How will the final regulations be implemented?

CMS will allow each laboratory that it inspects to have one educational survey following the April 24, 2003, effective date of the regulations. This will give laboratories time (2 years) and the opportunity to receive the technical assistance that may be needed to meet the updated requirements.

Where can I find additional information and guidance?

Assistance for meeting the requirements will be provided in Appendix C of the State Operations Manual (CMS Publication 7), which will be posted at a later date on CMS's CLIA Website. Information about CLIA and links to other laboratory-related resources can be found on the following Websites:

CDC: www.phppo.cdc.gov/clia/default.asp
CMS: www.cms.hhs.gov/clia/default.asp
FDA: www.fda.gov/cdrh/CLIA/index.html (for a listing of waived, moderate complexity and high complexity tests)

DEPARTMENT OF HEALTH & HUMAN SERVICES

CMS CENTERS for MEDICARE & MEDICAID SERVICES

Clinical Laboratory Improvement Amendments (CLIA)

Updated Regulations
Brochure #1*

How do they affect my laboratory?

Changes in the CLIA regulations include
A new format, some new terminology,
and updated requirements.

Important information to help keep your laboratory in compliance!

NOTE: On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final laboratory regulations (CLIA) that became effective April 24, 2003. A summary of the updated requirements are included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings. For more complete information, you may access the regulations on the Internet at http://www.phppo.cdc.gov/CLIA/regs/toc.asp

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

* This brochure is one in a series to follow.

New Format:

The regulations are now arranged to match the path a patient specimen takes as it moves through the laboratory; i.e., specimen receiving (preanalytic), testing (analytic), and result reporting (postanalytic). In addition, the previous subparts J, K and P have been combined into two new subparts, Subpart J-Facility Administration for Nonwaived Testing, and Subpart K-Quality System for Nonwaived Testing.

New terms:

QUALITY ASSESSMENT has replaced the term "quality assurance."

QUALITY SYSTEM refers to all of the laboratory's policies, processes, procedures, and resources needed to achieve quality testing.

NONWAIVED testing replaces the terms "moderate" and "high complexity" testing when referring to requirements that pertain to both levels of testing.

Updated Requirements:

The following requirements apply to laboratories performing nonwaived testing. The personnel qualifications specified in Subpart M of the regulations are now the only CLIA requirements linked to the complexity of testing performed by the laboratory.

Note: Some of the requirements below may be new for laboratories that perform only moderate complexity testing, but not new for laboratories that have been performing high complexity testing.

Federal, state, and local laws: In addition to the CLIA regulations, your laboratory must be in compliance with all other federal, state, and local laboratory laws. If your laboratory holds a CLIA Certificate of Accreditation, you must continue to meet your accreditation organization's standards.

Test requests: You must now request the patient's sex and age or date of birth and, when appropriate, the source of the specimen and the time it was collected.

Procedures: The laboratory director must sign and date new procedures and all modifications of procedures before they are used. The date the procedure is first used and the date the laboratory stops performing the procedure must be recorded and retained for 2 years.

Test method verification: Before you report patient results for a nonwaived FDA-approved test for the first time, you must verify that the test's performance in your laboratory is similar to the manufacturer's claims for accuracy, precision and reportable range. Retain your records showing the performance verification of the test system for as long as the test is used but for no less than 2 years.

Note: This requirement does not apply to tests performed in the laboratory prior to April 24, 2003, unless you were required to do so for high complexity tests under the previous regulation.

Calibration: For those tests that require calibration, you must continue to perform calibration and calibration verification as outlined in the manufacturer's instructions. However, calibration verification must be performed at least every six months and checked at a minimum of three levels that are within the reportable range of the test.

Personnel: Beginning February 24, 2003, all new PhD directors of high complexity testing must be certified by an approved board. PhD directors who are not board-certified but were directing (or have directed) high complexity testing before February 24 may continue to serve as directors under a grandfather clause. A list of approved boards is on the Internet at: http://cms.hhs.gov/clia/dirclcon.asp. Qualifications for an M.D. or D.O directing high complexity testing have not changed.

Quality control (QC): You must follow the manufacturer's directions for performing QC, but at a minimum, test two levels of control materials each day the test is performed. In addition:

- You must perform QC before resuming testing and reporting results when there is a complete change of reagents, if major preventative maintenance is performed or when any critical change occurs that may influence test performance.

- The frequency for testing control materials in several of the laboratory specialty and subspecialty areas has been reduced. Bacteriology and mycology reagent checks, general immunology, syphilis serology tests, and tests using hematology instruments now require less frequent QC.

"Equivalent" quality control procedures will be provided at a later date in Appendix C of CMS' State Operations Manual.

Proficiency testing (PT): More PT samples will be graded by your PT program because the percentage for agreement among laboratories for grading has been modified. You must review and evaluate all of the PT scores you receive from your program and check the accuracy of any test not scored based on your true performance such as a zero for a late submission, or a 100% score assigned for an ungradable challenge.

Record and specimen retention: If your laboratory closes or otherwise ceases to perform testing, you must make provisions to maintain all records, slides, blocks and tissue for the applicable time frames.

Quality assessment (QA): The QA requirements have not changed, but now appear throughout the regulation to emphasize the importance of assessing quality throughout the total testing process. This will allow you to more easily incorporate these practices into your day-to-day routine.