SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT 1995 SUBMISSIONS

Notice of Research Exception under the Genetic Information Nondiscrimination Act

A. 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. Sections 101 through 104 of Title I of GINA prevent employment-based group health plans, health insurance issuers in the group and individual markets, and issuers of Medicare supplemental (Medigap) policies from discriminating based on genetic information.
Under GINA, group health plans and health insurance issuers in the group, individual and Medigap markets (i.e., insurance companies or health maintenance organizations (HMOs)) cannot collect (defined in the regulations to mean "request, require, or purchase") genetic information for underwriting purposes or prior to or in connection with an individual's enrollment under the plan or coverage. With a few limited exceptions, plans and issuers are also prohibited from requesting or requiring an individual or family member to undergo a genetic test.

One of the exceptions to the prohibition from requesting or requiring an individual (or family member) to undergo a genetic test is the research exception. A plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including (i) the research complies with 45 CFR part 46 or equivalent federal regulations and applicable State or local law or regulations for the protection of human subjects in research, (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes.

The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA). Group health plans of private employers, issuers in group health insurance market, and issuers in both the group and individual market will be required to notify the Department of Labor. Nonfederal governmental group health plans and issuers solely in the individual health insurance market will be required to file with the Centers for Medicare & Medicaid Services (CMS).

The *Notice of Research Exception under the Genetic Information Nondiscrimination Act* (the Notice) is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement.

B. Justification

1. Need and Legal Basis

The Notice must be used by nonfederal governmental group health plans and by issuers solely in the individual health insurance market to file the required information with CMS as mandated by sections 2702(c)(4)(D) and 2753(d)(4)(D) of the Public Health Service Act. This information collection will permit CMS to track those health insurance issuers that are conducting genetic research and must comply with the genetic research requirements of GINA.

2. Information Users

The Notice must be submitted either by mail or by fax to CMS by nonfederal group health plans and issuers solely in the individual health insurance market who are conducting genetic research and are requesting individual beneficiaries to participate in genetic testing.

3. Use of Information Technology

Information will not be collected electronically. CMS does not have the system capability to accept electronic submissions and it is not cost effective to build a system in the time frame required to comply with the statutory obligation. The hard copy forms submitted by fax and mail are required to be signed.

4. Duplication of Effort

There is no duplication of effort regarding the Notice. Staff from CMS has coordinated with staff from the Departments of the Treasury and Labor in developing the Notice. Group health plans of private employers, issuers in group health insurance market, and issuers in both the group and individual market will be required to file the Notice with the Department of Labor. Nonfederal governmental group health plans and issuers solely in the individual health insurance market will be required to file with CMS.

5. Small Businesses

The information collection does not impose any burden on small businesses or entities.

6. Less Frequent Collection

This is a one-time collection. If the information collection is not conducted, CMS will not be notified as to which nonfederal governmental plans and issuers in the individual market are conducting genetic research in a manner that is in compliance with GINA.

7. Special Circumstances

None.

8. Federal Register/Outside Consultation

A 30 day comment period on the Notice is being provided through the GINA interim final rule, which is being published in the Federal Register on (*insert* date). Additionally, in drafting the Notice, CMS coordinated with the Department of the Treasury and Department of Labor to receive their input on the format of and data elements, and to ensure that burden of the information collection on respondents is minimized.

9. Payments/Gifts to Respondents

None.

10. Confidentiality

No personal identifiable information is being collected.

11. Sensitive Questions

None.

12. Burden Estimates (Hours and Wages)

CMS estimates that up to two such entities (consisting of either health insurance issuers solely in the individual health insurance market) 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.

CMS also estimates that completing and mailing the Notice will require 15 minutes of clerical time at an hourly rate of nearly $26 per hour. Therefore, the total hour burden associated with completing the Notice is estimated to be .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 $13.00.

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to the Federal Government

None.

15. Changes to Burden

As indicated in the Background, this collection is a result of a new statutory requirement under

GINA, which requires group health plans and issuers to notify either the Secretary of Labor or the Secretary of HHS that they are conducting genetic research.

16. Publication/Tabulation Dates

There are no plans to publish the results of this collection of information.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard a potentially large number of forms.

18. Certification Statement

No exceptions.

C. Collection of Information Employing Statistical Methods

None.