) *Conclusion.* In this *Example 5*, the plan violates the requirements of paragraph (d)(1) of this section because the requests for genetic information are not limited to those situations in which it is necessary to make a determination regarding whether the disease management program is medically appropriate for the individuals.

Example 6. (i) *Facts.* Same facts as *Example 4*, except the disease management program provides an enhanced benefit in the form of a lower annual deductible to individuals under the program; the lower deductible applies with respect to all medical expenses incurred by the individual. Thus, whether or not a claim relates to diabetes, the individual is provided with a lower deductible based on the individual providing the plan with genetic information.

(ii) *Conclusion.* In this *Example 6*, because the enhanced benefits include benefits not related to the determination of medical appropriateness, making available the enhanced benefits is within the meaning of underwriting purposes. Accordingly, the plan may not request or require genetic information (including family history information) in determining eligibility for enhanced benefits under the program because such a request would be for underwriting purposes and would violate paragraph (d)(1) of this section.

(f) *Applicability date.* This section applies for plan years beginning on or after December 7, 2009.

■ 8. Section 146.145 is amended by revising paragraph (b) as follows:

§ 146.145 Special rules relating to group health plans.

* * * * *

(b) *General exception for certain small group health plans.* The requirements of this part, other than § 146.130 and the provisions with respect to genetic

nondiscrimination (found in § 146.111(b)(6), § 146.121(b), § 146.121(c), § 146.121(e), § 146.122(b), § 146.122(c), § 146.122(d), and § 146.122(e)) do not apply to any group health plan (and group health insurance coverage) for any plan year, if on the first day of the plan year, the plan has fewer than two participants who are current employees.

* * * * *

■ 9. Section 146.180 is amended by—

■ A. Revising paragraph (a)(1)(iii).

■ B. Revising paragraph (h).

■ C. In paragraph (i), removing the reference ''(h)'' and added the reference ''(h)(1)'' in its place each time it appears.

■ D. Revising the last sentence of paragraph (k).

The revisions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) * * *

(1) * * *

(iii) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in § 146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from the requirements in § 146.121(a)(1)(vi) and § 146.122 that prohibit discrimination with respect to genetic information.

* * * * *

(h) *Requirements not subject to exemption.*

(1) *Certification and disclosure of creditable coverage.* Without regard to an election under this section, a non-Federal governmental plan must provide for certification and disclosure of creditable coverage under the plan with respect to participants and their dependents as specified under § 146.115 of this part.

(2) *Genetic information.* Without regard to an election under this section that exempts a non-Federal governmental plan from any or all of the provisions of § 146.111 and § 146.121 of this part, the exemption election must not be construed to exempt the plan from any provisions of this part 146 that pertain to genetic information.

(3) *Enforcement.* CMS enforces these requirements as provided under paragraph (k) of this section.

(4) *Examples.*

(i)

Example 1. (A) Individual *A* is hired by a county that has elected to exempt its self-funded group health plan from certain requirements of paragraph (a)(1) of this section, including prohibitions against enrollment discrimination based on health status-related factors. Individual *A* applies for enrollment in the county's group health plan. Applicants must pass medical underwriting before being allowed to enroll in the plan. The plan requires an applicant to complete a medical history form and to authorize the plan to contact physicians regarding any medical treatments the applicant has received in the past 5 years. Individual *A* has Type 2 diabetes. He submits the required form, which reflects that condition. The plan also receives information from Individual *A's* physicians. While the plan's request to Individual *A's* physicians did not include a request for genetic information, the plan received information from a physician in response to its request for health information about Individual *A,* that one of Individual *A's* parents has Huntington's Disease. The Plan denies enrollment to Individual *A.*

(B) Individual *A* files a complaint with CMS that he has been denied enrollment in the plan because of genetic information the plan received. CMS investigates the complaint and determines that the plan uniformly denies enrollment to anyone who has Type II diabetes. CMS resolves the complaint in favor of the plan on the basis that the plan permissibly denied enrollment to Individual *A* under its exemption election because of the existence of a medical condition that uniformly disqualifies individuals from participating in the plan.

(ii)

Example 2. (A) Same facts as in *Example 1,* except Individual *A* does not have diabetes or any other preexisting medical condition; that is, there is no manifestation of a disease or disorder with respect to Individual *A* at the time of his application for enrollment in the county's group health plan.

