

June 2006

CLINICAL LAB QUALITY

CMS and Survey Organization Oversight Should Be Strengthened





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.

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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.

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Abbreviations

AAAB	American Association of Blood Banks
AOA	American Osteopathic Association
ASHI	American Society of Histocompatibility and Immunogenetics
CAP	College of American Pathologists
CLIA	Clinical Laboratory Improvement Amendments of 1988
CMS	Centers for Medicare & Medicaid Services
CMSO	Center for Medicaid and State Operations
ER	emergency room
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
OSCAR	On-Line Survey, Certification, and Reporting system

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United States Government Accountability Office
Washington, DC 20548

June 16, 2006

The Honorable Charles E. Grassley
Chairman
Committee on Finance
United States Senate

The Honorable Mark Souder
Chairman
The Honorable Elijah E. Cummings
Ranking Minority Member
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
Committee on Government Reform
House of Representatives

Clinical lab tests are one of the most frequently billed Medicare procedures and, according to the American Clinical Laboratory Association, affect an estimated 70 percent of medical decisions.¹ To improve oversight of clinical labs, Congress passed legislation in 1967;² renewed concerns about quality, including errors in Pap smear tests used to diagnose cervical cancer, resulted in enactment of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).³ In recent years, despite CLIA, lab quality problems in several states have raised questions about the adequacy of lab oversight. Lab oversight is critical because inaccurate or unreliable lab tests may lead to improper treatment, unnecessary mental and physical anguish for patients, and higher health care costs.⁴

The Centers for Medicare & Medicaid Services (CMS) is responsible for overseeing compliance with CLIA requirements. As of December 2005, there were approximately 193,000 labs nationwide, ranging from very small physician office labs that conduct fewer than 2,000 tests annually to

¹Medicare is a federal health care program serving the elderly and disabled individuals.

²Clinical Laboratories Improvement Act of 1967, Pub. L. No. 90-174, §5, 81 Stat. 533, 536.

³Pub. L. No. 100-578, 102 Stat. 2903.

⁴Appendix I provides examples of the effect of lab errors on patient health.

hospital labs that conduct millions of tests each year. Most clinical labs regulated under CLIA must obtain a certificate from CMS but only about 19 percent—those that conduct moderate- to high-complexity tests—undergo biennial inspections, which are also referred to as surveys.⁵ The surveys assess lab compliance with mandated personnel and testing standards. In addition, surveyed labs must participate in proficiency testing, a program that requires them to test samples with unknown characteristics that are then graded by an external party. Labs with serious deficiencies may be sanctioned, e.g., required to cease testing. Labs have a choice of being surveyed by (1) their state survey agency, under contract with CMS; (2) their state CLIA-exempt program for labs in New York and Washington; or (3) one of six private accrediting organizations.⁶ State survey agency inspections use CLIA requirements that are intended to help ensure valid and reliable lab tests; the two state CLIA-exempt programs and six accrediting organizations survey labs using their own requirements that CMS has determined to be at least equivalent to CLIA's. Each survey organization is also responsible for investigating complaints about lab quality.⁷ Because of the critical importance of accurate lab test results and oversight, you asked us to conduct a nationwide assessment of (1) the quality of lab testing; (2) the effectiveness of surveys, complaint investigations, and enforcement actions in detecting problems and ensuring compliance; and (3) the adequacy of CMS oversight of the CLIA program.

To determine what is known about the quality of lab testing, we analyzed data on serious deficiencies identified during surveys by state survey agencies using CMS's On-Line Survey, Certification, and Reporting system

⁵Labs obtain a CLIA certificate that corresponds to the complexity of the testing they conduct. Generally, each lab has one certificate but a large hospital with multiple labs may have a corresponding number of certificates. By regulation, labs that are within a hospital campus and under common direction are allowed to file either a single application for a certificate or multiple applications for multiple certificates.

⁶CMS contracts with state survey agencies in the District of Columbia and 49 states (including New York but not Washington) to survey labs under CLIA requirements. Labs in Washington are surveyed either by the state's CLIA-exempt program or by an accrediting organization. Labs in New York are surveyed either by the state survey agency or New York's CLIA-exempt program. New York does not authorize accreditation as a basis for lab licensure.

⁷Throughout this report, we use the term "survey organizations" when referring collectively to state survey agencies, the two state CLIA-exempt programs, and accrediting organizations.

(OSCAR).⁸ The CLIA program inspection requirements are classified as either “standard-” or “condition-” level. Similarly, deficiencies are also characterized as standard- or condition-level, based on the requirement in which the deficiency occurs. Because condition-level requirements generally consist of one or more standard-level requirements, a deficiency at the condition-level denotes a serious or systematic problem. We requested comparable data on serious deficiencies from state CLIA-exempt programs and the three largest accrediting organizations—the College of American Pathologists (CAP), COLA, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)—which together survey about 97 percent of accredited labs.⁹ CAP, COLA, JCAHO, and exempt-state programs each maintain their own separate databases. We also analyzed proficiency testing data—another indicator of a lab’s ability to produce accurate test results. CMS officials generally recognize OSCAR and proficiency testing data to be reliable. We discussed the OSCAR database with CMS officials and tailored our analysis to ensure the accuracy of our findings. Because exempt states and accrediting organizations survey labs using their own requirements, we worked with them to develop data comparable to OSCAR deficiency data. We discussed our analyses with CMS and each of the survey organizations to ensure that we had interpreted the data correctly. Based on discussions with officials from the three accrediting organizations, we determined that they take appropriate steps to ensure the reliability of their data. Because it was not practical to independently test the reliability of accrediting organization data, we present these data as reported by those organizations.

To assess the effectiveness of lab surveys, complaint investigations, and enforcement mechanisms in detecting problems and securing compliance, we reviewed the processes used to ensure the quality of clinical lab testing and analyzed available data related to these issues. We also conducted structured interviews with officials from (1) CMS, (2) three CMS regional

⁸In addition to the results of state survey agency lab inspections, CMS’s OSCAR database stores other information on labs registered under the CLIA program including: (1) labs’ CLIA certificate history, such as switching from being inspected by accrediting organizations to being inspected by state survey agencies; (2) the results of complaint investigations; (3) labs’ billing history; and (4) proficiency testing enrollment and performance data.

⁹COLA was formerly known as the Commission on Office Laboratory Accreditation.

offices,¹⁰ (3) 10 state survey agencies,¹¹ (4) the New York and Washington CLIA-exempt programs, and (5) the three accrediting organizations. We judgmentally selected the 10 state survey agencies to include a mixture of states whose lab inspections identified a range of serious deficiencies from few to many. We also discussed the quality problems discovered at a Maryland hospital lab with a Maryland state survey agency official and interviewed 9 of the 36 CAP surveyors who participated in surveys of this lab from 1999 through 2003 to obtain a firsthand perspective on the CAP survey process.¹² Based on our review and discussions with CMS and survey organization officials, we focused on several key issues, including the rationale for announced surveys, the ability of lab surveys to identify serious deficiencies, the balance struck between the regulatory and educational goals of lab surveys, the implications of CAP's use of volunteer surveyors from neighboring labs to conduct inspections, how survey organizations facilitate the filing of complaints, and the use of sanctions to encourage compliance. We analyzed data on the number of complaints received by each survey organization from 2002 through 2004 and discussed CAP's initiatives to encourage the filing of complaints. In addition, we determined the extent to which labs had the same serious problems on consecutive surveys and discussed with CMS the steps the agency had taken to deter an inconsistent pattern of compliance.

To assess the effectiveness of CMS oversight of the CLIA program, we analyzed the laws and regulations that define CMS's role and authority. We also reviewed CMS's process for determining that the survey requirements and procedures of state CLIA-exempt programs and accrediting organizations are at least equivalent to those of CLIA. We analyzed the results of validation reviews that federal surveyors from CMS regional offices conducted for state survey agency lab inspections and that state survey agency staff conducted for accrediting organization inspections from 1999 through 2003. We also examined other mechanisms that CMS uses to hold survey organizations accountable for their performance:

¹⁰New York, Philadelphia, and Seattle.

¹¹California, Colorado, Connecticut, Idaho, Louisiana, Michigan, Nebraska, North Carolina, Pennsylvania, and South Carolina.

¹²A 2004 complaint investigation conducted by the Maryland state survey agency found that personnel at this lab falsified records to conceal problems with HIV and hepatitis testing equipment and that the lab provided hundreds of patients with potentially erroneous test results. These problems were not detected during the 2003 CAP inspection or a prior complaint investigation conducted by the state survey agency in 2002.

(1) the collection and analysis of data on surveys, complaints, and enforcement actions, including steps taken to address communication and coordination issues that became evident during a complaint investigation at a Maryland hospital lab; and (2) recently developed annual reviews that measure state survey agency compliance with CLIA program requirements, such as the timeliness of surveys. We conducted our work from January 2005 through May 2006 in accordance with generally accepted government auditing standards.

Results in Brief

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 stored in its OSCAR database and, as a result, data prior to 2004 no longer reflect key survey requirements in effect at the time of those surveys. 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, such as identifying the proportion of labs with condition-level deficiencies, which indicate serious or systemic quality problems. Although CMS has stated that it believes lab quality has improved since the early 1990s, the results of proficiency testing—the one available data source that can be used to uniformly compare lab quality across survey organizations—suggest that lab quality may not have improved at hospital labs and that the improvement for physician office labs may be misleading because a significant number of such labs are no longer inspected.

Weaknesses in surveys, complaint processes, and enforcement mask potential quality problems at labs. Lab survey findings may not accurately reflect the actual quality assurance process in place on a day-to-day basis because of several shortcomings. First, most survey organizations announce all surveys, allowing labs to prepare for their inspections. To address this problem, accrediting organizations that inspect hospital labs began conducting unannounced surveys in 2006. Second, the limited data available suggest that state survey agency inspections do not identify all serious deficiencies. Third, the balance struck between the CLIA program's educational and regulatory goals is sometimes inappropriately skewed toward education, which may also result in understatement of survey findings. For example, CMS instructed state survey agencies not to cite deficiencies for new lab quality control requirements for 2 years, in part because of a lack of lab "buy-in" for some of the new policies and procedures; CMS then extended this period and gave no specific end date. Regarding complaint processes, complaints are filed by a variety of

sources, including lab workers. Few labs were the subject of a complaint each year from 2002 through 2004—significantly less than one complaint per lab per year. Concern that labs can easily identify the lab workers who file complaints and lab workers’ lack of familiarity with how to file a complaint may explain why so few workers report problems. Since one accrediting organization required each lab it inspects to display a poster explaining how to file a complaint, the number of complaints it received about lab quality has doubled. Finally, 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, condition-level deficiencies on consecutive surveys—it is unclear how effective CMS’s enforcement process is at motivating labs to consistently comply with CLIA requirements.

CMS’s oversight of clinical lab quality is inadequate to ensure that labs are meeting CLIA requirements. The agency requires proficiency testing three times each year instead of on a quarterly basis, as required by CLIA. Nor is CMS meeting its own requirement to determine in a timely manner the continued equivalency of accrediting organization and exempt-state inspection requirements and processes. For example, New York’s and COLA’s reviews were about 4 years and 3 years past due, respectively, as of December 2005. CMS attributed these delays to having too few staff. Moreover, CMS allows the implementation of changes to accrediting organization and exempt state inspection requirements between periodic equivalency determinations before it reviews the proposed changes. Validation reviews—one of CMS’s most important oversight tools—do not provide an independent assessment of the extent to which surveys identify all serious deficiencies because many are performed simultaneously with such surveys. In addition, CMS’s requirement for validating state survey agencies’ inspections is vague, resulting in no validation reviews in some states. Finally, CMS does not effectively use data to monitor survey organization activities and processes, such as the proportion of labs with serious deficiencies, proficiency testing results, or trends in complaints. Realizing that its existing oversight activities need to be strengthened, CMS has begun instituting performance reviews to measure survey organization compliance with its requirements and is developing protocols to ensure improved communication among survey organizations concerning complaints about lab quality.

We are recommending that the CMS Administrator take actions that will standardize survey findings across survey organizations, enable it to compare changes over time, and make meaningful comparisons among organizations; strengthen survey, complaint, and enforcement processes;

and improve CMS oversight of the CLIA program. In commenting on a draft of this report, CMS endorsed our overall conclusion that quality assurance for the nation's clinical labs should be strengthened and said that it would take actions in response to 11 of our 13 recommendations. CMS disagreed with our recommendations concerning the frequency of proficiency testing and the extent of simultaneous accrediting organization validation reviews. We believe that implementing these recommendations is necessary to improve oversight of labs and accrediting organizations. CMS also provided an alternative assessment of lab quality, disagreed with our conclusion about the educational phase-in periods for new CLIA requirements, and expressed concern about identifying and sanctioning labs with repeat condition-level deficiencies. CAP, COLA, and JCAHO also provided comments on a draft of this report. CAP indicated that it would identify additional measures it could take to strengthen its own oversight, and COLA found merit in our recommendations to improve CMS oversight. CAP, COLA, and JCAHO disagreed with some of our findings and recommendations to CMS. We incorporated technical comments from CMS and the three accrediting organizations, as appropriate.

Background

A clinical lab is generally defined as a facility that examines specimens derived from humans for the purpose of disease diagnosis, prevention, and treatment, or health assessment of individuals. While hospital and interstate labs were previously subject to regulation, CLIA strengthened federal requirements and extended them to most other clinical labs, including physician office labs. For example, CLIA strengthened personnel requirements for lab workers, strengthened proficiency testing that evaluates the accuracy of lab testing between surveys, and created a range of sanctions to enforce compliance.¹³

Most clinical labs regulated under CLIA must obtain a certificate from CMS and pay fees every 2 years to cover the costs of administering the CLIA program, including surveys and other oversight activities.¹⁴ The fees

¹³Implementation of CLIA was phased in over a number of years. CLIA does not apply to forensic laboratories, research laboratories that do not report patient-specific results, drug testing laboratories certified by the Substance Abuse and Mental Health Services Administration, and Veterans Administration laboratories.

¹⁴Labs surveyed by either the New York or Washington CLIA-exempt programs do not obtain a CLIA certificate and do not pay fees to CMS. According to CMS, labs are billed a year in advance of the surveys to provide adequate time for them to pay their fees and for states to perform surveys prior to the expiration of labs' CLIA certificates.

vary based on the complexity and volume of testing performed. Lab tests are categorized as waived, moderate, or high complexity.¹⁵ Approximately 81 percent of all labs (about 157,000) are not subject to routine biennial surveys because they perform (1) “waived” tests, which are examinations and procedures that have an insignificant risk of erroneous results, including those approved for home use or determined to employ methodologies so simple or accurate that the likelihood of erroneous results is negligible;¹⁶ or (2) tests performed during the course of a patient visit with a microscope on specimens that are not easily transportable.¹⁷

Surveyed Labs

CLIA establishes more stringent requirements for the 19 percent (about 36,000) of labs performing moderate- or high-complexity testing, including the requirement for a survey and participation in routine proficiency testing. Since the early 1990s, the number and proportion of labs subject to surveys have declined, while the number and proportion conducting waived tests have increased.¹⁸ Surveys examine lab compliance with CLIA program requirements in several areas including: personnel qualifications, proficiency testing, quality control, quality assurance, and recordkeeping.

- Personnel: CLIA sets minimum qualifications for all persons performing or supervising moderate- or high-complexity lab tests and specifies responsibilities for each position.
- Proficiency testing: Surveyed labs must participate in an approved external proficiency testing program, which evaluates the accuracy of laboratory testing. Under this requirement, labs purchase samples with unknown characteristics several times each year from an approved

¹⁵In January 2000, the Food and Drug Administration assumed responsibility for categorizing tests conducted by labs from the Centers for Disease Control and Prevention.

¹⁶Pregnancy and blood sugar screenings are examples of such tests. Labs conducting waived tests are only required to follow manufacturers’ instructions and to limit testing to Food and Drug Administration-approved or cleared methods.

¹⁷Known as provider-performed microscopy procedures, such tests must be performed by a physician or other qualified provider as defined in CLIA regulations. Labs conducting such tests are required to have written procedures for the tests they perform and must also satisfy applicable proficiency testing requirements and have a system to ensure the competency of testing personnel. These labs and those performing waived tests are subject to complaint investigations. *See* 42 C.F.R. § 493.1773(f)(2005).

¹⁸From 1998 through December 2005, the proportion subject to surveys has declined from about 30 percent to about 19 percent, while the proportion of labs that are not surveyed because they perform waived testing has increased from 70 percent to 81 percent.

proficiency testing provider.¹⁹ The lab is required to test the samples with its routine patient testing, and the results are returned to the testing provider to be graded. A proficiency testing failure is defined as unsatisfactory performance on two consecutive or two out of three testing events. The results of proficiency testing for all inspected labs are transmitted to CMS and maintained in a database.

- Quality control: Labs must have a process for routinely monitoring personnel, testing equipment, and the testing environment to ensure proper operation and accurate results.
- Quality assurance: Labs must follow their plan to monitor the overall operation of the laboratory on an ongoing basis and must resolve identified problems that affect the quality of their testing.
- Recordkeeping: Labs must maintain an audit trail of testing that documents specimen integrity and test performance for all phases of the test process from the test order to the test report.

Survey Organizations

In general, labs have a choice of who conducts their surveys—state survey agencies using CLIA inspection requirements or other survey organizations that use requirements CMS has determined to be at least equivalent to CLIA's.²⁰ CMS contracts with state survey agencies in most states to inspect labs against CLIA requirements.²¹ CLIA established an approval process to allow states and private accrediting organizations to use their own requirements to survey labs.²² As noted earlier, New York and Washington operate CLIA-exempt programs and CMS has approved six private, nonprofit accrediting organizations to survey labs—the American Association of Blood Banks (AABB), the American Osteopathic Association (AOA), the American Society of Histocompatibility and Immunogenetics (ASHI), CAP, COLA, and JCAHO. The requirements of both state CLIA-exempt programs and accrediting organizations must be reviewed by CMS at least every 6 years to ensure CLIA equivalency, but may be more stringent than those of CLIA. For example, when inspecting

¹⁹Proficiency testing providers are private companies or state lab departments and are approved by CMS annually.

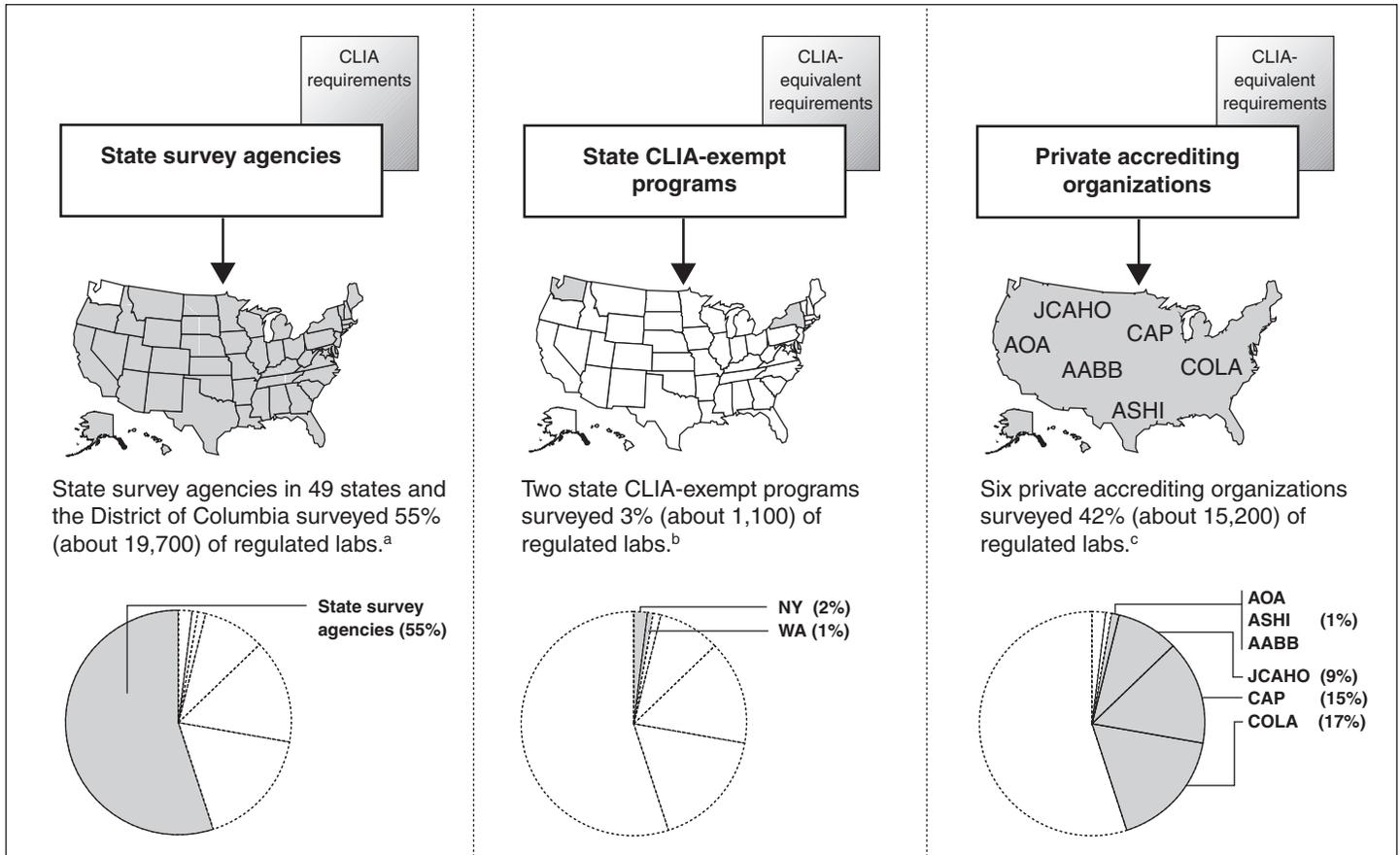
²⁰Some labs, including Indian Health Service labs, are surveyed by federal surveyors located in CMS's regional offices.

²¹CMS contracts with state survey agencies in the District of Columbia and 49 states (including New York but not Washington) to survey labs under CLIA requirements.

²²Prior to CLIA, CMS was not required to routinely determine the equivalency of accrediting organization and state CLIA-exempt program requirements.

labs engaged in moderate- and high-complexity testing, New York and some accrediting organizations also look at the labs' procedures for conducting "waived" tests, which is not required under CLIA. Figure 1 lists the three types of survey organizations and indicates whether they survey labs under CLIA requirements, or use their own CLIA-equivalent requirements. It also shows the percentage of labs performing moderate- to high-complexity testing surveyed by each type of organization. In general, state survey agencies, COLA, and Washington's CLIA-exempt program survey physician office labs, while New York's CLIA-exempt program, CAP, and JCAHO survey hospital labs.

