WHAT'S NEW IN THE FINAL REGULATIONS?

History/Background

The original Clinical Laboratory Improvement Amendments (CLIA) were enacted in 1988 to respond to concerns regarding the quality and accuracy of laboratory testing. On January 24, 2003, the Centers for Disease Control & Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final laboratory regulations (CLIA) effective April 24, 2003. The official CLIA program provisions are contained in the relevant law, regulations, and rulings. To access the complete regulations go to the Resources section at the end of this fact sheet.

Overview of Changes & Implementation

The changes in the CLIA regulations include a new format, new terminology, and updated requirements. CMS will allow each laboratory to have one educational survey following the April 24, 2003, effective date of the regulations. **This gives laboratories time (2 years) and the opportunity to receive the technical assistance that will help them meet the updated requirements.**

The regulations are now arranged to follow the path of the patient specimen as it moves through the laboratory; i.e., specimen receiving (pre-analytic), testing (analytic), and result reporting (post-analytic). The following bullets are an overview of the changes in the final rule:

- Provides one set of QC standards for non-waived tests
- Reduces QC frequency in some of the subspecialty and specialty areas, and merges moderate and high complexity QC requirements to simplify compliance
- Removes the prospective FDA review of manufacturers' QC instructions for compliance with CLIA that was to occur after the end of the QC phase-in (delayed effective date)
- Eliminates redundancy, clarifies, simplifies, and uses plain language where possible
- Reorganizes the existing requirements to parallel the flow of a patient specimen through the laboratory facilitating the prevention of errors
- "Grandfathers" individuals with a doctoral degree without a board certification who have served or are currently serving as a director of a laboratory performing high complexity testing and requires board certification for all future doctoral-degreed directors of high complexity testing

In addition, the previous subparts J, K, and P have been combined into two new subparts, Subpart J-Facility Administration for Non-waived Testing, and Subpart K-Quality System for Non-waived Testing. Surveyor guidelines have also been developed and can be used as guidance in meeting the requirements. You may also contact CMS State Agencies for compliance help. Some new terms CMS uses throughout the new regulations are defined below:

Quality Assessment: replaces 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 for Non-Waived Testing: Since the QC requirements for moderate and high complexity laboratories merged in the new regulations, some of the requirements discussed 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 your laboratory stops performing the procedure must be recorded. Retain these records for two years beyond the date of last use.

Test method verification: Before you report patient results for a non-waived 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 two 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. Also, for more information on test method verification see CLIA Facts 2 and 16B.

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. See CLIA Facts 16B for more details on this topic.

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, 2003, may continue to serve as directors under a grandfather clause. See the Resources section for where to locate a list of approved boards on the Internet. Qualifications for an MD or DO directing high complexity testing have not changed. Additional information on personnel requirements is located in CLIA Facts 22-25.

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 preventive 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.

For more detailed quality control information see CLIA Facts 16E and 18-21.

Resources

- Complete CLIA regulations are available at: www.phppo.cdc.gov/clia/regs/toc.aspx.
- The regulation has also been published in the Federal Register. You may access the Government Printing Office Web site at www.gpoaccess.gov/fr/index.html to download a copy. You may purchase a copy with a credit card by calling the order desk at 202.512.1800 or by faxing to 202.512.2250.
- The surveyor guidelines are available through the National Technical Information Services, 5285 Port Royal Road, Springfield, VA 22161, 703.487.4650.
- For a list of approved boards on the Internet go to: www.cms.hhs.gov/clia/16_certification_boards_clinical_consultants_&t_laboratory_directors.asp