



Kaiser Foundation Health Plan, Inc.  
Program Offices

December 9, 2008

Submitted electronically via <http://www.regulations.gov>

Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-4137-NC  
P.O. Box 8017  
Baltimore, MD 21244-8010

Re: CMS-4137-NC Request for Information regarding Title I, Sections 101-104 of the Genetic Information Nondiscrimination Act of 2008 (Pub. L. No. 110-233)

Dear Sir or Madam:

Kaiser Permanente offers the following comments in response to the Request for Information regarding Title I, Sections 101-104 of the Genetic Information Nondiscrimination Act of 2008 ("GINA"), issued on October 10, 2008 in the *Federal Register*, which is a collective request for information ("RFI") from the Departments of Labor, Health and Human Services and Treasury soliciting public comments in advance of future rulemaking regarding issues raised by Sections 101-104 of Title I of GINA, which applies to health insurers.

The Kaiser Permanente Medical Care Program (which offers services to the public under the Program's trade name "Kaiser Permanente") is America's largest private integrated healthcare delivery system. It comprises: Kaiser Foundation Health Plan, Inc. (and its local subsidiaries, collectively "Health Plan"), the nation's largest not-for-profit health plan; the nonprofit Kaiser Foundation Hospitals ("Hospitals"); and the Permanente Medical Groups ("Medical Group"), eight independent physician group practices that contract exclusively with Health Plan to meet the health needs of Kaiser Permanente's 8.7 million members in nine states and the District of Columbia. In addition to nearly all ambulatory and hospital care, most pharmacy, diagnostic, and laboratory services are performed within Kaiser Permanente by Health Plan, Hospitals or Medical Group employees in Health Plan or Hospitals-owned facilities.

As part of its commitment to the highest quality care, Kaiser Permanente has made a significant investment in developing its secure Electronic Health Record ("EHR") system, KP HealthConnect™ to support the delivery of care to its members and to enhance communications among the medical professionals who serve them. By allowing clinical information to be shared among a patient's providers, KP HealthConnect leverages the integrated approaches to health care practiced at Kaiser Permanente.

Kaiser Permanente also conducts and supports a broad agenda of health services research through its various research entities<sup>1</sup>. In particular, Kaiser Permanente, through its Northern California Division of Research, has launched the *Research Program on Genes, Environment and Health* (“RPGEH”) – a long-term research program to identify genetic and environmental factors that affect people’s health, and then use that information to improve health and health care in the years to come. While RPGEH is the largest research study involving genetics and has the highest profile, other Kaiser regions are planning research that may include genetic testing.

In both our research efforts as well as our delivery of health care, we provide protections for patient health information (including genetic information) that prevent unauthorized disclosure. Because of our long experience in health care delivery, finance and health services research, we understand our members’ concerns about discrimination on the basis of their genetic information. As a result, Kaiser Permanente supported GINA and worked closely with Congressional staff in the legislative process. We believe this legislation will help to promote innovative health research by assuring potential research participants that they will be protected from genetically-based discrimination.

We appreciate the opportunity to respond to specific questions in the RFI. We have referenced questions numbers in the following comments:

### **Uses and Collection of Genetic Information**

*Question 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?*

*Question 3. How do plans and issuers currently obtain genetic information (e.g., through health risk assessments, the Medical Information Bureau, or other entities under common control)?*

*Question 10. When might genetic information be collected incidentally?*

### **Response**

The availability of up-to-date clinical information across our integrated system through KP HealthConnect enhances preventive care, disease management programs, and other quality improvements aimed at delivering the best evidence-based treatment for specific conditions. Kaiser Permanente uses this information, which may include genetic information such as family history or testing results, to coordinate care on the individual member level, as well as to address population health needs, using aggregate data. Individual genetic information is used primarily for treatment, with appropriate privacy and security safeguards.

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<sup>1</sup> Research has long been a hallmark of Kaiser Permanente (“KP”) and is one of the ways KP demonstrates its benefit to the communities it serves. KP conducts research in each of its eight regions, both within research centers and in medical centers and other health care delivery venues.

Through KP HealthConnect, additional tools are provided to help members proactively manage their health. For example, an online health risk assessment helps them create a confidential, customized health improvement plan. Before starting the survey, our members are informed that none of their individual information, including family history or other genetic information, will be shared with anyone – their employer, insurance company (including Kaiser Permanente), or health care provider – unless they specifically give their permission.

GINA was not intended to prohibit the use of the genetic information in such efforts or for treatment, payment, and health care operations unrelated to underwriting or eligibility. In fact, many permitted uses of genetic information help promote and improve the health and care of individual Kaiser Permanente members.

Federal rulemaking should support legitimate uses of genetic information in programs or health initiatives that promote and improve the quality of health care delivery.

### **Genetic Research Exemption**

***Question 7.** What types of research do plans or issuers currently conduct or support using genetic tests?*

#### **Response**

The Research Program on Genes, Environment, and Health (“RPGEH”)<sup>2</sup> came about in response to Kaiser Permanente’s commitment to improving health and in response to new knowledge of genetics that made it possible. It is a long-term research program to identify genetic and environmental factors that affect human health and to use that knowledge to improve health care for Kaiser Permanente members and the general public. The findings could lead to entirely new ways of diagnosing, treating, and even preventing some diseases, especially common diseases like cancer, heart disease, asthma, diabetes, mental health problems, and many, many others.