Figure 1: Types of Survey Organizations, Requirements Used to Survey Labs, and Percentage of Labs Surveyed by Each Organization, as of December 2005



Source: GAO.

^aWashington is not included as it has only a CLIA-exempt program.

^bNew York uses CLIA-equivalent requirements to inspect larger hospital labs under the state's CLIA-exempt program and CLIA requirements to inspect smaller labs, including physician office labs. Only the labs in the CLIA-exempt program are counted here.

^cSome labs are counted more than once because labs may be accredited by more than one organization. While some labs in New York may be accredited, they are still subject to biennial surveys by the state survey agency or the state CLIA-exempt program, because New York does not authorize accreditation as the basis for lab licensure.

Surveys and Complaint Investigations

Survey organizations (1) conduct surveys and complaint investigations, and (2) monitor proficiency test results submitted by surveyed labs three times a year. Surveys are typically conducted by former or current lab workers, who assess lab compliance with CLIA or CLIA-equivalent requirements. Most lab inspections are announced, that is, the lab has advance notice of when the survey will occur. Generally, surveyors verify that lab personnel are appropriately qualified to conduct testing, evaluate proficiency test records, check equipment and calibration to ensure that appropriate quality control measures are in place, and determine whether the lab has a quality assurance plan and uses it to, among other things, appropriately identify and resolve problems affecting testing quality. Surveys also include an educational component to assist labs in understanding how to comply with CLIA requirements. The duration of a survey generally depends on the size—in terms of the number of tests conducted—and complexity of a lab as well as the number of surveyors. Thus, a survey conducted at a small lab may only take a few hours to complete, while a survey at a large hospital lab may take a survey team a full week or more.

In addition to inspections, survey organizations are responsible for determining the seriousness of and investigating all complaints. For those complaints that are determined to pose immediate jeopardy—an imminent and serious threat to patient health and a significant hazard to public health—CMS requires that the investigation be initiated within 2 working days. Complaints may be investigated on-site or through communications between the survey organization and the lab. Complaint investigations for all survey organizations are unannounced.

Lab survey requirements are classified as either “standard-” or “condition-” level. Generally, condition-level requirements are made up of one or more related standard-level requirements. For example, the condition-level requirement on enrollment and testing of samples through a proficiency testing program has two related standard-level requirements: (1) enrollment, which includes requirements for the lab to provide the name of the program it has enrolled in to the Department of Health and Human Services and authorize the release of testing data to the department; and (2) testing, which specifies that the samples must be tested in the same manner as any specimen and prohibits referring the test samples to another lab for analysis.

Deficiencies are also characterized as standard- or condition-level based on the requirement in which the deficiency occurs. Deficiencies in standard-level requirements, that is, standard-level deficiencies, denote

problems that generally are not serious, while condition-level deficiencies are cited when the problems are serious or systemic in nature. A serious problem is defined as an inadequacy in a lab's quality of services that adversely affects, or has the potential to adversely affect, the accuracy and reliability of patient test results. When deficiencies are found during surveys or complaint investigations, labs are required to submit a plan of correction, detailing how and when they will address the deficiencies. Additionally, CMS can impose principal or alternative sanctions, or both.²³ Principal sanctions include revocation of a CLIA certificate, cancellation of the right to receive Medicare payments, or limits on testing. Revocation of a CLIA certificate is equivalent to termination from the CLIA program. Alternative sanctions are less severe and include civil money penalties or on-site monitoring.²⁴ For condition-level deficiencies that do not involve immediate jeopardy, labs have an opportunity to correct the deficiencies, which we refer to as a grace period, before the sanctions are imposed. If a lab is unable to correct a deficiency during this grace period, CMS determines whether to impose a sanction and the type of sanction.

CMS Oversight

CMS, including its 10 regional offices, oversees state and accrediting organization survey activities.²⁵ CMS reviews and approves initial and subsequent applications from exempt-state programs and accrediting organizations to ensure CLIA equivalency. Validation reviews are one of CMS's primary oversight tools. Federal surveyors in CMS regional offices are responsible for conducting validation reviews of state survey agency and exempt-state program inspections, but state survey agency staff

²³State survey agencies may propose the imposition of sanctions for noncompliance but only CMS can impose sanctions. Accrediting organizations and exempt-state programs may revoke accreditation or remove a lab's state license, respectively, for noncompliance with their CLIA-equivalent requirements. While CMS regional office staff determine whether loss of accreditation should also result in revocation of a lab's CLIA certificate, loss of state licensure is tantamount to CLIA certificate revocation.

²⁴Because of congressional concern that available remedies were too limited and could dissuade CMS from enforcement, CLIA gave CMS additional tools, called alternative sanctions, to help motivate labs to comply with quality requirements.

²⁵The Centers for Disease Control and Prevention is also responsible for carrying out certain CLIA-related tasks, including (1) developing and evaluating technical standards for lab testing components; (2) working with CMS and the Food and Drug Administration to determine the regulatory impact of lab technical standards; (3) conducting lab research and analysis; and (4) facilitating the CLIA Advisory Committee, which makes recommendations to improve the CLIA program.

conduct the validation reviews of accrediting organization inspections.²⁶ An objective of these reviews is to determine if all condition-level deficiencies were identified.²⁷ These reviews are conducted within 60 days of a state's or 90 days of an accrediting organization's survey of a lab. Starting in 1999, CMS required that at least one validation review be conducted simultaneously with an accrediting organization's survey, a step intended to encourage an exchange of ideas and approaches among surveyors. CMS also encourages the use of simultaneous reviews of state survey agency inspections. By law, the number of labs selected for validation reviews must be sufficient to allow a reasonable estimate of the performance of each accrediting organization being assessed.²⁸ CMS requires fewer validation reviews of state survey agency lab surveys (1 percent) than for those of exempt-state programs or accrediting organizations (5 percent).

Beginning in 2003, CMS regional offices began reviewing the activities of state survey agencies against a set of 13 performance standards. The standards cover areas such as the timeliness of lab inspections, surveyor personnel qualifications and training, CLIA data management, and the handling of complaints. CMS's goal is to evaluate each state survey agency's ability to carry out its CLIA responsibilities and to make improvements. CMS is also developing performance standards for other survey organizations that inspect labs using their own CLIA equivalent requirements.

²⁶Unlike validation reviews of accrediting organization surveys, CMS refers to the validation of state surveys as Federal Monitoring Surveys. Because of their similar objective, we refer to all such surveys as validation reviews in this report. We refer to validation reviews that occur at the same time as the lab survey as simultaneous. Conversely, validation reviews that occur after the lab survey are referred to as independent validations.

²⁷According to CMS, the criterion for identifying a missed deficiency is the reasonableness of concluding that a condition-level deficiency was present at the time a survey organization conducted its survey but the survey organization's findings did not note the deficiency.

²⁸See 42 U.S.C. § 263a(e)(2)(D)(2000). By regulation, a similar requirement applies to validation reviews of labs under exempt-state programs. 42 C.F.R. § 493.563(b)(2)(2005).

Insufficient Data Exist to Identify Extent of Serious Lab Quality Problems

The extent of serious quality problems at labs is unclear because CMS has incomplete data on condition-level deficiencies identified by state survey agencies prior to 2004. We also found that the lack of a straightforward linkage between CLIA requirements and the CLIA-equivalent requirements of some survey organizations makes it virtually impossible to assess lab quality in a standardized manner, such as identifying the proportion of labs with condition-level deficiencies. Such deficiencies indicate serious or systemic quality problems. Proficiency testing results—the one available data source that can be used to uniformly compare lab quality across survey organizations—raise questions about whether lab quality has improved in recent years.

Limited Data Are Available on the Quality of Labs Inspected by State Survey Agencies

CMS's OSCAR database contains limited data on the quality of labs inspected by state survey agencies and, as a result, it is not possible to analyze changes in the quality of lab testing over time. In January 2004, CMS implemented revised CLIA survey requirements and modified the existing OSCAR data—state survey agency findings—to reflect the changes.²⁹ The revisions affected approximately two-thirds of the CLIA condition-level requirements.³⁰ As a result of the data modifications, the findings for surveys conducted prior to 2004 no longer reflect all key condition-level requirements in effect at the time of those surveys.³¹ Based on the available 2004 OSCAR data (which represent about one half of all labs surveyed by state survey agencies), we found that 6.3 percent of labs had condition-level deficiencies (see app. II for data on all state survey agencies, including the District of Columbia).³² As will be discussed below, similar data are not available for labs surveyed by other survey organizations.

²⁹CMS published the regulations for the new requirements in January 2003 and surveyors began using the new requirements on January 12, 2004.

³⁰For example, some condition-level requirements were reorganized and some were consolidated.

³¹When we asked for access to backup files, CMS told us that it did not have backup files of the original pre-2004 survey data.

³²We excluded survey results for the period January 1 through January 11, 2004, because CMS modified OSCAR data for findings prior to January 12, 2004, to reflect revised CLIA requirements.

Quality of Labs Inspected by Other Survey Organizations Is Very Difficult to Measure in a Standardized Manner

Differences between the inspection requirements that state survey agencies use to measure lab quality and those of exempt-state programs and accrediting organizations make it virtually impossible to measure lab quality in a standardized manner. Because exempt-state programs and accrediting organizations do not classify inspection requirements and related deficiencies as either standard- or condition-level, they cannot easily identify the number of CLIA condition-level deficiencies cited at the labs they survey or the proportion of surveyed labs with condition-level deficiencies.³³

We asked exempt-state programs and accrediting organizations what percentage of their requirements, and any deficiencies cited for failure to meet those requirements, indicated serious problems that were equivalent to CLIA condition-level deficiencies. While only 8 percent of CLIA requirements used by state survey agencies are classified as condition-level and therefore serious, the proportion of requirements that exempt-state programs and accrediting organizations classify as serious ranged from 20 percent up to 100 percent (see table 1).

Table 1: Percentage of Inspection Requirements Classified as Serious, by Survey Organization

Organization	Percentage of requirements classified as serious
State survey agencies	8
New York CLIA-exempt program	^a
Washington CLIA-exempt program	^a
COLA	20
CAP	80
JCAHO	100

Sources: GAO analysis of information provided by CMS, New York, Washington, CAP, COLA, and JCAHO.

^aThis state's CLIA-exempt program does not distinguish between serious and nonserious requirements.

³³Although CMS reviews the requirements of exempt-state programs and accrediting organizations to ensure that they are at least equivalent to CLIA's, there is not necessarily a one-to-one match with CLIA requirements. Thus, one CLIA condition-level requirement may equal several accrediting organization requirements or vice versa. For example, CMS's condition-level requirement for successful lab participation in approved proficiency testing corresponds to at least 19 CAP, 3 COLA, and 4 JCAHO requirements.

CAP and COLA crosswalked their recent survey findings to CLIA condition-level requirements.³⁴ Although their analysis suggested that from about 56 to 68 percent of labs surveyed during 2004 had a deficiency in at least one condition-level requirement, they acknowledged that these proportions overstated the subset of labs with serious problems. JCAHO did not crosswalk its inspection requirements to those of CLIA because staff would have had to manually review each survey report to determine which deficiencies were equivalent to deficiencies in CLIA condition-level requirements. However, JCAHO did tell us that in 2004, about 90 percent of the labs it surveyed had a deficiency in at least one requirement and, as previously noted, JCAHO classifies all its requirements as serious.

Despite the difficulty of identifying CLIA equivalent condition-level deficiencies, two of the three accrediting organizations we reviewed have systems to identify labs they survey that have serious quality problems. COLA estimated that about 9 percent of labs it surveyed in 2004 were subject to closer scrutiny because of the seriousness of the problems identified. According to JCAHO, about 5 percent of the labs it surveyed in 2004 were not in compliance with a significant number of requirements. The third accrediting organization, CAP, has criteria for identifying labs that warrant greater scrutiny, but CAP officials told us that identifying such labs had to be accomplished on a case-by-case basis rather than through a database inquiry. As a result, CAP plans to spend in excess of \$9 million during 2006 and 2007 to develop an integrated data system that pulls together multiple factors—survey results, complaints, proficiency testing, findings of other inspection bodies, and changes in lab directors—to enable it to readily identify problem labs. According to CAP officials, such labs will be targeted for greater monitoring, and CMS and other survey organizations will be notified about CAP's actions.

Proficiency Testing Results Suggest that Quality Has Not Improved at Hospital Labs in Recent Years

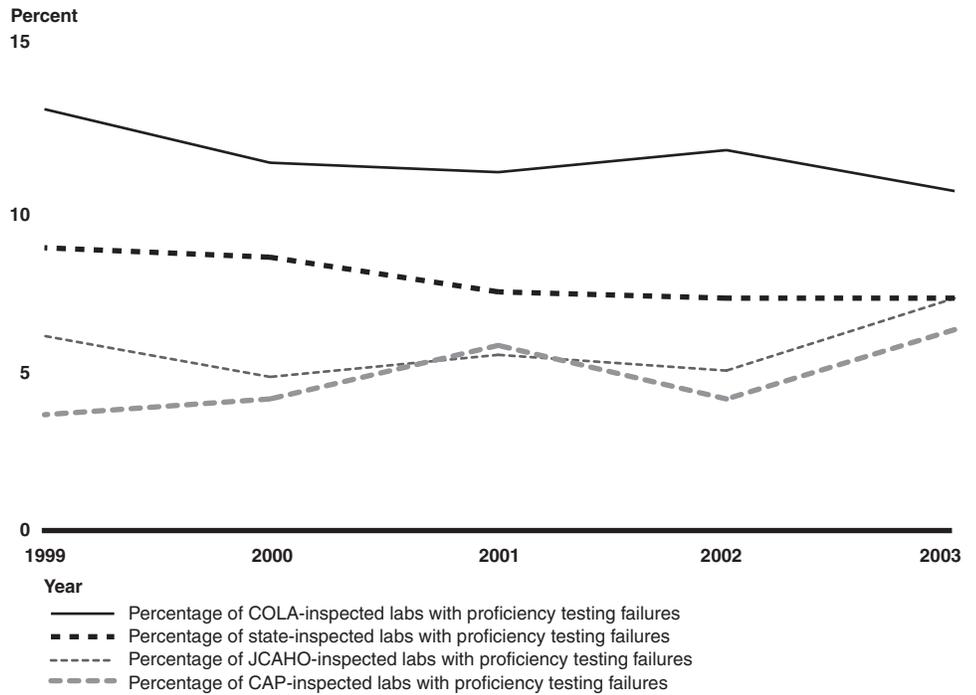
Although CMS noted that proficiency testing trend data show a decrease in failures for labs as a whole, the data suggest that lab quality may not have improved at hospital labs for the period 1999 through 2003. Proficiency testing is an important oversight tool for survey organizations because it is an objective indicator of a lab's ability to consistently produce accurate test results and is conducted more frequently than surveys—three times a year versus once every 2 years. In the absence of comparable survey data,

³⁴This effort took CAP and COLA about 4 months to complete.

proficiency testing results provide a uniform way to assess the quality of lab testing across survey organizations.

Our analysis of CMS proficiency testing data for 1999 through 2003 suggests that there has been an increase in proficiency testing failures for labs inspected by CAP and JCAHO, which generally inspect hospital labs, and a decrease in such failures for labs surveyed by state survey agencies and COLA, which tend to inspect physician office labs (see fig. 2). CMS defines failures as unsatisfactory performance in two consecutive or two out of three proficiency testing events. For example, the percentage of labs with proficiency testing failures surveyed by CAP and JCAHO from 1999 through 2003 increased from 4.1 percent to 6.8 percent and from 6.6 percent to 7.8 percent, respectively. It is unclear, however, whether the decrease in failures for physician office labs represents an actual improvement in lab quality or reflects the fact that some problematic labs are no longer surveyed. Specifically, many physician office labs now perform waived tests and therefore are no longer surveyed or participate in proficiency testing. Between 1998 and 2005, the percentage of labs subject to surveys and proficiency testing decreased from about 30 percent to about 19 percent.

Figure 2: Percentage of Labs with Proficiency Testing Failures from 1999 through 2003, by Survey Organization



Source: GAO analysis of CMS proficiency testing data.

Note: Data include labs affiliated with each organization during each year.

Oversight Weaknesses Mask Quality Problems

Weaknesses in surveys, complaint processes, and enforcement mask real and potential quality problems at labs. Survey weaknesses include: (1) inspections that most organizations announce ahead of the visit, which allows labs to prepare for their inspections and portray themselves in a manner that may not accurately reflect their day-to-day quality assurance processes; (2) variability in the proportion of labs with condition-level deficiencies in 2004, which suggests surveys are not conducted in a consistent manner; and (3) the goal of educating lab workers during surveys taking precedence over, or precluding, the identification and reporting of deficiencies. Furthermore, the significant increase in complaints since CAP took steps to help ensure that lab workers know how to file a compliant suggests that some quality problems at labs inspected by other survey organizations may not be reported. Finally, sanctions are not being used effectively as an enforcement tool to promote labs' compliance with CLIA requirements, as evidenced by the relatively

few labs with repeat condition-level deficiencies on consecutive surveys from 1998 through 2004 that had sanctions imposed.

Announced Surveys May Result in Unrealistic Picture of Lab Quality

Because labs can and do prepare for surveys, CMS regional office officials and most of the state survey agencies acknowledged that announced surveys may not always provide a realistic picture of lab quality.³⁵ As shown in table 2, the amount of advance notice for surveys varies from as little as 2 weeks up to 12 weeks; until recently, only the New York CLIA-exempt program conducted unannounced surveys. Survey agency officials in two states told us that surveyors had inspected labs where records documenting the implementation of periodic quality control procedures were completed in the same handwriting using the same colored pen. This degree of uniformity raises a concern about whether the quality control occurred at all, or as frequently as the records suggested. A CAP surveyor told us that the pathologist at one lab had cleaned up, and signed off on, about 3-months worth of quality control records the night before the survey. In hearings on the questionable test results at a Maryland hospital lab, a worker testified that lab staff prepared frantically for their announced inspections.

³⁵ CMS does require unannounced surveys for: (1) complaint investigations, (2) follow-up surveys conducted to verify correction of deficiencies, and (3) nonroutine surveys conducted when there is reason to believe a lab is operating in a manner that constitutes a risk to human health. In contrast, all nursing home surveys are required to be unannounced to help ensure that homes do not cover up problems that may exist when surveyors are not present. See GAO, *California Nursing Homes: Care Problems Persist Despite Federal and State Oversight*, GAO/HEHS-98-202 (Washington, D.C.: July 27, 1998).

Table 2: Amount of Advance Notice Given to Labs about Upcoming Inspections, by Survey Organization

Survey organization	Amount of advance notice ^a
New York CLIA-exempt program	None
State survey agencies	Up to 2 weeks ^b
Washington CLIA-exempt program	4 weeks
JCAHO	4 weeks ^c
CAP	7 weeks ^d
COLA	12 weeks ^e

Sources: CMS, New York CLIA-exempt program, Washington CLIA-exempt program, CAP, COLA, and JCAHO.

^aThese numbers reflect stated policy and may not represent actual practice.

^bAdvance notice permitted by CMS guidance.

^cIn January 2006, JCAHO stopped providing labs advance notice about upcoming inspections.

^dAverage actual notice provided to CAP labs for 2004. In 2006, CAP began conducting unannounced inspections.

^eCOLA confirms the survey date about 8 weeks in advance.

In 2006, both CAP and JCAHO began conducting unannounced inspections at most of the hospital labs they survey.³⁶ Both CAP and JCAHO officials told us that the unannounced surveys will occur as early as 6 months prior to the anniversary of a lab's prior survey. CMS and survey organizations that inspect physician office labs provided several justifications for continuing to announce inspections at such labs, including (1) ensuring that the lab is open and that appropriate personnel are available to answer surveyor's questions, and (2) minimizing disruptions to patient care. These justifications appear to be reasonable because they reflect the operating tempo at physician office labs. It may not be appropriate, however, to provide such labs with 4 to 12 weeks advance notice, given that CMS currently limits the advance notice provided by state survey agencies to no more than 2 weeks.

³⁶JCAHO implemented its unannounced surveys in January 2006 and CAP began phasing in unannounced inspections in the spring of 2006. CAP and JCAHO will continue to provide Department of Defense and prison labs that they survey with advance notice to enable surveyors to obtain the security clearances required to enter such facilities.

Variability in Reported Survey Deficiencies Suggests that Labs Are Not Surveyed Consistently

Variability in OSCAR data for state survey agency inspections conducted in 2004 suggests that labs are not surveyed in a consistent manner, and interviews with CMS and state survey agency officials confirmed this hypothesis. As a result, available data likely understate the extent of serious quality problems at labs. In 2004, the percentage of labs that state survey agencies reported with condition-level deficiencies varied considerably by state, ranging from none in 6 states to about 25 percent of labs in South Carolina. These data only included findings for about one-half of the labs surveyed by state survey agencies. Of the 33 states that survey more than 100 labs, 16 found condition-level deficiencies at fewer than 5 percent of labs, while 6 states identified such serious deficiencies in more than 10 percent of the labs they surveyed (see app. II).³⁷

Based on interviews with CMS and 10 state survey agencies, it appears that at least some of this variability is due to differences in states' approaches to surveys as opposed to true differences in lab quality. For example, CMS told us that, because there is not a prescriptive checklist to guide the survey process, the reliance on state surveyor judgment will result in variations in the citing of deficiencies. To compensate for the unstructured nature of the state survey process, officials we interviewed from 2 state survey agencies told us that they created checklists to help ensure that surveyors looked at all of the critical elements during lab surveys.³⁸ Furthermore, while some of the state survey agencies we spoke with told us that their surveyors always cite condition-level deficiencies that are identified during surveys, officials in other states said that there are circumstances under which condition-level deficiencies would not be cited. For example, according to officials from a state survey agency we interviewed, surveyors prefer not to cite condition-level deficiencies. Rather, surveyors in this state prefer to cite multiple standard-level deficiencies instead of a condition-level deficiency because it allows the imposition of state law sanctions, avoiding what was characterized as a

³⁷Our analysis excluded state survey agencies that inspect fewer labs because even a small change in the number of labs with condition-level deficiencies can produce a large percentage point change.

