An Update on the Clinical Laboratory Improvement Amendments of 1988

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The goal of the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88)¹ is to improve the quality of test results that clinical laboratories provide their patients. Through a variety of research, educational, and enforcement efforts, the Centers for Medicare and Medicaid Services (CMS) partners with other federal agencies, state agencies, and other survey organizations to provide regulatory oversight of laboratory performance.

As orders for clinical laboratory tests continue to rise and the costs of laboratory tests continue to climb, ensuring test accuracy and reliability in our nation is of the utmost importance. Laboratory testing affects more and more health care decisions in the United States—approximately 70%²—and is the most frequently billed Medicare procedure.²

Prior to CLIA ’88, little data was available to evaluate laboratory performance. Now that CLIA has been implemented for almost 20 years, there is considerable information available from which laboratory performance can be assessed. However, a recent Congressional investigation noted the paucity of available data on laboratory quality and therefore urged CMS to implement initiatives to restructure the data collection requirements already in place. This article will review some of the data that supports the assertion that the quality of laboratory performance has improved steadily since CLIA ’88 was enacted.

Specifically, it will examine:
• improvement in the quality of laboratory medicine;
• strengthening of the CLIA program oversight; and
• the impact of emerging technologies on quality in laboratory medicine.

Background
The Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) were established to ensure the accuracy, reliability, and timeliness of patient test results regardless of the laboratory environment.³ Primarily in response to reports of inaccurate Pap smears, President Ronald Reagan signed CLIA ’88. These regulations extended oversight of laboratory performance to include physician’s office laboratories (POLs).

At the time of CLIA’s enactment, research demonstrated that approximately half of all tests occurred in physicians’ laboratories, and that the volume of physician office-based testing was increasing at 16 percent annually.⁴ In a 1986 report titled The Final Report on Assessment of Clinical Laboratory Regulation,⁵ authored by Michael Kenney, unregulated laboratories in physician and group practice offices consistently demonstrated lower accuracy and precision results than regulated laboratories. The report concluded that compliance with regulations would increase accurate results and thereby increase public health protection.⁵

CLIA ’88 required laboratories to:
• maintain a procedure manual;
• operate test instruments as the manufacturer specifies, including calibration and calibration verification procedures;
• implement quality control measures; and
• ensure that their personnel meet specific educational and work experience standards.

The Quality of Laboratory Testing Continues to Improve
The quality of laboratory testing has improved since the inception of CLIA ’88. On-site laboratory surveys and proficiency testing (PT) scores provide valuable performance data about laboratory quality. Laboratories are required under CLIA to perform PT for regulated analytes. The Centers for Medicare and Medicaid Services conducted research that, based on PT scores for laboratories enrolled in the CLIA program, showed the PT performance of laboratories improved between 1996 and 2003.⁶

The data for 1995 indicates 89.6% of the laboratories that were required to be enrolled in proficiency testing were actually enrolled. Of that percentage, 69.4% reported proficiency scores with no failures. Since this was the first year proficiency testing was fully implemented, this data provided the baseline for improving laboratory performance.

In 1996, PT enrollment increased to 93.2%. Of the enrolled laboratories, 87.4% demonstrated no failures on any of their proficiency testing challenges. Continuing the trend, the
number of laboratories without proficiency testing failures rose to 91.9% in 2000 and increased again in 2003 to 92.8%.

From the 1995 and 1996 data, CMS anticipated that gains in enrollment and proficiency scores would continue as the proficiency testing program became a routine part of laboratory operations. The percentages in Table 1 show that the expectations of the CMS were met.

In 2005, a CMS study analyzed the number of deficiency citations laboratories received during survey cycles between 1994 and 2005. The study measured 2 types of regulatory deficiency data: standard and (the more serious) conditional. The findings revealed a significant decrease of 42% in both types of citations across all enrolled laboratories during that period.6

Standard deficiencies are those deficiencies that document the nature and extent of a deficient practice with respect to a particular laboratory function, as well as assess the level of compliance in relation to conditional requirements. Conditional deficiencies are characterized as those deficiencies that substantially limit the laboratory’s capacity to furnish adequate care or that adversely affect the health and safety of patients. Based on the conditional deficiencies found, the CMS will initiate enforcement actions against the laboratory, such as suspension, limitation, or revocation of CLIA certification, fines, or possible imprisonment.

