

## Policy Position: CLIA and Genetic Testing

Pharmacogenetics and pharmacogenomics hold enormous potential for improving health care by streamlining drug discovery, improving therapeutic decision-making and therapeutic response, and decreasing adverse reactions. The availability of tests that accurately and reliably identify variations in genes and gene expression that account for differences in drug response is critical to the success of pharmacogenetics. In turn, appropriate oversight of genetic testing laboratories is key to ensuring genetic testing quality and fostering public confidence in pharmacogenetics.

Currently, laboratories that perform genetic testing must meet general standards set by CMS under CLIA. Genetic tests are considered "high complexity" under CLIA. Federal advisory committees identified the creation of a genetic specialty under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 by the Centers for Medicare and Medicaid Services (CMS) as a critical component to improved oversight. In particular, the lack of a specialty area has meant that no specific proficiency testing requirements are mandated for genetic testing laboratories. Many laboratories go beyond the minimum through private-sector accreditation, but such accreditation is voluntary.

In response, in 2000 the Department of Health and Human Services (HHS) published a Notice of Intent (NOI) to propose a rule to create a genetic testing specialty. In April 2006, CMS placed the issuance of a proposed rule for a genetic testing specialty on its semi-annual regulatory agenda.

The creation of a genetic testing specialty under CLIA would help ensure the accuracy and reliability of genetic tests and would increase the public's trust in genetic testing and foster the promise of pharmacogenetics.

Therefore, the Personalized Medicine Coalition urges CMS to issue the proposed regulation for a genetic testing specialty under CLIA and to expeditiously issue a final rule following an appropriate period for public comment.

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