³⁸While checklists may be useful, some state survey agencies told us that use of the checklists may result in insufficient probing and observation. CAP officials told us that they plan to move beyond their current emphasis on requiring documentation of lab processes with probing techniques that require direct interaction with lab staff, observation of testing, and new survey tools to guide inspectors in assessing compliance with requirements. COLA's survey process includes a list of questions that surveyors must answer by asking probing questions of, and interacting with, lab staff. JCAHO's process, introduced in 2004, uses computer-based algorithms when making compliance determinations.

less efficient federal sanctions process.³⁹ Additionally, officials from 2 other state survey agencies explained that surveyors consider a lab's compliance history when determining what deficiencies to cite, while officials from a third state told us that surveyors will educate lab workers, particularly new lab workers, about the CLIA requirements rather than citing CLIA condition-level deficiencies.⁴⁰

Balance Between Educational and Regulatory Roles by CMS and Survey Organizations Appears to Be Inappropriate

The goal of educating lab workers sometimes takes precedence over, or precludes, the identification and reporting of deficiencies that affect the quality of lab testing. As a result, data on the quality of lab testing and trends in quality over time may be misleading. Although CLIA neither requires nor precludes an educational role for surveyors, the preamble to CMS's implementing regulation noted that surveys are intended, in part, to provide an opportunity for on-site education regarding accepted laboratory procedures. In addition, CMS guidance and training encourage state surveyors to play an educational role.⁴¹ Many state survey agency officials we interviewed also told us that their surveyors play a major educational role. As noted earlier, surveyors from one state survey agency do not cite condition-level deficiencies when lab workers are new but prefer to educate the new staff. Because CMS revised its OSCAR database in 2004, it is not possible to identify states that have consistently not cited condition-level deficiencies, data that would help to quantify the extent to which an educational role is substituting for appropriate regulation of labs.⁴²

³⁹When state survey agencies cite condition-level deficiencies, the CMS regional office for that state determines what, if any, sanctions should be imposed.

⁴⁰One example cited by a state survey agency involved a complaint investigation of a transfusion-related fatality, the result of a lab worker mixing up patient samples. Because the lab had already instituted extensive corrective actions by the time the surveyor arrived, the survey agency cited a standard-level deficiency for documentation errors rather than a condition-level deficiency. We discussed this case with CMS officials who told us that because the problem had been addressed, there was essentially no condition-level deficiency to cite.

⁴¹While combining the roles of educator and regulator may not be unique, it is different from the exclusively regulatory role state surveyors under contract with CMS play for other provider groups, such as nursing homes and home health agencies.

⁴²Using OSCAR trend data, we were able to identify state survey agencies that educated instead of regulated home health agencies. See *Medicare Home Health Agencies: Weaknesses in Federal and State Oversight Mask Potential Quality Issues*, GAO-02-382 (Washington, D.C.: July 19, 2002).

An inappropriate balance between the educational and regulatory role is also evident in some accrediting organization practices. One of the CAP surveyors we interviewed with over 30 years of lab experience estimated that the majority of pathologists—individuals who generally serve as CAP survey team leaders—view surveys as educational, rather than as assessments of compliance with lab requirements. Another surveyor told us that CAP’s survey process focuses heavily on education, and that some survey team leaders emphasize education more than others. For COLA, the process of educating labs begins even prior to a survey. For example, COLA encourages labs to submit a self-assessment for review prior to the scheduled survey so that the labs can identify COLA requirements with which they are not in compliance. About 20 percent of all labs surveyed during 2004 submitted a self-assessment (616 labs) and, compared to labs that did not submit a self-assessment, fewer deficiencies were identified at these labs during on-site surveys.⁴³

CMS appears to be inappropriately stressing education over regulation in its implementation of (1) 2003 lab quality control requirements for the CLIA program and (2) proficiency testing for lab technicians who interpret Pap smears, a test for cervical cancer. When state surveyors began assessing compliance with new lab quality control requirements in January 2004, they were instructed to note deficiencies on a cover letter to labs rather than on the survey report itself for a period of 2 years. Thus, such deficiencies are not recorded in the OSCAR database. In part because of a lack of lab “buy-in” for some of the new policies and procedures, CMS officials have extended the educational period for about another 2 years. CMS has taken a similar educational approach to Pap smear proficiency testing, which began in 2005. CMS will not cite deficiencies or impose sanctions against labs in which staff fail the new Pap smear proficiency testing in 2005 or 2006, as long as the labs and individuals involved complete such testing, including following the regulatory protocol for subsequent testing in the case of an initial failure. According to CMS, this educational focus allows labs and their staff to become familiar with the proficiency testing program and to prepare themselves for such testing, since there was about a 13-year time lag between the 1992 regulations that implemented CLIA and the 2005 implementation of Pap smear proficiency

⁴³This percentage includes both labs preparing for their initial survey and those with prior surveys. According to COLA officials, newer labs are most likely to perform the self-assessment; over time, they believe that the vast majority of COLA-inspected labs have completed the self-assessment.

testing.⁴⁴ This educational approach seems questionable given CMS's concern about some of the high initial proficiency test failure rates.

Use of Volunteer Surveyors by CAP Raises Concerns

Although state survey agencies, exempt-state programs, COLA, and JCAHO employ dedicated staff surveyors, CAP relies primarily on volunteer teams consisting of lab workers from other CAP-inspected labs to conduct surveys.⁴⁵ In contrast to the mandatory training and continuing education programs in place for the staff surveyors of other survey organizations, training for CAP's volunteer surveyors is currently optional. CAP plans to establish a mandatory training program beginning in mid-2006.⁴⁶ As a condition of accreditation, labs inspected by CAP must survey another CAP-accredited lab of similar size and composition at least once every 2 years. According to data provided by CAP, two-thirds of volunteer surveyors who had recently participated in a survey had no formal training in the 3 to 5 years preceding the survey. Two CAP surveyors we interviewed told us that they had not completed any training because it was optional. Two other surveyors told us that they had never been notified about the existence of optional CAP training. While full-time surveyors employed by other survey organizations conduct from 30 to about 200 surveys per year, CAP volunteer surveyors have much less experience conducting surveys because they only survey about one lab each year.

⁴⁴Because of lab testing errors that led to women's deaths from cervical cancer, Congress required a specific type of proficiency testing for individuals who interpret the results of Pap smear tests, which requires examining glass slides under a microscope. Although CLIA was enacted in 1988, CMS told us that cost, the inability to find a national testing provider, and other technical issues delayed establishing a Pap smear proficiency testing program until 2005.

⁴⁵As of November 2005, CAP also employed 11 full-time surveyors. Historically, CAP staff surveyors were responsible for inspections of smaller labs that conduct less complex tests. Increasingly, staff surveyors will (1) accompany survey teams assigned to labs with a large number of deficiencies on their prior survey, and (2) assist teams in conducting either a lab's initial survey or the team leader's initial survey. Staff surveyors will also conduct more nonroutine surveys, such as investigating a complaint or following up on performance concerns raised during surveys.

⁴⁶Currently, CAP volunteer surveyors are encouraged to participate in surveyor training at least once every 3 years. In July 2006, CAP plans to begin requiring survey team leaders to complete mandatory training. Mandatory training for survey team members is targeted to begin in 2007.

Three of the nine CAP surveyors we interviewed stated that they believed that mandatory training was important, but some surveyors wondered when lab workers would have time to complete the courses because of their demanding work schedules. According to CAP officials, however, the required training will take only 1 to 2 days and surveyors will have a choice of live seminars and workshops or e-learning completed at their own computers.⁴⁷ For ongoing training requirements, CAP plans to give surveyors a choice of taking additional training or passing a competency evaluation. CAP will track compliance with its new training requirements to ensure that surveyors successfully complete training and demonstrate competency within 2 years of participating in a survey. CAP's required training is less extensive than that required by other survey organizations. For example, state survey agency inspectors must complete 5 days of basic training and periodic advanced courses afterwards while COLA staff inspectors participate in a 5-week orientation program and an annual 20 hours of continuing education.

The use of volunteer inspectors by CAP also raises concerns about the appearance of a conflict of interest. These concerns arise because of the way CAP survey teams are structured. CAP's Commission on Laboratory Accreditation policy manual specifies that the inspection team leader is the individual responsible for the conduct of an ongoing site inspection, and must not be in a business, professional, or personal relationship that would preclude an objective inspection. Furthermore, the manual states that the inspection team leader is usually responsible for determining the size of, and assembling, the inspection team. However, until April 2006, CAP policy did not preclude competing labs from surveying one another or lab survey team members from soliciting business, such as referrals, from a lab at the conclusion of the survey.⁴⁸ The policy was also silent about survey team members' business, professional, or personal relationships that could cloud their independence.⁴⁹ Typically, inspection team leaders are pathologists who direct other labs in the community, and the inspection team is comprised of several employees from the team leader's lab.

⁴⁷In contrast, CAP staff surveyors complete a 6-month training program before they are allowed to conduct surveys independently.

⁴⁸In explaining this policy, CAP notes that it believes team leaders and inspectors will conduct the inspection of a competing lab professionally and in an objective manner.

⁴⁹In April 2006, CAP issued a revised conflict of interest policy that addresses these concerns.

We believe that the use of volunteers, including those from nearby labs, and the personal and professional relationships that may exist among lab staff and survey team members, creates the appearance of a conflict of interest and could undermine the integrity of the survey process.⁵⁰ Comments from some CAP surveyors we interviewed raise a concern about having survey team leaders who are also the day-to-day supervisors of team members. For example, lack of agreement about the seriousness of a deficiency could result in the team leader instructing the team to downgrade the deficiency to a recommendation, a less serious finding that does not appear in the inspection report. Team members who are subordinates to the team leader may feel that they have no other recourse than to follow the team leader's instructions. Recognizing that team members' objectivity may be compromised in this situation, CAP's revised conflict of interest policy instructs all parties to be cautious to retain objectivity in fact finding throughout the inspection process.

In discussing these findings with CAP officials, they told us that they plan to institute a number of initiatives to help ensure survey objectivity, including (1) resurveying the same lab by an independent team to assess the consistency of inspections, (2) centralizing survey team assignments performed by CAP staff, (3) not announcing surveys, and (4) not notifying labs of the survey team composition prior to the survey.

Lab Workers Who File Complaints About Quality Problems in Lab Testing Not Afforded Whistle-blower Protections

Some lab workers may not be filing complaints about quality problems at their labs because of anonymity concerns or because they may not be familiar with filing procedures. Complaints about labs can come from a variety of sources, including lab workers. Complaints are an important tool in detecting quality problems between lab surveys. For example, complaints about testing at a hospital lab were crucial because information had been concealed, complicating the detection of quality problems during the lab's surveys. As a result of a complaint, surveyors were able to substantiate inadequate calibration of testing equipment that could adversely affect patient care.

⁵⁰According to CAP, 57 percent of surveys in 2004 were conducted by surveyors who worked in nearby labs. For example, surveyors who inspected a Maryland hospital lab from 1999 through 2003 worked in labs that were from 5 to 42 miles away. The remaining 43 percent were conducted by surveyors who did not work in nearby labs and who therefore required air travel to carry out the survey.

Based on OSCAR data and data obtained from exempt-state programs and accrediting organizations for 2002 through 2004, few complaints were received about lab testing relative to the number of labs—significantly less than one complaint per lab per year.⁵¹ The low volume of lab complaints may be related to complainants’ concerns about anonymity and fear of retaliation for filing a complaint. It may be easy for a lab to determine the source of a complaint filed by a lab worker. For example, in some cases, either the nature of the complaint or the piece of testing equipment in question could narrow the list of possible complainants. Two CAP surveyors we interviewed commented that, in their opinion, it would be easy to determine the identity of a complainant. During congressional hearings in 2004, a Maryland hospital lab worker testified that she and her colleagues feared losing their jobs because of the complaints they filed.

Because of the difficulty of protecting the anonymity of lab workers who file complaints, whistle-blower protections for such individuals are particularly important. Two of the three accrediting organizations we interviewed have whistle-blower protections—CAP and JCAHO.⁵² For example, CAP implemented a comprehensive whistle-blower protection policy in July 2004 that includes revocation of accreditation or other appropriate action for any lab that directly or indirectly threatens, intimidates, or retaliates against a lab worker. While officials from New York and Washington’s exempt-state programs told us that whistle-blower laws in their states provide some protection for lab workers who file complaints, officials in most of the other 10 states we interviewed told us that they did not have any whistle-blower protections or were unable to identify specific protections that applied to lab workers in their state. Currently, there are no federal whistle-blower protections specifically for workers in labs covered by CLIA. In 2005, legislation was introduced to provide whistle-blower protections to workers in labs covered by CLIA.⁵³

We also found that lab workers may not know how to file a complaint. CAP experienced a significant increase in the number of complaints it received since October 2004, when it began requiring CAP-inspected labs

⁵¹The modifications to OSCAR did not affect data on the number of complaints. The complaint information in OSCAR excludes complaints that do not require an on-site survey.

⁵²COLA does not have a formal whistle-blower policy. COLA officials told us that they promptly investigate all complaints, many of them from former lab employees, and keep the identity of the complainants anonymous.

⁵³H.R. 686, 109th Cong. (2005).

to display posters on how to file complaints. Specifically, from October through December 2004, CAP received an average of 22 complaints per month, compared to an average of 11 complaints per month in the 9 months preceding the poster requirement. As a result, the number of complaints about the quality of lab testing more than doubled in 2004 and the number substantiated increased by more than 40 percent—even though the poster was only displayed for the last 3 months of 2004 (see table 3).⁵⁴ In September 2005, COLA also began requiring labs to display a complaints poster similar to CAP's. It is too early, however, to determine the impact of COLA's new complaints poster on the number, type, and substantiation rate of complaints. Neither CMS nor JCAHO plans to require a similar complaints poster.⁵⁵

Table 3: Number of Complaints Received by CAP, 2002-2005

Year	Received	Substantiated
2002	82	39
2003	84	40
2004	170	70
2005	290 ^a	74 (preliminary) ^b

Source: CAP.

^aThis number is as of November 30, 2005, and thus does not include complaints received in December.

^bAs of November 30, 2005, CAP had substantiated 74 complaints; over 100 complaints were still under active investigation.

Lab Sanctions Are Rarely Imposed

Few labs were sanctioned by CMS from 1998 through 2004—even those with the same condition-level deficiencies on consecutive surveys—because many proposed sanctions are never imposed. Our analysis of CMS enforcement data from 1998 through 2004 found that 501 labs were sanctioned, which equates to less than 3 percent of labs inspected by state survey agencies.⁵⁶ The most common were principal sanctions, which may result in suspension or limitation of testing or termination from the CLIA

⁵⁴CAP plans to hire an additional staff person to investigate complaints.

⁵⁵Effective July 2005, JCAHO required labs to educate staff on how to report concerns about lab quality to the Joint Commission, but does not specify use of a poster to do so.

⁵⁶According to CMS, sanctions generally result from deficiencies identified during an inspection by a state survey agency.

program; few labs were subjected to alternative sanctions, such as directed plans of correction or civil monetary penalties (see table 4). Appendix III shows the number of labs surveyed by state survey agencies and the number of sanctioned labs from 1998 through 2004.

Table 4: Number of Labs Inspected with Principal Only, Principal and Alternative, and Alternative Only Sanctions Imposed, 1998-2004

Sanction	Description	Number of labs
Principal only	<ul style="list-style-type: none"> • Revocation of CLIA certificate (termination) • Cancellation of approval to receive Medicare payments • Limits placed on testing • Suspension of testing 	269
Principal and alternative	<ul style="list-style-type: none"> • At least one principal sanction plus at least one alternative sanction 	170
Subtotal		439
Alternative only	<ul style="list-style-type: none"> • Directed plans of correction • Civil money penalties • State on-site monitoring • Partial or full suspension of Medicare payments 	62
Total		501

Source: GAO analysis of CMS lab registries.

Although few labs were sanctioned from 1998 through 2004, over 9,000 labs had sanctions proposed during that same time period.⁵⁷ Before sanctions go into effect, labs are given a grace period to correct condition-level deficiencies, unless the deficiencies involve immediate jeopardy, that is, an imminent threat to patient health and significant hazard to public health. Most labs correct the deficiencies within the grace period. CMS officials told us that it was appropriate to give labs an opportunity to correct such deficiencies within a prescribed time frame and thus avoid sanctions.⁵⁸ However, a principal objective of the enforcement process—one reflected in CMS guidance—is to motivate labs to comply with CLIA

⁵⁷Since CMS data lists only the number of labs with proposed sanctions by year, this number may double-count labs that had proposed sanctions in multiple years.

⁵⁸Labs surveyed by states have 23 days to correct immediate jeopardy deficiencies, 90 days to correct all other condition-level deficiencies, and up to 12 months to correct standard-level deficiencies. CAP and COLA give labs 30 days to correct all deficiencies, and effective July 1, 2005, JCAHO reduced the time labs have to correct deficiencies from 90 to 45 days. Labs may also appeal proposed sanctions, and depending on the outcome of such appeals, sanctions may be dismissed.

requirements, thereby helping to ensure the provision of accurate and reliable test results. Based on the large number of labs with proposed sanctions that were never imposed, it is unclear how effective the enforcement process is at motivating labs to consistently comply with CLIA requirements.

The number of labs with the same repeat condition-level deficiencies from one survey to the next also raises questions about the overall effectiveness of the CLIA enforcement process. From 1998 through 2004, 274 labs surveyed by state survey agencies had the same condition-level deficiency cited on consecutive surveys and 24 of these labs had the same condition-level deficiency cited on more than two surveys.⁵⁹ This analysis may understate the percentage of labs with repeat condition-level deficiencies because OSCAR data prior to 2004 no longer reflect about two-thirds of condition-level requirements and associated deficiencies at the time of those surveys. We found that only 30 of the 274 labs with repeat condition-level deficiencies had sanctions imposed—either principal, alternative, or both. According to the CLIA legislative history, congressional concern about labs with repeat deficiencies led to alternative sanctions to provide an enforcement option short of principal sanctions to encourage compliance.

From 1998 through 2004, less than 1 percent of accredited labs (81) lost their accreditation; few of these labs were subsequently sanctioned by CMS and many still participate in the CLIA program.⁶⁰ Our analysis of CMS reports on sanctioned labs found that only 9 of the 81 labs had either principal and/or alternative sanctions imposed and that 1 of the 9 still

⁵⁹Thirty-three states and the District of Columbia had at least one lab with the same repeat condition-level deficiency.

⁶⁰Twenty CAP-, 51 COLA-, and 10 JCAHO-inspected labs had their accreditation revoked. After notice of revocation of accreditation, a lab retains its CLIA certificate and may continue to test specimens for 45 days while a state survey agency inspects the lab and makes a recommendation concerning the lab's continued participation in the CLIA program to the responsible CMS regional office, unless CMS takes action sooner. Potential outcomes include (1) termination from the CLIA program; (2) determination that the lab meets CLIA requirements because they are less stringent than those of the accrediting organization, resulting in the lab switching to state survey agency oversight; (3) the lab's return to compliance and reapplication to be surveyed by an accrediting organization; or (4) cessation of moderate- to high-complexity testing and assumption of a CLIA certificate that only allows less complex, waived testing.

performs moderate- to high-complexity testing.⁶¹ Based on a review of its CLIA certificate database, CMS officials told us that about half of the 81 labs still perform moderate- to high-complexity testing but could not describe the actions taken by CMS regional offices in response to the loss of accreditation. We contacted state survey agencies or CMS regional office officials to determine why 3 labs that COLA concluded had cheated on proficiency testing by referring the samples to another lab to be tested had no sanctions imposed. The purpose of proficiency testing is to provide an objective, external evaluation of the accuracy of a lab's test results, which is negated when another lab analyzes the sample. By statute, the intentional referral of samples to another lab for proficiency testing is a serious deficiency that should result in automatic revocation of a lab's CLIA certificate for at least 1 year.⁶² Based on our interviews, we found that the 3 labs were allowed to continue testing because they had initiated corrective actions; in effect, these labs were given an opportunity to correct a deficiency that appears to have required a loss of their CLIA certificate for at least 1 year. A fourth lab was ultimately sanctioned for proficiency testing cheating by CMS but was allowed to continue testing for almost 2 years after having its accreditation revoked.

We also attempted to analyze data on other actions, short of revoking accreditation, used by accrediting organizations to encourage lab compliance and, in particular, how they respond to labs with serious repeat deficiencies. According to CMS, this information is dispersed across CMS regional offices. CAP officials told us that they could initiate four intermediate actions including probation (lab is closely watched to ensure correction of problems), accreditation with conditions (nonroutine inspection to be scheduled), suspension of a lab section, and cessation of a specific type of testing; suspension and probation were instituted in 2004. According to CAP, in 2005, 28 labs were on probation, 106 labs were accredited with conditions, 1 lab was suspended, and 7 labs were required to cease a specific type of test. In 2004, JCAHO awarded conditional accreditation to 3 percent of the labs it inspects because they were not in substantial compliance with its survey requirements, as evidenced by the number of requirements not met; JCAHO conducts an on-site follow-up survey at such labs. From 2002 through 2004, COLA required about 30 labs

⁶¹We created a database for the sanctions data contained in CMS's annual lab registry reports to Congress from 1998 through 2004 and were able to identify labs that both lost accreditation and had a sanction imposed.

⁶²Pub. L. No. 100-578, § 2, 102 Stat. at 2911, codified at 42 U.S.C. § 263a(i)(4)(2000).

per year to cease testing due to issues identified during surveys and about 217 labs per year to cease testing certain tests or specialties due to unsuccessful proficiency testing.⁶³

CMS Oversight of CLIA Is Inadequate

CMS's oversight is not adequate to help ensure that labs meet CLIA requirements. While CLIA requires proficiency testing quarterly, CMS only requires such testing three times each year. In addition, the agency is not meeting its responsibility to determine that accrediting organization and exempt-state requirements and processes continue to be at least equivalent to CLIA's. CMS attributed the delay in making equivalency determinations to having too few staff. Further, ongoing CMS validation reviews do not provide an independent assessment of the extent to which surveys identify all condition-level deficiencies—primarily due to their timing. Finally, CMS does not adequately use data, such as the results of surveys, to monitor survey organization activities and processes. Realizing that its existing oversight activities need to be strengthened, CMS has begun instituting performance reviews to measure survey organization compliance with its standards and is developing protocols to ensure improved communication among survey organizations concerning complaints about lab quality.

CMS's Implementation of Proficiency Testing Is Inconsistent with CLIA

CMS's decision to require proficiency testing for almost all laboratory tests only three times a year is inconsistent with the statutory requirement. CLIA requires that proficiency testing be conducted "on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year)."⁶⁴ The committee report on the bill that forms the basis for much of CLIA indicated that "proficiency testing should be the central element in determining a laboratory's competence, since it purports to measure actual test outcomes rather than merely gauging the potential for accurate outcomes."⁶⁵

⁶³In addition to suspension of or limits on testing, COLA uses directed plans of corrections, such as requiring a lab to hire a consultant or participate in specific training.

