

Genetics and Public Policy Center

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Comments of the Genetics and Public Policy Center, Johns Hopkins University on Proposed Rule Regarding the Privacy and Confidentiality of Genetic Information

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Department of Health and Human Services, Office of the Secretary
Office for Civil Rights
45 CFR Parts 160 and 164
RIN 0991-AB54

The Genetics and Public Policy Center at Johns Hopkins University is pleased to submit the following comments on the proposed rule implementing section 105 of the Genetic Information Nondiscrimination Act that was 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.

COMMENTS

GINA directed HHS to clarify that genetic information is protected health information and therefore subject to the Privacy Rule, and the proposed rule makes this clarification. GINA also requires HHS to change the Privacy Rule to prohibit health plans from using or disclosing genetic information for underwriting purposes, including determining eligibility or benefits, calculating premiums or contribution amounts, and imposing pre-existing condition exclusions. Although Title I of GINA specifies

that only certain plans be subject to this prohibition, OCR applies the prohibition to all health plans governed by the Privacy Rule, including long-term care policies and employee benefit welfare plans. HHS states that this interpretation is consistent with both GINA and HHS' authority under HIPAA. Finally, the proposed rule requires that plans that use or disclose protected information for underwriting purposes include a statement in their Notice of Privacy Practices about how they are prohibited from using or disclosing genetic information for underwriting purposes.

Overall, we support the proposed rule. Our comments are limited to the question of HHS' expansion of the new genetic information privacy standard for "any and all health plans that are governed by the HIPAA Administrative Simplification provisions." According to the proposed rule, covered entities would include (1) long-term care policies (excluding nursing home fixed-indemnity policies)(2) employee welfare benefit plans (3) high risk pools (4) certain public benefit programs including Medicaid, the military and veterans health care programs and the Indian Health Service program (5) any other individual or group plan or combination that provides or pays for the cost of medical care, including certain "excepted benefits" plans that would include dental, vision, disability income, and worker's compensation insurance among others.

GPPC supports laws and policies that prevent the misuse of genetic information to discriminate against individuals in many contexts beyond those explicitly addressed in GINA. Such protections will help improve the health and security of all Americans, by permitting the use of genetic medicine without fear of future discrimination. Health care and health insurance systems, such as Medicaid, the veteran's and military health care systems and others clearly ought to be included in applying GINA's privacy provisions.

We expect that the Department will receive comments objecting to its approach with regards to other insurance markets. As of this writing, 16 states regulate the use of genetic information in disability insurance, and 10 states regulate the its use in long-term care insurance. Although state approaches vary widely, the number of states acting in this area clearly has increased in recent years and the number is likely to continue to climb. As states move forward, we believe it is appropriate for the Federal government to move forward as well. However, the agencies implementing Title I of GINA should work to assure that this proposal does not negatively affect how GINA is implemented in the health insurance markets. In addition, HHS or other appropriate federal agencies should monitor the impact of GINA and this rule on the long-term care and disability income insurance markets.