



Highlights of [GAO-06-416](#), a report to congressional requesters

Why GAO Did This Study

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) strengthened and extended quality requirements for labs that perform tests to diagnose or treat disease. About 36,000 labs that perform certain complex tests must be surveyed biennially by either a state or one of six private accrediting organizations. CMS oversees implementation of CLIA requirements and the activities of survey organizations. GAO was asked to examine (1) the quality of lab testing; (2) the effectiveness of surveys, complaint investigations, and enforcement actions in detecting and addressing lab problems; and (3) the adequacy of CMS's CLIA oversight.

What GAO Recommends

GAO is making recommendations to the CMS Administrator to improve CLIA oversight including (1) standardizing the reporting of survey deficiencies to permit meaningful comparisons across survey organizations; (2) working with survey organizations to ensure that educating lab workers does not preclude appropriate regulation, such as identifying and reporting deficiencies that affect lab testing quality; and (3) allowing the CLIA program to fully use revenues generated by the program to hire sufficient staff to fulfill its statutory responsibilities. CMS concurred with 11 of GAO's 13 recommendations and noted that the report provided insights into areas where it can improve, augment, and reinforce oversight.

www.gao.gov/cgi-bin/getrpt?GAO-06-416.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Leslie G. Aronovitz at (312) 220-7600 or aronovitzl@gao.gov.

CLINICAL LAB QUALITY

CMS and Survey Organization Oversight Should Be Strengthened

What GAO Found

Because of limited comparable data from CMS and survey organizations, too little is known about the quality of lab testing. For example, a standardized assessment of lab quality across survey organizations is not possible because of different definitions of what constitutes a serious quality problem. One survey organization had no systematic way of identifying the problematic labs it inspects. However, GAO's analysis of an indicator that measures a lab's ability to consistently produce accurate test results suggests that lab quality may not have improved at hospital labs in recent years.

Based on an analysis of available data and interviews with CMS and survey organizations, real and potential lab quality problems are masked by survey, complaint, and enforcement weaknesses. Because most survey organizations announce the timing of biennial surveys, allowing labs to prepare for inspections, surveys may not provide a realistic picture of lab quality. Although two survey organizations that generally inspect hospital labs plan to begin unannounced surveys in 2006, they may not be possible at physician office labs that have irregular hours. Survey organizations that typically inspect such labs, however, provide more advance notice about upcoming inspections than CMS allows states to provide. Several other factors suggest that surveys and complaints do not present a realistic picture of lab quality. Interviews with officials from a sample of states confirmed that some survey organizations do not cite all serious deficiencies, as evidenced by variability in the limited available lab survey data. Officials said that surveyors may be reluctant to cite deficiencies because they view their role as educational, not regulatory; moreover, CMS has instructed state surveyors not to cite some deficiencies for over 2 years after implementing new lab requirements. Finally, lab workers may file complaints infrequently because of concern about retaliation and a lack of understanding about how to file a complaint. CMS rarely imposes sanctions, even for labs with the same repeat deficiencies, a reflection of the educational focus of the CLIA program.

CMS does not require labs to participate in a key quality assurance test as frequently as CLIA requires. Although funded by lab fees, CMS officials indicated that the program has not been allowed to hire sufficient staff to carry out the agency's oversight responsibilities. Moreover, CMS's principal oversight tool, intended to determine if all serious deficiencies were identified, lacks independence because many oversight reviews are conducted simultaneously with survey organizations. CMS's presence may make surveyors more attentive to survey tasks than when they are not being observed. Compared to independent reviews, simultaneous reviews rarely identify missed deficiencies. Furthermore, CMS does not collect and analyze data on serious deficiencies identified by each survey organization and thus, is unable to assess whether lab quality is improving or declining. Nor does CMS effectively analyze other key data such as the use of sanctions. To improve oversight, CMS is establishing a nationwide complaints database. CMS is also instituting annual survey organization performance reviews.