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New Rules Protect Patients' Genetic Information

Individuals' genetic information will have greater protections through new regulations issued today by the U.S. Departments of Health and Human Services (HHS), Labor, and the Treasury.

The interim final rule will help ensure that genetic information is not used adversely in determining health care coverage and will encourage more individuals to participate in genetic testing, which can help better identify and prevent certain illnesses.

“Echoing the late Senator Ted Kennedy, our efforts to protect Americans undergoing genetic testing from having the results of that testing used against them by their insurance companies is one of the ‘first major new civil rights’ of the new century,” said HHS Secretary Kathleen Sebelius. “Consumer confidence in genetic testing can now grow and help researchers get a better handle on the genetic basis of diseases. Genetic testing will encourage the early diagnosis and treatment of certain diseases while allowing scientists to develop new medicines, treatments, and therapies.”

The interim final rule with request for comments and the notice of proposed rulemaking implement Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA). Under GINA, and the interim final rule, group health plans and issuers in the group market cannot: increase premiums for the group based on the results of one enrollee's genetic information; deny enrollment; impose pre-existing condition exclusions; or do other forms of underwriting based on genetic information. In the individual health insurance market, GINA prohibits issuers from using genetic information to deny coverage, raise premiums, or impose pre-existing condition exclusions.

Further, under GINA and the new interim final regulations, group health plans and health insurance issuers in both the group and individual markets cannot request, require or buy genetic information for underwriting purposes or prior to and in connection with enrollment. Finally, plans and issuers are generally prohibited from asking individuals or family members to undergo a genetic test.

“Today's genetic technologies yield data that are vital to helping Americans make personal, medical decisions. It is essential that we protect such information and ensure it is not misused by health plans or insurers,” said Labor Secretary Hilda L. Solis. “The rules issued today protect individuals against the unwarranted use of information related to their personal health because no one should have to fear that disclosure of their medical data will put their job or health coverage at risk.”

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Additionally, HHS, through its Office for Civil Rights (OCR), issued a notice of proposed rulemaking with a 60-day comment period, to propose changes to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to prohibit health plans from using or disclosing genetic information for underwriting purposes.

The proposed rule published today modifies the HIPAA Privacy Rule pursuant to GINA Title I to clarify that genetic information is health information and to prohibit the use and disclosure of genetic information by covered health plans for eligibility determinations, premium computations, applications of any pre-existing condition exclusions, and any other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits. In combination with the new penalties for violations of the HIPAA Privacy Rule, as provided for by the American Recovery and Reinvestment Act of 2009, a use or disclosure of genetic information in violation of the HIPAA Privacy Rule could result in a fine of \$100 to \$50,000 or more for each violation.

Please visit http://www.federalregister.gov/OFRUpload/OFRData/2009-22504_PI.pdf to view the new regulations and www.dol.gov/ebsa for more information about them. For additional information on the OCR notice of proposed rulemaking, please visit: www.hhs.gov/ocr/privacy.

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