

CMS INITIATIVES TO IMPROVE QUALITY OF LABORATORY TESTING UNDER THE CLIA PROGRAM

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Overview:

In the wake of reports of inaccurate results from Pap smears intended to detect cervical cancer, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to ensure the accuracy and reliability of all laboratory testing. This legislation, for the first time, extended Federal regulation to all laboratories – hospital, independent, and physician office laboratories, etc. – that perform testing on human specimens for the purpose of diagnosing or treating a disease, illness, or assessment of the health of human beings. Among the tests commonly performed in laboratories regulated under CLIA are tests on blood, urine and other samples to detect cancer, HIV, diabetes, and multiple other diseases.

Significantly, although the Centers for Medicare & Medicaid Services (CMS) has primary responsibility under CLIA for regulating laboratories, CLIA oversight extends to testing on patients who are neither Medicare beneficiaries and Medicaid recipients.

Since 1988, the CMS, along with the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC), has worked continuously to improve the quality of laboratory testing through a variety of research, educational and enforcement activities.

This Backgrounder describes the current and planned initiatives undertaken by CMS to improve the quality of clinical laboratory testing wherever it is performed.

Background:

Approximately 195,000 labs are certified under CLIA, ranging from small physician office labs (many of which perform only simple tests for which most CLIA requirements are waived) that perform less than 2,000 tests per year to large hospital-based and independent labs performing millions of tests each year encompassing the simplest to the most complex tests, including a growing number of genetic tests.

Prior to CLIA, Federal regulation of laboratory testing was limited to testing performed in independent laboratories and hospitals. The CLIA statute extended regulation to all types of testing sites and based regulation on the complexity of tests, not the type of lab where the testing occurs. Thus, laboratories performing similar tests must meet similar standards, whether located in a hospital, doctor's office, or other site.

Current Regulation: CLIA established three categories of tests: waived tests, moderate complexity tests, and high complexity tests. Waived tests -- simple tests with small chance of error or risk -- are exempt from virtually all CLIA rules, so long as testing is performed in strict compliance with the manufacturers' instructions.

Moderate and high complexity testing, on the other hand, are subject to regulations setting minimum qualifications for all persons performing or supervising these tests, along with corresponding responsibilities for each position in the lab. These laboratories must also participate successfully in approved proficiency testing programs, which provide an external evaluation of the accuracy of the laboratory's test results. Finally, moderate and high complexity laboratories must have systems and processes for monitoring testing equipment, procedures to ensure proper test performance and accurate results and an overall plan to monitor the quality of all aspects of the laboratory's operation ongoing.

Special rules apply to cytology testing, such as Pap smears, including workload limits, specialized proficiency testing requirements that apply not just to the laboratory, but to the individuals performing the test, specialized personnel standards, and quality control procedures.

Survey Process: Moderate and high complexity laboratories must undergo on-site surveys at least every two years. These surveys may be conducted by the Federal CLIA program, a State survey agency under contract with CMS, or private CMS-approved agencies such as COLA, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or the College of American Pathologists (CAP). In a few cases, such as Washington and partially in New York, the CLIA program has exempted states that have established laboratory quality standards at least as stringent as CLIA's.

CMS utilizes an Outcome Oriented survey protocol with a quality assurance focus that evaluates the laboratories' systems and processes to ensure quality test results and reviews information that effectively identifies problems that could cause actual or potential harm to patients.

Program Funding: By law, the CLIA program must be completely self-funded. All laboratories subject to CLIA must register with the Department of Health and Human Services, and pay a certificate fee. Laboratories performing moderate or high complexity tests are assessed fees that are set to cover the costs of biennial inspections. Many labs are exempt from routine federal inspections, including those that perform only waived tests, or certain microscopic tests as part of a patient exam. Labs accredited by an approved accrediting organization and labs in CLIA-exempt states (with standards at least as stringent as CLIA) pay their survey fees to their accrediting organization or exempt State, respectively.