(B) In these circumstances, CMS resolves the complaint in favor of Individual *A* because CMS determines that the plan impermissibly denied enrollment to Individual *A* on the basis of genetic information. CMS instructs the plan to permit Individual *A* to enroll in the plan retroactive to the earliest date coverage would be effective under the terms of the plan based on the date of Individual *A's* enrollment application or hire, as applicable. CMS may impose a civil money penalty, as determined under subpart C of part 150.

* * * * *

(k) * * *. This may include imposing a civil money penalty against the plan or plan sponsor, as determined under subpart C of part 150.

* * * * *

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 10. The authority citation for part 148 continues to read as follows:

Authority: Secs. 2741 through 2763, 2791, and 2792 of the Public Health Service Act, 42 U.S.C. 300gg–41 through 300gg–63, 300gg–91, and 300gg–92.

■ 11. Section 148.101 is amended by revising the last sentence to read as follows:

§ 148.101 Basis and purpose.

* * *. It also provides certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth and protects all individuals and family members who have, or seek, individual health insurance coverage from discrimination based on genetic information.

■ 12. Section 148.102 is amended by revising the last sentence of paragraph (a)(2) and paragraph (b) to read as follows:

§ 148.102 Scope, applicability, and effective dates.

(a) * * *

(2) * * *. The requirements that pertain to guaranteed renewability for all individuals, to protections for mothers and newborns with respect to hospital stays in connection with childbirth, and to protections against discrimination based on genetic information apply to all issuers of individual health insurance coverage in the State, regardless of whether a State implements an alternative mechanism under § 148.128 of this part.

(b) *Effective date.* Except as provided in § 148.124 (certificate of creditable coverage), § 148.128 (alternative State mechanisms), § 148.170 (standards relating to benefits for mothers and newborns), and § 148.180 (prohibition of health discrimination based on genetic information) of this part, the requirements of this part apply to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs.

§ 148.120 [Amended]

■ 13. Section 148.120 is amended by—

■ A. In paragraphs (c)(5)(ii), (d)(2), and (e)(2) removing the cross-reference ''§ 148.200'' and adding in its place the cross-reference ''part 150'' each time it appears.

■ B. In paragraph (f)(1) removing the term ''If'' and adding in its place the phrase ''Except as prohibited by § 148.180, if''.

■ C. In paragraph (g)(4) removing the term ''This'' and adding in its place the phrase ''Except as prohibited by § 148.180, this''.

■ 14. A new § 148.180 is added to subpart C to read as follows:

§ 148.180 Prohibition of discrimination based on genetic information.

(a) *Definitions.* For purposes of this section, the following definitions as set forth in § 146.122 of this subchapter pertain to health insurance issuers in the individual market to the extent that those definitions are not inconsistent with respect to health insurance coverage offered, sold, issued, renewed, in effect or operated in the individual market:

Collect has the meaning set forth at § 146.122(a).

Family member has the meaning set forth at § 146.122(a).

Genetic information has the meaning set forth at § 146.122(a).

Genetic services has the meaning set forth at § 146.122(a).

Genetic test has the meaning set forth at § 146.122(a).

Manifestation or manifested has the meaning set forth at § 146.122(a).

Preexisting condition exclusion has the meaning set forth at § 144.103.

Underwriting purposes has the meaning set forth at § 148.180(f)(1).

(b) *Prohibition on genetic information as a condition of eligibility.*

(1) *In general.* An issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information.

(2) *Rule of construction.* Nothing in paragraph (b)(1) of this section precludes an issuer from establishing rules for eligibility for an individual to enroll in individual health insurance coverage based on the manifestation of a disease or disorder in that individual, or in a family member of that individual when the family member is covered under the policy that covers the individual.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* A State implements the HIPAA guaranteed availability requirement in the individual health insurance market in accordance with § 148.120. Individual *A* and his spouse *S* are not ''eligible individuals'' as that term is defined at § 148.103 and, therefore, they are not entitled to obtain individual health insurance coverage on a guaranteed available basis. They apply for individual coverage with Issuer *M.* As part of the application for coverage, *M* receives health information about *A* and *S.* Although *A* has no known medical conditions, *S* has high blood pressure. *M* declines to offer coverage to *S.*

(ii) *Conclusion.* In this *Example 1, M* permissibly may decline to offer coverage to *S* because *S* has a manifested disorder (high blood pressure) that makes her ineligible for coverage under the policy's rules for eligibility.

