United States Government Accountability Office (GAO) Targets Laboratory Quality

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Once again, the quality of services provided by clinical laboratories across the nation is under the scrutiny of the federal government. CLIA '88 was implemented in 1992 to ensure that all laboratories meet the same minimal standards, based on the complexity of testing performed rather than by location. However, laboratory quality problems recently surfaced in several locations, prompting proposed federal legislation and a study of clinical laboratory quality by the US Government Accountability Office (GAO) to assess:

- the quality of laboratory testing,
- the effectiveness of surveys, complaint investigations, and enforcement actions in detecting problems and ensuring compliance, and
- the adequacy of the oversight provided by the Centers for Medicare and Medicaid Services (CMS) to the CLIA program.

The study, presented to Congress in June 2006, focused on oversight by CMS, state CLIA-exempt programs, and laboratory accrediting agencies including the College of American Pathologists (CAP), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and COLA. Principal findings cited by GAO in the study include:

1. **Insufficient data exists to identify the extent of the problem.**
   CMS state survey data prior to 2004 is not available. When inspection guidelines changed in 2004, the prior data was purged. GAO is concerned that potential quality problems are masked.
2. **Announced inspections are problematic.**
   Laboratories prepare specifically for inspection so announced inspections fail to provide a true picture of the laboratory's quality. CAP and JCAHO inspections have since begun announced inspections. All agree that physician office laboratory inspections should be announced due to disruption of patient care, but the amount of notification provided should not exceed two weeks, the current maximum notice CMS allows for state agencies.
3. **State agencies do not use consistent terminology to identify all serious deficiencies.**
   Standard-level deficiencies cited in one state might be condition-level deficiencies in another state.
4. **The balance between an educational approach and a regulatory focus is skewed too much toward education.**
   Most agencies emphasize the importance of using the inspection process to educate; however, GAO states that such an approach has resulted in phase-ins for new quality control requirements and cytology proficiency testing that are too lenient.
5. **Few complaints have been submitted due to perceived risk of punitive action and individuals' not knowing how/where to direct complaint.**
   No federal whistleblower protection exists for laboratory workers regarding CLIA. CAP-substantiated complaints increased from 40 in 2003 to 70 in 2004. CAP-accredited laboratories are now required to display a poster with a number to report complaints and to have a non-retaliatory policy, however, the poster was not implemented until the fall of 2004.
6. **Proposed sanctions are not consistently implemented.**
   GAO expressed concern about the number of laboratories that have the same condition-level deficiency survey after survey. In practice, laboratories sometimes correct problems during the grace period before sanctions are actually issued.
7. **Proficiency testing (PT) is required three times per year and not four times as mandated by CLIA statute.**
   Initially CMS did not want to overwhelm PT providers so frequently, since many more laboratories became subject to PT when CLIA went into effect. GAO considers this to be a significant quality issue that may result in problems going undetected. CMS disagrees with this finding, contending three PT events per year allow time for laboratories to receive reports and take corrective action before retesting.

Washington Beat is intended to provide a timely synopsis of activity in the nation's capitol of importance to clinical laboratory practitioners. This section is coordinated jointly by Judy Davis and Linda Comeaux, Co-chairs of the ASCLS Government Affairs Committee; and Don Lavanty, ASCLS Legislative Counsel. Direct all inquiries to ASCLS, (301) 657-2768 ext. 3022, (301) 657-2909 (fax); or mail to ASCLS, 6701 Democracy Boulevard, Suite 300, Bethesda MD 20817, attn: Washington Beat.

8. **Too many validation surveys are done simultaneously.**
   Validation surveys are required for one percent of state surveys and five percent of accreditation organization surveys. A mix of simultaneous and independent surveys should occur to provide a true picture; however, comparing results remains challenging since accrediting organization requirements differ.
9. **CMS does not evaluate accrediting organization equivalency in a timely manner**
   Accrediting organizations submit changes in their standards or survey process to CMS but a review of the changes is not required prior to implementation. CMS says delays are due to staffing issues. Although CLIA is funded by fees paid by certified laboratories and funds are available for more staff, federal staffing limits prohibit hiring additional personnel.
10. **Proficiency testing suggests quality has not improved in hospital laboratories.**
    PT failures (two of three or two consecutive unsatisfactory PT events) in CAP laboratories have increased from 4.1% in 1999 to 6.8% in 2003.
11. **CAP volunteer surveyors are less trained and may have a conflict of interest; in addition, conflicts with supervisory team members may affect findings.**
    Although CAP says no factual data shows volunteers are less effective, the agency is increasing inspector-training requirements.
12. **CMS does not effectively use available data to assess quality with proficiency testing, sanctions, and complaints.**

GAO recommendations include:

- Standardize exempt-state and accrediting organization standards so meaningful comparisons can be done across organizations.
- Limit advance notice for POL inspections to two weeks.
- Focus inspections primarily on regulation, not education.
- Use appropriate sanctions for laboratories with consecutive condition-level deficiencies in the same areas.
- Require all survey organizations to require laboratories to post information on how to file anonymous complaints.
- Require quarterly proficiency testing.
- Evaluate equivalency of survey organizations prior to expiration of approval period. Review changes in survey organization inspection requirements prior to implementation.
- Use available revenue to hire enough CLIA staff to fulfill statutory responsibilities.
- Validate an adequate number of survey organizations' surveys each year.
- Collect and review findings to ensure CLIA requirements are being enforced. Establish a database to monitor actions taken on laboratories that lose accreditation.

CMS, CAP, JCAHO, and COLA all submitted comments and listed changes made in response to the GAO report. CMS and CAP both commented that laboratory quality has improved since CLIA '88. CMS has implemented a complaint tracking system and is working with accrediting and CLIA-exempt state agencies to improve communication regarding quality issues.

JCAHO also commented, "The personnel standards enacted by CLIA are insufficient to adequately protect patients and the public health" and "the problems underlying failure in laboratory performance that are most often cited by experts in the field are the growing shortage of laboratory technologists and the inadequacy of their training". ASCLS has long held that competency of laboratory professionals is essential for laboratory quality.