⁶⁴Pub. L. No. 100-578, § 2, 102 Stat. 2903, 2907-08, 42 U.S.C. § 263a(f)(3)(2000).

⁶⁵H.R. Rep. 100-899 at 28 (1988) *reprinted in* 1988 U.S.C.C.A.N. 3828, 3849.

In CMS's 1992 rule implementing CLIA, the agency provided a rationale for reducing the frequency of proficiency testing, but did not provide a technical and scientific basis for reducing the frequency for particular procedures or tests.⁶⁶ According to CMS's justification, experts were divided on the appropriate frequency of proficiency testing generally. In addition, requiring fewer events of proficiency testing would give laboratories more time to analyze the causes of test failures before the next event of proficiency testing and also enhance proficiency testing's value as an educational tool. Because CLIA increased the number of labs that were required to undergo proficiency testing, CMS believed that the number of organizations that provided proficiency testing services would not have been able to meet the anticipated increase in demand for testing services. To help avoid anticipated delays in completing proficiency testing and reporting requirements, CMS reduced the frequency of testing events to three times per year.⁶⁷

CMS's requirement for proficiency testing does not meet the conditions specified in the statute that must be satisfied in order to require testing less frequently than quarterly. The language of the statute, as well as relevant legislative history, indicate that a decision to reduce the frequency of testing should be in the nature of an exception made with regard to a particular test, not the norm for all tests, and must be based on "technical and scientific" considerations related to that particular test.⁶⁸ The reasons that CMS gave for requiring only three events per year were not based on scientific and technical considerations relevant to particular tests. Instead, CMS's decision was based on concerns of an administrative and logistical nature that CMS wanted to alleviate by reducing the frequency of testing events.

⁶⁶See 57 *Fed. Reg.* 7002, 7128-29 (1992). Prior to 1992, CMS required proficiency testing quarterly. See 55 *Fed. Reg.* 9538 (1990).

⁶⁷According to a CMS official, the adoption of less frequent proficiency testing was accompanied by an increase in the number of specimens subject to proficiency testing from two every 3 months to five every 4 months.

⁶⁸The committee report provided examples of technical and scientific considerations justifying an exception to the quarterly testing requirement. Those examples also stress the significance of excepting tests from the quarterly testing requirement on the basis of circumstances presented by the individual test. See H.R. Rep. 100-899 at 29 (1988), 1988 U.S.C.C.A.N. at 3850. That quarterly testing is intended to be the norm is further evidenced by the committee report's recommendation that the number of quarters that a laboratory had failed to pass proficiency testing determine the severity of sanctions imposed. See *id.* at 30, 1988 U.S.C.C.A.N. at 3851.

CMS Is Late in Ensuring CLIA Equivalency of Exempt States' and Accrediting Organizations' Inspection Requirements and Processes

We found that CMS has been late in determining that exempt states' and accrediting organizations' inspection requirements and processes are at least equivalent to CLIA's. CMS must verify their equivalency and, by regulation, CMS requires such survey organizations to seek reapproval at least once every 6 years, or more frequently if deemed necessary. CMS establishes the time frames for when the next reapproval should occur, which have ranged from about 15 months to about 6 years. However, CMS has not completed its equivalency reviews within these time frames and accrediting organizations and exempt state programs have continued to operate without proper approval. Equivalency reviews for CAP, COLA, JCAHO, and Washington due to be completed between November 1, 1997, and April 30, 2001, were an average of about 40 months late. In August 1995, CMS determined that New York's next equivalency review should be completed by June 30, 2001, but was over 4 years past due as of December 2005. Similarly, COLA's equivalency review was about 3 years past due.

Because accrediting organizations and exempt-state programs may choose to make changes to their inspection requirements between periodic equivalency reviews (1) accrediting organizations are required to submit changes to their inspection requirements and policies 30 days prior to changing their standards⁶⁹ and (2) exempt-state programs are required to provide notice when they change their licensure or inspection requirements. Although federal regulations require CMS to review equivalency when an accrediting organization or exempt-state program adopts new requirements, a CMS official told us that the agency is not required to review such changes before their implementation to ensure equivalency.⁷⁰ As a result, such survey organizations may introduce changes that are inconsistent with CLIA requirements. For example, JCAHO made a significant change to its inspection requirements in January 2004 but did not receive CMS approval until 6 months later; CMS did not begin an in-depth review of JCAHO's revised requirements until

⁶⁹For example, CAP typically reorganized, consolidated, or changed its requirements two times a year. As a result of these changes, about 1,000 requirements were removed and about 1,200 requirements were added over 5 years. COLA has changed its requirements five times since it was first approved by CMS in 1993. JCAHO officials stated that they make changes to their requirements each year.

⁷⁰See 42 C.F.R. § 493.573(a)(3)(2005).

early 2005—over a year after they were implemented by JCAHO.⁷¹ According to CMS, their review has identified several critical areas where JCAHO standards are less stringent than those of CLIA. JCAHO acknowledged the need to make some adjustments to its revised requirements.

CMS officials attributed delays in making equivalency determinations and reviewing interim changes to having too few staff. The CLIA program, located in CMS's Center for Medicaid and State Operations (CMSO), currently has approximately 21 full-time-equivalent positions compared to a peak of 29 such positions several years ago. The reduction occurred over time through attrition. As required by statute, the CLIA program is funded by lab fees and since its inception the program's fees have exceeded expenses. As of September 30, 2005, the CLIA program had a carryover balance of about \$70 million—far more than required to hire an additional six to seven staff members. However, CMS officials told us that because the CLIA program staff are part of CMSO, they are subject to the personnel limits established for CMSO, regardless of whether or not the program has sufficient funds to hire more staff. Although CMSO is at its authorized personnel allocation, the CLIA program could hire additional staff with approval from the Administrator. We were told that CMSO has not requested such approval.

We also noted issues that raise a question about the thoroughness of CMS equivalency reviews because some survey organizations' procedures or policies appear to be less stringent than those required by CMS for the CLIA program. For example:

- Accrediting organizations provide labs more advance notice about upcoming surveys than CMS allows state survey agencies to give to the labs they inspect.
- JCAHO surveyors focus their review of lab testing on the 12 months prior to the survey. CMS requires that state surveyors review the entire 24 months of testing since the last survey.⁷²

⁷¹On January 1, 2004, JCAHO launched a new accreditation process, which included a substantial consolidation of lab requirements. Additionally, JCAHO began using new methodologies, including a new software program that analyzes data to help focus on-site surveys on priority areas and a tracer methodology to track patients and specimens through the continuum of lab services.

⁷²According to JCAHO, the organization plans to change its survey process to include a review of a random sample of the other records and documents over the entire 24-month period.

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- While CMS requires initial and advanced surveyor training, CAP encourages but does not require its volunteer surveyors to participate in surveyor training.⁷³
 - As of August 2005, CAP's policy manual indicates that complaint investigations may be announced or unannounced. CMS guidance requires that complaint investigations be unannounced.

Prior to 2005, CMS's equivalency determination reviews focused on the inspection requirements themselves, and not the procedures and policies used by accrediting organizations and exempt-state programs in carrying out oversight of labs; this focus on inspection requirements may explain the divergence from the policies and procedures CMS requires for state survey agencies. During 2006, CMS is simultaneously reviewing the equivalency of COLA and JCAHO inspection requirements and, for the first time, incorporating on-site observations of accrediting organization policies and systems into the review and approval process. For example, CMS is checking to ensure that accrediting organizations have adequate systems in place to track such things as (1) complaints, (2) correction of deficiencies, and (3) proficiency testing.

Many CMS Validation Reviews Lack Independence and Reviews Skip Some State Survey Agencies

CMS validation reviews that are intended to evaluate lab surveys conducted by both states and accrediting organizations do not provide CMS with an independent assessment of the extent to which surveys identify all serious—that is, condition-level or condition-level equivalent—deficiencies. CMS requires its regional offices to conduct validation reviews of 1 percent of labs inspected by state survey agencies in a year. In contrast, validation reviews of 5 percent of labs inspected by accrediting organizations during a year are conducted by state survey agency personnel. CMS does not specifically require that validations occur in each state and some states do not have validation reviews each year. Furthermore, many validation reviews occur at the same time a survey organization conducts its inspection and, in our view, the collaboration

⁷³As noted earlier, CAP plans to begin requiring mandatory surveyor training in mid-2006.

Validation of State Survey
Agency Lab Surveys

among the two teams during these simultaneous surveys prevents an independent evaluation.⁷⁴

The requirement to validate 1 percent of labs surveyed by state survey agencies in a year—roughly 100 validation reviews each year—does not ensure sufficient oversight of state survey agencies. The validation review requirement, which is included in CMS regional office annual budget memorandums, does not specify how many validation reviews must be conducted in each state. While the 10 CMS regional offices generally validated 1 percent of the state survey agency inspections within their region, they often did not validate 1 percent of inspections within each state and, in fact, performed none in some states. From 1999 through 2003, federal surveyors:

- validated less than 1 percent of labs surveyed by state survey agencies in an average of about 25 percent of states, ranging from 7 states in 2002 to 17 states in 2003; and
- did not conduct any validation reviews in an average of 16 percent of states per year, ranging from 3 states in 2002 to 12 states in 1999.

In 11 states, no validation reviews were conducted in multiple years. For example, no validation reviews were conducted in Michigan and Washington, D.C. during 4 of 5 years from 1999 through 2003. Without validating at least some surveys in each state, CMS is unable to determine if the states are appropriately identifying deficiencies.

Seventy-five percent of validations of state lab surveys were conducted simultaneously from fiscal years 1999 through 2003.⁷⁵ According to CMS officials, the large proportion of simultaneous validation reviews provides an opportunity for federal surveyors to share information with state surveyors, monitor their conformance with CLIA inspection requirements, and identify training and technical assistance needs. However, we found

⁷⁴Simultaneous surveys resemble “observational” federal oversight surveys conducted at nursing homes. We previously reported that such surveys, in which federal surveyors accompany and observe state surveyors during the routine inspection of a nursing home, are not a realistic assessment of state surveyor performance because CMS’s presence may make state surveyors more attentive to their survey tasks than when they are not being observed, a phenomenon known as the Hawthorne effect. See GAO, *Nursing Home Care: Enhanced Oversight of State Programs Would Better Ensure Quality*, [GAO/HEHS-00-6](#) (Washington, D.C.: Nov. 4, 1999).

⁷⁵These validation reviews include both exempt-state and state survey agency lab surveys.

that such reviews do not provide an accurate assessment of state surveyors' ability to identify condition-level deficiencies. Of the 13 validation reviews that identified missed condition-level deficiencies, only 1 was a simultaneous review (see table 5). Validations of state surveys typically utilize one federal surveyor for either independent or simultaneous validation reviews;⁷⁶ therefore, increasing the proportion of independent validation reviews to strengthen CMS oversight likely would not require additional federal surveyors. Moreover, conducting independent validation reviews eliminates the extra effort required to coordinate schedules to ensure that the validation reviews occur at the same time as the state survey.

Table 5: Analysis of Results of Simultaneous and Independent Validation Reviews of State Surveys, Fiscal Years 1999–2003

Fiscal year	Number of validation reviews	Conducted simultaneously		Conducted independently	
		Number	Number with condition-level deficiencies state surveyors missed	Number	Number with condition-level deficiencies state surveyors missed
1999	223	141	0	82	2
2000	224	135	0	89	5
2001	218	184	1	34	0
2002	240	199	0	41	4
2003	195	167	0	28	2
Total	1,100	826	1	274	13

Source: CMS.

Validation of Accrediting Organizations' Lab Surveys

According to CMS guidance, at least one validation review of an accrediting organization's survey of labs should be conducted simultaneously each year, but not all validation reviews should be simultaneous because a combination of simultaneous and independent reviews provides a balanced view of surveyor performance. CMS officials were unable to tell us exactly how many of the roughly 275 validation reviews conducted each year from fiscal year 1999 through fiscal year 2003 were simultaneous.⁷⁷ However, one of the three accrediting organizations we reviewed told us that a significant proportion of their validation reviews are conducted simultaneously. JCAHO estimated that 33 percent

⁷⁶State survey agencies employ 96 full-time-equivalent staff to survey labs.

⁷⁷CMS did not begin tracking this information until August 2003.

of its validation reviews were conducted simultaneously. COLA estimated that 9 percent of validation reviews conducted in 2004 and 2005 were simultaneous. Finally, CAP officials told us that, from 2002 through 2004, 11 percent of validation reviews of CAP-accredited labs were conducted simultaneously.

Given the limitations of simultaneous reviews, conducting independent validation reviews are a more effective way of ensuring the equivalency of accrediting organization inspection requirements and processes between the equivalency determinations. CMS officials told us that the agency's intent in instituting simultaneous reviews was for state and accrediting organization surveyors to share best practices, to promote understanding of each other's programs, and to foster accrediting organization improvement. They indicated that they considered it a learning experience both if an accrediting organization surveyor added a deficiency noted by a state surveyor to a survey report and vice versa. However, most of the state survey agency officials we interviewed told us that simultaneous validation reviews do not provide a realistic evaluation of the adequacy of accrediting organizations' inspection process. In fact, CMS guidance encourages surveyors to discuss the survey findings prior to concurrent conferences with lab personnel to review their findings.

From fiscal years 1999 through 2003, state survey agency surveyors found condition-level deficiencies missed by accrediting organization surveyors on 64 validation reviews, but only 6 of these validation reviews were simultaneous.⁷⁸ In contrast, 58 (91 percent) of the validation reviews that identified serious deficiencies missed by accrediting organizations were independent validation reviews. (See table 6.)

⁷⁸Both survey organizations submit their findings to CMS, which then compares the findings to determine whether accrediting organization surveyors missed any condition-level deficiencies. Examples of condition-level deficiencies missed by accrediting organizations include: (1) lab did not correctly calculate the results of tests used to monitor patients using a blood-thinning medication, which could result in serious medical complications such as internal bleeding; (2) lab did not follow manufacturer's instructions for calibrating checks of certain test equipment; and (3) lab director failed to provide overall management and direction of lab, such as ensuring timely enrollment in a proficiency testing program and corrective actions following a proficiency testing failure.

Table 6: Analysis of Results of Simultaneous and Independent Validation Reviews of Accrediting Organizations' Surveys, Fiscal Years 1999–2003

Fiscal year	Number of validation reviews	Validation reviews that found condition-level deficiencies missed by accrediting organizations' surveyors		
		Total	Number conducted simultaneously	Number conducted independently
1999	227	8	0	8
2000	265	17	3	14
2001	214	8	1	7
2002	317	14	1	13
2003	348	17	1	16
Total	1,371	64	6	58

Source: CMS.

Note: While our analysis covered validation reviews for all six accrediting organizations, CAP, COLA, and JCAHO account for the vast majority of such reviews. CMS officials were unable to tell us the total number of validation reviews conducted simultaneously and independently during each fiscal year.

CMS Use of Data for Oversight of CLIA Program Is Limited

CMS does not routinely collect and analyze data essential for effective oversight of the CLIA program but has initiatives to automate some available data to make them more accessible for analysis. Using data to analyze activities across survey organizations can be a powerful tool in improving CMS oversight of the CLIA program. Such analyses include identifying and addressing inconsistencies in how surveys are conducted. Although CMS tracks the most frequently cited deficiencies at labs in an effort to improve quality, it does not routinely track the proportion of labs, by state, in which state survey agencies identify condition-level deficiencies—those that denote serious or systemic problems. According to a CMS official, the agency has not evaluated variability in such deficiencies since 1999.⁷⁹ As noted earlier in this report, variability in survey findings suggests inconsistencies in how surveys are conducted. CMS also does not require exempt-state programs and accrediting organizations to routinely submit data on serious deficiencies identified at the labs they inspect, unless the deficiencies pose immediate jeopardy to

⁷⁹Our nursing home work found a similar absence of analysis by CMS regarding trends in serious problems identified by state surveyors. See GAO, *Nursing Home Quality: Prevalence of Serious Problems, While Declining, Reinforces Importance of Enhanced Oversight*, GAO-03-561 (Washington, D.C.: July 15, 2003).

the public or an individual's health.⁸⁰ As noted earlier, the lack of a common vocabulary on what constitutes a serious deficiency would make it virtually impossible for CMS to analyze such data.

We also found that CMS does not effectively use available data to assess clinical lab quality in areas such as proficiency testing, sanctions, and complaints. For example, CMS's analysis of proficiency testing data for all labs showed improvements over time. As reported earlier, proficiency testing failures have increased for labs surveyed by CAP and JCAHO. Comprehensive analysis of the proficiency testing database is particularly valuable because it provides a uniform way to assess the quality of lab testing across survey organizations, which is not currently available for survey results. CMS is now in the process of automating the annual registry of sanctioned labs, which should help it identify important trends, such as the infrequent use of alternative sanctions. Automating the registry, however, will not address the lack of data on (1) steps taken by state survey agencies and regional offices when labs have their accreditation revoked or (2) interim steps, short of revocation of accreditation, that accrediting organizations take to help encourage lab compliance. CMS also lacks a complaints database, and therefore was unable to assess the impact of CAP's decision to require labs to prominently display a poster on how to file a complaint. CMS is developing, and plans to launch, a complaints database in March 2006.⁸¹

⁸⁰Officials from a state survey agency told us that, while they do not want to receive routine survey reports from accrediting organizations, they do want to receive information when accrediting organizations identify problem labs—before a lab loses its accreditation and becomes the responsibility of the state survey agency. When an accrediting organization revokes a lab's accreditation, the state survey agency becomes responsible for determining whether to recommend revocation of the lab's CLIA certificate to the appropriate CMS regional office.

⁸¹In response to communication problems highlighted by the complaint investigations at a Maryland hospital lab, CMS has been meeting regularly with officials from exempt-state programs, accrediting organizations, state survey agencies, and its regional offices to discuss and improve coordination and data sharing—particularly the handling of complaints. The Maryland state survey agency identified deficiencies during a 2004 complaint investigation but did not inform CAP, the organization responsible for surveys of the Maryland hospital lab. CAP officials told us that they first learned about the 2004 complaint investigation that revealed problems with HIV and hepatitis testing equipment from newspapers.

CMS Implementing Performance Reviews for Survey Organizations

CMS has implemented performance reviews for state survey agencies and is in the process of developing such reviews for accrediting organizations. First implemented in 2004, the annual CLIA state performance reviews evaluate each survey agency's ability to accomplish its lab oversight responsibilities.⁸² The reviews, conducted on-site by CMS regional office staff, measure performance in 13 areas, such as the timely conduct of surveys and the appropriate documentation of any deficiencies identified.⁸³ According to CMS, the reviews are based on the performance-improvement model that characterizes much of the administration of the CLIA program.⁸⁴ Consequently, the primary role of regional offices in conducting the reviews is to provide education and support for state survey agency improvement. For the 2004 reviews, 38 states were required to submit corrective action plans to their respective CMS regional offices in at least 1 of the 13 areas examined. Three areas required the most corrective action plans: principles of documentation, proficiency testing desk reviews, and survey time frames.⁸⁵

- Principles of documentation. CMS found that some state survey agencies lacked the supervisory personnel to conduct internal reviews intended to ensure the appropriate documentation of deficiencies. It also found that some state survey agencies did not follow the protocol instructions on how to quantify such reviews.
- Proficiency testing desk reviews. Because of personnel shortages, some state survey agencies were unable to perform proficiency testing desk

⁸²According to a CMS official, the Seattle regional office was in the forefront of developing a set of performance standards for Washington's CLIA-exempt program. The standards, though not identical to those implemented for state survey agencies, have been in place for several years. As of November 2004, the New York regional office is developing similar performance standards for the New York CLIA-exempt program.

⁸³The 13 areas are personnel qualifications, financial management, completion of workload targets, survey selection and scheduling, outcome-oriented survey process, acceptable plan of correction, complaints, ongoing training activities, data management, survey time frames, proficiency testing desk review, principles of documentation, and enforcement.

⁸⁴In explaining the purpose of the performance reviews to state survey agencies, CMS noted that they were designed to serve as an additional opportunity to further the agency's educational and supportive efforts of state survey agencies. The goal is to promote optimal performance by identifying areas needing improvement and corrective action. Survey agencies are expected to have systems in place for monitoring and evaluating the efficiency of their corrective actions.

⁸⁵During desk reviews, state survey agency staff track the proficiency testing results of labs using data reports from proficiency testing providers and request that labs initiate corrective actions when the results are below certain thresholds with some frequency.

reviews between surveys, waiting instead until the next on-site survey to address unsuccessful proficiency testing. CMS plans to provide additional surveyor training on desk review requirements.

- Survey time frames. CMS regional office staff were inconsistent in scoring whether state survey agencies met the established time frames for initial surveys. While some regions were lenient if a state missed the time frame by just 1 day or provided a reasonable explanation—such as staff turnover or illness—other regions were more stringent in scoring states against the standard.

However, it is not yet clear to what extent the 2004 scores represent state survey agency shortcomings or a learning curve for the states in understanding the performance review protocols.

In partnership with the accrediting organizations, CMS is developing performance standards comparable to, but different from, those implemented in 2004 for state survey agencies. For example, both the state survey agency review protocols and those proposed for accrediting organizations measure the timeliness of the surveys, but those proposed for the latter would also focus on several areas that are unique to accrediting organizations. The performance standards would include (1) timely and consistent information sharing and (2) alerting CMS about decisions to limit or remove accreditation in a timely manner. According to a CMS official, the agency plans to phase in the performance standards, starting with a standard on complaints. For example, if the CLIA complaints database is activated in March 2006, CMS could begin to monitor accrediting organization responsiveness to, and outcomes of, complaints. Because the database will contain national lab complaint data, CMS will be able to compare the volume and outcome of complaints across survey organizations. According to CMS, implementation of the accrediting organization performance standards will be a central—not regional—office responsibility.

Conclusions

Clinical labs play a pivotal role in the nation's health care system by diagnosing many diseases, including potentially life-threatening diseases, so that individuals receive appropriate medical care. Given this important role, lab tests must be accurate and reliable. CMS and survey organization oversight is intended to ensure that labs produce reliable test results, a key objective of CLIA. Our work demonstrated that the oversight of clinical labs needs to be strengthened in several areas.

Determining the quality of lab testing is difficult because it is virtually impossible to crosswalk inspection requirements across survey organizations. Without standardized survey findings across all survey organizations, CMS cannot tell whether the quality of lab testing has improved or worsened over time or whether deficiencies are being appropriately identified.