Figure 1 illustrates that the most pronounced reduction in citations occurred between the first 2 survey cycles (the 1994 to 1995 and the 1996 to 1997 survey cycles). This reduction has been attributed to improvements in technology, familiarity with requirements, and movement of laboratories to waived testing. Citations for deficiencies of all types continued to decrease up to the 2002 to 2003 survey cycle, but the reduction was not as rapid as it was during previous cycles. The number of citations given during on-site surveys slightly increased during the 2004 to 2005 survey cycle, which corresponds to recent CMS initiatives to strengthen CLIA quality control requirements.

### Strengthening CLIA Program Oversight

In 2003, CLIA ’88 was finalized. Changes included a new format, new terminology, and updated requirements. The new format for the requirements organized the regulations around the laboratory path of workflow—the path of a specimen as it moves through the laboratory testing process.

This concept introduced the new quality system philosophy. As for new terminology, “quality assessment” replaced the term “quality assurance.” “Nonwaived testing” replaced the terms “moderate” and “high complexity” as quality control requirements for these test complexities were harmonized. Note: Personnel requirements remain segregated for moderate- and high-complexity testing.

There were other major changes in the CLIA requirements, including:
- reducing the redundancy and complexity of the regulations and using plain language where possible;
- merging moderate- and high-complexity requirements for quality control, providing 1 set of quality control standards for nonwaived tests to simplify compliance;
- reducing quality control frequency in some subspecialties and specialty areas;
- removing the prospective FDA review of manufacturers’ quality control instructions for compliance with CLIA; and
- modifying personnel requirements for laboratory directors.7

In addition to the new requirements, CMS began several initiatives to strengthen oversight of the CLIA Program.

In 2004, several laboratories in Maryland had quality issues related to HIV and hepatitis C testing that were exposed publicly. As a result, a General Accountability Office (GAO) investigation was conducted to discuss quality issues in laboratory testing. The GAO examined the adequacy of CMS oversight of the CLIA program, the quality of laboratory testing, the effectiveness of surveys, complaint investigations, and enforcement actions in detecting laboratory problems. The investigation was conducted over 16 months and involved significant data collection from COLA, the College of American Pathologists (CAP), the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), and the CMS. In the report, Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened, the GAO recommended strengthening CMS oversight to improve clinical laboratory quality by (1) better tracking laboratory quality problems; (2) being consistent in laboratory oversight (eg, impose consistent notification policies;
appropriate sanctions at consecutive condition level deficiency; and (3) improving oversight practices (eg, ensure consistency with CLIA, perform equivalency review prior to expiration date).

Two of these initiatives are to improve communication among survey organizations, and to create an environment that encourages complaint reporting by laboratory workers. To improve communication among survey organizations, the CMS convenes all accrediting organizations, various state agencies, and CMS regional offices to share best practices in laboratory oversight among all stakeholders. At these biannual meetings, the organizations review common issues and promote improvements in their respective survey processes. One outcome of this group has been an agreement to improve data sharing, communications, and oversight activities. In addition, a new rapid response alert system has been implemented to enable faster, more efficient, and coordinated responses to situations with significant quality and health care implications.

Complaints from laboratory personnel are an important source of information about potential problems. To create an environment that encourages complaint reporting by laboratory personnel, the CMS encouraged each accreditation organization to require their laboratories to conspicuously post a notice explaining the appropriate way to make a complaint. In addition, the CMS has implemented a new data system to receive and track complaints. The new system will enable all surveying organizations to submit and access information collected on any laboratory and to monitor the findings.

Impact of New Technologies on Laboratory Medicine Quality

With the emergence of new technologies in everything from waived to genetic test systems, CLIA '88 can appear antiquated when applied to these technologies. Waived tests are simple to perform and require very little regulatory oversight. From 1993 to 2004, the number of waived test systems almost doubled, while nonwaived testing grew by only 9.8%. The number of waived analytes has grown from the initial 9 waived analytes to more than 70, and the number of waived test systems has grown from 203 to 1,638.

