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Kaiser Foundation Health Plan, Inc.
Program Offices

January 5, 2010

Submitted electronically *via* http://www.regulations.gov

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

Internal Revenue Service
Attention: REG–123829–08
Room 5205
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

U.S. Department of Labor
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Attention: RIN 1210–AB27
Room N–5653
200 Constitution Avenue, NW.
Washington, DC 20210

Re: *Prohibiting Discrimination based on Genetic Information*; Interim Final Rules. CMS–4137–IFC /REG–123829–08/ RIN 1210–AB27 (CMS docket no. CMS-2009-0081-0023)

Dear Sir or Madam:

Kaiser Permanente offers the following comments in response to the Interim Final Rules ("Rules") implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 ("GINA"), issued on October 7, 2009 in the *Federal Register* by the Departments of Labor, Health and Human Services and Treasury ("Departments").

Background

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 nonprofit health plan; the nonprofit Kaiser Foundation Hospitals ("Hospitals"); and the Permanente Medical Groups ("Medical Group"),

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seven 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 provide a variety of online tools, such as a health risk assessment tool and targeted wellness programs.

Kaiser Permanente also conducts and supports a broad agenda of health services research through its various research entities[1]. In particular, Kaiser Permanente, through its Northern California Division of Research ("DOR"), 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.[2] While Northern California's RPGEH is the largest Kaiser Permanente research study involving genetics and has the highest profile, many other studies involving genetic testing are conducted within the eight Kaiser Permanente regions.

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. GINA 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 offer the following comments:

[1] 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 all of its eight regions, both within research centers and in medical centers and other health care delivery venues. In addition to health services research, KP also conducts many studies involving FDA-regulated drugs, devices, and biologics.

[2] RPGEH 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 others. Participants are 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 do not, and then examining those factors more closely through further research.

The Impact of the Rules on the Use of Health Risk Assessments

Discussion

As the Rules note, health risk assessments ("HRA") "provide an opportunity for preventive treatment services referrals, disease management, and other behavioral change initiatives that are focused on creating higher quality medical outcomes." (74 FR 51672)

The statute prohibits covered plans and issuers from adjusting premiums or contribution amounts under a plan or policy on the basis of genetic information, but does not impose restrictions on disease management or wellness programs. However, the Rules expand the statutory definition of "underwriting purposes" to include "changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program" and "discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program." (74 FR 51685).

We believe the resulting restrictions on wellness programs, disease management and health risk assessments are not what Congress intended. Moreover, we are concerned that these Rules will have a negative impact on such programs, which carry little or no risk of discrimination because of the way they are designed. In the case of disease management and wellness programs, the receipt of an individual's family history (i.e., "genetic information" under the statutory definitions) is not required to adjust a premium or contribution amount. The basis for providing the incentive or reward is the individual's own choice to participate in and to complete the requirements of the program – not on the information collected or on health outcomes that may result from participating in the program.

Kaiser Permanente provides various tools to help members proactively manage their health, including an online, voluntary HRA survey that allows them to create confidential, customized health improvement plans. This HRA tool, developed and supported in collaboration with a third party vendor, is available free of charge to all Kaiser Permanente members through our member website. Before starting the survey, 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. However, if members choose to share results with their health care providers, the information may be used to manage diseases and achieve health goals. To reiterate, even in cases where Kaiser Permanente health care providers are aware of a member's information, this information is never shared with the health plan's insurance function.

Our online HRA includes questions about demographics, health conditions, health history and lifestyle or behavioral factors that can impact health, such as diet, exercise, smoking, and stress. Until December 2009, our HRA also included questions about family medical history, which may be important for identifying risk factors for certain diseases. However, under the Rules, questions about family medical information are considered genetic information and whenever a

HRA is tied to any activity that falls under the Rules' definition of "underwriting," asking those questions constitutes an impermissible request for genetic information.

Group plans may or may not link the completion of a HRA that includes genetic information to enrollment, or to incentive programs, premium reductions or other rewards. As the Rules note, "[t]he Departments assume that insured plans will rely on the health insurance issuer providing coverage to ensure compliance and that self-insured plans will rely on wellness vendors and other service providers to ensure compliance." (74 FR 51672)

Under this assumption of broad reliance on health insurance issuers and vendors, the only way to be certain of compliance is for insurers and vendors to completely eliminate a valuable component of the HRA tool – family medical history – from the survey, which is what we have done in conjunction with our HRA vendor.