Current and Planned Initiatives to Improve Quality of Testing:

Standardized Reporting of Survey Results

It has sometimes been suggested that CMS should standardize the reporting of survey deficiencies to permit meaningful comparisons across survey organizations including private accrediting organizations, CLIA-exempt State programs, and State agencies contracted by CMS to conduct CLIA surveys. However, the Federal CLIA standards set a baseline for laboratory quality, and standardization of reporting could prevent other surveying agencies from adopting more stringent standards. In addition,

CMS believes that the equivalency of all oversight organizations and States has been already determined; therefore, the more important oversight issue is ensuring each accrediting entity's *enforcement* of its standards. CMS has established a workgroup to develop performance indicators similar to those used to monitor State survey agency performance, and to work with survey partners to clearly define deficiencies comparably among all oversight entities. Then CMS will be able to solicit and monitor their citations of serious deficiencies and their resolution or imposition of sanctions by all oversight agencies.

Balancing Educational and Enforcement Efforts to Maximize Laboratory Quality

CMS is committed to a two-pronged approach to laboratory quality: education in quality requirements and enforcement of standards, but education would never preclude the identification and citation of deficiencies that affect lab testing quality, and, therefore, regulation of laboratories is the primary goal of survey organizations. In some cases, CMS has deferred sanctions for a specified period to give labs time to adapt to significant new requirements, including (1) new quality control requirements for moderate complexity testing issued in 2003, and (2) cytology proficiency testing implemented on a national basis in 2005. CMS also believes education is a valuable element of the CLIA survey process, enabling laboratories to understand CLIA requirements and to correct problems prior to the imposition of sanctions which meets the intent of CLIA.

Specific CMS initiatives to improve enforcement, while educating laboratories about quality testing include:

- action plan to increase enforcement consistency;
- protocols or refinements to surveyor guidance to ensure an appropriate balance between the enforcement and educational functions of the survey process;
- further comprehensive training for surveyors on differences between education and the outcome- oriented survey process, including identification of survey findings that always require citations;
- periodic review of key data to identify and minimize significant survey variations and trends; and
- increased communication between Central Office, Regional Offices, and State agencies to decrease variability and enhance consistency over time.

Creating an Environment that Will Encourage Complaint Reporting by Laboratory Workers

Complaints from laboratory workers are an important source of information about potential problems. CMS plans to work with surveying entities to increase awareness of the ways laboratory workers and others may report concerns and complaints about testing quality, and to ensure such reports are treated confidentially. Information on complaint procedures has been added to Surveyor Interpretive Guidelines, posted on the CMS website, and will be highlighted in letters to professional organizations and newsletters. Most States already have a complaint line available. In addition, in March 2006, CMS implemented a new, more sophisticated data system to receive and track complaints. This system will enable all surveying entities to submit and access information collected on any laboratory and to monitor the findings.

Validation Surveys Conducted By CMS To Validate Accrediting Entities' Findings

CMS conducts routine validation surveys to monitor the effectiveness of surveys by accrediting agencies. Most of these surveys are conducted separately, rather than concurrently with the accrediting agency surveys. In fact, CMS conducts, on average, only one concurrent survey, per state, per year. Conversely, about 88 percent of validation surveys are conducted independently. CMS is satisfied that this proportion provides sufficient opportunity to interact with and train the accrediting entities, while enabling CMS to independently verify that they are adequately fulfilling their responsibilities; i.e., their laboratories meet CLIA requirements.

Other CMS Quality Initiatives For Clinical Labs

Recent CMS initiatives to strengthen standards and increase lab testing quality include:

- ***Improved Quality Control Requirements*** for all non-waived testing through regulations issued in 2003, followed by extensive training and education.
- ***Cytology Proficiency Testing*** implemented nationwide in 2005 for all individuals who perform or interpret Pap smear testing. Every lab subject to cytology PT was enrolled, including more than 12,000 cytotechnologists and pathologists, and underwent such testing with an educational approach.
- ***Complaint Tracking System*** implemented in 2006, with further improvements underway for 2007.
- ***Performance Standards for State Survey Agencies*** and annual review of each State's performance. In 2005, thirty-three States implemented plans for improvement in at least one of thirteen possible areas.
- ***Performance Measures for Accrediting Organizations*** were also initiated in 2005.
- ***Accrediting Organization Response & Improvement*** through regular meetings and data sharing of the Partners for Laboratory Oversight. A new rapid response alert protocol enables faster, more coordinated responses to situations with significant public health implications.
- ***Improved Data Utilization and Analysis*** including overhaul of the CLIA databases and analytical systems used to manage the program.
- ***Waived Lab Quality Project*** to improve performance in labs doing only waived tests. Of 459 waived labs receiving an initial visit and a revisit, over 70 percent improved in their adherence to test manufacturers' instructions.