Lab oversight has weaknesses that make it difficult to determine the quality of lab testing because they mask quality problems. To help surveys provide a realistic picture of day-to-day operations, CAP and JCAHO began unannounced surveys of the labs they survey—generally hospital labs—in 2006. While unannounced surveys at physician office labs may not be practical, Washington’s exempt program and COLA currently give such labs more advance notice than the 2 weeks CMS prescribes for labs inspected by state survey agencies. Similarly, the greater weight that CMS and survey organizations sometimes place on their educational, as opposed to their regulatory role may lead to survey findings that do not accurately reflect lab quality. Educating labs to ensure high-quality testing should complement but not replace the enforcement of CLIA inspection requirements. The low number of lab complaints may be the result of a lack of information about how to file a complaint and lab workers’ fear of retaliation. Because protecting the anonymity of lab workers who file complaints is difficult, whistle-blower protections for such individuals are particularly important. Finally, labs with the same serious deficiencies on consecutive surveys often escape sanctions, even though Congress authorized alternative sanctions to give CMS more flexibility to achieve lab compliance. Without the threat of real consequences, labs may not be sufficiently motivated to comply with CLIA inspection requirements.

CMS’s oversight is not adequate to enforce CLIA requirements. The agency is not requiring labs to participate in proficiency testing on a quarterly basis, as required by CLIA. Furthermore CMS is not conducting CLIA-equivalency determinations within the time frames it established for such reviews, nor has it always reviewed changes to exempt-state and accrediting organizations’ inspection requirements before their implementation, even though it requires their submission to ensure continued CLIA equivalency of their requirements. Although the CLIA program has generated funds, CMS agencywide staffing limitations have prevented the program from hiring sufficient staff to complete equivalency reviews in a timely manner. Many validation reviews are conducted at the same time a survey organization conducts its survey, and such simultaneous reviews may not provide a true assessment of surveyor performance. Independent validation reviews of accrediting organization

surveys are critical because CMS has not conducted equivalency reviews within the time frames it established. We also found that few validation reviews of state survey agency lab inspections are conducted each year and that none occurred in some states. Because state surveyors conduct validation reviews of accrediting organizations to ensure the continuing CLIA equivalency of their inspection requirements, conducting an appropriate number of validation reviews of state survey agency lab inspections is critical. CMS also has not yet taken the lead in ensuring the availability and use of data from survey organizations to help it monitor their performance—particularly the consistency with which surveys are conducted. CMS is creating a new complaint database, but its plan to automate the existing sanctions registry will not address the lack of data on enforcement actions taken by state survey agencies and regional offices when labs have their accreditation revoked.

Recommendations for Executive Action

To enable CMS to track the nature and extent of lab quality problems across survey organizations, we recommend that the CMS Administrator take the following action:

- Work with exempt-state programs and accrediting organizations to standardize their categorization and reporting of survey findings in a way that tracks to CLIA inspection requirements and allows for meaningful comparisons across organizations, such as the analysis of trends in the citation of condition-level deficiencies.

To ensure consistency in the oversight of labs by survey organizations, we recommend that the CMS Administrator take the following four actions:

- Ensure that the advance notice of upcoming surveys provided to physician office labs is consistent with CMS's policy for advance notice provided by state survey agencies.
- Ensure that regulation of labs is the primary goal of survey organizations and that education to improve lab quality does not preclude the identification and reporting of deficiencies that affect lab testing quality.
- Impose appropriate sanctions on labs with consecutive condition-level deficiencies in the same requirements.
- Require all survey organizations to develop, and require labs to prominently display, posters instructing lab workers on how to file anonymous complaints.

To improve oversight of labs and survey organizations, we recommend that the CMS Administrator take the following eight actions:

- Consistent with CLIA, require quarterly proficiency testing, except when technical and scientific considerations suggest that less frequent testing is appropriate for particular examinations or procedures.
- Ensure that evaluations of exempt-state and accrediting organization inspection requirements take place prior to expiration of the period for which they are approved in order to ensure the continued equivalency of their requirements with CLIA's.
- Ensure that changes to the inspection requirements of exempt states and accrediting organizations be reviewed prior to implementation, as required by regulation, to ensure that individual changes do not affect the overall CLIA equivalency of each organization.
- Allow the CLIA program to utilize revenues generated by the program to hire sufficient staff to fulfill its statutory responsibilities.
- Ensure that federal surveyors validate a sufficient number of inspections conducted by each state survey agency to allow a reasonable estimate of their performance, including a minimum of one independent validation review for each state survey agency surveyor.
- Require that almost all validation reviews of each accrediting organizations' surveys be an independent assessment of performance.
- Collect and routinely review standardized survey findings and other available information for all survey organizations to help ensure that CLIA requirements are being enforced and to monitor the performance of each organization.
- Establish an enforcement database to monitor actions taken by state survey agencies and regional offices on labs that lose their accreditation.

Agency and Accrediting Organization Comments and Our Evaluation

We provided a draft of this report to CMS, and to CAP, COLA, and JCAHO—the three laboratory accrediting organizations included in our review. CMS strongly endorsed our overall conclusion that quality assurance for the nation's clinical labs should be strengthened and noted that the report provided insights into areas where it can improve, augment, and reinforce oversight of both labs and accrediting organizations to ensure quality testing. Overall, CMS concurred with 11 of our 13 recommendations. Despite this endorsement, however, CMS (1) provided an alternative assessment of lab quality, (2) disagreed that the phase-in of certain CLIA requirements inappropriately stressed education as opposed to regulation, (3) expressed concern about how to identify and sanction labs with repeat condition level deficiencies, (4) disagreed with our recommendation regarding the frequency of proficiency testing, and (5) stated that it was already meeting our recommendation to conduct

almost all validation reviews of each accrediting organization independently. We continue to believe that implementation of these recommendations is necessary for the effective oversight of labs. (CMS's comments are reproduced in app. IV.) CAP indicated that it took seriously our findings and recommendations and intended to determine if there were additional measures it could take to strengthen its own oversight. COLA said that our recommendations to improve CMS oversight of survey organizations had merit. Nonetheless, CAP, COLA, and JCAHO disagreed with some of our findings and recommendations to CMS. (CAP, COLA, and JCAHO's comments are reproduced in app. V, VI, and VII, respectively.) Our evaluation first responds to CMS's and related accrediting organizations' comments and then addresses additional comments by accrediting organizations.

Assessment of Lab Quality

CMS and COLA commented that lab performance has improved since the enactment of CLIA. In particular, CMS pointed to the substantial decline—from about 80 percent to about 42 percent—in the percentage of labs nationwide with deficiencies between 1994 and 2004. It is important to note that CMS's data (1) do not distinguish between serious condition-level deficiencies and less serious standard-level deficiencies,⁸⁶ (2) include the early start-up period when physician office labs were first regulated,⁸⁷ and (3) exclude deficiency data on the substantial number of labs surveyed by accrediting organizations and state CLIA-exempt programs. Due to these shortcomings, we do not believe that CMS's data provide an accurate assessment of lab quality nationwide.

Based on the limited data available on state survey agency inspections of labs since 1998 and the lack of any comparable data on accrediting

⁸⁶We asked CMS officials to provide the data points for fig. 1 in the agency's comments on our draft report. The data provided by CMS show that the percentage of labs with condition-level deficiencies remained relatively constant over time—fluctuating between 6 and 8 percent from 1996 through 2005. However, the pre-2004 and post-2004 data are not comparable because CMS revised CLIA survey requirements in January 2004. Additionally, the data likely understate the actual number of condition-level deficiencies. As noted earlier, state survey agencies do not consistently cite all condition-level deficiencies identified during inspections and CMS has instructed states not to include deficiencies related to the new 2003 lab quality control requirements in a lab's survey report.

⁸⁷Generally, our analysis focused on the period 1998 through 2004, recognizing that the early years of CLIA implementation were probably atypical because the law expanded oversight to previously unregulated physician office labs and many labs shifted from more complex testing that required routine inspections to less complex testing that did not.

organization and exempt-state program survey findings, we concluded that insufficient data existed to identify the extent of serious quality problems at labs. CMS did not retain backup files of pre-2004 data on deficiencies identified by state survey agencies. Although CMS has determined that accrediting organization and exempt-state program lab requirements are at least equivalent to CLIA's, there is no agreement across survey organizations on how to distinguish serious from less serious deficiencies. While CMS concurred with our recommendation to standardize the categorization and reporting of survey findings in a way that tracks to CLIA and allows meaningful comparisons across survey organizations, it noted that a straightforward linkage of requirements is limited by CMS's authority under the statute—that is, survey organizations are permitted by statute to have different requirements—and that it will approach implementation of our recommendation cautiously. JCAHO said that it agreed with the need for a common, agreed upon, taxonomy that could be used by all survey organizations to track serious deficiencies, but commented that it thought CMS's implementation of our recommendation would require a revamping of JCAHO's accreditation system. That was not the intent of our recommendation and it is clear from CMS's comments that its implementation of our recommendation would not require an overhaul of accrediting organizations' systems. CAP acknowledged the complexity and inherent challenges in measuring the quality of lab testing, but noted that it is committed to working to develop better systems to detect labs with serious quality problems—those that impact patient care.

The statutory authority that permits standards different from CMS's (provided they are at least as stringent) does not impair the ability to develop a crosswalk that allows for meaningful comparisons across survey organizations—such as an analysis of trends in the citation of condition-level deficiencies. In fact, CMS regulations already require accrediting organizations and exempt-state programs to submit a crosswalk—detailed comparisons of their individual accreditation or licensure approval requirements with comparable CLIA condition-level requirements—when they apply and reapply for approval from CMS.⁸⁸ Such a comparison is possible because CMS already identifies instances when accrediting organizations have missed condition-level requirements during validation reviews. For example, CMS should require survey organizations to (1) indicate which of their requirements relate to each CLIA condition-level requirement, and (2) explain which deficiencies in their

⁸⁸ See 42 C.F.R. § 493.553(a)(1)(2005).

requirements, if cited, should be considered equivalent to CLIA condition-level deficiencies.

CMS also pointed to the steady increase in successful proficiency testing across all labs as an indication of improvements in lab quality. Our analysis of proficiency testing results suggested that lab quality had not improved at hospital labs in recent years. CMS correctly noted that the overall proportion of labs with no test failures increased from about 88 percent in 1998 to about 93 percent in 2003—that is, fewer labs failed proficiency testing. However, by focusing on overall proficiency testing results, CMS data mask trends in failure rates for subsets of labs such as hospital labs. For example, from 1999 through 2003, the percentage of CAP-surveyed labs with proficiency testing failures increased from 4.1 percent to 6.8 percent; CAP generally inspects hospital labs. CMS also commented that the overall improvement cannot be dismissed as a result of some labs being granted waived status because the more dramatic improvements predated the recent increase in the number of waived labs. It further commented that removing waived labs from the data would not result in improved performance rates. First, the number of waived labs—those performing waived tests or provider-performed microscopy—increased by about 26,600 from 1993 through 1998 and then increased by another approximately 33,700 labs from 1998 through 2004. Second, CMS’s comment suggested that it had conducted an analysis of the impact of removing waived labs from the proficiency testing data. However, it did not provide any data analysis when we subsequently asked to see the evidence behind its assertion. COLA also addressed this issue, and did not challenge our conclusion that the decrease in proficiency testing failures for physician office labs might not represent an actual improvement in lab quality, but instead could reflect the fact that some problematic labs are no longer surveyed.

Educational Focus of CLIA

CMS agreed that it was important to maintain an appropriate balance between its regulatory and educational approaches to CLIA implementation. While CMS noted that objective review and feedback are the bedrock of education, it emphasized that the educational approach does not preclude surveyors from identifying lab deficiencies. CAP and COLA offered similar comments. However, we found evidence that the goal of educating lab workers sometimes takes precedence over, or precludes, the identification and reporting of deficiencies and recommended that CMS take steps to ensure that regulation remains the primary goal of surveys. To address this problem, CMS stated that it will provide additional state agency surveyor training, improve guidance,

develop an action plan to promote greater consistency among surveyors, and institute periodic performance and consistency reviews. CMS's comments did not address evidence we presented that an educational emphasis may also prevent fulfillment of regulatory responsibilities by some accrediting organizations.

CMS disagreed that the extended phase-in periods for new quality control requirements and proficiency testing for lab technicians who interpret Pap smears were inappropriate. COLA noted that federal requirements in many regulated industries are phased in to allow them time to understand and effectively implement the requirements. CMS reaffirmed that, in the case of significant new requirements and for the time period specified by CMS, the educational approach may result in identified deficiencies being communicated to laboratories without a concomitant citation, as is the case with quality control and Pap smear testing requirements. As discussed in the report, we believe that CMS's educational phase-in periods are excessive. We found that the phase-in period for new quality control requirements was extended from 2 years to about 4 years, in part because of the lack of lab "buy-in" for some of the new policies and procedures. Similarly, the phase-in period for Pap smear proficiency testing is 2 years, despite (1) CMS's concern about some of the high initial test failure rates, (2) the consequences of inaccurate test results on patients' diagnoses and treatment, and (3) the approximately 13-year time lag between the 1992 implementation of the CLIA regulations and the commencement of Pap smear proficiency testing.

Sanctioning Labs with Serious, Repeat Deficiencies

In commenting on our recommendation to appropriately sanction labs with repeat condition-level deficiencies, CMS acknowledged the need to carefully monitor repeat deficiencies but expressed concern that focusing on the condition cited may not indicate a true repeat deficiency because the underlying failures could have been different in the two consecutive surveys for those labs.⁸⁹ CMS's assertion is inconsistent with its own policy on serious, repeat deficiencies for other providers, such as nursing homes. In general, immediate sanctions must be imposed on nursing homes with consecutive serious deficiencies, regardless of whether the deficiencies are in the same care area. As we have previously reported, allowing providers to avoid sanctions by correcting serious deficiencies contributes to an up-and-down pattern of compliance and undermines the deterrent

⁸⁹JCAHO expressed a similar concern.

effect of sanctions.⁹⁰ According to the CLIA legislative history, congressional concern about labs with repeat deficiencies led to the introduction of alternative sanctions such as civil money penalties as a substitute for more severe principal sanctions, which include termination from the CLIA program.

Proficiency Testing Frequency

CMS disagreed with our recommendation that it require quarterly proficiency testing except when technical and scientific considerations indicate that less frequent testing is justified for particular tests; CMS insisted that proficiency testing three times a year was “appropriate.” CMS stated that CMS and the Centers for Disease Control and Prevention had together determined that the reduced frequency was based on technical and scientific grounds. We asked for a record of the agencies’ deliberation supporting that decision. CMS supplied a brief, undated narrative, which it attributed to the Centers for Disease Control and Prevention. It was not clear to us that this narrative was contemporaneous with the decision to reduce the frequency of proficiency testing. Moreover, the narrative focused on the relative costs and benefits of proficiency testing at various intervals. There was no analysis of technical and scientific considerations with regard to particular tests that presented a basis for reducing the frequency.

Based on CMS’s response, we maintain that CMS’s decision to require proficiency testing three times a year is not authorized by CLIA. CMS did not dispute that, according to CLIA, it must base the decision to reduce the frequency of proficiency testing on scientific and technical considerations relevant to particular tests, and that the decision to reduce the frequency is in the nature of an exception to the norm of quarterly testing. CMS also acknowledged that the “public explanation” contained in the preamble to the rule setting the proficiency testing requirement at three times a year referred only to general concerns about the perceived burden associated with quarterly testing. For example, CMS stated in its final rule that the prospect of reduced frequency would provide a “needed respite” to both laboratories and proficiency test providers. In sum, CMS has not adhered to the conditions set out in the statute for reducing the frequency of proficiency testing and has implemented a policy that is not supported by statutory authority.

⁹⁰See GAO, *Nursing Homes: Additional Steps Needed to Strengthen Enforcement of Federal Quality Standards*, GAO/HEHS-99-46 (Washington, D.C.: Mar. 18, 1999).

Equivalency of Accrediting Organization and Exempt State Programs

CMS acknowledged the need to complete timely equivalency reviews of accrediting organization and exempt-state requirements, which were an average of about 40 months late for the 3-1/2-year period we examined. Regarding interim changes made between periodic equivalency reviews, CMS agreed with our recommendation and stated it would review such interim changes for both accrediting organizations and exempt-state programs prior to implementation, as required by regulation.⁹¹

Furthermore, CMS indicated that changes to accrediting organization requirements did not necessarily impact CLIA equivalency determinations because accrediting organizations may have more stringent requirements than CLIA's. While possibly true, CMS must review the changes to determine whether CLIA equivalency is affected. For example, in 2005, when it reviewed JCAHO's revised standards a year after they were implemented, CMS identified several critical areas where JCAHO's standards were less stringent than those of CLIA.

CMS acknowledged that a significant increase in workload and the decline in CLIA program staff were factors which contributed to delays in making equivalency determinations and reviewing interim changes. Although CMS stated that it reserved the right to manage the work within available resources and its assessment of priorities, it also made a commitment to explore our recommendation to utilize revenues generated by the CLIA program to hire sufficient staff to fulfill its responsibilities. We believe that additional staff would not only improve the timeliness of equivalency reviews, but also their thoroughness.

Accrediting Organization Validation Reviews

CMS stated that, consistent with our recommendation, 88 percent of accrediting organization validation reviews were conducted independently in calendar year 2005. However, our recommendation was to require that almost all validation reviews of each accrediting organizations' surveys be conducted independently. CMS's comments do not indicate the proportion of independent validation reviews conducted for each accrediting organization. Because CMS did not begin collecting data on the number of simultaneous accrediting organization validation reviews performed until

⁹¹CMS's comments explained that its regulations require 30-day advanced notice by accrediting organizations but not by exempt-state programs.

August 2003, we relied on estimates from accrediting organizations.⁹² CMS did not challenge JCAHO's estimate that 33 percent of its validation reviews were simultaneous, compared to about 10 percent for CAP and COLA. We do not believe that performing an estimated 33 percent of JCAHO's validation reviews simultaneously is consistent with our recommendation.

COLA commented that simultaneous validation reviews are useful in assuring consistency and in providing an understanding of processes across survey organizations. It also questioned the accuracy of most of the missed condition-level deficiencies identified by CMS during independent validation reviews. We did not assess the process CMS uses to identify such missed deficiencies but based on a discussion with CMS officials it appears that the process is thorough and time consuming. JCAHO commented that we had misinterpreted the results of simultaneous and independent validation reviews of accrediting organizations because, by JCAHO's estimate, the proportion of missed condition-level deficiencies is roughly equivalent for both types of surveys. We did not find the assumptions behind JCAHO's estimate convincing, given the lack of data on the actual number of simultaneous versus independent validation reviews conducted for each accrediting organization. Furthermore, most of the state survey agency officials we interviewed, whose inspectors conduct accrediting organization validation reviews, told us that simultaneous validation reviews do not provide a realistic evaluation of the adequacy of accrediting organizations' inspection processes.

Additional Comments by Accrediting Organizations

Additional CAP comments. CAP commented that we underestimated the value of using lab professionals in the inspection process and that we provided no factual evidence that their use was less effective than other models. In contrast to CAP, other survey organizations employ dedicated staff surveyors who have mandatory and continuing education requirements. In addition, such dedicated surveyors conduct from 30 to about 200 surveys per year compared to CAP's lab professionals who volunteer to perform about 1 survey per year. CAP partially addressed our concern about the lack of mandatory training for its volunteer surveyors. It plans to begin requiring training for survey team leaders in July 2006 and

⁹²Our analysis of accrediting organization validation reviews covered fiscal year 1999 through fiscal year 2003. We excluded fiscal year 2004 because CMS had not yet completed its analysis of condition-level deficiencies missed by accrediting organizations.

for survey team members in 2007. However, CAP's proposed new mandatory training is much less extensive than that required by other survey organizations.

Moreover, we reported that some CAP surveyors we interviewed raised a concern about having survey team leaders who are also the day-to-day supervisors of team members. For example, lack of agreement about the seriousness of a deficiency could result in the team leader instructing the team to downgrade the deficiency to a recommendation, a less serious finding that does not appear in the inspection report. Team members who are subordinates to the team leader may feel that they have no other recourse than to follow the team leader's instructions. CAP recently revised its conflict-of-interest policy which now instructs all parties to be cautious to retain objectivity in fact finding throughout the inspection process. We do not believe that this change in CAP's conflict-of-interest policy addresses the concerns raised by the CAP surveyors we interviewed. In its comments, CAP indicated that it would continue to closely monitor this issue to determine if further actions were necessary.

Additional COLA comments. COLA disagreed with our assertion that announced surveys may result in an unrealistic picture of lab quality—a conclusion supported by CMS regional office staff and most state survey agency officials we interviewed. We acknowledged that unannounced surveys of the physician office labs typically surveyed by COLA and state survey agencies were not practical given the unpredictable operating hours of such labs and need to minimize disruptions to patient care. However, we recommended that the advanced notice be limited to the 2 weeks permitted by CMS for state survey agencies. COLA currently provides up to 12 weeks advanced notice. COLA contends that providing up to 6 months of advanced notice before a survey would only improve the lab's operation more quickly if the lab took that opportunity to review COLA's self assessment questions and correct any missing or incorrect processes or documentation. We believe that COLA's example underscores the importance of our recommendation; such actions should be an ongoing process at labs—not a reaction to an upcoming inspections.

Additional JCAHO comments. JCAHO said that our recommendation that all survey organizations develop and require labs to prominently display posters that instruct lab workers on how to file anonymous complaints was too narrow and prescriptive and may inadvertently limit organizations from using other, more effective ways to educate lab workers on this topic. JCAHO did not explain how implementing our recommendation would limit other initiatives. In fact, CMS's comments

identified a number of promising approaches that it believed could supplement posters. JCAHO also said that our analysis of the increase in CAP complaints after it required posters in the labs it inspects failed to recognize a broad national trend. JCAHO indicated that it also experienced a dramatic increase in lab complaints between 2004 and 2005 without the use of posters.⁹³ This increase may be related to JCAHO's July 2005 requirement for labs to educate staff on how to report concerns. CAP told us that during the 3 months after they required a poster to be displayed they observed an immediate increase in the number of complaints. Thus, CAP lab complaints increased by over 100 percent in 2004 compared to 2003 and by another approximately 71 percent in 2005. We continue to believe that CAP's experience suggests that complaint posters can be an important way to encourage lab workers to communicate their concerns.

CMS, CAP, COLA, and JCAHO also provided technical comments which we incorporated as appropriate.

As arranged with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to the Administrator of the Centers for Medicare & Medicaid Services and appropriate congressional committees. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

⁹³JCAHO miscalculated the increase in complaints from 2004 to 2005. According to the data provided by JCAHO, the increase was 57 percent, not 64 percent. JCAHO's 2005 complaint data were not available when we initially collected data on complaints received and substantiated by survey organizations.

