DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG–123829–08]

RIN 1545–BI02

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB27

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CMS–4137–NC]

45 CFR Parts 144, 146, and 148

RIN 0938–AP37

Request for Information Regarding Sections 101 Through 104 of the Genetic Information Nondiscrimination Act of 2008

AGENCIES: 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: Request for Information.

SUMMARY: This document is a request for comments regarding issues under sections 101 through 104 of the Genetic Information Nondiscrimination Act of 2008 (GINA). The Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments) have received inquiries from the public on a number of issues under these provisions and are welcoming public comments in advance of future rulemaking.

DATES: Comments must be submitted on or before December 9, 2008.

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 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:* GINA Comments.

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 HHS. Comments to the Department of HHS, identified by CMS–4137–NC, 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–NC, 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) was enacted on May 21, 2008 (Pub. L. 110–233). Title I of GINA amends 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. Sections 101 through 104 of GINA apply to employment-based health coverage, individual market health insurance, and Medicare supplemental (MedSupp or Medigap) coverage. The new requirements were added to Part 7 of Subtitle B of Title I of ERISA, Title XXVII of the PHS Act, Subtitle K of the Code, and section 1882 of the SSA.

GINA prohibits group health plans and health insurance issuers (that is, insurance companies or health maintenance organizations (HMOs)) in the group market from using genetic information to adjust premium or contribution amounts for the group covered under the plan. Plans and issuers in the group market are still allowed to increase the premium rate for an employer based on the manifestation of a disease or disorder of an individual enrolled in the plan, but they are prohibited from using the manifested disease or disorder of one individual as genetic information about other group members to further increase the premium.

In the individual market, health insurance issuers are prohibited from using genetic information to determine individual eligibility or premium rates, although they are allowed (to the extent consistent with other provisions of law) to use information about a manifestation of a disease or disorder to determine eligibility or premium rates for an individual who is covered or would be covered by a policy. Individual market health insurance issuers are also prohibited from using genetic information in imposing a preexisting condition exclusion, although a manifestation of a disease or disorder in an individual can be the basis for an exclusion. In the MedSupp market, GINA prohibits issuers from denying or conditioning the issuance or effectiveness of a policy (including the imposition of any exclusion of benefits based on a preexisting condition) or discriminating in the pricing of the policy based on an individual's genetic condition. However, if otherwise permitted under section 1882 of the Social Security Act, the issuer can still impose such limitations based on a manifested disease of an individual who is covered or would be covered under the policy.

GINA also prohibits group health plans and health insurance issuers in the group, individual, and MedSupp markets from requesting or requiring an individual or family member of an individual to undergo a genetic test. Plans and issuers are not precluded from obtaining and using the results of a genetic test to make a determination regarding payment, but they may only use the minimum amount of information necessary.

GINA includes a research exception under which a group health plan or a health insurance issuer in the group, individual, or MedSupp market may request (but not require) a participant or beneficiary to undergo a genetic test if the following five conditions are met:

- The request is made in writing 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.

• The plan or issuer clearly indicates to each participant or beneficiary to whom the request is made that compliance is voluntary and non-compliance will have no effect on enrollment status or premium contribution amounts.

• None of the genetic information collected can be used for underwriting purposes.

• The plan or issuer notifies the appropriate Secretary in writing that it is conducting such research activities, including a description of the activities conducted.

• The plan or issuer complies with such other conditions as may be required by regulations for such activities.

Group health plans and health insurance issuers in the group, individual, and MedSupp markets are prohibited from requesting, requiring, or purchasing genetic information for underwriting purposes or prior to an individual's enrollment under a plan or policy. Plans and issuers are still allowed to collect (that is, to request, require, or purchase) health information that relates to the manifestation of a disease or disorder of an individual enrolled in a plan or who is covered by or would be covered by a policy issued in the individual or MedSupp market, and use it for permitted underwriting purposes with respect to that individual. Furthermore, an exception to the prohibition on requesting, requiring, or purchasing genetic information is included for collection of genetic information which is incidental to the request, requirement, or purchase of other information concerning an individual, provided it is not used for underwriting purposes.

GINA defines genetic information with respect to any individual as information about that individual's genetic tests, the genetic tests of family members of the individual, and the manifestation of a disease or disorder in family members of the individual. The term genetic information also includes an individual's request for, or receipt of, genetic services, but does not include information about the sex or age of any individual. Genetic services are further defined as a genetic test, genetic counseling (which includes obtaining, interpreting, or assessing genetic information), or genetic education. A genetic test is defined for purposes of Title I of GINA as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. The term is not meant to 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 a health care professional with appropriate training and expertise could reasonably detect. Definitions of family member and underwriting purposes are also included, as well as provisions clarifying that references to genetic information concerning an individual include the genetic information of a fetus carried by a pregnant woman and of an embryo legally held by an individual utilizing an assisted reproductive technology.

