



Archived Policy Statement

Letter to CMS Administrator Mark McClellan regarding genetic testing quality

February 28, 2006

Dear Dr. McClellan:

On behalf of the Genetic Alliance board of directors, I am writing to urge you to issue proposed regulations for a genetic testing specialty under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

As knowledge of genetics continues to grow and the number of genetic tests made available to consumers increases, the U.S. government has an obligation to maintain a regulatory framework that ensures the safety and utility of the tests being conducted without limiting the accessibility of those tests.

To this end, in 2000 the Centers for Disease Control and Prevention (CDC) issued a Notice of Intent indicating that the Centers for Medicare and Medicaid Services (CMS) would be issuing a proposed rule based on stakeholders' comments received and elucidated by the CDC. More than five years later, no such rule has been issued, and the genetic testing specialty that was recommended has not been established.

The Genetic Alliance board of directors believes that the establishment of a genetic testing specialty under CLIA is a necessary first step toward a regulatory system that encourages new technology and ensures safety and accuracy when those technologies are implemented.

Since the CDC issued its Notice of Intent more than five years ago, the number of genetic tests available has increased substantially. Today, there are more than 900 diseases for which genetic tests are clinically available, several hundred used in research, and even more in various stages of development.

Without a genetic testing specialty, CLIA cannot adequately ensure that consumers receive genetic testing services that are safe, accurate, and clinically useful. I urge CMS to act quickly by issuing proposed regulations for a genetic testing specialty under CLIA.

I welcome the opportunity to meet with you and discuss these issues in further detail.

Sincerely,

Sharon F. Terry, M.A.
President and CEO, Genetic Alliance