If you or your staff have any questions about this report, please contact me at (312) 220-7600 or aronovitzl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VIII.



Leslie G. Aronovitz
Director, Health Care

Appendix I: Effects of Lab Errors on Patient Health

This appendix contains examples of lab errors and their consequences, illustrating the importance of the quality of lab testing and the effects of lab errors on patient health. The examples in table 7 are summarized from case studies in the journal *Laboratory Errors and Patient Safety*.

Table 7: Effects of Lab Errors on Patient Health

Description of lab error	Effects of error on patient health
Example 1: Delayed reporting of elevated lab value	
<ul style="list-style-type: none">A 59-year-old woman with a history of a rapid and irregular heart beat and stroke is taking coumadin, a blood thinning agent. Her primary care physician has lab tests completed regularly to ensure that the coumadin dose is sufficient to maintain a lab value in the range of 2-3. The results of one Friday's test was 5.7, a high value out of her target range, indicative that her blood is too thin and clots too slowly. This lab test value was documented but the patient's primary care physician was not notified about the elevated value. The following Monday morning a lead technologist noticed that the physician had not been called and immediately contacted a nurse at the physician's office. The nurse, alarmed that both the physician's office and the patient had not previously been notified, tried to contact the patient at home. The patient had gone to the emergency room (ER) and was admitted to the hospital with an even higher blood clotting value of 7.2. With hospital treatment, her blood clotting value was reduced to 2.3 and she was discharged 3 days later.The physician ordering the test did not receive notice of the high blood clotting lab value for 3 days, even though the lab result was documented within an hour of collection. In addition, the lab failed to follow up on the situation within an appropriate time frame.	<ul style="list-style-type: none">There was a delay in the diagnosis of a critically elevated blood clotting level.The patient took coumadin inappropriately for 2 days.The patient experienced significant bleeding in her digestive tract related to her impaired blood clotting status.The patient had to be hospitalized to stabilize her health condition.The patient was exposed to blood products, putting her at risk for a transfusion reaction and exposure to infectious agents.

Appendix I: Effects of Lab Errors on Patient Health

Description of lab error	Effects of error on patient health
Example 2: Human recording and data entry error	
<ul style="list-style-type: none"> A 60-year-old man with a history of chronic liver disease went to the ER with a 36-hour history of chest pain. The ER physician ordered a cardiac blood test that resulted in the patient's being diagnosed with a heart attack. The patient was started on multiple medications and admitted to the cardiac intensive care unit at the hospital. After 10 hours in intensive care, a second cardiac blood test was run and because of significant discrepancy in the results compared to the first test, a rapid investigation of the situation ensued. The investigation revealed that the results of the original ER test were recorded inaccurately. The patient was retested by cardiac specialty physicians, reevaluated, and thought to be stable. He was removed from heart monitors, taken off all cardiac medications, discharged from the hospital, and asked to return for a routine appointment in 2 days. The patient continued to have mild chest pain during the 2 days after he was discharged. During his return visit, the patient was found to have a stomach ulcer. The patient's chest pain was really referred pain caused by the ulcer. The patient was then treated correctly. An investigation of the error revealed that it was a human recording and data entry error. The result from a different patient's blood test had been entered incorrectly into this patient's record because the two patients' blood tests had been run within a few minutes of each other. 	<ul style="list-style-type: none"> The patient inappropriately received several unnecessary medications. The patient was unnecessarily admitted to the cardiac intensive care unit, endured the painful placement of intravenous lines, and was attached to several heart monitors. The patient suffered significant anxiety related to thinking that he had suffered a heart attack. During the 2-day delay between hospital admission and follow-up appointment, the patient remained symptomatic for his actual condition—an ulcer. If the patient's ulcer had been more severe and had started to bleed internally, the inappropriate administration of heart attack medications could have had harmful or even catastrophic effects on the patient's health.
Example 3: Inaccurate review of lab test results	
<ul style="list-style-type: none"> A woman who had been using birth control was referred to a dermatologist for severe acne. The dermatologist wanted to prescribe a drug known to cause birth defects so she ordered two pregnancy tests, one initially and the second 2 weeks later. The first test came back negative. When the dermatologist called for the results of the second test, a lab worker incorrectly told her that the pregnancy test was negative. The patient was given a prescription for the acne drug and advised to avoid pregnancy while taking this medication. Three days after the patient started taking the prescription, the dermatologist saw in the patient's record that the second pregnancy test for this patient was actually positive. Upon instruction, the patient stopped taking the medication and her number of prenatal visits was increased so she could be monitored for possible birth defects. The investigation revealed that the laboratory employee, an experienced technician who was busy when the incident occurred, reported the result of the patient's first pregnancy test when asked for results from the second pregnancy test. Both the physician and the technician neglected to follow lab policies to include the date and time of the test when orally communicating results. 	<ul style="list-style-type: none"> The patient inappropriately received a drug known to cause birth defects. This necessitated increased monitoring of the patient's pregnancy. Although the patient's pregnancy was ultimately unaffected, she experienced anxiety throughout. She continues to worry that her child is or will be negatively affected in the future because she took this drug early in her pregnancy.

Appendix I: Effects of Lab Errors on Patient Health

Description of lab error	Effects of error on patient health
Example 4: Inappropriate judgment concerning a microbiology lab test result	
<ul style="list-style-type: none">• After returning from a trip to West Africa, a 30-year-old woman went to the ER after experiencing high fever, chills, and a headache. The woman was tested for malaria, a potentially deadly disease transmitted via mosquito bites. The test result was negative and the patient was sent home on ibuprofen. Four days later she returned to the ER suffering from continued high fever, listlessness, and a severe headache. She was tested again for malaria. This time the lab test result was positive for a moderate case of the disease.• The laboratory director reviewed the testing from the initial ER visit and found that the tests had been positive for malaria. The cause for not identifying malaria initially was inappropriate judgment. Since there was a low pretest probability of a positive result, technicians assumed that there would be a negative result.	<ul style="list-style-type: none">• The patient experienced fever and other significant symptoms during the 4-day delay in receiving appropriate care.• After the malaria diagnosis was made, the patient was admitted to the hospital and successfully treated. There was no permanent disability.

Sources: All examples were summarized from case studies in the journal *Laboratory Errors and Patient Safety*. Example 1: Volume 2, Issue 1(2005): 10; Example 2: Volume 1, Issue 4(2005): 6; Example 3: Volume 1, Issue 3(2004): 6; Example 4: Volume 1, Issue 1(2004): 5.

Appendix II: Labs Surveyed by State Survey Agencies and the Percentage with Condition-Level Deficiencies, by State in 2004

State ^a	Number of labs surveyed	Percentage of labs surveyed with reported condition-level deficiencies
Alabama	236	3.4
Alaska	24	12.5
Arizona	122	4.1
Arkansas	197	9.1
California	666	3.9
Colorado	173	10.4
Connecticut	140	0.0
Delaware	18	0.0
District of Columbia	15	13.3
Florida	664	4.1
Georgia	369	4.3
Hawaii	57	5.3
Idaho	89	0.0
Illinois	292	7.5
Indiana	112	9.8
Iowa	141	2.1
Kansas	156	2.6
Kentucky	217	3.2
Louisiana	157	12.1
Maine	32	0.0
Maryland	180	3.3
Massachusetts	217	4.6
Michigan	192	2.6
Minnesota	155	3.2
Mississippi	202	7.9
Missouri	238	2.9
Montana	41	7.3
Nebraska	127	8.7
Nevada	98	4.1
New Hampshire	22	9.1
New Jersey	302	9.9
New Mexico	50	10.0
New York ^b	545	8.1
North Carolina	321	13.4

Appendix II: Labs Surveyed by State Survey Agencies and the Percentage with Condition-Level Deficiencies, by State in 2004

State^a	Number of labs surveyed	Percentage of labs surveyed with reported condition-level deficiencies
North Dakota	30	10.0
Ohio	221	5.9
Oklahoma	158	10.8
Oregon	147	4.1
Pennsylvania	354	1.4
Rhode Island	36	0.0
South Carolina	143	25.2
South Dakota	66	1.5
Tennessee	403	10.7
Texas	651	6.5
Utah	95	6.3
Vermont	33	0.0
Virginia	271	5.2
West Virginia	85	7.1
Wisconsin	226	9.7
Wyoming	23	8.7
Nation	9,509	6.3

Source: GAO analysis of OSCAR data as of May 15, 2006.

^aWashington is not included because it operates only a CLIA-exempt program.

^bExcludes labs surveyed under the state's CLIA-exempt program.

Note: Includes surveys conducted from January 12, 2004, through December 31, 2004. We excluded surveys conducted from January 1 to January 11, 2004, because surveyors began using new CLIA inspection requirements on January 12.

Appendix III: Number of Labs Subject to Surveys by State Survey Agencies in 2005 and Number of Labs with Sanctions, 1998 to 2004

State ^a	Number of labs (2005)	Number of labs with sanctions (1998-2004)
Alabama	491	1
Alaska	50	0
Arizona	265	7
Arkansas	398	14
California	1,570	134
Colorado	310	6
Connecticut	246	0
Delaware	46	0
District of Columbia	35	6
Florida	1,268	5
Georgia	737	5
Hawaii	81	4
Idaho	203	0
Illinois	517	15
Indiana	274	1
Iowa	281	1
Kansas	279	0
Kentucky	386	0
Louisiana	396	7
Maine	89	0
Maryland	467	28
Massachusetts	409	0
Michigan	387	62
Minnesota	274	1
Mississippi	441	0
Missouri	394	5
Montana	93	4
Nebraska	254	4
Nevada	159	3
New Hampshire	89	1
New Jersey	533	16
New Mexico	113	3
New York	1,125	75
North Carolina	676	1

Appendix III: Number of Labs Subject to Surveys by State Survey Agencies in 2005 and Number of Labs with Sanctions, 1998 to 2004

State^a	Number of labs (2005)	Number of labs with sanctions (1998-2004)
North Dakota	74	0
Ohio	428	12
Oklahoma	292	6
Oregon	270	0
Pennsylvania	749	7
Rhode Island	75	1
South Carolina	315	0
South Dakota	116	2
Tennessee	705	0
Texas	1,854	26
Utah	201	13
Vermont	46	0
Virginia	540	17
West Virginia	143	6
Wisconsin	480	1
Wyoming	54	1
Total	19,678	501

Source: GAO analysis of CMS lab registries and CLIA database.

^aWashington is not included because it operates only a CLIA-exempt program.

Appendix IV: Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: MAY 17 2006

TO: Leslie G. Aronovitz
General Accounting Office

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator

A handwritten signature in black ink, appearing to read "Mark McClellan".

SUBJECT: General Accountability Office's (GAO) Draft Report "Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened" (GAO-06-416)

Thank you for the opportunity to review and comment on the subject GAO report.

The Centers for Medicare & Medicaid Services (CMS) strongly endorses the overall GAO recommendation that quality assurance for the Nation's clinical laboratories be strengthened. To this end CMS has undertaken many initiatives in the past several years under auspices of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to strengthen standards and increase the quality of laboratory services. Such initiatives include the following:

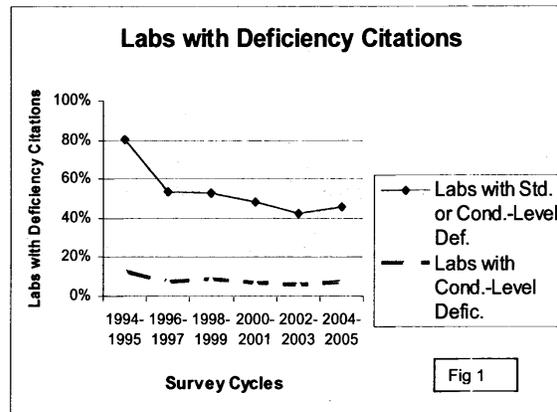
- **Improved Quality Control Requirements:** We improved quality control requirements for all non-waived testing under CLIA via regulations promulgated in 2003, followed by extensive training.
- **Cytology Proficiency Testing:** We implemented statutorily-required cytology proficiency testing for individuals who examine Pap smears and are also revising regulations governing cytology proficiency testing. More than 12,000 cytotechnologists and pathologists underwent such testing in 2005 (the first year of national testing).
- **Complaint Tracking System:** We designed and implemented an improved complaint tracking system and other informational infrastructure in 2006 (*S&C Administrative Information Memo 06-13 dated March 28, 2006*). Further improvements are underway for implementation in 2007.
- **Performance Standards for States:** We implemented a national system of performance metrics for performance of State survey agencies. We review each State's performance annually, and require plans for improvement wherever performance remains below the thresholds of acceptability. In 2005, thirty-three States implemented plans for improvement in at least one of thirteen possible areas.

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- **Performance Standards for Accrediting Organizations:** We initiated a comprehensive effort in 2005 to develop performance standards for accrediting organizations.
- **Accrediting Organization Response & Improvement:** We initiated a practice of convening all accrediting organizations together to review common issues and promote improvement in surveys. A new agreement for improved data sharing, communications, and performance has been one outcome of these regular meetings. In addition, a new rapid response alert agreement will enable faster, more efficient and more coordinated responses to situations with significant quality or public health implications.
- **Data and Analysis:** We are currently examining methods by which data may be more effectively employed in the oversight of both State agencies and accrediting organizations. We are planning for overhaul of the CLIA databases and analytical systems used to manage the program.
- **Waived Lab Quality Project:** We initiated a special project to improve performance in those laboratories that qualify for a certificate of waiver (i.e., are not required to be inspected provided they follow manufacturers’ test instructions appropriately). Of those laboratories in the sample that received a CMS revisit (n=459), more than 70 percent improved their performance in adhering to manufacturers’ instructions subsequent to the CMS reviews and initial visit¹.

The above actions build on a track record of progressively improved performance by laboratories that coincides with CMS’ implementation of the CLIA enacted by Congress in 1988.

For example, the percentage of laboratories determined to have deficiencies declined by 42 percent between 1994 and 2004 (Figure 1). The decline was most pronounced in the early years of implementation, before leveling off in 2004 subsequent to CMS’ strengthening of the quality control requirements².



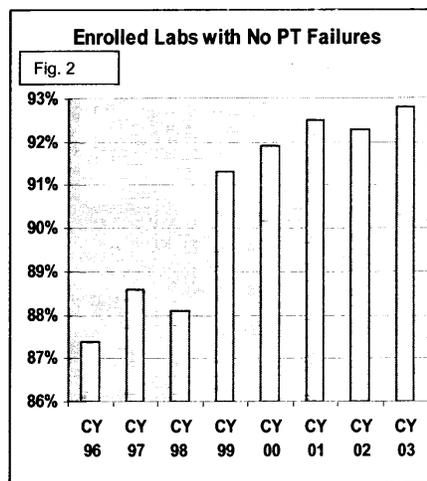
¹ Of the 2% sample of waived laboratories (2422) for FY 2005, preliminary data indicate that 751 laboratories did not adhere to manufacturers’ instructions. Of the 751 laboratories, 459 received a revisit. Of 459, initial data indicate that more than 70% showed improvement with manufacturers’ instructions after an initial determination of nonconformance on the initial visit.

² Improvements in the CMS information system have prevented the verification of data prior to 2004. However, the trend line (especially the substantial decline in deficiencies after 1994-1995 subsequent to CMS implementation of CLIA regulations) is consistent with a variety of other measures.

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The CMS also made it a national goal to improve the results of proficiency testing of laboratories³. Laboratories are required by statute to undergo proficiency testing for certain specialties and analytes that are specified in the regulations, if the laboratory’s business includes those specialties (for example, tests for blood type, blood chemistry, blood cell counts, viruses, parasites, fungus, bacteria, and blood antibodies). The proficiency tests are administered at least three times per year (except for once-per-year testing in cytology proficiency). The GAO highlights the importance of proficiency testing as a measure of performance. While the GAO points to a recent increase in failures among some labs between 1999 and 2003, the overall performance of all labs has improved, especially when viewed over a longer time period.

Figure 2 shows the performance of all labs (both accrediting organization and CMS certified). In 1996, 87.4 percent of all labs enrolled in proficiency testing had no test failures. The proficiency testing rates improved to 88.1 percent in 1998, to 91.9 percent in 2000, and to 92.8 percent in 2003.



These improvements cannot be dismissed as a result of some laboratories being granted “waived status,” since (a) the most dramatic improvements pre-dated the recent increase in the number of waived labs, and (b) removing waived labs from the data would not result in improved performance rates (i.e., labs with a CLIA certificate of waiver did not have a higher failure rate under their previous certificate of compliance or certificate of accreditation, when they were subject to proficiency-testing).

Balancing Enforcement and Educational Roles

The CMS believes that a careful survey process and identification of regulatory deficiencies, combined with our quality improvement and educational approach to CLIA implementation, has been a very effective strategy and has yielded substantial benefits to the public. The GAO report, however, expresses concern about whether CMS is adequately balancing regulatory and educational roles. In particular, the GAO states:

CMS appears to be inappropriately stressing education over regulation in its implementation of (1) 2003 laboratory quality control requirements for the CLIA program and (2) proficiency testing for lab technicians who interpret Pap smears, a test for cervical cancer.

³ The initiative was stimulated by the Government Performance and Results Act (GPRA), enacted by Congress to promote performance improvement in areas of national concern. The GPRA goal included both (a) increasing the percentage of labs that fully enroll their staff in proficiency testing, and (b) improving the proficiency of the laboratories, as measured by the results of proficiency tests.

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We agree that a careful balance must be maintained. We also believe that our response to specific GAO recommendations (discussed below) demonstrates our commitment to maintaining an appropriate balance.

We strongly disagree, however, with GAO’s statement regarding the 2003 quality control regulations and the cytology proficiency testing for Pap smears. In both instances we strengthened quality requirements and public protections. It was entirely fitting that we emphasize education of providers and full opportunity for laboratories to understand the new requirements, implement them appropriately, upgrade their systems and practices, and make necessary corrections without unnecessary sanctions.

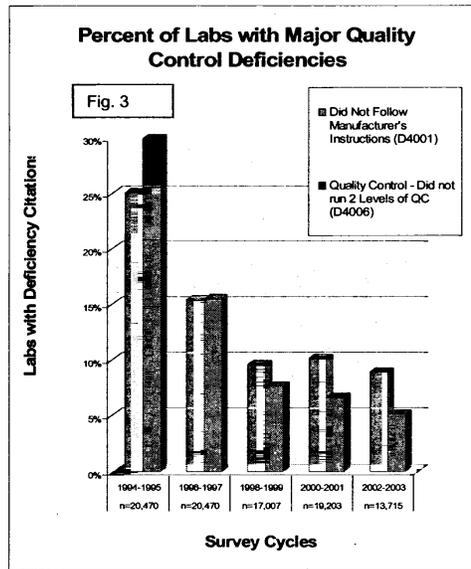
The CMS “educational approach” does not mean that surveyors refrain from identifying deficiencies on the part of laboratories; in fact, objective review and feedback is the bedrock of education. The educational approach does mean that we limit the exercise of sanctions in certain circumstances, particularly in cases of new requirements when the motivational power of sanctions is unnecessary (and may even be counterproductive).

The CMS published the improved quality control requirements in final form in January, 2003 as the **CLIA Quality System Rule**. The rule became effective April 24, 2003. Prior to this rule, laboratories that performed moderate complexity testing were only held to certain limited quality control requirements. Laboratories performing high complexity testing were already subject to the more stringent quality control requirements prior to the 2003 rule. The 2003 rule applied the more stringent quality control requirements to laboratories performing moderate complexity testing. As a result, all laboratories performing non-waived testing (i.e., moderate and high complexity testing) have subsequently been subject to the same quality control requirements.

Changes in the 2003 CMS rule required laboratories performing moderate complexity testing to upgrade their quality control. CMS adopted an educational period to allow those laboratories more time to understand and comply with the more stringent quality control requirements that applied to them for the first time, and have committed ourselves in the rule promulgation process to implement the change in a manner that would limit the immediate impact on laboratories.

In addition, the educational period has been important to permit CMS to evaluate various technological changes and work with the Clinical and Laboratory Standards Institute (CLSI) to (a) develop two new documents (one for manufacturers and one for laboratories) that provide guidance for quality control; (b) evaluate new quality control systems that do not fully comport with the 2003 regulations but which may offer useful innovation; and (c) develop technical assistance for laboratories in risk management (one of their quality control responsibilities).

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The CMS is also consulting with experts in the field of laboratory science to enable us to make future refinements to the quality control interpretive guidelines and also provide laboratories with more effective, practical applications for quality control.

Figure 3 shows the overall decline in the percentage of laboratories in which surveyors identified the top two quality control deficiencies. This trend suggests that our approach produces the desired results in the form of improved quality.

With regard to **Pap smear proficiency testing**, several factors contributed to a delay in implementing this provision of the 1988 law on a national basis. More recently, CMS successfully worked with potential testing programs and with laboratories to begin such testing in 2005. More than 12,000

cytotechnologists and pathologists were tested in that first year of national testing. Such national testing represented a significant accomplishment to ensure that the full protections afforded by CLIA have been put into effect.

CMS' educational approach refrains from punitive sanctions only if (a) each laboratory enrolls its staff in proficiency testing, (b) ensures the staff take the test, and (c) ensures that proper regulatory procedures are followed in the event that an individual fails the test (e.g., undertakes additional education and is re-tested). Under our enforcement discretion, we are not currently sanctioning laboratories if they are unable to ensure that 100 percent of staff achieves a passing score, provided the laboratory follows the requirements for re-testing.

CMS believes our educational approach strikes an appropriate balance between (a) the impositions of sanctions for anything less than immediate 100 percent compliance by all laboratories, and (b) any lessening of expectations for proficiency and protection of the public that are not fully reviewed and supported by both evidence and good practice.

For those laboratories that continue to incur repeat deficiencies, CMS will use a progressive enforcement approach. In that context CMS is appreciative of the GAO's external review, which provides insight into areas where we may improve, augment, and reinforce our oversight of both laboratories and accrediting organizations to ensure quality testing.

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Responses to Specific GAO Recommendations

Each GAO recommendation is quoted in italics below, followed by our comment and plan of action. We added numbering to the GAO recommendations for ease of reference.

***GAO Recommendation #1:** Work with exempt state-programs and accrediting organizations to standardize their categorization and reporting of survey findings in a way that tracks to CLIA inspection requirements and allows for meaningful comparisons across organizations, such as the analysis of trends in the citation of condition-level deficiencies.*

CMS Response: We endorse this concept but will be cautious as to its scope. In our experience, a straightforward linkage of accrediting organization requirements to CLIA condition-level requirements is limited by our authority under the statute, and still may not make it fully possible to assess labs in a standardized manner.