In November 2005, the CMS and the Centers for Disease Control and Prevention (CDC) published the results of an ongoing waived laboratory surveillance project. Good Laboratory Practices for Waived Testing Sites highlights a number of quality issues in waived testing sites (Table 2).

Similar to the growth in waived test systems, genetic test systems are being developed at a rapid pace. Several hundred genetic tests are in clinical use, and many more are expected to be developed with the sequencing of the human genome now complete. Genetic tests, which span the CLIA specialty and subspecialty categories for non-waived tests, involve the analysis of chromosomes, genes, and/or gene products to determine whether a genetic alteration related to a specific disease or condition is present in an individual. In addition to performing analytic validation to ensure the test measures the marker and characteristics as intended, genetic tests must have clinical validity and clinical utility.

**Conclusion**

As the clinical laboratory testing reimbursement system is projected to be transformed by the competitive bidding demonstration, maintaining the level of quality in laboratory medicine will be challenging. In an effort for laboratories participating in the demonstration to maximize reimbursement amounts, quality and access to laboratory testing could be compromised. The Centers for Medicare and Medicaid Services continues to work with other federal agencies, state agencies, survey organizations, and laboratory professionals in an effort to guarantee the continuing upward trend to improve laboratory performance in our nation.

To raise the bar for laboratory performance nationwide, the CMS, in its Annual Performance Plan for 2006, restated the agency goal to continually improve the accuracy of CLIA-regulated diagnostic laboratory tests and improve PT scores. The goals were to:

- Increase the total number of CLIA laboratories properly enrolled and participating in proficiency testing to 95%.
- Increase the percentage of proficiency-testing-enrolled laboratories nationwide that score at least 90% on their PT challenges.

In addition, the CMS remains dedicated to design program guidelines and collect data for areas of concern in the CLIA Program. These areas are:

- Waived testing. The CMS will continue the surveillance of laboratories with a new program, the Waived Lab Quality Project. The Waived Lab Quality Project, the CMS will perform surveys on a small percentage of laboratories doing waived testing only.
- Standardize reporting of survey results. The CMS will begin to develop a consistent lexicon to allow the CMS to improve data use and analysis for survey citations.
- Development of performance standards for accrediting organizations and state agencies.
- Genetic testing.

Collaborating with the genetic testing community, government agencies, and technical advisory groups, the CMS will design guidelines and recommendations for PT performance, quality control options, and clinical validity reviews. Quality in laboratory testing has improved since the inception of CLIA '88. It will continue to improve as long as the CMS continues to dedicate its efforts towards the promotion of quality in laboratory testing through enforcement, communication, partnerships, and vigilance. Furthermore, with the rapid growth of emerging technologies that will increase the

<table>
<thead>
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<th>Table 2 Waived Test Sites Quality Deficiencies</th>
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<tbody>
<tr>
<td>Failed to have current copy of manufacturer’s instructions</td>
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<tr>
<td>Failed to follow manufacturer’s instructions</td>
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<tr>
<td>Failed to perform quality control</td>
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<tr>
<td>Performed non-waived test</td>
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<tr>
<td>Failed to adhere to expiration dates for the test systems, reagents, and/or control materials</td>
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<tr>
<td>Did not refer for confirmation testing</td>
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<tr>
<td>Did not document name, lot number, and expiration date for test performed</td>
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<tr>
<td>Did not maintain quality-control logs</td>
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<tr>
<td>Did not maintain records or logs of tests performed</td>
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<tr>
<td>Did not require a requisition or test order documentation</td>
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demand for laboratory tests, high quality laboratory test systems will be paramount for public confidence and safety. 

2. GAO Letter to The Honorable Mark Souder, Chairman; the Honorable Elijah E. Cummings, Ranking Member of the Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, House of Representatives. GAO Report to Congressional Requesters, Clinical Lab Quality: CMS and Survey Organization Oversight Should be Strengthened, June 2006.
7. CLIA Facts #1, COLA, Incorporated; June, 2004
8. 42 U.S.C. § 263 a (d) (3)