Example 2. (i) *Facts.* Same facts as *Example 1,* except that *S* does not have high blood pressure or any other known medical condition. The only health information relevant to *S* that *M* receives in the application indicates that both of *S*'s parents are overweight and have high blood pressure. *M* declines to offer coverage to *S.*

(ii) *Conclusion.* In this *Example 2, M* cannot decline to offer coverage to *S* because *S* does not have a manifested disease or disorder. The only health information *M* has that relates to her pertains to a manifested disease or disorder of family members, which as family medical history constitutes genetic information with respect to *S.* If *M* denies eligibility to *S* based on genetic information, the denial will violate this paragraph (b).

(c) *Prohibition on genetic information in setting premium rates.*

(1) *In general.* An issuer offering health insurance coverage in the individual market must not adjust premium amounts for an individual on the basis of genetic information regarding the individual or a family member of the individual.

(2) *Rule of construction.* (i) Nothing in paragraph (c)(1) of this section precludes an issuer from adjusting premium amounts for an individual on the basis of a manifestation of a disease or disorder in that individual, or on the basis of a manifestation of a disease or disorder in a family member of that individual when the family member is covered under the policy that covers the individual.

(ii) The manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals covered under the policy issued to that individual and to further increase premium amounts.

(3) *Examples.* The rules of this paragraph (c) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *B* is covered under an individual health insurance policy through Issuer *N.* Every other policy year, before renewal, *N* requires policyholders to submit updated health information before the policy renewal date for purposes of determining an appropriate premium, in excess of any increases due to inflation, based on the policyholders' health status. *B* complies with that requirement. During the past year, *B*'s blood glucose levels have increased significantly. *N* increases its premium for renewing *B*'s policy to account for *N*'s increased risk associated with *B*'s elevated blood glucose levels.

(ii) *Conclusion.* In this *Example 1, N* is permitted to increase the premium for *B*'s policy on the basis of a manifested disorder (elevated blood glucose) in *B.*

Example 2. (i) *Facts.* Same facts as *Example 1,* except that *B*'s blood glucose levels have not increased and are well within the normal range. In providing updated health information to *N, B* indicates that both his mother and sister are being treated for adult onset diabetes mellitus (Type 2 diabetes). *B* provides this information voluntarily and not in response to a specific request for family medical history or other genetic information. *N* increases *B*'s premium to account for *B*'s genetic predisposition to develop Type 2 diabetes in the future.

(ii) *Conclusion.* In this *Example 2, N* cannot increase *B*'s premium on the basis of *B*'s family medical history of Type 2 diabetes, which is genetic information with respect to *B.* Since there is no manifestation of the disease in *B* at this point in time, *N* cannot increase *B*'s premium.

(d) *Prohibition on genetic information as preexisting condition.*

(1) *In general.* An issuer offering health insurance coverage in the individual market may not, on the basis of genetic information, impose any preexisting condition exclusion with respect to that coverage.

(2) *Rule of construction.* Nothing in paragraph (d)(1) of this section precludes an issuer from imposing any preexisting condition exclusion for an individual with respect to health insurance coverage on the basis of a manifestation of a disease or disorder in that individual.

(3) *Examples:* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *C* has encountered delays in receiving payment from the issuer of his individual health insurance policy for covered services. He decides to switch carriers and applies for an individual health insurance policy through Issuer *O. C* is generally in good health, but has arthritis for which he has received medical treatment. *O* offers *C* an individual policy that excludes coverage for a 12-month period for any services related to *C*'s arthritis.

(ii) *Conclusion.* In this *Example 1, O* is permitted to impose a preexisting condition exclusion with respect to *C* because *C* has a manifested disease (arthritis).

Example 2. (i) *Facts.* Individual *D* applies for individual health insurance coverage through Issuer *P. D* has no known medical conditions. However, in response to *P*'s request for medical information about *D, P* receives information from *D*'s physician that indicates that both of *D*'s parents have adult onset diabetes mellitus (Type 2 diabetes). *P* offers *D* an individual policy with a rider that permanently excludes coverage for any treatment related to diabetes that *D* may receive while covered by the policy, based on the fact that both of *D*'s parents have the disease.

(ii) *Conclusion.* In this *Example 2,* the rider violates this paragraph (d) because the preexisting condition exclusion is based on genetic information with respect to *D* (family medical history of Type 2 diabetes).

(e) *Limitation on requesting or requiring genetic testing.*

(1) *General rule.* Except as otherwise provided in this paragraph (e), an issuer

offering health insurance coverage in the individual market must not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test.* Nothing in paragraph (e)(1) of this section limits the authority of a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test.

(3) *Examples.* The rules of paragraphs (e)(1) and (e)(2) of this section are illustrated by the following examples:

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

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

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

(ii) *Conclusion.* In this *Example 2,* even though the physician is employed by the HMO, the physician is nonetheless a health care professional who is providing health care services to *F.* Therefore, the physician's recommendation that *F* undergo the genetic test does not violate this paragraph (e).