First, the law permits each accrediting organization to have different requirements compared to CMS, so long as their requirements are at least equivalent to CMS requirements.

Second, accrediting organization requirements may exceed CMS requirements (so their standard may not have a CMS equivalent).

Third, standardization of requirements does not automatically provide a total picture of the adequacy of an accrediting organization's survey and will not reduce the need for CMS to analyze in-depth those accrediting organization surveys that are subject to validation review⁴.

Fourth, after multiple review cycles, CMS has verified that the accrediting organization's published standards are at least equivalent to, if not more stringent than the CLIA regulations. We believe the more important issue in accrediting organization oversight is the accrediting organization's *enforcement* of their standards. Demonstrating that an accrediting organization is

⁴ For example, we might equate an accrediting organization's requirement for proficiency testing enrollment with CMS' CLIA condition-level requirement for proficiency testing enrollment. Beneath the surface, however, we must be aware that proficiency testing enrollment applies to the laboratory's enrollment in proficiency testing for a great many potential analytes. If an accrediting organization-to-CLIA linkage is based only on lack of enrollment in testing, regardless of how many analytes were omitted, the assessment of quality would be woefully incomplete. Such an incomplete picture of quality would represent an inadequate assessment of quality since it would not capture all the serious deficiencies that have occurred. In our CLIA validation review of accreditation organizations, a CMS team manually reviews and compares the entire narrative findings of the CLIA validation inspections to those of the accrediting organization inspections. The entire narratives are compared and not limited to whether or not the accrediting organization found a deficiency in proficiency testing enrollment. Otherwise, the picture would be incomplete and our review would be inadequate. We need to know more about the analytes involved. If the CLIA validation inspection found that the laboratory failed to enroll in proficiency testing for 2 analytes, e.g., prothrombin time and glucose, but the accrediting organization inspection found that the laboratory failed to enroll in proficiency testing for only 1 of those 2 analytes, prothrombin time, the review identifies an inadequacy on the part of the accrediting organization — the accrediting organization inspection has failed to identify a serious flaw in the laboratory's practices that can negatively impact the quality of the laboratory's testing and the outcome can be death. In a worst case scenario, the laboratory's lack of enrollment in proficiency testing for the analyte glucose can result in inaccurate and unreliable testing results, which could affect the health status of a diabetic patient. The flawed testing results could directly result in patient fatality from diabetic shock. If the laboratory performs thousands of tests each year under those circumstances, thousands of patients are at risk.

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enforcing its standards through comprehensive policies, procedures and internal monitoring processes is vital to the effectiveness of a program. An accrediting organization can have the highest standards, but if not enforced appropriately, these standards hold little value in ensuring laboratory quality. Toward that end, CMS has re-focused its approval and oversight of accrediting organizations to concentrate on outcomes. This re-focusing is not only a more efficient use of CMS resources, but also a more effective approach overall in overseeing accrediting organizations.

To supplement the validations and other information about accrediting organizations, CMS, through the Partners for Laboratory Oversight process, has convened a workgroup of accrediting organizations and CMS representatives to develop data-driven performance indicators similar to the State Agency Performance Review (SAPR) program that CMS utilizes to monitor State agency performance of CLIA responsibilities and adherence to policies. The accrediting organization indicators would monitor routinely, for example, whether biennial surveys were conducted timely, and whether laboratories that failed proficiency testing or incurred serious deficiencies corrected their problems promptly or had sanctions imposed. The Partners for Laboratory Oversight effort engages an exceptional collection of expertise and experience in laboratory oversight. By organizing the “best of the best” in a collaborative endeavor involving all accrediting organizations, we hope that accrediting organizations will make further improvements as well as advance the state of the art for laboratory quality.

CMS Action:

1(a) Categorization of Findings: CMS will work with exempt state-programs and accrediting organizations to promote greater standardization of categorizing and reporting survey findings in a way that enables improved tracking to CLIA inspection requirements and allows for more meaningful comparisons across organizations, such as the analysis of trends in the citation of condition-level deficiencies.

GAO Recommendation #2: *Ensure that the advance notice of upcoming surveys provided to physician office labs is consistent with CMS’ policy for advance notice provided by state survey agencies.*

CMS Response: We agree. CMS will require any accrediting organization using announced surveys to reduce its lead time to be consistent with CMS policy governing actions of State survey agencies.

CMS Action:

2(a) Advance Notice in Small Labs: CMS will ensure that the advance notice of upcoming surveys provided to physician office labs is consistent with CMS’ policy for advance notice provided by State survey agencies.

2(b) Consistency: CMS will work with accrediting organizations and State survey agencies to promote unannounced surveys in larger labs and achieve greater consistency among all oversight organizations.

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GAO Recommendation #3: *Ensure that regulation of labs is the primary goal of survey organizations and that education to improve lab quality does not preclude the identification and reporting of deficiencies that affect lab testing quality.*

CMS Response: We agree that education to improve lab quality should never preclude the identification of deficiencies that affect lab testing quality, and that regulation of labs is the primary goal of survey organizations. In the case of significant new requirements, and only within certain areas for the time period specified by CMS, the educational approach may include the possibility of identified deficiencies being communicated to laboratories without a concomitant citation. Currently, such allowance primarily applies to two situations:

- Quality control requirements that were new in the 2003 regulation for labs conducting moderate complexity testing;
- Cytology proficiency testing that was newly implemented on a national basis in 2005.

For the reasons explained previously, we do not anticipate a change in this policy.

CMS Action:

3(a) Consistency Action Plan: CMS will ensure that a CMS Consistency Workgroup comprised of Regional Office and Central Office CLIA staff formulates an action plan to increase consistency.

3(b) Guidance: CMS will develop protocols or refinements to surveyor guidance to ensure an appropriate balance between the enforcement and educational functions of the survey process.

3(c) Training: CMS will provide additional training for surveyors and management on the differences between the “educational approach” and the “outcome oriented survey process”, including concentrated training on which survey findings require citation without any variation.

3(d) Performance & Consistency Review: CMS will ensure Central and Regional Office data review of key identified data sets, on a periodic basis, to determine if observed variations are truly significant and to identify any significant trends. This increased communication between Central Office, Regional Offices, & State agencies as they work to explain and understand the variations will lead to decreased variability and enhanced consistency over time.

GAO Recommendation #4: *Impose appropriate sanctions on labs with consecutive condition-level deficiencies in the same requirements.*

CMS Response: This recommendation is already CMS policy; the issue is our approach to implementation of the policy. CMS’ policy of progressive enforcement involves the imposition of sanctions for laboratories failing to correct deficiencies that impact on the quality of

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laboratory testing, increasing in severity in the event of continuing failures. By looking only at the category of failure (the “conditions”), however, it is not possible to determine whether a laboratory has consecutively failed in the same requirement.

For example, the laboratory could fail in proficiency testing in one year due to neonatal testing, and fail in proficiency testing in a completely different division of the laboratory the next year (e.g., virology). In regard to laboratories with consecutive condition-level deficiencies, the data presented by GAO would not permit us to assess whether there is a serious problem because the underlying failures could have been different in the two consecutive surveys for those laboratories that the GAO included in its report. Nonetheless, we agree that the issue is important and that labs that consistently fail to assure quality must be subject to consistently stronger remedial action.

CMS Action:

4(a) Monitoring & Data Analysis: CMS will carefully monitor citations of repeat deficiencies as part of the overall redesign of the CMS information system (converting from the Online Survey and Certification Reporting System (OSCAR) database to the ASPEN information system).

4(b) Follow-up System: CMS will review the data with State survey agencies and accrediting organizations for the purpose of ensuring that the laboratories with true repeat deficiencies have accelerated and progressive enforcement actions imposed, if the deficiencies are not corrected expeditiously and effectively⁵.

GAO Recommendation #5: Require all survey organizations to develop, and require labs to prominently display, posters instructing laboratory workers on how to file anonymous complaints⁶.

CMS Response: Complaints from clients or laboratory workers can be an extremely important vehicle for identifying problems. For that reason, CMS follows up on all complaints. Information about filing complaints has already been included in the updated Surveyor and Laboratory Interpretive Guideline document and most States already have a Hotline for the receipt of complaints.

⁵ CMS provides laboratories with an opportunity to correct its problems prior to the imposition of sanctions. If the problem represents a threat to patient health and safety, then the time frame for correction is either very short or the laboratory is required to cease testing. Most laboratories find the threat of sanctions to be an enormous incentive and quickly correct their problems. The desired outcome in CLIA is regulatory compliance, high quality, and prompt and effective remedy of problems. For CMS certified laboratories, 396 laboratories received a notice of a proposed sanction and of those, 93 failed to take prompt corrective action and had sanctions imposed in 2005. The 2005 Laboratory Registry contains 236 laboratories listed for all oversight entities as having sanctions imposed. The number cases in which sanctions were threatened is approximately four times the sanction level, indicating that in the vast preponderance of cases the laboratories responded quickly to the potential for sanctions. CMS also assessed \$4.4 million in civil monetary penalties.

⁶ CMS data consistently indicate approximately 200 complaints alleged per year. This relatively low number may alternatively suggest either that quality is good, or that clients and workers do not know the avenues by which to lodge a complaint.

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In March 2006, CMS also implemented a new, more sophisticated data system to receive and track complaints. The system will significantly facilitate State agency documentation and follow-up of complaints to their conclusion.

CMS Action:

5(a) Filing Complaints: CMS will take action to promote greater awareness of the opportunity and methods to file a complaint with CMS, State survey agencies, and accrediting organizations regarding the quality of laboratory services. Such actions may include:

- Providing a complaint filing "fact sheet" and model complaint poster on our website;
- Issuing a CLIA brochure regarding complaint filing;
- Encouraging State agencies and partners to publicize the complaint process through their websites and publications; and
- Working with the laboratory industry to use publications to highlight the importance of complaint filing by laboratory workers to promote laboratory excellence.
- Consideration of requirements for all laboratories to display posters instructing laboratory workers on how to file anonymous complaints.

5(b) Complaint Information Sharing: CMS will work with accrediting organizations and States to increase the sharing of information regarding complaints and complaint investigations.

5(c) Complaint Tracking and Response: CMS will seek to augment its complaint tracking system to build in the capability for accrediting organizations to transmit their complaint data to that system, thereby enabling a national complaint information database (or repository) for the first time. Along with CMS' monitoring its own follow-ups of complaints, such a system would assist the accrediting organizations to follow up timely on complaints they receive.

GAO Recommendation #6: *Consistent with CLIA, require quarterly proficiency testing, except when technical and scientific considerations suggest that less frequent testing is appropriate for particular examinations or procedures.*

CMS Response: CMS already made this determination. While the public explanation emphasized limiting the burden on laboratories, CMS, in conjunction with the Centers for Disease Control and Prevention, concluded on both technical and scientific grounds that proficiency testing three times per year was appropriate.

GAO Recommendation #7: *Ensure that evaluations of exempt State and accrediting organization inspection requirements take place prior to expiration of the period for which they are approved in order to ensure the continued equivalency of their requirements with CLIA.*

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CMS Response: We recognize the need to complete timely reviews. However, we reserve the right to manage the work within available resources and assessment of priorities. Initially, we deemed accreditation organizations and exempt States for periods of less than 6 years. This allowed us to perform multiple assessments to evaluate their programs and assure their standards were consistently equivalent to those of CLIA. Over the years we have found that the accrediting organizations have been consistent in regard to equivalency of standards. To ensure continued equivalency or more stringent requirements than those of CLIA, we are refocusing our approval process and oversight on evaluating how exempt States and accrediting organizations are enforcing their standards and assessing patient testing outcomes through the validation survey process. We are managing the risk appropriately. For accrediting organizations, we are developing performance measures through our partners, and are using the validation process to monitor the outcomes of their survey processes, as well as CLIA compliance. The CMS-convened Partners' for Laboratory Oversight group has already raised the bar by collaborating to facilitate increased effectiveness, knowledge and consistency for all participating entities, with the aim of improving their application and assessment of compliance for CLIA purposes.

CMS Action:

7(a) Timely Review of Accrediting Organization Standards: CMS will ensure, within the limits of available resources and priorities, that evaluation of exempt State and accrediting organization inspection requirements takes place prior to expiration of the period for which they are approved in order to ensure the continued equivalency of their requirements with CLIA.

GAO Recommendation #8: *Ensure that changes to the inspection requirements of exempt states and accrediting organizations are reviewed prior to implementation, as required by regulation, to ensure that individual changes do not affect the overall CLIA equivalency of each organization.*

CMS Response: It is correct that the accreditation organization must submit changes to CMS 30 days prior to their implementation [42 CFR 493.557(a)(13)]. However, the regulatory language does not specify a time period for the review of this information by CMS. Additionally, State exemption has no similar requirement. Since accreditation organizations' requirements may be more stringent than CLIA, changes to requirements do not necessarily impact CLIA equivalency determinations.

The approval of accrediting organizations is only one portion of CMS' oversight responsibilities. While we appreciate the value of timely review, we reserve the right to manage the work within available resources and assessment of priorities. Due to the potential for concerns about accrediting organization performance (versus equivalency of standards), CMS increased the percentage of validation surveys performed per year from an initial 1% to the current level of 2.5%. CMS also receives anecdotal information regarding accrediting organization performance from State agencies and specific concerns through the complaint process.

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CMS Action:

8(a) Timely Review of Accrediting Organization Changes: CMS will, within the limits of available resources and priorities, ensure that changes to the inspection requirements of exempt states and accrediting organizations are reviewed prior to implementation, as required by regulation, to ensure that individual changes do not affect the overall CLIA equivalency of each organization.

GAO Recommendation #9: Allow the CLIA program to utilize revenues generated by the program to hire sufficient staff to fulfill its statutory responsibilities.

CMS Response: CMS faced a decline in CLIA program staff as our workload has increased significantly. We therefore will explore this GAO recommendation.

CMS Action:

9(a) CLIA Staffing: CMS will consider adjustments to CLIA staffing in CMS Central and Regional Offices, and will establish CLIA staffing levels consistent with workload and available CLIA revenues.

GAO Recommendation #10: Ensure that Federal surveyors validate a sufficient number of inspections conducted by each State survey agency to allow a reasonable estimate of their performance, including a minimum of one independent validation review for each State survey agency surveyor.

CMS Response: In its recommendation to perform a sufficient number of surveys “to allow a reasonable estimate of their performance,” GAO quotes from the language in section 353(e)(2)(D) of the Public Health Service Act (which contains the CLIA statute), which pertains only to the evaluation of approved laboratory accreditation organizations, not the State agency. There is no statutory requirement regarding the number of surveys to be performed in each State to assess surveyor competency. Nevertheless, we agree that oversight of State agency and surveyor competency is important and that Federal surveyors should conduct a sufficient number of Federal Monitoring Surveys to allow for a reasonable estimate of State agency performance. In CY 2004, CMS instituted the CLIA State Agency Performance Review, a more comprehensive State agency oversight mechanism. The CLIA State Agency Performance Review includes indicators that measure the mechanisms for improvement in response to findings of our Federal Monitoring Surveys concerning individual surveyor competency assessments.

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Types of Federal Monitoring Surveys include:

Comparative. The Regional Office surveyor(s) survey the laboratory after the State agency surveyor(s). This type of survey is also called Look-Behind and can be considered as independent survey of the laboratory. The GAO would consider this to be an “independent” validation survey.

Observational. The Regional Office surveyor accompanies the State agency surveyor(s) during the laboratory survey and interacts as necessary to provide guidance to the State agency surveyor(s) at appropriate times.

Participatory. The Regional Office surveyor and State agency surveyor(s) identify deficiencies during the laboratory survey.

The Federal Monitoring Survey is a powerful educational tool for surveyor training. Observational and participatory Federal Monitoring Surveys are balanced by the comparative survey. We estimate the comparative surveys accounted for about 15 percent of all CLIA oversight surveys during the period GAO studied.

We agree that the comparative survey or “independent validation review” offers a truer assessment of surveyor competency than the observational or participatory Federal Monitoring Survey, and for that reason continue to have the comparative survey as a tool available to Federal surveyors for their oversight responsibilities. We are convinced that Federal surveyors exercise appropriate judgement as to when to select or not select the comparative survey to fulfill their responsibilities for surveyor competency assessment. One must also consider that comparative Federal Monitoring surveys can be disruptive to laboratories as they require two separate surveys conducted during different time frames to separately determine laboratory compliance for CLIA.

CMS Action:

10(a) Validating State Agency Performance: CMS will increase their efforts to ensure that the Federal Monitoring Surveys are performed annually in each State in numbers sufficient to allow a reasonable estimate of State agency performance, including increasing the number of “independent” reviews.

10(b) Independent Validation Review: CMS will ensure that at least one comparative Federal Monitoring Survey is performed for each surveyor every year.

10(c) Strengthen Training: CMS will strengthen its training focus and application of the outcome-oriented approach to surveying for laboratory compliance with 42 CFR §493 by incorporating additional specific examples and case studies of deficiencies that demonstrate non-compliance in current and future training of laboratory surveyors.

GAO Recommendation #11: *Require that almost all validation reviews of each accrediting organizations' surveys be an independent assessment of performance.*

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CMS Response: We reviewed the statistics provided by GAO regarding the numbers of validation surveys performed simultaneously with the laboratory accreditation organizations, as well as our statistics regarding validation surveys. The numbers given for CAP (11 percent), COLA (9 percent) and JCAHO (33 percent) equate to the numbers of simultaneous validation surveys per year for each organization that are shown here in Figure 4.

Forty-seven is consistent with the number historically recounted by the staff in the CMS regional offices that authorize the validation surveys—an average of about 1 simultaneous validation survey per State per year. It is also consistent with statistics in the CLIA data system for calendar year 2005 (45 simultaneous validation surveys).

FIGURE 4: SIMULTANEOUS VALIDATION SURVEYS (Annual Nationwide Data)

Accrediting Organization	Number
CAP	9
COLA	15
JCAHO	23
TOTAL	47

The number of validation surveys performed nationwide has increased in recent years to almost 400 validation surveys to ensure that CMS is adequately overseeing accrediting organization performance. At the present level of 1 simultaneous validation survey per State, simultaneous validation surveys constitute about 12 percent of the total number of validation surveys performed. Conversely, about 88 percent of the total validation surveys are performed independently, which equates to the recommendation that almost all validation surveys be an independent assessment of performance. We believe 12-15 percent is a reasonable proportion to reserve for the opportunities afforded by simultaneous validation surveys, such as:

- promoting understanding of each other's programs;
- sharing of best practices; and
- fostering improvements in accreditation organizations' survey processes.

CMS Action:

11(a) Ensure Validation Surveys: CMS will continue to monitor and ensure that the vast preponderance of validation surveys for accrediting organizations takes the form of independent assessments.

GAO Recommendation #12: *Collect and routinely review standardized survey findings and other available information for all survey organizations to help ensure that CLIA requirements are being enforced and to monitor the performance of each organization.*

CMS Response: We strongly endorse the value of collecting and reviewing survey findings and other available information to monitor, sustain, and improve performance. For this reason we instituted standardized mechanisms for State survey agency performance through the State Agency Performance Review (SAPR) protocols. Those protocols utilize standard indicators of performance and data. More recently we initiated development of a similar system for application to the performance of accrediting organizations. We believe that the accrediting organization Performance Measures under development will effectively enhance current methods to fulfill our oversight responsibilities for accrediting organizations.

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With regard to the “standardized” aspect of this recommendation, we will put emphasis on improving our methods of standardizing interpretations of survey outcomes, even though the standards of each accrediting organization may be different⁷.

CMS Action:

12(a) Collection & Review of Accrediting Organization Survey Findings: CMS will explore methods to expand its collection, review, and analysis of survey findings and the follow-up actions of accrediting organizations in order to monitor, sustain and improve performance of accrediting organizations.

GAO Recommendation #13: *Establish an enforcement database to monitor actions taken by state survey agencies and regional offices on labs that lose their accreditation.*

CMS Response: We agree that laboratories losing accreditation due to CLIA quality issues require close attention to ensure they are not erroneously deemed CLIA compliant. Our development efforts for enforcement management, and planned future system enhancements, will assist us in tracking and monitoring such cases. We will also be working closely with our state agencies, regional offices and accreditation organizations to review present procedures to ensure that actions taken are appropriate and timely.

CMS Action:

13(a) CMS Enforcement Database. Complete the development of the CMS CLIA enforcement database to track and monitor labs that necessitate any potential federal enforcement actions.

⁷ The CLIA regulations do not require that an accreditation organization’s or exempt State’s standards be the same as CLIA. Rather, the accreditation organization and exempt State’s requirements, taken as a whole, must be equivalent to or more stringent than those of CLIA. The majority of the deemed organizations and exempt States’ requirements are at a level that elevates the quality of testing and the standard of practice. CLIA, on the other hand, represents minimum requirements, and is sometimes less rigorous than the routine standard of clinical laboratory practice.

Because their standards can be more stringent than CLIA, the accrediting organizations and exempt States can hold the labs to higher quality requirements. For example, CAP requires proficiency testing for all analytes, not just those that are specified at Subpart I, and the JCAHO has quality standards for waived tests. Standardization would make our reviews easier, but would weaken the accreditation organization standards that are more stringent than CLIA, restrain marketplace-enriching standard development, and change their unique corporate identity and organizational autonomy.

Appendix V: Comments from the College of American Pathologists



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Advancing Excellence

Direct Response To:
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May 16, 2006

Leslie G. Aronovitz
Director, Health Care
Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Aronovitz:

As an organization dedicated to improving laboratory medicine and patient care, the College of American Pathologists (CAP), takes seriously the findings and recommendations of the Government Accountability Office (GAO) report titled *Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened*. We were pleased to work with the GAO on this report and appreciate the opportunity to provide comments.

In general, we believe that the Clinical Laboratory Improvement Amendments (CLIA) provide for adequate federal oversight for ensuring accurate laboratory testing and promoting ongoing quality improvement. In 2004, the College initiated its own evaluation of its Laboratory Accreditation Program as a result of the events at Maryland General Hospital. The College's comprehensive review, which considered independent, external recommendations, resulted in the approval of a series of initiatives designed to strengthen the program, many of which are acknowledged by the GAO in this report. The CAP, however, is continuously looking for ways to improve and will be closely examining the findings of the GAO with respect to the CAP Laboratory Accreditation Program (LAP) to determine if there are additional measures that the College should take to strengthen its program. The CAP also will continue to work closely with the Centers for Medicare and Medicaid Services and other stakeholders to develop consensus on best practices in assessing laboratory quality.