While we fully support GINA's goal of prohibiting discrimination in health insurance based on genetic information, we also believe the clear benefits of HRAs outweigh the minimal risks of discrimination from the collection of family medical history in this context, especially because information is not shared with the health plan or insurer. We are concerned that the removal of family medical history questions diminishes the value of the HRA as a way to help patients and providers achieve the best health outcomes. Moreover, reward programs tend to be administered solely on whether or not an employee (or member) completed a HRA and not how that individual responded. When responses are not known by the insurer, there is little or no likelihood that discrimination based on family medical history could take place.

We also have concerns about how GINA has affected some ongoing reward programs. There is often a time lag between the completion of a HRA and the administration of a reward or incentive program. The Rules create confusion around this issue, especially because GINA's effective date for plans is tied to the beginning of the plan year.[3]

We also note that the Rules seriously underestimate the cost and time impact of this change to HRAs. The Rules state that the average cost per plan is about $142.00 (to account for one half hour each of attorney and clerical time). In our experience to date we have spent considerably more time than that working with our vendor to revise our HRA, to test the new version, to provide legal advice, to revise policies and procedures, and to develop internal and external communications about the actions we have taken to be compliant.

Recommendation

We recommend that the Departments conduct a more realistic assessment of the risks of discrimination likely to occur based on including confidential family medical history questions

[3] In one example, a plan with a renewal date of January 1, 2010 cannot administer its incentive program as planned. Monthly premium reductions for 2010 were offered to employees who completed a HRA prior to GINA's effective date (e.g., at open enrollment last October 1). However, under the Rules, these rewards cannot be given as promised until employees complete new HRAs without family medical history questions and we ensure that old versions with those questions are destroyed. In this instance, the vendor will have to permit an override to the online application, which only allows a member to take one HRA in a six-month time period.

in HRAs and wellness programs. We also urge the Departments to acknowledge and address the significantly higher actual costs associated with GINA compliance related to HRAs and wellness programs.

The Impact of the GINA Research Exception

Discussion

Except for certain exceptions, health plans or health insurance issuers may not request or require genetic testing. One such exception is for research in accordance with applicable federal, state and local laws or regulations. (74 FR 51685) Because it ensures protection against discrimination, GINA may promote greater use of the genetic information in research by providing this exception. In addition to abiding by other applicable laws, health plans seeking the research exception under GINA must also provide written requests to research participants and must file, with the appropriate federal agency, a notice of the exception and an attestation of compliance.

Written Notice to Participants

With its large, ethnically diverse, stable membership and the scientific expertise of its research centers, Kaiser Permanente is one of few organizations in the United States with the resources to conduct population-based research. Currently, 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 heath care effectiveness. Many of these projects have included or will include requests for genetic testing.

Participation in all research conducted at Kaiser Permanente, including research that involves genetic testing, conforms to all federal, state and local laws and regulations governing the protection of human research subjects. Members invited to participate are informed their decision will not affect their eligibility for benefits or their membership in Kaiser Permanente. Those who agree to participate are told they can withdraw from the study at any time. Privacy protection is an essential component of all research performed at Kaiser Permanente. For instance, no results from the RPGEH will be placed in the individual participant's medical record or shared with Kaiser Permanente's insurance functions.

The Rules state that "the Departments assume that all group health plans and group health insurance issuers using the exemption will not have to send a disclosure to participants in the genetic research because they will comply with the requirements of 45 CFR Part 46.116(a)(8)."[4] (74 FR 51673) However, the Rules themselves do not explicitly state this, but imply that separate notice may be required. (74 FR 51695)[5]

[4] A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

[5] "(ii) *Written request for participation in research.* The issuer makes the request in writing and the request clearly indicates to each individual (or, in the case of a minor child, to the child's legal guardian) that – (A) Compliance with the request is voluntary; and (B) Noncompliance will have no effect on eligibility for benefits…or premium amounts…."

If the Rules require separate written disclosure in addition to the 45 CRF Part 46-compliant notices that research participants already receive, the rules will impose administrative challenges and potential cost or other resource burdens that outweigh the intended benefits. Moreover, the Notice of Research Exception ("Notice") that must be filed (*see below*) requires the filing entity to attest that "each request of a participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) to undergo genetic testing as part of the research will be made in writing."[6] That is a different requirement than what is stated in the Rules (*see above*, fn. 5).

Kaiser Permanente research centers have numerous projects underway that have received institutional review board ("IRB") approval for all study materials, including consent forms and frequently asked questions ("FAQ") documents. In some cases, projects were begun before GINA was signed into law; in other cases, prior to the publication or the effective date of these Rules. Thus, while study materials fully meet the requirements of 45 CFR Part 46.118(a)(8), it is not clear from the Rules or the Notice whether or not this is sufficient to comply with GINA.