(4) *Determination regarding payment.* (i) *In general.* As provided in this paragraph (e)(4), nothing in paragraph (e)(1) of this section precludes an issuer offering health insurance in the individual market from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, ''payment'' has the meaning given such term in § 164.501 of this subtitle of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if an issuer conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on a covered individual's genetic makeup, the issuer is permitted to condition payment on the outcome of a genetic test, and may refuse payment if the covered individual does not undergo the genetic test.

(ii) *Limitation.* An issuer in the individual market is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in § 164.502(b) of this subtitle of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples. See* paragraph (g) of this section for examples illustrating the rules of this paragraph (e)(4), as well as other provisions of this section.

(5) *Research exception.* Notwithstanding paragraph (e)(1) of this section, an issuer may request, but not require, that an individual or family member covered under the same policy undergo a genetic test if all of the conditions of this paragraph (e)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local law or regulations.* The issuer makes the request pursuant to research, as defined in § 46.102(d) of this subtitle, that complies with Part 46 of this subtitle or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) *Written request for participation in research.* The issuer makes the request in writing, and the request clearly indicates to each individual (or, in the case of a minor child, to the child's legal guardian) that—

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in paragraph (b) of this section) or premium amounts (as described in paragraph (c) of this section).

(iii) *Prohibition on underwriting.* No genetic information collected or acquired under this paragraph (e)(5) can be used for underwriting purposes (as described in paragraph (f)(1) of this section).

(iv) *Notice to Federal agencies.* The issuer completes a copy of the ''Notice of Research Exception under the Genetic Information Nondiscrimination Act'' authorized by the Secretary and provides the notice to the address specified in the instructions thereto.

(f) *Prohibitions on collection of genetic information.*

(1) *For underwriting purposes.*

(i) *General rule.* An issuer offering health insurance coverage in the individual market must not collect (as defined in paragraph (a) of this section) genetic information for underwriting purposes. *See* paragraph (g) of this section for examples illustrating the rules of this paragraph (f)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (f)(1)(iii) of this section, *underwriting purposes* means, with respect to any issuer offering health insurance coverage in the individual market—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the coverage;

(B) The computation of premium amounts under the coverage;

(C) The application of any preexisting condition exclusion under the coverage; and

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

(iii) *Medical appropriateness.* An issuer in the individual market may limit or exclude a benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an issuer conditions a benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on a covered individual's genetic information, the issuer is permitted to condition the benefit on the genetic information. An issuer is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness, and may deny the benefit if the covered individual does not provide the genetic information required to determine medical appropriateness. *See* paragraph (g) of this section for examples illustrating the applicability of this paragraph (f)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment.*

(i) *In general.* An issuer offering health insurance coverage in the individual market must not collect genetic information with respect to any individual prior to that individual's enrollment under the coverage or in connection with that individual's enrollment. Whether or not an individual's information is collected prior to that individual's enrollment is determined at the time of collection.

(ii) *Incidental collection exception.*

(A) *In general.* If an issuer offering health insurance coverage in the individual market obtains genetic information incidental to the collection

of other information concerning any individual, the collection is not a violation of this paragraph (f)(2), as long as the collection is not for underwriting purposes in violation of paragraph (f)(1) of this section.

(B) *Limitation.* The incidental collection exception of this paragraph (f)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly provides that genetic information should not be provided.

(iii) *Examples.* The rules of this paragraph (f)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *G* applies for a health insurance policy through Issuer *Q. Q*'s application materials ask for the applicant's medical history, but not for family medical history. The application's instructions state that no genetic information, including family medical history, should be provided. *G* answers the questions in the application completely and truthfully, but volunteers certain health information about diseases his parents had, believing that *Q* also needs this information.

(ii) *Conclusion.* In this *Example 1, G*'s family medical history is genetic information with respect to *G.* However, since *Q* did not request this genetic information, and *Q*'s instructions stated that no genetic information should be provided, *Q*'s collection is an incidental collection under paragraph (f)(2)(ii). However, *Q* may not use the genetic information it obtained incidentally for underwriting purposes.

