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

Related Information
Revision 'B,' dated December 17, 2007, for the FAA AD Differences.

Other FAA AD Provisions
No corresponding requirements of this AD.

Related Information


Service Bulletin 84–32–51, Revision 'B,'

Modsum 4–126401, in accordance with the

Corrective actions are considered FAA-approved.

AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards Test Branch, ANE–172, FAA, has the authority to approve AMOCs for this AD, if

Note:

The AD differs from the MCAI and/

There have been several cases reported related information.

2, 2008.
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
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 required 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
future 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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