DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C- 07-12

DATE: **January 12, 2007**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: New and Revised Clinical Laboratory Improvement Amendments of 1988 (CLIA) Policies and Procedures

Memorandum Summary

This informational memorandum highlights areas of CLIA policies and procedures that were clarified and emphasized during the September 2006 Surveyor Consistency Training.

This memorandum clarifies certain aspects of the Centers for Medicare & Medicaid Services' Interpretive Guidelines (IG) for surveyors, and affirms or reinforces other existing guidance. The purpose is to improve the consistency with which CLIA surveys are conducted nationwide. The memorandum is both a product and a follow-up to the CLIA Surveyor Consistency Training organized by the Division of Laboratory Services in September 2006.

Attached is a list of policies and procedures that were given special emphasis at the September training.

Effective Date: Immediately. Please ensure that all CLIA staff are fully apprised of this information within 30 days.

Training: The information contained in this announcement should be shared with all survey and certification staff including managers and surveyors and their manager. The policies and procedures will be formalized in the appropriate sections of the State Operations Manual and IG.

For questions concerning this memorandum, please contact Judy Yost at 410-786-3407 or via email at Judith.Yost@cms.hhs.gov

/s/
Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management (G-5)

Attachment

CLIA Policies and Procedures Emphasized at the September CLIA Training

- **Two-week announced surveys—**The maximum lead time for announcing routine initial or recertification surveys is 2 weeks prior to the survey date.

- **Proficiency testing (PT) desk reviews must occur every 30-45 days—**The updated CLIA State Agency Performance Review protocol states this timeframe for ongoing monitoring of laboratories' PT performance.

- **Unsuccessful PT policy—**Unsuccessful PT is defined as 2 out of the most recent 3 surveys in which an unsatisfactory PT score results. These may be 2 consecutive unsatisfactory scores, or 1 satisfactory and 2 unsatisfactory scores, on a rolling basis, for the most recent 3 PT tests.

- **PT referral requires automatic revocation—**Any PT referral that meets the definitions in §493.801(b)(3) and (4) must result in a mandatory certificate revocation by law. PT referral of unregulated analytes is included in this requirement.

- **PT monitoring—**PT monitoring and quality assessment were expanded for laboratories in the 2003 Final Regulations at §493.1236(a), (b), (c), (d). The expansions require surveyors to conduct additional reviews onsite.

- **Errors in pre-analytical systems—**Studies indicate that most errors in the laboratory occur in the pre-analytical phase of testing. It is wise to review the laboratory's Quality Assurance procedures in this area.

- **Mandatory citations—**The Consistency Work Group identified four CLIA regulations that must be cited if noncompliance is determined. They are: Personnel qualifications, PT enrollment, PT performance, and PT referral. Noncompliance with any of these requirements, regardless of negative outcome or potential harm, would result in a deficiency citation. For example, any PT referral that meets the definitions in §493.801(b)(3) and (4) results in a mandatory certificate revocation.

- **Three components of immediate jeopardy (IJ)—**IJ is defined as having 3 components: seriousness, immediacy, and harm.

- **Allegation of Compliance (AOC)/Plan of Correction (POC) and four criteria of a POC/AOC—**There is a difference between an AOC and a POC and there are 4 criteria which identify if compliance has been achieved. Those 4 criteria are:

    1. Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3. What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur, and

4. How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

- **Repeat deficiencies—**Repeat deficiencies must be confirmed and are subject to progressive enforcement.

- **Accredited laboratory complaints –** The RO coordinates all complaints with the SA, including those alleged against accredited or exempt laboratories.

- **Laboratory director qualifications must be verified prior to the entry of the CMS-116 into the CLIA data system for new laboratories and for a change of directors—**It is more efficient to evaluate these credentials initially than when a problem occurs. Specific guidance on what to look for will be provided in the future.