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Comments of the Genetics and Public Policy Center, Johns Hopkins University, on  
Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance  
Coverage and Group Health Plans

December 3, 2009

Department of Labor, Employee Benefits Security Administration  
29 CFR Part 2590  
RIN 1210-AB27

Department of Health and Human Services, Centers for Medicare & Medicaid Services  
45 CFR Parts 144, 146, 148  
RIN 0938-AP37

Department of the Treasury, Internal Revenue Service  
26 CFR Part 54  
[TD9464  
RIN 1545-BI03

The Genetics and Public Policy Center at Johns Hopkins University is pleased to submit the following comments on the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act that were published in the Federal Register on October 7, 2009.

Established in 2002 with a grant from The Pew Charitable Trusts, the Genetics and Public Policy Center at Johns Hopkins University is a multi-disciplinary center working to help policy makers and the public better understand and respond to the challenges and opportunities arising from rapid advances in human genetics and their application to health care. The Center has conducted in-depth policy analysis and social science research, including public opinion and attitude research, on genetic testing and genetic technologies. We provided technical assistance to Members of Congress and Congressional staff throughout consideration of GINA. We have had the opportunity to testify in front of several Congressional committees considering GINA, and our research on public attitudes toward the use of genetic information was cited during final consideration of the bill on the House and Senate floors. Individual members of the Center's staff have been integrally involved in aspects of genetic nondiscrimination legislation since the first versions of legislation were proposed in 1995.

Our interest in genetic discrimination policy is inexorably linked to our belief that genetic research will lead to a clearer picture of the role of genetics in health and disease and help drive the development of new diagnostic tools and treatments. We have long been concerned that genetic discrimination, and the fear expressed by many that genetic test results could be used against them, inhibits volunteers from participating in genetic research and deters individuals from pursuing recommended genetic testing in their own health care. The regulations that implement GINA must carry out the intent of Congress by

clearing the way for new scientific and clinical advancements aimed at improving the health of all Americans.

Overall, the Genetics and Public Policy Center is pleased with the interim final rules. The approach taken by the federal regulators in interpreting and implementing GINA is consistent with both Congressional intent and the legislative history of GINA and provides strong protections to millions of Americans. Of particular note:

- Insurers are prohibited from collecting genetic information, except if that collection is “incidental”. Legitimate requests for medical records must explicitly state that genetic information, including family history, should not be provided.
- Underwriting is prohibited. This includes not only rating and pricing insurance policies, but also offering financial incentives for participating in health risk assessments or wellness programs. An insurer may collect family history or genetic information once individuals are enrolled in the plan, as long as no rewards are provided.
- An insurer may request but not require that an individual undergo a genetic test as part of a research study, if strict conditions are met.

Throughout the rules, numerous specific examples are provided to help guide health insurers and other parties in understanding what GINA does and how it must be implemented in practice. We commend the agencies that produced the regulations for their thorough approach to a complicated topic.

Our comments, organized by topic, highlight areas where further clarification may be needed. The topics are (1) definitions of key terms used in GINA; (2) impact on HRAs and wellness programs; and (3) genetic information in medical records.

## 1. Definitions

GINA generally prohibits plans and insurers from increasing group premiums and contributions based upon genetic information, and requesting or requiring genetic testing. The law also prohibits collecting “genetic information” either “prior to or in connection with enrollment” or for “underwriting” purposes. The rules define key terms, including “family member”, “genetic information”, “genetic test”, “genetic services”, and “manifestation or manifest”, and provides a very useful non-exhaustive list of examples of genetic tests. Although GINA does not prohibit underwriting on the basis of a manifested disease, the clarification that a disease is not “manifested” if a diagnosis is based principally on genetics helps ensure that health insurers do not discriminate on the basis of genetic information.

As we noted in GPPC’s response to the agencies’ Request for Information in 2008, “genetic services” may include a range of services. For example, a woman who seeks BRCA testing (genetic testing for breast and ovarian cancer risk) would seek and receive genetic counseling and/or education before and/or after the genetic testing:

- Before testing, a counselor or doctor would explain the risks and benefits of testing and what the test results mean.
- Before and after testing, a counselor or doctor would explain her lifetime risks of developing breast or ovarian cancer.
- Whether or not the woman decides to have the genetic test to learn about her risks, a counselor or doctor would review with her clinical options that can reduce her risks, and perhaps make

recommendations. Options in the case of BRCA might include earlier and more frequent mammograms, and preventive measures such as taking tamoxifen or having preventive surgery to remove the ovaries or breasts.

We suggest that the final regulations should include an example specifying that GINA protects all of the above examples as counseling, and therefore as “genetic services”.

## 2. Impact on HRAs and wellness programs

Wellness programs are organized and coordinated programs that have the goal of enhancing the physical, mental, and emotional status of individuals. These programs are often provided through employer-sponsored health insurance. As health care costs continue to rise and as health providers and insurers increase their focus on preventative care, more employers -- especially large companies -- are turning to such programs. According to a 2008 national survey by Harris Interactive, 91 percent of employers “believed they could reduce their health care costs by influencing employees to adopt healthier lifestyles,” and consequently 57 percent of employers with 500 or more employees are providing employees with a wellness program. Sixteen percent of small employers are currently offering such programs. Many of these programs begin with health risk assessments (HRAs) that are designed to elicit personal health information (including family health history) for purposes of individualization of wellness program options that can lead to more targeted, and therefore more effective, treatment. Some “wellness programs” consist almost entirely of HRAs followed by an increase in the insured individual’s responsibility for the cost of premiums based on whether they meet a predetermined target. Participation in such programs is often induced through financial incentives; four out of five employers that have wellness programs are providing incentives to encourage employee participation, and such incentives are regularly used in adjusting employee premiums.

