

**Clinical Laboratory Improvement Advisory Committee (CLIAC)**  
**Discussion on Clinical Laboratory Improvement Amendments of 1988 (CLIA)**  
**Oversight of Genetic Testing**  
**February 14, 2007**

In response to CLIAC's September 2006 request for further discussion on the Centers for Medicare & Medicaid Services (CMS) decision not to publish a Notice of Proposed Rulemaking (NPRM) for a genetics specialty, Ms. Judy Yost, Director, Division of Laboratory Services, Survey and Certification Group, CMS, provided an update on the status of CLIA and genetic testing oversight. (see attached)

Following Ms. Yost's presentation, the Committee expressed support for CMS efforts to improve its website, provide technical training to surveyors on genetic testing issues, and collaborate with the Centers for Disease Control and Prevention (CDC) to publish educational materials via a *Morbidity and Mortality Weekly Report Recommendations and Report*. The following comments and suggestions were made regarding enhancing CLIA oversight for genetic testing:

- Several CLIAC members disagreed with the CMS decision against establishing a genetics specialty under CLIA and stated that the rationale for this requires further justification. For example, the genetic testing community has expressed quality concerns in the areas of result interpretation and personnel qualifications; however, problems in these aspects are not captured by CMS survey data since genetic testing laboratories are not routinely inspected by CMS surveyors.
- Genetic testing should be recognized as a specialty under CLIA because genetics is an area of medicine recognized by the American Medical Association and a specialty approved by the American Board of Medical Specialties.
- There should be specific oversight for laboratories performing genetic testing, either in surveyor guidance or CLIA regulations, regarding personnel, proficiency testing (PT), and quality control (QC).
- Since most identified problems occur in the pre- and post-analytic phases rather than the analytic phase of genetic testing, minimum training and/or experience requirements are needed for technical supervisors and laboratory directors of genetic testing laboratories.
- The definition of genetic tests needs to be determined.
- Genetic tests ordered for patient care should have both analytical validity and clinical validity. This could be ensured through appropriate requirements for the pre-analytic phase and through education for laboratory personnel and users of laboratory services. CLIAC recognizes, however, that clinical validity of testing is beyond the scope of CLIA.
- Flexible and non-prescriptive QC and PT requirements for molecular genetics should be developed and included in survey guidelines.
- It is important to recognize voluntary standards developed by professional societies and use them as best practice guidelines.

At the conclusion of the discussion, the Committee acknowledged the expedience of exploring and using the current regulatory framework to attain enhanced oversight for genetic testing. CLIAC agreed that CMS and CDC should work with experts to further clarify the critical issues and subsequently include presentations by CDC staff and perspectives of other representatives for consideration at the next Committee meeting.