RPGEH will involve Kaiser Permanente Northern California adult members who are willing to provide background, health, and environmental information, and in some cases, genetic samples for analysis. This data will be entered into large, coded databases. Researchers will use the databases for studies on specific diseases, searching for common factors among people who have similar health conditions and those who don’t, and then doing more research into those factors.

This kind of research is called population-based research because it requires large numbers of people who are representative of the overall population to yield meaningful results that can be applied to Kaiser Permanente members and the population beyond Kaiser Permanente. Kaiser Permanente is one of few organizations in the United States with both the scientific expertise and a membership suitable for such an extensive effort. The membership is large, ethnically diverse, stable, and this provides a unique resource for the study of a large number of medical

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<sup>2</sup> <http://www.dor.kaiser.org/studies/rpgeh/index.html>

conditions. That is why we have asked most Kaiser Permanente Northern California adult members to take part in the program.

No other health plan or medical care organization in the U.S. has the high quality, comprehensive health information from large numbers of people. Electronic health records are a key component of a research program such as this one. Also, the 400-person Division of Research (“DOR”) staff is well-known for their innovation in medical information technology and for having a broad range of expertise in epidemiological and health services research. The DOR has more than 230 projects underway, looking into the environmental, behavioral, and genetic causes of a broad range of diseases; conducting clinical trials; and measuring health care effectiveness. Most of the funding for these projects comes from governmental agencies and private foundations.

Participation in this research program is entirely voluntary. Whether members decide to participate or not, their decision will not affect their health care or their membership in Kaiser Permanente. Those who agree to participate can drop out at any time. Privacy protection is an essential component of this research. No results from the RPGEH will be placed in the individual participant’s medical record or shared with Kaiser Permanente’s insurance functions.

GINA expressly permits the use of the genetic information in research conducted in accordance with HIPAA and other laws governing research. Federal regulations should ensure that integrated health care delivery systems can continue to conduct and support research that involved the appropriate collection and use of genetic information and genetic testing.

***Question 8:** 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 GINA? If so, what information would be most helpful to participants and beneficiaries?*

**Response**

While a model notice might provide research participants valuable information about GINA’s research exception and requirements, it should be written to provide information that is neither duplicative nor inconsistent with other disclosures or informed consent required under all applicable laws and regulations. The model should be flexible enough to accommodate modifications that can reflect an accurate description of the particular research program or project.

Federal agencies should develop a model notice for research participants that is consistent with the requirements of GINA and includes other legal requirements that may apply to research projects or programs, such as informed consent.

***Question 9:** Would a model form be helpful to report to the Departments if a plan or issuer claims the research exception? If so, what information should plans and issuers report?*

## Response

Health plans conducting or sponsoring research that includes genetic testing must meet certain conditions (referenced as “Items 1 – 5”) to qualify for the research exception in GINA:

1. The request for genetic testing must be in writing and related to research that complies with applicable federal, state or local laws or regulations;
2. The health plan must clearly indicate that participation on the research is voluntary and refusal to participate will have no effect on enrollment status or premium amounts;
3. None of the genetic information collected can be used for underwriting purposes;
4. The health plan must notify the Secretary in writing that it is conducting such activities, including a description of the activities conducted;
5. The plan must comply with other conditions required by regulation.

A model form would provide helpful guidance about what information is required and would lead to consistent reporting by plans seeking the research exception. In addition, more specific guidance about the timing and content of notice would be helpful, for instance, before enrollment begins but after Institutional Review Board (“IRB”) approval. The description of the research (Item 4) could capture essential information in a relatively brief form. For example:

- Project Title
- Sponsor
- Principal Investigator/Contact
- Proposed Study Dates (begin, end)
- Proposed Study Location(s)
- IRB Application Information (IRB Approval Status, Date)
- N, Study Population
- Brief Description (similar to an abstract, including design, objective(s), methodology - and specifically what genetic testing will be involved) of 200 words or less.
- Certify (check box format, with signature):
  - i. written notice given to participants/compliant research/informed consent;
  - ii. voluntary participation;
  - iii. no underwriting use.

This approach would reduce the amount of paperwork involved, simplify the notification process, and establish standard notification criteria without requiring health plans to attach other materials in order to meet requirements. It would allow health plans to meet the requirements in Items 1, 2 and 3. It would be important for the model form to also spell out other conditions required (Item 5), if any.

While the language of the statute suggests individual notice will be required for each project, we recommend that multi-study, long range programs like RPGEH, which will include a number of separate projects, be allowed to submit notification on a regular basis in a periodic

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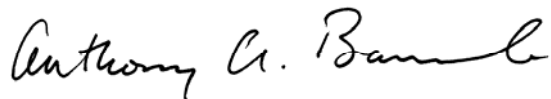
report (annually, semi-annual or quarterly), summarizing the projects in the program that will involve genetic testing. Such a report would include the elements listed above.

Finally, with respect to this provision, Federal regulations should clarify that GINA does not intend, through the research exception, to set up a separate approval process for individual projects or programs conducted by health plans – a process that is already conducted by IRBs.

Federal agencies should develop a model form for notification, as well as guidance about the timing and content of notification. Rulemaking should clarify that the research exception is limited to notification.

We appreciate the chance to provide you with information. We would welcome the opportunity to discuss these matters with you further. If you have questions or concerns, please contact me at 510.271.6385 (email: [anthony.barrueta@kp.org](mailto:anthony.barrueta@kp.org)).

Sincerely,

A handwritten signature in black ink that reads "Anthony A. Barrueta". The signature is written in a cursive style with a large, prominent initial 'A'.

Anthony Barrueta  
Vice President, Government Relations