Under GINA, underwriting of any kind is prohibited. The interim final rules accurately note that GINA’s definition of underwriting is broader than activities relating to rating and pricing a policy. For example, many group health plans currently request family medical history information and may use the information in connection with wellness and disease management programs, to identify individuals at risk for certain conditions and provide an opportunity for prevention, disease management, or risk-reduction through changes in behavior. The regulation clearly prohibits insurers from offering discounts, rebates, payments in kind, or the imposition of punitive measures related to an individual completing a health risk assessments (HRA) or participating in a wellness program. The rule does not provide any exceptions; any reward or benefit given for the completion of an HRA or participation in a wellness program that collects family history violates GINA. Prior to or in connection with an enrollment, an HRA may not collect genetic information, including family history information, regardless of whether any benefit or reward is offered. And an HRA must include an explicit statement that genetic information should not be provided if it asks a general question like “Is there anything else you wish to share about your health?” Under the rules’ approach to incidental collection of genetic information, in the absence of such a statement any genetic information collected will violate GINA.

Since publication of the interim final rule, insurers and other entities administering wellness programs have expressed concern about these provisions. Although the rule does require a change in procedures for wellness programs, it is clear that insurers and others can continue to administer wellness programs that are strong, effective, and compliant with GINA. For example, some effective wellness approaches such as smoking cessation, weight loss programs or gym memberships can and should be offered broadly – there is no reason to collect genetic information before allowing access to these programs. In

addition, insurers and employers may choose to involve actual clinicians in conducting wellness programs. A treating clinician may, in the context of providing care to an individual, ask for family history or recommend genetic testing before referring individuals to particular wellness programs. Once an individual is enrolled, the insurer may collect family history or genetic information through an HRA as long as no rewards are provided (and as long as the information is not used for underwriting). An insurer may also reward the completion of an HRA or participation in a wellness program so long as no genetic information is collected.

In GINA, Congress took a two-pronged approach to eliminating genetic discrimination in employment and insurance. It not only prohibits the discriminatory *use* of genetic information, but also aims to prevent such use by strictly limiting the collection and acquisition of genetic information by employers and insurers to narrow circumstances where it is needed. Exempting wellness programs from GINA, as some have suggested, would create an enormous loophole for insurers and employers alike to have access to individual's genetic information. There is no need for such a loophole.

We believe that wellness programs can continue to grow and thrive under GINA, and that the provisions related to wellness programs should remain unchanged. There are numerous approaches to encouraging wellness that insurers and employer-sponsored health plans may take without violating GINA. We believe that changes in this area would be a tremendous mistake and would be counter to the plain language of GINA. Title II of GINA requires that the implementation of wellness programs outside the insurance context – in which the employer directly contracts with a third-party provider for the wellness program -- must be done on a voluntary basis. Final rules from the EEOC are expected to clarify this provision and what is meant by “voluntary”. We urge the agencies to coordinate efforts to clarify the overall impact of GINA on wellness programs.

### 3. Genetic information in medical records

GINA prohibits the *use* of genetic information by insurers for setting insurance rates and denying coverage. However, proving the basis of underwriting decisions can be difficult. Thus, the law includes prohibitions intended to prevent insurers from *obtaining* genetic information in the first place. The regulation generally prohibits requesting, requiring, or otherwise collecting genetic information, but there are several exceptions. “Incidental” collection would not violate GINA, and the interim final rules clarify when collection may be considered “incidental.” For example, if an insurer asks for health information, such as asking an applicant in the individual market to provide medical records, or asking as part of enrollment whether an individual has had recent laboratory tests, the request must be explicit that genetic information, including family history, should not be provided. If the insurer follows this rule, any collected genetic information will be considered “incidental” and will not violate GINA, as long as it is not used for underwriting.

According to comments received by the agencies, insurers in the individual insurance market request medical records for approximately 20 percent of applicants. These insurers will need to state explicitly that genetic information should not be provided, and request that providers redact any family medical history information.

GPPC believes that clear guidance on this issue will be critical to smooth and successful implementation of GINA overall. Undoubtedly, insurers will need to change forms and paperwork to comply with this new requirement. However, we believe the long-term impact of making these changes will be small.

We believe health care providers and their administrative staff will need clear guidance that, in the context of provision of clinical care, GINA does not prohibit, restrict, or otherwise discourage asking about and recording in a patient's medical record information about family history and other genetic information where appropriate. Indeed, such information can often be critical to good clinical care. It is the collection of this information by health insurers that is problematic. The burden appropriately falls on the health insurers to be explicit that they are not seeking genetic information when they are otherwise legitimately seeking medical records.

Even if a health care provider does not formally take a complete family history, discussions of illness in family members often arise in the context of a visit to a provider and may be noted in a patient's medical record. Thus, family history information may be noted in a patient's chart in more than one place. We recognize that in some cases it may be difficult for those who hold medical records, including providers, hospitals, insurers, and other entities and administrators, to remove or redact all genetic information from a medical record before sending it in response to a request. Although GPPC believes the rule takes an appropriate approach to liability on this issue, we urge the agencies to monitor the frequency with which "incidental" collection occurs through general requests for medical records. Currently, it may be difficult for health care entities to remove genetic information from records, but with the spread of electronic medical records and other automated systems it may soon be possible to develop better techniques for efficiently removing this information when records are sent to insurers while maintaining it for providers' use. The agencies enforcing GINA may be in an excellent position to provide additional guidance on this issue in the future.

Please do not hesitate to contact Joan Scott at [jscott22@jhu.edu](mailto:jscott22@jhu.edu)

Sincerely,

A handwritten signature in cursive script that reads "Joan Scott".

Joan Scott, M.S., C.G.C.

Director

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