Recommendation
We strongly recommend that the Departments clearly state that meeting the requirements of 45 CFR Part 46 (in particular, 46.116(a)(8)) will satisfy the Rules' requirement to provide written disclosure to participants and no separate notice will be required.

Notice of Research Exception
While we support the requirement to notify the Departments about research involving genetic testing, we are concerned that both the process and the actual Notice form are not flexible enough to accommodate the various organizations conducting genetic research. Under the Rules, a health plan or issuer must file a "Notice of Research Exception" for each research project that will include a request for genetic testing. The Notice template and information about how to file are posted on the Department of Labor ("DOL") website.[7]

Where to File
The Notice form was not designed with organizations like Kaiser Permanente – or any organization where various plan types will contribute to a research database – in mind. The Notice assumes that the filing entity will fit into single category of plan or insurer, and thus will file Notice with only the Department having jurisdiction over that particular type of health plan.

Kaiser Permanente offers a broad array of health coverage products (group and individual) in the commercial market; for Medicare eligible participants through Medicare Advantage programs; for Medicaid/CHIP recipients; and through the Federal Employee Health Benefits (FEHB) program. Coverage is primarily under a capitated pre-payment model, but a small percentage of Kaiser Permanente members are under self-insured plans. Participants recruited

[6] http://www.dol.gov/ebsa/pdf/GINAexceptionnotice.pdf
[7] http://www.dol.gov/ebsa/GINAexceptioninstructions.html

for any given study may include beneficiaries from nearly every type of plan, and therefore will correspond to multiple entities on the form, and require duplicate filing.

To avoid confusion and the additional paperwork,[8] Kaiser Permanente will file with the DOL and not file duplicate Notices with the Centers for Medicare and Medicaid (CMS) and the Internal Revenue Service (IRS), because the three agencies will share reporting information. However, in the absence of more specific guidance on this issue, we are also filing an attachment with every Notice explaining why Kaiser Permanente research studies involve several types of entities and why we are filing Notice with one agency only.[9]

When to File
The DOL website instructions state that , "[a] plan or issuer claiming the research exception must file at least 60 days prior to the date the first request is made to a participant or beneficiary to undergo a genetic test."

We also contacted DOL for guidance about the instruction to file Notice 60 days prior to any request for genetic testing, because we have very serious concerns about how this requirement will impact ongoing studies. Within Kaiser Permanente's research community, a number of current research projects involve requests for genetic testing. In certain individual studies, requests have already been made of some participants, with the remainder to be made after GINA's effective date. To delay study activities to meet this requirement could jeopardize recruitment, study personnel, funding, study timelines and protocols, etc. DOL advised us that for studies already underway, Notice should be filed as soon as possible, but no studies should be suspended to meet the 60-day requirement.[10]

While the 60-day prior Notice may be more feasible for new studies, we question the need for such a requirement in general, even for new research. Meeting this requirement may force studies to reorganize other preliminary activities to minimize periods of inactivity – or worse, to support a 60-day wait between filing Notice and contacting participants. As there is no provision in the statute or the Rules that gives the Departments authority to approve or reject research studies, there seems to be no rationale for including this or any prior Notice provision.

Recommendation
We strongly recommend that the Departments clarify the Notice filing requirements to accommodate organizations that fall into multiple categories of health plans and avoid duplicate filing. We also recommend the Departments ensure that Notice requirements do not delay or impede research projects and we specifically request that the 60-day prior Notice provision be removed.

Studies Requiring Notice

[8] Regarding the issue of duplicate notice, Kaiser Permanente contacted the DOL by telephone on December 1, 2009.
[9] *See* Attachment A (appendix to this letter)
[10] December 1, 2009 telephone contact with DOL

Individual Notice

The Rules state that "up to five entities…will use the genetic research exception…." (74 FR 51673) We believe the Departments have substantially underestimated the volume of research planned or being conducted that incorporates genetic testing. For example, in December 2009, shortly after the effective date of these Rules, Kaiser Permanente initially filed Notices for over 200 research studies and several dozen more over the next few weeks. The amount of administration, oversight, and documentation is considerable. We estimate IRB managers and staff have spent, to date, over 250 hours to comply with the research exception. Over 750 Kaiser Permanente researchers have been contacted and surveyed about their projects. Moreover, ensuring compliance with the Notice requirement is an ongoing task, requiring continuous monitoring and reporting.

While the Rules indicate individual notice will be required for each project, we had previously recommended that the Departments allow organizations, in particular those with substantial research enterprises, to submit notification on a regular basis in a periodic report (annually, semi-annually, or quarterly), summarizing the projects in the program that will involve genetic testing.[11] Such a report could include the same elements required by the Notice.