Example 2. (i) *Facts.* Individual *H* applies for a health insurance policy through Issuer *R. R*'s application materials request that an applicant provide information on his or her individual medical history, including the names and contact information of physicians from whom the applicant sought treatment. The application includes a release which authorizes the physicians to furnish information to *R. R* forwards a request for health information about *H,* including the signed release, to his primary care physician. Although the request for information does not ask for genetic information, including family medical history, it does not state that no genetic information should be provided. The physician's office administrator includes part of *H*'s family medical history in the package to *R.*

(ii) *Conclusion.* In this *Example 2, R*'s request was for health information solely about its applicant, *H,* which is not genetic information with respect to *H.* However, *R*'s materials did not state that genetic information should not be provided. Therefore, *R*'s collection of *H*'s family medical history (which is genetic information with respect to *H*), violates the rule against collection of genetic information and does not qualify for the incidental collection exception under paragraph (f)(2)(ii).

Example 3. (i) *Facts.* Issuer *S* acquires Issuer *T. S* requests *T*'s records, stating that *S* should not provide genetic information and should review the records to excise any genetic information. *T* assembles the data requested by *S* and, although *T* reviews it to delete genetic information, the data from a specific region included some individuals' family medical history. Consequently, *S* receives genetic information about some of *T*'s covered individuals.

(ii) *Conclusion.* In this *Example 3, S*'s request for health information explicitly stated that genetic information should not be provided. Therefore, its collection of genetic information was within the incidental collection exception. However, *S* may not use the genetic information it obtained incidentally for underwriting purposes.

(g) *Examples regarding determinations of medical appropriateness.* The application of the rules of paragraphs (e) and (f) of this section to issuer determinations of medical appropriateness is illustrated by the following examples:

Example 1. (i) *Facts.* Individual *I* has an individual health insurance policy through Issuer *U* that covers genetic testing for celiac disease for individuals who have family members with this condition. *I*'s policy includes dependent coverage. After *I*'s son is diagnosed with celiac disease, *I* undergoes a genetic test and promptly submits a claim for the test to *U* for reimbursement. *U* asks *I* to provide the results of the genetic test before the claim is paid.

(ii) *Conclusion.* In this *Example 1,* under the rules of paragraph (e)(4) of this section, *U* is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for *U* to make a decision regarding the payment of *I*'s claim, *U*'s request for the results of the genetic test violates paragraph (e) of this section.

Example 2. (i) *Facts.* Individual *J* has an individual health insurance policy through Issuer *V* that covers a yearly mammogram for participants starting at age 40, or at age 30 for those with increased risk for breast cancer, including individuals with BRCA1 or BRCA2 gene mutations. *J* is 33 years old and has the BRCA2 mutation. *J* undergoes a mammogram and promptly submits a claim to *V* for reimbursement. *V* asks *J* for evidence of increased risk of breast cancer, such as the results of a genetic test, before the claim for the mammogram is paid.

(ii) *Conclusion.* In this *Example 2, V* does not violate paragraphs (e) or (f) of this section. Under paragraph (e), an issuer is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the issuer requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the covered individual's genetic makeup, the minimum amount of information necessary includes the results of the genetic test. Similarly, *V* does not violate paragraph (f) of this section because an issuer is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and the genetic information is not used for underwriting purposes).

Example 3. (i) *Facts.* Individual *K* was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of *K*'s physician, *K* has been taking a regular dose of tamoxifen to help prevent a recurrence. *K* has an individual health insurance policy through Issuer *W* which adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients with certain variations of the gene for making the CYP_2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, *W* does not pay for the tamoxifen prescription.

(ii) *Conclusion.* In this *Example 3, W* does not violate paragraph (e) of this section if it conditions future payments for the tamoxifen prescription on *K*'s undergoing a genetic test to determine the genetic markers *K* has for making the CYP_2D6 enzyme. *W* also does not violate paragraph (e) of this section if it refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *K.*

(h) *Applicability date.* The provisions of this section are effective with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after December 7, 2009.

■ 15. The heading for subpart D is revised to read as follows:

Subpart D—Preemption; Excepted Benefits

■ 16. Section 148.220 is amended by adding two new sentences at the end of paragraph (b)(4) to read as follows:

§ 148.220 Excepted benefits.

* * * * *

(b) * * *

(4) * * *. The requirements of this part 148 (including genetic nondiscrimination requirements), do not apply to Medicare supplemental health insurance policies. However, Medicare supplemental health insurance policies are subject to similar genetic nondiscrimination requirements under section 104 of the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110–233), as incorporated into the NAIC Model Regulation relating to sections 1882(s)(2)(e) and (x) of the Act (The NAIC Model Regulation can be accessed at *http://www.naic.org.*).

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Approved: May 7, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 15, 2009.

Kathleen Sebelius,

Secretary.

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