Supporting Statement – Part A
Notice of Research Exception under the Genetic Information Nondiscrimination Act
(CMS-10286/OMB Control No. 0938-1077)

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 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 GINA. Group health plans of private employers, issuers in the group health insurance market, and issuers in the group as well as individual and/or Medigap markets will be required to notify the Department of Labor (DOL). Non-Federal governmental group health plans and issuers solely in the individual health insurance or Medigap 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 DOL or CMS to comply with the notification requirement.

CMS is requesting an extension of the Office of Management and Budget (OMB) approval for the information collection included in this information collection request (ICR).

B. Justification

1. Need and Legal Basis

The Notice must be used by non-Federal governmental group health plans and by issuers solely in the individual health insurance market and/or Medigap market to file the required information with CMS as mandated by sections 2705(c)(4)(D) and 2753(d)(4)(D) of the PHS 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 by mail to CMS by non-Federal group health plans and issuers solely in the individual health insurance market and/or Medigap 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. The hard copy forms must be signed and submitted by mail.

4. Duplication of Efforts

There is no duplication of effort regarding the Notice. CMS has coordinated with 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 the group market as well as the individual and/or Medigap markets will be required to file the Notice with the DOL. Non-Federal governmental group health plans and issuers solely in the individual health insurance market and/or Medigap 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 non-Federal governmental plans and issuers in the individual or

Medigap market are conducting genetic research in a manner that is in compliance with GINA.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

A notice was be published in the Federal Register on April 21, 2025 (90 FR 16685), providing the public with a 60-day period to submit written comments on the ICR. A 30-day notice published on July 11, 2025 (90 FR 30939. One out-of-scope comment was received.

9. Payments/Gifts to Respondents

No payments or gifts are associated with this information collection.

10. Confidentiality

No personal identifiable information is being collected. CMS will protect privacy of the information provided to the extent provided by law (Privacy Act of 1974 (5 U.S.C. §552(a)) and FOIA Exemption (5 U.S.C. §552(b))).

11. Sensitive Questions

This information collection does not involve any sensitive questions.

12. Burden Estimates (Hours & Wages)

We used data from the Bureau of Labor Statistics (BLS) to derive median labor costs (including a 100 percent increase of the median hourly wage to incorporate the cost of fringe benefits and other indirect costs) for estimating the burden associated with the information collection.[1] Table 1 presents the median hourly wage, the cost of fringe benefits and other indirect costs, and the adjusted hourly wage.

Table 1: Adjusted Hourly Wage Used in the Burden Estimate

BLS Occupation Title	Occupational Code	Median Hourly Wage ($/hour)	Cost of Fringe Benefits and Other Indirect Costs ($/hour)	Adjusted Hourly Wage ($/hour)
Secretaries and Administrative Assistants,	43-6014	$22.26	$22.26	$44.52

1 May 2024 National Occupational Employment and Wage Estimates United States, available at https://www.bls.gov/oes/current/oes_nat.htm.

Except Legal, Medical, and Executive				

CMS estimates that up to two such entities will take advantage of the research exception annually, 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, for each respondent, completing and mailing the Notice will require 15 minutes of clerical time (at an hourly rate of $44.52) with an equivalent cost of approximately $11. Therefore, the total hour burden associated with completing the Notice is estimated to be 0.5 hours of clerical time for two respondents, with an equivalent cost of approximately $22.

13. Capital Costs

The cost of materials (paper and ink) for each two-page Notice is estimated to be $0.10 and mailing cost is $0.73 for each Notice.[2] Therefore, the total materials and postage cost for each notice is $0.83, with the total materials and postage cost for two respondents being $1.66.

14. Cost to Federal Government

There is no cost to the Federal government.

15. Changes to Burden

There are no changes in burden.

16. Publication/Tabulation Dates

There are no plans to publish the outcome of the information collection.

17. Expiration Date

The expiration date will be displayed on each instrument (top, right-hand corner).

2 U.S. Postal Service. (n.d.). Mailing and Shipping Prices. Retrieved November 25, 2024, from https://www.usps.com/business/prices.htm.