The interpretation of genetic test

The limitation on requesting or requiring genetic testing provides an exception for requests by health plans made pursuant to research. The statutory definition of "genetic test"[12] can be difficult to interpret when applied in the research context. Since the publication of the Rules, our researchers have had numerous questions about which studies will require Notice to the Departments as well as to participants. In particular, confusion has arisen around the application of the definition of genetic test in various studies.

For example, some studies test the DNA or RNA of tumors or viruses rather than of individuals. To a researcher, this is a genetic test, but for purposes of GINA, this is not a genetic test. Other studies may perform genetic testing retrospectively, i.e., after the condition that is the subject of the test has already been diagnosed ("manifested"); some of these tests are done to determine whether certain treatments may be more effective than others in certain patient populations or to estimate the likelihood of recurrence in groups of participants with certain genetic characteristics. Some studies involve submitting de-identified specimens to bio-repositories for future study. The examples are varied and complex – and GINA's definitions are not always easily applied to individual studies.[13] We believe that interpreting the

[11] This approach would necessarily require eliminating prior Notice. Our suggestion was included in our comments in response to the Departments' *Request for Information regarding Title I, Sections 101-104 of the Genetic Information Nondiscrimination Act of 2008*, issued on October 10, 2008 in the *Federal Register*

[12] "*Genetic test* means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations or chromosomal changes. However, a genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. Accordingly, a test to determine whether an individual has a BRCA1 or BRCA2 variant is a genetic test."

[13] For example, researchers (and clinicians) regard germline changes differently than somatic changes and GINA does not clearly differentiate between these types of genetic information. It is not clear whether practices such as

requirement for Notice under the Rules' definitions of genetic testing is difficult without further guidance and the resulting confusion may lead to either over- or under-filing of Notices.

Recommendation

The Departments should permit periodic Notice to reduce the burdens on organizations supporting high volumes of research involving genetic testing. We further recommend that the Departments develop more specific guidance about which studies require Notice, in particular with regard to how to interpret the statutory definition of "genetic test" in the research context.

We appreciate the opportunity to offer our comments. We are available to discuss these matters with you further. If you have questions or concerns, please contact me at 510.271.6621 (email: lori.potter@kp.org).

Sincerely,

Lori Potter
Counsel
Legal & Government Relations

KRAS testing of a tumor (which is now regular clinical care in oncology), or molecular profiling of tumors, may be considered the same as looking for an inherited predisposition to cancer. Testing for ER and PR tumors, although an immunohistochemical test, could also be considered a genetic test in this context since they can determine protein expression in a tumor cell that is different than protein expression in normal tissue, and those changes in expression have been brought about by genetic alteration. Thus those tests measure the tumor's phenotype of ER and PR.

Attachment A – Notice of Research Exception

Type of Entity (Q.2 and Q.3):

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., the nation's largest not-for-profit health plan; the nonprofit Kaiser Foundation Hospitals; and the Permanente Medical Groups, seven 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. Kaiser Permanente offers a broad array of health insurance products in the commercial market (group and individual); for Medicare eligible participants through Medicare Advantage programs; for Medicaid/CHIP recipients; through the Federal Employee Health Benefits (FEHB) program; coverage is primarily under a capitated pre-payment model.

Kaiser Permanente also conducts and supports a broad agenda of health services research through its various research entities in each of its eight regions, both within research centers and in medical centers and other health care delivery venues. 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.

Kaiser Foundation Research Institute ("KFRI") is a national program that administers and supports research in Kaiser Permanente. Supporting a system of nine IRBs, KFRI holds the Federalwide Assurance for human subjects' protection for all Kaiser Permanente regions.

KFRI, on behalf of all regional KP research organizations, reviews and submits all applications for federal research funds and executes all contracts and subcontracts involving federal funds. As the fiscally responsible party, KFRI also is the authorized recipient of all federal research funding awarded to KP.

KFRI, sometimes in collaboration with other KP departments and groups such as the regional research departments, National Legal, National Compliance, and National Controller, offers comprehensive review and support services to investigators to ensure compliance with federal regulations. As such, KFRI is the appropriate entity to file this Notice of Research Exception ("Notice") on behalf of Kaiser Permanente.

Filing with Department of Labor

Kaiser Permanente, which represents more than one entity as noted above, files this Notice for _____ (Title of Research Project/Project #) with the Department of Labor only. As advised by the Department of Labor on December 1, 2009, Kaiser Permanente is not required to file duplicate reports with the Centers for Medicare and Medicaid (CMS) and the Internal Revenue Service (IRS); the three agencies will share reporting information.