

Association for Molecular Pathology

Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology 9650 Rockville Pike, Bethesda, Maryland 20814 Tel: 301-634-7939 • Fax: 301-634-7990 • Email: amp@asip.org • www.amp.org

November 13, 2009

U.S. Department of Health and Human Services Office for Civil Rights Attention: GINA NPRM (RIN 0991-AB54) Hubert H. Humphrey Building, Room 509F 200 Independence Ave., SW Washington, DC 20201

To Whom It May Concern:

The Association for Molecular Pathology (AMP) is an international medical professional association representing approximately 1,700 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. AMP has been a long time supporter of the Genetic Information Nondiscrimination Act (GINA) and commends the HHS Office of Civil Rights on drafting regulations that will effectively protect all Americans from this concerning form of discrimination. The fear of genetic discrimination and its ability to restrict patients' willingness to seek out medical genetics services has been well documented. AMP hopes that with the implementation of GINA, patients will more actively engage in research and utilize the advances in personalized medicine and molecular pathology.

AMP writes to you today in support of the draft proposed regulatory changes to amend the HIPAA Privacy Rule to implement GINA. The proposed rule extends the protections conferred by GINA to all health plans subject to the Privacy Rule, including health group plans, health insurance issuers, health maintenance organizations, Medicare supplemental policies, long-term care policies, employee welfare benefit plans, high risk pools, Medicare parts A & B, the military and veterans health care programs and the Indian Health Service. AMP agrees with the proposed rule's interpretation to apply GINA protections to all entities under the purview of the Privacy Rule.

AMP has recently co-signed letters to Congress to protect GINA from attempts to weaken the Title 1 provisions as they relate to employer based wellness programs. GINA allows employers to collect genetic information as part of a workplace wellness and prevention program as long as the program is voluntary. Employers would like to offer financial incentives to encourage people to complete health risk assessments. AMP views financial incentives as a penalty for those who choose to keep their sensitive genetic information private from their employer. Wellness programs are capable of encouraging healthy behaviors within the current legal framework, and they do need not to collect private, sensitive genetic information to be effective. Therefore, AMP endorses the proposed rule's interpretation of underwriting as it relates to wellness programs and supports restricting the use of financial incentives when collecting genetic information. AMP support for the draft proposed regulatory changes to amend the HIPAA Privacy Rule to implement GINA Nov. 13, 2009; page 2 of 2

Thank you very much for your attention and consideration of our comments. Please do not hesitate to contact us if we may be of assistance as you work to implement the privacy protections afforded by GINA.

Please do not hesitate to contact AMP if we can provide any further information or assistance.

Sincerely,

Jan Nowak, MD, PhD President