The provisions of GINA are effective with respect to group health plans and health insurance issuers in the group market for plan years beginning after May 21, 2009. For health insurance issuers in the individual market, the provisions are effective with respect to health insurance coverage sold, issued, renewed, in effect, or operated in the individual market after May 21, 2009. For MedSupp coverage, States must incorporate the GINA provisions into their regulatory programs no later than July 1, 2009.

II. Solicitation of Comments

A. Comments Regarding Economic Analysis, Paperwork Reduction Act, and Regulatory Flexibility Act

Executive Order 12866 requires an assessment of the costs and benefits of a significant rulemaking action and the alternatives considered, using the guidance provided by the Office of Management and Budget. These costs and benefits are not limited to the Federal government, but pertain to the affected public as a whole. Under Executive Order 12866, a determination must be made whether implementation of GINA sections 101 through 104 will be economically significant. A rule that has an annual effect on the economy of $100 million or more is considered economically significant.

In addition, the Regulatory Flexibility Act may require the preparation of an analysis of the economic impact on small entities of proposed rules and regulatory alternatives. An analysis under the Regulatory Flexibility Act must generally include, among other things, an estimate of the number of small entities subject to the regulations (for this purpose, plans, employers, and issuers and, in some contexts small governmental entities), the expense of the reporting and other compliance requirements (including the expense of using professional expertise), and a description of any significant regulatory alternatives considered that would accomplish the stated objectives of the statute and minimize the impact on small entities. The Departments seek additional information from small entities regarding any special problems they might encounter in implementing the requirements of sections 101 through 104 of GINA and any regulatory guidance that might minimize those problems.

The Paperwork Reduction Act requires an estimate of how many ''respondents'' will be required to comply with any ''collection of information'' aspects of the regulations and how much time and cost will be incurred as a result. A collection of information includes record-keeping, reporting to governmental agencies, and third-party disclosures.

The Departments are requesting comments that may contribute to the analyses that will be performed under these requirements, both generally and with respect to the following specific areas:

(i) What policies, procedures, or practices of group health plans and health insurance issuers may be impacted by regulations under GINA? What direct or indirect costs would result? What direct or indirect benefits would result? Which stakeholders will be impacted by such benefits and costs?

(ii) Are there unique costs and benefits for small employers or small plans? What special consideration, if any, is needed for small employers or small plans?

B. Comments Regarding Regulatory Guidance

The Departments are seeking comments to aid in the development of regulations regarding sections 101 through 104 of GINA. To assist interested parties in responding, this request for information describes specific areas in which the Departments are particularly interested; however, the Departments also request comments and suggestions concerning any area or issue pertinent to the development of regulations.

Specific Areas in Which the Departments Are Interested Include the Following

1. To what extent do group health plans and health insurance issuers currently use genetic information, such as family medical history, and for what purposes? For example, is genetic information currently used for group rating purposes, or for purposes of a wellness program that otherwise

complies with HIPAA's nondiscrimination requirements?

2. How do plans and issuers currently obtain genetic information (for example, through health risk assessments, the Medical Information Bureau, or other entities under common control)?

3. Under what circumstances do plans or issuers currently request or require an individual to take a genetic test?

4. Under what circumstances do plans or issuers currently ask for the results of a genetic test in order to make a determination regarding payment of benefits? What is the minimum amount of information necessary for a plan or issuer to make a determination under such circumstances?

5. What types of research do plans or issuers currently conduct or support using genetic tests?

6. Would a model notice be helpful to facilitate disclosure to plan participants and beneficiaries regarding a plan's or issuer's use of the research exception? In this regard, what information would be most helpful to participants and beneficiaries?

7. Similarly, would a model form be helpful for reporting to the Departments by a plan or issuer claiming the research exception? In this regard, what information should plans and issuers report?

8. When might genetic information be collected incidentally?

9. What terms or provisions (such as genetic information, genetic test, genetic services, or underwriting) would require additional clarification to facilitate compliance? What specific clarifications would be helpful?

Signed at Washington, DC this 4th day of June, 2008.

Alan Tawshunsky,

Deputy Division Counsel/Deputy Associate Chief Counsel, Tax Exempt and Government Entities, Internal Revenue Service, Department of the Treasury.

Signed at Washington, DC this 5th day of June, 2008.

W. Thomas Reeder,

Benefits Tax Counsel, Department of the Treasury.

Signed at Washington, DC this 2nd day of October, 2008.

Bradford P. Campbell,

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

Dated: June 30, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

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