

July 13, 2006

Administrator Mark B. McClellan
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Dr. McClellan:

We, the undersigned organizations from the women's health community, write to urge you to issue proposed regulations for a genetic testing specialty pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1998. We are concerned that the science of genetic testing has outpaced the regulations currently in place to ensure the quality of genetic testing laboratories.

In 2000, the Centers for Medicare and Medicaid Services (CMS) issued a Notice of Intent of proposed rulemaking that incorporated recommendations and feedback from various stakeholders regarding the development of a genetic testing specialty. More than five years have passed and no proposed rule has been issued, and the recommended genetic testing specialty has yet to be established.

Meanwhile, the use of genetic testing as a tool for screening, diagnosis, prevention, and treatment has grown dramatically in the past decade. Currently, there are tests for close to 1000 genetic diseases available clinically, and several hundred more are under development. These tests provide information that patients use to help make life-altering decisions about whether to initiate or terminate a pregnancy; select an embryo to transfer after IVF through pre-implantation genetic diagnosis (PGD); undergo a prophylactic mastectomy; or take a particular drug or dosage of a drug.

Unfortunately, currently there are notable gaps in the regulatory oversight of genetic tests and of the laboratories that offer them. In order to protect consumers and to advance the potential benefits offered by genetic testing, the U.S. government has a responsibility to establish and uphold a regulatory framework under CLIA that, at a minimum, helps to ensure the safety, accuracy and effectiveness of the genetic tests being conducted.

We believe the establishment of a genetic testing specialty under CLIA is a critical first step in creating a regulatory system that helps ensure the safety and accuracy of new technologies, and encourages the development of new ones.

We urge CMS to take immediate steps to issue proposed regulations for a genetic testing specialty under CLIA.

Sincerely,

Association for Reproductive Health Professionals

Hadassah, the Women's Zionist Organization of America
NARAL Pro-Choice America
National Council of Women's Organizations
National Council of Jewish Women
National Organization for Women
National Partnership for Women and Families
National Research Center for Women and Families
National Women's Health Network
Nurse Practitioners in Women's Health
Planned Parenthood Federation of America
Reproductive Health Technologies Project
RESOLVE, The National Infertility Association
Society for Women's Health Research