The GAO was charged with examining the quality of laboratory testing and was unable to make a determination about this issue. The CAP believes there are inherent challenges to measuring the quality of laboratory testing due to the complexity of the issue, and the CAP is working to develop better systems for detecting laboratories with quality issues that potentially impact upon patient care. As noted in the report, the CAP is investing \$9 million dollars over the next two years in new information systems and processes to strengthen our ability to monitor a laboratory for sustained compliance throughout its two-year accreditation cycle.

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CAP also will be developing a sophisticated computer program that will integrate quality factors, such as proficiency testing results and trend analysis, inspection findings and complaints, that contribute to a knowledge management system which will be utilized to support more effective accreditation decision-making that relies upon a comprehensive, multi-dimensional assessment of laboratory performance.

Ultimately, the most important outcome for patients is consistently accurate laboratory results. As noted by GAO, the only comparative data available at this time to evaluate the quality of laboratory results in a systematic way is proficiency testing data. The CAP believes that the proficiency testing data cited in the report, for the most part, demonstrates that laboratories accredited by the CAP perform better on proficiency testing than those that are not. We believe that is a relevant measure of the quality of testing performed by laboratories accredited by the CAP.

However, quality improvement is never a static exercise. As is noted in the report, the College's laboratory accreditation program continues to undergo change. Many of our recent initiatives directly address issues of concern raised by the GAO. For example

- **Unannounced Inspections:** The CAP's move to unannounced inspections directly addresses the GAO's concerns related to the accreditation system's ability to emphasize continuous regulatory compliance and adds credibility to the accreditation survey's conclusions as to the laboratory's ability to provide quality patient care.
- **Complaint Posters and Whistleblower Policies:** The CAP's "anonymous complaint" poster, which, as of October 2004 must be displayed in any CAP accredited laboratory, and the CAP whistleblower protection policy both address some of the GAO's concerns about identifying emerging laboratory quality problems.
- **Mandatory Inspector Training:** The CAP's new mandatory inspector training addresses the GAO's concerns about using active and current laboratory professional to conduct CAP surveys. This training will supplement their professional experience with specific guidance on inspection techniques.

While we believe the GAO provides valuable insights and information to consider, there are also portions of the report where we have a different perspective.

The GAO expresses concerns about our program's use of practicing laboratory professionals as inspectors. The CAP believes that the GAO underestimates the value of utilizing laboratory professionals in the inspection process. CAP accredited laboratories voluntarily choose CAP accreditation, which includes requirements that are more stringent than CLIA. We believe that this dedication to enhanced quality by laboratory professionals demonstrates a commitment to undertake more than is required by the federal government to assure quality laboratory testing.

College of American Pathologists

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Further, the report provides no factual evidence that the CAP's use of laboratory professionals is less effective than other inspection models. In fact, the available evidence suggests that the CAP system is comparable to other models.

The GAO also raises concerns that the use of volunteer inspectors creates the appearance of conflicts of interest, but also notes steps the College has taken to address this issue. It is important to note that the College has always had policies and procedures to protect against conflicts of interest interfering with the objectivity of the inspection process. In addition, a component of our recent initiative to strengthen the LAP was to tighten and make more comprehensive our existing conflict of interest policies and procedures. The CAP expects that our enhanced policies and procedures will more effectively guard against potential conflicts impairing the inspection process, and the CAP will continue to closely monitor this issue to determine if further actions are necessary.

The GAO also raises concerns regarding the educational versus the regulatory aspects of CLIA. As the GAO correctly notes, CLIA neither requires nor precludes an educational role for surveyors. The College believes that these dual objectives are not mutually exclusive and that education is an inherent and important outcome to the inspection process of identifying and correcting deficiencies.

Conclusion

The CAP accreditation program is dedicated to a single mission: raising the quality of laboratory testing to improve patient care. As with the laboratories we accredit, we are committed to the continuous improvement of our program and therefore, take seriously the analysis provided in this report. We believe our actions demonstrate this commitment. The CAP will continue to work closely with Centers for Medicare and Medicaid Services and other stakeholders on further improving laboratory quality and the laboratory inspection process.

Sincerely,



Thomas M. Sodeman, MD, FCAP
President

College of American Pathologists

Appendix VI: Comments from COLA



Douglas A. Beigel
Chief Executive Officer

CHAIR

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May 16, 2006

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CHIEF EXECUTIVE OFFICER

Douglas A. Beigel

COLA appreciates the opportunity to review and comment on your draft report "CLINICAL LAB QUALITY: CMS and Survey Organization Oversight Should be Strengthened (GAO-06-416)". As you know, during the course of your study, we responded to numerous written and verbal inquiries from the GAO and performed several in-depth data analyses. As COLA assisted you in this effort, we welcomed your critical, but focused examination of CLIA oversight and we used the process to discover opportunities to improve our accreditation program. Your report reinforces and validates for COLA many of the guiding principles that were used to design the most widely used laboratory accreditation program in the U.S. You specifically mentioned surveyor training and consistency of assessments as key factors to a strengthened laboratory oversight system. COLA is proud of its significant and extensive surveyor training program and our high level of inter-rater reliability.

However, COLA has a number of concerns regarding several assumptions and conclusions the GAO has drawn in the report. Specifically, we disagree with your suggestion that education and enforcement are mutually exclusive. We feel that enforcement can successfully be coupled with education so that laboratories can learn tools they need for compliance. Furthermore, your findings draw conclusions regarding notice for onsite inspections and overall laboratory preparedness that run contrary to a quality improvement philosophy. While you argue that data on laboratory improvement are misleading, we are confident that laboratory quality has improved since the promulgation of CLIA regulations in 1992. Finally, your recommendations for mechanisms to improve CMS oversight of survey organizations have merit, however, some are rooted in overstated problems and incorrect conclusions. We have addressed these substantive areas in our comments below. We have appended some technical comments under separate cover.

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Substantive Comments

Education should not be confused with lack of accountability

Education is a critical and key component to the reasonable and appropriate implementation and enforcement of laboratory performance requirements. COLA feels that such an educational approach is essential to the desired outcome of real improvement in laboratory performance and to prevent the continuation of deficiencies across inspection cycles. Many federal requirements in many regulated industries are “phased-in” in order to allow regulated entities the time to understand and effectively implement the requirements. There is little benefit to the laboratory and no benefit to public health and safety for the establishment of expectations that laboratories cannot meet. Education is essential to the improvement process so as to empower laboratories to meet or exceed the minimum expectations. COLA takes its enforcement responsibilities very seriously and we are proud of our consistent track record in the appropriate enforcement of CLIA. We are also proud of our unwavering commitment to laboratory quality improvement. You are absolutely correct that COLA begins educating laboratories upon enrollment in our accreditation program. This approach allows us to have meaningful improvement-based interactions with our accredited laboratories over the course of their two year accreditation period. The onsite inspection is but one aspect of the program. As we described to you during the course of your examination, we continually monitor laboratory performance on Proficiency Testing and we regularly communicate with and educate laboratories—before and after an onsite survey.

COLA's comprehensive surveyor training program in conjunction with individual surveyor exposure to hundreds of laboratories yearly, provides the COLA surveyors with a unique opportunity to share their knowledge and experience during a laboratory's onsite survey. It has always been the goal of COLA's Accreditation program to bring laboratories, particularly the smaller Physician Office Laboratory (POL) with its less experienced staff, into compliance with the law by a combination of approaches which identifies the deficiencies present and shares with the lab the correct way to assure quality patient testing. COLA then follows up on the identified deficiencies and requires an evidence-based response from the laboratory before their accreditation is approved or continued. COLA cites ALL problems in the lab.

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While COLA laboratory inspections are highly educational, we enforce 100% of our [CMS-approved] accreditation requirements].

Laboratory Preparation

We disagree with your assertion that allowing a laboratory to prepare for a survey masks the discovery of laboratory problems. We know of no research that would support such a conclusion.

While much of a laboratory's evidence of compliance is documentary, there is little of this evidence that can be fabricated in a short period of time. Personnel qualifications, root cause analyses of "out of limit" Quality Control (QC), failed Proficiency Testing (PT), the release of patient results when QC is out of limits, incorrect frequency of QC, the use of expired reagents, proper specimen identification, proper report elements - are all virtually impossible to create retrospectively after a survey is scheduled. If contact from a laboratory's accrediting organization about their upcoming survey occurs with three or even six months notice, it would only improve the lab's operation more quickly if the lab took that opportunity to review their self-assessment questions and corrected any missing or incorrect processes or documentation.

Clearly, laboratories that "fix" or complete records immediately prior to an announced onsite inspection (an example used in your report) have critical management and laboratory operations issues. Our surveyors are trained to spot these problems as well as others that may arise when a laboratory attempts to "fix" documents or data just before an onsite survey.

As you know, documentation is only one part of the onsite assessment. The qualitative, interactive assessment of the laboratory, coupled with the ongoing participation in proficiency testing, provides COLA with a more accurate picture of the overall quality of the laboratory.

It is important to note that logistically, any reduction in final notice of scheduled survey to laboratories will likely raise the cost to inspect laboratories by the national survey organizations. The increased costs will ultimately be borne by the laboratories themselves and will be further increased by any necessary rescheduling as a result of scheduled inspections that could not be performed because of a variety of reasons—including staff vacations, laboratory operating hours etc. Moreover, the root cause of problems like those at Maryland General Hospital were not discovered by unannounced or short notice inspections—they were brought to light by whistleblowers. Lab personnel who could be potential whistleblowers, may not be available during unannounced and short notice surveys.

We completely agree with your conclusion that unannounced inspections in the smaller lab environment are impractical and have a negative impact on patient care. We have discussed the same with CMS, JCAHO and others.

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COLA exists to help improve laboratory medicine and patient care- the primary tenets of which are lasting improvement mechanisms and quality systems generated by committed, informed, and prepared laboratory directors and staff. CLIA's intent is to improve the quality of laboratory testing. As new technologies emerge and laboratory testing evolves it is more important than ever that the industry understand the principles of quality laboratory testing and apply them correctly.

Laboratory Quality has Indeed Improved

We were disappointed that you seemingly discounted the improved proficiency testing performance by COLA accredited laboratories and further intimated that overall laboratory quality has not improved. The percentage of COLA laboratories that fail PT has decreased. COLA is vigilant in the continual monitoring of proficiency testing performance by our laboratories. We educate laboratories on how to remedy proficiency testing problems and ultimately on how to ensure that all tests are performed in a controlled and analytically sound fashion. COLA is proud of the fact that our program is having a positive impact on laboratories and on patient care.

Statistically, your assertion that the explanation for improved PT performance by COLA labs is because poorly performing laboratories have withdrawn from oversight (by performing only waived testing) is remarkable on the following counts:

- 1) It should be encouraging that poorly performing laboratories that are beyond help are "weeded out" and no longer perform clinical laboratory testing other than waived procedures. As you know, COLA takes PT performance very seriously and requires laboratories to cease testing problem analytes or specialties on the basis of systemic and continual PT failures.
- 2) COLA now accredits more laboratories than it has in the past 10 years. We are delighted to see our rolls of accredited laboratories filled by conscientious, quality-minded laboratories.

Data that COLA provided the GAO (but not used in the draft report) shows that, in general, condition-level deficiencies declined in laboratories that have been surveyed over multiple years. We view this as evidence that the quality of laboratories subject to continual and regular oversight has improved.

We also note that since the advent of CLIA, there have been a number of contributing factors which affect both the smaller and more sophisticated laboratory and their performance on Proficiency Testing. For example, testing technologies and reagent stability have improved tremendously, especially in consistency, reliability, and ease of use. Proficiency testing results should have been expected to improve. The fact that they haven't in larger labs may be related to the difficulties in attracting and retaining a well-trained workforce in laboratory medicine.

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CMS Improvements

In general, we believe that your recommendations for how CMS can improve the oversight of survey organizations have merit. For example, we believe that CMS should hire sufficient staff. However, we believe that you have fundamentally misunderstood and/or overstated the shortcomings you have identified in the following:

- 1) The validation process of survey organizations (by CMS) can certainly be improved. However, we feel that simultaneous validations are often of benefit and helpful to assuring some consistency and predictability between surveying groups. Simultaneous validations should not be assumed to be improper or ineffective. In fact, CMS and survey organizations have greatly improved their understanding of each other's processes because of simultaneous validations. This type of cooperation is critical to an effective public/private partnership as CLIA oversight has become.
- 2) Furthermore, the report asserts that simultaneous validations are not independent and do not identify as many "condition-level deficiencies". In our experience, most of the discrepant findings in non-simultaneous validation reports are, in fact, incorrect because they are based on false assumptions. For example, CMS' validation process (by virtue of its structure) fails to recognize that COLA performs continual monitoring and enforcement of PT performance is not confined to the onsite survey alone. In all, despite the potential improvements in the validation process, no accrediting organizations have come close to the 20% discrepancy threshold defined in CLIA.
- 3) We agree that the deeming approval and renewal process (by CMS of survey organizations), should be timely, consistent, standardized and thorough, however, we caution that the GAO, Congress, and CMS respect that the approved accrediting organizations are all unique in approach and methodology. All survey organizations meet the CLIA required validation thresholds; all thoroughly investigate complaints, and all take immediate action when risk of harm situations is evident. In short, we oversee labs differently, and laboratory quality has improved. We do not agree that standardized surveys would be inherently more accurate or appropriate for the wide range of laboratories and laboratory environments currently overseen by CMS and the accrediting organizations.¹

¹ No evidence has been presented to show that the oversight as described in the regulation has not been sufficient. CMS should provide for an effective process to review accrediting organizations at time of approval and renewal. If process and procedure review were adequate, there would not be any question of equivalency. Approving laboratory accrediting organizations should be likened to accrediting colleges—it is done on a periodic basis and every college does not provide the exact same path to a Bachelor of Science degree. Every laboratory accrediting organization does not need to provide the same path to accreditation as long as the agreed to minimums is met.

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Critical Factors

As we noted above, we are very pleased with the many accomplishments of the CLIA program and COLA's accreditation program in particular in improving laboratory quality over the years. Generally, quality of laboratory testing can be measured in two ways: 1) by evaluating quality of laboratories and providing resources to assist them to correct deficient practices; and 2) by preventing laboratories that do not meet quality standards from continuing to provide clinical laboratory testing. We are appropriately achieving this outcome.

When CLIA was enacted, there were many problems that have since been rectified. COLA, as the first CLIA approved accrediting organization was designed to promote quality improvement and excellent patient care through an interactive approach through effective enforcement, oversight, and education. When the CLIA regulations were promulgated, many laboratories were unfamiliar with the concepts of "quality assurance", "quality control", and "proficiency testing". We committed ourselves to a program of comprehensive surveyor training, coupled with consistent, efficient survey methodologies to instill a culture of quality in our accredited laboratories. COLA's surveyors, all of whom are employed by COLA, are cross trained in multiple laboratory disciplines, quality systems, and more importantly, trained in communications, conflict management, investigation, and root cause analysis techniques.

We applaud the GAO for noting the critical role played by trained, professional surveyors.

Thank you for the opportunity to comment on this important report.

Sincerely,



Douglas A. Beigel
Chief Executive Officer
COLA

Appendix VII: Comments from the Joint Commission on Accreditation of Healthcare Organizations



Joint Commission

on Accreditation of Healthcare Organizations

Setting the Standard for Quality in Health Care

May 15, 2006

Mr. David Walker
Comptroller General
Government Accountability Office
441 G Street, N.W.
Washington, DC

Dear Mr. Walker:

We would like to thank the Government Accountability Office for the opportunity to review the draft report *CLINICAL LAB QUALITY: CMS and Survey Organization Oversight Should be Strengthened* (GAO-06-416). Soliciting the views of entities that are the subject of your review helps to ensure accuracy and provides context for your assessment. The Joint Commission congratulates the GAO on its efforts made in conducting this study of the quality of testing in our nation's clinical laboratories, the effectiveness of survey organization oversight of laboratory performance, and CMS' oversight of the CLIA program.

Ensuring that our nation's laboratories are providing high quality and safe services is one of the Joint Commission's highest priorities. Most clinical diagnoses are based on the results of lab tests; yet, the level of quality in our nation's laboratories often goes unnoticed because these health care providers rarely have direct patient contact. Recognizing the critical and essential importance of laboratory services, the Joint Commission has designated the laboratory as an essential service and therefore factors the laboratory's accreditation status into the hospitals accreditation decision. This policy underscores the patient care implications of laboratory quality; and the need for hospital leadership to pay particular attention to laboratory processes and outcomes.

We would next like to comment on the GAO recommendation that CMS standardize the categorization and reporting of survey findings, while having the theoretical potential to simplify administrative oversight of the program, has several serious shortcomings. First, compliance with this GAO recommendation would require revamping of our entire accreditation system. GAO fails to recognize that the Joint Commission—like its colleague accrediting bodies—uses a different and more sophisticated approach to assess laboratory performance. This recommendation

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essentially assumes that CLIA requirements and categorizations are the “gold standard;” however our experience has shown that the Joint Commission’s systems approach is much more effective in identifying the causes of performance problems and helping labs correct the underlying factors that contribute to these problems. The Joint Commission’s approach also drives sustained improvement in lab performance. Second, the concept underlying federal reliance on private sector accreditation is that it provides a level of flexibility not available in a regulatory environment. When Congress established the accreditation option, with the caveat that the relevant standards “meet or exceed” federal regulations, it recognized that other approaches can be more innovative and more effective at ensuring quality and patient safety. As an accrediting organization, the Joint Commission is not a contractor to CMS, in contrast to the CMS relationship with state survey agencies.

Notwithstanding the foregoing, the Joint Commission believes that CMS could and should play a role in developing a common, agreed-upon taxonomy that could be used by all laboratory survey organizations to track serious deficiencies. As the draft GAO reports notes state survey agency determinations that condition-level requirements are out of compliance are highly subjective and, by their nature, inconsistent. If all survey organizations were to agree on criteria as to what constitutes a serious deficiency, this would create the desired comparability without requiring accrediting organizations to change the ways in which they categorize and report findings. We believe that the GAO should replace its current recommendation to standardize the categorization and reporting of survey findings with a new one that directs CMS to take the lead in coordinating a joint effort to develop a common definition of what constitutes a serious deficiency.

The Joint Commission further disagrees with the GAO recommendation that CMS uniformly impose more sanctions on labs with repeat condition-level deficiencies. A number of variables may contribute to circumstances in which a lab is found to have consecutive condition-level deficiencies for the same requirement, including a lack of sufficient resources or a lack of understanding of the tools needed to fix the problem. Further, the same condition may be found to be out of compliance as a result of the contribution of different standards to the overall deficiency. Determining when to employ a punitive versus an educational (or collaborative) approach to promoting compliance can be a difficult judgment. Quality experts maintain that an educational approach is the best way to evaluate weaknesses and achieve and sustain improved performance over time. The following three types of behaviors have been identified as contributing to poor performance:¹

- Human error. Inadvertent action; inadvertently doing other than what should have been done; slip, lapse, or mistake.
- At-risk behavior. Behavior that increases risk, where risk is not recognized, or is mistakenly believed to be justified.

¹ See: The Just Culture Community, located at www.justculture.org.

- Reckless behavior. Behavioral choice to consciously disregard a substantial and unjustifiable risk.

The most appropriate way to manage reckless behavior is through remedial (or disciplinary) action, such as sanctions; however, we contend that most labs with consecutive condition-level deficiencies are actually exhibiting at-risk behavior. The best way to manage at-risk behavior is to remove the negative incentives, create incentives for healthy behaviors, and increase situational awareness. In the patient safety literature overwhelmingly supports the conclusion that punishment encourages organizations to cover up problems.^{2,3} Thus, Joint Commission believes that GAO's call for CMS to impose more sanctions on laboratories with repeat condition-level deficiencies is likely to be counterproductive.

Next, to ensure consistency of laboratory oversight by survey organizations, the GAO recommends that all survey organizations develop and require labs to prominently display posters that instruct lab workers on how to file anonymous complaints. The Joint Commission believes that this recommendation is too narrow and prescriptive, and may inadvertently limit organizations from using other more effective ways to educate lab workers on how to file a complaint. Furthermore, GAO's commentary on the increase in complaints received by CAP after it required the display of posters neglects to recognize a broad national trend. During the same period, the Joint Commission also experienced a dramatic increase in lab-related complaints. The number of complaints the Joint Commission received in 2004 was 44 and this number rose to 69 in 2005, an increase of 64 percent, without any requirement for displaying posters.

We further believe that GAO has misinterpreted its validation survey data. It concludes that "independent" surveys—more commonly referred to as look-behind surveys—are more effective than simultaneous surveys in identifying condition-level deficiencies that were missed by accrediting organizations. However, the data presented in the draft report do not support this assertion. The Joint Commission estimates that 3 percent of the simultaneous validation surveys resulted in findings of condition-level deficiencies missed by accrediting organization surveyors, compared to the identification of such findings in 5 percent of the "independent" validation. Thus, the proportion of condition-level findings is roughly equivalent in both types of surveys.

Finally, while the GAO's lengthy and detailed review addresses many issues associated with laboratory quality, it fails to address a long acknowledged shortcoming of CLIA requirements—the qualifications and supply of lab personnel. The Joint Commission believes that the personnel standards currently required by CLIA are insufficient to adequately protect patients and the public health. For example, CLIA requires only an Associate degree and minimal lab training to perform tests of high complexity and has no personnel requirements for waived tests. Today, the problems underlying failures in laboratory performance that are most commonly cited by experts in the field are the

² Leape, L., Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. JAMA 1995; 274:35-43.

³ Reason JT. Understanding adverse events: The human factor. In: Vincent C, ed. Clinical Risk Management: Enhancing Patient Safety. 2nd ed. London: BMJ: 2001:9-30.

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growing shortage of laboratory technologists and the inadequacy of their training. These shortcomings become especially glaring in the face of the expanding array and increasing complexity of laboratory test in hospitals. By not addressing this serious regulatory shortcoming in the scope of its review, GAO has missed an important opportunity to leverage potential improvements in laboratory performance and protect the public interest.

The Joint Commission is submitting technical comments on the GAO draft report as an attachment to this letter. If you have any questions concerning these comments, please contact Trisha Kurtz of my staff at 202.783.6655.

Sincerely,



Dennis O'Leary
President and CEO

Enclosure

Appendix VIII: GAO Contact and Staff Acknowledgments

GAO Contact

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Acknowledgments

In addition to the contact named above, Walter Ochinko, Assistant Director; Lucia P. Fort; Dan Lee; Kevin Milne; Dean Mohs; Elizabeth T. Morrison; Michelle Rosenberg; and Elizabeth Scherer made key contributions to this report.

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