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CLINICAL LABS

CMS and Survey Organization Oversight Is Not Sufficient To Ensure Lab Quality

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Highlights

Highlights of GAO-06-879T, a testimony before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform, House of Representatives

Why GAO Did This Study

Today's hearing focuses on oversight of clinical labs. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) strengthened 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 a state survey agency, a state CLIA-exempt program, or a private accrediting organization. CMS oversees implementation of CLIA requirements, which includes determining the CLIA equivalency of the inspection requirements used by exempt states and accrediting organizations. GAO was asked to discuss (1) the quality of lab testing and (2) the adequacy of CLIA oversight. To examine these issues, GAO analyzed data on lab performance and reviewed the procedures used by CMS and survey organizations to implement CLIA and oversee lab performance. This testimony is based on the GAO report, *Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened*, GAO-06-416 (June 16, 2006).

What GAO Recommends

In a report released today, GAO made numerous recommendations to the CMS Administrator that would strengthen program oversight. CMS noted that the report provided insights into areas where it can improve oversight and said that it would implement 11 of GAO's 13 recommendations.

www.gao.gov/cgi-bin/getrpt?GAO-06-879T.

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.

What GAO Found

In summary, insufficient data exist to identify the extent of serious quality problems at labs. When CMS implemented revised CLIA survey requirements in 2004, it modified historical state survey agency findings and, as a result, data prior to 2004 no longer reflect key survey requirements in effect at the time of those surveys. The limited data available suggest that state survey agency inspections do not identify all serious deficiencies. In addition, the lack of a straightforward method to link similar requirements across survey organizations makes it virtually impossible to assess lab quality in a standardized manner. Furthermore, CMS does not effectively use available data, such as the proportion of labs with serious deficiencies or proficiency testing results, to monitor lab quality. Proficiency testing is an objective measurement of a lab's ability to consistently produce accurate test results. GAO's analysis of proficiency testing data suggests that lab quality may not have improved at hospital labs in recent years.

Oversight of clinical lab quality is not adequate to ensure that labs are meeting CLIA requirements. Weaknesses in five areas mask real and potential quality problems at labs. First, the balance struck between the CLIA program's educational and regulatory goals is sometimes inappropriately skewed toward education, which may result in understatement of survey findings. For example, even though the initial test failure rates were high, CMS instructed state survey agencies not to cite deficiencies during the first two years of required Pap smear proficiency testing, to allow labs and their staff to become familiar with the program. Second, the manner in which one accrediting organization structures its survey teams raised concerns about appropriate levels of training and the appearance of a conflict of interest that could undermine the integrity of the survey process. Third, concerns about anonymity and lab workers' lack of familiarity with how to file a complaint suggests that some quality problems are not being reported. Fourth, based on the large number of labs with proposed sanctions from 1998 through 2004 that were never imposed—even for labs with the same serious deficiencies on consecutive surveys—it is unclear how effective CMS's enforcement process is at motivating labs to consistently comply with CLIA requirements. Finally, CMS is not meeting its requirement to determine in a timely manner the continued equivalency of accrediting organization and exempt-state program inspection requirements and processes, nor has the agency reviewed changes to accrediting organization and exempt-state program inspection requirements before implementation.